Optimising the impact of ex-post legislative evaluations in healthcare

Bridging the gap between healthcare legislation and practice

Linda J. Knap

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“The life of the law has not been logic; it has been experience.”

— Oliver Wendell Holmes Jr.

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List of abbreviations

CER	ZonMw Committee for Evaluation of Regulations
CMO	Context-Mechanism-Outcome
PFN	Patient Federation Netherlands
P/N	Patients and/or their Next of Kin
RE	Realist Evaluation
SAE	Serious Adverse Event
The Inspectorate	Dutch Health and Youth Care Inspectorate
The Minister	Minister of Health, Welfare and Sport
UK	United Kingdom
VWS	Ministry of Health, Welfare and Sport
Wkkgz	Healthcare Quality, Complaints and Disputes Act
ZonMw	The Netherlands Organisation for Health Research and Development
ZonMw Programme	ZonMw Regulatory Evaluation Programme

Chapter 1

General introduction

1. General introduction

1.1 The impact of healthcare legislation versus the impact of its evaluations

Legislation in healthcare is a powerful policy instrument that forms the core of an organised and well-functioning healthcare sector. These laws regulate vital aspects of healthcare, including patient safety, care quality standards, privacy of medical data, and the responsibilities of healthcare providers. Considering that in the Netherlands alone, over 1.6 million people are employed in the healthcare sector, accounting for more than 15% of the national workforce (CBS, 2022), and there were an estimated 1.82 million physicians working in the European Union in 2021 (Eurostat, 2023), the significance of this sector cannot easily be overstated.

Effective healthcare is essential for every citizen, making it crucial that healthcare laws function well in practice. These laws directly impact various stakeholders in the daily healthcare practice, including patients, healthcare professionals, and healthcare institutions. This highlights the need for these laws to be both effective and properly enforced to ensure consistent, reliable, and high-quality healthcare for everyone.

To assess whether the legislative goals are being achieved, thorough legislative evaluations are conducted. These evaluations examine the effectiveness of legislation, providing insights into its performance in the daily practice and identifying unintended consequences. In this way, legislative evaluations are a specialised form of the broader concept of policy evaluation, focusing on the effectiveness of legislation—a unique policy instrument with distinct characteristics and traditions. This specialisation justifies our emphasis on this specific type of evaluation, a perspective supported by existing literature (e.g. Knap et al., 2023; Van Aeken, 2011; Van Voorst, 2018; Zwaan et al., 2016).

Legislative evaluations can be conducted either before (ex-ante) or after (ex-post) the implementation of a law. This thesis primarily concentrates on ex-post legislative evaluations (hereafter also referred to as legislative evaluations). Ex-post legislative evaluations have the potential to optimise both the legislation and its practical application (Mastenbroek et al., 2016). However, such optimisation can only be achieved if these evaluations are impactful and their findings are effectively utilised. Therefore, this thesis focuses particularly on the impact of ex-post legislative evaluations. This choice is based on insights gained during our research. Initially, we aimed to explore both the methodology and impact of legislative evaluations, but as the research progressed, our emphasis shifted more towards impact, where we identified the most significant research gap. We realised that exploring the impact of legislative evaluations could offer a more substantial scientific contribution. Consequently, we began to view methodology more explicitly in the context of impact, reframing it as a strategic approach rather than merely a collection of methods and techniques. Our discussions led us towards the relatively unexplored relationship between impact and methodology, as well as other influencing factors. This new direction promised to enhance our understanding and to provide more meaningful insights.

1.2 Various approaches to conducting ex-post legislative evaluations

Conducting ex-post legislative evaluations is a growing trend, with diverse approaches employed across countries (OECD, 2020). Many countries have institutionalised ex-post legislative evaluations, making them a standard practice (Anglmayer & Scherrer, 2020). Also at the European Union level, these evaluations are integral to the Commission's Better Regulation policy, aimed at enhancing effective public policy choices and the value of European Union interventions (OECD, 2020).

The positioning and execution of ex-post legislative evaluations vary significantly (Humbeeck, 2000). In different countries, different entities are responsible for conducting ex-post legislative evaluations. In most European countries, the department responsible for crafting legislation conducts ex-post legislative evaluations. Some countries primarily use internal parliamentary committees for these evaluations, while others rely on external parties, or a combination of both. However, in only a minority of European Union countries and outside the EU, external bodies or committees handle ex-post evaluations (OECD, 2019). Countries like the United States and Canada often assign this task to independent evaluation agencies or committees, such as the Government Accountability Office in the US and the Office of the Auditor General in Canada (Brown, 1988). These agencies conduct systematic evaluations of laws and programmes, analysing their outcomes and impacts and issuing reports to parliaments or legislative bodies with recommendations for enhancements.

Regardless whether they are conducted within or outside the parliament, ex-post legislative evaluations often employ a variety of methodologies, such as data analysis, case studies, interviews, surveys, and cost-benefit analyses (Bussmann, 2010). These methods are used to assess both the direct and indirect effects of legislation, including economic impacts, social effects, compliance costs, and administrative burdens. Which methods are used may vary depending on whether the legislation is primarily focused on establishing a framework for behaviour (social ordering) or on addressing specific social issues to achieve desired outcomes (social problem-solving) (Bussmann, 2010).

The decision on which law to evaluate may depend on how the ex-post legislative evaluation is initiated, either based on an evaluation clause in the law itself or at the request of the political domain (Bussmann, 2010). Overall, the approach to ex-post legislative evaluations varies significantly from country to country, reflecting a broad diversity in methods and practices.

1.3 Ex-post legislative evaluation within Dutch healthcare

The Netherlands has adopted a unique external approach to evaluating health-related legislation. Since 1997, ZonMw, a Dutch funding organisation for innovation and research in healthcare, has been a key player in evaluating health-related laws through the ZonMw Programme for Regulatory Evaluation (the ZonMw programme) (Huijbregts & Slijper, 2022). This programme is dedicated to evaluating a wide range of Dutch health-related laws, spanning from ethical to instrumental laws. For example, the Embryo Act addresses a highly ethically charged topic, focusing on the

careful handling of eggs, sperm cells, and embryos by physicians and laboratory technicians. In contrast, the Healthcare Quality, Complaints and Disputes Act (Wkkgz) organises the quality of healthcare and addresses complaints and disputes in healthcare settings. Additionally, the Youth Act is another important health-related law, providing regulations for the care and support of children and young people under 18 years old.

Currently, 56 evaluations have been conducted within the ZonMw Programme (ZonMw, 2024). These evaluations were either single or thematic. Single evaluations focus on specific laws, while thematic evaluations explore overarching themes across multiple pieces of legislation, such as forced, or involuntary care. To date, four evaluations were thematic evaluations. Although many laws include an evaluation clause, it is the Minister responsible for the law who decides on the timing of a legislative evaluation. While the programme exclusively features ex-post legislative evaluations, the timing of the evaluations varies, with some occurring shortly after a law's implementation and others being conducted later.

The execution of legislative evaluations is entrusted to independent, multidisciplinary research groups, selected for each study. The ZonMw programme ensures a consistent approach in execution, as all evaluations integrate legal and empirical research. Legal research examines a law's validity, internal and external consistency, clarity, and accessibility while empirical research evaluates its practical functioning. The combination of these two types of research enables an integrated reflection on the legislation and its impact on society. This approach distinguishes the evaluations within the ZonMw programme from those in other policy domains outside it (Niemeijer & Klein Haarhuis, 2008), making it unique to the ZonMw programme. As part of the ZonMw programme, the ZonMw Committee for Evaluation of Regulations (CER) is responsible for the programme execution, advising on task formulation, selecting the research team, guiding research, and ensuring quality control following established procedures.

The well-established tradition of this ZonMw programme provides a valuable source of information to get insight into the actual impact of the evaluations conducted within it. As previously mentioned, it is vital that ex-post legislative evaluations are not just carried out, but that actionable steps are taken based on their results. It is important to examine whether this action actually occurs. Without effectively implementing the evaluation insights, they risk becoming mere procedural exercises.

Recognition of the need to learn from evaluations goes beyond the realm of legislative evaluations or healthcare, as evidenced by the broad national pilot initiative "Learning Evaluation" launched in 2018 by the Ministry of Health, Welfare, and Sport (VWS). The pre-pilot evaluation revealed that policy directorates often perceive audits as obligatory activities primarily aimed at justifying policies, rather than seizing the opportunity for learning. Moreover, it is frequently unclear to what extent the lessons learned from evaluations are actually implemented (VWS, 2019). By advocating for learning from evaluations, VWS aims to catalyse a movement towards higher-quality evaluations that encourage the utilisation of evaluation results. Both ZonMw and VWS are

dedicated to maximising the utilisation of knowledge from legislative evaluations and recognise the societal imperative of identifying strategies to accomplish this objective.

1.4 What is already known about the impact of ex-post legislative evaluations?

It is worth noting that there is a distinction to be made between the impact of the law itself and the impact of a legislative evaluation. Here, we explicitly refer to the latter form of impact.

The dominant focus of legislative evaluations is to enhance the quality of legislation. Consequently, the impact of an evaluation can be measured by assessing how significantly it contributes to improving the legislation's quality. Previous research has shed light on the influence of legislative evaluations on the quality of legislation (Winter, 1996). In assessing this quality, various aspects must be distinguished. Winter (1996) made a distinction between the quality of the law as a legal instrument and the quality of the law in its application. These perspectives offer two lenses through which the quality of a law can be assessed: Is the law effective as a legal instrument, consistent with other laws, and clear in its wording? This pertains to meeting the legal standards of what constitutes a well-crafted law. It concerns the design and the text of the law itself. The second lens involves assessing how the law performs in practice, evaluating its efficacy in achieving its intended goals within society.

Yet, the implementation of laws can encounter challenges when users perceive them, or certain parts thereof, as complex or unclear. This may stem from to the structure of a law or the use of specific terminology in the legal text. The drafting technique of a statutory regulation plays a crucial role here, particularly in relation to its functions such as the assurance or instrumental function (Legemaate, 1997). Nevertheless, nearly every legislative evaluation shows that a technically well-drafted law may not always be successful in achieving its objectives in practice. Despite being well-drafted on paper, a law can fall short in the societal reality due to various circumstances. These factors can include the level of public awareness about the law, the knowledge and attitude of involved parties, and the availability of resources and facilities in the sector to which the law applies. Such factors can strongly influence the quality of the law in practice, as described in previous literature (Winter, 1996).

Achieving impact through legislative evaluations, such as improving the quality of legislation, involves several influencing factors. Klein Haarhuis and Parapuf (2016) demonstrated that conditions on the 'policy side' are also necessary to achieve impact. They argue that it starts with the evaluation provision in the law. Additionally, they emphasise the importance of policy departments' ability to utilise the results of an evaluation. Weiss (1999) also observed that the use of evaluation results largely depends on whether politicians, policy officials, or legislative lawyers have the time and inclination to act upon the findings. Later studies noticed that ex-post legislative evaluations can also be used for accountability purposes or have a more forward-looking motive, aimed at agenda-setting and policy change (Zwaan et al., 2016).

1.5 Research aims, questions and outline of this thesis

As described earlier, legislation serves as a crucial instrument for organising and regulating various aspects of societal and governmental operations, notably within sectors like healthcare. It is essential to assess whether legislation achieves its intended goals. This is the primary focus of legislative evaluations, which in some countries, such as the Netherlands, are conducted within extensive evaluation programmes. Despite assuming that ex-post legislative evaluations have an impact, we currently lack clarity on the actual outcomes of these evaluations and whether they result in tangible effects.

Recognising the importance of ensuring that legislative evaluations have an impact, our study aims to illuminate the effects of ex-post legislative evaluations and explore opportunities for optimisation. In contexts where the emphasis appears to be primarily on the quality of legislation, we are interested in exploring whether there are additional outcomes stemming from legislative evaluations, beyond mere enhancement of legislative quality.

Drawing on insights from existing literature and leveraging the extensive experience of the ZonMw programme spanning over 25 years, we strive to develop a well-founded understanding that is both scientifically supported and practically applicable within Dutch healthcare and beyond. We aim to clarify existing knowledge and contribute new insights.

The central research question guiding our study is:
How can the impact of ex-post legislative evaluations in healthcare be optimised?

To answer this question, we have formulated the following sub-questions:

Sub-question 1: What is a relevant framework for assessing the impact of ex-post legislative evaluations and the factors influencing this impact?

1a. What types of impact of ex-post legislative evaluations can be distinguished?

1b. What factors influence the impact of ex-post legislative evaluations?

Sub-question 2: What is the impact of ex-post legislative evaluations in Dutch healthcare?

Sub-question 3: What do the ex-post legislative evaluations in Dutch healthcare teach us about the factors that influence impact?

This thesis is structured in three phases to thoroughly explore and understand the impact of ex-post legislative evaluations.

Part one – Creating a framework for assessing the impact of ex-post legislative evaluations
We first look at the broad international literature on legislative evaluations, including outside of the Netherlands and beyond the healthcare domain, in chapters **2 and 3**. In chapter 2, we explore the various types of impact visible in the literature, and in chapter 3, we examine the factors influencing the impact of ex-post legislative evaluations. This analysis is based on an extensive literature review, that encompasses research conducted outside the Netherlands and beyond healthcare law.

Part two – Case studies on ex-post legislative evaluations in Dutch healthcare
Chapters 2 and 3 form a theoretical foundation to establish a broad conceptual framework that serves as a tool for in-depth empirical research. This framework is detailed in **chapter 4**. Here, it describes how the broader insights from this framework can be applied to a more specific context, namely the legislative evaluations within the Dutch ZonMw programme focused on healthcare legislation. This framework was developed using the Realist Evaluation method, which aims to uncover how and why certain outcomes occur in specific contexts. It involves identifying context-mechanism-outcome configurations to understand how legislative evaluations operate within the ZonMw programme and their impact on healthcare legislation and practices.

In **chapter 5**, three distinct case studies – the evaluation of the Youth Act, the Embryo Act, and Wkkgz - are conducted. These case studies apply the theoretical framework to investigate the various types of impact, the factors influencing this impact, and the interconnections between them.

Part three – In depth research on serious adverse event investigations in Dutch hospitals following an ex-post legislative evaluation
Following this, **chapters 6 and 7** delve further into one of the ex-post legislative evaluations introduced earlier in chapter 5, the evaluation of the Wkkgz. Following the Wkkgz evaluation, the Dutch Health and Youth Care Inspectorate (the Inspectorate) found healthcare institutions focus more on reporting incidents than learning from them. One of the Wkkgz evaluation recommendations suggests that the Inspectorate should have the flexibility to tailor its oversight of 'the learning organisation' to fit the developmental stage of the respective sector. The Inspectorate requested additional details not covered in the evaluation which were the focus of in-depth research. For this study, we invited all Dutch hospitals, including academic, top clinical, and regional hospitals, to participate and many accepted. We conducted questionnaires, consulted patient councils, interviewed professionals and patients, and held focus groups with individuals involved in serious adverse event investigations. The research concluded with a meeting where participants from various hospitals gathered to discuss and share the initial findings of the study.

Chapter 6 exemplifies next steps to reach the field with evaluation recommendations, while chapter 7 illustrates the potential roles envisioned by these stakeholders themselves in this process.

In **chapter 8**, the thesis's discussion unfolds, ultimately delineating specific recommendations from this study to highlight key aspects of the evaluation process. The aim is to contribute to optimising the impact of ex-post legislative evaluations. This approach aligns with our research goal of establishing a robust understanding that is both scientifically rigorous and readily applicable in practice.

The empirical chapters (5-7) have been published as individual scientific articles. These chapters build upon one another to provide a comprehensive overview, transitioning from broader theoretical concepts to their practical application in the specific context of Dutch healthcare.

1.6 Conceptual approach

The domain of ex-post legislative evaluations is multifactorial, with different factors interacting and influencing each other. In such multifactorial domains, the interplay between various factors creates a dynamic and interconnected environment. Traditional deterministic methods, which often assume linear cause-and-effect relationships, fall short in capturing this complexity. Instead, a more nuanced and flexible approach is required—one that accounts for the multitude ways in which factors interact and influence outcomes.

To address this need, the research process starts with comprehensive reviews of the existing literature. These reviews serve to map out the current state of knowledge, identify gaps, and highlight the diverse factors at play. By synthesising insights from previous studies, we gain a deeper understanding of the multifactorial nature of the domain and the challenges it presents.

Building on this foundation, the Realist Evaluation (RE) method is employed. RE is particularly well-suited for exploring complex systems because it seeks to understand not just whether an intervention works, but how, why, and in what contexts it produces its effects. This approach allows us to develop theories about the underlying mechanisms that drive outcomes and to test these theories against empirical evidence.

The ambition of using RE is to construct a more comprehensive and nuanced understanding of the domain, leveraging the knowledge already available. RE does not produce final answers, but it adds new and deeper insights to the available knowledge. By systematically examining the interactions between various factors and their impacts, RE aims to generate actionable insights that inform more effective interventions and policies.

Based on this RE method, the empirical phase involves conducting three in-depth case studies within the ZonMw programme; a well-established research programme. The preference for case studies is reinforced in the broader evaluation literature, emphasising their importance in contextual explanations and their capacity to enrich learning through evaluations. Mouton (2009) notably champions evaluative case studies over experimental or quasi-experimental designs, as well as outcome monitoring and assessment, for assessing the impact of complex social interventions. The evaluative case study design prioritises contextual explanations, often

conveyed through narratives. Similarly, Sridharan (2008) advocates for evaluative case studies, highlighting their emphasis on contextual explanations and their capacity to enrich learning through evaluations.

Armed with these methodological tools, we delve into the intricacies of ex-post legislative evaluations.

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Section I

Creating a framework for assessing the impact of ex-post legislative evaluations

Chapter 2

The impact of ex-post legislative evaluations

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Abstract

In various countries, laws are increasingly being evaluated by examining the effects in practice once a law enters into force. No systematic overview currently exists on the impact of these ex-post legislative evaluations. Therefore, this scoping review systematically examines the various types of impact of ex-post legislative evaluations. The studies we looked at demonstrate different types of impact that can be divided into the following seven categories: knowledge and understanding; confirmation of well-functioning legislation; legislative revision; influence on the legislative process; influence on the policy process; influence in the political sphere; and influence on society. The various types of impact are sometimes interrelated and can exist in various degrees. At the national and European levels, legislative revision and the tactical use of evaluation results in the political sphere, are the two most often mentioned categories. In contrast, the impact on society category is rarely mentioned.

2.1 Introduction

Ex-post legislative evaluations, also referred to as post-legislative scrutiny,[1] assess the functioning of legislation by examining whether the legislation works, how it works, and the effects that occur in practice after a law enters into force. These evaluation studies are conducted either systematically – e.g. on the basis of an evaluation clause in the law, a budgetary threshold or out of a general principle – or, on an ad hoc basis. In some literature, legislative evaluations are seen as a form of policy evaluation, leading to both being considered related (Klein Haarhuis & Parapuf, 2016; Wollmann, 2016). However, despite the many similarities between policy evaluations and legislative evaluations, there are essential characteristics of legislative evaluations that warrant specific attention to this type of evaluation (van Aeken, 2011). This is especially true because legislation can be seen as one of the most powerful policy instruments, influenced by policy agendas, legal debates, and societal developments. Therefore, ex-post legislative evaluations can impact the policy domain, the surrounding legal debate, and society itself.

In recent decades, the evaluation of legislation has received more attention, both at the national and European Union (EU) levels, as the increasing number of laws has created a greater need to understand the effectiveness of legislation. The Organisation for Economic Cooperation and Development also highlighted the importance of keeping the accumulated stock of legislation consistent and up-to-date (OECD, 2020). This has led to an institutionalisation of ex-post legislative evaluations (Anglmayer & Scherrer, 2020).

Furthermore, the importance of contributing to better regulation through legislative evaluations is particularly recognised by legislators and policy makers (Bussmann, 2010; European Court of Auditors, 2018; The Law Commission, 2006; Winter, 2002). Ex-post legislative evaluations have gained prominence and are now considered an integral part of regulatory governance. Many countries, as well as the EU, have institutionalised ex-post legislative evaluations. For example, in 2013, as part of the European Union better regulation concept, the European Commission introduced the 'evaluate first' principle, which means that the European Commission aims to conduct an ex-post legislative evaluation before revising existing legislation (European Court of Auditors, 2018). Furthermore, the need for ex-post legislative evaluations became evident in the context of legislation enacted in response to the COVID-19 pandemic, when the urgency of the situation did not allow for an ex-ante evaluation or impact assessment and parliaments were often bypassed. Ex-post legislative evaluations can be used to examine whether emergency measures are still in the public interest and should be abolished or continued (OECD, 2021).

[1] Post-legislative scrutiny is defined by the Law Commission of England and Wales as "A broad form of review, the purpose of which is to address the effects of legislation in terms of whether intended policy objectives have been met by the legislation and, if so, how effectively. However this does not prevent the consideration of narrow questions of a purely legal or technical nature." (p. 7) (The Law Commission, 2006).

While there is a clear call for ex-post legislative evaluations, research on the impact of these evaluations is scattered. An extensive and diverse body of scientific literature describes all types of actual and potential impact on parties involved at various times in the legislative process and with various degrees. However, this very diversity confirms the need for a comprehensive overview of its different types of impact. This scoping review therefore aims to systematically examine what types of potential and actual impact can be broadly identified, without limitation to jurisdictions, and what is known in the literature about the different types of potential and actual impact of ex-post legislative evaluations. The contributions of this study are manifold: we broaden our understanding of ex-post legislative evaluations (without limiting ourselves to national borders); we add to existing literature on legislative evaluation; and we develop the qualitative knowledge base for understanding the different types of impact.

2.2 Research method

This study aims to present a broad spectrum of insight derived from literature on the types of impact of ex-post legislative evaluations in order to identify the available evidence on the same, and to analyse knowledge gaps in this field (Colquhoun et al., 2014). Therefore, this scoping review followed the methodological PRISMA-ScR framework (Arksey & O'Malley, 2005; Levac et al., 2010). Scoping reviews are an ideal tool to determine the scope or coverage of a body of literature on any given topic that is not yet well charted (in this case, the impact of ex-post legislative evaluations) providing an overview (broad or detailed) of the literature's focus.

2.2.1 Phase 1

In an effort to capture all relevant literature, the study started with a broad research question: What can be found in the scientific literature about the methodology and impact of ex-post legislative evaluations? To ensure a broad search strategy, the research question did not include any specific jurisdiction or field of law. After conducting a detailed search, the research question was narrowed (see phase 4).

2.2.2 Phase 2

A search was made of the Web of Science, Worldcat and Legal Intelligence scientific databases using different search strings for an initial scope of the scientific literature (first quarter of 2021). Given that literature on this topic was expected to be scarce, no timespan was selected for the search. Identical search strings were applied per database with both English and Dutch search terms, provided with Boolean operators (AND, OR), wildcard symbol, quotation marks, parenthesis and truncation in order to improve the search strategy. We initially started with a broad search strategy followed by two more specific search strategies, one related to methodology and the other to impact. Synonyms were applied for this purpose. The final search strings are included in Table 1.

Table 1. Final scientific search strategies.

Web of Science, Worldcat Discovery and Legal Intelligence
Dutch search terms
1st strategy TI=(wetsevaluatie* OR ‘’Evaluatie wet*’’ OR ‘’evaluatie regel*’’)
2nd strategy TI= (wetsevaluatie* OR ‘’Evaluatie wet*’’ OR ‘’evaluatie regel*’’ AND aanpak OR uitvoering OR method*)
3rd strategy TI=((wetsevaluatie* OR evaluatie wet* OR evaluatie regel*) AND (impact OR gevolg OR invloed OR effect**))
English search terms
1st strategy TI=(‘’Legislative evaluation* OR ‘’Law evaluation*’’ OR ‘’Evaluation of legislation*’’ OR ‘’Legal evaluation*’’)
2nd strategy TI=((legislative evaluation* OR law evaluation* OR evaluation of legislation OR legal evaluation*) AND method*))
3rd strategy TI=((legislative evaluation* OR law evaluation* OR evaluation of legislation OR legal evaluation*) AND (impact OR influence OR result* OR utilization OR utilisation))

2.2.3 Phase 3

In total, 4,204 studies were found with English search terms, and 413 studies were found with Dutch search terms (see Figure 1 for the entire search process, which is explained in more detail below). All literature was uploaded in Rayyan software, an administrative tool that facilitates the process of identifying and selecting studies when conducting a systematic literature review (Ouzzani et al., 2016). After merging the data, duplicates were removed (1,340 out of 4,617 studies). The literature (n = 3,277) was screened and selected by the first author (LK) based on title (e.g. excluding titles that were not on the subject of ex-post legislative evaluations) and abstract. Independently, another author (RvG) reviewed a random selection of 5% (164 studies) using the initial criteria. For 7 of the 164 studies, disagreements between the authors about the selection had to be resolved through discussion.

Studies were deemed relevant if they focused in full or in part on the methodology and/or impact of ex-post legislative evaluations and were written in English or Dutch. Since the Netherlands has a long history of ex-post legislative evaluations and much literature is written in Dutch, the research group considered this a valuable addition to the English language literature. During the selection of studies, those on the impact of legislation itself rather than the impact of ex-post legislative evaluations were excluded, as were studies on the impact of evaluations in general without a reference to ex-post legislative evaluations. Policy evaluations without a legal aspect were also excluded. Finally, ex-ante legislative evaluations were excluded from this study due to the different research designs used and their significance, as they are conducted before legislation

is passed. On this basis, a total of 3,045 out of 3,277 studies were excluded and 232 studies were included (see Figure 1).

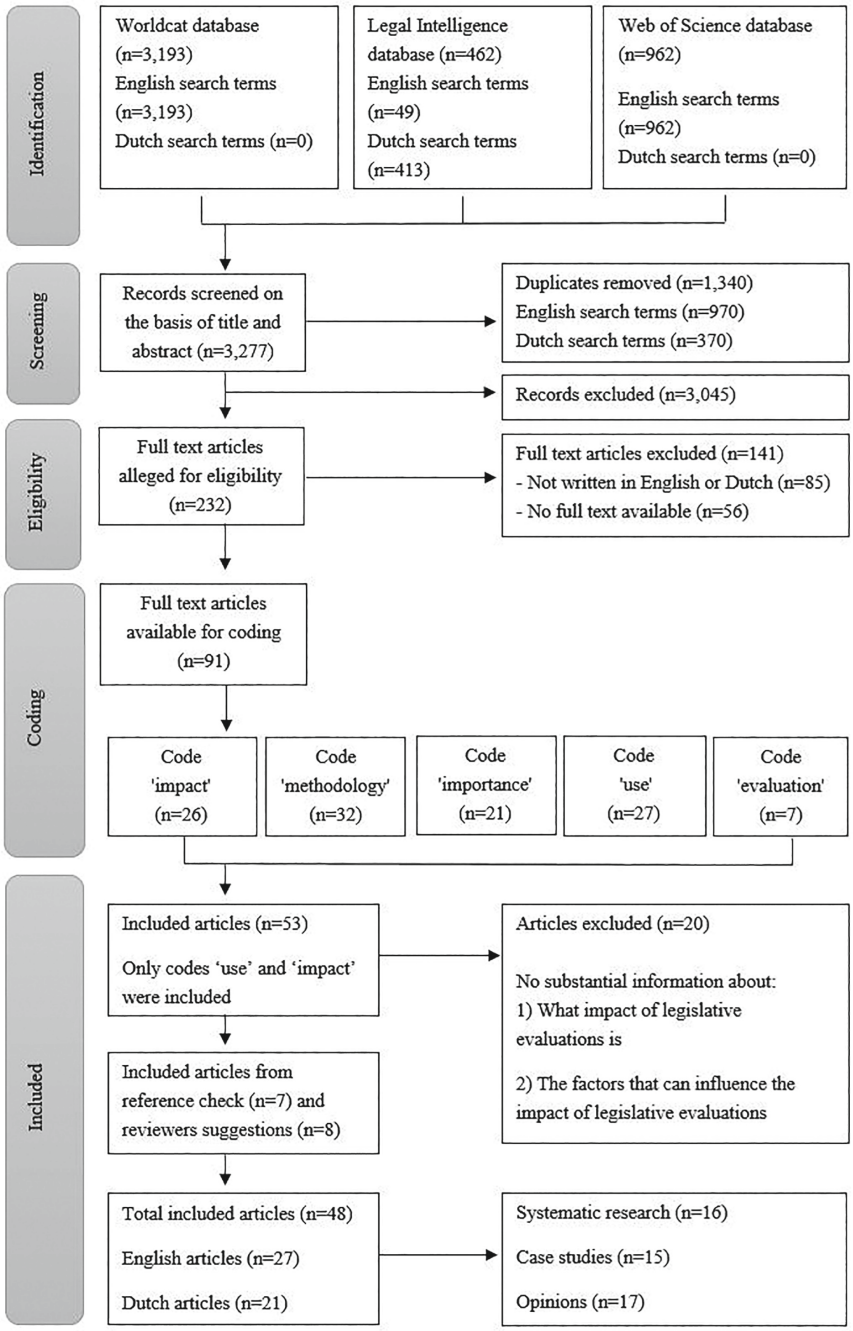


Figure 1. Methods flowchart.

After selecting the studies and, in order not to miss any relevant coding, authors (LK) and (RvG) coded the studies based on title and abstract without agreeing on the codes beforehand. After, all authors agreed on the coding for the full text assessment; namely, methodology, use, impact, importance, and evaluation. Disagreements in the assigned types of coding after full text assessment were resolved through discussion between the authors. The full text versions of all 232 studies were manually searched. The studies that were either unavailable in full text (n = 56) or not written in English or Dutch (n = 85) were excluded (141 out of 232 studies). With regard to data openness, a list of the remaining 91 articles is included in Appendix 1.

2.2.4 Phase 4

In phase 4, the research question was narrowed down: What can be found in the scientific literature about the impact of ex-post legislative evaluations? In this scoping review, impact is seen as the influence of ex-post legislative evaluations on various directly and indirectly affected parties.

As it appeared that much had already been written on the methodology of ex-post legislative evaluations, the focus on the impact of ex-post legislative evaluations could make a greater scientific contribution. For this purpose, a filtered selection was made of only studies coded with 'impact' (n = 26) and 'use' (n = 27). The 53 studies were fully read and assessed for relevance by both authors (LK) and (RvG), after which 20 studies were excluded (see Figure 1). The relevant studies (n = 33) were divided into three categories, including: systematic research in which a certain number of legislative evaluations were studied in a systematic manner (12 out of 33); case studies (12 out of 33); and expert opinions (9 out of 33). Importance was allocated in this order to the included literature and opinions could be empirically verified by case studies or systematic research. In the results of this scoping review, specific reference is elaborately made to these three research types.

References from the relevant studies were hand-searched by authors (LK) and (RvG) resulting in seven additional studies (four systematic research studies, and three expert opinion publication) that were added to the number of included studies. A final addition was made based on suggestions from reviewers of the manuscript. Due to the strict focus on ex-post legislative evaluations, the term 'post-legislative scrutiny' fell outside the scope of included data. This term was manually searched in all three databases, after which eight studies were added to the dataset (three systematic research studies, three case studies and two expert opinions). The relevant literature (n = 48) was schematically mapped on the basis of which the categories were created.

2.3 Results

The included literature shows that there is a longer history of ex-post legislative evaluations, as over half of the articles were published between 1990 and 2015, slightly less than half were published between 2015 and 2022. The studies show a strong focus on European countries, and

the European Union, and mainly focus on specific fields of law, such as, health, criminal, EU, and administrative law. The studies written in English mostly relate to post-legislative scrutiny, and European Union law. The studies written in Dutch related mostly to health, criminal, and administrative law (one study was related to family law).

Since the ex-post legislative evaluations are conducted in different countries, the context in which an ex-post legislative evaluation takes place differs (van Aeken, 2011).

There are many factors that determine the context, including how countries include the ex-post legislative evaluation into their parliamentary practices, and the different executors of ex-post legislative evaluation studies (such as the Ministry, Parliament or independent researchers). Depending on the country's evaluation system, the evaluation is conducted by different parties such as the government, parliamentary committees or external researcher groups. In the Dutch system, for example, ex-post legislative evaluations are conducted by independent researchers outside Parliament, while in the United Kingdom, they are also conducted by parliamentary committees (Caygill, 2019a). The influence this difference has on the impact of ex-post legislative evaluations goes beyond the scope of this article. Further in-depth research is therefore necessary in terms of factors that could influence the impact of ex-post legislative evaluations.

Despite these different contexts, similar types of impact have been described in the reviewed literature. These are extracted in this results section and divided into seven categories. A systematic mapping of the literature reveals that older literature on this topic mainly contains opinions on the impact of ex-post legislative evaluations. Several case studies and systematic research studies have taken place in more recent years.

2.3.1 Knowledge and understanding of the effects of the law

The first type of ex-post legislative evaluation impact identified in the included literature is the knowledge and understanding of the effects of the law in practice (Scheltema, 2002), acquired primarily by the commissioner of the legislative evaluation (such as the Ministry, Parliament or politicians). Different forms of knowledge are cited in the literature, such as: knowledge about economic and social impact of policies (van Schagen, 2020); fulfilment of policy objectives; the implementation of legislation; the need for legislative amendments; legislative bottlenecks and knowledge of the relationship with other legislation (Hendriks, 2000; van Schagen, 2020; Verschuuren & van Gestel, 2009; Winter, 1997; Winter, 2002; Zwaan et al., 2016). Additionally, systematic research on the implementation and use of legislative and policy evaluations in the Netherlands emphasises that evaluations also bring knowledge to the surface about the implicit assumptions on which the law or policy rests (Klein Haarhuis & Parapuf, 2016). This subsequently leads to policy transparency in the public domain (Anglmayer & Scherrer, 2020). At the European level, ex-post legislative evaluations of European legislation lead to more knowledge on the implementation of legislation by Member States (Mastenbroek et al., 2015).

Early publications mention knowledge of evaluation results as the most substantive function of evaluation research (Veerman, 1991). This is in line with early systematic research on the use of ex-post legislative evaluations in the Netherlands, which showed that perusal is the most common form of use of evaluation results (Winter et al., 1990). More recent studies, however, highlight the specific functions of knowledge and insight from legislative evaluations, such as stimulating interaction between the professional players in the field, such as the Legislature, the Parliament, the judge and the administration (Hendriks, 2000; Scheltema, 2002), reducing uncertainties about the operation of the law in practice (Veerman, 2014), or informing the Legislature on the basis of which legislative decisions can be made in similar situations (Nelen, 2000; Winter, 1997). Although several studies mention that ex-post legislative evaluations also provide knowledge about issues in the implementation of legislation (Doust & Hastings, 2019), systematic research on post-legislative scrutiny in the United Kingdom shows that only a small number of recommendations call for action with regard to the implementation of legislation (Caygill, 2019b).

Another function of knowledge acquired from ex-post legislative evaluations described in the included literature is the insight provided as a review mechanism for other forms of advice. For example, ex-post legislative evaluations were used to test the quality of the Dutch Council of State's advice. This Council provides a form of ex-ante evaluation of upcoming legislation. Information from ex-post evaluation is used to assess the framework and the working method of the Legislative Advisory Council on legislative proposals (Vranken & van Gestel, 2008).

Furthermore, acquiring knowledge and understanding from ex-post legislative evaluations is not only relevant at the individual national or European level, but can also have cross-border relevance. For example, the literature notes that Dutch legislative evaluations on ethical issues, like the Dutch Termination of Life on Request and Assisted Suicide (Review Procedures) Act, also have an effect outside the Netherlands. Other countries, such as Belgium, Italy and France closely follow the practice of euthanasia in the Netherlands, taking into account the knowledge from ex-post legislative evaluations (De Goeij, 2007).

2.3.2 Confirmation on well-functioning legislation

The second type of impact of ex-post legislative evaluations identified in the included literature is the confirmation of well-functioning legislation. Evaluation results can show that (a part of) a law works properly and thus confirm the intended legislative ideas of policymakers and legislators. Only a few studies included in this scoping review recognise the ability of evaluations to confirm the effectiveness of legislation. For example, one case study concluded that the evaluation had shown that the law had been applied in a careful manner (De Goeij, 2007). In another case study on the ex-post evaluation of the Dutch General Administrative Law Act, the author stated that while confirmation of a well-functioning law (on certain points) is important, it is a less spectacular research result (Michiels, 2010). However, according to the author, such confirmation does not detract from a successful evaluation (Michiels, 2010). A later systematic research on the theory of legislation in the Netherlands (examining 74 legislative evaluations) concluded that

legislation in general achieves its goals to a very decent degree (Veerman et al., 2013). Besides achieving the purpose of the law, compliance with the law also scored high in this study. A later study of post-legislative scrutiny in the United Kingdom also mentioned that evaluating legislation can lead to the conclusion that little or nothing needs to be changed (Norton, 2019) – which implies that legislation is functioning well.

2.3.3 Legislative revision

Legislative revision (also referred to as legislative amendment) is the third type of impact of ex-post legislative evaluations as identified in the included literature. Over the years, several authors have concluded that ex-post legislative evaluations can improve the quality of the evaluated legislation through instrumental use of the evaluation results (European Court of Auditors, 2018; Klein Haarhuis & Parapuf, 2016; Scheltema, 2002; van Humbeeck, 2000a; van Voorst & Zwaan, 2019; Veerman, 2014; Winter, 1997). Ex-post legislative evaluations contribute to this quality by keeping legislation simple, consistent and up to date (European Commission, 2005; OECD, 2020). Moreover, evaluation results can lead to modification of the law, but also to its abolition (Legemaate, 1997; Veerman, 1991). There are many reasons for this; for example, the results may uncover flaws in a law (Legemaate, 1997) or detect recent societal and/or medical-technological developments that may reveal the need to adapt legislation to new circumstances (De Goeij, 2007). According to one author, it is usually the Parliament, Ministry or one or more political departments that is particularly interested in evaluation results which can be used concretely in terms of legislative amendments (Veerman, 1991).

Other authors also refer to concrete use when legislative amendments are actually implemented (Veerman, 1991; Winter et al., 1990). However, as shown in a case study on Danish and Dutch parental responsibility laws, implemented legislative amendments can be less extensive than recommended in the ex-post legislative evaluation (Jeppesen de Boer, 2014). In fact, researchers can make farfetched recommendations that are little supported by evaluation research (Winter, 1997). In addition, evaluation result recipients can ignore or reject recommendations to amend the law (Nelen, 2000). This is supported by the results of a case study on post-legislative scrutiny in Western Australia, which showed that of all the recommendations from four case studies, only 11% were implemented (Doust & Hastings, 2019). Systematic post-legislative scrutiny in the parliament of the United Kingdom also produced similar results, with only 20% of recommendations in need of amendments being implemented in full or in part (Caygill, 2019a).

However, this is not an entirely new insight; previous research has often shown that legislative evaluations do not often lead to legislative amendments, nor to significant changes. For example, systematic research has shown that of more than half of the 35 ex-post legislative evaluations examined resulting in legislative amendments, these concerned relatively marginal amendments of procedural or organisational provisions (Winter et al., 1990). The same conclusion was made on the basis of five case studies that were also conducted in this study. The legislative amendments mainly clarified and refined the legal texts (Winter et al., 1990). Another author, however, criticised this conclusion, alleging that the research results were based primarily on a survey of

policymakers, legislative lawyers, and politicians – saying more about their perspectives than about the relationship between evaluation results and the impact on legislative amendments (Nelen, 2000). A later case study on the evaluation of the Dutch General Administrative Law Act also emphasises that the already limited number of recommendations addressed to the Legislature has a limited impact on legislative amendments (Michiels, 2010). However, the author noted that it is not easy to determine the extent to which amendments are fully or partly a direct or indirect result of the ex-post legislative evaluation. Moreover, it should be noted that recipients of legislative evaluations are not required to implement legislative evaluation recommendations, but must be open to this. Otherwise the evaluation will miss its target (Legemaate, 1997).

2.3.4 Influence on the legislative process

In addition to improving legislative texts, several authors mention that ex-post legislative evaluations can also improve the legislative process itself (Gevers, 1995; Hendriks, 2000; Mansaray, 2019; Michiels, 2010; van Humbeeck, 2000a). This is not about the amendments made to the existing legal text but about the process of learning on the role of legislation in society. One author believes that the evaluation process is often more important, as it contributes to the quality of legislation more than the outcome of the evaluation itself. The process leads to gradual understanding of the problems and possible solutions by conducting analyses during the evaluation process (van Humbeeck, 2000a). Other authors see legislative evaluations as part of the legislative process (Eijlander, 1993; Veerman, 1991, 2014). According to these authors, this process should not only focus on the preparation of new legislation but also on the evaluation of existing legislation and regulations in terms of effectiveness and relevance. By being open to lessons learned, contributions can influence the continuation of a good legislative process (Mansaray, 2019). They can also create the possibility to retrospectively test the assumptions of a law (Winter, 2002). Moreover, ex-post legislative evaluations can contribute to the appropriate use of the legislation instrument (Gevers, 1995) because it enables politicians during the legislative process to make considerations based on reliable information about the operation of the law in practice. This enhances the quality of a good debate during the legislative process (Winter, 1997) and may also help to prevent previous mistakes made by the Legislature (Hendriks, 2000). In this way, legislative evaluations can have a potential deterrent effect that make policy makers think twice before introducing new legislative proposals (Norton, 2019).

In some countries (and especially at the European level), ex-ante legislative evaluations are also part of the legislative process. Findings of ex-post legislative evaluations are often used in the regulatory impact assessments conducted to inform amending proposals (Poptcheva, 2013). Insights derived from ex-post legislative evaluations into the effects of a law or regulation serves as important input for ex-ante legislative evaluations and the drafting of new laws and regulations (Verschuuren & van Gestel, 2009; Zwaan et al., 2016). This has been demonstrated by systematic research on the use of evaluative information in the European Union (van Golen & van Voorst, 2016). Half of the 225 studied ex-ante legislative evaluations on proposals for legislative amendments used available information from ex-post legislative evaluations (van Golen & van Voorst, 2016). Using ex-post legislative evaluations results in ex-ante legislative evaluations and

vice versa can assess and improve the quality of ex-ante legislative evaluations and, thus, lead to a learning loop in the European regulatory cycle (Verschuuren & van Gestel, 2009).

In this regard, ex-post legislative evaluations can be used at the final stage of the regulatory cycle (European Court of Auditors, 2018; Klein Haarhuis & Parapuf, 2016) to assess the implementation of European legislation by Member States (Mastenbroek et al., 2015) or to improve the effectiveness of European legislation with legislative amendments (van Voorst, 2018). Yet, the European Court of Auditors describes ex-post legislative evaluations as "a key element of the European Union policy cycle as it contributes to the better regulation cycle" (p. 33) (European Court of Auditors, 2018). The important role that ex-post legislative evaluations play in the European legislative process is also evident from it forming part of the 'Better Regulation Agenda', launched in 2015 by the European Commission (European Court of Auditors, 2018). Before revising or introducing new legislation, the European Commission prioritises the evaluation of existing legislation, also referred to as the 'evaluate first principle', in place since 2013 (European Court of Auditors, 2018).

This is supported by systematic research of the European Court of Auditors, where 27 of the 32 legislative initiatives were based on ex-post evaluations (European Court of Auditors, 2018). The European Commission intended to adhere strictly to the 'evaluate first' principle, since "Already, over 80% of the European Commission's impact assessments supporting legislative revisions are based on an evaluation." (p. 17) (European Commission, 2021). Although the European Commission seems to make proper use of ex-post legislative evaluation results, it has stated that the European Parliament, the Council and the national actors make too little use of the insights resulting from ex-post legislative evaluations (van Schagen, 2020).

2.3.5 Influence on the policy process

The fifth type of impact of ex-post legislative evaluations identified in the included literature is the influence ex-post legislative evaluations have on the policy process. Although the policy process and the legislative process share many characteristics and sometimes overlap, the former is much broader in scope as compared to the legislative process. According to various authors, the policy process can be influenced by ex-post legislative evaluations (Vanlandingham, 2011; Winter, 1997) due to the knock-on effects of evaluation results in improved policies or policy decision making (Eijlander, 1993; van Aeken, 2018; van Humbeeck, 2000a). The evaluation results provide a better understanding on the effects of different alternatives (van Humbeeck, 2000b) and enable choices to be made for or against certain policy options in a more objective and transparent manner (van Schagen, 2020). Both new and existing policy decisions can be adjusted on the basis of ex-post legislative evaluation results (Nelen, 2000) as they can, for example, lead to agenda-setting on the basis of which the process of amending the law can be initiated (Anglmayer & Scherrer, 2020). However, the evaluation of legislation only serves to support policy-making and cannot replace political decision-making. In addition, some authors noted that legislative evaluations sometimes have a minor impact on the policy process (Veerman, 1991) or final policy decisions (van Humbeeck, 2000b).

From another perspective, final legislative evaluations as well as ongoing ones can contribute to the policy process, as mentioned in a publication on the utilisation of evaluation results in legal policy-making and administration (Wollmann, 2017). The ongoing evaluation process may create the opportunity to rectify and modify a policy design or implementation process based on interim evaluation results (Wollmann, 2017).

Several authors also mention the oversight and accountability function of ex-post legislative evaluations in the policy process at both the national (Doust & Hastings, 2019; Mansaray, 2019; Winter, 1997) and European levels (Anglmayer & Scherrer, 2020; European Commission, 2021; van Voorst, 2018). ex-post legislative evaluations can act as an executive oversight tool (Griglio, 2019) by increasing government accountability, thereby adding value to the Parliament's oversight role (Mansaray, 2019). One case study also suggests that "Overall, the fact that the European Parliament's ex-post evaluations have, in a number of cases, been successful in influencing or informing the European Commission's policy cycle could encourage other national parliaments to expand their own evaluation activities, from a passive to a more active role, in order to possibly strengthen their oversight function." (p. 423) (Anglmayer & Scherrer, 2020).

Systematic research of Zwaan et al. (2016) on the usage of ex-post legislative evaluations of European Union legislation by members of the European Parliament for holding the European Commission political accountable presents an analysis of 220 evaluations. The authors examined the number of evaluations that were followed up via parliamentary questions posed to the EC, concluding that 49 evaluations were followed up on -and mostly with forward looking agenda-setting and policy change purposes, rather than accountability purposes (Zwaan et al., 2016). In total, 34 evaluations were used to steer the behaviour of the EC. However, the members of the European Parliament seemed particularly interested in the actions to be taken rather than in exposing the European Commission's shortcomings (Zwaan et al., 2016).

2.3.6 Influence in the political sphere

The sixth type of impact of ex-post legislative evaluations identified in the included literature is the impact of ex-post legislative evaluations in the political sphere. Several authors stated that ex-post legislative evaluations can start a political discussion on certain topics, such as the objectives of a law and the balancing of interests enshrined in it (De Goeij, 2007; Gevers, 1995). Ex-post legislative evaluations of ethically sensitive legislation (such as the Dutch laws on abortion and euthanasia) frequently lead to political and social discussions which ensures that evaluation results are taken seriously (De Goeij, 2007). In addition, evaluation results can help to increase the quality of democratic deliberation with plausible arguments (Bussmann, 2010); resolve political conflicts (Eberli, 2018); or clarify and give more weight to political discussions or decisions at both national and European levels by providing support with evaluation data (Eberli, 2018; van Voorst, 2018; Veerman, 1991; Winter, 1996). Evaluation data can also influence existing political positions, as demonstrated by early research on five case studies on Dutch regulations (Winter et al., 1990). These case studies examined whether the findings of the evaluation report were considered by political actors. The results showed that there was evidence of positional influence

on political actors in all five case studies, and only to a lesser extent in one of these five case studies (Winter et al., 1990).

Evaluation results can also tactically be used in the political sphere. Politicians can use evaluation data to defend decisions that have already been made (van Humbeeck, 2000a); delay a decision (Eberli, 2018); or hide behind the data when legislative results are disappointing (Nelen, 2000). In this way, legislative evaluations have a legitimising or justificatory function (Eijlander, 1993). Moreover, the political debate following an ex-post legislative evaluation can also lead to selective use of evaluation results by politicians (Gevers, 1995; Veerman et al., 2013). After all, there is always a risk that legislative evaluations will produce results other than those expected, giving new ammunition to the opponents of those who requested the evaluation (Nelen, 2000). Actors who feel threatened by those evaluations may, for political reasons, try to prevent the use of evaluation results or selectively use results that fit their agenda (Veerman, 1991; Veerman et al., 2013). This was also shown in a publication on the fitness check of European consumer law in which the author compared an evaluation study conducted by a consulting company with the subsequent commission report (van Schagen, 2020). The author concluded that the European Commission selectively used the evaluation results by omitting a critical point about unclear general conditions from the evaluation study in its report (van Schagen, 2020).

Another tactical form of using ex-post legislative evaluations is to let them function as political bargaining to win over parliamentarians who oppose a law that has yet to pass (Veerman, 2014). However, as demonstrated in a case study on the use of ex-post legislative evaluations by the European Commission, such opposition by key political actors at the European level does not stop the instrumental use of ex-post legislative evaluations (van Voorst & Zwaan, 2019). At the national level, the insertion of an evaluation clause in the law sets as a condition that the law will be discussed again after entering into force (Veerman, 1991; Vranken & van Gestel, 2008; Winter, 1996). A potential risk here is that the political landscape may change by the time the evaluation is due (according to the evaluation clause) (Legemaate, 1997).

An example is described in a case study on the Dutch Directors' Liability Act, where the House of Representatives doubted the usefulness of this act and its burden on business. The Minister of Justice proposed conducting an evaluation in order to ensure a majority for the bill (Veerman, 1991).

An additional political strategic advantage of ex-post legislative evaluations may be to win time, to get the issue off the table for a while so that it is no longer on the political agenda (Veerman, 1991). This can also ensure that the interlocutors (and their constituencies) can get used to each other's political positions (Veerman, 1991).

2.3.7 Influence on society

In addition to having an impact on the formal participants in the ex-post legislative evaluation process, evaluation results may also have impact on society. Laws have a codifying and modifying

character. As such, they have become more instrumental in modifying social behaviour, offering certain guarantees, to society, and in influencing it overall. Ex-post legislative evaluations can provide insight on the extent to which legislation matches citizens' perceptions (De Goeij, 2007), and could as a result "(..) provide an important link between citizens and parliament, but may not always live up to its promise." (p. 2) (Moulds & Khoo, 2020). However, despite it being clear that legislation directly affects society, only a few authors indirectly mention the impact of ex-post legislative evaluations on society. In earlier research, the literature pointed to there being an opportunity for citizens to benefit from evaluation results as potential users of legislative evaluations (Hendriks, 2000; Poptcheva, 2013). The authors claimed that evaluation results could, for example, influence societal opinions, lead to debates among the citizenry, and strengthening the democratic debate. Since evaluation results are accessible to any interested party, including citizens and the media, they ensure transparency in the public domain, which means that people are better informed (Anglmayer & Scherrer, 2020; Norton, 2019).

Van Aeken (2018) has conducted a surprising addition to the body of research in the form of a conceptual exercise, examining whether ex-post legislative evaluations could also contribute to the democratic process. The author noted that a shift from government to governance in Belgium presented an opportunity for the democratic functionality of an ex-post legislative evaluation (among other things), but concluded that there are no signs of political support for this (van Aeken, 2018). Besides direct effects, ex-post legislative evaluations also have indirect effects on society. One study affirmed, for example, the importance of involving citizens in the implementation of ex-post legislative evaluations in an effort to rebuild trust between citizens and institutions (Moulds & Khoo, 2020). A different perspective was given in the OECD's policy outlook describing the importance of ex-post legislative evaluations in relation to the COVID-19 pandemic. It emphasised that knowledge from ex-post legislative evaluations about what has and has not worked or could be improved is crucial for improving future well-being and, thus, has an indirect impact on society (OECD, 2021).

2.4 Discussion

This scoping review shows that different types of actual and potential impact of ex-post legislative evaluations can be retrieved from the literature. Although the literature makes no explicit distinction between types of impact of ex-post legislative evaluations, reviewing the included studies in this study resulted in the following categories: 1) knowledge and understanding of the effects of the law, 2) confirmation of well-functioning legislation, 3) legislative revision, 4) influence on the legislative process 5) influence on the policy process, 6) influence in the political sphere, and 7) influence on society. The different types of impact of ex-post legislative evaluations relate in varying degrees to the different parties involved and different stages in the legislative process. Strikingly, a comprehensive understanding of the first category must be completed before moving onto any of the subsequent categories. Knowledge and understanding can be seen as a prerequisite for the other types of impact, as they relate to a form of exploitation

of the knowledge and understanding derived from ex-post legislative evaluations. In addition, the other types of impact (numbers 2–7) are interrelated and are more or less existing perspectives that are expressed in the material reviewed for this study. However, they are not mutually exclusive because of their interconnectedness.

Despite the different contexts in which ex-post legislative evaluations take place due to the different evaluation systems that exist in every country, similar types of impact can be found in every country. Thus, the seven categories are relevant to a wide range of ex-post legislative evaluations. With this study, we aim to contribute to existing literature on ex-post legislative evaluation usage, but also to develop a better understanding of the different types of impact. In addition, the research results show that there is room for more in-depth, follow-up research into the factors that influence the impact of ex-post legislative evaluations. This scoping review shows, for example, that there are different parties who conduct ex-post legislative evaluations, and different conditions amidst which evaluations take place. It would be interesting to examine to what extent these differences lead to different types or degrees of impact of ex-post legislative evaluations.

Earlier ex-post legislative evaluation research has already shown three phases of ex-post legislative evaluation use, including: gaining knowledge, influencing political points of view and legislative knock on effects (Winter et al., 1990). According to one of the authors in a later dissertation study, these concern three successive phases (Winter, 1996). The first phase -knowledge-, is a necessary prerequisite for the following two phases because without knowledge, there can be no influence on political points of view, or knock-on effects of evaluation results in legislative amendments (Winter, 1996). This is in line with the insight derived from this study: that knowledge and understanding is a requisite to achieve one of the other categorised types of impact. Furthermore, the author refers to seven models of use distinguished by another author (Weiss, 1979), from which the following three main categories are derived: specific use, generic use and tactical use. Winter et al. (1990) conducted five case studies and a meta-analysis in which 35 legislative evaluations are studied from these three phases of use. Since this study was conducted in 1990, the current scoping review also includes more recent literature, and thus adds more recent insights to this earlier study. This scoping review found similar types of impact (e.g. knowledge and understanding, policy influence and improved legislative texts); tactical use also emerged in this study. However, this scoping review distinguishes additional forms of impact being: confirmation of well-functioning legislation, influence on the legislative and policy process, political debate and society.

A later dissertation study on post-legislative scrutiny in the United Kingdom (UK) parliament mentioned three different areas of impact (of these evaluations): stopping or persuading the government to not take action, putting the issue on the political agenda and a lack of impact all round (Caygill, 2019a). These areas are recognisable, but not exhaustive. They are also based on the degree to which recommendations from post-legislative scrutiny were accepted, which can be considered a limited scope. In contrast, our study used a broad scope, looking at all ex-

post legislative evaluations in different countries. From this we have been able to obtain a more complete picture of the various types of impact of ex-post legislative evaluations.

To begin with, only a few studies point out that ex-post legislative evaluations address the succeeding of a law. Yet, surprisingly, such result is described as 'less spectacular'. This could be seen as a remarkable description, since knowing what works well should, in our view, also be considered a spectacular result, as it is a positive affirmation of the proposed policy and legislative decisions. Nevertheless, the reviewed literature shows a clear focus on making amendments to legislative texts based on ex-post legislative evaluations. Moreover, some literature seems to indicate that evaluations are successful only if the results show that amendments to the law are needed. These amendments would subsequently improve the quality of legislation. The legislators or policy makers would be particularly interested in evaluations with a view to concrete legislative amendments. In most cases, however, these are minor amendments. Therefore, we believe that, for ex-post legislative evaluations to contribute to a learning cycle, it is essential not to focus on required amendments only, but also on what was successful. Whether or not a law needs to be amended may be revealed by the evaluation results, but should not be considered the only starting point. Being open to all possible effects can provide a better picture of the efficacy of the law in practice.

The strong focus on the impact of ex-post legislative evaluations on the law itself and the legislative process confirms the specificity of legislative evaluations as compared to policy evaluations. Given this observation, whether this impression is a fair representation of reality or a biased representation by those writing on this subject could be questioned: is the focus on the law itself a characteristic of legislative evaluations or of those writing about these evaluations? In one of the included publications, the author stated that "The legal system is in the end not concerned with budgets and effects, but with legitimacy, and ultimately with fairness and justice." (p. 286) (van Aeken, 2018). This confirms the focus on legal aspects in ex-post legislative evaluations instead of broader effects. On the other hand, another author (Nelen, 2000) also notes that a narrow view on impact may lead to a bias in reporting on the impact of legislative evaluations, for example, by involving only officials working within the legislative process in a survey study, which could lead to their perceptions being labelled as the empirical truth. These observations raise the question about whether this provides a realistic overview of the impact of ex-post legislative evaluations, or a more selective overview. It is important that future evaluations and reflection on this subject move away from a focus on merely the impact of ex-post legislative evaluations on minor legislative amendments, and instead move towards having a broader perspective.

The impact of ex-post legislative evaluations on society is an equally important factor, and yet the effect of legislative evaluations on society does not seem to be a key point of attention. However, ex-post legislative evaluations can ultimately have an impact on society, as citizens are the implementers of the law in practice (e.g. by giving substance to self-regulation). Legislative evaluations can have an instrumental impact on the daily life of citizens by influencing rules and arrangements and by strengthening or undermining the legal position of citizens. Since citizens

are also important stakeholders in this domain, it would be fundamental for future research to include the influence and role of legislative evaluations in society. How they may benefit or what impact a legislative evaluation may have is, however, not examined or described in the reviewed literature.

This scoping review also shows that at both national and European levels, ex-post legislative evaluations can be used tactically in the political and legislative debate. Ex-post legislative evaluations could, for example, function as political bargaining tools to get a bill passed, postpone the political discussion, win time or to defend decisions already made. In this way, selective use can be made of the evaluation results, (which is often referred to in the literature). Actors who feel threatened by legislative evaluations may try to prevent the use of such results or perhaps opt only to selectively use those results that fit their own agenda. It is worth questioning whether tactical intentions do not overstep the bounds of the objectives of ex-post legislative evaluations, as they should be instruments to open eyes, not to hide behind or use selectively.

A noteworthy limitation of this study is that not every form of impact is visible because the impact can take longer to be appear or is either not equally visible or not measurable (Norton, 2019). It can sometimes be unclear whether something is a direct result of a legislative evaluation. Another limitation of this study is that some of the included literature does not focus solely on ex-post legislative evaluations, but has a broader scope and thus also includes policy evaluations. The second important limitation of this study is that most authors speak of potential effects of ex-post legislative evaluations. These are not based on conducted empirical research. Despite a proportionate distribution of the different types of included publications, mainly expert opinions deal with the different forms of impact. This is supported to a lesser extent by case studies or systematic research. As a result, it is hard to determine whether the expert opinions can be substantiated beyond the author's experience. On the other hand, including both studies on potential and on actual types of impact make it possible to compare these two types of studies in this scoping review.

2.5 Conclusion

The research findings in this scoping review presented an overview of the literature's focus on the impact of ex-post legislative evaluations. The literature shows that the impact of ex-post legislative evaluations cannot be described as a unambiguous concept. There is no such a thing as 'the' impact of ex-post legislative evaluations, but there are several types than can range from informational to law-changing and can take place in different domains such as in politics or in society.

However, although legislation always has an impact on society, this scoping review shows that little is written about whether ex-post legislative evaluations also have an impact on society. The literature focuses on legislative revision and tactical use within the political sphere.

As the knowledge base for this scoping review mainly consists of expert opinions and case studies, more extensive empirical research could contribute to a more validated insight in the impact of ex-post legislative evaluations.

This scoping review is limited to the question of what types of impact of ex-post legislative evaluations are described in the current literature. The resulting question is what factors influence the realisation of these different types of impact. A closer analysis of the actual impact of ex-post legislative evaluations or the factors that influence the impact of ex-post legislative evaluations would therefore be an interesting step for further research. The insights gained from this scoping review provide valuable starting points for future research because it invites one to move away from the current narrow view on legislative amendments and open a broader view in future studies.

Appendix 1

Related search data - full text articles available for coding (n=91)

Title	Author	Year	Journal
Legislative history and evaluation	Caulley, D.N.	1982	Evaluation and Program Planning v5 n1 (1982): 45-52
The Role of Evaluation in Legislative Decision Making	Green, A.	1984	Public Administration Review v44 n3 (19840501): 265-267
The Role of Evaluation Information in Legislative Decision Making: A Case Study of a Loose Cannon on Deck	Malen, B.; Murphy, M.J.; Geary, S.	1988	Theory Into Practice v27 n2 (19880401): 111-125
Een beschouwing over de veelsoortigheid in wetsevaluaties	van Veldhoven, W.M.	1988	
The Politics of Legislative Evaluations: Fire-Alarm and Police Patrol as Oversight Procedures	Wohlstetter, P.	1990	Evaluation Practice v11 n1 (1990): 25-32
De paradox van wetsevaluatie	Veerman, G.J.	1991	Wetgeven en evalueren (WODC) 591
Wetgeving en beleid: pleidooi voor een heroverweging van de rol van het parlement in het wetgevingsproces en een systeem van wetsevaluatie	Adams, M.	1993	Ger deurw 1993, p. 1041-1050 (afl. 31)
Evaluatie van gezondheidswetgeving	Gevers, J.K.M.	1995	Tijdschrift voor Gezondheidsrecht 1995/2
Evaluatie van wetgeving	Polak, J.M.	1996	Nederlandsch juristenblad v71 n33 (1996): 1369
Evaluatie van het gezondheidsrecht: de Wet Bopz als casus	Winter, H.B	1997	Tijdschrift voor Gezondheidsrecht 1997/7.2
Evaluatie van wetgeving in de gezondheidszorg	Legemaate, J.	1997	Nederlands Tijdschrift voor Sociaal Recht 1997/12.9
Evaluatie van wetgeving in de gezondheidszorg en causaliteit	Leenen, H.J.J.	1998	Tijdschrift voor Gezondheidsrecht 22, no. 1 (1998):
Wetsevaluatie vanuit bestuurskundig perspectief	van Humbeeck, P.	2000	
Evaluatie van gezondheidswetgeving – enkele impressies	Hendriks, A.C.	2000	Tijdschrift voor Gezondheidsrecht 2000/2.3
Wetsevaluatie en administratieve vereenvoudiging. Overzicht van de situatie in Vlaanderen.	van Humbeeck, P.	2000	VIOM – Studiedag Wetsevaluatie en Administratieve Vereenvoudiging

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Evaluating the Effects: A Contribution to the Quality of Legislation	Mader, L.	2001	Statute Law Review 22, no. 2 (2001): 119-131
Evaluation in EC Legislation	Gallas, T.	2001	Statute Law Review - Volume 22, Issue 2, pp. 83-95
Giving Effect to European Fundamental Rights Through Evaluation of Legislation	Karpen, U.	2002	Statute law review v23 n3 (2002): 191-202
Holistic thinking is not the whole story. Alternative or adjunct approaches for increasing the accuracy of legal evaluations.	Faust, D.	2003	Assessment, 10(4), 428-441
Evaluation of legislation in the Netherlands?	Voermans, W.J.M.	2003	Legislação, 33/34, 33 - 61 (2003)
Implementation of Legislative Evaluation in Europe: Current Models and Trends	Karpen, U.	2004	European Journal of Law Reform, 6, no. 1/2, (2004): 57-86
Harmonization of Legislation on Migrating EU Citizens and Third Country Nationals: Towards a Uniform Evaluation Framework?	Slot, P. J.; Bulterman, M.	2006	FORDHAM INTERNATIONAL LAW JOURNAL 29, no. 4, (2006): 747-789
Evaluators' role in facilitating the convergence of factors to create legislative impact	Greer, H.	2006	New Directions for Evaluation v2006 n112 (Winter 2006): 41-49
Beleids- en wetsevaluaties: trends en topics	Leeuw, F.L. e.a.	2006	RegelMaat 2006/3.1
The Practice and Discourse of Legislative Evaluation in Portugal	Garoupa, N.M.; Vilaça, G.V.	2007	SSRN Electronic Journal (2007)
Wetsevaluatie: een maatschappelijke noodzaak	Goeij de, J.I.M.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.2
Wet en werkelijkheid: bevindingen uit evaluaties van wetten	Klein-Haarhuis, C.M.; Niemeijer, E.	2007	Book
Wetsoverstijgende evaluatie inzake toezicht op de kwaliteit van zorg	Legemaate, J.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.4 -
Wetsevaluatie in de gezondheidszorg	Buruma, O.J.S. e.a.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.1
Wetsoverstijgende evaluaties	Winter, H.B. e.a.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.7
Thematische (horizontale) wetsevaluatie – kwalitatief betere toepassing (gezondheids) regelgeving	Roscam Abbing, H.D.C.	2007	Tijdschrift voor Gezondheidsrecht 2007/8
Wetsevaluaties; enig commentaar	Eijkman, M.A.J.	2008	Tijdschrift voor Gezondheidsrecht 2008/2.6 -

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Kwaliteit van de beleidsanalytische wetgevingsadviezen van de Raad van State getoetst aan de hand van ex post evaluaties	Vranken, J.B.M.; van Gestel, R.A.J.	2008	Universiteit Tilburg
Wetten in werking. Over interventies, werking, effectiviteit en context.	Klein-Haarhuis, C.M.; Niemeijer, E.	2008	WODC
Assessing the accuracy of ex ante evaluation through feedback research: A case study	Vranken, J.B.M.; van Gestel, R.A.J.; Verschuuren, J.M.	2009	The impact of legislation: A critical analysis of ex ante evaluation, 199 - 277
Conclusions: A conditional yes to ex ante evaluation of legislation	Verschuuren, J.M.; van Gestel, R.A.J.	2009	The impact of legislation: A critical analysis of ex ante evaluation, 255 - 272
"Ex ante" Evaluation of Legislation : an Introduction	Verschuuren, J.M.; van Gestel, R.A.J.	2009	Book chapter in J. M. Verschuuren (Ed.), The impact of legislation: A critical analysis of ex ante evaluation (pp. 3-10). Martinus Nijhoff Publishers.
The impact of legislation: A critical analysis of ex ante evaluation	Verschuuren, J.M.	2009	E-Book
Chapter 3: Ex ante Evaluation of Legislation torn among its rationales in The impact of legislation	Larouche, P.; Verschuuren, J.M.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 39-62
Synthesising legislative evaluations – Putting the pieces together	Niemeijer, E.; Klein Haarhuis, C.M.	2009	Evaluation v15 n4 (2009): 403-425
Chapter 2: The Context of the Rise of "Ex ante" Evaluation	Popelier, P.; Verlinden, V.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 13-37
Chapter 5 "Ex ante" Evaluation of Legislation : between Puzzling and Powering in The impact of legislation	Hoppe, R.	2009	Book
Chapter 6: Pushing evaluation forward: Institutionalization as a means to foster methodological growth of legislative ex ante evaluation	van Aeken, K.; Verschuuren, J.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 105-134
The Politics of the "Ex Ante" Evaluation of Legislation	Bohne, E.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 63-79
The Introduction for the Legislation-Evaluation System about the Municipal Ordinance	Hwanyong C.	2009	Local Government Law Journal - Volume 9, Issue 2, pp. 341-355

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Negen aanwijzingen voor wetsevaluatief onderzoek	Veerman, G.J.M. e.a.	2009	RegelMaat 2009/4.2 -
Evaluation of Legislation: Skating on Thin Ice	Bussmann, W.	2010	Evaluation - Volume 16, Issue 3, pp. 279-293
Measuring Law for Evaluation Research	Tremper, C; Thomas, S; Wagenaar, AC;	2010	Evaluation review 2010 Jun; 34(3): 242-66
Ex ante-evaluatie in de gezondheidszorg	Ploem, M.C.	2010	Tijdschrift voor Gezondheidsrecht 2010/2.1
Het evalueren van de Awb: een voortdurend proces	Michiels, F.C.M.A.	2010	Bestuursrecht harmoniseren: 15 jaar Awb, 41 - 55
Over het belang van feitenonderzoek bij de voorbereiding en evaluatie van wetgeving	Leeuw,F.L.; Willemsen, F.; de Jongste, W.M.	2010	RegelMaat - Volume 25, Issue 2, pp. 51-65
Ex ante evaluation of EU legislation intertwined with judicial review? Comment on Vodafone Ltd v Secretary of State for Business, Enterprise and Regulatory Reform (C-58/08)	Keyaerts, D.	2010	European law review. 35, no. 6, (2010): 869
'Ex ante-evaluatie' en de toetsing door het Hof van Justitie	Keyaerts, D.	2010	S.E.W. - Volume 58, Issue 2, pp. 61
Can legal research benefit from evaluation studies?	Leeuw, F.L.	2011	Utrecht Law Review, 7(1), pp.52–65.
Escaping the Dusty Shelf: Legislative Evaluation Offices' Efforts to Promote Utilization	Vanlandingham, G. R.	2011	American Journal of Evaluation - Volume 32, Issue 1, pp. 85-97
The Impact of Right-to-Carry Laws and the NRC Report: Lessons for the Empirical Evaluation of Law and Policy	Aneja, A.; Donohue, J.J.; Zhang, A.	2011	American Law and Economics Review v13 n2 (10 2011): 565-631
Ex Ante Evaluation and Alternatives to Legislation : Going Dutch?	Van Gestel, R.A.J.; Menting, M.	2011	Statute Law Review, Volume 32, Issue 3, October 2011, Pages 209–226
From Vision To Reality: Ex Post Evaluation of Legislation	van Aeken, K.	2011	Legisprudence v5 n1 (2011): 41-68
Study on Educational Legislation Evaluation	Junseong, H.	2011	The Journal of Law of Education v23 n1 (201106): 259-288
Evaluating legislation : an alternative approach for evaluating EU internal market and services law	Fitzpatrick, T.	2012	Evaluation v18 n4 (2012 10 01): 477-499

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
A study on development of method for sustainability assessment in legislative evaluation	Park, Y.; Bae, G.	2013	
Evaluatie van wetgeving? Bouwstenen voor beslissingen	Veerman, G.J.	2014	Recht en Overheid
Ex ante onderzoek in beeld: over aard, aantal en gebruik van ex ante onderzoek bij beleidsvoorbereiding	Klein-Haarhuis, C.M. e.a.	2014	Beleidsonderzoek Online 2014
Gezamenlijk ouderschap na scheiding: over de interactie tussen de doelstellingen van de Deense wet op de ouderlijke verantwoordelijkheid, de bevindingen in de uitgevoerde wetsevaluatie en de daaropvolgende wetswijzigingen	Jeppesen de Boer, C.G. e.a.	2014	F&R 2014
Welke lessen kunnen we trekken uit evaluaties met het oog op effectieve wet- en regelgeving?	Klein-Haarhuis, C.M.	2014	WODC
Klaarheid over het Clearing House voor Wetsevaluatie	Veerman, G.J.	2014	RegelMaat 2014/4.2
Naar een regelgevingcyclus? Evaluatie in de Europese Unie	Mastenbroek, E.; Meuwese, A.; van Voorst, S.	2014	RegelMaat - Volume 29, Issue 4
De rol van empirisch-etisch onderzoek in wetsevaluaties	Landeweer, E; Widdershoven, G.	2014	NVBe
Ex-post evaluatie	Lokin, M.H.A.F.	2014	RegelMaat 2014/4.1
Empirical Evaluation of Law: The Dream and the Nightmare	Donohue, J. J.	2015	AMERICAN LAW AND ECONOMICS REVIEW - Volume 17, Issue 2, pp. 313-360
Closing the regulatory cycle? A meta evaluation of ex-post legislative evaluations by the European Commission	Mastenbroek, E; van Voorst, S; Meuwese, A.	2016	Journal of European Public Policy v23 (2016): 1329-1348
Ex post legislative evaluation in the European Union: questioning the usage of evaluations as instruments for accountability	Zwaan, P; van Voorst, S; Mastenbroek, E.	2016	International Review of Administrative Sciences, 82(4), 674-693
Towards a Rational Legislative Evaluation in Criminal Law	Nieto Martín, A.; Muñoz de Morales Romero, M.	2016	Book
New Zealand's new alcohol laws: protocol for a mixed-methods evaluation	Maclennan, B; Kypri, K; Connor, J; Potiki, T; Room, R; Maclennan, Brett; Kypri, Kypros; Connor, Jennie; Potiki, Tuari; Room, Robin	2016	BMC public health 2016 Jan 13; 16: 29

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Evaluatievermogen bij beleidsdepartementen; praktijken rond uitvoering en gebruik van ex post beleids- en wetsevaluaties	Klein-Haarhuis, C.M.; Parapuf, A.	2016	Boek, WODC
Utilization of evaluation results in policy making and administration	Wollmann, H.	2016	HKJU-CCPA 16(3), 433–458
Enforcement tool or strategic instrument? The initiation of ex-post legislative evaluations by the European Commission.	van Voorst, S.; Mastenbroek, E.;	2017	European Union politics - Volume 18, Issue 4, pp. 640-657
Meer dan de som der delen? Beschouwingen over de implementaties en evaluatie van Europese regelgeving	Mastenbroek, E.	2017	Inaugurele rede
Rechtstekorten in het gezondheidsrecht	Legemaate, J.	2018	Tijdschrift voor Gezondheidsrecht 2018
Ex-post legislative evaluations in the European Commission : between technical instruments and political tools	van Voorst, S.	2018	Acadamic thesis, Tilburg University
Legislative evaluation as alternative democratic engagement	van Aeken K.	2018	Diritto and Questioni Pubbliche v18 n1 (2018 06 01): 271-289
Tracing the use of evaluations in legislative processes in Swiss cantonal parliaments	Eberli, D.	2018	Evaluation and Program Planning v69 (August 2018): 139-147
De evaluatie van de wetsevaluatie	Boer, T.	2018	TGE
Evaluations as a decent knowledge base? Describing and explaining the quality of the European Commission's ex-post legislative evaluations	Mastenbroek, E.; van Voorst, S.	2019	Policy Sciences - Volume 52, Issue 4, pp. 625-644
The (non-)use of ex post legislative evaluations by the European Commission	van Voorst, S.; Zwaan, P.	2019	Journal of european public policy v26 n3 (2019): 366-385
Assessing the European Commission's legislative cycle: The problems of linking ex ante impact assessments and ex-post legislative evaluations	van Golen, T.	2020	Doctoral thesis
Ex-post evaluation in the European Parliament: an increasing influence on the policy cycle	Anglmayer, I.; Scherrer, A.	2020	The Journal of Legislative Studies v26 n3 (20200702): 405-426
Regional legislative evaluation capacity and the oversight function: a diagnostic study of the Economic Community of West African States (ECOWAS) Parliament	Adaku, E.; Amoatey, C.T.; Agomor K.S.; Tandoh-Offin P.	2020	Journal of Legislative Studies

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Testing an ex-ante framework for the evaluation of impact assessment laws: Lessons from Canada and Brazil	Fonseca, A.; Gibson, R.B.	2020	ENVIRONMENTAL IMPACT ASSESSMENT REVIEW - Volume 81,
Leren van evaluaties - De fitness check van het Europees consumentenrecht	van Schagen, E.A.G	2020	RegelMaat 2020/5.3
The instigation of hatred: questions of legal evaluation and procedural issues	Murauskiene, D.; Jurka, R.; Zajanckauskiene, J.	2020	Entrepreneurship and Sustainability Issues v8 n2 (20201230): 896-913

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Jeppesen de Boer, C. G. (2014). Gezamenlijk ouderschap na scheiding: over de interactie tussen de doelstellingen van de Deense wet op de ouderlijke verantwoordelijkheid, de bevindingen in de uitgevoerde wetsevaluatie en de daaropvolgende wetswijzigingen. *Familie & Recht.*

Klein Haarhuis, C. M., & Parapuf, A. (2016). *Evaluatievermogen bij beleidsdepartementen. Praktijken rond uitvoering en gebruik van ex post beleids- en wetsevaluaties*. Cahier.

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Chapter 3

Factors influencing the impact of ex-post legislative evaluations

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Abstract

This article explores the factors that influence the impact of ex-post legislative evaluations and suggests that these factors can be divided into three main categories: context, research quality, and interaction. Contextual factors, including the evaluation's initiation, timing and function, and the level of political or social attention, are beyond researchers' control. However, researchers can influence research quality and interaction with stakeholders, such as the evaluations' commissioner, as well as the society at large, thereby increasing the likelihood of achieving impactful results. They should engage with the evaluation context to improve impact, but must also maintain independence while being influenced by the context. These findings are in line with the much broader literature on the impact of policy and programme evaluations which pays less attention to the policy instrument legislation. Therefore, both disciplines have an interest in a better exchange of knowledge.

3.1 Introduction

Ex-post legislative evaluations, also known as post-legislative scrutiny, offer insights into the practical functioning of legislation following its enactment. These evaluations are crucial within the legislative process, concentrating specifically on assessing the effectiveness of legislation, a government instrument with significant societal impacts. Despite legislation's profound impact on society, such as in critical sectors like healthcare, previous research has indicated that the impact of ex-post legislative evaluations is largely confined to legislative and political domains, with limited impact on society at large (Knap et al., 2023). This is concerning, given the anticipated substantial benefits for the general public through effective evaluations (Moulds & Khoo, 2020). Various scholars have emphasised the need to comprehend the factors that influence or enhance the impact of ex-post legislative evaluations (Doust & Hastings, 2019; van Voorst & Zwaan, 2019), creating a gap in the literature that underscores the importance of conducting a dedicated study on these influences. Such research will enrich our understanding of the conditions fostering successful evaluation and their ultimate impact on pertinent domains.

This scoping review exclusively focuses on ex-post legislative evaluation literature due to the unique characteristics and complexities of this practice, setting it apart from other types of policy evaluations. Combining empirical and legal research, legislative evaluations impact not only the political or policy sphere, but also the legal domain, shaping legislation design (Knap et al., 2023). Despite this common ground, there are significant differences emerge in the global conduct of these evaluations. Concentrating on this distinct policy evaluation type proves valuable, an approach already acknowledged in existing literature (e.g. Knap et al., 2023; van Aeken, 2011; van Voorst, 2018; Zwaan et al., 2016). Ex-post legislative evaluations often hold a unique position within academic discourse, with minimal exploration in the broader context of policy and programme evaluation. Therefore, this scoping review aims to delve into the depth of knowledge and insights of the ex-post legislative evaluation domain concerning impact, ensuring the relevance of this study's findings in this specialised field.

In the field of policy and programme evaluations, a longstanding of research focuses on the factors that influence the utilisation of such evaluations. Since the late 1900s, an ongoing discourse has surrounded the utilisation of evaluations, with notable contributions of Alkin et al. (1979), Patton (1988), and Weiss (1979). Central to this discourse is the repeated exploration of the definition of 'use' and the broader concept of 'influence' (Alkin & King, 2017; Henry & Mark, 2003; Kirkhart, 2000; Leviton & Hughes, 1981). The broader evaluation literature has identified numerous factors that can foster the utilisation of evaluations. These include the relevance of the evaluations and the quality of their dissemination (timeliness, credibility, quality of presentations and means of dissemination, as well as incentives and capacities) (Feinstein, 2002). Additionally, the degree of polarisation and the distribution of costs between producers and users (Contandriopoulos & Brousselle, 2012), as well as the organisational context in which evaluations are conducted (Højlund, 2014) are important factors. To facilitate the utilisation of evaluations, various frameworks have been proposed. One such framework zeroes in on five clusters of

variables that influence utilisation and posits hypotheses about the reasons for their effects (e.g. relevance, communication, information processing, credibility, user involvement and advocacy) (Leviton & Hughes, 1981). Another framework proposed a distinction between the utilisation of evaluations (e.g. the evaluative culture and organisational context and user characteristics) and the usability of evaluations (e.g. the evaluation design process and evaluation design quality) (Saunders, 2012).

In a more recent publication, Alkin and King (2017) highlight essential factors that affect evaluation usage. These factors were drawn from three significant studies: Cousins and Leithwood (1986), Shulha and Cousins (1997), Johnson et al. (2009), and the Program Evaluation Standards by Yarbrough et al. (2010). The authors observed that these studies identified similar factors, resulting in a significant overlap between them.

Alkin and King categorise these factors into four groups:
User factors: Users' positive prior experiences and meaningful involvement in the evaluation impact their predispositions towards evaluation. An explicit commitment to use evaluations is crucial within the 'user factors' category.
Evaluator factors: The evaluator's commitment to stimulate use and engage potential users, as well as their political sensitivity and credibility, are significant factors in the evaluation process. Establishing a good working relationship and involving users in the evaluation's conduct can also impact the evaluator's credibility.
Evaluation factors: The third category pertains to the evaluation itself, including procedures, relevance of information, and communication quality. Appropriateness and credibility of methods are more important than technical excellence. Information must meet users' needs, and communication should be understandable and timely.
Organisational/social context factors: The nature of the organisation in which an evaluation is conducted has a substantial impact on the successful achievement of evaluation use. Various factors include organisational characteristics of the programme, unit level autonomy, institutional arrangements, and external factors like the community and other agencies. Other sources of information beyond the evaluation are likely to be employed in decision-making.

It is worth noting that these four groups of factors are all part of the context of any evaluation, as per the authors' observations.

These established notions about the utilisation of evaluations in general could contribute to the specific doctrine on the impact of legislative evaluations. In this scoping review, we aim to analyse the existing literature concerning the factors influencing the impact of ex-post legislative evaluations, both at the European and national legislative levels. We will approach this from the researchers' perspective on the evaluation process. Subsequently, we will reflect on how these factors align with the broader evaluation literature's discourse on evaluation utilisation. This approach aims to take an initial step toward integrating these spheres.

3.2 Research method

This study aims to present the insights derived from literature on the factors that influence the impact of ex-post legislative evaluations in order to identify the available evidence on the issue, and analyse knowledge gaps in this field (Colquhoun et al.,2014). For this reason, this scoping review has followed the methodological PRISMA-ScR framework (Arksey & O'Malley, 2005; Levac et al., 2010). Scoping reviews are an ideal tool to determine the scope or coverage of a body of literature on any given topic that is not well charted yet (in this case, the factors that influence the impact of ex-post legislative evaluations) and provide an overview (broad or detailed) of the literature's focus. This scoping review is based on the same dataset as our previous scoping review on the different types of impact of ex-post legislative evaluations (Knap et al., 2023). Despite the fact that the data was analysed with a different research question, the description of the first three phases of this method section contains similarities with the previous scoping review.

Additionally, these findings will be reflected according to the categorisation presented in the introduction of the article, which is derived from a broader evaluation literature classification (Alkin & King, 2017).

3.2.1 Phase 1

In an effort to capture all relevant literature, the study started with a broad research question: *What can be found in the scientific literature about the methodology and impact of ex-post legislative evaluations?* To ensure a broad search strategy, the research question did not include any specific jurisdiction or field of law. After conducting a detailed search, the research question was narrowed (see phase 4).

3.2.2 Phase 2

A search was conducted of the Web of Science, Worldcat and Legal Intelligence scientific databases using different search strings for an initial scope of the scientific literature (first quarter of 2021). Given that literature on this topic was expected to be scarce, no timespan was selected for the search. Identical search strings were applied for each database with both English and Dutch search terms, using Boolean operators (AND, OR), a wildcard symbol, quotation marks, parenthesis and truncation in order to improve the search strategy. We initially started with a broad search strategy followed by two more specific search strategies, one related to methodology and the other to impact. Synonyms were applied for this purpose. The final search strings are included in Table 1.

Table 1. Final scientific search strategies.

Web of Science, Worldcat Discovery and Legal Intelligence
Dutch search terms
1st strategy TI=(wetsevaluatie* OR ‘’Evaluatie wet*’’ OR ‘’evaluatie regel*’’)
2nd strategy TI= (wetsevaluatie* OR ‘’Evaluatie wet*’’ OR ‘’evaluatie regel*’’ AND aanpak OR uitvoering OR method*)
3rd strategy TI=((wetsevaluatie* OR evaluatie wet* OR evaluatie regel*) AND (impact OR gevolg OR invloed OR effect**))
English search terms
1st strategy TI=(‘’Legislative evaluation* OR ‘’Law evaluation*’’ OR ‘’Evaluation of legislation*’’ OR ‘’Legal evaluation*’’)
2nd strategy TI=((legislative evaluation* OR law evaluation* OR evaluation of legislation OR legal evaluation*) AND method*))
3rd strategy TI=((legislative evaluation* OR law evaluation* OR evaluation of legislation OR legal evaluation*) AND (impact OR influence OR result* OR utilization OR utilisation))

3.2.3 Phase 3

In total, 4,204 studies were found with English search terms, and 413 studies were found with Dutch search terms (see Figure 1 for the entire search process, which is explained in more detail below). All literature was uploaded in Rayyan software, an administrative tool that facilitates the process of identifying and selecting studies when conducting a systematic literature review (Ouzzani et al., 2016). After merging the data, duplicates were removed (1,340 out of 4,617 studies). The literature was screened and selected by the first author (LK) based on title (e.g. excluding titles that were not on the subject of ex-post legislative evaluations) and abstract. Independently, another author (RvG) reviewed a random selection of 5% (164 studies) using the initial criteria. For 7 of the 164 studies, disagreements between the authors about the selection had to be resolved through discussion.

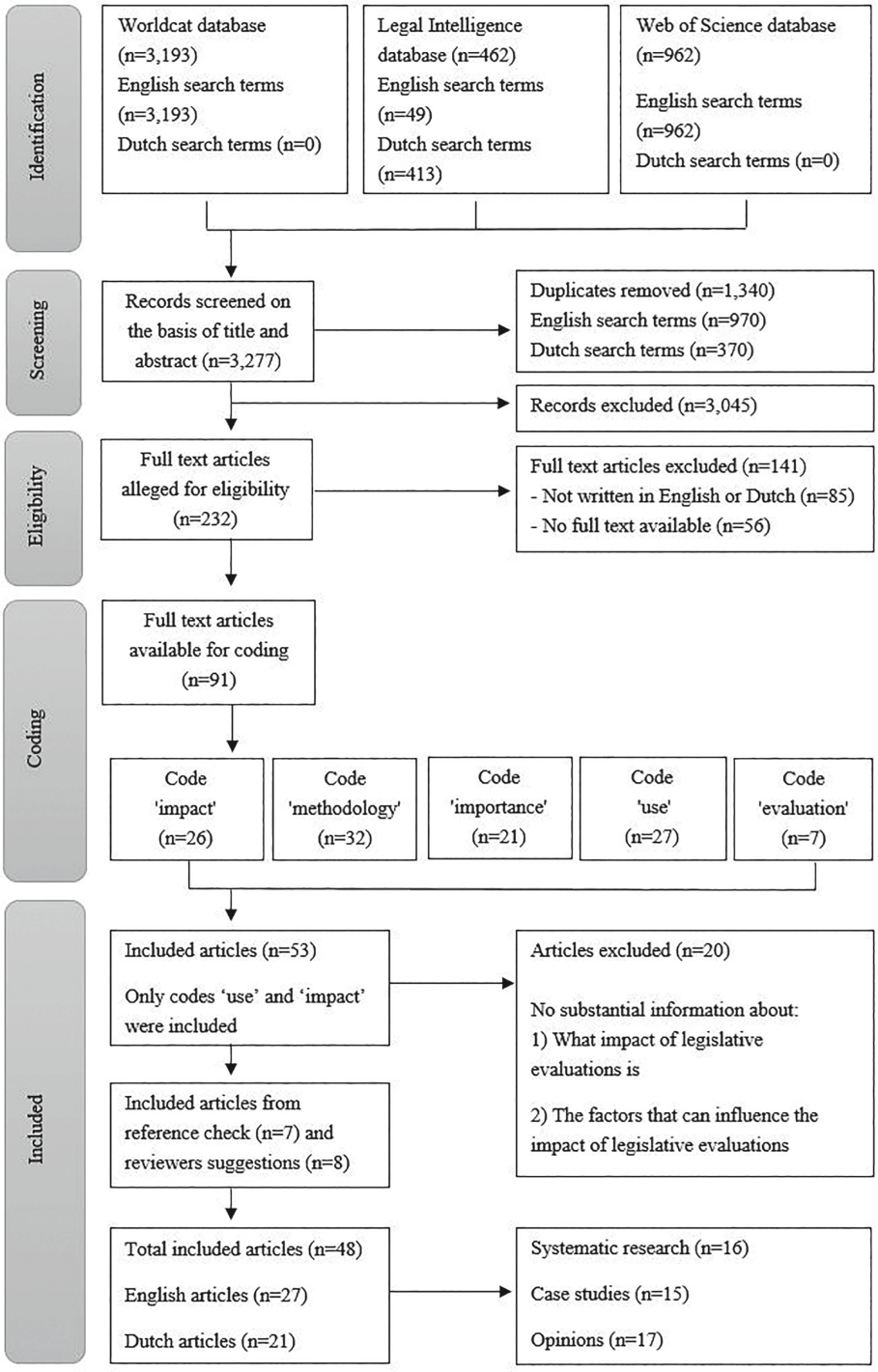


Figure 1. Methods flowchart.

Studies were deemed relevant if they fully or partly focused on the methodology and/or impact of ex-post legislative evaluations and were written in English or Dutch. Since the Netherlands has a long history of ex-post legislative evaluations and much literature is written in Dutch, the research group considered this a valuable addition to the English-language literature. During the selection of studies, those on the impact of legislation itself rather than the impact of ex-post legislative evaluations were excluded, as were studies on the impact of evaluations in general without a reference to ex-post legislative evaluations. Policy evaluations without a legal aspect were also excluded. Finally, ex-ante legislative evaluations were excluded from this study due to the different research designs used and their significance, as they are normally conducted before legislation is passed. On this basis, a total of 3,045 out of 3,277 studies were excluded and 232 studies were included (see Figure 1).

After selecting the studies and, in order not to miss any relevant coding, authors (LK) and (RvG) coded the studies based on title and abstract without agreeing on the codes beforehand. After, all authors agreed on the coding for the full text assessment; namely, methodology, use, impact, importance, and evaluation. Differences of opinion in the assigned types of coding after full text assessment were resolved through discussion between the authors. The full text versions of all 232 studies were manually searched. The studies that were either unavailable in full text (n = 56) or not written in English or Dutch (n = 85) were excluded (141 out of 232 studies). With regard to data openness, a list of the remaining 91 articles is included in Appendix 1.

3.2.4 Phase 4

In phase 4, the research question was narrowed down: What can be found in the scientific literature about the factors that influence the impact of ex-post legislative evaluations? As it appeared that much had already been written on the methodology of these evaluations, the focus on their impact could make a greater scientific contribution. For this purpose, a filtered selection was made of only studies coded with ‘impact’ (26 out of 91 studies) or ‘use’ (27 out of 91 studies). These 53 studies were fully read and assessed for relevance by both authors (LK) and (RvG), after which 28 studies were included (see Figure 1). References from the relevant studies were hand-searched by authors (LK) and (RvG) resulting in three additional studies that were added to the number of included studies. A final addition was made based on suggestions by reviewers. Due to the strict focus on ex-post legislative evaluations, the term ‘post-legislative scrutiny’ fell outside the scope of included data. Reviewers of the previous article pointed this out, so this term was manually searched in all three databases, after which four studies were added to the dataset. Based on the methods used, three types of studies were distinguished: systematic research in which a certain number of ex-post legislative evaluations were studied in a systematic manner (15 out of 35); case studies (7 out of 35); and expert opinions (13 out of 35). Importance was allocated to the included literature in this order and opinions could be empirically verified by case studies or systematic research. In the results of this scoping review, specific reference is made to these three types of studies.

3.3 Results

The reviewed literature reveals several factors that influence the impact of ex-post legislative evaluations. These factors are predominantly presented in a descriptive and case-by-case manner, which does not provide insight into their relative significance. The identified factors were classified into three main categories: 1. Contextual factors; these lie outside the domain of the research process; 2. Quality of the evaluation research; and 3. Interaction factors, which are situated. The latter two categories lie within the domain of the research process. The three main categories include several subcategories, which are described successively below (Table 2).

Table 2. Factors influencing the impact of ex-post legislative evaluations.

Factors influencing the impact of ex-post legislative evaluations	
1.	**Context** Characteristics of the law and legislative process Evaluation initiation, function and openness to results Political and societal influence
2.	**Research quality** Composition and independence of the research group Methods employed Quality and content of evaluation report
3.	**Stakeholder interaction** Interaction between researchers and stakeholders Presentation and availability of research results Timing

3.3.1 Context

The first category of factors that can influence the impact of ex-post legislative evaluations is the context in which these evaluations are commissioned, conducted and landed. These contextual factors may determine the need and necessity for an ex-post legislative evaluation, as well as the attainability of impact after the evaluation has been conducted. In other words, the use of evaluation results may depend on various contextual factors. In this scoping review, we see the concept of context as a factor that is outside the evaluation process but with which the evaluation is concerned; it is the setting in which the evaluation process takes place.

The first contextual factor, as found in this study, relates to the type of legislation being evaluated and the way in which ex-post legislative evaluations are initiated. Early literature notes that not every law is suitable for evaluation research (Gevers, 1995; Legemaate, 1997; Veerman, 1991). Laws, for example, can be codifying in nature, be complex (Gevers, 1995; Legemaate, 1997) or vague in content, and have different or contradictory objectives that are not always expressed (Veerman, 1991). This complicates the evaluation and hinders the drawing of conclusions, resulting in little benefit from the evaluation. Legislation with a modifying character, on the other hand, introduces new processes or practices in society and is more verifiable (Gevers, 1995). This type of legislation works more as a policy tool and its evaluation can be valuable to

the legislative process (Gevers, 1995). In this regard, early case studies have shown that the degree of elaboration of norms in a law or regulation affects the likelihood of using the evaluation results (Winter et al., 1990). If the norms of the statutory regulation are less developed, evaluations that require the presence of a legal perspective in the legislative evaluation are more likely to be used (Winter et al., 1990).

Which law is evaluated may depend on how an ex-post legislative evaluation is initiated: based on an evaluation clause in the law itself or at the request of, say, the political domain (Bussmann, 2010). The way an evaluation is initiated appears to influence the impact the evaluation subsequently has. A pronounced situation is seen in the European Union (EU) context where evaluations are conducted ad hoc at the request of the European Parliament. These evaluation requests are presumably based on a strategic goal, giving the ex-post legislative evaluation a strategic function. An example was mentioned in one of the included studies. The results indicated that 'the European Commission prioritises evaluating legislation for which the chances of non-compliance are relatively high, and that evaluation may at least partly be initiated to scrutinise member state implementation'. (p. 653) (van Voorst & Mastenbroek, 2017).

This is different from ex-post legislative evaluations that are conducted systematically on the basis of an evaluation clause included in the legislation itself (Bussmann, 2010). The main reason for conducting such legislative evaluations is the legal obligation to do so, as shown by two comprehensive studies on the European Commission (Mastenbroek et al., 2016; van Voorst, 2018). They are conducted because it is mandatory, not because there is a specific interest in doing so. Those mandatory evaluations may be seen as less politically relevant (Klein Haarhuis & Parapuf, 2016) but do ensure that the specific law is put back on the political agenda (Winter, 1996). There seems to be a perception that mandatory systematic ex-post legislative evaluations have less impact due to less current relevance. This is supported by data from an empirical study which showed that the European Commission's compliance with such clauses only occurred in about half of the cases (van Voorst & Mastenbroek, 2017).

The second contextual factors identified in the literature is the importance of the openness to evaluation results and the willingness to implement the evaluation results, as mentioned by several authors (Doust & Hastings, 2019; Legemaate, 1997; van Voorst & Zwaan, 2019; Veerman, 1991). In the first place, the legislative process must allow for the results of an ex-post legislative evaluation to have impact. The way the process is designed may influence the extent to which results will be used. In order to feed evaluation results into the legislative process, there must be a place in this process to adapt legislation based on an evaluation (Bussmann, 2010). A fixed routine can create a learning system, also known as a 'regulatory cycle' (Klein Haarhuis & Parapuf, 2016). In the Netherlands, a policy response should be formulated within three months of the delivery of the evaluation report. This response should report what the Minister intends to do with the study (Klein Haarhuis & Parapuf, 2016). It is ultimately up to the various actors to incorporate the evaluation results into the legislative process. In particular, one of the case studies showed that if parliament has no interest in the evaluation report, little is done with

the recommendations given in that report (Doust & Hastings, 2019). Although evaluations can never oblige the legislator to amend the law, it is important that there is a willingness to tackle actual bottlenecks by amending the law if necessary or by incorporating the evaluation results into policy (Klein Haarhuis & Parapuf, 2016; Legemaate, 1997). Otherwise, evaluation can be meaningless, because without the effective support of the parliament and the government, an ex-post legislative evaluation can never be properly implemented in the decision-making process (Hendriks, 2000). A robust relationship between the legislative and executive branches seems to be necessary for this (van Aeken, 2011).

An important reason for acting or not acting on the evaluation results lies in the function given by stakeholders to the ex-post legislative evaluation. Several functions can be assigned to ex-post legislative evaluations, which can influence the way they are used. An evaluation can, for example, be focused on efficiency, but also on process optimisation or the investigation of side effects. The literature suggests that different stakeholders assign different functions to (the same) legislative evaluation (Veerman, 1991), such as a tactical, symbolic or legitimising function (Nelen, 2000). Depending on these functions, the evaluation results will be used to a greater or lesser extent (Eijlander, 1993; Veerman, 1991). If the function, for example, is given to gain knowledge about the efficacy of the law in practice, it is more likely to be acted upon than if the function is procrastination (Veerman, 1991). Another example is described in a case study on the Dutch Director Liability Act where the House of Representatives had doubts about the usefulness of this act and its burden on business. The Minister of Justice proposed an evaluation in order to ensure a majority for the bill, indicating a tactical function. For the members of parliament, the acquisition of knowledge was the primary function (Veerman, 1991). Different interests give different functions to legislative evaluations that determine how they are used. Another example takes place in the United Kingdom (UK), where both Houses have different motivations and approaches to oversight, resulting in sporadic or limited post-legislative scrutiny. The nature of the incentive is crucial to explain the extent of such scrutiny (De Vrieze & Norton, 2020).

The final contextual factors relate to the social and political atmosphere in which ex-post legislative evaluations are conducted. As the literature shows, the political and administrative decision-making context is considered an important factor influencing the use of evaluation research (Klein Haarhuis & Parapuf, 2016; van Voorst & Zwaan, 2019). This is supported by two systematic studies on the use of ex-post legislative evaluations in both the Netherlands (Winter et al., 1990) and the European Union (Zwaan et al., 2016) showing that the level of political conflict is the most important variable to explain differences in the use of evaluation results. The perception from the literature is twofold, on the one hand it is mentioned that controversial evaluations during the legislative process are most likely to be used (van Voorst, 2018; Zwaan et al., 2016). On the other hand, there is a perception in the literature that when political conflict is high the impact of using evaluation results is limited (Bussmann, 2010; Eberli, 2018). Unforeseen political issues can also arise and affect the political process and the use of evaluation findings (Bussmann, 2010).

Regarding the social sphere, the literature argues that the level of involvement of so-called interest groups can influence the impact of ex-post legislative evaluations. For example, one study concluded that 'Such groups may have no formal veto over policy proposals, but they can put pressure on policy-makers to ignore or implement evaluation results, either directly via lobbying or indirectly via the media. To produce a policy that satisfies a wide range of actors, policy-makers may prioritise such interest group preferences over evidence from evaluations' (pp. 368–369) (van Voorst & Zwaan, 2019). On the other hand, policy-makers can be stimulated to include evaluation results in the policy by strong public opinion on the matter, for example in the media (van Voorst & Zwaan, 2019).

3.3.2 Research quality

The second category of factors influencing the impact of ex-post legislative evaluations is associated with the research quality itself and the group of researchers conducting the evaluation. First, literature highlights the importance of an independent position for those conducting the evaluation, particularly for sensitive or politically charged topics (Vranken & van Gestel, 2008; Winter, 1997). Differences exist between countries, as ex-post legislative evaluations can be conducted by various institutions with varying levels of independence from parliament based on the parliamentary culture. For instance, in the United Kingdom, post-legislative scrutiny can be performed by parliamentary committees, commissions, external working bodies, or independent state agencies, depending on the nature of incentive: formalistic review is suitable for officials, while evaluative oversight is better undertaken by legislators (De Vrieze & Norton, 2020). In the Dutch context, ex-post legislative evaluations are typically conducted by external parties like research institutes or university departments, where the British subdivision is not made. The literature often suggests that external execution can enhance research independence (Hendriks, 2000; van Aeken, 2011; Vranken & van Gestel, 2008), allowing researchers to maintain a greater distance from the law and policy (Hendriks, 2000). Government departments or parliamentary committees may be too closely involved with existing regulations (van Humbeeck, 2000b), and executive-led research tends to lack independence in the literature (Doust & Hastings, 2019).

However, opinions in the literature differ about the degree of independence. On the one hand it is argued that the lack of independence can have an obfuscating effect because reliability and validity can be doubted (Vranken & van Gestel, 2008). On the other hand, it is argued that too much independence creates a separation between the ex-post legislative evaluation and policy development, which can also reduce its credibility (van Humbeeck, 2000a). This can lead to evaluations of legislation not being taken seriously and therefore not being used. Since the credibility of the report is also an important factor in the use of the ex-post legislative evaluation, it is argued that there should be a proper balance between the level of independence and sufficient involvement of the commissioning party (Vanlandingham, 2011). Otherwise, if the evaluators are too concerned with the incentives and objectives of the regulatory bodies on which their administration depends, 'evaluation research degenerates toward a formalistic ritual without real content or impact' (p. 63) (van Aeken, 2011). Early research comparing five case studies on the

evaluation of Dutch laws found that when a balance is achieved between policy proximity and independence, the likelihood of using evaluation results is higher (Winter et al., 1990).

Several authors consider the methodological quality of the evaluation research essential for the use of evaluation results (European Court of Auditors, 2018; Hendriks, 2000; Winter, 1997). In The Netherlands, quality is stimulated by appointing a guidance committee, among other things (Klein Haarhuis & Parapuf, 2016). This committee monitors the progress of the evaluation study and meets several times during the evaluation process, usually to discuss successively at least the research design, progress and the draft and final versions of the report. They can make timely interventions and adjustments if the research is not going according to plan (Klein Haarhuis & Parapuf, 2016).

The way in which ex-post legislative evaluations are generally conducted involves a combination of legal and empirical research. According to early researchers, the legal part in particular increased the use of the evaluation results (Winter et al., 1990). Other authors emphasise the standardisation of research methods, which, despite being able to constrain the flexibility of using research methods, proves important for the effectiveness of evaluations (van Humbeeck, 2000b). In contrast, the literature also argues that methodological quality is less decisive for the use of evaluation results. For example, a case study on the comparison of the Dutch and Danish evaluation on the promotion of joint parenthood after divorce showed that a good evaluation does not necessarily lead to increased use of evaluation results (Jeppesen de Boer, 2014). The Danish evaluation was very detailed and comprehensive, but the results of the ex-post legislative evaluation were hardly taken into account in the subsequent amendment of the law. Early case studies also showed that research quality does not always determine the extent to which evaluation results are used. Despite low quality, evaluations did contribute to influencing views (Winter et al., 1990). The authors note that if there is consensus, there is not much need for hard research findings (Winter et al., 1990).

The actual findings of an ex-post legislative evaluation can also determine the use of the results. An included meta-analysis of ex-post legislative evaluations showed, for example, that the use of evaluation results was promoted if the results confirmed the usefulness of the deployed policies and related legislation (Veerman et al., 2013). Another systematic research study showed that recommended amendments can have a significant effect on the use of evaluation results. The study showed that the chances of an evaluation being used increases by 2.1% for every extra amendment proposed in the evaluation report (Zwaan et al., 2016). The strength of the recommendations and the action they call for also seem to have a strong influence on the acceptance of the recommendations in the research report (Caygill, 2019). Therefore researchers tend to focus on recommending small and medium actions to increase the likelihood of acceptance, as suggested by a systematic research study on post-legislative scrutiny recommendations in the UK parliament (Caygill, 2019). This was also shown by a multiple case study in which the authors concluded that recommendations that do not deviate, or only a little, from the existing legal system are more likely to be implemented (Winter et al., 1990).

3.3.3 Stakeholder interaction

The third category of factors that influence the impact of ex-post legislative evaluations is the interaction between evaluation researchers and stakeholders that takes place both before the evaluation assignment as well as during and after the execution of the ex-post legislative evaluation.

First, the interaction between the commissioner of an ex-post legislative evaluation and the research group begins with the commissioner's assignment. Thus, a clear research question is important because this question can influence the entire research process, which in turn can influence its impact (Veerman, 1991). Veerman (2014) suggests that a non-specific but global evaluation assignment may lead to disappointment afterwards. In such situation, it often only becomes clear afterwards what information the commissioner would like to have investigated. In that case, the results are used less and perhaps only received as knowledge, which could have been avoided with a more focused research assignment at the beginning of the evaluation process (Veerman, 2014). Case studies showed the importance of properly translating the policy question into the research question to maximise policy relevance (Winter et al., 1990). From the perspective of achieving impact, it is therefore important that policy and legislation on the one hand and researchers on the other consult on what is most relevant to investigate. It also means that during the research process, the commissioner should keep in touch with the researchers about the status of the research (Veerman, 2014). The authors of a systematic research article even claimed that contact and consultation between the commissioner and researchers during the evaluation process is a crucial way to increase the likelihood of use (Klein Haarhuis & Parapuf, 2016).

Several authors point out the importance of interaction during the research process, not only with respect to the commissioner, but also the legislative stakeholders. The literature first notes that this can be done by addressing the recommendations in the evaluation report not only to the legislator, but also to the courts, the administration (Scheltema, 2002) and society. However, this is only done at the end of the evaluation when the research is already completed. Several authors conclude that involving different stakeholders at an earlier stage of the evaluation process leads to greater impact. For example, as shown by a case study, good contact with policy makers during the evaluation process led to policy relevance, which subsequently led to reasonable use of evaluation results (Winter et al., 1990). Vanlandingham (2011) also showed that researchers who were able to consult regularly with stakeholders had more value and impact in the legislative process. Another example was given in a case study, where the authors emphasised society involvement and even advocated a more bottom-up approach by directly engaging the people at all stages of the review process to improve public engagement (Moulds & Khoo, 2020).

A more or less 'last' step in the interaction between researcher and stakeholders in the broad sense, is the way in which evaluations results are shared. Although earlier research expected that the manner of publication may influence the use of ex-post legislative evaluations (Veerman, 1991), systematic research on ex-post legislative evaluation offices' efforts to promote utilisation concluded that 'report distribution activities were not found to be statistically related to utilisation

differences' (p. 90) (Vanlandingham, 2011). However, the lack of use of the evaluation results is sometimes explained by the way in which the information is presented (Poptcheva, 2013) and the fact that the information is not available (van Schagen, 2020). It is important that evaluation results are available and usable. The researchers play an important role here because they can influence the way the evaluation report is disseminated, for example by giving presentations or writing a scientific article summarising or reflecting on the evaluation results (Klein Haarhuis & Parapuf, 2016). Additionally, the language in which the report is written may affect its use. 'Evaluations are usually only published in one language (generally English), which hinders their usability for stakeholders and citizens' (p. 4) (Poptcheva, 2013).

Last, the reviewed literature shows timing as an important part of interaction. Some of the studies claim that timing is important into the extent to which the evaluation results are used and thus the potential impact they can have. Several authors stated that evaluation results are often not available when key decisions must be made (Vanlandingham, 2011; Vranken & van Gestel, 2008): an evaluation process may come too late to lead to further processing (Klein Haarhuis & Parapuf, 2016). Also the European level, the timely availability of ex-post legislative evaluations is also crucial in allowing the results to be used in (ex-ante) impact assessments, and this shows the importance of strictly enforcing the Commission's 'evaluate first' principle (van Voorst, 2018). In order to maintain the regulatory cycle, it is crucial that the ex-post legislative evaluation is available before the (ex-ante) impact assessment is conducted (Golen & Voorst, 2016).

On the other hand, evaluations can also be conducted too early and thus have a minimal impact. Legislators are often impatient and want an early evaluation for various reasons. However, this means that these evaluations are conducted at a time when the policy area to be examined is still in full swing. If the ex-post legislative evaluation is conducted in a very 'early' stage, the picture of the results may not yet be complete (Vranken & van Gestel, 2008) or it could be too early for adequate conclusions to be drawn (Klein Haarhuis & Parapuf, 2016). The pitfall, therefore, is that the evaluation will provide misleading information and cannot lead to quality improvement (Winter, 1997).

3.4 Discussion and conclusions

The importance of ex-post legislative evaluations is recognised worldwide. Countries conduct ex-post legislative evaluations to varying degrees to assess effectiveness in practice and to improve laws and regulations. These evaluations are meant to be used. It is therefore important they are not only conducted but actually acted upon. Otherwise, an ex-post legislative evaluation will be relegated to a formal ritual with little or no effect and whose usefulness can be questioned. This scoping review clarifies the factors that influence the impact of these ex-post legislative evaluations.

One of the most comprehensive studies referred to in this scoping review is the study by Winter et. al. (Winter et al., 1990) in which a framework was established based on empirical research. Using five case studies and a survey of 25 legislative evaluations, the authors systematically examined, among other things, the determinants of the use of evaluation results. They examined the characteristics of the regulation (e.g. determinacy, vagueness and intrusiveness), characteristics of the evaluation process (e.g. policy proximity, independence and elaborate standardisation), characteristics of the evaluation product (e.g. research quality, policy relevance and feasibility of recommendations) and the degree of conflict in the decision-making context. The study found that the determinacy and vagueness of the legal regulation was not found to be a clear driver of the use of evaluation results. However, the intrusiveness of the regulation does play a role in the likelihood of use. Highly intrusive regulation has a closed context in which room for making changes is limited.

The study showed with regard to the evaluation process, that ex-post legislative evaluations are more likely to be used when there is a proper balance between policy proximity and independence. In addition, it was found that there is a higher probability of usage when the norms in the legal regulation are less elaborated. Therefore, the impact of the ex-post legislative evaluation will be directed at refining and elaborating upon de underdeveloped norm.

With regard to the evaluation product, it was found that evaluation results are used especially if they are policy-relevant. This also transcends low research quality: even if an evaluation is of low quality, the evaluation can be used to a great extent if the policy relevance is present. With regard to policy relevance, it was concluded that this is greater when the policy question is properly translated into the problem definition of the study, when there is periodic consultation with the client and the evaluation report is published at the right time (Winter et al., 1990). The likelihood of use is, however, higher if the recommendations differ slightly from the existing situation (Winter et al., 1990).

This scoping review, based on more recent and international publications, confirms the importance of characteristics of the evaluation process (e.g. policy proximity and independence) and characteristics of the evaluation product (policy relevance and feasibility of recommendations), but displays more factors influencing impact of ex-post legislative evaluations.

In contrast to the study of Winter et al. (1990), where the categories to be analysed were predetermined, we maintained an open-minded approach in this scoping review and established a categorisation based on the existing literature on the factors that (may) affect the impact of ex-post legislative evaluations.

Caution is needed as not all studies are based on robust empirical research. Over the years, empirical studies have had a limited presence in investigating the factors that influence the impact of ex-post legislative evaluations. However, despite this limitation, the included empirical studies have identified additional factors such as the evaluation function (Nelen, 2000), evaluation

initiation (European Court of Auditors, 2018; Mastenbroek et al., 2016; van Voorst, 2018; van Voorst & Mastenbroek, 2017), timing (Golen & Voorst, 2016; Klein Haarhuis & Parapuf, 2016; van Voorst, 2018) and the interaction between researchers and those involved (Klein Haarhuis & Parapuf, 2016; Vanlandingham, 2011). In addition, this scoping review also included case studies and opinion articles that noted or suggested additional factors. The results point to a clear tripartite division of factors that matter to the degree of impact of ex-post legislative evaluations.

3.4.1 The relevance of context for impact

First, the literature shows that the context of the evaluation process plays an important role in the impact of ex-post evaluation of legislation. Context is determined by the initiation and function of the evaluation, stakeholders' openness towards the evaluation results and the political and social context.

A recurring observation is that the impact of ex-post legislative evaluations is influenced by the willingness of actors, such as the commissioner and policy-makers, to adopt the evaluation results and have them translated into legislation and policy. Such willingness also depends on the extent to which actors could use an evaluation for their specific interests and agenda (e.g. legitimisation, monitoring or political-strategic purposes). For a given ex-post legislative evaluation, the interests of each actor may vary, owing to their distinct concerns and objectives. In particular, political interests seem to play a role in deciding whether or not to follow up on ex-post legislative evaluations. These interests may already come into play at the commissioning stage of an ex-post legislative evaluation. Such an evaluation may be actively requested or be the result of a mere legal obligation. An ex-post legislative evaluation that is actively requested is likely to have more impact, as at least one actor has a specific interest in the results of the evaluation. This could, for example, be a political interest. However, the influence a political interest has on the use of evaluation results is ambiguous. Some authors argue that political involvement ensures that the impact of ex-post legislative evaluations is more present, while others conclude that significant political attention ensures that, on the contrary, evaluation results are not used.

3.4.2 The relevance of research quality for impact

Second, the literature shows that some factors related to the research quality may affect the impact of ex-post evaluations of legislation. This includes both the quality of the research (methods used, research findings and recommendations) and the research group (independence of the research group). The results show that, with regards to recommendations made in the evaluation report, the use of evaluation results was promoted if the evaluation report made recommendations or if the evaluation results confirmed the usefulness of the implemented policy and related legislation. Surprisingly, little evidence was reported on the effect of the methodological quality as determining factor for the impact of an ex-post legislative evaluation. One aspect of research quality, the independence of the research, is frequently discussed in the literature. Independent research is described as an important condition for the reliability and validity of evaluation research, especially if the topic is sensitive or politically charged. Independent research contributes to the objectivity of research findings and can be achieved, for example, by choosing an external

research group. However, too much independence is not considered desirable. Evaluators aim to speak the truth to powerful entities instead of lobbying for specific interests. However, if the focus on independence becomes too extreme, it can lead to a lack of effective communication and the truth not being conveyed to anyone (Vanlandingham, 2011).

3.4.3 The relevance of interaction for impact

The third and last factor that influence the impact of ex-post legislative evaluations, as described in the literature is the interaction between the researchers on the one hand and the recipients of the evaluation results on the other. Recipients of evaluation results may include both the commissioner of the evaluation, the political domain, the legal domain and society as a whole. The literature shows that during the whole evaluation process, interaction with these different actors plays an important role in the possible impact of ex-post legislative evaluations. Interaction already starts with the commissioning of an evaluation assignment. During the process, interaction with stakeholders such as the commissioner and participants is also reported to be a crucial way to increase the likelihood of use. Some scope for client involvement helps to create support after delivery of the evaluation report. There are also opportunities to increase impact at the end of the evaluation process by the way in which evaluation results are available and presented. For the whole process, the timing of the evaluation plays a crucial role. In order to gain as much impact as possible, evaluation results should be available when key decisions must be made.

3.4.4 Research findings in the light of Alkin and King's study

The three categories outlined in this scoping review are broadly consistent with those described in Alkin and King's (2017) study, with both studies highlighting the significance of recognisability and relevance to end-users in stimulating evaluation use. The research quality and interaction factors we have describe align with those presented by Alkin and King (2017), but there are significant differences in their context. These may be attributed to the researcher's perspective in our analysis, as well as the unique characteristics and stakeholders of the legislative domain as compared to the broader field of policy and programme evaluation. Unlike policy and programme evaluations, ex-post legislative evaluations primarily impact the design of legislation and thus the impact is mainly found in the legal domain. Specific mechanisms, such as elaborating norms in legislation based on evaluation results, are unique and not found in the broader evaluation literature. Another notable difference is the emphasis in the legal literature on the relevance of the initiative to commission the evaluation.

On the other hand, the ex-post legislative evaluation field may benefit from the more established ideas in the broader evaluation literature based on more extensive and empirical research. This provides a call for the ex-post legislative evaluation field to leverage the broader evaluation literature and conduct more empirical research. Additionally, the field of ex-post legislative evaluations could contribute to the field of policy and programme evaluation by providing insight in how evaluation results are integrated into the legal domain.

3.4.5 A current dilemma

The results of this scoping review also reveal a dilemma for researchers: how to combine productive interactions with the stakeholders of an evaluation while ensuring the independence of the evaluation. Conducting an evaluation and thereby having impact requires the convergence of two worlds, the evaluator on the one hand and the recipient or user of the evaluation results on the other.

The context of an evaluation is a given that researchers have to deal with when conducting an ex-post legislative evaluation. Researchers cannot control the context and have to 'work' with it, but researchers can take the contextual factors into account. They can seek to interact with the various stakeholders in this context and respond to the given context. This interaction can take place at different stages of the evaluation process (e.g. in the preparation phase, the execution phase or the implementation phase). Interaction works in two ways: interaction allows researchers to respond to the field to increase the likelihood of impact of the ex-post legislative evaluation. On the other hand, interaction may influence researchers during the evaluation process, making evaluation results more responsive to questions in the field. The right balance is needed, which has also been described by Winter et al. (1990). While research independence is considered essential for impact, researchers depend largely on the input from respondents during the evaluation process, which can reflect the strategic agendas of involved parties.

Balancing impact and independence requires understanding these agendas, aiding researcher in presenting results that resonate with these parties. However, evaluation results and conclusions should not be the result of stakeholder pressure; they should be based on good research quality. On the other hand, evaluation conclusions will have more impact when they align with the strategic agendas of involved parties. This is a dilemma that places demands on the evaluation process, such as in the form of an external guidance committee. This dilemma also warrants more in-depth research, that will be relevant for the specific field of ex-post legislative evaluations and the broader field of policy and programme evaluation.

Another aspect warranting in-depth investigation is the complexity of responsible institutions for ex-post legislative evaluations across countries, combined with diverse conceptualisations within parliamentary cultures. These variations in approach arise from distinct contextual backgrounds and frameworks in each nation, resulting in diverse methods – like the UK's customised approach and the Netherlands' reliance on external entities. This scoping review underscores how the significance and positioning of evaluations affect their outcomes, implying potential for enhanced comparative research despite its absence in this study.

Appendix 1

Related search data - full text articles available for coding (n=91)

Title	Author	Year	Journal
Legislative history and evaluation	Caulley, D.N.	1982	Evaluation and Program Planning v5 n1 (1982): 45-52
The Role of Evaluation in Legislative Decision Making	Green, A.	1984	Public Administration Review v44 n3 (19840501): 265-267
The Role of Evaluation Information in Legislative Decision Making: A Case Study of a Loose Cannon on Deck	Malen, B.; Murphy, M.J.; Geary, S.	1988	Theory Into Practice v27 n2 (19880401): 111-125
Een beschouwing over de veelsoortigheid in wetsevaluaties	van Veldhoven, W.M.	1988	
The Politics of Legislative Evaluations: Fire-Alarm and Police Patrol as Oversight Procedures	Wohlstetter, P.	1990	Evaluation Practice v11 n1 (1990): 25-32
De paradox van wetsevaluatie	Veerman, G.J.	1991	Wetgeven en evalueren (WODC) 591
Wetgeving en beleid: pleidooi voor een heroverweging van de rol van het parlement in het wetgevingsproces en een systeem van wetsevaluatie	Adams, M.	1993	Ger deurw 1993, p. 1041-1050 (afl. 31)
Evaluatie van gezondheidswetgeving	Gevers, J.K.M.	1995	Tijdschrift voor Gezondheidsrecht 1995/2
Evaluatie van wetgeving	Polak, J.M.	1996	Nederlandsch juristenblad v71 n33 (1996): 1369
Evaluatie van het gezondheidsrecht: de Wet Bopz als casus	Winter, H.B	1997	Tijdschrift voor Gezondheidsrecht 1997/7.2
Evaluatie van wetgeving in de gezondheidszorg	Legemaate, J.	1997	Nederlands Tijdschrift voor Sociaal Recht 1997/12.9
Evaluatie van wetgeving in de gezondheidszorg en causaliteit	Leenen, H.J.J.	1998	Tijdschrift voor Gezondheidsrecht 22, no. 1 (1998):
Wetsevaluatie vanuit bestuurskundig perspectief	van Humbeeck, P.	2000	
Evaluatie van gezondheidswetgeving – enkele impressies	Hendriks, A.C.	2000	Tijdschrift voor Gezondheidsrecht 2000/2.3
Wetsevaluatie en administratieve vereenvoudiging. Overzicht van de situatie in Vlaanderen.	van Humbeeck, P.	2000	VIOM – Studiedag Wetsevaluatie en Administratieve Vereenvoudiging

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Evaluating the Effects: A Contribution to the Quality of Legislation	Mader, L.	2001	Statute Law Review 22, no. 2 (2001): 119-131
Evaluation in EC Legislation	Gallas, T.	2001	Statute Law Review - Volume 22, Issue 2, pp. 83-95
Giving Effect to European Fundamental Rights Through Evaluation of Legislation	Karpen, U.	2002	Statute law review v23 n3 (2002): 191-202
Holistic thinking is not the whole story. Alternative or adjunct approaches for increasing the accuracy of legal evaluations.	Faust, D.	2003	Assessment, 10(4), 428-441
Evaluation of legislation in the Netherlands?	Voermans, W.J.M.	2003	Legislação, 33/34, 33 - 61 (2003)
Implementation of Legislative Evaluation in Europe: Current Models and Trends	Karpen, U.	2004	European Journal of Law Reform, 6, no. 1/2, (2004): 57-86
Harmonization of Legislation on Migrating EU Citizens and Third Country Nationals: Towards a Uniform Evaluation Framework?	Slot, P. J.; Bulterman, M.	2006	FORDHAM INTERNATIONAL LAW JOURNAL 29, no. 4, (2006): 747-789
Evaluators' role in facilitating the convergence of factors to create legislative impact	Greer, H.	2006	New Directions for Evaluation v2006 n112 (Winter 2006): 41-49
Beleids- en wetsevaluaties: trends en topics	Leeuw, F.L. e.a.	2006	RegelMaat 2006/3.1
The Practice and Discourse of Legislative Evaluation in Portugal	Garoupa, N.M.; Vilaça, G.V.	2007	SSRN Electronic Journal (2007)
Wetsevaluatie: een maatschappelijke noodzaak	Goeij de, J.I.M.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.2
Wet en werkelijkheid: bevindingen uit evaluaties van wetten	Klein-Haarhuis, C.M.; Niemeijer, E.	2007	Book
Wetsoverstijgende evaluatie inzake toezicht op de kwaliteit van zorg	Legemaate, J.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.4 -
Wetsevaluatie in de gezondheidszorg	Buruma, O.J.S. e.a.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.1
Wetsoverstijgende evaluaties	Winter, H.B. e.a.	2007	Tijdschrift voor Gezondheidsrecht 2007/8.7
Thematische (horizontale) wetsevaluatie – kwalitatief betere toepassing (gezondheids) regelgeving	Roscam Abbing, H.D.C.	2007	Tijdschrift voor Gezondheidsrecht 2007/8
Wetsevaluaties; enig commentaar	Eijkman, M.A.J.	2008	Tijdschrift voor Gezondheidsrecht 2008/2.6 -

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Kwaliteit van de beleidsanalytische wetgevingsadviezen van de Raad van State getoetst aan de hand van ex post evaluaties	Vranken, J.B.M.; van Gestel, R.A.J.	2008	Universiteit Tilburg
Wetten in werking. Over interventies, werking, effectiviteit en context.	Klein-Haarhuis, C.M.; Niemeijer, E.	2008	WODC
Assessing the accuracy of ex ante evaluation through feedback research: A case study	Vranken, J.B.M.; van Gestel, R.A.J.; Verschuuren, J.M.	2009	The impact of legislation: A critical analysis of ex ante evaluation, 199 - 277
Conclusions: A conditional yes to ex ante evaluation of legislation	Verschuuren, J.M.; van Gestel, R.A.J.	2009	The impact of legislation: A critical analysis of ex ante evaluation, 255 - 272
"Ex ante" Evaluation of Legislation : an Introduction	Verschuuren, J.M.; van Gestel, R.A.J.	2009	Book chapter in J. M. Verschuuren (Ed.), The impact of legislation: A critical analysis of ex ante evaluation (pp. 3-10). Martinus Nijhoff Publishers.
The impact of legislation: A critical analysis of ex ante evaluation	Verschuuren, J.M.	2009	E-Book
Chapter 3: Ex ante Evaluation of Legislation torn among its rationales in The impact of legislation	Larouche, P.; Verschuuren, J.M.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 39-62
Synthesising legislative evaluations – Putting the pieces together	Niemeijer, E.; Klein Haarhuis, C.M.	2009	Evaluation v15 n4 (2009): 403-425
Chapter 2: The Context of the Rise of "Ex ante" Evaluation	Popelier, P.; Verlinden, V.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 13-37
Chapter 5 "Ex ante" Evaluation of Legislation : between Puzzling and Powering in The impact of legislation	Hoppe, R.	2009	Book
Chapter 6: Pushing evaluation forward: Institutionalization as a means to foster methodological growth of legislative ex ante evaluation	van Aeken, K.; Verschuuren, J.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 105-134
The Politics of the "Ex Ante" Evaluation of Legislation	Bohne, E.	2009	The impact of legislation : a critical analysis of 'ex ante' evaluation , P. 63-79
The Introduction for the Legislation-Evaluation System about the Municipal Ordinance	Hwanyong C.	2009	Local Government Law Journal - Volume 9, Issue 2, pp. 341-355

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Negen aanwijzingen voor wetsevaluatief onderzoek	Veerman, G.J.M. e.a.	2009	RegelMaat 2009/4.2 -
Evaluation of Legislation: Skating on Thin Ice	Bussmann, W.	2010	Evaluation - Volume 16, Issue 3, pp. 279-293
Measuring Law for Evaluation Research	Tremper, C; Thomas, S; Wagenaar, AC;	2010	Evaluation review 2010 Jun; 34(3): 242-66
Ex ante-evaluatie in de gezondheidszorg	Ploem, M.C.	2010	Tijdschrift voor Gezondheidsrecht 2010/2.1
Het evalueren van de Awb: een voortdurend proces	Michiels, F.C.M.A.	2010	Bestuursrecht harmoniseren: 15 jaar Awb, 41 - 55
Over het belang van feitenonderzoek bij de voorbereiding en evaluatie van wetgeving	Leeuw,F.L.; Willemsen, F.; de Jongste, W.M.	2010	RegelMaat - Volume 25, Issue 2, pp. 51-65
Ex ante evaluation of EU legislation intertwined with judicial review? Comment on Vodafone Ltd v Secretary of State for Business, Enterprise and Regulatory Reform (C-58/08)	Keyaerts, D.	2010	European law review. 35, no. 6, (2010): 869
'Ex ante-evaluatie' en de toetsing door het Hof van Justitie	Keyaerts, D.	2010	S.E.W. - Volume 58, Issue 2, pp. 61
Can legal research benefit from evaluation studies?	Leeuw, F.L.	2011	Utrecht Law Review, 7(1), pp.52–65.
Escaping the Dusty Shelf: Legislative Evaluation Offices' Efforts to Promote Utilization	Vanlandingham, G. R.	2011	American Journal of Evaluation - Volume 32, Issue 1, pp. 85-97
The Impact of Right-to-Carry Laws and the NRC Report: Lessons for the Empirical Evaluation of Law and Policy	Aneja, A.; Donohue, J.J.; Zhang, A.	2011	American Law and Economics Review v13 n2 (10 2011): 565-631
Ex Ante Evaluation and Alternatives to Legislation : Going Dutch?	Van Gestel, R.A.J.; Menting, M.	2011	Statute Law Review, Volume 32, Issue 3, October 2011, Pages 209–226
From Vision To Reality: Ex Post Evaluation of Legislation	van Aeken, K.	2011	Legisprudence v5 n1 (2011): 41-68
Study on Educational Legislation Evaluation	Junseong, H.	2011	The Journal of Law of Education v23 n1 (201106): 259-288
Evaluating legislation : an alternative approach for evaluating EU internal market and services law	Fitzpatrick, T.	2012	Evaluation v18 n4 (2012 10 01): 477-499

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
A study on development of method for sustainability assessment in legislative evaluation	Park, Y.; Bae, G.	2013	
Evaluatie van wetgeving? Bouwstenen voor beslissingen	Veerman, G.J.	2014	Recht en Overheid
Ex ante onderzoek in beeld: over aard, aantal en gebruik van ex ante onderzoek bij beleidsvoorbereiding	Klein-Haarhuis, C.M. e.a.	2014	Beleidsonderzoek Online 2014
Gezamenlijk ouderschap na scheiding: over de interactie tussen de doelstellingen van de Deense wet op de ouderlijke verantwoordelijkheid, de bevindingen in de uitgevoerde wetsevaluatie en de daaropvolgende wetswijzigingen	Jeppesen de Boer, C.G. e.a.	2014	F&R 2014
Welke lessen kunnen we trekken uit evaluaties met het oog op effectieve wet- en regelgeving?	Klein-Haarhuis, C.M.	2014	WODC
Klaarheid over het Clearing House voor Wetsevaluatie	Veerman, G.J.	2014	RegelMaat 2014/4.2
Naar een regelgevingcyclus? Evaluatie in de Europese Unie	Mastenbroek, E.; Meuwese, A.; van Voorst, S.	2014	RegelMaat - Volume 29, Issue 4
De rol van empirisch-etisch onderzoek in wetsevaluaties	Landeweer, E; Widdershoven, G.	2014	NVBe
Ex-post evaluatie	Lokin, M.H.A.F.	2014	RegelMaat 2014/4.1
Empirical Evaluation of Law: The Dream and the Nightmare	Donohue, J. J.	2015	AMERICAN LAW AND ECONOMICS REVIEW - Volume 17, Issue 2, pp. 313-360
Closing the regulatory cycle? A meta evaluation of ex-post legislative evaluations by the European Commission	Mastenbroek, E; van Voorst, S; Meuwese, A.	2016	Journal of European Public Policy v23 (2016): 1329-1348
Ex post legislative evaluation in the European Union: questioning the usage of evaluations as instruments for accountability	Zwaan, P; van Voorst, S; Mastenbroek, E.	2016	International Review of Administrative Sciences, 82(4), 674-693
Towards a Rational Legislative Evaluation in Criminal Law	Nieto Martín, A.; Muñoz de Morales Romero, M.	2016	Book
New Zealand's new alcohol laws: protocol for a mixed-methods evaluation	Maclennan, B; Kypri, K; Connor, J; Potiki, T; Room, R; Maclennan, Brett; Kypri, Kypros; Connor, Jennie; Potiki, Tuari; Room, Robin	2016	BMC public health 2016 Jan 13; 16: 29

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Evaluatievermogen bij beleidsdepartementen; praktijken rond uitvoering en gebruik van ex post beleids- en wetsevaluaties	Klein-Haarhuis, C.M.; Parapuf, A.	2016	Boek, WODC
Utilization of evaluation results in policy making and administration	Wollmann, H.	2016	HKJU-CCPA 16(3), 433–458
Enforcement tool or strategic instrument? The initiation of ex-post legislative evaluations by the European Commission.	van Voorst, S.; Mastenbroek, E.;	2017	European Union politics - Volume 18, Issue 4, pp. 640-657
Meer dan de som der delen? Beschouwingen over de implementaties en evaluatie van Europese regelgeving	Mastenbroek, E.	2017	Inaugurele rede
Rechtstekorten in het gezondheidsrecht	Legemaate, J.	2018	Tijdschrift voor Gezondheidsrecht 2018
Ex-post legislative evaluations in the European Commission : between technical instruments and political tools	van Voorst, S.	2018	Acadamic thesis, Tilburg University
Legislative evaluation as alternative democratic engagement	van Aeken K.	2018	Diritto and Questioni Pubbliche v18 n1 (2018 06 01): 271-289
Tracing the use of evaluations in legislative processes in Swiss cantonal parliaments	Eberli, D.	2018	Evaluation and Program Planning v69 (August 2018): 139-147
De evaluatie van de wetsevaluatie	Boer, T.	2018	TGE
Evaluations as a decent knowledge base? Describing and explaining the quality of the European Commission's ex-post legislative evaluations	Mastenbroek, E.; van Voorst, S.	2019	Policy Sciences - Volume 52, Issue 4, pp. 625-644
The (non-)use of ex post legislative evaluations by the European Commission	van Voorst, S.; Zwaan, P.	2019	Journal of european public policy v26 n3 (2019): 366-385
Assessing the European Commission's legislative cycle: The problems of linking ex ante impact assessments and ex-post legislative evaluations	van Golen, T.	2020	Doctoral thesis
Ex-post evaluation in the European Parliament: an increasing influence on the policy cycle	Anglmayer, I.; Scherrer, A.	2020	The Journal of Legislative Studies v26 n3 (20200702): 405-426
Regional legislative evaluation capacity and the oversight function: a diagnostic study of the Economic Community of West African States (ECOWAS) Parliament	Adaku, E.; Amoatey, C.T.; Agomor K.S.; Tandoh-Offin P.	2020	Journal of Legislative Studies
Testing an ex-ante framework for the evaluation of impact assessment laws: Lessons from Canada and Brazil	Fonseca, A.; Gibson, R.B.	2020	ENVIRONMENTAL IMPACT ASSESSMENT REVIEW - Volume 81,

Related search data - full text articles available for coding (n=91) (continued)

Title	Author	Year	Journal
Leren van evaluaties - De fitness check van het Europees consumentenrecht	van Schagen, E.A.G	2020	RegelMaat 2020/5.3
The instigation of hatred: questions of legal evaluation and procedural issues	Murauskiene, D.; Jurka, R.; Zajanckauskiene, J.	2020	Entrepreneurship and Sustainability Issues v8 n2 (20201230): 896-913

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Section II

Case studies on ex-post legislative evaluations in Dutch healthcare

Chapter 4

A study protocol for conducting case studies on the impact of ex-post legislative evaluations in dutch healthcare

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Abstract

Recent studies on the impact of ex-post legislative evaluations show that there are different types of impact and different factors that can influence it. These include the context of a legislative evaluation, research quality, and interactions between researchers and other actors within the evaluation process. However, thorough empirical research in this area is lacking. This warrants empirical research into the factors that influence the impact of ex-post legislative evaluations, so these insights can be used to increase the likelihood of ex-post legislative evaluations having an impact.

In this protocol, we report on the Realist Evaluation methodology that will be used to evaluate the impact of three ex-post legislative evaluations in the Dutch healthcare sector. The mixed methods Realist Evaluation approach will facilitate this theory-driven, qualitative research. The study will consist of the following three steps: (1) Initial programme theory development, (2) theory validation, and (3) theory refinement. Knowledge from two scoping reviews conducted previously, and two subsequent expert meetings will form the basis for developing the initial programme theory. During this study, three case studies will be conducted, in which three individual ex-post legislative evaluations will be examined. Specific methods for data collection will include: documentary review, observation, structured questionnaires and focus group discussions with purposefully identified key stakeholders. Using the framework approach, the data will be analysed thematically in a within-case analysis followed by a cross-case analysis.

This protocol provides insight into how the study will be conducted. As this study uses multiple qualitative research methods to answer one question, this protocol supports refining data collection procedures. Careful consideration of the approach beforehand can minimise pitfalls, reduce publication bias and improve reproducibility. The protocol therefore specifies how the research question will be answered in detail, and this provides solid guidance for the research process.

4.1 Introduction

In this article, we report on a protocol for a Realist Evaluation study into the factors that may influence the impact of ex-post legislative evaluations (hereafter also referred to as legislative evaluations) in the Dutch healthcare sector. Legislation is an important and constantly evolving government instrument. It regulates healthcare, among other things, and directly affects the people involved, such as healthcare providers and patients. This justifies the need to check whether legislation actually does what it is supposed to after it has entered into force. To this end, ex-post legislative evaluations are conducted to examine the effectiveness of a law. They do so by ascertaining whether the law's stated objectives have been achieved and what effects it has in practice. In order to improve the evidence base for healthcare legislation, the importance of conducting legislative evaluations is recognised globally. Consequently, legislative evaluations are being conducted to an increasing extent.

In the Netherlands, the evaluation of legislation is an increasing trend. In line with the broader development of legislative evaluations, the Netherlands has run the ZonMw programme for the evaluation of health laws and regulations since 1997. ZonMw is a Dutch funding organisation for innovation and research in healthcare. The programme is designed to contribute to the quality of health law legislation. Legislative evaluations are initiated at the request of the Ministry of Health, Welfare and Sport. They are carried out by independent, multidisciplinary research groups, selected for each study by the ZonMw regulatory evaluation committee. For each evaluation, ZonMw appoints an advisory committee with several experts from the field. This committee oversees the research process and acts as a sounding board. After the completion of the evaluation study, the evaluation report is presented to the ZonMw regulatory evaluation committee and the Ministry of Health, Welfare and Sport.

With nearly a quarter of a century's experience in conducting legislative evaluations using this programme, an important question has arisen: what is the actual impact of these evaluations, and what mechanisms are in place to support this impact? Within the ZonMw programme, numerous evaluations have been conducted with the aim of implementing the gained insights. However, it remains to be seen whether and how this implementation takes place effectively.

Prior to writing this protocol, an extensive literature research was conducted to provide insight into the existing knowledge on the topic. Two scoping reviews (Knap et al., 2023a; Knap et al., 2023b) described what is currently known in the existing literature about the types of impact of ex-post legislative evaluations and about the factors that may influence them. It should be noted that these scoping reviews were based on a broad-based literature review, without limitation to a specific country or jurisdiction.

The first scoping review showed that legislative evaluations fall within three domains: policy, politics and society (Knap et al., 2023a). Although society is directly affected by the presence of legislation, the impact of legislative evaluations seems to be particularly present in the domain of

policy and politics. The findings of the second scoping review clarified the factors that influence the impact of legislative evaluations, namely context, research quality and interaction (Knap et al., 2023b). However, in contrast to extensive empirical research, more than a third of the data in both scoping reviews consisted of expert opinions. This justifies the need for empirical research into the factors that influence the impact of legislative evaluations. Since the evaluations carried out within the ZonMw programme potentially contain a great deal of useful information on this, it provides an excellent opportunity to conduct empirical research into evaluations of health legislation. The outcome of the second scoping review can thus be assessed in the context of a defined programme.

Given the factors mentioned above, the research question in this study will be: *What factors influence the impact of ex-post legislative evaluations in the Dutch healthcare sector?*

The methods section describes a theory-based protocol to conduct this empirical research. The study that will be conducted based on this protocol aims to better understand the mechanisms that provide insight into influenceable factors that can contribute to increasing the likelihood of legislative evaluations having an impact. Since legislative evaluations are conducted worldwide, this is an important contribution to the literature on the impact of legislative evaluations. By describing the research design in this protocol, we are compelled to thoroughly think about the rationale, approach and purpose of this study. Moreover, this protocol reduces publication bias and improves reproducibility.

The specific objectives of the study that follows based on this protocol are as follows:
1. To develop a literature-based and empirically validated theoretical framework to maximise the impact of ex-post legislative evaluations.
2. To develop an in-depth understanding of the influenceable factors that support the impact of Dutch healthcare ex-post legislative evaluations.
3. To identify, assess and compare the outcomes of different case studies in which the impact of Dutch healthcare ex-post legislative evaluations is studied.

4.2 Methods and analysis

A Realist Evaluation design is well suited to assessing how interventions work in complex situations because it allows the evaluator to deconstruct the causal web of conditions underlying them (Pawson & Tilley, 1997). These interventions are particularly useful for evaluating programmes that produce mixed outcomes, such as the ZonMw programme, to better understand how and why differential outcomes occur.

4.2.1 Realist Evaluation

This study is designed as a mixed methods process and will be conducted on the basis of the Realist Evaluation (RE) method (Shamseer et al., 2016) developed by Pawson and Tilley (Pawson

& Tilley, 1997). This method assumes that the same intervention will not work everywhere and for everyone. As opposed to the question of whether it works, this theory focuses on what works in what circumstances and for whom. The complete RE question is: "What works, for whom, in what respects, to what extent, in what contexts, and how?" In short, the key questions in RE are about causality and attribution. To answer these questions, realist evaluators aim to identify the underlying generative mechanisms that explain how the outcomes were caused and the influence of context.

The RE method consist of three key concepts: context, mechanisms and outcomes. Initially, a Context-Mechanism-Outcome (CMO) hypothesis about which mechanisms are likely to work in different contexts and which outcomes will be observed is developed. The context determines whether mechanisms work during a programme and may vary depending on various circumstances (e.g., social and political). Mechanisms intermediate between the concrete components of the interventions and the outcomes. They need the right context to work; any changes in the system can affect the causal process. The outcomes of a programme can be intended or unintended and can be short, medium and long-term. There can also be multiple outcomes of varying importance for different stakeholders. Both context and mechanisms must be systematically researched alongside interventions and outcomes.

The use of the RE method fits well with earlier research on the impact of ex-post legislative evaluations because it reflects the elements of context, mechanism and outcome mentioned above. The previously conducted scoping reviews show that context matters. In addition, there can be different types of impact (outcomes) and there are several factors (mechanisms) that can influence the impact of ex-post legislative evaluations. The RE method enables us to look deeper into the factors that can be influenced regarding the impact of legislative evaluations.

4.2.2 Study design and setting

The 6-month study (April – September 2023) will be carried out in the Netherlands, building upon the 25 years of experience with legislative evaluations in the Dutch healthcare sector. Since realistic evaluation is method-neutral (Pawson & Tilley, 1997) and does not force the use of certain methods, in this study, a mixed methods approach is chosen for three case studies. Each case study examines one ex-post legislative evaluation from the ZonMw programme in detail. In this way, the case studies will focus on the Dutch situation, specifically within the Dutch healthcare sector.

4.2.3 Data collection

Phase 1. Initial programme theory development

The first phase is almost completed and consists of two parts: two scoping reviews and two expert meetings. Based on these inputs, an initial programme theory (IPT) will be developed that connects the CMO configurations. The IPT outlines how mechanisms work in a specific context to achieve certain outcomes, which fits well with this study's aims. The first scoping review

showed that different types of impact of ex-post legislative evaluations could be distinguished in the literature; these can be divided into seven categories (see Table 1).

Table 1. Types of impact of ex-post legislative evaluations (Knap et al., 2023).

	Types of impact of ex-post legislative evaluations
1.	Knowledge and understanding
2.	Confirmation of well-functioning legislation
3.	Legislative revision
4.	Influence on the legislative process
5.	Influence on the policy process
6.	Influence on the political sphere
7.	Influence on society

These types of impact can be connected to varying degrees and relate to different parties: the legislative community, policymakers and broader society. The second scoping review examined factors that can be influenced during the evaluation process. The results from this study showed various factors that can influence the impact of legislative evaluations (Knap et al., 2023b). These factors were divided into three categories: context, research quality and stakeholder interaction (see Table 2).

Table 2. Factors that influence the impact of ex-post legislative evaluations (Knap et al., 2023).

	Factors that influence the impact of ex-post legislative evaluations
1.	**Context**
	Characteristics of the law and legislative process
2.	Evaluation initiation, function and openness to results
	Political and societal influence
3.	
	Research quality
	Composition and independence of the research group
	Methods employed
	Quality and content of evaluation report
	Stakeholder interaction
	Interaction between researchers and stakeholders
	Presentation and availability of research results
	Timing

The authors cited in this scoping review specifically mention the context in which an evaluation of legislation takes place. Contextual factors affect the evaluation process, but they are fixed and cannot be influenced by researchers. Factors that can be influenced by researchers are described and divided according to research quality (in a broad sense) and in terms of the interactions between researchers and stakeholders (Knap et al., 2023b). The influencing factors on the researchers' side are the focus of this study. To test and further specify the findings in the literature, two expert sessions were held in which the recognition or absence of factors was discussed. These sessions also highlighted interest in research quality, with specific reference to research independence and how this relates to the impact of evaluation results and interactions

between the researchers and stakeholders throughout the evaluation process. During these expert sessions, it was concluded that research quality and independence can be at odds with interactions. Both research quality and interactions were seen as modifiable factors. Therefore, these two factors were included as separate mechanisms in two CMO configurations.

Since the subject of this study is the evaluation process as a whole, the process from the creation of the evaluation proposal (initiation phase) to the dissemination of the results (implementation phase) will be included. The assumption in this IPT is that devoting attention to interaction and research quality during the evaluation process affects the impact of ex-post legislative evaluations. Two CMO configurations were prepared to test this IPT (see Table 3).

Table 3. Initial programme theory.

Initial programme theory (IPT) *Devoting attention to interaction and research quality during the evaluation process affects the impact of an ex-post legislative evaluation*				
Context	+	**Mechanism**	=	**Outcome**
C_1 – Characteristics of the law and legislative process, evaluation initiation, function and openness to results, and the political and societal influence		M_1 – Paying attention to and implementing interaction between researchers and stakeholders during the evaluation process		O_1 – Impact of ex-post legislative evaluations (in the legislative community, policy area and broader society)
C_2 – Characteristics of the law and legislative process, evaluation initiation, function and openness to results, and the political and societal influence		M_2 – Paying attention to and implementing research quality during the evaluation process		O_2 – Impact of ex-post legislative evaluations (in the legislative community, policy area and broader society)

The IPT will be refined using these two CMO configurations. With regard to both CMO configurations, both the evaluation initiation phase and the actual implementation phase will be examined. The specific methods to examine these two phases within both CMO configurations are described in the section 'Research methods and respondents'.

Phase 2. Data collection and theory validation

The initial IPT will be continuously validated and refined during data collection and analysis in Phase 2, which is planned to start in April 2023 and will last approximately six months. In this phase, three case studies will be carried out to understand and validate the above illustrated IPT that links context, mechanisms and outcomes of the impact of legislative evaluations. In each case study, an individual ex-post legislative evaluation from the ZonMw programme will be investigated. The three evaluations were chosen on the basis of time (not having been evaluated too recently or too long ago), diversity in whether or not the subject matter was ethical in nature, and the substance of the evaluation. Based on these considerations, the following ex-post legislative evaluations from the ZonMw programme will be examined:

- First evaluation of the Youth Act (January 2018)

- First evaluation of the Healthcare Quality, Complaints and Disputes Act (February 2021)
- Third evaluation of the Embryo Act (March 2021)

4.2.4 Research methods and respondents

To achieve these objectives, several qualitative research methods will be used. As mentioned earlier, this study will be conducted using two CMO configurations. The first CMO configuration is based on interaction (see Table 3). In this context, 'interaction' refers to productive interactions and mutual influence. It centres on interactions that lead to expectations among stakeholders and agenda-setting among researchers as an outcome of the actual interaction. The second CMO configuration is based on research quality (see Table 3). In this context, 'research quality' concerns the composition of the research group, the combination of legal and empirical research methods, the presence of different perspectives, and the recommendations made in the final research report. For both CMOs the whole evaluation process will be examined: from the initiation phase to the implementation phase.

4.2.4.1 Document review and observation

First, an objective document review will be made of key documents resulting from the evaluation process. For the initiation phase, these documents include the programme text, accepted project proposal and feedback from an advisory committee. For the implementation phase, the products delivered by the research group will be examined, such as the final research report.

4.2.4.2 Structured questionnaires and focus groups

After the document review and observation, respondents will be asked to examine the CMOs subjectively. As noted earlier, different categories of actors could be derived from the first scoping review describing the different impact areas (Knap et al., 2023a). These different groups of actors include both providers of legislative evaluations (i.e., researchers) as well as the users of the evaluation results (policymakers, politicians, legal community and society). In addition, there is the specific situation in the Netherlands that ex-post legislative evaluations are commissioned by an external party: ZonMw. This is a funding organisation of innovation and research in healthcare, such as the healthcare legislative evaluations, for which they have run the Evaluation Legislation and Regulation programme since 1997. The regulatory evaluation committee is responsible for implementing the programme as well as formulating the content of the evaluation assignments and selecting a multidisciplinary, independent research group for each legislative evaluation. ZonMw also appoints an advisory committee for each legislative evaluation that guides the evaluation process and acts as a sounding board. These advisory committees always include members of the regulatory evaluation committee of ZonMw. Owing to this special role in the evaluation process, members of the regulatory evaluation committee and the advisory committees will also be involved in this study.

A description of each group is provided in Table 4. For each individual case study, the specific individuals and organisations that belong to the seven groups identified in Table 4 will be indicated. This information will help to provide a clear understanding of the different perspectives

and experiences involved in the evaluation process. In some cases, however, there may be overlap. For example, policymakers are considered users. However, in some cases, they can also be classified as commissioners. After Phase 1, a detailed list of respondents will be drawn up without divisions in terms of age or gender. Representatives from each of these seven different categories of actors will be included if they played an active role in the design or implementation of the evaluation, or if they belong to the groups of users of the law targeted by the evaluation.

Table 4. Categories of respondents included.

Categories of respondents		
Group of actors	***Description***	***Methodology***
Providers		
Researchers	Individuals who are part of the research group conducting the legislative evaluation.	Structured questionnaire and focus group discussion
Users		
Policymakers	Commissioning parties/policy officers at the Ministry of Health, Welfare and Sport.	Structured questionnaire and focus group discussion
Politicians	Members of parliament, such as ministers and members of a political party who have the evaluation topic in their portfolio.	Structured questionnaire and focus group discussion
Legal community	Lawyers, healthcare legal counsels, jurists and academics in the field of (health) law who are not involved in the legislative evaluation.	Structured questionnaire and focus group discussion
Society	People in society who are subjects of the legislative evaluation, such as healthcare providers, patients and umbrella organisations within the healthcare sector.	Structured questionnaire and focus group discussion
ZonMw advisory committees	ZonMw appoints an advisory committee for each legislative evaluation, which guides the evaluation process and acts as a sounding board.	Structured questionnaire and focus group discussion
ZonMw regulatory review committee	This committee consists of professionals whose activities relate in some way to healthcare legislation. These may include academics, jurists, policy officers and healthcare professionals.	Focus group discussion

Structured questionnaires that are partly open ended have been chosen because the questions are concrete and defined based on a fixed template, which specifies the exact wording and order of the questions (see Table 5 for the topics), and because this ensures that a larger population can be reached. In all three case studies, one questionnaire will be sent to each group of actors with a maximum of 100 people per group. This number is sufficient to capture key perspectives and achieve data saturation. The questionnaires align with the study's four objectives (see Table 5). With regard to the distinction between the questions for the providers and the users, two different versions of the questionnaires will be developed. This approach ensures that the specific perspectives of both groups are adequately addressed.

4.2.4.3 Theory validation

In addition to data collection using structured questionnaires, a focus group discussion with key stakeholders will be held for each case study to validate the theory. During these focus groups, we will delve deeper into the possible factors and the context that influenced the impact of the evaluation in question with a number of key players, to ensure that our interpretations and conclusions are consistent with respondents' views and experiences. Focus group discussions were chosen to uncover factors influencing opinions, behaviour or motivation (Krueger & Casey, 2015) and to compare the perspectives of different groups of actors in the three case studies.

The aim is to represent different groups of actors, but all actors' experiences relate to the same case, so experiences can be exchanged. To enable all respondents to share insights and observations, the focus groups will consist of a maximum of 12 people (two from each group of actors) (Krueger & Casey, 2015). Group intelligence and deliberation will give us a more thorough understanding of these groups' perceptions and reasoning (Manzano, 2022). There is no agreement in the literature on the optimal number of focus groups (Guest et al., 2017), the content and people spoken to is considered more important than the number of focus groups (Manzano, 2022); accordingly, three focus groups should be sufficient for this study. In this way, one overarching focus group is held for each case study (see Table 4). Since ZonMw's regulatory evaluation committee largely consists of the same people for the three case studies, a separate focus group will be organised with them to discuss all three cases.

4.2.4.4 Recruitment strategies and data ethics

The questionnaires will be sent digitally, so respondents' email addresses will first have to be collected. Some of these email addresses are publicly available, and for the non-public email addresses, we will approach our contacts at ZonMw and the Ministry of Health, Welfare and Sport. Respondents will be sent a single invitation to participate in the questionnaire. Should they fail to respond, they may receive up to two subsequent reminders. Completion of the questionnaire is voluntary and will not be financially compensated. The accompanying text informs the respondents about the purpose of the survey, the duration, the use of the data and the retention period. They will be asked to agree to these conditions prior to the questionnaire. Focus group participants will be invited to participate in a separate email.

The data received will be entered directly into a secured database, from which analyses can be carried out. The focus group discussions will be held online and, after informed consent is given, audio-recorded and transcribed. The audio file will be destroyed after transcription. As shown by a comparative analysis study, the content of the data generated from both online and in-person focus group discussions is remarkably similar (Woodyatt et al., 2016). As the focus groups will be held in Dutch, the excerpts used for the report will be translated into English.

As this study will involve human participants, ethical approval has been sought and received from the Ethics Review Board Tilburg School of Social and Behavioral Sciences [TSB_RP998] for this phase of the study.

Phase 3. Data analysis and theory refinement

During this phase, the IPT will be refined based on an empirically tested CMO configuration. The research phases described above are represented schematically in Figure 1.

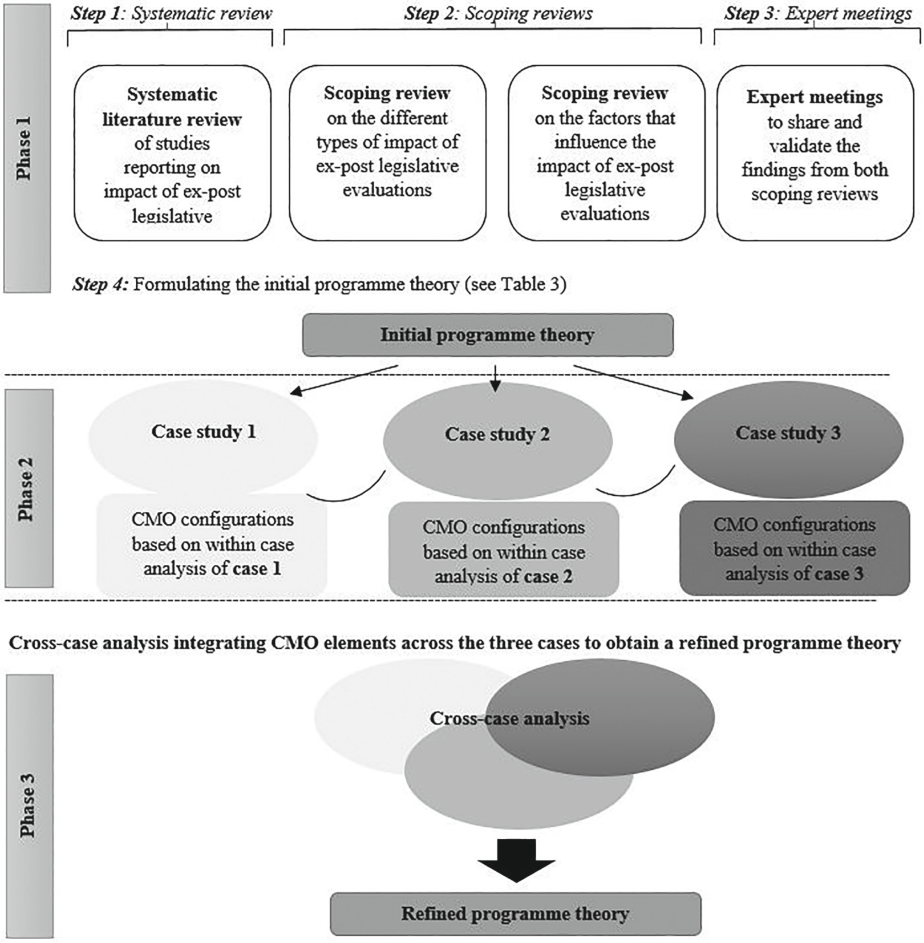


Figure 1. Schematic overview of research phases in Realist Evaluation (Makumbang, Marchal, Van Belle, et al. 2018).

4.2.4.5 Data analysis

As the structured questionnaires and focus group discussions contain both closed-ended and open-ended questions, a combination of descriptive statistics, graphs and some nonparametric inferential statistics will be used for the data analysis. During the data analysis, the IPT will be leading. This means the questionnaire and focus group data will be analysed in light of the IPT.

Based on the data analysis, it will be investigated whether there are additions to the IPT and whether they are widely supported.

4.2.4.6 Within-case analysis

The data will be analysed thematically using the framework approach. This approach is suitable for studies using different qualitative approaches (Hack-tt & Strickland, 2019), such as the questionnaires and focus group discussions in this study. The framework analysis consists of five stages: (1) familiarisation, (2) identifying themes, (3) indexing, (4) charting and summarising, and (5) interpretation/mapping (Hackett & Strickland, 2019). First, the data will be analysed for each actor for the different topics and provided with a narrative for the fragments that are found to be related to each topic. The narratives will be summarised and inserted into the corresponding cell in a matrix (see Table 6). Subsequently, the information per topic can be compared for each actor involved. This allows the researchers to delve deep into the data of a single case and assess the different perspectives of different actors on each topic (see Table 6). Due to the exceptional role of the ZonMw regulatory evaluation committee both before and during the evaluation process, this data will be analysed separately.

Table 6. Within-case analysis matrix.

	Case study 1: First evaluation of the Youth Act					**Case study 2:** First evaluation of the Healthcare Quality, Complaints and Disputes Act					**Case study 3:** Third evaluation of the Embryo Act				
	Impact	Context	Research quality	Interaction	Other factors	Impact	Context	Research quality	Interaction	Other factors	Impact	Context	Research quality	Interaction	Other factors
Researchers															
Policymakers															
Politicians															
Legal community															
Society															
ZonMw advisory committee															

4.2.4.7 Cross-case analysis

After the within-case analysis, a cross-case analysis will be conducted comparing the different case studies. In this way, similarities and differences of perspectives between the three case

studies regarding the topics can be identified (see Table 7). The interpretation of the research findings will consider whether the perspectives are consistent, partially consistent or inconsistent. It will also be examined whether new topics have emerged that are or are not widely supported. Following the cross-case analysis, interpretations and summary findings of the analysis will be shared with all key stakeholders during a focus group discussion. This is discussed above as part of Phase 3. The CMO configurations will be refined based on both the within-case analysis and the cross-case analysis.

Table 7. Cross case analysis matrix.

	Cross-case analysis of all three case studies				
	Impact	Context	Research quality	Interaction	Other factors
Researchers					
Policy makers					
Politicans					
Legal community					
Society					
ZonMw advisory committee					

Legend:

	= Consistent
	= Partly consistent
	= Inconsistent

4.3 Strengths and Limitations

This is the first study that will provide insight into the influenceable factors that researchers can use to increase the likelihood of ex-post legislative evaluations having an impact in the Dutch healthcare sector. This paper should be relevant to researchers interested in adapting and applying the Realist Evaluation method to assessing complex interventions, such as ex-post legislative evaluations.

Conducting the study in only one country and specific jurisdiction, in this case Dutch health law, may affect the generalisability of the study findings. However, the Realist Evaluation applies the idea of generative causality. This means mechanisms only work if the context is conducive. It can identify the circumstances under which an intervention does or does not work, and how this

happens. This allows stakeholders to assess whether interventions that have proved successful in one setting can also be successful in another. It also helps to adapt interventions to specific contexts. Realist Evaluation implies continuous assessment of where to focus. Consequently, only a few 'black boxes' (mechanisms) can be unravelled. Concentrating on mechanisms may lead to bias but, on the other hand, the focus is based on prior research. Moreover, it is impossible to unravel every mechanism.

4.4 Discussion

With this study, we aim to provide an in-depth understanding of the impact of ex-post legislative evaluations of Dutch health law, and specifically of the factors that may influence this impact. To this end, this study uses RE as the overarching conceptual framework to examine the actual impact of Dutch ex-post legislative evaluations in the healthcare sector. RE guides the development, validation and refinement of theories through analysis of the interplay between context, mechanisms and outcomes. In this way, the study sheds light on how the context of legislative evaluation implementation (e.g., evaluation initiation, function and political or social sphere) influences intervention mechanisms (e.g., research quality and interaction between researchers and stakeholders) to produce both intended and unintended outcomes. Since contextual factors are fixed and cannot be influenced, in this study, the RE method will be used to examine researcher influenced factors related to the impact of ex-post legislative evaluations. The existing literature suggests that there are two influential factors: the quality of the research, in a broad sense, and the interaction between the parties involved in the research. The study described in this protocol will provide insight into the presence of these factors and the extent to which they can be influenced and, subsequently, if they affect the impact of ex-post significantly influence the impact of legislative evaluations will also be identified. The aim is to empirically validate and refine the factors that researchers can influence regarding the impact of ex-post legislative evaluations. In this way, the probability of evaluation research having an impact may be increased. As ex-post legislative evaluations are carried out worldwide, this could be a major contribution to the existing evaluation literature.

Gaps in the literature on the impact of legislative evaluations combined with practical issues raised by researchers and funders of evaluation studies provide a clear research focus. The current literature does not yet provide a solid basis for mapping the impact of legislative evaluations. The aim of this study, therefore, is to reflect on the basic theory (IPT), which is based on two scoping reviews and two expert meetings. This protocol transparently provides insight into how the study will be conducted. As this study uses multiple qualitative research methods (such as document review, structured questionnaires and focus group discussions) to answer a single question, this protocol provides support in refining data collection procedures. By carefully considering the approach beforehand, pitfalls can be minimised. The protocol therefore specifies in detail how the research question will be answered. This provides solid guidance during the research process. In addition, this protocol offers the possibility of replicating the study in other jurisdictions. The

results of this study may also be of great interest to those involved in legislative evaluation in other countries since legislative evaluations are conducted worldwide.

While RE is a valid evaluative way of looking at the context, underlying mechanisms and outcomes of a complex intervention, there are also potential limitations. First, conducting the study in only one country and specific jurisdiction, in this case Dutch health law, may affect the generalisability of the study findings. However, RE applies the idea of generative causality, meaning that mechanisms only work if the context is conducive. It can identify the circumstances under which the intervention does or does not work, and how this happens. This allows policymakers to assess whether interventions that have proved successful in one setting can also be successful in another, and it helps them to adapt interventions to specific contexts. Second, RE implies continuous assessment of where to focus. Consequently, only a few 'black boxes' (mechanisms) can be unravelled. Concentrating on mechanisms may lead to bias but on the other hand, the focus is based on prior research. Moreover, it is impossible to unravel all mechanisms.

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Chapter 5

Case studies of three ex-post legislative evaluations of Dutch health laws

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Abstract

Globally, ex-post legislative evaluations are becoming increasingly important for understanding how laws function in practice, identifying their limitations and their effects upon stakeholders. This study delves into the impact of ex-post legislative evaluations within the Dutch healthcare system. Building upon insights from previous literature, we aim to refine existing ideas within the field through empirical data. Utilising the realist evaluation method, we examine three distinct case studies followed by a cross-case analysis. Our research underscores that the impact of these evaluations extends beyond policy and politics to the broader societal arena. Our findings also point towards opportunities for strengthening the impact of ex-post legislative evaluations within this broader societal arena. Specifically, we identify strategic phases within the evaluation process through which we aim to maximise impact. Finally, the study emphasises the importance of context awareness, the strategic utilisation of research quality as well as interactional factors for enhancing impact.

5.1 Introduction

Legislation plays a pivotal role in shaping healthcare policies and practices, which, in turn, affect the lives of both providers and patients. The practical effects of legislation often remain unclear until ex-post legislative evaluations (hereafter: legislative evaluations) have been conducted. These evaluations, also referred to in the literature as post-legislative scrutiny, are vitally important for assessing the effectiveness, efficiency, and impact of legislation once it has been implemented (van Schagen, 2020). They also provide opportunities for lawmakers to gather feedback, identify unintended consequences, and make informed adjustments to improve existing laws and policies (Anglmayer, 2020; Caygill, 2019; Kuchava, 2019; van Voorst & Mastenbroek, 2017).
Moreover, legislative evaluations strengthen transparency and accountability within governance, alongside ensuring that decisions are both based upon facts and responsive to the needs of the public (Griglio, 2020; Martín, 2016; van Voorst & Zwaan, 2019; Zwaan et al., 2016). In this respect, they can play a crucial role in terms of enhancing the quality of legislation and fostering trust in democratic institutions.

The importance of legislative evaluations is increasingly recognised (European Court of Auditors, 2018). Various countries have entities responsible for these evaluations. For instance, in the United States, the Government Accountability Office evaluates federal programmes, with congressional committees providing oversight. Similarly, in the UK post legislative scrutiny is conducted by select committees in both the House of Commons and House of Lords (Caygill, 2019; Norton, 2019). In Germany, Bundestag committees oversee legislative implementation and assess their societal impacts (Siefken, 2021). Australia, Canada, and Sweden also have parliamentary committees dedicated to post-legislative scrutiny, testifying to the increased global acknowledgment of the significance of legislative evaluation (Moulds, 2020).

Also approaches to legislative evaluations can vary worldwide. De Vrieze categorises them into passive, informal, formal, and independent scrutinizers. The UK and Switzerland are identified as independent scrutinisers, while the federal parliament of Germany is a passive scrutiniser (De Vrieze 2020; De Vrieze 2023). In some jurisdictions, such as Australia, the process is ad hoc, lacking a systematic framework (Moulds, 2020). Conversely, the House of Commons' systematic approach to post-legislative scrutiny has not yet become a regular part of committee work, and the extent of scrutiny in the House of Lords is also limited (Caygill, 2020). Despite these variations, the need for a structured and deliberate approach to post-legislative scrutiny is clear, as it can lead to meaningful outcomes for citizens (Moulds, 2020).

However, although the importance of legislative evaluations is widely recognised, a research gap remains concerning the actual impact of legislative evaluations and the strategies to optimise this impact. International practices, such as those observed in the European Parliament and parliaments of countries like the UK, Malaysia, and Australia, highlight the importance of post-legislative scrutiny in adding value and enhancing legislative processes. For example, Norton (2019) discusses how the UK Parliament has integrated post-legislative scrutiny to improve

legislative outcomes. Additionally, OECD reports (2020, 2021) emphasise the need for systematic reviews of regulatory frameworks to ensure their effectiveness and relevance over time. This broader international perspective underscores the necessity to empirically substantiate the factors influencing legislative evaluation impact and to explore strategies for optimising this impact, thereby learning from diverse legislative environments to refine and enhance the impact of ex-post legislative evaluations globally.

Recognising the importance of a systematic approach to legislative evaluations, the Netherlands has been running the ZonMw Regulatory Evaluation Programme (hereafter: the ZonMw programme) since 1997 to evaluate healthcare legislation and regulations. ZonMw, the Netherlands Organisation for Health Research and Development, is a governmental organisation that funds health research and promotes the use of developed knowledge to improve health and healthcare in the Netherlands. The primary objective of the programme is to enhance the quality of healthcare legislation. To achieve this aim, independent, multidisciplinary research groups are selected to carry out each evaluation, utilising a blend of empirical and legal research methods. Evaluations within the programme can be based on individual regulations or overarching themes that span multiple laws. Oversight of the programme's implementation ultimately rests with the Committee for Evaluation of Regulations (CER). This long-term programme has resulted in numerous legislative evaluations, the development of a well-defined approach, and the strengthening of the capacity to carry out these evaluations.

To address the research gap on the impact of legislative evaluations initiated by the ZonMw programme, we launched a project investigating the impact of ex-post legislative evaluations in healthcare in the Netherlands. We began with a literature review that highlighted impacts across both policy and political domains, as well as societal domains, with a notable emphasis on policy and political impacts (Knap et al., 2023a). We systematically identified key factors influencing these impacts, emphasizing the importance of the political environment and the institutionalisation of evaluation processes, which are beyond researchers' control (Knap et al., 2023b). The review also revealed several modifiable factors affecting evaluation impact, such as research quality and researcher-stakeholder interactions. However, the literature primarily consists of expert opinions and case descriptions, lacking empirical data. Many authors discuss the effects of evaluations without empirical support, with expert opinions dominating the discourse (Knap et al., 2023a). Thus, there is a pressing need for empirical research to validate the assumptions from our earlier review (van Aeken, 2011).

Drawing upon both recent research insights and the rich heritage of the ZonMw programme, we aim to answer this need, by delving deeper into three ex-post legislative evaluations in the Netherlands. We answer the following two research questions:

(1) What impact do these evaluations have?
(2) Which factors influence the impact (context, research quality, stakeholder interaction or other factors)?

5.2 Research methods

This study adopted a mixed methods approach, which was grounded in realist evaluation. The study focuses on three ex-post evaluations of legislation within the ZonMw programme. The study spanned from March to October 2023. The three cases were selected based on the following considerations: timing (all were at least two years old to allow for impact to unfold), the subject matter (diversity in the ethical or non-ethical nature of the topic), and variation in the frequency of prior evaluations of the law. Guided by these criteria, the study encompassed the following distinctive cases:

The first evaluation of the Youth Act (published in January 2018)
The first evaluation of Healthcare, Quality, Complaints and Disputes Act (Wkkgz) (published in February 2021)
The third evaluation of the Embryo Act (published in March 2021)
It is noteworthy that the researchers in this study formed part of the research group for the Wkkgz and partly for the Youth Act. We consider this to be an advantage in terms of obtaining in-depth information from the researchers' perspective.
This study comprehensively explores the process from proposal creation during the initiation phase to the dissemination of results in the implementation phase.
This research project underwent a rigorous ethical evaluation by the Ethics Review Board of Tilburg University (ref. no. TSB_RP998), which found no ethical or legal objections to the research.

A comprehensive study protocol detailing the methodology of this study was previously published (Knap et al., 2023c). This methods section provides an overview along with modifications or enhancements to the initial protocol. The study findings were presented in accordance with RAMESES II reporting guidelines for realist evaluations (Wong, 2016). A realist evaluation design is well-suited to assessing what works in specific circumstances and for whom. Aligned with this design, the study began with the initial programme theory (IPT) development, which outlines how mechanisms (M) operate in a specific context (C) to achieve certain outcomes (O) (Pawson & Tilley, 1997). The literature review identified research quality (composition and independence of research group, methods used, quality and content of evaluation report) and stakeholder interaction (interaction between researchers and stakeholders, presentation and availability of research results, timing of evaluation) as key and modifiable factors influencing the impact of ex-post legislative evaluations (Knap, Friele, et al., 2023). In the context of realist evaluation methods, these factors represent the mechanisms (M), while the impact(s) of ex-post legislative evaluations are the outcomes (O), all occurring within the context (C) of the legislative evaluation process, such as the characteristics of the law and legislative process, and the political and societal influence. The IPT connects C, M and O and is tested and refined based on the research findings of this study. Together, the IPT and the so called CMO configuration (context, mechanisms and outcomes) provide a framework for unravelling the causal web of conditions

underlying the outcomes (Pawson & Tilley, 1997). Table 1 provides an overview of the IPT, and CMO configuration that were used as framework to study the three ex-post legislative evaluations.

Table 1. Initial programme theory (Knap et al., 2023c).

Initial programme theory *Devoting attention to research quality and interaction during the evaluation process affects the impact of an ex-post legislative evaluation*				
Context	+	**Mechanism**	=	**Outcome**
Characteristics of the law and legislative process Evaluation initiation, function and openness to results Political and societal influence		A) Research quality: Composition and independence of research group, and Methods employed Quality and content of evaluation report B) Stakeholder interaction: Interaction between researchers and stakeholders Presentation and availability of research results Timing		Impact of ex-post legislative evaluations within: 1. The legislative community 2. The policy area 3. The society more broadly

To examine this CMO configuration, we employed a mixed methods approach, consisting of a document analysis, focus group discussions and questionnaires. Given our desire to involve the field in this research, we chose to conduct focus groups and questionnaires. Running concurrently, the three methods addressed identical research questions:
(1) What impact do these evaluations have?
(2) Which factors influence the impact (context, research quality, stakeholder interaction or other factors)?

In the paragraphs below, we provide an detailed description of each data source and methods used.

5.2.1 Document analysis

As part of our comprehensive document analysis to address the research inquiries, numerous documents spanning various points of the evaluation process, from initiation to implementation phases of the ex-post legislative evaluations, were scrutinised. Our analysis focused exclusively on visible, objectively, and explicitly stated impact-related information concerning the legislative evaluations.

In our document analysis, several key aspects were emphasised. The impact was assessed through the responses from the Minister of Health, Welfare and Sport (hereafter: the Minister), political figures, and relevant stakeholders in the field. Contextual factors were also considered, such as media attention garnered through the internet and newspapers, as well as political attention manifested in House of Representatives debates. Stakeholder interaction was evaluated by examining the evaluation report to understand what interactions were sought by the researchers.

The quality of the research was scrutinised through the evaluation report, which included the composition of the research group, the recommendations and intended addressees, and the methodologies used, whether qualitative, quantitative, legal, empirical, or a combination thereof. Additional documents from ZonMw, including the programme text and advisory committee opinions, were reviewed to assess awareness of context and impact. The reaction of the Minister was also noted, particularly opinions on the evaluation and subsequent steps in law, policy, or society.

5.2.2 Questionnaire

A computerised questionnaire was distributed to all stakeholders engaged in the evaluation process, with a distinction being drawn between creators (researchers) and users (policy members, politicians, legal experts, ZonMw advisory committees and a range of relevant societal stakeholders). Consequently, two distinct versions of the questionnaire were devised (see Appendices 1 and 2) but both contained the same topics, all related to impact on one hand and to context, stakeholder interaction, and research quality on the other hand. Respondents could also provide additional topics or factors. Despite substantial points of commonality, the questionnaires exhibited subtle variations as a result of being tailored to the two respective groups. Notably, researchers were asked whether pre-considerations related to the anticipated impact of their ongoing evaluation had been undertaken (see Appendix 2).

The response time for the survey was six weeks, with those who did not complete the questionnaire being reminded on two occasions. The questionnaire was sent to all the researchers in the three cases (N=23) and to 467 users in total. The questionnaire was primarily completed by researchers and relevant societal stakeholders such as healthcare professionals and members of a professional organisation. The cumulative response rate was 45.5%. The questionnaire data were reported using radar charts, merging outcomes from each legal evaluation into one radar chart for each question. This method quantified responses into percentages, which provided a comprehensive understanding of the participants' feedback distribution. Radar charts were chosen because of their ability to simultaneously present the data from the three evaluations.

5.2.3 Focus group discussions

A series of five distinct focus group discussions, each lasting one-and-a-half hours, were conducted. These sessions involved an average of six key stakeholders who were directly relevant to the three ex-post legislative evaluations. The participants comprised both creators and users. While joint sessions were organised whenever possible, when scheduling conflicts arose, separate meetings for researchers or users were arranged. In instances involving user-focused conversations, meticulous attention was paid to ensuring that the diversity of the participants was well-balanced, in order to sufficiently represent patients' interests. The questions that were central to the focus group discussions were aligned with the research questions: (1) What impact do these evaluations have? and (2) Which factors influence the impact?

During the focus group discussions, respondents from the field struggled to think solely about the impact of the legislative evaluation and, in fact, on several occasions responded by referring to the broader context of the impact of the legislation itself. This issue was clarified by the researchers on multiple occasions during the discussions.

5.2.4 Data analysis

The data collected from the three research methods were analysed concurrently. Focusing on actors, we report on both creators (the evaluation researchers) and users, categorised into three groups: policy, politics, and society more broadly.

Initially, a within-case analysis was conducted to identify the unique characteristics of each case study. In line with the research questions of this study, the first author systematically extracted all types of impact and factors influencing impact for each case. This systematic overview produced objective findings from all three research methods. The third author independently conducted this analysis, followed by discussions between the first and third authors to reach a consensus on any points of contention. These findings were then extensively deliberated by all the authors. A detailed overview was created for each case, outlining all the different types of impact and identifying the various influencing factors (see Appendix 3).

Subsequently, the first and third authors interpreted the results for each case study in order to establish connections between the impact and influencing factors. These interpretations were discussed with four external experts during three individual expert meetings. The within-case analysis followed a similar format for each case study. A cross-case analytical approach was then employed to identify similarities and differences between the cases with respect to these topics. At this stage, the emphasis shifted from the respondents' opinions to the researchers' interpretation of the within-case data. Based on the cross-case analysis, the CMO configuration was refined to clearly incorporate and highlight the newly acquired insights.

5.3 Results

In this results section, we start by outlining the institutionalisation of legislative evaluations in Dutch healthcare, providing the overarching context within which the three evaluations took place. This is followed by a within-case analysis that describes the specifics of each case separately. Finally, we present a cross-case analysis that examines the three cases together, highlighting comparative insights and overarching themes.

5.3.1 The institutionalisation of ex-post legislative evaluations

The evaluations we examined were conducted within the ZonMw Regulatory Evaluation Programme, a well-established framework dedicated to assessing healthcare legislation and regulations, overseen by the ZonMw Committee for Evaluation of Regulations (CER). Each evaluation was initiated at the request of the Minister of Health, Welfare and Sport, in accordance

with an evaluation clause within the law itself. The CER invited independent research groups to submit a research proposal. In two of the three cases, more than one proposal was received, and these were reviewed and assessed by independent reviewers. Based on these reviews and the answers provided by the research groups, the committee then selected the best research proposal. For each of the subsequent evaluations, an advisory committee was formed on behalf of ZonMw, consisting of members from the CER and experts from the field, in order to oversee the evaluation process. Upon completion, the evaluation report of each evaluation was submitted to the Minister, who provided a written response detailing whether the recommendations proposed were adopted or rejected and specifying the subsequent course of action.

5.3.2 Within-case analysis

In Table 2, we present the summarised data for all three case studies side-by-side. See Appendix 3 for a more detailed elaboration. We found no factors influencing impact other than those covered by context, research quality, and stakeholder interaction, despite explicitly seeking other factors. However, we did identify additional phases within the evaluation process, outside of the formal evaluation itself. Therefore, we added these additional phases to Table 2. We then consider, for each case, the relationship between impact and the factors influencing impact.

Table 2. Summarised data of the three case studies. Within-case analysis.

	Case 1 – Evaluation of the Youth Act	Case 2 – Evaluation of Wkkgz	Case 3 – Evaluation of the Embryo Act
Impact	Impact within the political sphere: parliamentary questions, extensive political debate and amendment stemming from the evaluation. Impact within policy circles: agenda setting by the Minister. Impact within society: The evaluation was widely shared online, efforts by field parties were made to improve access to youth care and written responses were sent from professional associations to the House of Representatives. No impact upon legislation.	Impact within policy circles: the Minister planned to amend various aspects of the law and recommendations were implemented at the policy level as part of ministerial and regulatory oversight. Impact within society: The evaluation was widely shared online, with professional associations expressing concerns in a letter to the House of Representatives. Dispute resolution bodies actively engaged in discussions over the evaluation results. Additionally, the Health and Youth Care Inspectorate commissioned further research into patient involvement after serious adverse events in Dutch hospitals, partly influenced by the evaluation's findings.	Impact within policy circles: the Minister announced two amendments to the law. Impact within the political sphere: The House of Representatives conducted an internet consultation, sought advice from the Health Council, and addressed recommendations within ministries. Additionally, a coalition agreement outlined intentions and plans regarding specific evaluation recommendations. Impact within society: The evaluation was widely shared online. The societal impact was evident amongst stakeholders who were directly involved in the domain of the Embryo Act. A research institute produced a report with remarks and criticisms in response to its findings.
Context	First evaluation. New law brought about systematic change. Timing brought forward by two years. Unrest in the field regarding the law, many dynamics resulting from the legislation. A lot of other studies emerged at the same time,	First evaluation. Broad and organisational law that resulted in new obligations. Timing in line with evaluation clause. No unrest in the field regarding the law. Evaluation was carried out during COVID-19 pandemic.	Third evaluation. Existing specific law. Timing extended. No unrest within the field regarding the law, very delimited domain.
Research quality during the execution	Researchers focused on legal framework and the implementation. Ministers' transparency in conducting a fair evaluation was doubted due to their exclusion of pertinent field-related topics. The evaluation included 21 recommendations without specifying the recipients,	Researchers focused on five exemplary sectors in healthcare, rather than covering all sectors. Recommendations were made practical and concrete, focusing on specific laws and policies, and were deemed to be beneficial by the field. The evaluation included 32 recommendations aimed at seven groups of addressees (especially legislators and policy makers).	Researchers focused on six themes, including unresolved issues from previous evaluations and the future viability of the law. Both researchers and users emphasised the importance of researchers' authority and independence. Some researchers had prior involvement in Embryo Act evaluations. The evaluation included 12 recommendations, which were directed at specific addressees (especially the Legislature).

Table 2. Summarised data of the three case studies. Within-case analysis. (continued)

	Case 1 – Evaluation of the Youth Act	Case 2 – Evaluation of Wkkgz	Case 3 – Evaluation of the Embryo Act
Research quality after the execution	CER praised the report but called for more assertive findings and recommendations. Field respondents rated both the quality of the research group and the quality of the evaluation as good in the questionnaire. Field emphasised the evaluation report's good summary.	CER praised the report but highlighted some limitations, including a low response rate, too much focus on professionals, and a lack of sharpness in the recommendations. Field respondents rated both the quality of the research group and the quality of the evaluation as neutral to good in the questionnaire.	CER praised the report but called for the adjustment of certain formulations in the recommendations. Field respondents rated the quality of the research group as good to very good and the quality of the evaluation as good in the questionnaire.
Stakeholder interaction during the execution	Various stakeholders, including legal perspectives, municipalities, clients, and youth care were engaged. Participants had ample opportunity to give input despite the limitations of the evaluation. Participants kept informed about the results. However, participant involvement in preparation, setup, completion, and meetings was either minimal or entirely lacking.	An expert meeting was organised at the start to identify any practical issues. Relevant stakeholders were involved in online focus groups and interviews during the evaluation as a result of the COVID-19 pandemic. Participants noted that their involvement in the research led to increased interest in the results and the follow-up of the research. It provided them with food for thought, and sometimes led to the initiation of processes within their own organisation. They felt that participating in the evaluation research allowed them to address relevant themes to varying degrees. From the field questionnaire, it was found that stakeholders were involved in the preparation, execution, and informed about the outcomes and meetings, but were either less or barely involved in the setup and completion of the research.	Relevant Dutch and foreign stakeholders were involved during the evaluation, including professional and patient organisations. Prior to the evaluation and formulation of the recommendations, the researchers took into account the chances of implementation. According to the researchers, the way that recommendations are formulated is important for impact. From the field questionnaire, it was found that participants were involved in the preparation, design, and execution, and were informed about the results, but were either less or barely involved in the conclusion and meetings.
Stakeholder interaction after execution	Evaluation report was made available online. Researchers presented the results at regional and national meetings. Researchers authored a scientific article. Not all researchers viewed generating impact as their responsibility; after completion, they let go of the research.	Evaluation report was made available online. Researchers presented the results at a webinar. Researchers authored a scientific article. Researchers distributed the report via email to stakeholders. A patient council network requested a simplified report for patients due to both its length and technical nature.	Evaluation report was made available online. Researchers were invited to present their results at a conference. Researchers authored a scientific article. Not all the researchers viewed generating impact as their responsibility; after completion, they let go of the research.

Abbreviations: CER: The ZonMw Committee for Evaluation of Regulations; Minister: Minister of Health, Welfare and Sport; Wkkgz: Healthcare Quality, Complaints and Disputes Act; ZonMw: A Dutch funding organisation for innovation and research in healthcare.

5.3.2.1 Within-case reflection of case 1: Evaluation of the Youth Act (2018)
The Youth Act introduced significant changes in a turbulent domain, especially regarding decentralisation, shifting responsibility from the national government to local authorities such as municipalities. There was significant concern in the field about budget cuts and municipal procurement practices. Numerous other studies emerged both during and after the evaluation, potentially limiting its impact as it was overshadowed by this additional research.

The early review, requested by the House of Representatives, restricted researchers from drawing firm conclusions about the law's effectiveness. However, this early evaluation met the Minister's need to take control and direct the reform agenda based on the results. During the evaluation, a new cabinet with a new Minister sought greater direction. The evaluation report allowed the Minister to formulate and share their policy vision with the field.

Field stakeholders expressed concerns that researchers' focus on implementation and opportunities for improvement led to the omission of important topics from the evaluation. This raised questions among societal stakeholders about why certain topics, they considered vital to the law, were not addressed. Furthermore, it raised doubts about whether the Minister genuinely sought a fair evaluation and was open to the practical realities, potentially diminishing its impact. The absence of specifically addressed recommendations and concrete action points may also have contributed towards a reduced impact insofar as no one could be held accountable for the implementation.

Engaging stakeholders prior to, during, and after the evaluation resulted in them having knowledge about the conducted evaluation and its resulting outcomes.

The presentation of the research results during regional and national meetings following the evaluation may have contributed to a greater impact within the field.

5.3.2.2 Within-case reflection of case 2: Evaluation of the Wkkgz (2021)
The Wkkgz is a law that is organisational in nature and has a broad scope, and it did not cause unrest within the field. As the law had been in force for five years already, it could be evaluated according to the timing stipulated in the law itself. This time span enabled researchers to draw well-informed conclusions and provide recommendations on the legislation itself. Indeed, several of these recommendations were taken up by the Minister.

The researchers chose to structure the study around five selected healthcare sectors to provide a representative overview of the wide range of areas covered by the Wkkgz. It appears that the impact within these five sectors is greater than in sectors not included in this selection.

Involving respondents from the field and policy circles in an expert meeting at the beginning of the evaluation led to the identification of currently relevant topics and issues, thus aligning the evaluation well with stakeholders' experiences. By continuing to involve respondents throughout the evaluation process, impact was thus created within the field. Participation in the evaluation

research itself was even considered to be somewhat of an intervention, resulting in new useful insights within the selected healthcare sectors, according to the participants.

The recommendations in the evaluation were primarily addressed to the policy domain and the legislator, which in itself may have contributed to the fact that most of the impact occurred there. Furthermore, researchers opted to formulate practical and concrete recommendations, which were found to be useful within these domains. Finally, the decision of the researchers to present the results during a webinar also likely contributed towards the generation of impact within the field.

5.3.2.3 Within-case reflection of case 3: Evaluation of the Embryo Act (2021)

The Embryo Act focuses on a very specific domain where stakeholders know each other, and the lines of communication are short. This facilitated collaboration between the field and national policy, potentially speeding up the uptake of evaluation results. The researchers were deeply embedded in the domain and were considered the appropriate authorities to conduct the evaluation, with some having prior involvement in evaluations of the Embryo Act.

The postponement of the evaluation by the House of Representatives resulted in an evaluation that did not coincide with the implementation actions outlined in the previous evaluation. This may have provided greater room for impact within both the policy and political domains.

Given that this was the third evaluation, the assignment was more specific and refined in scope, building upon previous insights into how the law functioned in practice.

Due to the politically sensitive nature of this law, the researchers were well aware that the political context was crucial for the potential influence of evaluation results on legislation and regulation.

In terms of the design of the evaluation and both the formulation and addressing of the recommendations, the researchers took into account the potential areas in which the evaluation could generate an impact. This, in turn, allowed for maximum impact within relevant areas to be achieved.

The decision of the CER to exclude the societal perspective from the assignment influenced both the focus and scope of the research.

5.3.3 Cross-case analysis

In this cross-case analysis, we examine the three aforementioned legislative evaluations together, focusing on overarching themes related to context, research quality, and stakeholder interaction in relation to their impact. We aim to uncover discernible patterns across the different cases.

5.3.3.1 Cross-case reflection on impact

Each evaluation generated significant impacts across various domains, as evidenced by the document analysis, focus groups, and the responses to the questionnaire (see Appendix 3 and

Appendix 4, question A). For instance, the evaluation of the Youth Act yielded substantial effects upon politics, policy, and society more broadly. It prompted immediate parliamentary inquiries and debates, shaped subsequent political discussions, and informed policy reforms. At the societal level, the evaluation was widely disseminated and elicited responses from professional associations focused on improving access to youth care. Unlike the evaluations of the Wkkgz and the Embryo Act, this evaluation did not influence legislation. Although the evaluation of the Wkkgz and Embryo Act led to legislative changes, as shown by the document analysis, this was not always known to members of the professional field and was therefore not always mentioned in the questionnaire.

The evaluation of the Wkkgz also influenced policy, resulting in legislative revisions and recommendations implemented at both the ministry and regulatory levels. It also generated broader societal impacts, with professional associations raising concerns and dispute resolution bodies increasing their level of cooperation with one another. Additionally, the Inspectorate commissioned further research prompted by the evaluation findings.

Similarly, the evaluation of the Embryo Act had a significant impact upon policy, legislation, and political circles. Specifically, it led to amendments, consultations, and recommendations addressed within ministries, thus indicating its influence on legislative processes and political agendas. However, according to the questionnaire, the greatest impact was observed in the societal domain amongst healthcare providers (see Appendix 4, question A). The reason for this is presumably because it is a tightly defined domain in which professionals in the field maintain close contact with policymakers at the ministry.

Below, we continue the cross-case analysis for each factor. First, we describe the relevant contextual factors, followed by research quality and stakeholder interaction. We will then illustrate the connections between these factors and the observed impact in the discussion section.

5.3.3.2 Cross-case reflection upon the influence of context on impact

The first contextual factor shared by all three evaluations is that the legislative evaluation process is structured within the ZonMw programme, which remains consistent across all cases. An institutionalised system like the ZonMw programme not only assures overall evaluation quality but also facilitates impact in key domains, such as policy and politics, including legislative revisions, agenda-setting, and requests for further research. This can be seen as a ‘main route’, reflected in the predominant focus of existing literature.

Secondly, the timing of the evaluations, determined by the Minister, establishes a more concrete context for each evaluation. In all three cases, the initiative for the legislative evaluations came from a clause in the law. However, in two of the evaluations, the House of Representatives intervened to adjust the timing, advancing and postponing the evaluations of the Youth Act and Embryo Act, respectively. This timing significantly influenced the dynamics of each legislative evaluation, shaping the focus and mandate at hand. For instance, in response to the adjusted

timing, the evaluation of the Youth Act concentrated on observing the evolving process of change in response to this act. By advancing the evaluation, there was ongoing momentum and an evolving situation. Consequently, no firm statements could be made by the evaluation researchers about either the operation or texts of the law; instead, they could only discuss about the ongoing process of change. Additionally, no changes were made to the legal text based on this evaluation. On the other hand, this allowed the Minister to respond effectively to the findings of the evaluation and adjust their policy accordingly. However, the societal field questioned the relevance of the evaluation to their daily practice.

Conversely, delaying the evaluation of the Embryo Act potentially increased its impact upon the policy and political spheres, insofar as it provided ample time for the implementation of prior recommendations from the previous Embryo Act evaluation and garnered attention for the latest evaluation results and recommendations. Being the third evaluation also solidified the Minister's mandate. That is to say, from the previous Embryo Act evaluations, it was clear which topics needed further research so this could be a focused evaluation with potentially more impact. A more neutral example was observed in the Wkkgz, where the law was already sufficiently integrated, and the five-year timing clause in the law could be adhered to.

Thirdly, each evaluation took place within a unique context, influenced by various factors such as the type of law, its function, and the political and social climate. For example, the Embryo Act was highly politicised because of ethical and religious issues, whereas the Youth Act was hotly debated in the field due to its impact upon the daily activities of youth care providers and municipalities. Indeed, the law had such a substantial impact within the field that the chances of the evaluation itself making a notable impact were reduced. In contrast, the Wkkgz is a broad law that is applicable to a very large group of healthcare providers but has more of an organisational character. Thus, unique context of the legislation (which is partly shaped by the legislation itself) determines the evaluation's context and potential impact.

5.3.3.3 Cross-case reflection upon the influence of research quality on impact

There were no meaningful differences observed in the quality of the evaluations with respect to both the research group or the research itself. The ZonMw procedure ensures a minimum quality standard for each evaluation. The respondents' perceptions of the research group's quality resonate with this assurance, as they assumed that it was maintained through the ZonMw procedure. The evaluation researchers were viewed as the appropriate authorities.

Comments from users across all three cases indicates that the choice of evaluation topics significantly influences its impact. Specifically, selecting relevant topics in the initial phase of the evaluation process can enhance its impact by aligning with the needs and current interests of stakeholders. This alignment can be achieved either by conducting research in a well-defined domain where policy and practice are closely interconnected and experts are actively involved, as seen in the evaluation of the Embryo Act, or by organizing an expert meeting at the start of the evaluation, as done with the Wkkgz evaluation. Conversely, a lack of alignment with

field interests, as observed in the evaluation of the Youth Act, can lead to missed opportunities for achieving maximum impact. In this case, the evaluation was aligned with the needs of the Minister, resulting in impact within that specific domain.

In addition to topic selection, the sharpness of the recommendations and their targeted addressing to specific stakeholders were also reported in all three cases as being essential for generating impact in the relevant places.

5.3.3.4 Cross-case reflection upon the influence of stakeholder interaction on impact

Across the three case studies, we observed a relationship between the involvement of stakeholders—both prior to, during, and after the evaluation—and the resulting impact. Specifically, various stakeholders were engaged, including the Minister, policy members, healthcare providers, patients, professional associations, municipalities, and the inspectorate. These parties were involved at different stages. The Minister's role was primarily as the commissioner of the evaluation, participating before and after its execution, while respondents actively engaged during the evaluation process. Across the three cases, we observed that the interaction between researchers and stakeholders began with the engagement between researchers and the CER, acting on behalf of the Minister, to commission the evaluation and reach out to potential research groups to write proposals to conduct the evaluation. Upon receiving the commission, researchers engaged with stakeholders involved in the practical application of the law. The respondents in all three cases reported that the evaluation resulted in new knowledge and insights, while in some instances, as seen in the Wkkgz evaluation, stakeholders began to implement insights even during the evaluation process. The cases thus demonstrate that involvement in the evaluation increases the relevance for stakeholders, thereby enhancing the likelihood of impact being generated.

During the assessment and dissemination phase, researchers had the opportunity to present their findings to a wider audience. In all three cases examined, the evaluations were published on websites, whilst researchers also authored one or more scientific articles. Additional steps were also taken, including engaging in discussions with field parties and organised webinars or conferences by invitation. However, it remains unclear if these efforts resulted in additional impact. What the respondents did deem to be important, though, was making the research results accessible by creating a practical version or summary that was suitable for the broader field.

5.4 Additions to CMO configuration

This research was guided by the framework of an initial programme theory and a CMO (Context-Mechanism-Outcome) configuration (see Table 1). The CMO configuration incorporates mechanisms that influence the impact of legislative evaluations within their contextual parameters. The first mechanism addresses research quality (under A), while the second focuses on stakeholder interaction (under B). Based on the data collected in this study, we have refined

and expanded our understanding of the relevance and interrelatedness of context, research quality, stakeholder interaction, and impact. Additional insights, reflecting the main findings of this study, are highlighted in italics in Table 3.

Table 3. Updated framework (Programme theory and CMO configuration), (Knap et al., 2023c).

Initial programme theory: Devoting attention to research quality and interaction during the evaluation process affects the impact of an ex-post legislative evaluation. ***Updated programme theory:*** *Anticipating contextual factors during the evaluation process, along with prioritising research quality and stakeholder interaction, enhances the impact of an ex-post legislative evaluation on policy, politics and society.*				
Context	+	**Mechanism**	=	**Outcome**
Institutionalisation of the evaluation process Characteristics of the law and legislative process Evaluation initiation *(including evaluation timing and the number of times the law has been evaluated),* function and openness to results Political and societal influence		A) Research quality: Composition, *authority* and independence of research group Methods used *and research setup* Quality and content of evaluation report *(topic selection, formulating and addressing recommendations)* B) Interaction: Interaction between researchers and stakeholders Presentation and availability of research results Timing *of involving stakeholders (prior to, during and after the evaluation*)		Impact of ex-post legislative evaluations within: The legislative community *(within political and policy domains)* *The political sphere* The policy area The society more broadly

Updates, based on the findings of the three evaluations, shown in italic.

5.5 Discussion

In the discussion, we sequentially reflect upon the two research questions of this study in relation to impact, context, research quality, and stakeholder interaction, as well as the outcomes from the CMO configuration in order to address the research questions posed in this study. We also reflect on strengths and limitations and finish with some concluding remarks.

5.5.1 Answering the research questions

Research question 1: What impact did these evaluations have?
We did find evidence that the impact of legislative evaluations within healthcare extended beyond the policy and political domains into the societal domain, which is also a crucial actor when it comes to legislation. Especially in the healthcare sector, citizens, professionals, and healthcare organisations are directly affected by healthcare-related legislation. Moreover, both healthcare providers and patients play an important role in achieving the goals of the law. By explicitly focusing on the potential impact of legislative evaluations within the societal domain, we have thus observed various types of impact. Specially, we discovered that the field takes note of the evaluation, spreads the evaluation on websites or in newsletters amongst its members, and in some instances also acts upon the evaluation. For example, in response to the Wkkgz evaluation, dispute resolution bodies sought each other out and held discussions. It was also reported that other (government-affiliated) organisations acted upon the evaluation results, such as the example of municipalities responding to the evaluation of the Youth Act and the inspectorate. Although these were not the primary addressees in the evaluation, in practice, they turned out to be relevant parties with respect to working with the results. Whilst international literature often focuses narrowly on impact within policy and political domains, such as legislative revisions and the strategic use of evaluation findings in politics (Knap et al., 2023a), only a few studies have addressed the broader impact of legislative evaluations in practice. For instance, research has shown that legislative evaluations contribute towards enhancing the public's understanding of laws (Klein Haarhuis, 2009) and facilitates greater democratic debate (van Aeken, 2018). Despite the societal domain being identified as a potential user of legislative evaluations (Hendriks, 2000; Poptcheva, 2013), empirical research with respect to its impact remains limited. Our study shows that these evaluations do generate societal impact, in spite of the fact that the societal field was not the primary focus of these three evaluations. Hence, paying greater attention to ex-post legislative evaluations within both academic literature and daily practice can increase the societal impact of legislative evaluations. Failing to recognise the relevance of the societal domain as a potential impact area, risks overlooking opportunities for potential impact. The impacts generated in this field are incredibly diverse, and we have observed, in particular, that this field has taken note, disseminated the results and, albeit to a lesser extent, field parties have engaged with the evaluation results.

The observations regarding the societal field questioning the relevance of evaluations to their daily practice and the lack of alignment with field interests underscore critical issues in understanding the impact of legislative evaluations. Direct beneficiaries, such as healthcare providers and municipalities, play a crucial role in the practical application of legislative frameworks. For instance, health-related laws serve an instrumental function by providing a structured framework within which complaint handling can occur, enabling the optimisation of processes and ensuring better service delivery. In the context of youth services, decentralisation has granted municipalities significant freedom to design and implement their processes. However, the field expressed a desire for the evaluation of the Youth Act to address other subjects more relevant to their immediate

needs, illustrating the two-way interaction between evaluations and practice. Practitioners can leverage evaluations to highlight and advocate for issues they consider important, thereby strengthening their position and ensuring that evaluations are not only retrospective analyses but also proactive tools for driving improvements. This alignment between legislative evaluations and the practical needs of the field can enhance the overall impact, fostering more responsive and effective legislative frameworks that better serve the public.

Research question 2: How does the context, research quality and stakeholder interaction influence this impact?

We will answer this question per factor (context, research quality and stakeholder interaction).

The influence of context on impact

Context influences impact in manifold ways. This research highlights that context creates a window of opportunity while simultaneously closing others for the potential impact of a legislative evaluation. Our findings add two new contextual insights: institutionalisation and timing (see Table 3). In the cases studied, the context of the evaluations is shaped by several elements, ranging from the institutionalisation by the ZonMw programme to the specific features of the law being evaluated and its surrounding environment. Legislative evaluations have also been institutionalised in other countries. The exact manner of institutionalisation varies, but typically involves government agencies, parliamentary committees, and independent bodies analysing laws for their effectiveness and impact. These mechanisms support evidence-based governance, and earlier literature has endorsed the merits of institutionalising this process (van Humbeeck, 2000). Institutionalising ensures that there is a set system that is the same for all evaluations within that system. This institutionalisation, in turn, paves a direct route towards impact, primarily within the policy and political domains with a specific focus on legislative revision. It also supports institutional learning on how to conduct evaluations. While institutionalisation is a consistent factor across all evaluations, we have identified a new contextual factor that varies significantly from evaluation to evaluation and influence their potential impact: the timing of the evaluation. In two of the cases, explicit decisions were made regarding the timing of the evaluation. For instance, in the evaluation of the Youth Act, the decision to conduct the evaluation prematurely reduced the availability of conclusive results regarding the legislation's effectiveness. This served to limit the potential impact of the evaluation with respect to improving the legislation. Conversely, in the case of the Embryo Act, postponing the evaluation enhanced its impact. Besides timing, the political and social landscape also varied for each of the evaluations examined, which affected their potential impact. In the evaluation of the Youth Act, for example, we saw extensive debates about budget cuts and municipalities' purchasing strategies that were covered only to a limited extent in the evaluation, but played an important role in the daily practice of youth care organisations and professionals (see Appendix 4, question B). In the evaluation of the Embryo Act, there was a highly politicised debate with strong opinions about what could and could not be discussed, which, in turn, defined the options for impact. Despite the fixed nature of these contextual factors and the predefined framework within which evaluation researchers operate, we found that the topics covered in the evaluation matched the scope for actual impact offered by the context. In

this case, researchers demonstrated a keen awareness of the politicised landscape within which the evaluation results would be situated, as well as the likelihood of the recommendations being implemented as a result of the evaluation. As a researcher, being aware of the fixed context and anticipating it appropriately can open up windows for greater impact.

The influence of research quality on impact

This study examined how the quality of both the research group and the research itself contributed to the impact of the three evaluated legislative evaluations. Our study added refined insights across all three subcategories of research quality. We found that alongside diversity in composition and the independence of the research group, the authority of its members also plays an important role. When respected individuals are involved in evaluations, the acceptance of results tends to be expedited.

In all cases, both the evaluations and composition of the research groups were rated as good (see Appendix 3 and Appendix 4, question C). While institutionalisation of legislative evaluations within the ZonMw programme implies inherent quality, our study highlights that researchers can make choices that directly influence both the quality and impact of evaluations. This study emphasises that researchers can select specific methods and tailor the research setup, significantly affecting potential impact. For example, in evaluating the Youth Act, researchers used a mixed-method approach combining quantitative surveys with qualitative interviews of youth service providers, local officials, and community leaders. This inclusive method provided comprehensive insights into the Act's implementation challenges and successes, enabling targeted recommendations that resonated with local stakeholders and enhanced the study's impact. All cases indicate that aligning research topics with the interests of stakeholders, and not only those of the Minister, is crucial for improving the relevance of the evaluation for the field. Additionally, this study has demonstrated that it can be valuable to specify and address recommendations to the appropriate parties, which is also within researchers' control (see Appendix 3 and Appendix 4, question E). Finally, it is important to consider the specific addressee responsible. For example, in the case of the Youth Act, the relevant addressee shifted from the national government to the municipal government. The researchers' decision not to address the recommendations was not positively evaluated by the respondents in our focus groups (see Appendix 3). Addressing recommendations allows these addressees to be held accountable.

The influence of stakeholder interaction on impact

This study has provided examples of interactions between researchers and stakeholders that contribute towards the impact of legislative evaluations. Beyond presenting and making research results available after the evaluation, our research underscores the significant potential of early stakeholder involvement in the evaluation process. Specifically, this study has shown that involving stakeholders early on, by identifying issues that are relevant to them in practice and by engaging individuals as active respondents in the research, can help to generate impact even during the evaluation process. For example, during the Wkkgz evaluation, participants reported that by participating in discussions during the evaluation, they were already working with insights

gained during these discussions. We therefore believe that involving people throughout the process increases the likelihood of impact. In addition, it is clear that greater attention needs to be paid to the potential impact within the field and more needs to be done to reach out to the field.

While dissemination after the evaluation appears to be crucial, less visible impact was observed from these actions. Our research also emphasises the importance of making the evaluation accessible to a broader audience by creating, for example, a practical version or a summary targeted at those within the field. While existing literature primarily focuses on communication after the evaluation, our research indicates that communication before and during the evaluation is equally important for impact.

5.6 Strengths and limitations

This study marks the first systematic effort to assess the impact of ex-post legislative evaluations in the Dutch context, drawing on insights from international literature. Our innovative approach involves all stakeholders engaged in evaluating legislation, shedding light on previously overlooked dynamics. While we acknowledge the significance of societal impact, our study did not directly investigate this field, which presents opportunities for future research. Distinguishing between the impact of legislation and that of legislative evaluation poses challenges, as not all of these aspects are easily observable or quantifiable.

Our direct involvement in two of the evaluations ensured a thorough examination, with findings transparently reported to mitigate any claims of bias. We conducted three case studies, each displaying significant diversity. However, there is a clear need for additional research in different contexts, as all three cases were within the evaluative framework of the ZonMw programme. The realist evaluation method was chosen for its emphasis on contextual nuances, aligning with our goal to comprehensively explore specific contexts, mechanisms, and outcomes. A detailed study protocol was developed to rigorously execute this method. As part of the realist evaluation, we conducted a literature review, which revealed a limited presence of empirical research. Despite this, we developed a conceptual framework based on existing ideas about impact from this review. While the review underscores the importance of empirical studies like ours, it also points out a limitation: our use of this framework may have led to a perspective that was too narrowly defined in the case studies, despite our efforts to remain open to emerging themes outside the framework.

In this study, our aim was to identify the impact of legislative evaluations and the factors influencing them. To achieve relevant results, we focused on modifiable factors within the case studies. However, this emphasis on modifiable factors, which can influence impact, also represents a limitation of our study as it necessitated a narrowly defined perspective.

The insights gained primarily focus on Dutch healthcare, but they may offer practical information for other countries considering or conducting similar evaluations, though specific examples

are not provided in this study. The findings from this study offer important implications for other countries seeking to enhance the impact of their legislative evaluations. Regardless of the responsible entity or the approach they currently employ, different countries can learn from our results. By refining the CMO configuration to include additional contextual factors, research quality indicators, and stakeholder interaction mechanisms, other countries can adopt a more nuanced approach to legislative evaluations. For instance, institutionalising the evaluation process, as observed in the studied ZonMw programme, ensures consistency and supports evidence-based policy-making. Countries can also benefit from considering the timing and political landscape surrounding evaluations to maximise their impact. Furthermore, ensuring the independence and methodological rigor of research teams, alongside targeted and inclusive stakeholder engagement, can significantly enhance the relevance and uptake of evaluation findings. As demonstrated, broadening the focus to include societal impacts beyond political and policy domains can lead to more comprehensive and actionable insights. These practices can help other countries to improve their legislative frameworks, fostering greater public understanding, democratic debate, and overall societal benefits.

This wider applicability bolsters the value of our research by informing and improving evaluation processes across diverse contexts.

5.7 Conclusion

This study contributes to existing literature by shedding light on the global landscape of ex-post legislative evaluations, revealing a significant gap in empirical research with respect to their impact. It emphasises that current structures primarily target influencing the policy and political domains, whilst overlooking the potential impact in the societal domain, which is particularly crucial in fields like healthcare. Our research underscores the importance of involving stakeholders not merely as sources of information but rather as active participants to enhance the relevance and impact of evaluations.

Researchers can proactively make choices throughout the evaluation process in order to align the content with the field, involve stakeholders, and respond to the evaluation context, thus contributing to impactful legislative evaluations. Despite the challenges involved, ignoring this opportunity would represent a missed chance to create meaningful impact through legislative evaluations. In this respect, our findings provide valuable insights into the complex dynamics of ex-post legislative evaluations, laying a crucial foundation for informed decision-making and potential policy enhancements within healthcare settings.

Appendix 1

Questionnaire for the evaluation creators
Translated to English, (x) refers to the specific law.

Impact of the evaluation of (x).

1. The context in which the evaluation of (x) took place.

Would you like to answer the following statements regarding the context of the evaluation of (x)?

a) During the evaluation of (x), there was a highly active **political debate** about one or more aspects of (x).
- o No
- o Somewhat
- o Yes
- o I don't know

b) During the evaluation of (x), there was a highly active debate amongst national and municipal **policymakers** about one or more aspects of (x).
- o No
- o Somewhat
- o Yes
- o I don't know

c) During the evaluation of (x), there was a highly active debate within **(depending on the law, a relevant field party is mentioned)** about one or more aspects of (x).
- o No
- o Somewhat
- o Yes
- o I don't know

2. In your opinion, has the evaluation of (x) had an impact, and if so, in what way?
Multiple answers possible.
- o The evaluation has provided more knowledge and insight into the points where the Healthcare Insurance Act works well
- o The evaluation has provided more knowledge and insight into the points where the Healthcare Insurance Act is not working so well
- o The evaluation has led to adjustments in (x)
- o The evaluation has influenced government policy on (x)
- o The evaluation has led to a broader discussion in the field about the way (x) came about or the principles of (x)

- o The evaluation has led to discussion within the political arena
- o The evaluation has influenced the policy of healthcare organisations
- o The evaluation has influenced healthcare professionals
- o Other, namely:
- o The evaluation did not have an impact in any way
- o Do not know

3. The quality of the evaluation of (x)

a) Can you provide an assessment of the quality of the evaluation of (x)?
   - o Very bad
   - o Bad
   - o Neutral
   - o Good
   - o Very good
   - o I don't know

b) Can you provide an assessment of the composition of the research group that evaluated (x)?
   - o Very bad
   - o Bad
   - o Neutral
   - o Good
   - o Very good
   - o I don't know

4. The interaction between the researchers and the stakeholders in the evaluation of (x)

Would you like to respond to the following statements regarding the interaction between the researchers and the stakeholders in the evaluation of (x)? *Please check all that apply, multiple answers possible.*

- o Relevant individuals from the field and/or policy sphere were actively involved in the preparation of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere influenced the design of the evaluation of (x).
- o During the execution of the evaluation of (x), relevant individuals from the field and/or policy sphere were actively involved, such as, for example, as respondents, in focus group discussions, or as experts.
- o Relevant individuals from the field and/or policy sphere actively contributed to the finalisation phase of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere were actively informed about the outcomes of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere attended meetings in which the outcomes of the evaluation of (x) were shared.

o The results and recommendations of the evaluation of (x) were well-aligned with the needs of the field and/or policy sphere.

5. What factors do you think played a role in the impact generated by the evaluation of (x)?
Multiple answers possible.
o The composition of the research group
o The quality of the research
o The fact that the field was actively involved in the study
o The fact that the researchers formulated recommendations
o The relevance of the results and/or recommendations of the legal evaluation for the field
o The political attention paid to the results and/or recommendations of the legal evaluation
o The fact that the researchers actively disseminated the results through, for example, a webinar, gave presentations and wrote (scientific) publications
o The fact that others, such as the media or stakeholders, paid attention to the results and recommendations of the legislative evaluation
o Other, namely:

6. During the design or implementation of the research, was there consideration given to generating impact through the evaluation of (x)?
o Yes
o No
o I don't know

7. What efforts were made by the researchers to generate impact through the evaluation of (x)?
Open text field.

8. What more could have been done by the researchers to increase the impact generated by the evaluation of (x)?
Open text field.

9. Would you like to receive the results of this research? If so, please provide your email address.
10. *Open text field.*

Appendix 2

Questionnaire for the evaluation users

Translated to English, (x) refers to the specific law.

Impact of the evaluation of (x).

Legislative evaluations can have an impact in various ways. First, people take note of the results and recommendations. Another form of impact can be that people form their own opinions about them and potentially share them with others. Alongside this, people may also engage with the results and/or recommendations of a law review in their work. We would like to hear from you about what you have done with the results and/or recommendations of the evaluation of (x).

1. Are you familiar with the evaluation of (x)? *Multiple answers are possible.*
   - o Yes, I have begun working with the results/recommendations of the evaluation in the following way:
   - o Yes, I have begun working with the results/recommendations of the evaluation in the following way:
   - o Yes, I have discussed it with others
   - o Yes, I have read the evaluation
   - o Yes, I received information about (some of) the outcomes of the evaluation
   - o Yes, I have heard about it
   - o No, I am not familiar with the evaluation
   - o No, I am not familiar with the evaluation

If you answered no, then move on to question 1.1.
If you answered a variant of yes, then move on to question 2.

1. In your opinion, what should have happened so that the evaluation of (x) would have come to your attention?
Open text field.

2. At what point should this have happened?
   - o Prior to the evaluation itself
   - o During the execution of the evaluation study
   - o Upon completion of the evaluation study
   - o Do not know

2. Can you indicate what the main reason was for you not beginning to work on the results/ recommendations from the evaluation of (x)?
Open text field.

3. The context in which the evaluation of (x) took place.

Would you like to answer the following statements regarding the context of the evaluation of (x)?

a) During the evaluation of (x), there was a highly active **political debate** about one or more aspects of (x).
b) During the evaluation of (x), there was a highly active debate amongst national and municipal **policymakers** about one or more aspects of (x).
c) During the evaluation of (x), there was a highly active debate within **(depending on the law, a relevant field party is mentioned)** about one or more aspects of (x).

4. In your opinion, has the evaluation of (x) generated an impact, and if so, in what way?
Multiple answers are possible.

o The evaluation has provided more knowledge and insight into the points where the Healthcare Insurance Act works well
o The evaluation has provided more knowledge and insight into the points where the Healthcare Insurance Act is not working so well
o The evaluation has led to adjustments in (x)
o The evaluation has influenced governmental policy on (x)
o The evaluation has led to a broader discussion in the field about the way (x) came about or the principles of (x)
o The evaluation has led to a discussion in the political arena
o The evaluation has influenced the policy of healthcare organisations
o The evaluation has influenced healthcare professionals
o Other, namely:
o The evaluation did not have an impact in any way
o Do not know

5. The quality of the evaluation of (x)

a) Can you provide an assessment of the quality of the evaluation of (x)?

o Very bad
o Bad
o Neutral
o Good
o Very good
o I don't know

b) Can you provide an assessment of the composition of the research group that evaluated (x)?

o Very bad
o Bad
o Neutral
o Good

- o Very good
- o I don't know

6. The interaction between the researchers and the stakeholders in the evaluation of (x)

Would you like to respond to the following statements regarding the interaction between the researchers and the stakeholders in the evaluation of (x)?

Please check all that apply, multiple answers possible.

- o Relevant individuals from the field and/or policy sphere were actively involved in the preparation of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere influenced the design of the evaluation of (x).
- o During the execution of the evaluation of (x), relevant individuals from the field and/or policy sphere were actively involved, such as, for example, as respondents, in focus group discussions, or as experts.
- o Relevant individuals from the field and/or policy sphere actively contributed to the finalisation phase of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere were actively informed about the outcomes of the evaluation of (x).
- o Relevant individuals from the field and/or policy sphere attended meetings in which the outcomes of the evaluation of (x) were shared.
- o The results and recommendations of the evaluation of (x) were well-aligned with the needs of the field and/or policy sphere.

7. What factors do you think played a role in the impact generated by the evaluation of (x)?
Multiple answers possible.

- o The composition of the research group
- o The quality of the research
- o The fact that the field was actively involved in the study
- o The fact that the researchers formulated recommendations
- o The relevance of the results and/or recommendations of the legal evaluation to the field
- o The political attention paid to the results and/or recommendations of the legal evaluation
- o The fact that the researchers actively disseminated the results through, for example, a webinar, giving presentations and writing (scientific) publications
- o The fact that others, such as the media or stakeholders, paid attention to the results and recommendations of the legislative evaluation
- o Other, namely:

8. In what way could the impact of the evaluation of (x) been increased for you?
Open text field.

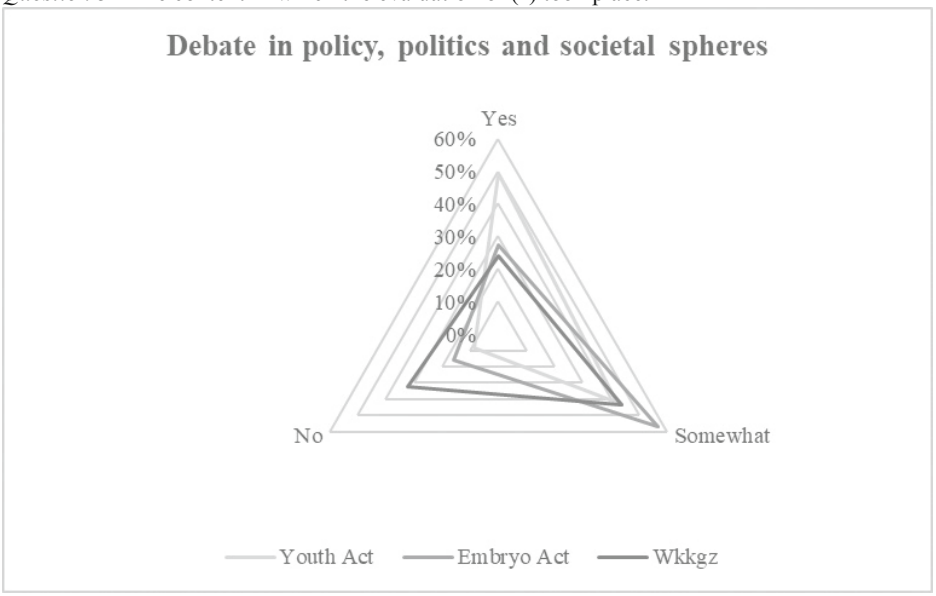
9. From which position/role did you complete this questionnaire?
Open text field.

10. Would you like to receive the results of this survey? If so, please provide your e-mail address
Open text field.

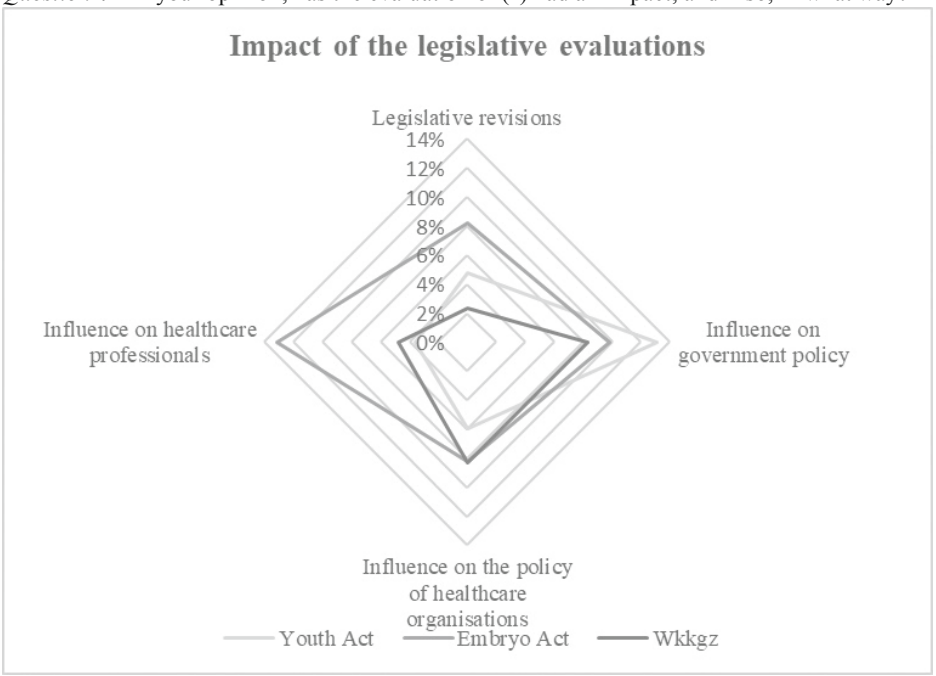
Appendix 3

Results of the multiple-choice questions from the users' questionnaires

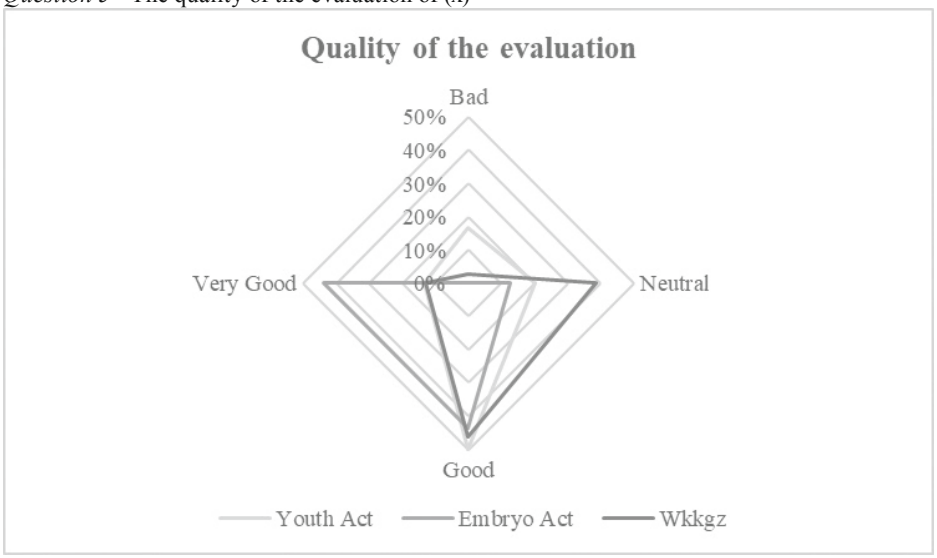
Question 3 - The context in which the evaluation of (x) took place.

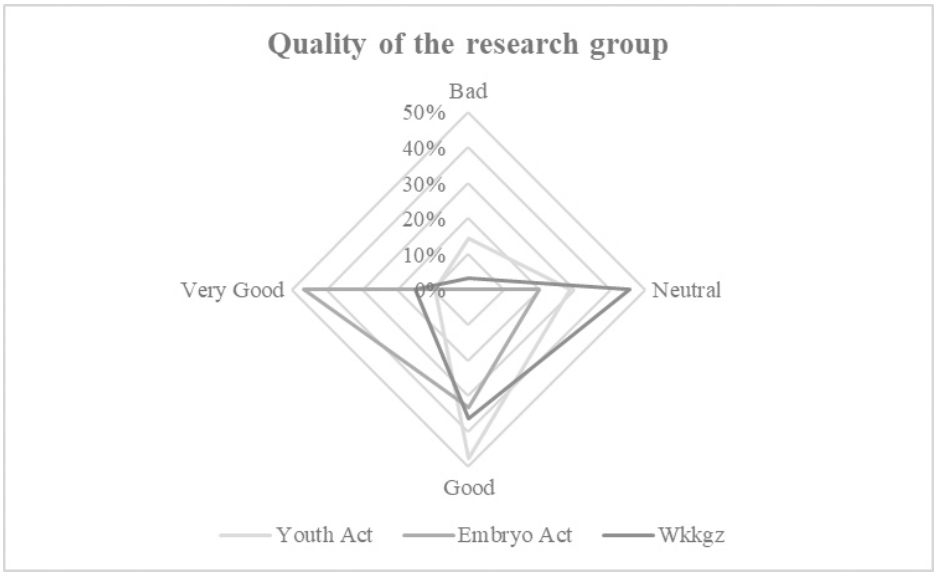


Question 4 - In your opinion, has the evaluation of (x) had an impact, and if so, in what way?

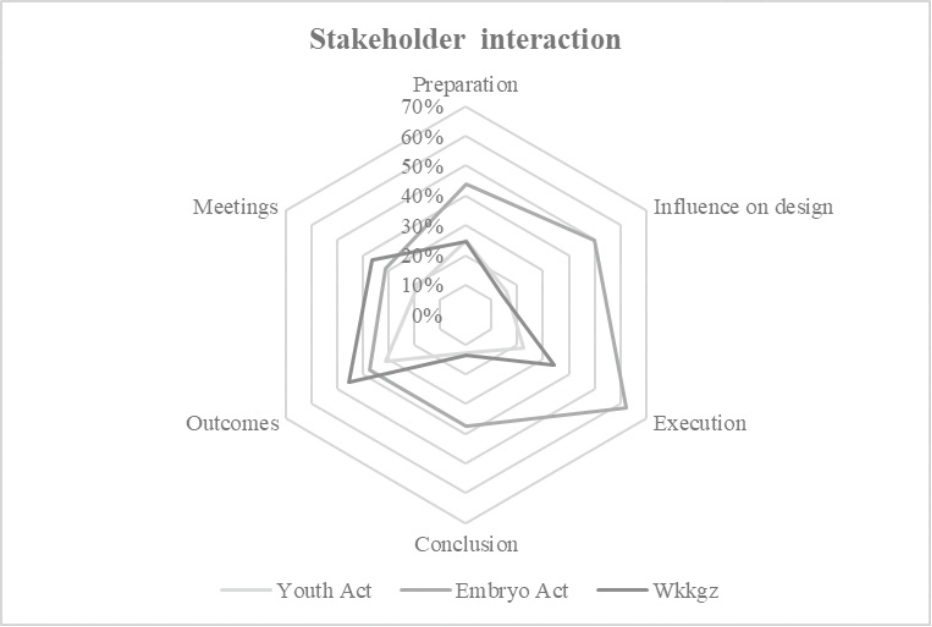


Question 5 - The quality of the evaluation of (x)

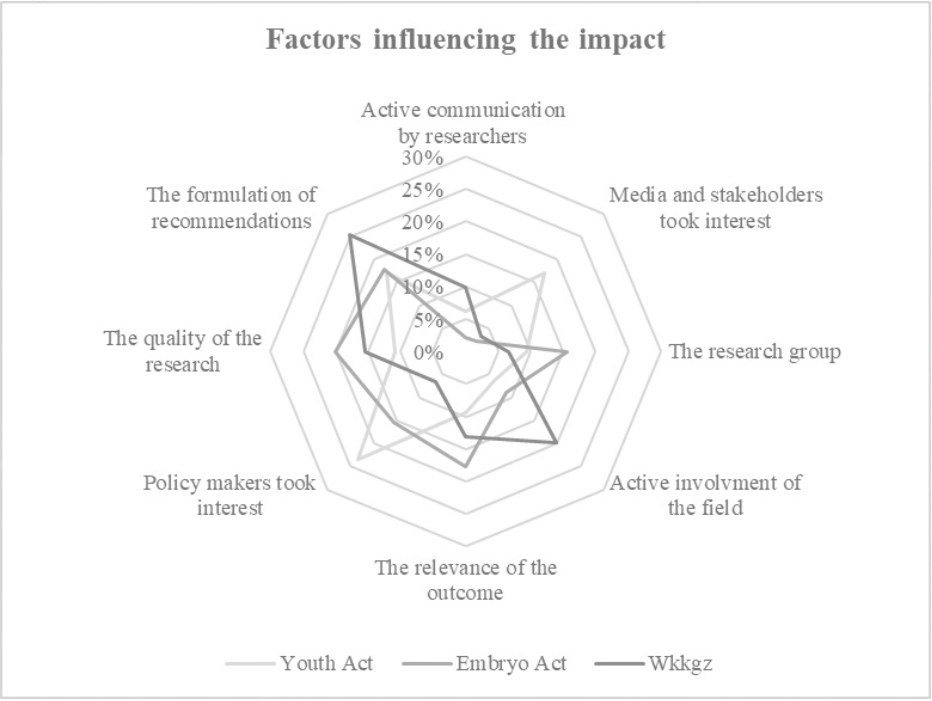




Question 6 - The interaction between the researchers and the stakeholders in the evaluation of (x)



Question 7 - What factors do you think played a role in the impact generated by the evaluation of (x)?



Appendix 4

Overview of the data results for each case.

Evaluation of the Youth Act (publication date: January 2018)

Impact within legislation	Source
The evaluation did not result in changes to the legal text.	None
Impact within the political sector	
Hearing/roundtable with municipalities, institutions, and clients initiated by the House of Representatives (2018)	Document analysis
Additional questions to the Minister from political parties (13 March, 2018) Minister's response to additional questions (9 May, 2018)	Document analysis
Letter from the Standing Committee on the Evaluation of the Youth Act to the Minister (23 October, 2018) Letter from the Minister regarding the evaluation of the Youth Act in response to the letter from the Standing Committee on 23 October, 2018 (28 November, 2018)	Document analysis
A debate was held in the House of Representatives regarding the evaluation of the Youth Act (21 June, 2018)	Document analysis
Additional questions from political parties PvdA and SP regarding the establishment of the Youth Authority (1 February, 2019) Response from the Minister to the Senate (13 March, 2019)	Document analysis
Motion regarding recommendation two, mapping out waiting lists in youth care (27 June, 2023)	Document analysis
During a later political debate in the House of Representatives on the Reform Agenda for youth care, the PVV referred to the evaluation of the Youth Act in relation to the combination of decentralisation and budget cuts (27 June, 2023)	Document analysis
Impact within policy circles	
The Minister responded substantively (particularly policy-wise) to the evaluation in a letter to the Senate (30 January, 2018). It was indicated that the policy response to the interim evaluation of the Youth Act would follow in April to the Chamber in the form of a new programme entitled "Care for Youth."	Document analysis
The inspectors drafted a report based on this evaluation. This report was submitted to the House of Representatives by the Minister and Legal Protection (22 May, 2018).	Document analysis
The evaluation provided a justification for subsequent actions taken by the Minister, such as the launch of the "Care for Youth" Action Program on 16 April, 2018, which was developed in response to, amongst other things, the interim evaluation of the Youth Act.	Document analysis and focus group with researchers
"In the oversight domain, the evaluation internally assisted in familiarising colleagues from other domains who suddenly had to deal with youth-related issues with the problems surrounding the Youth Act. Externally, the evaluation contributed to making choices for a number of focal points, such as the forced framework and the child protection chain."	Focus group with users
"Certain bottlenecks identified in the evaluation are now being readdressed in the reform agenda."	Focus group with users

Evaluation of the Youth Act (publication date: January 2018) (continued)

Impact within the legal field	
References to the evaluation in legal publications, such as: 'De Jeugdwet: tijd voor een evaluatie' in Gst. 2017/120 M. Bruggeman (17-8-2017) 'Drie ingrepen om de jeugdzorg te redden in JusVer 2019/6.3 – I.E. Weijers – (1-12-2019) 'Zes jaar later: met z'n allen verstrikt geraakt in het stelsel?!' in Tijdschrift voor Jeugdrecht, E. Lam en I.J.M. Schepens (2021)	Document analysis and focus group with researchers
"The daily legal practice does not show that anything has been done with the recommendations."	Focus group with users
Impact within society more broadly	
There were many messages and reactions on websites from a wide variety of parties, including professional organisations, industry associations, and advocacy groups.	Document analysis
Letter from joint sector associations to the House of Representatives. Position Paper Specialised Youth Care Branches (BGZJ) 'Roundtable Discussion Evaluation of the Youth Act 23 April, 2018'. In this, the industry associations expressed their main criticism of the interim evaluation (that insufficient attention was paid to crucial policy-related areas and laws that are associated with the functioning of the Youth Act and that the government must ensure that the most important conditions are met by actively fulfilling its system responsibility).	Document analysis
The evaluation has been well read in the field, many conclusions are recognisable, but some field parties do not agree with the findings.	Document analysis and focus group with users
"The evaluation has set a number of things in motion, such as the connection with the general practitioner and the reduction of closed youth care."	Focus group with users
In response to the findings of the interim evaluation, it is indicated that efforts have already been made to improve access.	Document analysis and focus group with users
The field is critical of the choice of topics in the evaluation and finds certain subjects to be missing or underemphasised. Amongst other things, the voice of professionals are missed. To amplify this voice, 15 professional associations conducted their own survey, resulting in recommendations.	Focus group with users and focus group with researchers
""The evaluation has brought field parties closer together in their frustrations about the system."	Focus group with researchers
The Dutch Youth Institute states that the evaluation provides an agenda for a joint approach by municipalities, care providers, and clients to further advance the transformation.	Document analysis
"The impact varies for each municipality. In some municipalities, the evaluation has had significantly more influence than in others. The impact is less clearly observable at the municipal level than at the policy or political level. Some administrators have addressed specific statements in the evaluation with researchers during meetings following the evaluation."	Focus group with researchers

Evaluation of the Youth Act (publication date: January 2018) (continued)

Context in which the evaluation took place	
Evaluation initiative and function The initiative for the evaluation was taken by the House of Representatives. In the autumn of 2013, the House of Representatives advanced the original evaluation period from 5 to 3 years by amendment. Subsequently, in the spring of 2016, they requested via a motion to designate this as an interim evaluation because it concerned the initial phase of a transformation process. The evaluation after five years could thus be considered in conjunction with the evaluation of other complementary laws. The evaluation could be used to strengthen the Minister's information position.	Document analysis
Subsequently, in the spring of 2016, the House of Representatives requested via a motion to designate the evaluation as an interim evaluation.	Focus group with users
The assignment was as follows: 'The ultimate goal of this legislative evaluation is to provide insight into the effectiveness and (side) effects of the Youth Act in practice. Given both the scale and impact of the systemic change, this initial evaluation can only lead to preliminary conclusions. This evaluation can serve as the basis for monitoring the transformation periodically in the coming years and thus mapping out how municipalities and providers take on their new tasks over a longer period, and whether parents and children are better off in the new situation than before the systemic change. The evaluation research should generate more knowledge than is available based on previous studies.'	Document analysis
Political and societal influence Youth care is a broad and dynamic domain with many actors and a complex system that is politically and financially influenced. There has been a continuous struggle over the financial resources allocated to youth care. At the time of the evaluation, a new government came into office, with a new Minister who had their own agenda.	Focus group with users and questionnaire with users
The evaluation took place concurrently with other research, causing it to be 'overshadowed.' From the questionnaire sent to the field, it appears that there was discussion about the Youth Act, particularly in the healthcare sector, but also in policy and political circles.	Focus group with users and questionnaire with users
The Social Domain Transition Committee urgently advises, in its fourth progress report, to consider and evaluate the Social Support Act, the Youth Act, and the Participation Act in conjunction due to their complementary nature. Furthermore, three years is deemed to be too short to form a definitive judgment on a law that brings about a transformation over several years. Consequently, there is a request for the government to consider the evaluation of the Youth Act after three years as an interim evaluation and to conduct the regular evaluation after five years in conjunction with that of the Social Support Act and the Participation Act.	Document analysis
Openness to the evaluation results "The Minister was curious about the angles the evaluation could provide." "The Minister wanted an interim assessment and control."	Focus group with researchers

Evaluation of the Youth Act (publication date: January 2018) (continued)

Quality factors that could have influenced the impact	
Composition and independence of the research group Five ZonMw referees rated the research group as 'good' and 'very good'. According to the referees, the research group is broadly composed, knowledgeable, and experienced.	Document analysis
Respondents from the field questioned whether the evaluation was independent and whether the Minister/political sector wanted a fair evaluation due to the limited design of the evaluation assignment.	Focus group with users
Research design The evaluation consisted of a combined legal and empirical study. The design was partly based on two initial notes from a legal perspective and the Dutch Youth Institute. The evaluation focused on the implementation of the Youth Act, the direction of development, improvement possibilities, and the efficiency of the legal framework.	Document analysis
The researchers' approach was to think along with the law, maintain peace, and give the transformation process time. "From the field, there was a need to evaluate the system as a whole; that's where they encountered the most issues in practice."	Focus group with researchers and focus group with users
Quality and content of the evaluation The project proposal was evaluated by five referees from ZonMw based on quality (objective and question-tasking, plan of approach, project group, and feasibility). The summary quality assessment was 'very good', 'good', and 'sufficient'.	Document analysis
The final report was discussed by the ZonMw Regulatory Evaluation Committee, and they gave a positive recommendation on the report. However, it was noted that the findings and/or recommendations could have been more assertive. The report contained 21 recommendations that were not addressed to specific recipients. The field considers it important to address recommendations, for example, to municipalities, so that the appropriate party feels addressed and takes responsibility, but can also be held accountable. According to the field, the recommendations contained few concrete hooks, which made it difficult to implement in practice.	Document analysis Document analysis and focus group with users
The early evaluation also meant that many points did not yet have solid findings or statements because the law had not yet crystallised in practice. This also led to a cautious formulation of certain results and/or recommendations.	Focus group with users
According to field parties, certain topics were described less concretely and more reflectively, whilst other topics either lacked depth or were not covered. A common remark during the presentation of the results in the field by the researchers was that the evaluation did not address the budget cuts associated with the introduction of the Youth Act, which the field considered to be problematic.	Focus group with researchers
Sector associations felt that the evaluation lacked connection to other laws such as the Education Act, Social Support Act, Participation Act, Long-term Care Act, and the Health Insurance Act. They also believed that there was no consideration of the connection between the Youth Act and the judicial chain, not to mention that there was no specific attention paid to young people with developmental issues or disabilities. The industry associations agreed with the conclusions but felt that the evaluation had too narrow a focus.	Focus group with users, document analysis, and questionnaire with researchers Document analysis

Evaluation of the Youth Act (publication date: January 2018) (continued)

From the questionnaire sent to the field, most of the respondents rated the quality of the research group and the quality of the evaluation as being good and neutral, respectively.	Questionnaire with user
According to the field, the evaluation contained a good summary.	Focus group with users
Interactional factors that could have influenced the impact	
Interaction between researchers and the commissioner or participants During the research, there was ample opportunity for input from the field.	Focus group with users
The report was discussed at regional and national 'round tables' with municipalities, institutions, and clients, after which a balanced policy response could be provided.	Document analysis
It was difficult to implement recommendations from the evaluation. According to some, there was not enough discussion. From clients' perspective, there should have been more involvement with users and consumers.	Focus group with users
From the questionnaire distributed to the field, it appears that people were both involved in the implementation and informed about the results, but they were either less or barely involved in the preparation, design, completion, and meetings.	Questionnaire with users
According to one researcher, stakeholders were involved in discussions, different actors were separately surveyed through surveys and discussions, and attention was generated for the final report together with the clients.	Questionnaire with researchers
Presentation and availability of the research results The evaluation report was published on various platforms including the websites of ZonMw, the Dutch Government, the Dutch Youth Institute, and Nivel. Furthermore, the legal experts from the evaluation research group wrote an article for the Journal for Family and Youth Law (FJR 2018/46) entitled "First evaluation of the Youth Act from a legal perspective".	Document analysis
According to the field, there was little publicity around the evaluation.	Focus group with users
After the completion of the evaluation, researchers, at the initiative of the Ministry of Health, Welfare and Sport (VWS), travelled across the country to share the results, and a public congress was organised.	Questionnaire with researchers
On 12 February, a national roundtable meeting was held in Utrecht. The researchers presented the results of the first evaluation of the Youth Act, followed by a brief explanation of the Action Programme for Child Abuse & Domestic Violence. After these two plenary presentations, around 100 representatives from municipalities, provider advocacy organisations, professionals, clients/experienced individuals, and the government engaged in discussions at eight thematic tables regarding the evaluation of the Youth Act and were able to contribute their input for both the Youth Care programme and Child Abuse and Domestic Violence programme.	Document analysis
Following the evaluation, the researchers held discussions with various stakeholders across the Netherlands, including networks of aldermen and youth care organisations, to discuss the findings of the evaluation. The researchers reported that the responses were varied, ranging from positive to critical comments concerning the choice of topics.	Document analysis
Not all of the researchers saw impact as being the responsibility of the researchers. After completing the research, the researchers let it go.	Focus group with researchers

Evaluation of the Youth Act (publication date: January 2018) (continued)

Timing In the autumn of 2013, the House of Representatives adjusted the original evaluation period from five to three years by amendment due to the complexity of the law, which involved a large package of tasks in the field of care and assistance to a vulnerable group of young people being transferred to municipalities.	Document analysis
At this preliminary stage, the law had yet to fully crystallise, and thus no solid findings or statements could be made. The signals regarding bottlenecks or systemic problems could also be easily dismissed by the early evaluation because only two years had passed.	Focus group with users and focus group with researchers

Evaluation of Wkkgz (publication date: January 2021)

Impact within legislation	Source
The Minister intended to amend and/or expand the Wkkgz and the Implementation Decree in response to various recommendations from the legislative evaluation. This was coordinated on certain points with, amongst others, the Health and Youth Care Inspectorate (the Inspectorate), the Dutch Healthcare Authority (NZa), and field parties.	Document analysis and focus groups
Impact within political circles	
The Minister referred in a response to parliamentary questions on another topic (sexual misconduct in youth care) to the evaluation of the Wkkgz.	Document analysis
Various political parties asked additional questions to the Minister prior to the government's response. The Standing Committee on the VWS asked the Minister questions about the response to the evaluation of the Wkkgz.	Document analysis
Impact within policy circles	
The Minister responded substantively to the evaluation in a letter to the House of Representatives (1 July 2022).	Document analysis
The Minister acted on various recommendations, including conducting further research, providing additional support to the field, adjusting policy regulations, and holding further discussions with other parties, including the Inspectorate. Some recommendations were not adopted because the Minister did not consider the proposed situation desirable, preferred to maintain the current state of affairs, or believed that the recommendation was directed at other parties.	Document analysis
The inspectorate was eager to engage in discussions with field parties to explore how it can ensure that such matters are brought to the attention of care providers (even) more effectively. This also applied to stimulating the dissemination of lessons learned amongst care providers themselves.	Document analysis
Along with the Inspectorate, it was explored whether the lack of clarity regarding subcontracting, as outlined by the researchers but for which no recommendation was made, posed a problem for supervision practice. If so, both the extent of this problem and whether the Inspectorate could manage with the current regulations in the Wkkgz were examined.	Document analysis
Within policy departments of the VWS, the evaluation was consulted weekly as a reference. The evaluation provided guidance, for example, in understanding the perspective of healthcare providers.	Focus group with users
Impact within the legal domain	
Law firm KBS Advocaten posted a message about the results of the Wkkgz on their website. The University of Amsterdam also posted a message about the results of the Wkkgz on their website, with specific reference to the two legal researchers who worked there.	Document analysis
The outcomes of the evaluation regarding complaints and dispute resolution were the subject of discussion during an accredited course for legal professionals entitled "Dispute Resolution under the Wkkgz: Theory in Practice".	Document analysis
Impact within society more broadly	
Several industry associations responded in a letter to the House of Representatives regarding the evaluation. In one of the letters, it was highlighted that certain topics were not investigated in the evaluation.	Document analysis

Evaluation of Wkkgz (publication date: January 2021) (continued)

Various organisations posted articles about the results of the evaluation, including industry associations, a management consultancy firm, a knowledge and learning network, and a healthcare news website.	Document analysis
"Dispute resolution bodies have approached each other following the legislative evaluation to engage in more collaborative discussions."	Focus group with users
Research institute Nivel conducted in-depth research on involving patients and their relatives after an incident within a Dutch hospital, at the request of the Inspectorate, partly in response to the evaluation.	Document analysis
Context in which the evaluation took place	
Evaluation initiative and function The Wkkgz has been fully in effect since 1 January, 2017. It regulates healthcare quality and complaint procedures, partially replacing existing legislation that was evaluated in the past. In addition to familiar provisions, the law also introduced new obligations. The Wkkgz is a broad and organisational law that is applicable to all healthcare providers.	Document analysis
To effectively monitor the law, the Minister commissioned a baseline measurement of the Wkkgz in 2016. Subsequently, an annual monitor of the Wkkgz was conducted, focusing on developments in complaints and disputes.	Document analysis
Five years after its enactment, the Wkkgz was evaluated based on the evaluation clause in the law.	Document analysis
In the assignment of the evaluation, it was stated that the evaluation of the Wkkgz aimed to report on both the effectiveness and effects of the law in practice. Researchers were tasked with answering this central question comprehensively, whilst also taking into account several sub-questions formulated into four categories: the scope of the law, accessibility of complaint procedures, monitoring and promoting healthcare quality, and supervision by the Inspectorate.	Document analysis
Political and societal influence In the form of a commitment to the Senate, the Minister announced that the evaluation should examine the extent to which the goals of the law were being achieved. The evaluation would compare the situation during the baseline measurement and the conducted monitors, and specific questions from the Senate would be addressed.	Document analysis
Later, the Minister added several additional commitments regarding the right to lodge complaints, the obligation to provide information in the event of incidents, the supervisory role of the Inspectorate, and Article 20 of the Wkkgz.	Document analysis
The evaluation took place during the COVID-19 pandemic.	Focus group with users and questionnaire with users
The responses to user surveys indicated that there had been discussion about the Wkkgz, particularly in policymaking circles but also within the fields of healthcare and politics.	Questionnaire with users
Openness to the evaluation results No information.	

Evaluation of Wkkgz (publication date: January 2021) (continued)

Quality factors that influenced the impact	
Samenstelling en onafhankelijkheid van de onderzoeksgroep The project team received ratings of "excellent" and "good" in the ZonMw referee comments.	Document analysis
Research Design The evaluation consisted of a combined legal and empirical research approach. The researchers chose to organise an expert meeting at the beginning of the evaluation to identify the key issues and conducted the evaluation with a particular focus on five specific healthcare sectors.	Document analysis
This broad approach, according to the stakeholders, whilst affording a general impression of the functioning of the law also prevented in-depth analysis. As a result, the policy domain lacked sufficient guidance to formulate responses on certain topics.	Focus group with users
Several stakeholders argued that the report primarily targeted policymakers. Consequently, it may be less suitable for clients and professionals, even though they also need to engage with it. The report was perceived as overly abstract by the field, which may have meant that stakeholders did not fully understand the implications of the legislative evaluation. Professional associations could assist in this regard.	Focus group with users
The researchers indicated that this report was indeed intended for policymakers rather than the field.	Focus group with researchers
Quality and Content of the Research Report The evaluation yielded 32 recommendations, directed at seven different groups of addressees: legislators (16), the Ministry (15), the regulatory authority (8), professional associations (8), patient organisations (4), healthcare providers (2), and the field (1).	Document analysis
Stakeholders reported that they would act upon the evaluation results when the recommendations were concrete and feasible.	Focus group with users
During a final advisory committee meeting in which the draft version of the research report was discussed, it was noted that the report was thorough, but that there were some issues regarding consistency in the structure, the distinction between main and secondary issues, and in terms of the alignment between the findings and recommendations.	Document analysis
The final report was reviewed by the Evaluation of Legislation Committee of ZonMw, who provided a positive assessment of the report. However, it was observed that the research had a low response rate, was focused more on professionals than patients, and lacked sharpness in its recommendations on topics that concerned practice, due to the ways in which the questions were formulated.	Document analysis
According to the feedback from the field via a questionnaire, most respondents rated the quality of the research group and the evaluation as being good and neutral.	Questionnaire with users
Interactional factors that could have influenced the impact	
Interaction between researchers and stakeholders In the draft version of the report, it was not specified who should be primarily responsible for the recommendations. The researchers adjusted this in the final version based on feedback from the advisory committee. The Minister stated that field parties would be involved in the actions resulting from the policy response to the evaluation of the Wkkgz.	Document analysis

Evaluation of Wkkgz (publication date: January 2021) (continued)

Regardless of how the evaluation was received (through participation, a webinar, or other communication), the field emphasised that it initiated processes. This was recognised by the field because, for example, dispute resolution bodies approached each other to collaborate more as a result of the evaluation.	Document analysis
Because the evaluation took place during the COVID-19 pandemic, the researchers interacted with respondents in a different (digital) manner. According to one researcher, this impacted upon the research process, especially in terms of how they interacted with respondents during the study. For example, physical meetings were not possible for a long period, so they took place digitally, which was a new experience. The circumstances related to the COVID-19 pandemic also delayed the policy response from the VWS to the evaluation.	Focus group with users
According to the (legal) field, involvement in the research led to a greater interest in the results and the follow-up of the research, and there was a feeling that participation in the evaluation research could to some extent influence the outcome(s). Field parties mentioned that being involved also provided them with food for thought, even during the evaluation. The evaluation itself was already called 'an intervention in itself'. The exchanges that arose during the focus group discussions made the involved parties think and were incorporated into their own organisation. These insights created awareness and sometimes even helped to initiate processes.	Focus group with users
According to the researchers, at the start of the project, various parties discussed which (sub)topics would be examined in the context of the evaluation, or where the focus would lie. The field was involved in the evaluation from various health sectors, resulting in a lot of interaction during the research, and there was a lot of contact with policymakers. The addressees were explicitly mentioned in the recommendations.	Focus group with researchers and questionnaire with researchers
According to the field's responses in the questionnaire, they were involved in the preparation and execution, and were informed about the outcomes and meetings, but were either less or barely involved in the design and conclusion.	Questionnaire with users
Presentation and availability of the research results The evaluation report was published on the websites of ZonMw, the Dutch government, Nivel, and some industry organisations.	Document analysis
The researchers distributed the evaluation report to stakeholders.	Questionnaire with researchers
The researchers organised a webinar to discuss the results of the evaluation with field parties and professionals.	Document analysis and questionnaire with researchers
Four researchers involved in the evaluation authored an article for the Journal of Health Law entitled (translated: "Three Core Themes from the Evaluation of the Wkkgz)" (2021).	Document analysis

Evaluation of Wkkgz (publication date: January 2021) (continued)

A network of patient councils in healthcare requested an accessible version of the Wkkgz evaluation report. According to them, the current document contained a lot of important information for patients and patient councils. "The current document is very extensive and contains a lot of legally technical information. This makes it mainly suitable for policymakers, whilst people in practice need to work with it. We request the committee members to ask the Minister for a more accessible version of the research report. It should be suitable for patient councils and staff representation to have broad discussions about good care within the healthcare organisation."	Document analysis
Timing No information.	

Evaluation of the Embryo Act (publication date: February 2021)

Impact within legislation	Source
The Minister wrote in his response that the Embryo Act would be adjusted in two aspects based on the evaluation.	Document analysis, focus group with users and focus group with researchers
Two governing parties were drafting a private members' bill that aligned with a recommendation from the legislative evaluation.	Document analysis and focus group with researchers
From the two main human-animal combinations currently not regulated, the Minister, in response to the evaluation, intended to regulate one (cybrid) via the Embryo Act and exclude the other (hiPSC-chimera) from the Embryo Act. This aligned with the recommendation from the legislative evaluation.	Document analysis
Impact within political circles	
Various parties posed additional questions to the Minister.	Document analysis
In a coalition agreement in preparation for a new term of office, it was described what would be done with specific recommendations from the legislative evaluation.	Document analysis
The House of Representatives held an online consultation on the 'Amendment Law abolishing the prohibition on the creation of embryos.	Document analysis
"The government has left some topics untouched and not adopted recommendations, such as germline modification."	Focus group with researchers
Impact within policy circles	
The Minister responded substantively to the evaluation in a letter to the House of Representatives.	Document analysis
The cabinet, in accordance with the interim evaluation, requested advice from the Health Council regarding both the desirability and acceptability of extending the fourteen-day limit to twenty-eight days (recommendation seven) and how to deal with a developmental limit for ELS (recommendation eight). This advice was provided on 31 October, 2023.	Document analysis
In his response to the evaluation, the Minister stated that the Netherlands would participate in the dialogue on germline modification at the European level. If there was a discussion about the possibilities of preclinical research, then the Minister stated that they would strive to prevent European regulations or treaties from complicating preclinical research, which is in line with the recommendation of the legislative evaluation.	Document analysis
The Ministry was taking up the recommendations and was looking into how they could be followed up on.	Document analysis
Impact within the legal field	
The evaluation was included in the course material for the course 'Legal Issues Surrounding the Beginning and End of Life' (3864REC7KY) at the University of Amsterdam.	Document analysis

Evaluation of the Embryo Act (publication date: February 2021) (continued)

Impact within society more broadly	
The Lindenboom Institute wrote the report entitled 'Annotations on the third evaluation of the Embryo Act,' in which criticism is offered on the recommendation of the evaluators to abolish the prohibition on culturing embryos.	Document analysis
Stakeholders posted the evaluation on their website, whilst references to the evaluation were made in articles published in the Healthcare Journal, namely: 'Embryo Act Amended for the First Time Since 2002' or 'Is Germline Modification Ethically Responsible?' by G. de Wert and W. Dondorp, published in the NtvG on November 28, 2022.	Document analysis
Context in which the evaluation took place	
Evaluation initiative and function The Embryo Act was evaluated twice before (in 2006 and 2012, respectively). This was thus the third evaluation of the Embryo Act.	Document analysis, focus group with users and focus group with researchers
In the Ministry's assignment letter, it was stated that the third evaluation should broadly address the general functioning of the Embryo Act. Additionally, the research would be used to focus on themes identified as bottlenecks in previous legislative evaluations (which had not yet been resolved) and/or that required further attention due to medical-scientific or societal developments.	Document analysis
The CER chose not to include the societal perspective in the research.	Document analysis
Political and societal influence The domain covered by the Embryo Act was delimited, and stakeholders and policy officials were familiar with each other.	Focus group with users and focus group with researchers
By conducting evaluations periodically, alignment with everyday practice could be continually sought. Discussions were also held following the evaluation.	Focus group with users, focus group with researchers and questionnaire with users
New developments in embryo research increased the relevance of topics mentioned in previous evaluations and required adjustments to the law. These topics were important for the selection of subjects for the legislative evaluation.	Focus group with researchers
During the evaluation, changes in staff working on this dossier occurred at the VWS. It was noted from the field that they felt they had to start over completely with each of these changes.	Focus group with users
Whether recommendations were followed up on and implemented largely depended on political positions, the composition of the coalition, and the agreements of the cabinet.	Focus group with users
In the political arena, certain subjects, such as the specific cultivation of embryos, were simply not up for discussion. This meant that, for example, policy could not proceed with the outcomes of the societal dialogue.	Focus group with researchers

Evaluation of the Embryo Act (publication date: February 2021) (continued)

The political context did not influence how the evaluation assignment was established because there was simply a need for scientific and independent advice. At most, emphasis could be placed on certain aspects.	Focus group with researchers
The questionnaire results indicated that discussions about the Embryo Act primarily took place in policy and political circles, with less emphasis within the healthcare sector.	Questionnaire with users
Openness to evaluation results /	
Quality factors that could have influenced the impact	
De composition and independence of the research group The project group was rated 'excellent' in the referee comments and they were considered experts in the field. Only a small group of people were sufficiently qualified and well-versed in the field to be able to conduct such evaluations (field focus group). Therefore, the field assumed that the evaluation was conducted scientifically and was well substantiated.	Document analysis and focus group with users
The authority of the research group was important for the impact.	Focus group with researchers
Researchers had to safeguard their independent positions as experts and avoid becoming part of the political discussion. To ensure this independence, it was important to strike the delicate balance between various interests, moral positions, and societal perspectives. A critical debate within a multidisciplinary research group contributed towards balanced recommendations.	Focus group with researchers
Research design The evaluation consisted of a combined legal and ethical investigation. The researchers chose to focus on six themes because most of the related problems and bottlenecks identified in previous evaluation studies had yet to be resolved, and questions about the future viability of the law also particularly related to those themes.	Document analysis
The project proposal was evaluated by three referees with respect to its quality (objective and question-tasking, approach plan, project group, and feasibility). The summary quality assessment was rated 'excellent' by one referee, 'good' by one referee, and 'moderate' by one referee.	Document analysis
To achieve maximum impact, researchers during an evaluation should look at bottlenecks and gaps in practice and be aware of debates or pressing issues in society.	Focus group with researchers Document analysis
There was a discussion within the ZonMw Committee for Evaluation of Regulation (CER) about whether societal perspectives should form part of the evaluation. Gaining information about these perspectives was very important for the Ministry. Ultimately, the CER chose not to include this perspective in the research. It was proposed to look more at societal legitimisation in the next assignment, in order to supplement what had already been done.	
Quality and content of the research report Fifteen recommendations were made, with 12 addressed to the legislator, five to the VWS, one to the research field, and one to KLEM.	Document analysis

Evaluation of the Embryo Act (publication date: February 2021) (continued)

The final report was discussed in the CER of ZonMw, who provided a positive recommendation about the report. However, it was advised to adjust certain formulations in the recommendations.	Document analysis
The questionnaire results indicated that both the quality of the evaluation and the research group were rated very good to good.	Questionnaire with users
Interactional factors that could have influenced the impact	
Interaction between researchers and stakeholders During the evaluation, the researchers engaged with various individuals who held different viewpoints. The selection of respondents was not based on their specific stances but rather on their expertise and experience.	Focus group with researchers
The field experts were closely involved in discussions pertaining to legislation and regulations, such as private members' bills, as these developments had significant potential for societal impact. These initiatives were, in part, derived from legislative evaluations. Involving experts during the evaluation process lent weight to crucial points for stakeholders in the field. Understanding current issues was essential for an effective evaluation.	Focus group with users
In addition to involving field experts, there was also emphasis at that time within the policy domain on societal dialogue to better understand public perspectives on certain Embryo Act-related topics, such as the specific cultivation of embryos. This provided insight into these necessary debates. However, not every topic was conducive to this approach, and careful consideration of terminology was crucial. Attention to societal consensus likely also played a key role in the evaluation assignment with respect to outlining prerequisites.	Focus group with users
According to respondents from the field, there had been a lot of discussion in recent years without corresponding action, although this was also viewed as a valuable learning experience. Researchers directed their recommendations towards the appropriate recipients.	Focus group with users
The results from the user questionnaires indicated that they were involved in the preparation, design, and execution as well as being informed about the results, but were either less or barely involved in the finalisation and meetings.	Questionnaire with users
According to the responses from the researchers, in the case of legislative evaluations, a cabinet response to recommendations was necessary, given parliamentary involvement. This subject was already garnering societal and political attention, and thus necessitated fewer additional actions	Questionnaire with researchers
Presentation and availability of the research results The evaluation report was published on the websites of various organisations, including ZonMw, the Dutch government, the Central Committee on Research Involving Human Subjects (CCMO), and Maastricht University.	Document analysis
An article in TvGr entitled 'Kiembaanmodificatie: goed geregeld in de Embryowet?' M. Spaander, M.C. Ploem, G.M.W.R. de Wert (2023).	Document analysis
According to the researchers, publications were written, and a conference was organised at the end of the trajectory.	Questionnaire with researchers
Timing The evaluation took place in 2020. Originally, the evaluation was scheduled for 2017, but it was postponed for several years by the Minister due to ongoing legislative changes at that time (which stemmed from the two previous legislative evaluations).	Document analysis

Evaluation of the Embryo Act (publication date: February 2021) (continued)

Other Researchers took the implementation opportunities into account when formulating their recommendations, for example by ensuring sufficient policy discretion in the recommendations directed at the government (such as the recommendation to seek advice from the Health Council).	Focus group with researchers
Carefully formulated recommendations directed at the appropriate recipient are important. Recommendations must be relevant and substantively strong and can lead to changes in policy, legislation, scientific practices, and healthcare. The researchers were acutely aware that the manner in which the recommendations were formulated was crucial. For example, it was important to retain sufficient policy discretion in recommendations directed at the government.	Focus group with researchers

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Section III

In depth research on serious adverse event investigations in Dutch hospitals following an ex-post legislative evaluation

Chapter 6

The hospital perspective on the involvement of patients and/or their next of kin in serious adverse event investigations in healthcare

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Abstract

The involvement of patients and/or their next of kin (P/N) after a serious adverse event (SAE) is evolving. Beyond providing mandatory information, there is growing recognition of the need to incorporate their interests. This study explores practical manifestations of P/N involvement and identifies significant considerations for hospitals. The data collection involved various qualitative research methods: seven focus groups with 56 professionals from 37 hospitals, an interview with two representatives from the Dutch Association of Hospitals, and an interactive reflection seminar with over 60 participants from 34 hospitals. Before the focus groups, a brief questionnaire was sent out to survey participants' practices regarding SAE investigations. After the study, another questionnaire was distributed to gather suggestions for future improvements and to identify their lessons learned. Thematic analysis was applied to the gathered data to identify key themes. Hospitals are increasingly acknowledging the interests and perspectives of P/N, recognising their potential contributions to organisational learning and improvement. P/N involvement following SAEs includes active participation in different stages of the investigation process, not just passive information dissemination. Important factors influencing involvement are the provision of (emotional) support, identification of needs and transparency of the SAE investigation. This study enhances understanding of evolving practices surrounding P/N involvement in the context of SAEs in Dutch hospitals. The findings highlight the importance of promoting meaningful involvement, recognising the significance of P/N experiences, and fostering a culture of transparency and collaboration. By examining the dynamics of involvement, this research aims to inform policy development and facilitate the implementation of patient-centered approaches to post-SAE care.

6.1 Introduction

In healthcare, when a serious adverse event (SAE) occurs, impacting patient care quality and resulting in death or severe harm, hospitals can be mandated to conduct thorough investigations. These investigations aim to identify the contributing factors, extract valuable lessons, and implement preventive measures.

Several countries, such as the Netherlands, Australia, the United Kingdom (UK), France and certain states in the USA (e.g. Maryland and Minnesota), have established mandatory reporting systems for all or specific severe patient harm incidents (Schwappach et al., 2022). However, in the UK, the new national policy, The Patient Safety Incident Response Framework (PSIRF), mandates a shift from the broad approach to focusing on those incidents that provide valuable learning opportunities to enhance patient safety. This targeted approach aims to allocate resources more effectively and prioritise incidents with the greatest potential for learning to improve patient safety (NHS England, 2022).

Research on SAEs has evolved significantly, with a movement towards involving patients and/or their next of kin (P/N) in the investigation process (Ramsey et al., 2022). This study examines hospitals' perspectives on this remarkable movement and explores the potential implications of this new collaborative approach.

Previous research underscores the value of involving P/N in identifying medical errors and improving patient safety (Weingart et al., 2005), highlighting the importance of exploring new approaches tailored to the specific information and improvement needs of both research authorities and family members (Wiig et al., 2020). It is crucial for SAE investigations to be flexible and sensitive to both clinical and emotional aspects of care to avoid compounding harm (Wailling et al., 2022). Integrating P/N in SAE investigations can be achieved in various ways and may offer an untapped reservoir of learning potential (Busch et al., 2021).

Several studies have shown that P/N highly value being involved in the process, as it can facilitate reconciliation after a traumatic event and restore their trust in the healthcare system (McQueen et al., 2022; Wiig et al., 2021a; Wiig et al., 2021b). Indeed, the coping process for P/N continues even after the completion of formal procedures related to the SAE process (Merten et al., 2019). However, within the Dutch context, prior research has revealed a limitation in P/N involvement – often restricted to a single interview (Kok et al., 2018). Regrettably, a prevailing notion persists that the P/N perspective, despite its significance, possesses restricted utility and validity in the realm of SAE investigations, where the professional perspective takes precedence (Kok et al., 2018).

The evaluation of Dutch legislation, the Healthcare Quality, Complaints, and Disputes Act (Wkkgz), emphasised that P/N's interest in not only being informed but also being seen and heard (Friele et al., 2021). This insight calls for a shift from a ritualistic approach to a more restorative

justice-driven involvement of P/N, aligning with global perspectives (Card, 2023; Farrell et al., 2020; Nickson et al., 2020). This evaluation recommendation prompted the Dutch Health and Youth Care Inspectorate (the Inspectorate) to initiate this study, examining P/N involvement in Dutch hospitals. Thus, our central question remains: *How do hospitals involve P/N after a SAE and what drives their decisions?*

Several studies highlight a clear need to develop comprehensive and efficient policies for involving P/N in SAE investigations. O'Connor (2010) and Busch (2020) both emphasise the importance of patient involvement in these investigations, with O'Connor specifically calling for improved disclosure practices and Busch proposing a framework for patient participation.

Therefore, this study aims to contribute to the practice-based learning curve by guiding the integration of P/N into the SAE process. By offering globally relevant insights, this research contributes to the development of comprehensive and efficient policies for involving P/N in SAE processes.

6.2 Research Methods

6.2.1 Research design

This study is part of a broader exploratory research project focusing on P/N involvement after a SAE in Dutch hospitals, commissioned by the Inspectorate and assigned to us by ZonMw (Friele et al., 2023). Before the research commenced, the research protocol was reviewed and approved by the Ethical Review Board of Tilburg University's Faculty of Law. Additionally, the VUmc Medical Ethical Review Board confirmed that this study does not fall under the Medical Research Involving Human Subjects Act.

The study involved two concurrent sub-studies: one examining the patient perspective and the other exploring the hospital's perspective on involving P/N in SAE investigations. The patient perspective sub-study included 11 interviews with a total of 8 patients and 11 next of kin. Additionally, two broad consultations were held with 16 chairpersons and members of client councils, and an interview was conducted with a representative of the Netherlands Patients Federation (Dijkstra et al., 2024). Further details on the patient sub-study are beyond the scope of this article.

This study specifically examines the viewpoint of healthcare professionals and representatives from an umbrella hospital association on the involvement of P/N in a SAE investigation.

The central research question is: *How do hospitals involve P/N after a SAE and what drives their decisions?*

6.2.2 Participant recruitment

We invited all 74 Dutch hospitals, of which 37 hospitals (50%) participated. These included 4 academic, 13 top clinical, and 20 peripheral hospitals. We used contact information provided by the hospitals to invite specific professionals to participate, sending digital invitations containing information and registration links. Our inclusion criteria specified that participants must be professionally involved in handling SAE investigations within their respective hospital. The exclusion criteria ruled out individuals without such involvement.

6.2.3 Data collection

The data collection included several qualitative research methods, which are outlined below.

6.2.3.1 Questionnaire before focus groups

Before conducting the focus groups, a brief questionnaire was sent to all participants (n=56) to gather data on their hospital's approach for handling SAEs, and their awareness of the Wkkgz evaluation's recommendation on this topic (see Appendix 1). This provided a solid foundation regarding investigation approaches, saving discussion time during the focus groups on organisational details. As researchers of the Wkkgz evaluation, that inspired this follow-up study, we were also interested in participants' familiarity with this evaluation, helping us to better contextualise discussions during the focus groups.

6.2.3.2 Focus groups

We expanded our focus groups from five to seven due to high registration, including professionals like quality and safety employees, complaints officers, patient representatives, and SAE investigators from Dutch hospitals. A total of 56 participants from 37 hospitals took part (see Table 1), averaging eight participants per group to ensure effective discussions (Guest et al., 2016; Krueger et al. 2014). Led by the same researcher for consistency, each session started with a standardised opening question about P/N involvement in hospitals, aligned with the research question (Appendix 2). All focus groups lasted one hour, were conducted digitally, recorded with consent, and transcribed for summarisation. Summaries were then shared with participants for feedback within a two-week window.

6.2.3.3 Interview with the Dutch Association of Hospitals

An interview with two representatives from the Dutch Association of Hospitals provided a national-level perspective. Conducted digitally, it mirrored the questions used in the focus groups and was recorded with participants' consent. The transcription and summary of the interview were shared with participants for verification and approval.

6.2.3.4 Interactive reflection seminar

An interactive reflection seminar engaged over 60 professionals from 34 hospitals to discuss preliminary research findings and promote mutual learning. Participants included healthcare professionals and patient council chairs from all hospitals, including those not involved in the initial study. Reflecting on our findings, we sought to understand the general consensus,

implementation of shared views, and remaining challenges. Following the seminar, participants received a digital questionnaire to provide feedback and insights for implementing in their work, completed by 18 participants. This feedback provided valuable suggestions for future improvements and identified key lessons learned from the study.

6.2.4 Analysis

To ensure a comprehensive analysis, data from multiple sources were systematically integrated. The initial questionnaire established baseline practices and awareness levels, guiding subsequent focus groups. The focus groups offered qualitative insights into hospital approaches and considerations to P/N involvement in SAE investigations. An interview with the Dutch Association of Hospitals broadened the perspective to national policies. By integrating data from these different sources, a robust analysis of challenges and strategies around P/N involvement was achieved.

The analytical procedures involved open coding, categorisation, and interpretation of qualitative data to thoroughly explore the research aims. Anonymous transcripts from all focus groups were initially open-coded using MAXQDA software by the primary author, with significant themes abstracted by the secondary author. Both authors adhered to Braun and Clarke's six phases of thematic analysis, incorporating input from the tertiary author to identify major themes (Braun & Clarke, 2019; Braun & Clarke, 2023) The results were reported following SRQR standards and discussed during the reflection seminar (OPEN Netwerk, 2019).

6.3 Results

Since this research was prompted, in part, by a recommendation from the Wkkgz evaluation, we were interested in understanding its awareness and impact within hospital settings. The pre-focus group questionnaire, sent to the participants (n=56), was completed by 12 individuals (21.43%). Half of the respondents (n=6) were unaware that the Wkkgz had been evaluated. The remaining respondents had either heard about it (n=4) or discussed some results with colleagues (n=2). Interestingly, all respondents indicated that the evaluation had no impact on hospital policies (n=8) or were unsure of any impact (n=4). A similar pattern emerged from the focus groups, where most respondents had heard about the evaluation but had not taken any concrete actions in practice, despite the evaluation containing a focused recommendation in this regard.

Our analysis of the questionnaire, focus groups, and the interview with the Dutch Association of Hospitals, showed that hospitals have long considered P/N involvement after SAEs, implementing diverse approaches shaped by multiple considerations. Our data identified three distinct stages in this process: (1) at the start of the investigation, (2) during the investigation, and (3) after the investigation. Each stage addresses unique focus points, detailed below.

(1) Shaping patient involvement at the start of the investigation

- Classification of a SAE
  Hospitals have the autonomy to determine whether an incident qualifies as a SAE, as this designation carries certain obligations such as reporting to the Inspectorate within three days and conducting an investigation within six weeks. We have noticed that hospitals tend to adopt a cautious approach to ensure accuracy, often organising multidisciplinary discussions to make well-informed determinations. However, this cautiousness can result in delays in the decision-making process and in informing the P/N about categorising the incident as a SAE.

  Considerations: Early classification can potentially harm the patient-provider relationship if it turns out afterwards that the situation is not classified as a SAE. To prevent implausible scenarios and false expectations for the P/N, hospitals are taking careful measures through preliminary examination. By doing so, they aim to avoid inconveniences caused by reversing decisions made too early. Moreover, hospitals are keen on safeguarding the safety and well-being of the physicians involved in the incident. This includes monitoring their welfare and ensuring that decisions taken during the process do not put them at risk. By taking these measures, hospitals are striving to strike a balance between transparency, patient care, and the interests of their medical staff.

- Initiation of the first contact with the P/N
  Based on our observations, it is evident that several hospitals prioritise prompt communication of SAEs to P/N as soon as it becomes apparent that such an event has occurred. While the specific party responsible for initiating this initial contact varies among hospitals, this approach is handles with careful consideration. The treating physician, who maintains the highest level of interaction with the patient, the primary caregiver, the SAE committee, or a complaints officer could be involved in making the first contact.

  > *''We contact the patient or relative as soon as possible to explain the procedure and ask if they have any specific questions for the analysis. Their responses are included verbatim in the report, often revealing surprising and valuable insights.''*
  >
  > *Participant focus group 1*

  Considerations: Hospitals aim to establish a relationship of trust and transparency through open and honest communication. They prioritise keeping P/N informed, demonstrating accountability, and providing opportunities for clarification. The Dutch Association of Hospitals also explicitly mentions that restoring the trust of the P/N is the most important, as it forms the foundation of the doctor-patient relationship, and starts with a conversation.

- Identifying the needs and perspectives of the P/N

  Our study revealed that hospitals place a high priority on early identification of the needs of P/N during the SAE process, aiming to provide personalised support. Furthermore, we noticed that hospitals stress the importance of respecting the preferences of individuals who opt not to be involved, while making efforts to accommodate the preferences of those who choose to participate. Interestingly, certain hospitals go a step further by integrating the information and inquiries from engaged P/N into the investigation and subsequent report.

> *"Every case is unique and asks for a tailored approach. We strive to respond to the needs of the patient or their next of kin in the hospital. If there is no desire for a conversation, we fully respect that, no matter how much we would like their input. What the patient wants is our priority."*
>
> *Participant focus group 4*

Considerations: Hospitals prioritise patient needs to demonstrate their commitment to taking patients seriously and providing patient-centered care. By valuing patient perspectives, they identify areas for improvement, enhance patient outcomes, and promote patient safety. This approach can foster a culture of continuous learning and ensure that hospitals are responsive to the needs and preferences of the individuals they serve.

> *"That is also often what the patient or next of kin are looking for - some recognition of their emotions and feelings. This was not the intention, and we would like to investigate it to understand and learn from it. We always receive a positive reaction from the patient or their next of kin when we do this".*
>
> *Participant focus group 2*

(2) *Shaping patient involvement during the investigation*

- P/N support services

  Numerous hospitals recognise the importance of having a designated contact person to provide support to P/N. This role may encompass various titles such as disclosure coach, client contact person, or complaints officer. The crucial aspect is that this individual possesses undivided responsibilities and is accountable for guiding P/N throughout the process. In smaller hospitals, it was observed that this role tends to be frequently undertaken by a member of the SAE committee or the complaints officer.

> *''Because you see that the more open you are, there is actually much better collaboration, which ultimately helps us work more effectively with the patient or their next of kin.''*
>
> *Participant focus group 1*

Considerations: Hospitals acknowledge the emotional impact that SAEs can have on P/N. They aim to provide compassionate care, offering support and assistance in navigating the

healthcare system during challenging times. By being accessible and responsive, hospitals aim to ensure the well-being and comfort of P/N. Some hospitals see this as a separate process from the SAE investigation because they consider the investigation to be primarily for their internal purposes and the Inspectorate. Therefore, the conversations held with P/N serve the dual purpose of facilitating hospital learning and providing attention and space for the interests of the P/N.

(3) *Shaping patient involvement after the investigation*

- Decision to share or withhold the investigation report

We noticed a lot of variation concerning the decision to share the investigation report.

Generally, hospitals share the report or a modified version, such as a summary or governance reflection. Most hospitals do note that sharing should be accompanied by a conversation providing explanations. Some also include a disclaimer highlighting that the report focuses on learning and improving quality rather than assigning liability. They prioritise systemic issues over individual responsibility.

Hospitals often highlight that the report is intended for internal learning purposes, sanctioned by the Inspectorate, rather than for patients. This viewpoint is also supported by the Dutch Association of Hospitals.

Considerations: Hospitals value transparency and openness by sharing the report or key findings to demonstrate their commitment to learning and improvement. However, concerns about legal implications and negative media exposure may cause hesitation in some hospitals, as they aim to protect their reputation.

> *"In the beginning, we sometimes created a summary, but the reports have become so concise that a summary is no longer necessary. We have nothing to hide; on the contrary, we want to share everything openly, and this is very well received. (...) It is, however, important to provide a clear explanation alongside the report.''*
>
> *Participant focus group 5*

> *"Ultimately, that report ended up in some Facebook group as soon as she had it. So, it raises the question of how safe it is to share the report. The report is anonymous, of course, but she can still attach names to it. These are difficult issues, in my opinion."*
>
> *Participant focus group 7*

- Final conversation or meeting

In accordance with the available data, hospitals invite P/N to participate in a concluding discussion. Some hospitals consider this discussion mandatory for receiving the report, seeing it as essential for providing comprehensive explanations. The composition of attendees

at these discussions varies among hospitals and may include healthcare professionals directly involved in the case, a representative from the complaints department, a designated contact person, and, in some instances, a member of the Board of Directors.

Considerations: Through these final discussions, hospitals aim to ensure a comprehensive understanding of the incident, address any unresolved issues, and offer an opportunity for P/N to express their thoughts and concerns. This approach promotes transparency, supports patient-centered care, and fosters a sense of trust and accountability.

> *"We also keep our group small, so we do not sit there with four or five people facing one or two vulnerable individuals. Besides the report, we always have legal information with us, because some people, not always, still ask questions like 'What now?' or 'Can I get something?' We are very open about what the possibilities are in that regard."*
>
> *Participant focus group 2*

- Follow-up care and support
  Most hospitals state that the responsibility of the SAE committee ends with report delivery. However, some hospitals extend post-care through dedicated patient contact persons, continuing support until the P/N expresses satisfaction or no longer requires further clarification.

Considerations: Hospitals recognise the importance of repairing and recovering the relationship with the P/N after a SAE. By providing ongoing support and addressing any remaining concerns or questions, they demonstrate their commitment to taking patients' feelings seriously and ensuring their satisfaction. This approach aims to rebuild trust, foster a positive patient experience, and strengthen the patient-provider relationship.

> *''We continue until the patient is satisfied. We try to prevent discrepancies by discussing the factual part with the patient before it goes to the Inspectorate. (...) We also want the patient to be satisfied with the content of the report, without compromising the accuracy of what actually happened.''*
>
> *Participant focus group 5*

After collecting data, we conducted an interactive reflection seminar to discuss our findings. It was evident that while the consensus on the benefits of P/N involvement was strong, there were diverse approaches to its application. Post-seminar feedback indicated that all participants viewed the reflection seminar positively, gaining new insights and practical tips applicable to their hospitals. Some saw it as validation of their current practices, while others identified areas for substantial improvement in how they involve P/N throughout the phases of SAE investigations. Participants appreciated the opportunity to exchange experiences and found it

very useful to receive research results translated into concrete tips and recommendations for practical implementation.

6.4 Discussion

This study highlights a notable shift where hospitals increasingly acknowledge the importance of SAE investigations for P/N. Previously, Dutch hospitals showed reluctance, such as hesitancy in sharing investigation reports (OPEN Netwerk, 2019). This study shows that while there is now greater openness, hospitals vary in how they implement this approach. Hospitals' decisions in this regard are primarily driven by two motives: viewing P/N as valuable sources of information for learning and recognising them as stakeholders with their own interests.

National and international literature support these findings, illustrating various global approaches that hospitals adopt to integrate P/N perspectives into SAE processes (Kok et al., 2018; Wiig et al., 2020; Wiig et al., 2021a). Involving P/N in SAE investigations has been shown to provide valuable information and contribute to the investigation quality, although it can also be emotionally challenging and increase the workload for investigators (Wiig et al., 2021a). To address these challenges, it is important to structure the involvement in a patient-centered way (Etchegaray et al., 2014). This can be achieved by providing support and preparation for the P/N, using easily accessible language, and offering different methods of involvement (Wiig et al., 2020). Overall, the involvement of P/N in SAE investigations can lead to a more comprehensive understanding of events and contribute to the learning potential (Wiig et al., 2021a).

A significant contribution of our study is the identification of a third motive for involving P/N in SAE investigations: the restoration of the patient-provider relationship. This goes beyond viewing P/N as valuable sources of information for learning and recognising them as stakeholders with their own interests. It emphasises the need to continue care and move forward together following a SAE. This relational intervention does not have to compromise the research quality but rather enhances it by fostering trust between patients and providers, as emphasised by the Dutch Association of Hospitals and corroborated by our interviews with P/N (Dijkstra et al., 2024).

We learned that most hospitals in our study, along with the umbrella hospital organisation, stress the importance of restoring the patient-provider relationship by involving P/N throughout all stages of the SAE process. We identified three stages in which hospitals can take action to rebuild this relationship. The later this action is taken, the more challenging it appears to be.

Dutch hospitals are actively exploring strategies to balance the increased central role of P/N with other important interests, such as physician safety and institutional reputation. The diverse approaches highlight the nuanced decision-making hospitals face in maintaining credibility and operational integrity during SAE investigations. This complexity presents challenges. For example, as SAE investigations progress and conclusions are drawn, hospitals vary in how they

share the investigation report with P/N, balancing organisational learning with concerns about institutional reputation.

The way we conducted our study contributed to learning at various levels. Hospitals shared insights and practices, such as sharing investigation reports with P/N, informed by discussions in our focus groups and reflection seminar. Our findings also inform regulatory bodies like the Inspectorate on adapting supervision to these evolving practices. Additionally, we hope our study promotes international knowledge exchange.

6.5 Strengths and limitations

The study engaged a substantial number of hospitals (n=37), exceeding initial expectations. An extensive reflection seminar with over 60 participants was also organised, along with discussions with the Dutch Association of Hospitals. This comprehensive approach provided a reliable overview of the situation in the Netherlands, forming a strong foundation for insights in other countries. It addresses universal challenges faced by healthcare systems globally. Many countries are grappling with how to effectively involve P/N in the aftermath of SAEs, aiming to improve transparency, accountability, and trust within the healthcare system. By examining the approaches and motives for P/N involvement in the Netherlands, our study provides insights that can be applied in various international settings. The emphasis on restoring the patient-provider relationship and balancing interests such as physician safety and institutional reputation resonates with global healthcare priorities. As healthcare systems worldwide strive to improve patient safety, our findings offer actionable insights that can help shape international best practices and policies.

However, this research primarily focuses on P/N involvement during the SAE process, leaving aspects like post-SAE care less examined. It captures hospital staff perspectives, offering insight into their viewpoints but does not detail how these align with healthcare providers' daily experiences or P/N perspectives. Additionally, while hospitals believe that P/N participation leads to deeper insights, it remains unclear whether this actually contributes to more effective learning from SAEs.

6.6 Conclusion

Involving P/N in all stages of the SAE process—initiation, investigation, and post-investigation—ensures transparency and fosters trust. Hospitals involve P/N in SAE investigations not only to promote learning and recognise their interests but also to restore the patient-provider relationship. By emphasising this third motive, our findings extend beyond the existing literature, illustrating a holistic approach to post-SAE care that prioritises ongoing patient support and trust-building. The insights gained offer practical guidelines for involving P/N in SAE processes, addressing universal concerns about transparency, safeguarding institutional and physician interests,

accountability, and trust within the healthcare system. By sharing these findings, hospitals worldwide can learn from our well-developed experiences, fostering global improvements in patient safety and care quality.

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Chapter 7

The patient perspective on the involvement of patients and/or their next of kin in serious adverse event investigations in healthcare

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Abstract

Over the last decade attention has grown to give patients and/or their next of kin (P/N) a more substantial role in serious adverse event (SAE) investigations. SAE investigations occur after SAEs that resulted in death or severe injury. Few studies have focused on the patient perspective on their involvement in such investigations. The present study sets out to investigate how P/N and patient representatives (client councils and the Patient Federation Netherlands) view the involvement of P/N in SAE investigations, particularly whether and why they want to involved, and how they want to shape their involvement. The study features qualitative data on three levels: interviews with P/N (personal), focus groups with representatives of client councils (institutional), and an interview with the Patient Federation Netherlands (national). Researchers used inductive, thematic analysis and validated the results through data source triangulation. The initiative taken by the hospitals in this study provided P/N with the space to feel heard and positions as legitimate stakeholders. P/N appreciated the opportunity to choose whether and how they wanted to be involved in the investigation as stakeholders. P/N emphasised the need for hospitals to learn from the investigations, but for them the investigation was part of a more encompassing relationship. P/N's views showed the inextricable link between the first conversation with the healthcare professional and the investigation, and the ongoing care after the investigation was finalised. Hence, a SAE investigation is part of a broader experience when understood from a patient perspective. A SAE investigation should be considered as part of an existing relationship between P/N and hospital that starts before the investigation and continues during follow up care. It is crucial for hospitals to take the initiative in the investigation and in the involvement of P/N. P/N motivations for involvement can be understood as driven by agency or communion. Agentic motivations include being an active participant by choice, while communion motivations include the need to be heard.

7.1 Introduction

Unfortunately, standing at the receiving end of healthcare harm is an experience shared by patients and/or their next of kin (P/N) all over the world. Sometimes such harm is the consequence of an avoidable serious adverse event (SAE), for example in case of wrong-site surgery. In case of a SAE, Dutch healthcare organisations in the Netherlands are obliged to conduct an official, internal investigation. SAEs are defined by law as "unintended or unexpected events, related to the quality of healthcare, that have led to either the death of a client or severe injury" (Article 1 Dutch Healthcare Quality, Complaints, and Disputes Act). By conducting SAE investigations, healthcare organisations aim to learn and to compensate and for P/N to heal (Dijkstra et al., 2021; Ramsey et al., 2022). Increasing attention has been given to offering P/N a more substantial role in SAE investigations (Etchegaray et al. 2014; Grissinger et al. 2011; Kok et al. 2018; Zimmerman et al. 2007). Following legislation passed in 2016, it is mandatory for hospitals in the Netherlands to involve P/N in these SAE investigations (Article 10(3) Dutch Healthcare Quality, Complaints, and Disputes Act). The mandatory involvement of P/N indicates a move towards a more solid position for P/N (article 8.2 Executive Order of the Dutch Healthcare Quality, Complaints and Disputes Act) and broader goals for SAE investigations than (just) quality improvement. Subsequently, patient involvement in such investigations in some form increased from 15% to 85% in cases documented by the Dutch Health and Youth Care Inspectorate (the Inspectorate) between 2013 and 2016 (Kok et al., 2018). Patient involvement can vary between submitting a question to being interviewed by the investigating committee (MqQueen et al, 2022; Knap et al., 2023; Peerally et al., 2017).

To understand why P/N are involved in adverse investigations, Kok et al. (2018) identified two main motivations: a moral justification (to do the right thing) and an epistemological justification (to learn from their experiences). P/N have unique knowledge that could contribute to learning and could support P/N in their healing and understanding of what occurred (Kok et al., 2018; Zimmerman & Amori, 2007; Etchegaray et al., 2016). Friele et al. (2023) considers these aspects along the lines of instrumental and relational value. Involving P/N for either of these goals has sparked concern among healthcare organisations regarding legal risks, additional trauma, emotional impact and (psychological) readiness of P/N (Zimmerman & Amori, 2007). Regardless, little is known about the P/N's own motives to indeed participate.

As designated stakeholders, P/N might have their own expectations and motivations about if, when, and how they want to contribute to SAE investigations. Motivations for participation might also reflect Friele's notion of instrumental or relational value (Friele et al., 2023). This distinction traces the so-called "Big Two" of social motivation: agency and communion (Pemberton et al., 2017). These concepts could support a more thorough understanding of how and why P/N want to be involved in SAE investigations and what they hope to gain. Agency motivations concern "individual striving, competence, power and instrumentality", while communion-related motivations include "social relatedness, warmth, expressiveness and affiliation" (Pemberton et al., 2017). This research aims to explore patient perspectives on the involvement of P/N in such

investigations, particularly whether and why they want to be involved, and how they want to shape their involvement as stakeholders to the investigations. Having said that, how to involve P/N in the investigation remains a topic of discussion in Dutch hospitals (Knap et al., 2024).

7.1.1 Serious adverse event investigations

Generally, Dutch hospitals assemble internal investigation committees. The committees consist of an average of five internal members. These members usually include the head of the patient safety department, a medical specialist, a nurse, and a medical specialist specifically appointed to deal with patient safety (Heuver et al., 2016). This is different from Norway for example, where the investigative committees consist of regulatory inspectors (Wiig et al., 2021). In the Netherlands the committees examine whether a SAE indeed occurred by investigating medical records and interviewing the healthcare professionals and P/N involved (Knap et al., 2024). According to hospital managers and incident investigators patients were generally interviewed once in the course of the hospital investigation (Kok et al., 2018). This practice differs from Scotland, where patient involvement varies between submitting questions to sharing observations (McQueen et al., 2022). Each hospital communicates the results in an investigative report to the Inspectorate within six to eight weeks after the SAE (Bouwman et al., 2018; Kok et al., 2018). In 2021 the Inspectorate received 810 notifications of SAEs in medical specialist care (Dutch Health and Youth Care Inspectorate, 2024).

Existing scholarship on the involvement of P/N in SAE investigations in Scotland, Norway and the Netherlands shows elements that P/N experience as "good". P/N underline the importance of being heard, being included in the investigation, and being made aware of hospitals' learnings (MqQueen et al., 2022; Wiig et al., 2021; Bouwman et al., 2018). P/N also emphasise an explanation of the investigation, a tailormade approach, and adequate responses to questions or concerns (MqQueen et al., 2022; Merten et al., 2019).

7.2 Research Methods

7.2.1 Aim, design and participants

A qualitative research design was chosen, including interviews and focus groups. The study employs data source triangulation to include a variety of perspectives and to validate the findings (Carter et al., 2019). The data are collected on three levels: P/N (personal perspective), representatives of client councils at sixteen Dutch hospitals (institutional perspective), and a key representative of the Patient Federation Netherlands (PFN) that represents over 200 patient organisations (national perspective). Ethical approval was given by the Tilburg Law School Ethics Review Board.

7.2.2 Participant recruitment

7.2.2.1 Participant recruitment: patients and next of kin

The recruitment of P/N was part of a larger study (Friele et al., 2023) and followed a step by step approach because researchers could not approach participants themselves due to privacy regulations. Researchers reached out to all 74 hospital boards in the Netherlands for participation in the broader study, of whom 37 participated. All 37 were asked to approach P/N and 20 hospitals indeed approached them.

The recruitment of P/N is based on a convenience sample because of the way researchers had to approach P/N, potentially causing selection bias. Each participating hospital (n=20) was asked to approach eight P/N. Each P/N's SAE investigation was finalised at least six months and at most 18 months before this research to support recent cases where patient involvement was mandatory. Not all hospitals were able to approach eight P/N given the low number of SAEs so they approached fewer potential participants or widened their scope to earlier SAE investigations. The information letter compiled by the researchers was distributed by the hospitals. It contained all information pertaining to the study, a topic list for the interview, and a registration form that P/N could send directly to the researchers. The topic list informed the line of questioning and had five main topics: respondents' demographic characteristics, the specifics of the SAE, respondents' involvement with the SAE investigations, respondents' experiences with the SAE investigations, and person-centered aftercare. Researchers sent out reminders to all hospitals and asked the two participating academic hospitals to approach an extra eight P/N because of their higher frequency of SAE investigations.

7.2.2.2 Participant recruitment: representatives of client councils

Researchers sent out digital invitation letters to the client councils connected to the 74 hospitals. Client councils are mandatory and serve as a representative body to healthcare institutions to serve the best interests of patients and clients (Article 3 Participation of Clients in Health Care Institutions Act 2018). In total two focus groups were held with sixteen representatives of client councils, one digital (n=12) and one live (n=4). To keep the number of participants reasonable (max twelve) we conducted two focus groups instead of one. Three additional representatives wanted to participate, but their registration was filed after the focus groups were concluded and data saturation had been reached.

7.2.2.3 Participant recruitment: Patient Federation Netherlands

Researchers approached the PFN directly and received contact information of one key representative who advises on patients' interests and was most suitable to the topic. The PFN represents over 200 patient organisations and aims to give patients a voice, for example in politics or at healthcare insurance agencies. Figure 1 shows a flow chart of all participant recruitment.

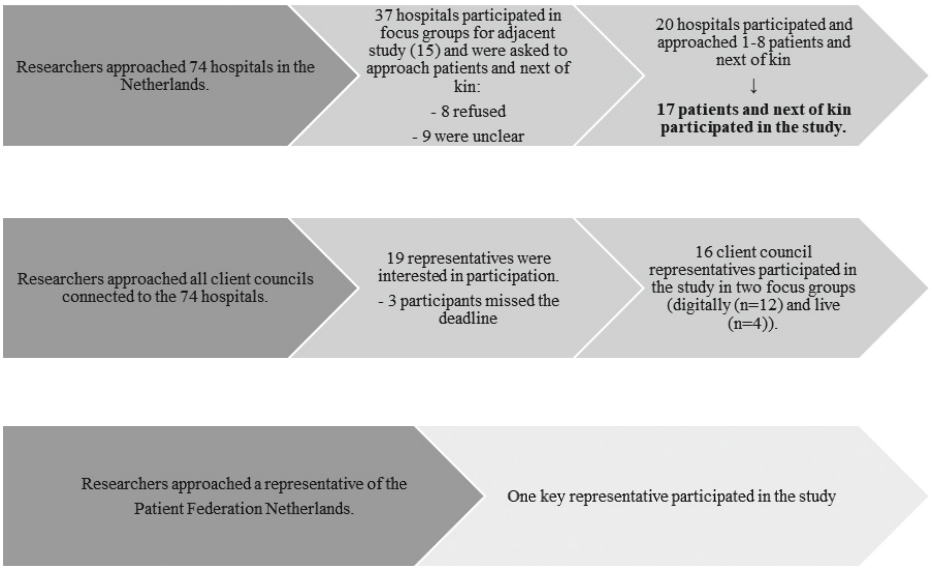


Figure 1. Recruitment of respondents.

7.2.3 Data collection

The interviews with P/N were conducted by three researchers (RD and LK or intern) from December till February 2022-2023. Researchers conducted eleven semi-structured, face-to-face interviews with seventeen P/N until data saturation was reached. No new themes emerged from the last interviews. The cases were spread geographically across the Netherlands. Interviews took place at the participant's house or at a conference center in one occasion. Informed consent was given prior to the interview.

Three researchers (RD and LK or intern) conducted the focus groups with client council' representatives and the interview with the PFN in October-November 2022. The two focus groups were conducted digitally (n=12) and live (n=4), based on the preference of the participants. The interview with the PFN had an open structure and was done digitally by two researchers (RD and RF). The interviews with P/N took between 52 minutes and 70 minutes, the interview with the PFN took 45 minutes, and both focus groups lasted 60 minutes. All data were recorded, transcribed verbatim, and anonymised. Researchers sent out a resume of each interview or focus group to the participants for validation, asking for active approval by e-mail or passive approval by not responding and therefore not disputing the contents. No one withdraw from participation.

The main interview question was: how do P/N or their representatives view the involvement of P/N in SAE investigations? Additionally, how did P/N experience their own involvement? Questions during the interviews and focus groups centered on five themes. For the interviews, the first line of questions concerned demographics and the background of the SAE. The second part considered the beginning of P/N involvement with SAE investigations. For example: How

was the communication regarding the SAE investigation and your role in it? Third, questions focused on P/N's experiences with the investigation process, resulting in questions such as: How did you experience your own role during the SAE investigation? As a follow up: How did you feel you were heard? Fourth, P/N were asked about the closing of the SAE investigations. For example: How were you kept informed about the progress of the SAE investigation? The final theme considered person-centered aftercare after the investigation was finalised. These questions centered for example on the extent to which P/N had experienced aftercare. For the focus groups, each of the five themes was brought up as starting point for an in-depth discussion. We have included the translated questions that we asked the P/N in Appendix 1.

7.2.4 Analysis

In analysing the interviews with P/N and the PFN and both focus groups, the first and second author (RD and LK) followed Braun and Clarke's six phases of thematic analysis (Braun & Clarke, 2023). The analysis was inductive, data-driven and done using MAXQDA software. Both authors (RD and LK) extracted themes from the data and crossmatched them to see whether all important themes were flagged and included in the results. The focus in all analyses was on views, experiences where applicable, and reflection (depicting the patient perspective).

Both authors (RD and LK) first read through all transcripts (phase one) and applied a first round of open, initial codes to the data (phase two). Then they combined and regrouped codes to form themes (phase three). They reviewed and cross-matched the themes (phase four) and

finalised them (phase five). This article reports the main results relevant to the research question (phase six) and is in line with Tong's 32-item checklist (Tong et al., 2007). This filled-in checklist is included in the article as Appendix 2. The article contains quotes to illustrate the results and Table 1 shows an example of how themes were extracted from the data (interviews and focus groups). All quotes have been translated from Dutch to English by the first author.

Table 1. Example of data analysis, final theme "Being heard and listening to individual needs".

Data extract →	Initial coding (phase two) →	Searching for themes (phase three) →	Reviewing themes (phase four) →	Final theme (phase five)
"Because we sifted through the serious adverse event investigation report, really to the letter, to the comma […]" (#11A and B)	Feeling of wanting to contribute and ask questions	Active participation in the investigation	Ideas about your own role	P/N as stakeholders that choose how to participate
"It is best if they do their own internal investigation without me asking all sorts of questions. Because what kind of questions should I ask?" (#5)	Feeling no need to contribute to the investigation.	Consciously passive during the investigation		
"She said: 'well, do you want to participate? And I said: 'yes, I do want to participate.' Of course, that is the main question.'" (#1)	The main question is whether I want to participate.	Important to be able to say whether and how you want to be involved.	Everyone is different and has different needs	
"I knew that [the investigation] was going to happen, and that was enough for me." (#10)	Knowing that the investigation would happen was sufficient.	Having no insight into the investigation was OK.		
"[…] we find it important, at such a serious adverse event investigation, that you listen to the individual needs of patients and next of kin" (focus group 1)	The individual matters.	Listen to individual needs.	Listening to individual needs	
"Who is sitting across from you and what is important to that person?" (focus group 2)	People are different.	Consider what is important for different people.		

Table 1. Example of data analysis, final theme "Being heard and listening to individual needs". (continued)

"[…] it is the most important that you ask the patient what he or she needs" (Patient Federation Netherlands)	Ask the patient what he or she needs.	Needs can be different, make sure to discover them.	Listen to individual needs.

7.3 Results

7.3.1 Respondents' characteristics

Respondents can be subdivided into three groups: P/N, client council representatives, and the PFN. P/N identified as male (n=7) and female (n=10). The SAEs occurred in a multitude of hospital departments, including gynecology, urology, oncology, neurology, gastro-enterology, internal medicine, and cardiology. For an overview of P/N and their specific cases, see Table 2. Representatives of the client councils identified as male (n=5) and female (n=11), see Table 3. The representative of the PFN identified as female, see Table 3.

Table 2. Demographics of patients and/or their next of kin.

Interview	Patient and/ or their next of kin	Gender	Age	Short case description
1	Patient	Female	40-60 years	Patient undergoes a severe operation after a missed diagnosis.
2A and B	Patient and husband	Female and male	>60 years	Severe heart attack after following the advice of her physician.
3A and B	Patient and wife	Male and female	>60 years	Malfunctioning device resulting in severe pains.
4A and B	Patient and wife	Male and female	>60 years	Patient undergoes intestinal surgery after a missed diagnosis.
5A and B	Patient and wife	Male and female	40-60 years	Invasive heart surgery after an earlier heart attack was overlooked.
6	Wife	Female	>60 years	Patient undergoes intestinal surgery after trauma was overlooked.
7	Wife	Female	>60 years	Damage to digestive tract, eventually resulting in the death of the patient.
8	Husband	Male	>60 years	Patient undergoes surgery. Scepsis led to the death of the patient.
9A and B	Patient and wife	Male and female	40-60 years	Patients suffers from a severe tumor due to a missed diagnosis.
10	Patient	Female	>60 years	Physician starts to operate on the wrong side, no irreparable damage.
11A and B	Husband and son	Male and male	>60 years 20-40 years	Patient undergoes surgery but her deteriorating condition is not properly diagnosed, resulting in the patient's death.

Table 3. Demographics of client council representatives & Patient Federation Netherlands.

Focus groups Client Council Representatives	Number of participants	Gender
1 (digital)	12	8 female, 4 male
2 (live)	4	3 female, 1 male
Interview Patient Federation Netherlands Representative	**Number of participants**	**Gender**
1	1	Female

Six main themes emerged that were paramount in what P/N, client council representatives and the PFN considered important. The identified themes were: P/N as legitimate stakeholders: recognition on hospital initiative (3.2); P/N as stakeholders that choose how to participate (3.3); the investigative report as a symbol of being a stakeholder (3.4); understanding SAE investigations as primarily aimed at learning (3.5); the inextricable link between the first conversation and the investigation (3.6); understanding SAE investigations as part of a broader experience (3.7).

7.3.2 P/N as legitimate stakeholders: recognition on hospital initiative

P/N appreciated that the SAE investigations started with the hospitals taking initiative (#2A and B, 4A and B, 5A and B, 8, 9A and B, 10, 11A and B). The hospitals in this sense took ownership of the problem and legitimated the P/N's positions as stakeholders to the investigations. Most P/N were asked to come in for one or more interviews with the investigating committee and a closing conversation with the responsible healthcare professional. Both were important elements for P/N (#1, 3A and B, 4A and B, 5A and B, 7, 8, 9A and B, 10, 11A and B). Being able to tell the story in your own sequence and pace felt good (#4, 8, 9A and B). As one patient recalled: *"Actually, the story I am telling you now, they let me tell it then, they had lots of patience. They did not make me feel like a layman [...]."* (#3). One patient explained that she did not feel she had to *"defend"* her position and was heard (#10). The transparency of the investigation provided one patient with the feeling of being taken seriously (#1). Client councils also considered that merely listening or having an actual conversation with P/N are two distinct things and they sometimes missed the latter.

7.3.3 P/N as stakeholders that choose how to participate

P/N were specific regarding whether and how they wanted to be involved as stakeholders during the SAE investigations. This shows different views on their roles as partners in the investigations. Some P/N valued an active role and considered themselves potentially contributing stakeholders during the investigation. They prepared for the meetings with the investigation committee (#1, 11A and B) and wanted to contribute (#4A and B, 11A and B). To one patient it felt logical to be involved, given that he was the subject of the investigation (#5A). One patient particularly considered setting the agenda together: *"They should have said: 'Let's set the agenda together and what are your items and what are our items?' [...] I don't sit here to contribute nothing."* (#1) Similarly, another P/N felt that adding questions to the report would have *"improved the quality of the report"* (#11B). Generally speaking, many P/N appreciated the potential to ask questions (#4A and B, 5A and B, 7, 8, 9A and B, 11A and B). This was also pointed out by the PFN as an

important element of the proceedings. Client council representatives generally emphasised the value of patient participation.

However, some P/N actively chose to refrain from participating or asking questions and did not consider themselves stakeholders that needed to be involved. Sometimes P/N (#5B, 6, 10) did not feel that they could add valuable information: *"What would you or I be able to add to the investigation?"* (#5B). Another patient considered that it was valuable and sufficient to know that the investigation was being done (#10). Also, one patient and her husband who were not heard by the investigation committee did not miss this (#2A and B).

The differences in whether and how P/N wanted to be involved emphasises the value of a tailormade approach. Listening to individual needs and really hearing and recognising the patient was also reiterated by the client councils (focus group 1 and 2) and the PFN. They emphasised the value of an approach *"tailored to the needs of the patient or next of kin"* (focus group 1).

7.3.4 The investigative report as a symbol of being a stakeholder

Generally, P/N felt that it was very logical for them (as stakeholders) to receive the final investigative report. This is not mandatory for hospitals in the Netherlands to provide. All P/N received the final report, except for two P/N (#3A and B, 10). One of them mentioned that she would probably not understand 80% of the report, even if she would have received it (#10). The other P/N (#3A and B) had notified the committee that they did not want to receive it. They were preoccupied by follow up care and had other things on their minds.

The positive meaning of the report for some P/N was recognition because it provided transparency (#1) and a feeling of being taken seriously (#5A and B), or it reflected the patient perspective (#9A): *"[...] the report was certainly written from my perspective"*. Sometimes the report even had symbolic value merely by its existence. The patient in this case did not feel like she needed to read it to understand its importance (#1). For some P/N the report meant an emotional confrontation with the SAE (#5A and B, 11A and B). Client council representatives agreed with the value of sharing the report and underscored ownership of the report by P/N (focus group 1). Though sometimes they considered that a summary would be sufficient, with the option to receive the full report upon request (focus group 2).

Oftentimes P/N did not particularly mention whether or not the SAE eventually was confirmed in the report. However, in two cases P/N did not agree with the final outcome of the report (#6 and 11). One spouse (#6) felt that the whole report was simply a *"denial"* of the SAE, particularly because the healthcare professional had said different things in an earlier conversation. Two next of kin (#11A and B) did not grant their approval for the final report that concluded that a *"potential serious adverse event"* had taken place. The adding of *"potential"* led to a lot of anger. They continued correspondence with the hospital until the *"potential"* element was retracted, which cost a lot of energy. They did not know whether the Inspectorate was made aware of the changed outcome.

7.3.5 Understanding serious adverse event investigations as primarily aimed at learning

Many P/N considered it to be crucial that the healthcare organisation and professional had learned from the SAE and that changes were made to prevent reoccurrence (#1, 2A and B, 3A and B, 4A and B, 5A and B, 7, 9A and B, 11A and B). For example, a spouse recalled: *"We only wanted them to show us what they would change so that there would be no more victims."* (#9B) Client councils also considered that SAE investigations are less relational and more preventative in nature, but thought this might conflict with patients' needs (focus group 1). The PFN was explicit about the need to be transparent about changes made, ideally beyond just mentioning them in the report.

Some P/N felt reassured that changes were made as a result of the SAE investigation (#2A, 3A and B, 4A and B, 5A and B, 7, 8, 9A and B, 10, 11A and B). For example, several reports included improvement measures and specified what had been done already (#4A and B, 5A and B, 8, 11A and B). In some cases the healthcare professional was very specific and thorough with regards to communicating how he or she had learned and would prevent reoccurrence (#10).

In other cases, P/N did not have specific knowledge of the changes made (#3A and B, 7, 10). And finally, some P/N felt they did not have sufficient insight into improvements and changes made or even experienced a lack of changes (#1, 2B).

7.3.6 The inextricable link between the first conversation after the serious adverse event and the investigation

P/N identified their (continued) contact and connection with the healthcare professional and started with their experiences of speaking with the first responder – many times the same healthcare professional. This disclosure conversation was therefore inextricably linked to the SAE and the subsequent investigation. During the disclosure conversations, P/N considered openness about the events to be crucial (#4A and B, 5A and B, 7, 10). Taking responsibility and admitting that something went wrong was also highly appreciated, sometimes as recognition (#1, 2A and B, 5A and B, 10): *"When you are prepared to say: 'sorry, this did not go well and I want to take responsibility for this', then you immediately open the way."* (#10) This patient asked her physician to perform the next surgery despite the SAE. She did so to find closure together and for her physician to move on. Some P/N emphasised that it is human to make mistakes and some P/N sympathised with the professional (#2A and B, 3A and B, 4A and B, 5A and B, 8, 9A and B). Some P/N reiterated the trust they still had in the hospital (#7, 9A and B).

Client council representatives and the PFN also underlined the necessity of openness and honesty during disclosure talks, even though this might be hard for healthcare professionals (focus group 2). Client council representatives and the PFN considered the importance of *who* conducts the conversation with P/N, leaning towards a combination of the healthcare professional with an independent patient contact person. Generally, consistent communication should be *"top of mind"* (focus group 1). This was also underlined by P/N. The PFN emphasised the value of equal partners in the conversation. P/N considered it to be positive that healthcare professionals did not hide behind their co-workers and external circumstances (#2A and B, 10). A different response

might have triggered a different, angrier reaction (#2A and B, 10): *"If he had slipped off all this [responsibility, red.] on someone else, then it would have been something else entirely."* (#2A)

7.3.7 Understanding serious adverse event investigations as part of a broader experience
Apparent in many of the cases was the continuing need for healthcare, even after the investigation was finished, and the major impact of the SAEs on the lives of P/N. The SAEs meant a prolonged duration or intensification of the care needed, for example oncological or surgical care due to a missed diagnosis (#1, 9A). The continuing substantive care and poor health as a result of the SAE meant that many of the P/N were preoccupied with surviving or caring for their loved ones during the time of the SAE investigations. Despite its felt importance, P/N had other things to deal with: *"We did not concern ourselves with it (the investigation, red.) because we were busy with other things – his recovery, his rehabilitation."* (#5B).

Therefore the relationship between P/N and healthcare provider oftentimes continued. With regards to this relationship, P/N expressed how they appreciated a heightened level of (customised) care (#1, 2A and B, 4A and B, 5A, 10). P/N felt like they – unofficially – received a bit of preferential treatment, for example extra attention (#2A and B, 5A) or fast follow up appointments (#4A and B). One patient phrased this as: *"[...] now I am a VIP patient"* (#2A). Client councils also highlighted the value of *"customised caring"* (focus group 1), but the PFN stressed that there are limits to aftercare in terms of time lapsed. Some P/N missed extra sensitivity after the SAE (#1, 9). For one patient follow up care felt rude and reactivated the endured trauma (#1). It made her feel like the hospital had learned nothing. She would want an "*exclamation mark behind [her] name"* to not be overlooked.

All P/N were aware of the option to file a complaint or claim, but only one spouse indeed hired a lawyer (#6). The spouse and her family felt that the hospital was unjustly denying what had occurred. In another case the next of kin wanted to take some more time to decide on further proceedings (#11A and B). All other P/N consciously refrained from further proceedings for a variety reasons. Some did not want all the fuss and the *"circus"* (#4A) of extra proceedings (#2A and B, 4A and B, 5A and B, 9A and B, 10), the *"negative energy"* (#1) or questioned what you would gain (#2A and B, 4A and B, 9A and B). One patient ironically said *"this is not America"*(#3A).

7.4 Discussion

This research set out to understand how P/N and patient representatives view patient involvement in SAE investigations, particularly whether, why, and how they want to be involved. Main results include that P/N appreciated the initiative of hospitals to start SAE investigations and to include them in these processes as legitimate stakeholders. The hospitals' initiative made people feel heard. P/N generally wanted to know of changes made but they differed in how much they wanted to partake in the investigations. P/N considered the investigations in correlation with their first

talks with the healthcare professionals disclosing the event and with the enduring relationship after the investigations.

7.4.1 Patient perspectives

First, the experiences and views of P/N in this study all correspond to each P/N's position as a stakeholder. This position is not restricted to the SAE investigation. It rather spans the whole care relationship that starts with the first intake and continues after the investigation is finalised. In these relationships all P/N have a stake, namely their health and safety. The SAE investigation in this regard is a procedure that is introduced in the *existing* relationship between P/N and the healthcare provider. It is therefore, from the perspective of P/N in the Netherlands, nearly impossible to evaluate SAE investigations in a vacuum.

Hence, P/N's experiences of SAE investigations are highly influenced by the first responder after the SAE, the interview by the investigating committee, and by the ongoing care after the investigation is finalised. P/N in this study reported positive experiences regarding open and non-defensive conversations with healthcare professionals, who usually were the first responders disclosing the SAE. These conversations were not the official start of the investigations, though inextricably linked to them. The importance of an open demeanor was also emphasised by client council representatives and the PFN. It confirms previous findings regarding open disclosure (Dijkstra et al., 2021) and indeed shows the importance of the professionals' interpersonal skills (Merten et al., 2019; Wiig et al., 2021;). The existence of just (organisational) culture is paramount in this regard, safeguarding an environment in which learning can co-exist with accountability (Dijkstra et al., 2022; Peerally et al., 2017; Zimmerman et al., 2007). P/N were interviewed during the course of the investigation, which they appreciated. P/N's positive experiences could explain why P/N in this study generally felt that there was room for their emotions, despite the inherent variety (Kok et al., 2018). The ongoing care after the investigation was also important. Peerally et al. (2017) have suggested a professionalisation of SAE investigations, meaning specialist expertise, which could indeed support good practices. The present study shows that such professionalisation should address all stages, i.e. before, during and after the SAE investigation. Scholarship regarding (good) open disclosure therefore applies. Notwithstanding differences between different healthcare settings, parallels can be drawn between P/N views in this study to other forms of (long-term) care such as disability care centers. The continuity of the care relationship is even more prominent in those settings.

Second, the data show that the hospital initiating the proceedings was paramount to signal to P/N that they were taken seriously as stakeholders and that they felt heard. The need to be heard resonates with scholarship worldwide (Dijkstra et al., 2017; Moore et al., 2017). The initiative shown by hospitals in this study solidifies P/N's "place at the table" (Etchegaray et al., 2016) and we believe it could be considered an exemplary practice. The initiative to start up these investigations lies with hospitals, who in this sense take ownership of the problem. Such initiative lacks in complaints processes and adversarial litigation. For example, at dispute committee proceedings you as a complainant are burdened with filing a complaint (Dijkstra et

al., 2017). Similarly, filing a civil lawsuit is always dependent on the plaintiff (Moore et al., 2017). Scholarship regarding the experiences of P/N in dispute committees for example shows a lack of feeling heard (Dijkstra et al., 2017).

Another relevant aspect related to initiative was the unconditional offer of the report to P/N as stakeholders. P/N felt entitled to the reports dealing with their cases, sometimes simply as a symbol of their involvement, which hospitals should not deny them. Previous work has emphasised legal challenges or fears associated with sharing the report or its use in the media in addition to covert patient conduct (Bouwman et al., 2018; Grissinger, 2011; Kok et al., 2018; Zimmerman et al., 2007).

However, this study does not show such risks. Respondents, apart from one, did not start follow up, legal processes, despite the fact that (almost) all of them received the investigative reports. On the contrary, the mandatory and valued inclusion of P/N could be seen as preventing these challenges, as was suggested by Wiig et al. (2021). Especially since negative experiences of feeling overlooked and excluded did show an increased risk of legal proceedings (McQueen et al., 2022). Cultural differences should be born in mind when translating this particular finding to international settings.

Finally, many P/N considered it crucial that the healthcare organisation would learn. In this sense they underlined the original goal of such investigations and echoed earlier findings on the need to be made aware of the changes made for prevention (Bouwman et al., 2018; Dijkstra et al., 2017; McQueen et al., 2022; Wiig et al., 2021). However, whether or not they wanted to actively contribute was a more nuanced affair. A factor in this regard might have been the intensive care needed for some P/N after the SAE, taking up all energy, or the emotional toll of participation (Grissinger, 2011; Wiig et al., 2021). Given these multiple interpretations regarding involvement, P/N should be considered autonomous stakeholders and given the opportunity to choose whether or not to participate and in what form. Such autonomy would be hindered by making it contingent on psychological and emotional readiness and screening as suggested by Peerally et al. (2017) and Zimmerman & Amori (2007). In a way, the 'conflict' caused by the SAE between P/N and the healthcare provider is taken away from them if the P/N is not allowed to participate (Christie, 1977). The P/N as a victim is a "loser" in this sense, whilst participation in the investigation and thus the conflict could be valuable for healing (Christie, 1977).

7.4.2 P/N motivations to participate in serious adverse event investigations

The different motivations P/N expressed about being involved in SAE investigations can be understood in the framework of the Big Two of social motivation: agency and communion (Abele & Wojciszke, 2007; Moore et al., 2017). Agency motivations concern "individual striving, competence, power and instrumentality", while communion-related motivations include "social relatedness, warmth, expressiveness and affiliation" (Pemberton et al., 2017). Victimological work discusses the infringement on a victim's agency and communion through crime, which justice processes could potentially help to rebuild (Pemberton et al., 2017). At criminal trials for

example, this could be done by a victim impact statement that requires a victim to share his or her victimisation experience (Willinsky & McCabe, 2021). From this angle, a healthcare incident could be construed as an infringement on P/N's sense of agency and communion. Understanding healthcare incidents as such infringements could illuminate the motivations of P/N to participate in SAE investigations. Participation in these processes could help restore their sense of agency or communion and therefore support their well-being (Kragting et al., 2023).

Respondents in this study show several agency motivations, most prominently the freedom as stakeholders to choose whether or not to participate and in what form. By being offered the choice to be a part of the investigation, respondents show a certain regaining of control, of agency. The initiative taken by the hospitals provided room for this. Some P/N in the study wanted to have an active role, to ask questions, and to actively contribute to the investigation. They prepared thoroughly for their interviews with the investigative committees. Enacting influence in this manner shows agency motivation, the same as demonstrated by victims of crime (Willinsky & McCabe, 2021). Other P/N specifically did not want to participate, which emphasises their need to choose. Also related to agency is the finding that many P/N felt entitled to the report. P/N as such seem to understand their own position and status (Pemberton et al., 2017) as stakeholders that have a right to the investigative report.

The present study also shows communion motivations, which center around relations and making connections. P/N appreciated that they were taken seriously. They oftentimes felt continuously heard throughout the investigation by the healthcare professional disclosing the SAE, the investigative committee, and the healthcare professionals in charge of the follow up care (the notion of a VIP patient). Safeguarding and being mindful of the relationship between P/N and healthcare provider and offering dialogue are all aspects that support communion, as was apparent with victims of crime (Willinsky & McCabe, 2021). Such communion is even more noteworthy in those instances where P/N felt sympathetic towards the healthcare professionals: the relationship continues or is reestablished. Lastly, P/N emphasised the need for hospitals to learn from the SAEs and to make sure it would not happen again. This focus on prevention shows a certain care for others, a communion-driven idea that we as humans should not suffer from the same mistakes again.

As described above, P/N motivations to participate in SAE investigations are fueled by both agency and communion. Respondents often embodied motivations originating in both. Bearing that in mind while shaping the involvement of P/N is important to connect to patients' needs. Not addressing them can incite the opposites of agency and communion: feelings of ineffectiveness and alienation (McCabe & Dinh, 2016). A tailormade approach provides the space to really tune in and see what P/N need in terms of agency and communion, in an attempt to let the SAE investigation aid the restoration of these infringed aspects and the well-being of P/N.

7.5 Strengths and limitations

This study provides an in-depth exploration of a multi-level patient perspective on patient involvement in SAE investigations. The findings in the Dutch context could inform similar processes internationally, given that SAE investigations and learning from SAEs are of interest to healthcare institutions worldwide. The results were validated through data source triangulation, data saturation, and data analysis by two authors (RD and LK).

A limitation of the study is the risk of selection bias because of the convenience sample of P/N and our inability to approach them directly. The hospitals had to approach them for us, adding an extra layer of potential bias. We might have spoken predominantly with P/N who had a positive experience during the SAE investigations. In addition, we only spoke with a small sample (eleven cases) and did not encounter P/N from a multicultural background. However, by using data source triangulation we attempted to counter these shortcomings. Particularly because client councils and the PFN can be considered associations where patient perspectives and experiences accumulate and are therefore most suitable to reflect on the views of P/N. Our focus on the patient perspective meant we explicitly left out the perspective of healthcare professionals.

7.6 Conclusions and recommendations

As opposed to previous studies, the majority of P/N in the present study seemed content with how the SAE investigations were conducted and what their roles were. Hospitals in the Netherlands should continue their efforts to actively initiate SAE investigations and involve P/N (Knap et al., 2024). Such ownership of the 'problem', albeit partially fueled by legislative requirements, should inspire healthcare institutions worldwide. When doing so, hospitals should provide P/N with the emotional and procedural room to choose whether and how to participate and be aware that to P/N the SAE investigation is only a part of the overarching care relationship. Providing room, means asking P/N about their preferences and making sure the investigation process allows P/N to participate in their own way. This can be fully, partially or not; immediately or later; face-to-face or through written accounts. How to do so while safeguarding legal guidelines, for example regarding terms, is beyond the scope of this paper. It would require a close reading of hospital guidelines on SAE investigations and the room it leaves for individualised processes.

Given the importance of open and non-defensive communication with the healthcare professional, attention should be paid to the interpersonal skills of these professionals. In addition, hospitals should be aware of the impact of the first responders – usually the healthcare professionals – on the subsequent investigations for P/N. Hospitals should make sure their healthcare staff has the training and skills to conduct these conversations in a sensitive and clear way. Previous findings on how to do open disclosure (well) are paramount.

By addressing the elements outlined above, SAE investigations can be tailored more closely to the motivations that drive the participation of P/N. P/N as stakeholders can therefore support learning and the safety of other P/N. If participation can be tailored to each individual's specific needs, chances of positive outcomes are greater both in terms of learning and healing.

Appendix 1

Interview questions patients *Translated to English.*

Background Information	
Demographic Characteristics	Gender Age Education level Employment Sector
Serious adverse event characteristics	Background of the Serious Adverse Event Healthcare Sector
Start: Involvement in the Serious Adverse Event Investigation	
Main Questions	Additional Questions
Can you describe the event that led to the serious adverse event procedure?	
What was the initial reaction and attitude of the hospital?	How did the hospital treat you?
	What was the attitude of the hospital (open/defensive)?
	What steps followed after that?
	To what extent was there room for your needs and expectations?
What were your expectations of the serious adverse event investigation?	What did you hope to achieve?
How was the communication regarding the serious adverse event investigation and your role in it?	Can you tell us about the information provided?
How was your involvement in the serious adverse event investigation structured?	At what point were you involved in the investigation? And by whom?
	What was the form of your involvement?
	How often were you involved in the investigation? Was it also possible not to participate?
Process: Experiences with the Incident Procedure	
Main Questions	Additional Questions
How did you experience your own role in the serious adverse event investigation?	How did you feel about being heard?
	To what extent did the procedure feel transparent and clear to you?
	In what way did you have room to guide the direction of the serious adverse event investigation?
	To what extent did you feel taken seriously?
What did you perceive as the goal of the serious adverse event procedure?	Did you feel there was room for restoration?

Interview questions patients *Translated to English. (continued)*

How was appreciation shown for your experiences and emotions during the serious adverse event procedure?	To what extent did you feel your interests were represented?
	To what extent did you feel taken seriously in your experience?
End: Discussions Concluding the Investigation	
Main Questions	Additional Questions
How did you learn about the Inspectorate report?	To what extent did you, or did you want to, review this report (fully, key points, provide feedback)?
How did you perceive the impact of your input on the hospital's learning process?	To what extent do you feel your input had a positive effect on the quality of care?
How were you kept informed about the progress of the incident investigation?	Did you have a specific point of contact?
To what extent were you satisfied with the design of the incident investigation?	What went well?
	What should the hospital or healthcare provider have done?
	What could be improved? Any recommendations?
Aftercare: Person-Centred Aftercare	
Main Questions	Additional Questions
To what extent did you experience aftercare during and after the serious adverse event procedure?	How long after the incident was this important to you? What form of aftercare do you find appropriate?
What are your expectations and needs regarding aftercare?	Was the aftercare tailored to you (customised)?
	Did you specifically need extra support or recognition?
	To what extent do you feel you have been able to close or process the serious adverse event?
What does good aftercare look like in your opinion?	What is needed for good aftercare?
	To what extent is aftercare necessary?
Has the serious adverse event investigation affected your trust in healthcare?	

Appendix 2

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Qualitative Health Care, 19(6): 349-357.

1.Interviewers	RD, LK, and RF.
2. Credentials	Refer to Title page.
3.Occupation	Refer to Title page.
4.Gender	Two female and one male.
5.Experience and training	Two PhD students, one professor.
6. Relationship established	No.
7. Participants' knowledge of the interviewer	Limited, participants were informed prior to the interviews about the goals of the research.
8. Interviewer characteristics	None.
9. Methodological orientation	Thematic analysis.
10. Sampling	Convenience sampling.
11. Method of approach	By mail.
12. Sample size	17 P/N, 2 focus groups, 1 interview with PFN.
13. Non-participation	None.
14. Setting of data collection	Homes of participants, digital (one focus group and the PFN-interview) and workplace (one focus group).
15. Presence of non-participants	No.
16. Description of sample	Table 2 and 3 on demographics (gender, age, background of adverse events).
17. Interview guide	Added as a supplementary file.
18. Repeat interviews	No.
19. Audio/visual recording	Audio recording.
20. Field notes	No.
21. Duration	The interviews with P/N took between 52 minutes and 70 minutes, the interview with the PFN took 45 minutes, and both focus groups lasted 60 minutes.
22. Data saturation	Discussed.
23. Transcripts returned	No, but a resume of each transcript was sent to each respondent for validation.
24. Number of data coders	Two.
25. Description of the coding tree	No, but the six main themes were described and an example of the coding process is given in Table 1.
26. Derivation of themes	They were derived from the data.

27. Software	MAXQDA.
28. Participant checking	Yes, they gave their approval.
29. Quotations presented	Yes, with the participant number.
30. Data and findings consistent	Yes.
31. Clarity of major themes	Yes, at the start of results section.
32. Clarity of minor themes	Yes, throughout the results section.

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Chapter 8

General discussion and recommendations for practice

8. General discussion

In various countries, there is a growing emphasis on evaluating laws through national procedures designed for this purpose. These evaluations are essential to assess the effectiveness of laws in practice. It is not only important that that these evaluations are conducted meticulously, it is equally important that actions are taken based on the evaluation results. If insights from legislative evaluations are not utilised, one may question the purpose of conducting them. A real challenge lies in the effective implementation and utilisation of the evaluation insights and recommendations. While it is not the common practice to simply file away evaluation reports, there is always a risk that, without a strategic approach, valuable findings might not translate into actionable changes.

With this research, we aim to identify strategies that optimise the use of ex-post legislative evaluations, ensuring that their results are put into practice and drive meaningful improvement. By analysing the impact of previous evaluations, we seek to bridge the gap between theory and practice, reflecting the understanding that the evolution of law and its implementation is deeply informed by the practical experiences documented in these evaluations.

We offer insights and recommendations for practice, policy, and research to optimise the impact of ex-post legislative evaluations in the realm of healthcare and beyond.

In this chapter, we explore the main findings from each chapter of this thesis and highlight the study's strengths and weaknesses. Based on these findings, we answer the research questions in the subsequent paragraphs. Following this, we propose ideas for further research and provide recommendations for practical application.

8.1 Main findings

In this paragraph, we outline our main findings for each chapter, which are divided into three parts, each with its own focus and depth, following a logical progression. We will provide a clear and detailed overview of the insights we obtained. This approach helps to paint a coherent picture of the overall narrative and highlighting the key results of our work.

Part one – Creating a framework for assessing the impact of ex-post legislative evaluations

In the first two chapters, we conducted two scoping reviews that formed the basis for a framework that later served as a reference point in our research.

Chapter 2

The impact of ex-post legislative evaluations

In the international literature review on the impact of ex-post legislative evaluations extending beyond the healthcare sector, we identified the existing knowledge about the impact of ex-post legislative evaluations. It is important to note that about one-third of the literature included in the review were expert opinions, suggesting that we should be cautious in presenting these findings as definitive truths. Instead, they serve as a starting point for further exploration.

The review highlighted that the impact of these evaluations is not a singular, straightforward concept. Instead, it encompasses various types of impact that can be distinguished into seven categories: 1) knowledge and understanding, 2) confirmation of well-functioning legislation, 3) legislative revision, 4) influence on the legislative process, 5) influence on the policy process, 6) influence in the political sphere, and 7) influence on society. The study emphasised that the first type, knowledge and understanding, has a conditional nature in relation to the other types of impact.

We also identified a gap in the literature concerning the societal implications of ex-post legislative evaluations. While the impacts on legislative revision and tactical use within the political sphere were frequently mentioned at both national and European levels, the category of societal impact was rarely discussed, despite some incidental examples being reported. For example, legislative evaluations could raise public awareness on health-related issues such as patient complaints or more ethically charged topics like euthanasia and abortion. Through these evaluations, the public can gain a better understanding of the complexities and implications surrounding these issues, leading to more informed discussions and decisions. There remains a question of whether the impact on society is overlooked or may indeed be incidental.

Chapter 3

Factors influencing the impact of ex-post legislative evaluations

Building on the same extensive literature review from chapter 2, chapter 3 explored the factors that might influence the impact of ex-post legislative evaluations. Here we identified three main categories of factors: context, research quality, and stakeholder interaction. Contextual factors include the evaluation's initiation and function, commissioner's openness to the evaluation results, and the level of political or social attention. For example, if an evaluation of healthcare legislation is initiated at a time when there is a lot of public interest in that topic, it is more likely to receive attention and have an impact. These are external variables that researchers cannot directly control, yet they must contend with them.

The other factors, research quality and stakeholder interaction, represent categories where researchers might exert influence. Research quality involves the composition and independence of the research group, the research methods used, and the quality and content of the evaluation

report. For example, an evaluation conducted by a well-respected, independent team using robust methods will likely be more credible and could have more impact. Stakeholder interaction pertains to the engagement between researchers and stakeholders, the presentation and availability of research results, and timing. For instance, if researchers maintain regular communication with stakeholders such as policymakers and field parties and provide timely updates, the findings might be more likely to be utilised. Enhancing research quality and fostering productive interactions with stakeholders from preparation to implementation, could potentially increase the likelihood of impactful results.

Although a need was felt for stakeholder input, at the same time, a tension was noticed between this input and maintaining evaluation independence, a challenge highlighted in prior research (Winter et al., 1990). While stakeholder engagement can tailor evaluations to their needs, it may risk compromising independence.

Part two – Case studies on ex-post legislative evaluations in Dutch healthcare

In the following chapters, we illustrate how the insights gathered from the previous chapters converge into a framework for conducting our case studies. Additionally, we outline the methodology used for these case studies and subsequently present the findings derived from them.

Chapter 4

A study protocol for conducting case studies in Dutch healthcare
Chapter 4 outlines the study protocol detailing the practical implementation of insights gained from chapters 2 and 3. Here, we introduced the Realist Evaluation (RE) methodology for examining the impact of ex-post legislative evaluations in the Dutch healthcare sector. A RE design is well suited to assessing how interventions work in complex situations because it allows the evaluator to deconstruct the causal web of conditions underlying them (Pawson & Tilley, 1997). The evaluations conducted within the ZonMw programme, which are also the cases studies in this thesis. are such complex situations due to the multitude of variables at play, all of which interact with each other. Each evaluation is unique in terms of its impact and the factors that may influence it. To gain a deeper understanding of the factors influencing these divergent outcomes, the RE methodology is particularly well-suited for navigating such complex situations. This method served as a guide, aiding us in making informed choices necessary for conducting research within the complex dynamics of ex-post legislative evaluations. For example, we had to make strategic decisions on which specific factors to investigate and determine the breath or limitations of our scope. Following the RE method, our study protocol unfolds across three pivotal stages: the development of an initial programme theory, its subsequent validation, and eventual refinement. Informed by our earlier scoping reviews and expert consultations, we crafted

the following initial programme theory to steer our investigative efforts: 'Devoting attention to interaction and research quality during the evaluation process affects the impact of an ex-post legislative evaluation'. To validate this theory, we decided to conduct three distinct case studies, employing mixed-methods data collection including documentary reviews, structured questionnaires, and focus group discussions with pertinent stakeholders. In the protocol, the RE method remained central, enabling us to design a study to explore the relationships between contextual factors, research quality, stakeholder interactions, and the impact of the three ex-post legislative evaluations. Ultimately, based on the results of the three case studies, we refined the initial programme theory.

Chapter 5

Case studies of three ex-post legislative evaluations in Dutch healthcare
In chapter 5, we applied the framework we developed in chapters 2 and 3, and outlined in chapter 4, to three distinct and diverse ex-post legislative evaluations from the Dutch ZonMw programme: The third evaluation of the Embryo Act, the first evaluation of the Youth Act and the first evaluation of the Healthcare Quality, Complaints and Disputes Act (Wkkgz). These case studies were chosen specifically for their substantial differences, allowing us to test the robustness and versatility of our framework across varied contexts.

In contrast to the scoping reviews, which barely noted societal impact, our findings showed that all evaluations demonstrated significant impacts across policy, political, and societal domains.

The study identified three distinct phases in the evaluation process where decisions can be made to influence the potential impact. These phases include: preparation, execution, and dissemination/ follow up- which span a broader timeframe than the evaluation's execution phase itself. Factors influencing the impact of ex-post legislative evaluations, as identified in the previous scoping review, include context, research quality, and stakeholder interaction, all of which traverse these three phases.

Chapter 5 provided additional insights into these three categories of factors. An important new contextual factor influencing the impact of ex-post legislative evaluations within the ZonMw programme is the institutionalisation of evaluation practices. In earlier chapters where we developed the theoretical framework, we saw that in the existing literature contextual factors such as the evaluation initiation and function, and levels of political or societal engagement were mentioned critical in achieving impact. Additionally, we discovered from our case studies in this chapter that institutional structures also significantly influence impact. The institutionalisation of the ZonMw programme facilitates a natural path to impact on policy and politics and offers quality assurances for the reliability and validity of evaluations.

Furthermore, chapter five highlighted the timing decisions of the Minister as an important additional contextual factor. The Minister has the authority to advance or postpone evaluations,

a decision that can significantly influence the opportunity for the evaluation's impact. In two of the three cases, we examined that the Minister made adjustments to the timing. For example, the evaluation of the Youth Act was advanced and conducted shortly after its implementation, providing insights into the implementation status rather than prompting legislative changes. In contrast, the evaluation of the Embryo Act was postponed to align with prior evaluation recommendations that were still under consideration by the Ministry. This demonstrates that the Minister can assign different functions to evaluations, such as interim updates or comprehensive assessments, depending on the chosen timing. The function selected by the Minister is closely linked to the timing decision.

Chapter 5 also showed new insights regarding research quality and stakeholder interaction. We have seen that the content and structure of the evaluation, particularly the topic selection made by the researchers, are important for the potential impact of legislative evaluations. Additionally, all case studies highlighted the significance of how recommendations are formulated and whether they are specifically addressed. If recommendations are not clearly and concrete formulated and targeted to a specific recipient, it can be challenging to translate them into actionable steps in practice, and accountability may become unclear.

Insights into stakeholder interaction have also evolved from the study. During the execution phase, researchers can choose to engage stakeholders early to align the evaluation with their relevant concerns. All case studies demonstrated that this approach enhances the evaluation's relevance for involved stakeholders. Continuous involvement of diverse stakeholders throughout the evaluation process generates impact during the evaluation itself. At the conclusion of the evaluation process, researchers can assess the potential success of their recommendations within the evaluation's context. For instance, in the evaluation of the Embryo Act, researchers choose to recommend further in-depth research instead of legislative changes.

These insights underscore that while legislative evaluations operate within an established contextual framework, various actors—including ministers and researchers—have opportunities throughout the evaluation process to optimise its impact.

Part three – In depth research on serious adverse event investigations in Dutch hospitals following an ex-post legislative evaluation

In the next two chapters, we delve into an in-depth study conducted at the request of the Inspectorate, prompted in part by a recommendation from the evaluation of the Wkkgz. These chapters provide a deeper examination of the impact of this evaluation in the societal domain.

Chapter 6

The hospital perspective on the involvement of patients and/or their next of kin in serious adverse event investigations in healthcare

The study in chapter six was conducted as a follow-up to the evaluation of the Wkkgz, one of the case studies from chapter 5. In this evaluation, a recommendation was made to professional and patient organisations, in consultation with the Ministry and the Inspectorate, to develop an application framework for the Wkkgz. This framework should prioritise the importance of a learning organisation in the context of analysing and reporting a serious adverse event (SAE). The recommendation proposed to allow the Inspectorate the flexibility to tailor its supervision to the developmental phase of the respective sector and thus contribute to the hospital as a learning organisation. Although this recommendation offered guidance for the supervision, it offered the Inspectorate too little actionable perspective. Therefore, the Inspectorate commissioned further research with a more focused question on how patients and/or their next of kin (P/N) are involved in SAE investigations in Dutch hospitals and how their involvement related to the hospital as a learning organisation. It is noteworthy that the fact that the Inspectorate commissioned this further research can be seen as a form of impact resulting from the evaluation of the Wkkgz. This action demonstrates a direct response to the evaluation's findings and recommendations, indicating that the evaluation has influenced decision-making and prompted concrete steps towards improving practices in healthcare.

During the research we examined two perspectives: that of hospitals, particularly professionals involved in SAE investigations, and that of P/N. This chapter focuses on the hospital perspective. The topic proved to be of significant interest, as evidenced by the participation of 56 professionals from 37 out of the in total 74 Dutch hospitals (Friele et al, 2023). At the start of this study participants were asked about the impact of the Wkkgz evaluation on their daily practice, as it served as one of the reasons for this further in-depth study. The study revealed that the evaluation of the Wkkgz was relatively unknown among hospital professionals. While some were aware of the evaluation, they had taken minimal to no action based on the evaluation results and recommendations. This is noteworthy given that nearly one third of the evaluation recommendations were directed towards societal stakeholders including professional organisations, patient associations, and healthcare providers. Relevant individuals within the hospitals were closely involved in this in depth-study. Through active participation and the exchange of experiences and ideas, hospital professionals received concrete and practical tips and advice for involving P/N in SAE investigations. This equipped them with concrete tools that they could immediately implement and act upon insights during the study. The exchange of experiences and ideas among hospitals facilitated significant positive changes in hospital policies even before the study concluded. This in-depth study underscored the importance of making research results actionable for the relevant stakeholders. Specifically, it revealed that the initial evaluation recommendation from the Wkkgz evaluation lacked concreteness to effectively reach stakeholders within the societal domain.

Chapter 7

The patient perspective on the involvement of patients and/or their next of kin in serious adverse event investigations in healthcare

In chapter 7, the study that complements the findings of chapter 6 is detailed. Although part of the same overall study, this chapter delves deeper into the perspectives of P/N regarding their involvement in SAE investigations within Dutch hospitals. The study shows how P/N view themselves not merely as passive objects but as active participants in the process. P/N clearly articulated their role as stakeholders, emphasising their desire for meaningful involvement. While hospitals often seem to consider P/N primarily as sources of information or as objects to be studied during the SAE investigation process, the patients' perspective underscores their wish to be recognised and engaged as key stakeholders. They emphasised the importance of their experiences, insights, and concerns, advocating for a shift from being perceived as mere 'objects' to being acknowledged as 'subjects' with agency and valuable contributions to the study and its outcomes. One of the patients, for example, mentioned that being actively involved in the investigation process not only empowered them to contribute valuable insights based on their firsthand experiences but also fostered a sense of ownership and responsibility in improving patient safety within the hospital.

This shift in perspective highlights the need for a more inclusive approach to SAE investigations, where P/N are not just passive recipients of care but active partners in the healthcare process. Recognising and respecting their perspectives can lead to more comprehensive and patient-centered evaluations, ultimately enhancing the quality and relevance of the findings and thus contribute to learning from these investigations. This approach also addresses the somewhat open advice from the Wkkgz evaluation to the Inspectorate, emphasising that P/N want to be seen as active partners or stakeholders with their own interests.

8.2 Reflections on main findings

Answering the central question, which is broader than the specific sub-question on the Dutch situation, requires reflection on both the impacts themselves and the factors influencing these impacts.

To address the central question, we must first understand what impact entails. We have seen that impact can take many forms and occur in various domains. This is the focus of reflections 1 and 2. Understanding this is crucial before we can reflect on how impact can be influenced.

We observed that there is an institutionalisation of the evaluation process, primarily oriented towards policy and legislation. This is one of the strategies to optimise impact within these domains. In contrast, the route towards societal impact is not institutionalised. While societal

impact does occur, it requires different approaches, with an emphasis on interaction. This presents opportunities and leads to a new agenda, which is the focus of reflection 3 and 4.

Reflection 1. Impact is a multifaceted subject

Evaluating the impact of ex-post legislative evaluations is inherently complex, requiring careful consideration of numerous factors and variables. The multifaceted nature of impact stems from the divers types of impact, the diverse contexts in which impact can occur, the variety of stakeholders, and the different methodologies used in evaluations. To navigate this effectively, we first examined what impact actually entails. We defined impact in the context of ex-post legislative evaluations as ''the influence of these evaluations on various directly and indirectly affected parties''. This includes not only the immediate effects on legislative decision-making but also the broader societal consequences and changes in behaviour or practices within relevant stakeholders. Moreover, we saw impact as a mechanism consisting of three possible movements: becoming informed, disseminating information from the evaluation, and taking action based on participation in the evaluation study or the evaluation results. Understanding impact in this comprehensive way allowed us to assess the meaning of impact in the context of ex-post legislative evaluations.

The complexity of evaluating impact is a recurring theme in the broader evaluation literature. For example, earlier research on evaluating social interventions noticed that the complexity of evaluating impact lies in their multi-sectoral, non-linear, and time-delayed impacts (Mouton, 2009). This complexity is further compounded by the need to consider qualitative and multidimensional aspects, as well as the coherence of evaluation techniques (Bentivegna, 1994). In the context of health and social care interventions, the involvement of multiple stakeholders and the complexity of inputs and outcomes present significant challenges to economic evaluation (Byford, 2003). These studies collectively underscore the multifaceted nature of impact of evaluation studies, requiring a nuanced and flexible methodology. In line with this, it may be worth expanding our focus beyond the strict confines of legislative evaluations and considering the broader domain of evaluations where creating impact is also a central concern. By doing so, we can gain valuable insights and strategies that can be applied to legislative evaluations, enhancing their overall effectiveness and impact.

Reflection 2. Impact does not solely arise within the legal domain but also extends into society

In our study, we explored the concept of impact based on existing knowledge, as we did not discover new types of impact. The various types of impact identified in our research were already well-documented in the literature and were confirmed by our findings. We observed that international literature primarily focuses on impact within the legislative domain, encompassing both political and policy aspects (e.g. Mastenbroek et al., 2016; van Voorst & Zwaan, 2019; Zwaan et al, 2016). An example can also be seen in a guide to post-legislative scrutiny, where the conclusion is to use legislative evaluations to ensure parliamentary strengthening (De Vrieze, 2018). However, our study showed that the impact of ex-post legislative evaluations also extends

into the societal domain. For example, in the Wkkgz evaluation, we found that dispute resolution bodies, which fall under the Wkkgz and were involved in the evaluation research as respondents, actively responded in practice to the results of the evaluation.

This raises an intriguing question: Is it the intended purpose of legislative evaluations to create societal impact? Conducting multidisciplinary research at the intersection of law and social sciences provides a unique vantage point from which to interpret this question. From the perspective of a legal professional, the revelation that legislative evaluations can have implications beyond the legislative domain prompts reflection on the intended scope and purpose of such evaluations. Ultimately, it is the Legislature that can adjust legislation based on such evaluations, rather than society itself.

The focus of legislative evaluations has traditionally been on informing legislative decision-making, with adjustments to legislation being the primary outcome. This perhaps explains why the formal route is primarily orientated towards the legislative domain rather than the societal domain. Following legislative evaluations, the findings and recommendations are typically presented to the Minister. Adjustments to legislation are proposed and discussed based on the evaluation's findings. This formal process primarily focuses on the legislative domain, emphasising the role of policymakers in implementing changes to the legal framework. However, our study highlights the ripple effects that legislative evaluations can have on societal stakeholders and practices. This challenges conventional notions of the legislative process and underscores the importance of considering broader societal impacts when evaluating laws and regulations.

Legal professionals are thus tasked with acknowledging the transformative potential of legislative evaluations, recognising their capacity to shape not only legislation but also the wider societal landscape in which laws operate. This underscores the necessity for a different approach to legislative evaluations that encompasses the diverse stakeholders and societal contexts affected by legislative reforms.

From the perspective of a social sciences researcher, our findings offer a broader understanding of the impact of legislative evaluations, transcending the traditional boundaries of political and policy domains. The revelation of societal impact across all three cases underscores the intricate interplay between legislation and societal dynamics. This prompts a reevaluation of the intended purpose of legislative evaluations and their potential to catalyse societal change. Embracing this multidisciplinary perspective enriches our comprehension of the complex relationship between law and society, inviting further investigation into the role of legislative evaluations in shaping societal norms and practices. This holistic approach encourages exploration into the multifaceted ways in which legislative reforms intersect with broader societal dynamics, paving the way for deeper insights and transformative interventions. Thinking about the legal frameworks, rather than within them, as we do with legislative evaluations, can open the doors to greater societal participation.

Neglecting to consider societal impact represents a missed opportunity, particularly within domains like healthcare, where well-functioning laws hold immense societal importance. The overarching objective of legislative evaluations is to enhance the quality of legislation and make laws work better in the daily practice. Adjusting the legal text based on the evaluation results is just one approach to improve legislative quality. Legislative quality is not only about the legal text itself; it also concerns the implementation of these legal texts in practice. Hence, the daily practice can also be encouraged by legislative evaluations to improve the implementation of existing laws and regulations. This is a second approach to improving the quality of legislation and making laws work better in practice.

We must bear in mind that laws in healthcare involve parties with significant organisational capacity. Ultimately, it is the daily practice that is regulated by laws and regulations, and this practice shapes the reality for patients, professionals, and organisations. The field is essential for implementing the law, as it makes decisions through policy development and operational adjustments. These decisions influence how the organisation is perceived and shape the reality experienced by society.

Research impact is a topic that has been around for a long time and is receiving increasing attention (e.g. Penfield et al., 2014; Redman et al., 2015; Williams, 2020), also within ZonMw. However, ZonMw acknowledges that achieving impact in daily practices is difficult due to the implementation gap: the large gap between science and practice (ZonMw, 2023). This challenge also extends to legislative evaluations, given the current view that impact is primarily concentrated in the legislative domain rather than in the societal domain. An ex-post legislative evaluation could ideally bring these worlds closer together to minimise this gap. Therefore, it is all the more important to pay greater attention to the impact of ex-post legislative evaluations in the societal domain.

A significant amount of research has already explored ways to bridge the gap between science and practice (e.g. Green, 2014; Kankaria et al., 2024; Wilson, 2008). Action research, for example, which aims to bring knowledge and practice closer together, aligns with this effort. This approach is gaining traction in the research community and could provide valuable strategies for closing our identified gap. Such strategies may be useful for increasing societal impact of legislative evaluations as well.

Reflection 3. Impact can be influenced in different phases of the evaluation process

From our study, it is evident that achieving impact is not a singular event occurring after the completion of an evaluation; rather, it is integrated throughout the entire legislative evaluation process. This process spans from the initial preparation phase, through execution, dissemination, and follow up phases.

While conventional views tend to emphasise the impact of the final evaluation report upon its completion, our study underscores that the ongoing evaluation process itself offers numerous

opportunities for generating impact. Participants engaged in the evaluation can contribute ideas and insights that are swiftly integrated into evolving policies within their healthcare institutions or policy departments, even before the evaluation concludes.

This dual potential raises critical questions about desirability and control. While early impact can draw attention to the ongoing evaluation process, actions based on preliminary insights may lack comprehensive depth or completeness. This poses challenges in terms of managing expectations and maintaining rigorous control over the evaluation process, which could be seen as an opportunity as well as a vulnerability. Evaluation researchers might advocate for decisions and actions to await the final conclusions and comprehensive recommendations drawn from the entire evaluation process, ensuring a more controlled and informed approach to impact.

Starting to think about impact early in the process offers several opportunities. Firstly, it allows for the inclusion of relevant stakeholders from the beginning, ensuring their insights and needs are integrated into the evaluation design. This early engagement can increase the relevance and acceptance of the evaluation findings among those who will be affected by or responsible for implementing changes. We will discuss this point further in the next reflection point. Secondly, it helps guide the evaluation process, ensuring that the research addresses the most critical issues and produces actionable recommendations. By focusing on specific outcomes, researchers can tailor their methodologies and data collection efforts to generate insights that are directly applicable to policy and practice.

Another important impact of the evaluation process is its potential to foster widespread support for the evaluation results, thereby increasing the likelihood of achieving meaningful impact. By engaging participants throughout the evaluation process, immediate improvements and policy changes can be inspired, enhancing its relevance and effectiveness in informing future (legislative) decisions. This participatory approach, though potentially less controlled, can be instrumental in building a broader consensus and fostering a more profound and immediate impact on both policy and practice.

Early consideration of impact can help identify and address potential barriers to implementation, as we saw in the evaluation of the Embryo Act. By anticipating challenges, strategies can be developed to increase the likelihood that the evaluation findings will be acted upon. This proactive approach can involve creating a dissemination plan that targets key stakeholders and decision-makers, ensuring that the evaluation results reach the right audience at the right time. Moreover, early planning for impact encourages a more holistic view of the evaluation process. This means seeing impact as relevant throughout the whole evaluation process – from preparation to dissemination and considering not only the immediate outcomes of impact-related actions but also the long-term effects and broader implications of these actions and decisions from the outset. It promotes the integration of impact considerations into every phase, from setting objectives and selecting methodologies to analysing and reporting data, and disseminating the evaluation

results. This is in line with what is seen in implementation research in other domains (Geneletti, 2014; Roche, 1999).

The three factors influencing the impact as found in this study - context, research quality, and stakeholder interaction - play an important role in this way. Although we mentioned that the context is a more or less established given, research quality and stakeholder interaction can be seen as the buttons you need to tweak to increase the likelihood of impact. Our study showed the importance of making recommendations from evaluations actionable and concrete to be implementable. We have seen little effect of recommendations on society, no matter how well they were formulated. This indicates that more effort is needed to make recommendations from evaluations actionable and concrete.

We observed that, despite nearly a third of the recommendations from the Wkkgz evaluation being directed towards field parties, participants were largely aware of the existence of the evaluation, but not of its content and its recommendations. This suggests that the recommendations were not sufficiently concrete, actionable for application, or they were not effectively communicated to the societal domain. Subsequent in-depth research, based on a recommendation from this evaluation, underscored the necessity for further steps to reach the field and make the results actionable. It showed that the field require greater involvement and more concrete, practical tips and advice rather than abstract recommendations for practice to effectively utilise the evaluation results.

Reflection 4. Stakeholder interaction seems the dominant factor influencing the impact of ex-post legislative evaluations

Our research highlights that stakeholder interaction is the predominant factor influencing the impact of ex-post legislative evaluations. Engaging stakeholders throughout the evaluation process—particularly those from the societal domain—enhances the practical relevance and applicability of the research findings. It optimises impact, already during the execution of the evaluation.

The significance of stakeholder involvement extends beyond our research and resonates within the broader evaluation literature. Examining specific studies on stakeholder engagement in evaluation processes sheds light on its profound impact on the utilisation of evaluation findings. For instance, Cummings (1997) delved into the influence of stakeholder involvement in evaluation studies, uncovering that stakeholders not only substantially utilise evaluation information but also that their level of engagement directly affects the extent of this utilisation. This emphasises the pivotal role stakeholders play in shaping the outcomes and impact of evaluations. Building upon this insight, subsequent research by Fulton (2013) explored the implications of stakeholder engagement in management strategy evaluation. The findings revealed that such interaction not only enhances impact but also catalyses tangible changes across various dimensions. From alterations in project development to shifts in network interactions and even adjustments in stakeholder attitudes, the effects of stakeholder engagement permeate throughout the evaluation process.

While these studies underscore the importance of stakeholder involvement, it is crucial to acknowledge that each study brings its own nuances, tailored to specific evaluation domains and contexts. However, all studies mention that stakeholder interaction is vital for achieving impact.

In the realm of our own research, we observed that stakeholder involvement is crucial not only during the execution phase of the evaluation but also in subsequent activities after the finalisation of the evaluation report, such as further research and implementation. When stakeholders are actively engaged early on, including in the formulation of the evaluation assignment, the evaluations are better aligned with both the Minister's needs and the practical needs of the field. This early involvement ensures that the evaluation addresses relevant issues and that the findings are more likely to be embraced and acted upon by all parties involved (Oliver et al., 2018).

Furthermore, while the Minister's involvement is typically guaranteed as part of the commissioning process, it is equally important to organise engagement for stakeholders outside the Minister's immediate sphere. Effective engagement of these stakeholders can be a more significant determinant of impact than simply addressing recommendations to them. Field parties have expressed a clear preference for being active participants in the evaluation process rather than mere sources of information. This active participation aligns with the concept of co-creation, where researchers and stakeholders collaborate throughout the research process (Kaisler & Missbach, 2020). Co-creation fosters mutual learning, shared decision-making, and the co-development of solutions, making the research outcomes more robust and applicable. Along these lines, consideration could be given to selecting research methods that enhance interaction to varying degrees. A questionnaire, for example, typically fosters less interaction compared to methods like expert meetings or focus groups. Opting for these participatory methods can engage stakeholders in different ways and potentially facilitate greater exchange of information. Empowering stakeholders with a larger role can yield diverse outcomes by increasing their engagement and contributing to a broader construction of reality that may hold greater value for them. This insight suggests that contemplating more interactive methods over deductive approaches could enrich the research perspective.

However, a possible bottleneck with early and close stakeholder involvement is the independence of the research. If the focus is too much on achieving impact by accommodating the wishes of stakeholders, the question arises whether the research is still sufficiently independent. While research independence can be influenced by factors such as the assignment and the preferences of the Minister as the commissioner, it is essential that independence is adequately safeguarded at all times. Stakeholder involvement could potentially undermine this independence. This challenge is also underscored in policy evaluation theory, where various studies emphasise the challenges and dilemmas that evaluators face in finding the right balance between involvement and independence (e.g. Pleger & Hadorn, 2018; Pleger & Leeuw, 2021; Simons, 2006; Singh, 2021). On the one hand, close involvement of stakeholders can provide valuable insights, increase support for evaluation results, and strengthen the relevance and usability of the findings. On the other hand, excessive involvement can undermine the objectivity of the research because evaluators may

be influenced by the interests of stakeholders, thereby compromising their independence. This approach aligns with principles from participatory action research, which involves stakeholders throughout the research process to ensure practical applicability and relevance (Dorant, 2020). While participatory action research can significantly enhance the impact and acceptance of the evaluation findings, it also poses the risk of compromising research objectivity if stakeholder interests overly influence the process. Therefore, while participatory methods can be instrumental in building consensus and fostering immediate policy improvements, it is crucial to maintain a careful balance to preserve the integrity and independence of the research.

It is crucial to recognise these challenges and develop strategies to maintain the balance between involvement and independence. One potential strategy is to schedule specific moments where stakeholders can be involved in different roles at various stages of the evaluation process. For instance, they could participate as experts during the preparation phase, as active participants during the execution phase, and at the end of the study to review draft recommendations as potential recipients and implementers of these recommendations. Additionally, transparency in the research process, clear guidelines for researchers and stakeholders, and regularly evaluations of the level of involvement can also help to ensure a balanced and objective approach to the evaluation research.

8.3 Answering the research quetions

Drawing from the findings of this study and our reflections, we can now answer both the sub-questions and the central research question that guided our work.

This research question is intentionally broad, designed to encompass a wide range of impacts and factors. To address this comprehensively, we have formulated sub-questions that progressively narrow the focus. This approach allows us to start with a broad understanding and then delve deeper into specific areas of the Dutch context. By doing so, we ensure a thorough examination that covers both general and detailed insights into the impact of ex-post legislative evaluations.

We will start by answering the sub-questions before proceeding to the central question.

Sub-question 1. What is a relevant framework for assessing the impact of ex-post legislative evaluations and the factors influencing this impact?
This sub-question consists of two parts, both of which we address below.

1a. What types of impact of ex-post legislative evaluations can be distinguished?
In this study, we explored impact not merely as a static concept but as a dynamic manifestation of how ex-post legislative evaluations influence a wide range of directly and indirectly affected parties. This perspective allowed us to delve into the multifaceted ways in which these evaluations shape policies, practices, and perceptions within their respective domains.

The scoping review resulted in seven distinct categories of impact of ex-post legislative evaluations : 1) knowledge and understanding, 2) confirmation of well-functioning legislation, 3) legislative revision, 4) influence on the legislative process, 5) influence on the policy process, 6) influence in the political sphere, and 7) influence on society.

With the first category knowledge and understanding as a preconditional type of impact, this study showed that categories 2-7 can be divided into four domains in which impact can be present: legislative domain, political domain, policy domain, and the societal domain. Although politics and policy fall under the legislative domain, we mention this domain separately to specifically address the legislative functions.

1b. What factors influence the impact of ex-post legislative evaluations?
The results of this study showed that we can distinguish three main categories of factors that may influence the impact of ex-post legislative evaluations: context, research quality, and stakeholder interaction.

Contextual factors encompass the institutionalisation of the evaluation process, the characteristics of the law and legislative process, evaluation's initiation (including timing and the number of timed the law has been evaluated), function, and openness to results and the level of political or social attention.

Research quality factors encompass the composition, authority and independence of the research group, the research methods employed and the research setup, and the quality and content of the evaluation report (topic selection, formulating and addressing recommendations).

Stakeholder interaction factors encompass the engagement between researchers and stakeholders, the presentation and availability of research results, and the timing of involving stakeholder.

The domains from sub-question 1a and the factors from sub-question 1b form a relevant theoretical framework from this study for optimising impact of ex-post legislative evaluations. See this overview:

Identified domains:	Identified factors:
• Legislative domain • Political domain • Policy domain • Societal domain	**Context** • Institutionalisation of the evaluation process • Characteristics of the law and legislative process • Evaluation initiation (including evaluation timing and the number of times the law has been evaluated), function and openness to results • Political and societal influence **Research quality** • Composition, authority, and independence of the research group • Methods employed and research setup • Quality and content of the evaluation report (topic selection, formulating and addressing recommendations) **Stakeholder interaction** • Interaction between researchers and stakeholders • Presentation and accessibility of research findings • Timing (prior to, during and after the evaluation)

Sub-question 2. What is the impact of ex-post legislative evaluations in Dutch healthcare?
The long-term ZonMw programme dedicated to evaluating healthcare legislation has not only produced legislative evaluations but has also contributed the development of a well-defined approach, strengthening the capacity to conduct these evaluations effectively. The impact of evaluations from this programme is multifaceted and extends beyond the traditional legislative, policy and political domains. The three evaluations studied also showed impact within the societal domain.

These evaluations enable stakeholders to do three things: become informed, disseminate information from the evaluation, and take action based on participation in the evaluation study or the evaluation results. Specifically, we observed that individuals within the policy and political domains, including the Minister, are perceived to become informed and take action, whereas those within the societal domain primarily become informed and disseminate information from the evaluations, for example on their website or in newsletters.

With regard to policy and political impact, the ex-post legislative evaluations have been instrumental in enhancing the quality of legislation governing healthcare in the Netherlands. The evaluations have influenced policy decisions and political discourse by providing evidence-based insights into the effectiveness and efficiency of healthcare legislation. For example, after the evaluation of the Wkkgz and Embryo Act the Minister announced amendments to the law and planned further changes based on evaluation recommendations. Politically, the House of Representatives conducted after the Embryo Act evaluation an internet consultation, sought advice from the Health Council, and incorporated recommendations within ministries. Additionally, the coalition agreement included plans based on specific evaluation recommendations, leading to parliamentary questions and extensive political debate. Legislative evaluations have played a crucial role in enhancing transparency and accountability within governance, ensuring that decisions are evidence-based and responsive to the needs of the public. By providing feedback,

identifying unintended consequences, and making informed adjustments, the evaluations have contributed to improving the quality of legislation and fostering trust in democratic institutions. These evaluations have facilitated knowledge sharing and learning within the healthcare sector, leading to improvements in legislative quality and governance practices.

The impact of the ex- post legislative evaluations extends to the societal domain, involving citizens, healthcare professionals, and organisations directly affected by health-related legislation. Stakeholders in the healthcare sector have taken notice of the evaluations, disseminating findings through websites, newsletters, and discussions, leading to actions taken based on evaluation results. The evaluations have contributed to enhancing the public's understanding of laws, fostering greater democratic debate, and facilitating interactions among various stakeholders in the healthcare system. In all three cases, though incidentally, individuals within the societal domain took action either during or after the evaluation. For example, in the evaluations of the Wkkgz and the Youth Act, sector associations criticised the scope of the evaluations in letters to the House of Representatives. Similarly, for the Embryo Act, a research institute produced a critical public report. Despite this, societal parties also acted upon the evaluations in their own organisation. In the case of the Youth Act evaluation, youth care providers aimed to use the findings to improve access to youth care. Meanwhile, in the Wkkgz case, dispute resolution bodies proactively discussed the evaluation results to better organise their processes. These actions demonstrate that ex-post legislative evaluations can lead to constructive actions and improvements within the societal domain.

Sub-question 3. What do the ex-post legislative evaluations in Dutch healthcare teach us about the factors that influence impact?

Firstly, concerning contextual factors, the ZonMw programme operates within an institutionalised system primarily focused on generating impact in the political and policy domains, including the legislative domain, with relatively less emphasis on societal impact. In addition to this institutionalised system, within which all evaluations are conducted, each evaluation possesses its own unique context. This context is chiefly determined by the timing of the evaluation, which can be adjusted by the Minister, as was the case with the evaluations of the Youth Act and the Embryo Act. The Minister advanced the evaluation of the Youth Act and postponed the evaluation of the Embryo Act to better facilitate actions based on the evaluation results. Furthermore, the context is shaped significantly by the specific law under evaluation and the political and societal attention surrounding it. For instance, the Embryo Act was surrounded by an ethical and politicised debate, while the Youth Act pertained to a socially relevant topic that sparked considerable discussion within the realm of youth care. In contrast, the Wkkgz law was perceived as a more instrumental law with relatively less discussion in political and societal spheres. The cases also highlighted differences in how often they were evaluated. While the Wkkgz and the Youth Act underwent their first evaluations, the Embryo Act was being evaluated for the third time. The evaluation of the Embryo Act was based on more concrete research question, leading to more focussed recommendations. In contrast, the evaluations of the Wkkgz and the Youth Act

were more comprehensive, as they were conducted for the first time, resulting in a wider range of recommendations. These different contexts influence the potential impact of the evaluations.

Beyond these specific contexts, in all three cases researchers made choices regarding research quality and stakeholder interaction to respond to these specific contexts and enhance the impact of ex-post legislative evaluations. While the quality of the research group and the quality of the overall research standard remained consistently high due to institutional standards, as confirmed by relevant stakeholders in the evaluations' questionnaire, this study underscored the importance of various decisions that researchers can make to influence the evaluation impact. For example, concerning research quality, aligning research topics with stakeholders' interests, not solely those of the Minister, proves crucial for enhancing the relevance of the evaluation for the field. Also the way in which researchers decide to formulate recommendations - making them concrete, clear and addressed to appropriate parties- proves essential for generating impact in relevant places.

Researchers also can make choices concerning stakeholder interaction to enhance the impact of evaluations. This study highlights how early and continuous engagement with stakeholders from both the field and policy spheres can maximise relevance and impact. Involving stakeholders at various stages of the evaluation process—during preparation, execution, and dissemination—enables researchers to better align the evaluation with stakeholders' needs.

Examples, such as the Wkkgz evaluation, illustrate that stakeholders who actively participated in discussions during the evaluation began implementing insights gained from these interactions even before the evaluation was completed. This early involvement suggests that continuous stakeholder engagement throughout the process significantly increases the likelihood of impact. Furthermore, this study emphasised the importance of making evaluation findings accessible to a broader audience. This can be achieved by creating practical versions or summaries tailored for field professionals.

Central research question: How can the impact of ex-post legislative evaluations in healthcare be optimised?

Answering the central research question on optimising the impact of ex-post legislative evaluations in healthcare requires a nuanced exploration of both the nature of impact and the factors influencing it. Our study has revealed that impact encompasses diverse dimensions and operates across multiple domains, from legislative decision-making to broader societal changes. By examining these dimensions, we have underscored the complexity inherent in evaluating impact and the need for a comprehensive understanding of its various manifestations.

Reflecting on our findings, we recognise that institutionalising the evaluation process within policy and legislative frameworks is a pivotal strategy for optimising impact within these domains. However, our research also highlights a disparity: while institutionalisation supports impact within legislative spheres, societal impact requires a different strategy, emphasising engagement

and interaction. This recognition has shaped a new agenda, prompting us to consider how to effectively bridge these domains and enhance overall impact.

Our study further illuminated that achieving impact is intricately linked to the phases of the evaluation process itself. Impact is not a singular outcome but rather a continuum that begins with early engagement and extends throughout the whole evaluation process. Early stakeholder involvement, for instance, not only enriches the evaluation process with diverse perspectives but also increases the likelihood that findings will be embraced and acted upon by important stakeholders of the law. This participatory approach, while enhancing relevance and applicability, also introduces complexities regarding research independence and objectivity.

Moreover, our research highlighted stakeholder interaction as critical in optimising the impact of evaluations. Actively engaging stakeholders throughout the process—from initial design through to implementation— not only increases the practical relevance of findings but also fosters ownership and support for subsequent actions. This highlights the value of participatory methods in aligning research with practical needs effectively. However, careful management of stakeholder involvement is necessary to maintain research integrity and independence.

In conclusion, optimising the impact of ex-post legislative evaluations requires a holistic approach that considers the diverse dimensions of impact, the phases of the evaluation process, and the dynamics of stakeholder interaction. By integrating these insights, we can develop strategies that enhance the effectiveness and relevance of legislative evaluations, thereby optimising their potential to inform policy, improve practice, and catalyse societal change.

8.4 Strenghts and limitations

The strength of this thesis lies in its integration of both theoretical and empirical research methodologies, effectively bridging the gap between theory and practice. This dual approach provides a comprehensive framework for exploring the impact of ex-post legislative evaluations and the factors influencing them. To navigate the complexity of real-world contexts characterised by numerous stakeholders and intricate dynamics, we employed the Realist Evaluation method. This method was chosen for its ability to address such complexity, focusing on understanding not just what works, but how, why, for whom, and under what circumstances (Pawson & Tilley, 1997; Pawson et al., 2005). By detailing this approach in a comprehensive study protocol, we were able to execute the research robustly, allowing for a nuanced understanding of the multifaceted concept of impact and the factors influencing the impact of ex-post legislative evaluations.

This thesis represents the first systematic exploration of three cases within the ZonMw programme, providing valuable insights into the impact of ex-post legislative evaluations. The cases were carefully selected to ensure a diversity of contexts and variables, allowing for a thorough examination of different contexts and their respective outcomes. These case studies validated

and enriched theoretical concepts with real-world data, each contributing unique insights into the complex nature of ex-post legislative evaluations. This systematic analysis enhances the quality of existing knowledge. Currently, this study provides the most comprehensive insights available on optimising the impact of ex-post legislative evaluations, offering a valuable foundation for future research. Conducting evaluations is an ongoing process globally and is most effective when based on the latest and most reliable knowledge. Future legislative evaluations can build on this enriched knowledge base, thereby increasing their likelihood of impact.

While our initial empirical attempt is a valuable step forward, it is not without its limitations. The researchers involved in this thesis were also participants in two of the legislative evaluations studied. While this dual role may introduce bias, it enabled a deeper engagement with the subject matter, enriching the analysis with insider perspectives. To mitigate potential bias, rigorous measures were implemented throughout the research process. These included maintaining transparency about the researchers' involvement in the evaluations, employing diverse data sources and analytical methods, and subjecting the findings to peer review. Collaboration with colleagues not involved in the evaluations provided an external perspective, offering further checks and balances to enhance the credibility of the research outcomes.

A significant limitation is our specific focus on ex-post legislative evaluations within Dutch healthcare under the ZonMw programme. While we included a variety of evaluations in our case studies, this focus limits our ability to generalise findings across different types of laws outside of healthcare.

Although we believe the insights from this study hold potential relevance for legislative evaluations outside the healthcare domain and beyond the Netherlands, also for other types of policy evaluations, further research is needed to explore their broader applicability. Context matters, and outcomes may vary in countries with different healthcare organisation systems and legislative evaluation frameworks. This raises questions about the generalisability of insights from complex settings. Research in such situations does not lead to universal truths, but gradually contributes to a deeper understanding of the complexities involved in achieving impact from ex-post legislative evaluations. By incorporating these insights, future research can better navigate the nuanced realities of legislative evaluations and enhance their practical applications. Additionally, while we aimed for depth in our analysis, the third part of this study indicates that further exploration could uncover additional layers of understanding, underscoring the potential for continued research to provide more valuable insights.

8.5 Suggestions for further research

While not our primary focus, our study identified instances of societal impact, prompting us to advocate for more research in this area. We strongly believe that there are ample opportunities to enhance the impact of legislative evaluations within society. Neglecting further investigation

into this discovery represents a missed opportunity and highlights the necessity for dedicated research into societal impact.

Exploring this further presents an intriguing challenge and an opportunity for dedicated empirical studies. Our insights, enriched through empirical research, suggest the continuation and expansion of such studies on societal impact. Understanding how legislative evaluations influence broader societal outcomes, particularly in healthcare settings, can offer valuable insights for policymakers and practitioners. For example, it can help identify best practices and strategies to maximise the positive societal impact of legislative evaluations. We encourage researchers to embark on studies that specifically examine societal impact, considering the diverse and dynamic contexts in which these evaluations occur. Additionally, it would be interesting to investigate whether these findings extend beyond the domain of healthcare law.

Recognising the importance of context, we acknowledge that conducting similar studies in different settings may yield different conclusions. Our study underscores the importance of context in ex-post legislative evaluations, demonstrating how contextual factors are intricately linked to the specific settings in which these evaluations are conducted. This observation also calls for further exploration.

Moreover, the findings from the Netherlands may hold relevance internationally. While evaluations are structured differently in various countries, resulting in unique contextual environments, there is potential for mutual learning from the Dutch experience. In the Netherlands, evaluations primarily serve the Minister, yet we advocate for greater involvement of stakeholders in the field. This approach mirrors the Dutch context and calls for further investigation into conducting similar studies elsewhere, considering their distinct contextual factors. By conducting comparative studies across countries and settings, we can gain deeper insights into how diverse contexts influence the impact of legislative evaluations and identify opportunities to enhance societal impact by stakeholder engagement throughout the evaluation process.

We are aware that evaluations are conducted with the best available knowledge at the time. Since knowledge continues to evolve, it is beneficial to learn from each other and build upon this existing knowledge base. While our study significantly contributes to current knowledge, it also paves the way for further empirical research. We encourage scholars to expand upon our findings, investigate diverse contexts, and emphasise societal impact to enhance the overall effectiveness and relevance of legislative evaluations. Through these endeavours, we aim for evaluations to not only achieve their immediate objectives but also foster meaningful and lasting societal improvements.

8.6 Recommendations for practice

Building upon the findings of this study, we formulate practical recommendations in this concluding chapter. These recommendations aim to optimise the likelihood of impact across the entire process of ex-post legislative evaluations. The recommendations divide into specific phases and target the parties that were central to this study.
The impact of ex-post legislative evaluations should not be left to chance but approached with structured and deliberate planning. While we observe this development taking place in an ad hoc manner, we propose these recommendations to foster a more systematic and structured discourse on this subject.

These recommendations are crafted specifically for the Dutch context, with a particular focus on the ZonMw Programme for Regulatory Evaluation. Consequently, they address the key stakeholders involved in this programme, including the Ministry of Health, Welfare and Sport (VWS), the ZonMw Committee for Evaluation of Regulations (CER), and the external research teams that conduct the evaluations (Researchers). However, these recommendations apply beyond the ZonMw programme alone. We believe that the insights and strategies outlined here hold relevance for evaluations beyond this specific programme.

The overview below presents recommendations for each phase of the evaluation process. We begin with phase 0, as we identified several safeguards crucial for subsequent evaluation stages, such as the value of institutionalising legislative evaluations. Additionally, we observed that decisions made during this phase can have implications for impact. Recommendations pertaining to these decisions are provided in phases 1-3.

Phase 0: The law and institutionalisation of ex-post legislative evaluations		
1. Institutionalisation of ex-post legislative evaluations	Maintain the ZonMw programme with the CER as an independent, specialised body responsible for conducting ex-post legislative evaluations. The CER operates with autonomy to ensure objectivity and credibility. Ensure that the CER is adequately funded and staffed with experts in legislative evaluation and relevant subject matters.	VWS
2. Guarantee quality mechanisms	Maintain quality mechanisms such as peer review for research proposals and advisory committees to ensure the quality of the evaluation process and findings.	ZonMw CER

3. Evaluation initiative	Ensure that every law includes an evaluation clause, mandating periodic assessments after a specified timeframe. This provision not only enhances the relevance of evaluations for stakeholders but also allows for more focused and targeted research questions in subsequent evaluations. Repeat evaluations as necessary to refine and deepen understanding, ensuring continuous improvement in policy effectiveness.	Minister
Phase 1: Preparation		
1. Evaluation assignment	Formulate a specific evaluation assignment and consider whether the law should be evaluated in its entirety or only partially and thematically. Recognise the importance of societal impact in legislative evaluations and actively assess and address its implications. Expand the scope of evaluations to include societal stakeholders and consider broader societal outcomes beyond legislative and policy changes.	Minister and ZonMw CER
2. Timing	Strategically plan the timing of the evaluation to coincide with optimal political and policy-making windows. Adjust the start of the evaluation to ensure results are available at the most impactful moments for decision-makers.	Minister
3. Engage stakeholders	Actively involve relevant stakeholders, including professionals and patients throughout the evaluation process. This ensures that the evaluations address their needs and concerns, increasing the relevance and potential impact of the findings.	Minister and ZonMw CER
Phase 2: Execution		
1. Maintain high research quality	Ensure the research team is composed of independent and well-qualified members. Employ rigorous research methods and maintain transparency in the evaluation process. Focus on producing high-quality, detailed evaluation reports that are comprehensive and accessible.	ZonMw CER and Researchers
2. Context analysis	Analyse the Minister's timing for the evaluation, its openness to the evaluation results, the type of law, and the political and societal context in which the evaluation takes place to identify potential limitations and opportunities for impact.	Researchers

3. Stakeholder analysis and interaction	Identify and involve key stakeholders from the onset to align evaluation topics and objectives with their interests and needs. Foster open communication channels to understand their expectations and incorporate their input into the evaluation design. Maintain stakeholder engagement throughout the evaluation process to ensure relevance and ownership. Regular consultations with stakeholders should be conducted to exchange insights, gather feedback, and uphold the evaluation's relevance.	Researchers
4. Determine objectives and choose methods	Clearly define the purpose of the evaluation, including both the formal function (assessing the effectiveness of the law) and the instrumental function (achieving impact). Choose an appropriate methodology that aligns with the objectives of the evaluation and the nature of the law.	Researchers
5. Discuss the draft recommendations and conclusions with the field	Consider engaging stakeholders regarding the draft recommendations and conclusions. This involves sharing the initial findings and proposed actions with relevant parties such as policymakers, healthcare professionals, and patient representatives. Seek their input, insights, and perspectives to refine and validate the recommendations. This collaborative approach ensures that the proposed actions resonate with the needs and realities of the field, fostering buy-in and facilitating successful implementation.	Researchers
6. Actionable recommendations	Formulate clear and concrete recommendations based on the findings of the evaluation, directed towards the appropriate recipients to inform stakeholders and drive changes in practice. Additionally, ensure that the report is accessible to a broad audience in terms of both format and content.	Researchers
Phase 3: Dissemination and follow up		
1. Effective communication of results	Present evaluation findings in a manner that is easily understandable and accessible to all relevant audiences, including policymakers, practitioners, and the general public. Utilise various dissemination channels, such as reports, policy briefs, presentations, and interactive workshops to maximise reach and impact.	Researchers

2. Engage stakeholders	Foster ongoing dialogue with stakeholders to facilitate the practical application of findings and address any concerns or questions. Encourage stakeholders to take ownership of the results and collaborate on implementing recommended actions.	Researchers, ZonMw CER
2. Monitor and follow up	Establish mechanisms for monitoring the implementation of recommendations to assess their impact over time. Engage in follow-up activities to support stakeholders in translating evaluation findings into concrete actions and policies.	Researchers, ZonMw CER and Minister

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Summary

Legislation and regulations form important foundations of an organised society. They have a profound influence on virtually all aspects of daily life, including healthcare. They establish norms, regulate behaviour and activities, provide protection, and safeguard rights for, among others, patients and healthcare providers. But how do we know whether these rules are actually effective in practice and achieving their intended goals?

To assess this, ex-post legislative evaluations (hereafter also referred to as legislative evaluations) are conducted. These evaluations examine how existing laws and regulations function in practice, identifying strengths and areas for improvement. Although the importance of such evaluations for the quality and effectiveness of legislation is recognised worldwide, it often remains unclear to what extent the outcomes are actually utilised to improve policy and practice.

This dissertation, therefore, focuses on investigating the impact of ex-post legislative evaluations, with the aim of further optimising their effectiveness. The research in this dissertation seeks to bridge the gap between legislation and practice by placing practical experiences at the heart of the further development of legislation. It provides valuable insights and recommendations that contribute to better-informed and more effective legislation in healthcare. This not only helps improve the quality of care but also enhances the societal relevance of legislation.

The findings of the dissertation are divided into three consecutive parts: first, a framework is developed to assess the impact of legislative evaluations; second, case studies are conducted within the Dutch healthcare sector; and third, an in-depth study is carried out on the impact of a specific recommendation from one of the case studies.

Part 1 – Developing a framework for assessing the impact of ex-post legislative evaluations

The first part of this research focuses on developing a conceptual framework for assessing the impact of ex-post legislative evaluations. A conceptual framework is a structured model that helps analyse and understand complex processes or systems. In this research, a framework is developed to evaluate the impact of ex-post legislative evaluations. This means that the framework helps determine how effective legislative evaluations are in improving legislation, policy, or practice. The framework is based on an extensive literature review, including international insights and evaluations outside the healthcare sector. Two scoping reviews, derived from this literature review, form the building blocks of the framework. This framework then serves as the foundation for further analyses in the later chapters of the dissertation.

The first review examines the different types of impact of ex-post legislative evaluations. This analysis shows that the impact of legislative evaluations is multifaceted and complex, influencing various domains. The review identified seven categories of impact: (1) knowledge

and understanding, (2) confirmation of well-functioning legislation, (3) revision of legislation, (4) influence on the legislative process, (5) influence on the policy process, (6) influence in the political sphere, and (7) influence on society.

Knowledge and understanding, while essential, are merely the first step in achieving change. Without corresponding action, this knowledge remains limited to theoretical understanding and does not lead to concrete improvements or adjustments in practice. It forms a conditional basis for further actions in the other categories. The review also highlighted a significant gap: the societal impact of legislative evaluations is often overlooked. While the effects on legislation and politics are well documented, the impact on society, such as stakeholders who implement the law daily, is less discussed. This finding points to the need for future research into whether societal effects are less present or systematically ignored.

The second review builds on these insights and identifies three main factors influencing the impact of ex-post legislative evaluations: context, the quality of the evaluation research, and stakeholder interaction.

- ***Context*** refers to the circumstances in which the evaluation takes place, such as the timing, the purpose of the evaluation, the level of political or social interest, and the openness of the client (e.g., the minister) to the evaluation findings. Contextual factors are often external and beyond the control of the evaluators but can significantly affect the impact of an evaluation.

- ***Quality of evaluation research*** refers to the independence and expertise of the research team, the robustness of the research methods, and the clarity of the evaluation report. The higher the quality of the research, the greater the chance that the findings will influence decision-making.

- ***Stakeholder interaction*** focuses on the involvement between researchers and relevant actors, such as policymakers, healthcare professionals, and patient organisations. Ongoing communication and stakeholder engagement throughout the evaluation process is crucial to ensuring that the findings are relevant and usable.

A recurring challenge in evaluation research is balancing stakeholder involvement with maintaining the independence of the evaluation. While stakeholder engagement can lead to more impact, there is a risk that the objectivity of the findings may be compromised if stakeholders exert too much influence.

Part 2 – Case studies on ex-post legislative evaluations in Dutch healthcare

The second part of this dissertation applies the conceptual framework to legislative evaluations within Dutch healthcare. Since 1997, the ZonMw Programme for Regulatory Evaluation (the ZonMw programme) has systematically conducted evaluations of healthcare laws with the aim of improving the quality of this legislation. These evaluations are carried out by independent,

multidisciplinary research teams. The extensive experience of more than twenty-five years within the ZonMw programme provides valuable insights for future evaluations. This research aims to unlock these insights and translate them into concrete recommendations, so they can form the basis for further optimisation and impact of future legislative evaluations.

To structure the case studies, a research protocol was developed that centres on the Realist Evaluation (RE) methodology. This method is particularly suitable for evaluating complex interventions because it is based on the premise that context significantly influences cause-and-effect relationships. This is relevant when analysing the impact of legislative evaluations, as each evaluation takes place in a unique context.

In legislative evaluations, an intervention, such as a new or amended law, can yield different results in various social, legal, or policy environments. The RE methodology uses the 'Context-Mechanism-Outcome' (CMO) configuration. Using this configuration, the study examined how context, research quality, and stakeholder interaction as mechanisms affect the impact of three Dutch legislative evaluations: the third evaluation of the Embryo Act, the first evaluation of the Youth Act, and the first evaluation of the Healthcare Quality, Complaints, and Disputes Act (Wkkgz). These evaluations were selected for their diversity in timing (all evaluations were at least two years old to allow for the impact to emerge), subject matter (diversity in the ethical or non-ethical nature of the law), and the frequency of previous evaluations of the law. This diversity offered various contexts, allowing the theoretical framework to be robustly tested.

The insights from the case studies subsequently contributed to further refining and strengthening of the framework, leading to a more robust and contextually richer understanding of the impact of ex-post legislative evaluations. This refinement helps to design and conduct future legislative evaluations more effectively and accurately.

The case studies show that ex-post legislative evaluations in Dutch healthcare have a broad impact on the policy, political, and social domains. The results make it clear that the impact is not solely determined by the publication of the final report but is strongly influenced by how the entire evaluation process is structured. Notably, while the ZonMw programme places significant emphasis on the quality and feasibility of evaluation research, the focus on increasing impact remains relatively limited.

Strategic decisions by evaluators regarding the timing, preparation, execution, and dissemination of the evaluation play a crucial role in increasing the likelihood of impact. Early and continuous stakeholder interaction enhances the relevance of the findings for both policymakers and practitioners.

The case studies provide additional and in-depth insight into the framework from Part 1. The case studies show that institutional structures and timing decisions have a significant influence on the impact of legislative evaluations. The minister responsible for the commission can adjust

the timing of the evaluation to political or policy priorities. For example, the evaluation of the Youth Act was brought forward to provide timely feedback on the implementation of the law, while the evaluation of the Embryo Act was delayed to allow recommendations from the previous evaluation to be better implemented. These timing decisions greatly determine the function of the evaluation and the impact it can have.

Part 3 – In-depth study on adverse event investigations in Dutch hospitals following an ex-post legislative evaluation

The third part of this dissertation contains an in-depth study on the involvement of patients and/or their next of kin (P/N) in serious adverse event (SAE) investigations in Dutch hospitals, conducted following a recommendation from the evaluation of the Wkkgz. This follow-up research provides a concrete example of how a legislative evaluation can directly influence policy and practice. The evaluation of the Wkkgz recommended that professional organisations and patient organisations develop a framework for the application of the law, with a specific focus on the functioning of hospitals as learning organisations in the analysis of SAEs. The research, initiated by the Health and Youth Care Inspectorate, illustrates how the recommendations from the legislative evaluation have led to further research and action.

The follow-up study focused on two perspectives: that of the healthcare professionals involved in SAE investigations and that of P/N. From the perspective of healthcare professionals, it was found that the involvement of P/N not only contributed to the learning process within the hospital organisation but also helped improve the research results. This highlights how valuable their insights can be in improving care processes.

The research also revealed that the evaluation of the Wkkgz was relatively unknown among hospital professionals and that little action had been taken based on the original evaluation results. The recommendation from the Wkkgz evaluation was far removed from the daily practice of healthcare professionals, resulting in limited impact on hospital policy. In contrast, the recommendations from the follow-up research did lead to concrete actions in hospitals. This was because healthcare professionals were extensively involved in the follow-up research, leading to more opportunities for the exchange of knowledge and experiences. Additionally, the concrete advice resulting from the research was directly applicable in practice. This insight underscores the crucial role of involvement and communication in achieving impact, especially when research findings are translated into concrete and practical recommendations for daily healthcare practice.

The perspective of P/N also shows that they see themselves as active participants in the process, not as passive recipients of care and information. They place great value on meaningful involvement, where their experiences and insights are recognised as valuable contributions. The findings suggest that a more inclusive approach, in which P/N are recognised as active partners, can lead to more patient-centred evaluations and better-aligned results. This closely aligns with the recommendations from the Wkkgz evaluation and emphasises the need to view patients not only as sources of information but as full participants in the process. In this way, legislative

evaluations contribute to the development of learning organisations and improved patient safety in healthcare.

Reflections on key findings

This research emphasises the versatile nature of the impact of ex-post legislative evaluations. Impact manifests itself in different domains—policy, politics, and society—and is influenced by various factors, such as context, research quality, and stakeholder interaction. The institutionalisation of evaluation practices, such as those under the ZonMw programme, has led to a structured approach to legislative evaluations with guaranteed impact on legislation and politics. However, the path to societal impact is less formally established.

Achieving impact is not a one-time event but a process that begins in the early stages of the evaluation and continues through dissemination and follow-up. Early stakeholder interaction is essential to ensure that the evaluation addresses relevant issues and that the findings are actually acted upon. This, however, presents challenges, such as ensuring the independence of the research and managing expectations throughout the evaluation process. This dissertation has produced four key reflections:

Reflection 1: The versatile nature of impact

Reflecting on the findings about the complexity of impact, it becomes clear that impact is not a singular or linear concept. The complexity arises from the diversity of stakeholders, the different contexts in which laws are applied, and the various ways in which impact manifests. The results of the research identified different domains where impact occurs, with knowledge and insight as prerequisites for achieving impact. When zooming in, impact on individuals within these domains can be seen as a mechanism with three movements: becoming informed, spreading information, and taking action based on the evaluation results. These processes are influenced by the specific context, such as the level of stakeholder involvement, the political environment, and the degree of societal interest. Understanding these dynamics and often non-linear processes is crucial for effectively assessing and optimising the impact of ex-post legislative evaluations.

The complexity of impact evaluations is also recognised in broader evaluation literature, such as with social interventions, where effects are often multiple, non-linear, and delayed. This calls for an approach that considers both qualitative and multidimensional aspects. Therefore, it is useful to learn from evaluations in other domains, such as healthcare, where multiple stakeholders and complex outcomes present additional challenges. By applying these insights to legislative evaluations, strategies can be developed to enhance the effectiveness and impact of these evaluations.

Reflection 2: Expanding impact beyond the legislative domain

Traditionally, ex-post legislative evaluations primarily focus on their impact within the legislative and political domains. However, this dissertation shows that evaluations can also have broader societal impacts, such as influencing public perceptions, shaping debates, and changing the

behaviour of stakeholders. An example of this is the societal impact of the Wkkgz evaluation, in which dispute committees used the findings to improve internal processes and healthcare providers applied the results to optimise patient care. These examples show how legislative evaluations can stimulate changes that go beyond the legal text and politics, influencing the daily practices of organisations and individuals in society.

This raises an important question: Is societal impact an intended outcome of ex-post legislative evaluations, or should we see it as a by-product? While ex-post legislative evaluations can be viewed as tools for improving the quality of laws, with legislators and policymakers as the primary target group, this research shows that the potential for broader societal impact should not be overlooked. Legislation, particularly in sectors such as healthcare, affects the daily lives of patients, professionals, and organisations. Ex-post legislative evaluations, therefore, have a unique opportunity not only to inform legislative reforms but also to influence societal norms and behaviours. Consequently, there is a responsibility for the authors and implementers of ex-post legislative evaluations to consciously anticipate this societal impact. By explicitly including it in the evaluation process, the potential for positive societal change can be better harnessed, and the influence of legislative evaluations can extend beyond legislative decisions alone. Ex-post legislative evaluations should thus be seen not only as tools for policymakers but also as powerful means for improving broader societal structures and practices.

Reflection 3: Impact emerges throughout the evaluation process

This research shows that impact is not an isolated event that occurs only after the completion of an evaluation, such as upon the release of the evaluation report. The entire evaluation process—from preparation to execution, dissemination, and follow-up—offers numerous opportunities to exert influence on potential impact. Early stakeholder interaction, for example, can lead to quicker adjustments in policy or practice, even before the evaluation is completed. This underscores that impact is not limited to the final report but can arise throughout the entire process.

Anticipating impact early offers significant advantages, such as engaging relevant stakeholders and aligning the research with their needs. This not only enhances the relevance of the findings but also helps anticipate barriers and develop strategies to maximise impact. In the evaluation of the Embryo Act, for example, early anticipation of impact led to broader acceptance and use of the findings. A proactive approach throughout the process increases the likelihood of the evaluation having an impact both in the short and long term. Therefore, a proactive approach is essential to maximising the impact of evaluations. Early planning increases the chances of relevance and acceptance of the findings, both in the short and long term.

Reflection 4: Stakeholder interaction as the dominant factor for impact

Our research shows that stakeholder interaction is a crucial factor in the impact of ex-post legislative evaluations. When stakeholders are involved early, for example in the drafting of the evaluation commission, the evaluation better aligns with the needs of both the minister and the practical needs in the field. This early engagement ensures that relevant issues are evaluated and

that the findings gain more support and follow-up from all parties involved. This promotes impact already during the evaluation process. In the case studies, we saw that stakeholder involvement during the evaluation led to more useful results and broader acceptance of the recommendations.

However, the challenge with intensive stakeholder interaction is maintaining the independence of the research. Too close involvement of stakeholders can compromise the objectivity of the evaluation. Therefore, it is essential to find a balance between involvement and independence. Participatory methods can enhance impact, but it is important to prevent stakeholders' interests from jeopardising the integrity of the evaluation. To maintain this balance, specific moments for involvement can be planned, and clear, transparent guidelines can be followed. In this way, both the independence and relevance of the evaluation are ensured, while the impact and acceptance of the results are maximised.

Recommendations

This dissertation formulates several practical recommendations to optimise the impact of ex-post legislative evaluations. These recommendations are aimed at different phases of the evaluation process and are specifically applicable to the Dutch ZonMw Programme for Regulatory Evaluation, although they can also be applied more broadly. The five main recommendations are briefly outlined below:

Institutionalisation of Legislative Evaluations: Ensure that evaluations, such as the ZonMw programme, are structurally anchored with independent bodies, such as the CER as a committee of ZonMw, to guarantee objectivity and quality.

Stakeholder Engagement: From the outset, all relevant stakeholders, including patients and professionals, should be actively involved in the evaluations to enhance the relevance and applicability of the findings.

Concrete and Action-Oriented: Ensure clear, concrete recommendations that are directly applicable for policymakers and professionals.

Timing and Context: Plan evaluations strategically to coincide with policy and political windows, so that the results are available to decision-makers at the right time.

Continuity and Follow-Up: Create follow-up mechanisms to ensure that the recommendations are acted upon and their long-term impact is monitored.

These recommendations support a more systematic and targeted approach to legislative evaluations, aimed at maximising impact at both policy and societal levels.

Samenvatting

Wet- en regelgeving vormen belangrijke fundamenten van een georganiseerde samenleving. Ze hebben een diepgaande invloed op vrijwel alle aspecten van het dagelijks leven, waaronder de gezondheidszorg. Ze stellen normen, reguleren gedrag en activiteiten, bieden bescherming en waarborgen rechten voor onder andere patiënten en zorgaanbieders. Maar hoe weten we of deze regels in de praktijk daadwerkelijk effectief zijn en de beoogde doelen bereiken?

Om dit te beoordelen worden ex-post wetsevaluaties uitgevoerd. Deze evaluaties onderzoeken hoe bestaande wet- en regelgeving functioneert in de praktijk, waar de sterke punten liggen en waar ruimte is voor verbetering. Hoewel het belang van dergelijke evaluaties voor de kwaliteit en effectiviteit van wetgeving wereldwijd wordt erkend, blijft vaak onduidelijk in hoeverre de uitkomsten daadwerkelijk worden benut voor de verbetering van beleid en praktijk.

Dit proefschrift richt zich daarom op het onderzoeken van de impact van ex-post wetsevaluaties, met als doel hun effectiviteit verder te optimaliseren. Het onderzoek in dit proefschrift streeft ernaar de kloof tussen wetgeving en praktijk te verkleinen, door praktijkervaringen centraal te stellen in de verdere ontwikkeling van wetgeving. Het biedt waardevolle inzichten en aanbevelingen die bijdragen aan beter geïnformeerde en effectievere wet- en regelgeving in de gezondheidszorg. Dit draagt niet alleen bij aan de verbetering van de zorgkwaliteit, maar versterkt ook de maatschappelijke relevantie van wetgeving.

De bevindingen van het proefschrift zijn opgedeeld in drie elkaar opvolgende delen: ten eerste wordt een raamwerk ontwikkeld voor het beoordelen van de impact van wetsevaluaties; ten tweede worden casestudies uitgevoerd binnen de Nederlandse gezondheidszorg; en ten derde wordt een verdiepend onderzoek uitgevoerd naar de impact van een specifieke aanbeveling uit een van de casestudies.

Deel 1 – Het ontwikkelen van een raamwerk voor het beoordelen van de impact van ex-post wetsevaluaties

Het eerste deel van dit onderzoek richt zich op het ontwikkelen van een conceptueel raamwerk voor het beoordelen van de impact van ex-post wetsevaluaties. Een conceptueel raamwerk is een gestructureerd model dat helpt om complexe processen of systemen te analyseren en te begrijpen. In dit onderzoek wordt een raamwerk ontwikkeld om de impact van ex-post wetsevaluaties te beoordelen. Dit betekent dat het raamwerk helpt vaststellen hoe effectief wetsevaluaties zijn in het verbeteren van wetgeving, beleid of praktijk. Het raamwerk is gebaseerd op een uitgebreid literatuuronderzoek, waarbij ook internationale inzichten en evaluaties buiten de gezondheidszorg zijn meegenomen. Twee scoping reviews, die voortkomen uit dit literatuuronderzoek, vormen de bouwstenen van het raamwerk. Dit raamwerk dient vervolgens als fundament voor de verdere analyses in de latere hoofdstukken van het proefschrift.

De eerste review onderzoekt de verschillende vormen van impact van ex-post wetsevaluaties. Uit deze analyse blijkt dat de impact van wetsevaluaties veelzijdig en complex is, met invloed op verschillende domeinen. De review identificeerde zeven categorieën van impact: (1) kennis en inzicht, (2) bevestiging van goed functionerende wetgeving, (3) herziening van wetgeving, (4) invloed op het wetgevingsproces, (5) invloed op het beleidsproces, (6) invloed in de politieke sfeer, en (7) invloed op de samenleving.

Kennis en inzicht, hoewel essentieel, vormen slechts de eerste stap in het realiseren van verandering. Zonder bijbehorende actie blijft deze kennis beperkt tot theoretisch begrip en leidt het niet tot concrete verbeteringen of aanpassingen in de praktijk. Het vormt een voorwaardelijke basis voor verdere acties in de overige categorieën. De review bracht ook een aanzienlijke lacune aan het licht: de maatschappelijke impact van wetsevaluaties wordt vaak over het hoofd gezien. Terwijl de effecten op wetgeving en politiek goed gedocumenteerd zijn, wordt de impact op de samenleving, zoals veldpartijen die dagelijks uitvoering geven aan de wet, minder besproken. Deze bevinding wijst op de noodzaak voor toekomstig onderzoek naar de vraag of maatschappelijke effecten in mindere mate aanwezig zijn of systematisch worden genegeerd.

De tweede review bouwt voort op deze inzichten en identificeert drie hoofdfactoren die de impact van wetsevaluaties beïnvloeden: context, kwaliteit van het evaluatieonderzoek en interactie met belanghebbenden.

- Context verwijst naar de omstandigheden waarin de evaluatie plaatsvindt, zoals de timing, het doel van de evaluatie, het niveau van politieke of sociale interesse, en de openheid van de opdrachtgever (bijvoorbeeld de minister) voor de evaluatiebevindingen. Contextuele factoren zijn vaak extern en buiten de controle van de evaluatieonderzoekers, maar kunnen de impact van een evaluatie aanzienlijk beïnvloeden.

- Kwaliteit van het evaluatieonderzoek heeft betrekking op de onafhankelijkheid en expertise van het onderzoeksteam, de robuustheid van de onderzoeksmethoden, en de helderheid van het evaluatierapport. Hoe hoger de kwaliteit van het onderzoek, des te groter de kans dat de bevindingen invloed zullen hebben op besluitvorming.

- Interactie met belanghebbenden richt zich op de betrokkenheid tussen onderzoekers en relevante actoren, zoals beleidsmakers, zorgprofessionals en patiëntenorganisaties. Doorlopende communicatie en betrokkenheid van belanghebbenden gedurende het evaluatieproces is cruciaal om ervoor te zorgen dat de bevindingen relevant en bruikbaar zijn.

Een terugkerende uitdaging in evaluatieonderzoek is de spanning tussen de betrokkenheid van belanghebbenden en het behoud van de onafhankelijkheid van de evaluatie. Hoewel betrokkenheid van belanghebbenden kan leiden tot meer impact, bestaat het risico dat de objectiviteit van de bevindingen in het geding komt als belanghebbenden te veel invloed hebben.

Deel 2 – Casestudies over ex-post wetsevaluaties in de Nederlandse gezondheidszorg
Het tweede deel van dit proefschrift past het conceptuele raamwerk toe op wetsevaluaties binnen de Nederlandse gezondheidszorg. Sinds 1997 voert het ZonMw-programma Evaluatie Regelgeving systematisch evaluaties uit van gezondheidsrechtelijke wetten, met als doel de kwaliteit van deze wetgeving te verbeteren. Deze evaluaties worden uitgevoerd door onafhankelijke, multidisciplinaire onderzoeksteams. De uitgebreide ervaring van meer dan vijfentwintig jaar binnen dit programma biedt waardevolle inzichten voor toekomstige evaluaties. Dit onderzoek heeft als ambitie om deze inzichten te ontsluiten en te vertalen naar concrete aanbevelingen, zodat ze de basis kunnen vormen voor verdere optimalisatie en impact van toekomstige wetsevaluaties.

Om de case studies gestructureerd uit te uitvoeren, is een onderzoeksprotocol opgesteld waarin de Realist Evaluation (RE)-methodologie centraal staat. Deze methode is bijzonder geschikt voor de evaluatie van complexe interventies, omdat zij gebaseerd is op het uitgangspunt dat de context een grote invloed heeft op oorzaak-gevolgrelaties. Dit is relevant bij het analyseren van de impact van wetsevaluaties, omdat elke wetsevaluatie plaatsvindt in een unieke context.

Bij wetsevaluaties kan een interventie, zoals een nieuwe of aangepaste wet, in verschillende maatschappelijke, juridische of beleidsomgevingen andere resultaten opleveren. De RE-methodologie maakt gebruik van de 'Context-Mechanism-Outcome' (CMO)-configuratie. Met behulp van deze configuratie werd onderzocht in hoeverre de context, onderzoekskwaliteit en interactie met belanghebbenden als mechanismen de impact beïnvloeden van drie belangrijke Nederlandse wetsevaluaties: de derde evaluatie van de Embryowet, de eerste evaluatie van de Jeugdwet en de eerste evaluatie van de Wet kwaliteit, klachten en geschillen zorg (Wkkgz). Deze evaluaties zijn geselecteerd vanwege hun diversiteit in de timing (alle evaluaties waren ten minste twee jaar oud om de impact te laten ontstaan), het onderwerp (diversiteit in de ethische of niet-ethische aard van de wet), en de variatie in de frequentie van eerder uitgevoerde evaluaties van de wet. Deze diversiteit biedt verschillende contexten, waardoor het theoretisch raamwerk robuust getest kon worden.

De inzichten uit de case studies hebben vervolgens bijgedragen aan de verdere verfijning en versterking van het raamwerk, wat leidde tot een robuuster en contextueel rijker begrip van de impact van wetsevaluaties. Deze verfijning helpt om toekomstige wetsevaluaties effectiever en nauwkeuriger te ontwerpen en uit te voeren.

Uit de casestudies blijkt dat wetsevaluaties in de Nederlandse gezondheidszorg een brede impact hebben op zowel het beleids-, politieke als maatschappelijke domein. De resultaten maken duidelijk dat de impact niet enkel wordt bepaald door de publicatie van het eindrapport, maar sterk wordt beïnvloed door de manier waarop het hele evaluatieproces is ingericht. Opvallend is daarbij wel dat, hoewel binnen het ZonMw-programma veel aandacht wordt besteed aan de kwaliteit en uitvoerbaarheid van het evaluatieonderzoek, de focus op het vergroten van de impact relatief beperkt blijft.

Strategische keuzes door de evaluatieonderzoekers over de timing, voorbereiding, uitvoering en verspreiding van de evaluatie spelen een cruciale rol in het vergroten van de kans op impact. Zo versterkt de vroegtijdige en voortdurende betrokkenheid van belanghebbenden de relevantie van de bevindingen voor zowel beleidsmakers als praktijkpartijen.

De casestudies bieden een aanvullend en verdiepend inzicht op het raamwerk uit deel 1. De casestudies laten namelijk zien dat institutionele structuren en timingbeslissingen een aanzienlijke invloed hebben op de impact van wetsevaluaties. De minister die verantwoordelijk is voor de opdracht kan de timing van de evaluatie aanpassen aan politieke of beleidsmatige prioriteiten. Zo werd de evaluatie van de Jeugdwet vervroegd om tijdig feedback te geven over de implementatie van de wet, terwijl de evaluatie van de Embryowet juist werd uitgesteld om aanbevelingen uit de voorgaande evaluatie beter te kunnen verwerken. Deze timingbeslissingen bepalen in hoge mate de functie van de evaluatie en de impact die zij kunnen hebben.

Deel 3 – Verdiepend onderzoek naar calamiteiten in Nederlandse ziekenhuizen naar aanleiding van een aanbeveling uit de Wkkgz evaluatie

Het derde deel van dit proefschrift bevat een verdiepend onderzoek naar de betrokkenheid van patiënten en/of naasten bij calamiteitenonderzoeken in Nederlandse ziekenhuizen, uitgevoerd naar aanleiding van een aanbeveling uit de evaluatie van de Wkkgz. Dit vervolgonderzoek biedt een concreet voorbeeld van hoe een wetsevaluatie directe invloed kan hebben op beleid en praktijk. In de evaluatie van de Wkkgz werd aanbevolen dat professionele organisaties en patiëntenorganisaties een kader ontwikkelen voor de toepassing van de wet, met een specifieke focus op het functioneren van ziekenhuizen als lerende organisaties bij de analyse van calamiteiten. Het onderzoek, geïnitieerd door de Inspectie Gezondheidszorg en Jeugd, illustreert hoe de aanbevelingen uit de wetsevaluatie hebben geleid tot verder onderzoek en actie.

Het vervolgonderzoek richtte zich op twee perspectieven: dat van de zorgprofessionals die betrokken zijn bij de calamiteitenonderzoeken en dat van patiënten en/of naasten. Vanuit het perspectief van de zorgprofessionals bleek dat de betrokkenheid van patiënten en/of naasten niet alleen bijdroeg aan het leerproces binnen de ziekenhuisorganisatie, maar ook hielp bij het verbeteren van de onderzoeksresultaten. Dit benadrukt hoe waardevol hun inzichten kunnen zijn bij het verbeteren van zorgprocessen.

Het onderzoek bracht ook aan het licht dat de evaluatie van de Wkkgz onder ziekenhuisprofessionals relatief onbekend was en dat er weinig actie was ondernomen op basis van de oorspronkelijke evaluatieresultaten. De aanbeveling uit de Wkkgz-evaluatie stond ver af van de dagelijkse praktijk van de zorgprofessionals, waardoor de impact op het ziekenhuisbeleid beperkt bleef. Daarentegen leidden de aanbevelingen uit het vervolgonderzoek juist wél tot concrete acties in ziekenhuizen. Dit kwam doordat zorgprofessionals uitvoerig betrokken waren bij het vervolgonderzoek, wat leidde tot meer mogelijkheden voor uitwisseling van kennis en ervaringen. Daarnaast waren de concrete adviezen die voortkwamen uit het onderzoek direct toepasbaar in de praktijk. Dit inzicht onderstreept de cruciale rol van betrokkenheid en communicatie in het realiseren van

impact, met name wanneer de onderzoeksresultaten vertaald worden naar concrete en bruikbare aanbevelingen voor de dagelijkse zorgpraktijk.

Ook het perspectief van patiënten en/of naasten laat zien dat zij zichzelf zien als actieve deelnemers in het proces, niet als passieve ontvangers van zorg en informatie. Zij hechten veel waarde aan betekenisvolle betrokkenheid, waarbij hun ervaringen en inzichten als waardevolle bijdragen worden erkend. De bevindingen suggereren dat een meer inclusieve benadering, waarbij patiënten en/of naasten worden erkend als actieve partners, kan leiden tot patiëntgerichtere evaluaties en beter afgestemde resultaten. Dit sluit nauw aan bij de aanbevelingen uit de evaluatie van de Wkkgz en benadrukt de noodzaak om patiënten niet alleen als informatiebronnen te zien, maar als volwaardige deelnemers in het proces. Op deze manier dragen wetsevaluaties bij aan de ontwikkeling van lerende organisaties en een verbeterde patiëntveiligheid in de gezondheidszorg.

Reflecties op de belangrijkste bevindingen

Dit onderzoek benadrukt de veelzijdige aard van impact van ex-post wetsevaluaties. Impact manifesteert zich in verschillende domeinen—beleid, politiek en samenleving—en wordt beïnvloed door diverse factoren, zoals context, onderzoekskwaliteit en interactie met belanghebbenden. De institutionalisering van evaluatiepraktijken, zoals die onder het ZonMw-programma, heeft geleid tot een gestructureerde aanpak van wetsevaluaties met een gegarandeerde impact richting wetgeving en politiek. De route naar maatschappelijke impact is echter minder formeel vastgelegd.

Impact realiseren is geen eenmalige gebeurtenis, maar een proces dat begint in de vroege stadia van de evaluatie en doorloopt tot de verspreiding en opvolging. Vroege betrokkenheid van belanghebbenden is essentieel om ervoor te zorgen dat de evaluatie relevante kwesties aanpakt en dat de bevindingen daadwerkelijk worden opgevolgd. Dit brengt echter uitdagingen met zich mee, zoals het waarborgen van de onafhankelijkheid van het onderzoek en het managen van verwachtingen gedurende het evaluatieproces. Dit proefschrift heeft vier belangrijke reflecties opgeleverd:

Reflectie 1: De veelzijdige aard van impact

Reflecterend op de bevindingen over de complexiteit van impact, wordt duidelijk dat impact geen enkelvoudig of lineair concept is. De complexiteit ontstaat door de diversiteit aan belanghebbenden, de verschillende contexten waarin wetten worden toegepast en de uiteenlopende manieren waarop impact zich manifesteert. De resultaten van het onderzoek lieten verschillende domeinen zien waar impact ontstaat met kennis en inzicht als voorwaarden om impact te realiseren. Als we hier op inzoomen kan impact bij individuen binnen deze domeinen worden gezien als een mechanisme met drie bewegingen: geïnformeerd raken, het verspreiden van informatie en actie ondernemen op basis van de evaluatieresultaten. Deze processen worden beïnvloed door de specifieke context, zoals de mate van betrokkenheid van belanghebbenden, de politieke omgeving en de mate van maatschappelijke interesse. Het begrijpen van deze dynamische en vaak niet-lineaire processen is cruciaal om de impact van wetsevaluaties effectief te kunnen beoordelen en te optimaliseren.

De complexiteit van impactevaluaties wordt ook erkend in bredere evaluatieliteratuur, zoals bij sociale interventies, waar de effecten vaak meervoudig, niet-lineair en vertraagd zijn. Dit vraagt om een aanpak die rekening houdt met zowel kwalitatieve als multidimensionale aspecten. Het is daarom nuttig om te leren van evaluaties in andere domeinen, zoals de gezondheidszorg, waar meerdere belanghebbenden en complexe resultaten extra uitdagingen vormen. Door deze inzichten toe te passen op wetsevaluaties, kunnen strategieën worden ontwikkeld die de effectiviteit en impact van deze evaluaties vergroten.

Reflectie 2: Impact uitbreiden voorbij het wetgevende domein
Traditioneel richten wetsevaluaties zich primair op hun impact binnen het wetgevende en politieke domein. Dit proefschrift toont echter aan dat evaluaties ook bredere maatschappelijke impact kunnen hebben, zoals het beïnvloeden van publieke percepties, het vormgeven van debatten en het veranderen van gedrag van veldpartijen. Een voorbeeld hiervan is de maatschappelijke impact van de Wkkgz-evaluatie, waarbij geschillencommissies de bevindingen gebruikten om interne processen te verbeteren en zorgaanbieders de resultaten toepasten om de patiëntenzorg te optimaliseren. Deze voorbeelden laten zien hoe wetsevaluaties veranderingen kunnen stimuleren die verder gaan dan de juridische tekst en de politiek en invloed hebben op de dagelijkse praktijken van organisaties en individuen in de samenleving.

Dit roept een belangrijke vraag op: is maatschappelijke impact een bedoeld resultaat van wetsevaluaties, of moeten we dit zien als een bijproduct van wetsevaluaties? Hoewel wetsevaluaties als instrument voor het verbeteren van de kwaliteit van wetten kan worden gezien, met wetgevers en beleidsmakers als primaire doelgroep, laat dit onderzoek zien dat het potentieel voor bredere maatschappelijke impact niet over het hoofd gezien moet worden. Wetgeving, vooral in sectoren zoals de gezondheidszorg, beïnvloedt het dagelijkse leven van patiënten, professionals en organisaties. Wetsevaluaties hebben daarom een unieke kans om niet alleen wetgevende hervormingen te informeren, maar ook maatschappelijke normen en gedragingen te beïnvloeden. Daarom ligt er een verantwoordelijkheid bij de opstellers en uitvoerders van wetsevaluaties om bewust te anticiperen op deze maatschappelijke impact. Door dit expliciet mee te nemen in het evaluatieproces kan het potentieel voor positieve maatschappelijke veranderingen beter worden benut, en kan de invloed van wetsevaluaties verder reiken dan enkel wetgevingsbeslissingen. Wetsevaluaties zouden dus niet alleen als een instrument voor beleidsmakers moeten worden gezien, maar ook als een krachtig middel voor het verbeteren van bredere maatschappelijke structuren en praktijken.

Reflectie 3: Impact ontstaat gedurende het evaluatieproces
Uit dit onderzoek blijkt dat impact geen geïsoleerde gebeurtenis is die pas na de voltooiing van een evaluatie optreedt, bijvoorbeeld bij het uitkomen van het evaluatierapport. Het hele evaluatieproces – van voorbereiding tot uitvoering, verspreiding en opvolging – biedt tal van mogelijkheden om invloed uit te oefenen op mogelijke impact. De vroege betrokkenheid van belanghebbenden kan bijvoorbeeld zorgen voor snellere aanpassingen in beleid of praktijk, zelfs

vóór de voltooiing van de evaluatie. Dit benadrukt dat impact zich niet beperkt tot het eindrapport, maar gedurende het hele proces tot stand kan komen.

Het vroeg anticiperen op impact biedt belangrijke voordelen, zoals het betrekken van relevante stakeholders en het afstemmen van het onderzoek op hun behoeften. Dit vergroot niet alleen de relevantie van de bevindingen, maar helpt ook bij het anticiperen op barrières en het ontwikkelen van strategieën om impact te maximaliseren. Zo zagen we in de evaluatie van de Embryowet hoe vroegtijdige anticipatie op impact leidde tot bredere acceptatie en gebruik van de bevindingen. Een proactieve benadering door het gehele proces verhoogt de kans dat de evaluatie impact heeft op zowel korte als lange termijn. Daarom is een proactieve benadering essentieel om de impact van evaluaties te maximaliseren. Vroegtijdige planning vergroot de kans op relevantie en acceptatie van de bevindingen, zowel op korte als lange termijn.

Reflectie 4: Stakeholderinteractie als de dominante factor voor impact
Ons onderzoek toont aan dat stakeholderinteractie een cruciale factor is voor de impact van ex-post wetsevaluaties. Wanneer belanghebbenden al vroeg, bijvoorbeeld bij het opstellen van de evaluatieopdracht, worden betrokken, sluit de evaluatie beter aan bij zowel de behoeften van de minister als de praktische behoeften in het veld. Deze vroege betrokkenheid zorgt ervoor dat relevante kwesties worden geëvalueerd en dat de bevindingen meer draagvlak en opvolging krijgen bij alle betrokken partijen. Dit bevordert de impact al tijdens het evaluatieproces. Zo zagen we in de case studies dat de betrokkenheid van veldpartijen tijdens de uitvoering van de evaluatie zorgde voor meer bruikbare resultaten en bredere acceptatie van de aanbevelingen.

Echter, de uitdaging bij intensieve stakeholderinteractie is het bewaren van de onafhankelijkheid van het onderzoek. Te nauwe betrokkenheid van stakeholders kan de objectiviteit van de evaluatie onder druk zetten. Het is daarom essentieel om een evenwicht te vinden tussen betrokkenheid en onafhankelijkheid. Participatieve methoden kunnen de impact vergroten, maar het is belangrijk om te voorkomen dat de belangen van stakeholders de integriteit van de evaluatie in gevaar brengen. Om dit evenwicht te behouden, kunnen specifieke momenten voor betrokkenheid worden ingepland en heldere, transparante richtlijnen worden gehanteerd. Zo wordt zowel de onafhankelijkheid als de relevantie van de evaluatie gewaarborgd, terwijl de impact en acceptatie van de resultaten worden gemaximaliseerd.

Aanbevelingen
In dit proefschrift worden een aantal praktische aanbevelingen geformuleerd om de impact van ex-post wetsevaluaties te optimaliseren. Deze aanbevelingen zijn gericht op verschillende fases van het evaluatieproces en zijn specifiek van toepassing op het Nederlandse ZonMw-programma Evaluatie Regelgeving, hoewel ze ook breder inzetbaar zijn. Hieronder worden de vijf hoofdaanbevelingen kort uiteengezet:

Institutionalisering van wetsevaluaties: Zorg ervoor dat evaluaties, zoals het ZonMw-programma, structureel blijven verankerd met onafhankelijke organen, zoals de CER als commissie van ZonMw, om objectiviteit en kwaliteit te waarborgen.

Betrokkenheid van belanghebbenden: Vanaf het begin moeten alle relevante belanghebbenden, inclusief patiënten en professionals, actief worden betrokken bij de evaluaties om de relevantie en toepasbaarheid van de bevindingen te vergroten.

Concreet en actiegericht: Zorg voor duidelijke, concrete aanbevelingen die direct toepasbaar zijn voor beleidsmakers en professionals.

Timing en context: Plan evaluaties strategisch om samen te vallen met beleidsmatige en politieke vensters, zodat de resultaten op het juiste moment beschikbaar zijn voor besluitvormers.

Continuïteit en opvolging: Creëer opvolgingsmechanismen om ervoor te zorgen dat de aanbevelingen worden opgevolgd en dat hun impact op de lange termijn wordt gemonitord.

Deze aanbevelingen ondersteunen een meer systematische en gerichte aanpak van wetsevaluaties, gericht op maximale impact op zowel beleids- als maatschappelijk niveau.

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Linda Knap

About the author

Linda Knap was born on April 6, 1991, in Purmerend. After completing her early education, she earned a Bachelor's degree in Business Administration from the Amsterdam University of Applied Sciences, followed by a Bachelor's degree in Law at the University of Amsterdam. She continued her studies with a Master's degree in Private Law at the Vrije Universiteit Amsterdam.

Driven by an interest in the intersection of health law and societal impact, Linda pursued doctoral research at the Netherlands Institute for Health Services Research (Nivel) and Tilburg University, where her multidisciplinary PhD integrated health law with social sciences. Her research resulted in publications on the practical functioning of health law, policies governing adverse event investigations in Dutch hospitals, and the impact of ex-post legislative evaluations.

Throughout her academic and doctoral journey, Linda worked as a paralegal at De Brauw Blackstone Westbroek. After completing her PhD, she started working as a civil litigation lawyer at Pels Rijcken & Droogleever Fortuijn, with a specialised focus on the healthcare sector.