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Great expectations

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Great expectations:

**The implementation of integrated care and its contribution
to improved outcomes for people with chronic conditions**

Lorraine Busetto



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Great expectations:

The implementation of integrated care and its contribution to improved outcomes for people with chronic conditions

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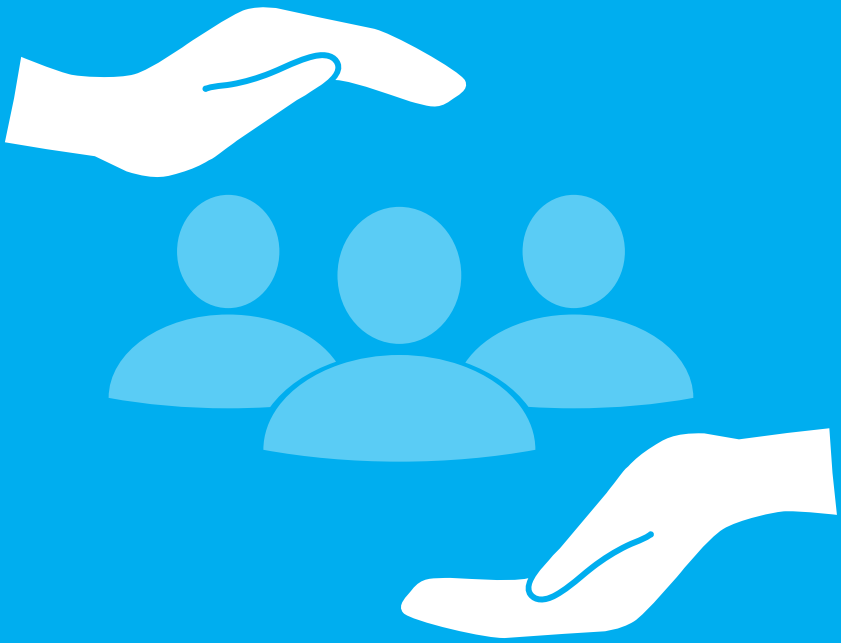


TABLE OF CONTENTS

Chapter 1

General introduction p. 9

Part A: Integrated care for diabetes and geriatric conditions

Chapter 2

Implementation of integrated care for type 2 diabetes: a protocol for mixed methods research p. 21

Chapter 3

Intervention types and outcomes of integrated care for diabetes mellitus type 2: a systematic review p. 41

Chapter 4

Context, mechanisms and outcomes of integrated care for diabetes mellitus type 2: a systematic review p. 59

Chapter 5

Implementation of integrated care for diabetes mellitus type 2 by two Dutch care groups: a case study p. 79

Chapter 6

Implementation of integrated geriatric care at a German hospital: a case study to understand when and why beneficial outcomes can be achieved p. 99

Part B: Workforce changes in integrated care interventions

Chapter 7

The development, description and appraisal of an emergent multimethod research design with multiphase combination timing p. 123

Chapter 8

Exploration of workforce changes in integrated chronic care: findings from an interactive and emergent research design p. 139

Chapter 9

Barriers and facilitators to workforce changes in integrated care p. 163

Chapter 10

Outcomes of integrated chronic care interventions including workforce changes p. 181

Part C: Methodological tools for the comprehensive evaluation of integrated care**Chapter 11**

Development of the COMIC Model for the comprehensive evaluation of integrated care interventions p. 201

Chapter 12

Advancing integrated care and its evaluation by means of a universal typology p. 223

Chapter 13

General discussion p. 233

Summary

English summary p. 266

Nederlandse samenvatting p. 272

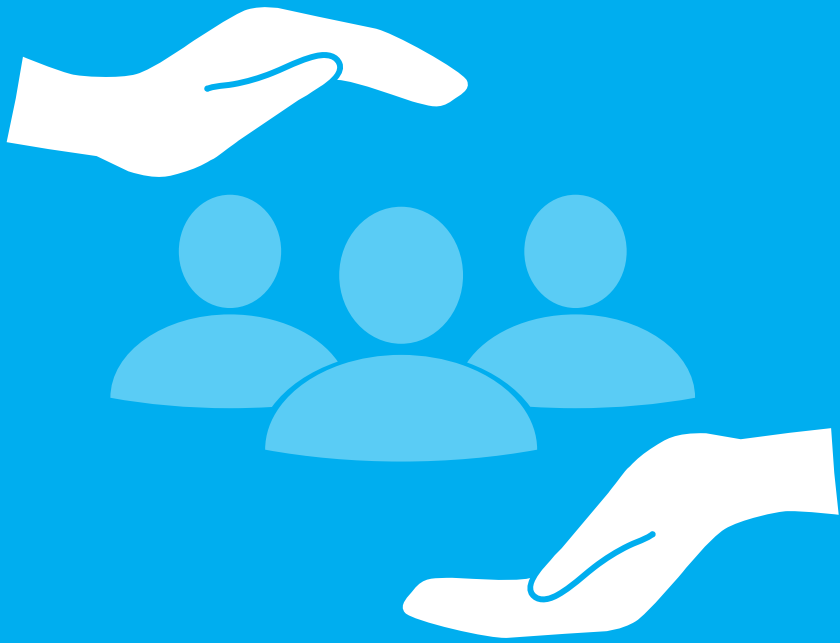
Deutsche Zusammenfassung p. 274

Sintesi in italiano p. 276

Resumen en español p. 278

Acknowledgements p. 281

Curriculum Vitae p. 283



CHAPTER 1

General introduction

The chronic disease crisis

Health systems around the globe find themselves in a chronic disease crisis. Chronic diseases, also referred to as noncommunicable diseases, are defined as conditions of long duration and generally slow progression [1]. They are responsible for approximately 50% of the world's burden of disease [2] and approximately two thirds of deaths worldwide each year [3, 4]. Between 2008 and 2030, the annual number of deaths resulting from chronic conditions is projected to further increase from 36 million to 52 million globally, which equals a relative growth of 44% [5, 6]. Moreover, the World Health Organization (WHO) estimated a 1-5% reduction in Gross Domestic Product between 2005 and 2015 due to expenditure to treat chronic disease and labour units lost from deaths by chronic disease [7]. The crisis is driven by socio-economic, cultural, political and environmental developments such as globalisation, urbanisation and population ageing, which contribute to the prevalence of modifiable risk factors such as unhealthy diet, physical inactivity and tobacco use [3, 8, 9]. In combination with non-modifiable risk factors such as age and heredity, they contribute to raised blood pressure, raised blood glucose, abnormal blood lipids and overweight or obesity, and eventually, to chronic disease [3, 8, 9].

People with chronic conditions are likely to experience multi-morbidity and tend to use more and more varied health services than their counterparts without chronic conditions [10]. The increase in the number of people with chronic conditions has therefore led to an increased demand for complex long-term care [11, 12]. However, most current health care systems are characterised by acute, episodic and single-disease-focused care provision [13]. This mismatch between what patients need and what health systems offer can lead to fragmented, duplicative, unsafe and poorly coordinated health care for people with chronic conditions [12, 14]. It has been argued that health systems must be better geared towards the needs of people with chronic conditions, for example by focusing on patient-centeredness, self-management support, multisectoral policies, clinical information systems, health workforce reconfigurations, population health management, and prevention [15]. By targeting these areas, integrated care is currently seen as one of the most promising approaches to providing appropriate care to people with (multiple) chronic conditions.

Integrated care as a solution?

Integrated care has been defined in many ways and currently, there is no consensus on one definition. In 1999, Leutz defined integration as "(...) the search to connect the health care system (acute, primary medical, and skilled) with other human service systems (e.g. long-term care, education, and vocational and housing services)" [16]. Three years later, Kodner and Spreeuwenberg defined care integration as "a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors" [17]. The results of these efforts were considered to constitute integrated care.

In 2008, the World Health Organization defined integrated care as “(t)he management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system” [18]. A more concise definition was provided by Goodwin et al. who defined integrated care as “(...) an approach that seeks to improve the quality of care for individual patients, service users and carers by ensuring that services are well-coordinated around their needs” [19]. In line with existing approaches in the international scientific literature [20-22], and for the purpose of having an operational definition of the concept despite the lack of consensus on one definition, in this dissertation integrated care is linked to the widely supported Chronic Care Model (CCM) by Wagner [23]. The CCM states that improvements in care for people with chronic conditions require changes in six components: health system, self-management support, delivery system design, decision support, clinical information system and community [23]. Interventions targeting at least two of these components are considered integrated care.

There are great expectations regarding the outcomes that integrated care is supposed to contribute to, such as improved quality of care and health outcomes, better patient experiences, and increased cost efficiency – also known as the Triple Aim [16, 24-27]. However, so far, findings have been mixed. For example, a scoping review by Foglino et al. found a positive relationship between integrated care and cancer patient experiences [28]. A meta-review of integrated care programs for adults with chronic conditions (including chronic heart failure, diabetes, chronic obstructive pulmonary disease (COPD) and asthma) found positive outcomes for hospital (re-) admissions, adherence to treatment guidelines and quality of life, but not for cost reductions [29]. Similarly, a review of integrated care for patients with schizophrenia found improvements in symptoms, functioning, quality of life, adherence, patient satisfaction, and caregiver stress, but results for costs were mixed [30]. Moreover, the authors cautioned that it was difficult to draw firm conclusions based on studies that were heterogeneous in terms of study population, therapeutic approaches, outcome measures, length of follow-up, the interventions themselves, and the specific healthcare context in which they were implemented [30]. A systematic review of integrated care for depression treatment found positive results in most trials, but the authors cautioned that questions about the specific form and implementation of the interventions remained [31]. A Cochrane review of integrated care interventions for the prevention of diabetic foot ulceration found only little evidence of positive outcomes, and, according to the authors, this evidence was based on low-quality research [32]. A systematic review and meta-analysis of integrated care programs for patients with psychological comorbidity found moderate evidence for cost-effectiveness, patient satisfaction and emotional well-being, as well as insufficient evidence for health-related quality of life, medication adherence, Hb1Ac levels and mortality [33]. Four parallel reviews and meta-analyses of integrated care for diabetes, heart failure, depression and COPD found varying effects on mortality, hospitalisation, emergency department visits, and quality of life [20, 22, 34, 35]. They specifically investigated whether this heterogeneity in intervention effectiveness could be explained by factors such as study quality, length of follow-up, or the number of CCM components included in the interventions, but this was only partially the case.

The above approaches have in common that they try to determine the effectiveness of integrated care by assessing specific outcome measures before and after the implementation of the intervention, and, if

the research design is sound, differences in outcomes are attributed to the intervention. In doing so, the “net effect” of the intervention is estimated relatively irrespectively of what exactly the intervention consisted of. The same holds true for context factors, which are usually stripped away so as not to confound the “pure” effect of the intervention [36]. This reasoning has been described as reductionist, because it considers interventions as isolatable from the setting in which they are implemented as well as the process by which they are implemented [36, 37]. This logic might indeed be the best way to evaluate conceptually simple interventions such as drugs, especially when conducted in the form of randomised controlled trials [38, 39]. However, it has been argued that the logic is an inappropriate (even “impoverished” [38]) basis for the evaluation of complex interventions. In contrast to single component interventions, complex interventions tend to include multiple components, target multiple levels, contribute to multiple outcomes, and are generally implemented in complex systems [36-38]. Berwick has argued that this specific mismatch of studying complex interventions by using reductionist methods typically results in inconsistent findings or the assertion that nothing works [38]. However, even if findings are significantly negative or positive, these insights can only inform whether or not the intervention should be continued (to be invested in) or not [39]. We would not know whether the outcomes can be attributed to certain active components of the intervention, the interaction between different components, the interaction between components and context factors, or context factors that act independently of the intervention. This lack of knowledge makes it impossible to learn from experience, and to improve an intervention based on what has been learned [36, 40, 41]. Additionally, it makes it difficult to gauge to what extent and in which form seemingly successful interventions can be implemented in other settings [38, 39].

Research objective

Due to the inconclusiveness of previous effectiveness reviews of integrated care and the methodological difficulties in evaluating complex interventions using reductionist approaches, it has been argued that rather than asking whether integrated care contributes to better outcomes, we should focus on trying to understand when, why and how some interventions do, while others do not [38, 39, 41-43]. To answer these types of questions, it is necessary to focus on the implementation of an intervention, including which type of intervention was implemented, how the setting in which the intervention was implemented affected its implementation, and which outcomes were achieved [38, 44, 45]. We use a broad understanding of implementation that includes the initial implementation of the intervention in practice as well as the execution of the intervention from that period on [40, 46]. Rather than assessing whether integrated care “works”, the aim of this dissertation is to answer the question:

How is integrated care implemented and to which outcomes does it contribute?

We approached this question from two different angles. First, we aimed to study the implementation of integrated care for different (groups of) chronic conditions. This research was part of Project INTEGRATE on “Benchmarking Integrated Care for Better Management of Chronic and Age-related Conditions in Europe”, running from September 2012 to August 2016. Project INTEGRATE aimed to gain insights into the leadership, management and delivery of integrated care in Europe (31). In Phase 1 of

the project, four case studies of integrated care implementation were investigated, focusing on COPD in Spain, type 2 diabetes in the Netherlands, geriatric conditions in Germany and mental conditions in Sweden. The main aim was to study what constitutes good quality integrated care provision. We, a research team from Tilburg University, were the work package leader of the study on type 2 diabetes and collaborated with the leader of the German case study on geriatric conditions. We made use of Pawson and Tilley's "context + mechanism = outcome model" (CMO Model) as an umbrella framework for the collection, analysis and interpretation of data. The CMO Model proposes that interventions only have successful outcomes when they introduce appropriate mechanisms in the appropriate social and cultural contexts [45].

Second, we aimed to study the implementation of a specific aspect of integrated care interventions. This research was also part of Project INTEGRATE, where in Phase 2 of the project, five so-called "cross-cutting" issues were examined that were expected to play an important role in all of the case studies. These included care process design, workforce changes, financial flows, patient involvement and information technology (IT) management. We were the work package leader of the study on workforce changes, for which we collaborated with a research team from the University of Lugano in Switzerland. Given health professionals' involvement in all aspects of integrated care delivery, changes to the health workforce affect the implementation of integrated care profoundly and are therefore seen as key enablers of integrated care provision [47, 48]. Again, we made use of the CMO Model as an umbrella framework for the collection, analysis and interpretation of data.

In addition to these two angles, we aimed to develop appropriate methodological tools to support the comprehensive evaluation of integrated care interventions. This research was not formally part of Project INTEGRATE, but a consequence of the obstacles encountered during the various phases of the research. As already mentioned, we made use of the CMO Model, but soon found it to be problematic that there was no consensus on the definition and operationalisation of its elements [49, 50]. Moreover, there was no explicit link between the CMO Model and integrated care, which was challenging given the lack of consensus on how integrated care should be defined. As a remedy to this, we developed a preliminary model, based on the CMO Model, which operationalised mechanisms as intervention types, context as barriers and facilitators to the implementation of the intervention, and outcomes as effects triggered by mechanisms and context. More specifically, we categorised mechanisms according to the six components of the CCM described above. The barriers and facilitators were categorised according to the Implementation Model by Grol and Wensing, which specifies six levels of healthcare at which barriers and facilitators to change can occur (i.e. innovation, individual professional, patient, social context, organisational context and economic and political context) [51]. Outcomes were not yet linked to a specific model, because we were not certain about the appropriateness of the types of outcomes reported in traditional types of evaluation studies [37]. This preliminary CMO-based model was applied to and further developed based on the different studies we conducted within the scope of Project INTEGRATE. The aim of this effort was to develop a model, based on CMO-thinking but with operationalised elements and an explicit link to integrated care, that would enable the comprehensive evaluation of integrated care interventions, including the interplay between intervention types, context factors and outcomes, and thereby provide insights into when, why and how integrated care can

contribute to improved outcomes. Additionally, given the variation in understandings of what integrated care is or should be, we aimed to contribute to the development of a universal typology of integrated care interventions that would allow for the description, and thereby comparison, of different interventions despite the lack of consensus on one “best” definition. We believe this to be a necessary tool to make integrated care interventions and their components observable, identifiable, measurable and therefore comparable, which would also contribute to more systematic and consistent evaluations of integrated care interventions.

Outline of the dissertation

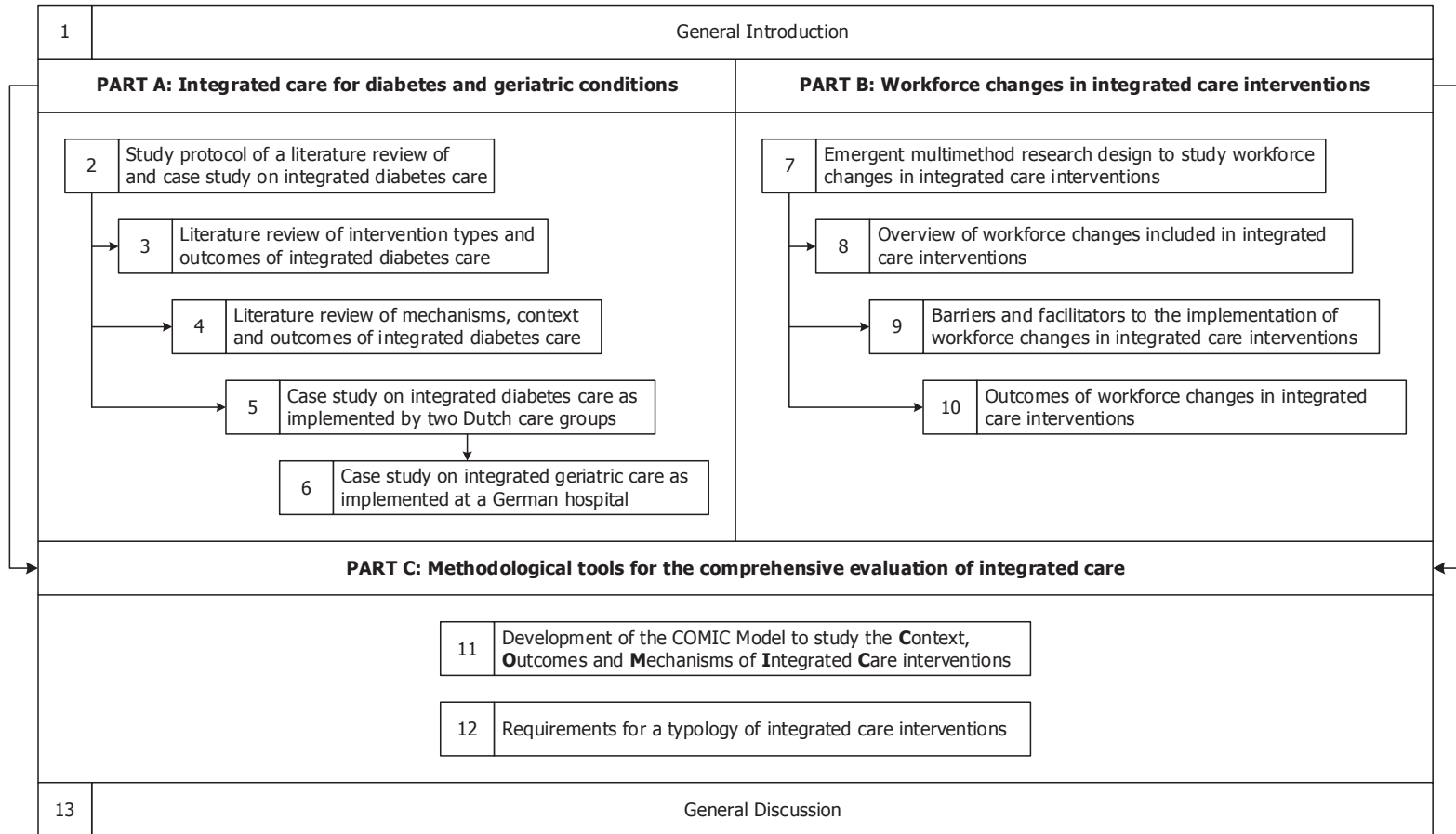
The outline of the dissertation is shown in Figure 1. The studies are numbered according to the respective chapters of the thesis in which they are presented, starting with this General Introduction in Chapter 1 and ending with the General Discussion in Chapter 13. Arrows indicate that studies are based on insights presented or methodologies developed in previous studies.

Part A is concerned with the implementation of integrated care for diabetes and geriatric conditions. Specifically, Chapter 2 describes the study protocol of a review of the international scientific literature on integrated care for type 2 diabetes and a case study on Dutch integrated care for type 2 diabetes. Chapter 3 presents the first part of the literature review which focusses on the intervention types and outcomes of integrated care for people with type 2 diabetes. The second part of the literature review, reported in Chapter 4, investigates the context, mechanisms and outcomes of integrated care for people with type 2 diabetes. In Chapter 5, a Dutch case study on integrated care for type 2 diabetes in the primary care setting is reported, while Chapter 6 reports a German case study on integrated care for people with geriatric conditions in a secondary care setting.

Part B is concerned with the implementation of workforce changes as part of integrated care interventions. Chapter 7 introduces the emergent multimethod research design which connects our studies on workforce changes. In Chapter 8, we describe which workforce changes were implemented as part of integrated chronic care interventions and Chapter 9 describes the barriers and facilitators to their implementation. Chapter 10 describes the outcomes of the workforce changes. All studies on workforce changes discuss the difference between focussing on workforce changes in integrated care interventions, as opposed to studying integrated care interventions that include workforce changes.

Part C is concerned with the development of methodological tools for the comprehensive evaluation of integrated care. Chapter 11 describes the development of the COMIC Model to study the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions. In Chapter 12, we argue for the advancement of integrated care and its evaluation by means of a universal typology of integrated care interventions.

Figure 1: Outline of the dissertation



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PART A

Integrated care for diabetes and geriatric conditions



CHAPTER 2

Implementation of integrated care for type 2 diabetes: a protocol for mixed methods research

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Implementation of Integrated Care for Type 2 Diabetes:
A Protocol for Mixed Methods Research.
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Abstract

Introduction: While integrated care for diabetes mellitus type 2 has achieved good results in terms of intermediate clinical and process outcomes, the evidence-based knowledge on its implementation is scarce, and insights generalisable to other settings therefore remain limited.

Objective: This study protocol provides a description of the design and methodology of a mixed methods study on the implementation of integrated care for type 2 diabetes. The aim of the proposed research is to investigate the mechanisms by which and the context in which integrated care for type 2 diabetes has been implemented, which outcomes have been achieved and how the context and mechanisms have affected the outcomes.

Methods: This article describes a convergent parallel mixed methods research design, including a systematic literature review on the implementation of integrated care for type 2 diabetes as well as a case study on two Dutch best practices on integrated care for type 2 diabetes.

Discussion: The implementation of integrated care for diabetes type 2 is an under-researched area. Insights from this study could be applied to other settings as well as other chronic conditions to strengthen the evidence on the implementation of integrated care.

Introduction

Diabetes mellitus type 2 has become a widespread problem in many Western societies. In 2010, the global diabetes prevalence among people aged 20-79 years was estimated at 6.4%; in the European Union and Netherlands, prevalence in similar age groups was respectively 6% and 7% in the same year [1-3]. Due to these high prevalence rates, diabetes has a major impact on society in terms of the economic costs incurred by diabetes patients. Research indicates that 12% of global health expenditure was spent on diabetes in 2010 [4]. European Union countries spent approximately 10% of their total health expenditure on diabetes in 2010 [2, 4] and in the Netherlands, 2-9% of total health expenditure was spent on diabetes care in 2010/2011, depending on the registration of co-morbidity and the extent to which diabetes-related complications are considered in the estimations [4, 5].

Previous systematic reviews have shown that integrated approaches to diabetes care can yield improvements in care delivery process as well as intermediate clinical outcome indicators. Benefits have been found for process indicators such as screening for retinopathy [6-8], foot lesions [6-8], peripheral neuropathy [7], proteinuria [7], and monitoring of lipid concentrations [7] and glycated hemoglobin [7], as well as intermediate clinical outcome indicators such as glycated hemoglobin [6, 8-10], blood pressure [8, 11] and blood lipid control [10, 11]. In addition, previous systematic reviews have demonstrated the added value of integrated chronic care in terms of economic benefits [12]. However, other reviews have shown no (significant) impact on the above process and outcome indicators [7, 13], or have disputed the clinical relevance of statistically significant findings [10]. There is still a lack of evidence regarding the question which integrated care programmes are effective in which circumstances. Despite the fact that several previous studies have pointed out the importance of studying implementation [14-16], all of the above shows that there is a disproportionate emphasis on the goal-achievement and effectiveness of integrated care for type 2 diabetes rather than the intricacy of the implementation. By stripping away all confounding factors so as to be able to study the intervention's pure effect on the outcome, researchers run the risk of proclaiming program failures prematurely as well as being blinded to the actual determinants of success or failure [17].

This article describes the design of a mixed methods study on the implementation of integrated diabetes care, combining a literature review of international integrated diabetes care with a case study on two Dutch best practices on integrated care for type 2 diabetes. The aim of the proposed research is to identify the different contexts in which and mechanisms by which integrated care for type 2 diabetes has been implemented, to report the outcomes achieved, and to investigate how the contexts and mechanisms have affected these outcomes. This study is part of Project INTEGRATE on "Benchmarking Integrated Care in Chronic and Age-related Conditions in Europe", financed by the European Commission (project reference 305821). Project INTEGRATE aims to investigate the leadership, management and delivery of integrated care to help European care systems responding to the challenges of an ageing population and the increasing number of people living with chronic conditions [18, 19]. The proposed research focuses on the following four overall research questions:

1. By which mechanisms has integrated care for type 2 diabetes been implemented?
2. In which contexts has integrated care for type 2 diabetes been implemented?
3. What were the outcomes of integrated care for type 2 diabetes?
4. How have the contexts and mechanisms by which integrated care for type 2 diabetes has been implemented affected its outcomes?

Methods

Research Design

A mixed methods design will be used for this study as this is the most appropriate research design for studying the implementation process as well as the outcomes of integrated care. As Pawson and Tilley point out, classical methodologies usually focus on observations at two specific points in time, namely before the intervention and after the intervention [20]. In order to increase the ability to attribute the differences observed post-intervention to the intervention itself (instead of 'third variables'), most factors expected to have a confounding effect on the causal relationship are stripped away. However, for complex interventions, which can be seen as "dynamic complex systems thrust amidst complex systems" [21], it is often precisely those factors left out of the equation which hold the most valuable information [17, 20]. To avoid this methodological pitfall, several qualitative methodologies will be used and combined with quantitative methods, which, according to Berwick, is an approach superior to the more classical methodologies such as randomised controlled trials [17]. We decided to use a convergent parallel mixed methods design which involves concurrent implementation of the qualitative and quantitative research strands, equal prioritisation of the quantitative and qualitative methods, independent analysis of both strands with traditional methods and merging of strands during overall interpretation [22]. Specifically, the design includes a systematic literature review and a case study to be qualitatively analysed with an explicit focus on context, mechanisms and outcomes. Moreover, local wisdom will be emphasised by actively involving local stakeholders instead of excluding them for fear of bias [17]. This will enable the researchers to access the stakeholders' insights into the details of the implementation that might otherwise remain hidden from their view. In addition, for the case study, quantitative patient outcome data will be collected and analysed. After independent analyses, the qualitative and quantitative results will be combined for overall interpretation.

Operationalisation

Integrated Care

In order to determine which interventions can be considered integrated care, it is important to operationalise what we mean by integrated care. Given the quasi-universal acceptance of Wagner's chronic care model and its widespread use throughout the literature [23-25], we decided to link our understanding of integrated care to the chronic care model. In line with previous research, it was decided that if an intervention targets at least two of the four core chronic care model components, the intervention is to be considered integrated care [8, 26, 27]. When assessing whether a study is indeed concerned with integrated care, it is important to ensure that all researchers apply the same understanding of the components. Hence, it was decided to operationalise the four chronic care model

components to be used for the review. This operationalisation is largely based on the checklist used in the 'Developing and Validating Disease Management Evaluation Methods for European Health Care Systems' (DISMEVAL) project [28], and complemented by other definitions and examples of the chronic care model components in the literature [29-32]. Table 1 (Appendix) depicts the operationalisation of the chronic care model to be used in the literature review.

Implementation

By 'implementation' we mean the bringing into practice of a model for change, which is always implemented by certain mechanisms and in a certain context. The specific terminology of 'mechanism' and 'context' used in this study is derived from Pawson and Tilley's work on realistic evaluation [20]. Their main claim is that it is both the context in which an intervention is implemented (including the organisational, financial, political, technological and human constraints) as well as the mechanisms by which it is implemented (including assumptions of how change can be achieved) that will affect the outcomes that can be achieved by the intervention [20, 33]. This means that instead of asking whether an intervention worked, the purpose of realist enquiry is to identify the mechanisms and context and to find out which mechanisms work in which context to achieve which outcomes [20, 21, 33].

Mechanism: By 'mechanism' we mean the different types of integrated care for type 2 diabetes distinguished into 'programmes' and 'interventions'. By 'programme' we mean a set of at least two interventions whose combined implementation is intended to lead to the achievement of a certain goal, often an improvement in the quality of care. By 'intervention' we mean the tangible actions that, combined, constitute a programme.

Context: The context of implementation consists of implementation strategies and an implementation process. By 'implementation strategies' we mean information and plans concerning what to do to facilitate and improve the working of the change model in practice, explicitly formulated prior to the realisation of the model for change in practice. By implementation process we mean the process of 'social change' triggered by the mechanisms, which inherently, is sensitive to a multitude of context factors that impact on this process [17]. We describe the implementation process through the description of those factors encountered during the implementation process and explicitly identified by the stakeholders as barriers or facilitators to the implementation of the integrated diabetes care program or intervention.

Outcomes: By 'outcomes' we mean the intended and unintended consequences triggered by mechanism and context, including both process outcome measures and intermediate clinical outcome measures. Process outcome measures include (but are not limited to): frequency of measurements of HbA1c/A1C, blood pressure, and lipids, frequency of patient consultations, recommendation to take aspirin, dilated retinal examinations, urine tests, statin therapy prescription, and receipt of influenza vaccination. Intermediate clinical outcome measures include (but are not limited to): HbA1c/A1C, blood pressure, and LDL values.

Literature Review

The literature review aims to provide answers to the research questions from an international perspective. For the first research question, the integrated care programmes and interventions identified through the systematic literature search will be described in detail and classified according to the chronic care model as operationalised by the authors (see Table 1, Appendix). For the second research question, qualitative analyses will be performed to summarise the strategies for as well as barriers and facilitators to the implementation of integrated care for type 2 diabetes, as identified in the literature. For the third research question, qualitative analysis will yield an overview of the outcomes of the integrated diabetes care programmes and interventions described in the literature. Finally, it will be investigated to what extent and in what way the implementation strategies and process affected the outcomes.

Search Strategy

In order to find relevant articles, four groups of search terms will be created: (1) search terms related to the health condition, (2) search terms describing the type of intervention, (3) search terms related to the four chronic care model components and (4) the search term "implementation" (Table 2, see Appendix). The four groups of search terms will be connected with Boolean operators in such a way that articles concerned with diabetes and an integrated care type intervention (or combinations of two out of the four chronic care model components) and implementation will be retrieved. The databases Pubmed/Medline and Cochrane will be searched for eligible articles.

Selection

A total of three screening rounds will be performed based on readings of titles, abstracts and full texts. In each round, articles will be included based on the following inclusion criteria: (1) published between 2003 and 2013; (2) concerns integrated care; (3) focusses on type 2 diabetes or focusses on type 2 diabetes and one or more additional condition(s) and reports results for each condition separately. Articles written in a language other than English or one of Project INTEGRATE's case study languages (German, Dutch, Spanish and Swedish) will be excluded. Articles with a target population consisting only of children, adolescents, prisoners or homeless persons will be excluded as they do not match the target population of the two Dutch case studies. Articles not concerning empirical research analysing the implementation of interventions will be excluded. Additionally, systematic reviews and meta-analyses will be excluded because these types of studies report results on a rather abstract level of evidence which might mask insights that are relevant for this implementation-focussed type of study. In all exclusion rounds, articles can be excluded for more than one reason. When in doubt or when the title or abstract does not give enough information to base a decision on, articles remain included. The screenings will be performed by three independent researchers. To ensure a homogeneous selection, a checklist based on the above operationalisation of the chronic care model and the previously mentioned in- and exclusion criteria will be used by all researchers. After this, the results will be discussed in pairs in order to create agreement on the interpretation of the criteria. When in doubt or disagreement, discussions between the researchers will take place until consensus is achieved.

Data analysis

After the article selection, the included studies will be analysed. Data extraction and quality assessment for each article will be performed independently by three researchers using a standardised data extraction form to ensure uniformity. The following information will be extracted from the articles: general information (including author, year of publication and title), methodological information (including data collection methods, type of data collected, setting or context of data collection, follow-up period, population and participants, researcher's influence, data analysis, research questions and/or article objective, study limitations), information on the integrated care program or intervention (including the name of the program or intervention, its purpose, and the specific interventions of which the program consists), implementation strategies, barriers, facilitators and outcomes of the integrated care program or intervention. Based on this information, the articles' quality will be assessed by using the 2011 version of mixed methods appraisal tool [34, 35]. The mixed methods appraisal tool is a unified tool that can be used for the simultaneous quality assessment of qualitative, quantitative and mixed methods studies [34]. Despite its relative novelty, the mixed methods appraisal tool has already been used as a comprehensive quality assessment tool in various systematic reviews in the health sciences [36-38]. See Table 3 (Appendix) for a tabular overview of the quality aspects to be assessed per type of study. After the extraction and assessment, the researchers will compare and discuss the forms until disagreements can be resolved by consensus. Additionally, the implementation model by Grol and Wensing will be used for the categorisation of the context factors identified in the literature review [39]. According to this model, barriers to and incentives for change occur at six different levels of health care, namely innovation, individual professional, patient, social context, organisational context, and economic and political context [39]. Grol and Wensing's model has been used for the categorisation of barriers and facilitators to integrated care for diabetes type 2 in several previous studies [16, 40, 41]. The results from the literature review will be used as a context for the insights gained from the case study and will enable the identification of differences and commonalities between the international literature and the Dutch case.

Case Study

In order to answer the research questions from the Dutch perspective, a case study on Dutch integrated diabetes care will be conducted at two separate case sites.

Case selection

Two care groups will be invited to participate as best practice case sites in the case study research. Care groups are legal entities with their own managerial and administrative staff, often (co-) owned by general practitioners, that cooperate with a variety of health care providers involved in the provision of chronic care. The decision to focus on national best practices is based on the assumption that identifying success factors encountered by the frontrunners of diabetes care innovation will generate meaningful lessons for those that are now encountering or will still have to encounter similar barriers in the future. Moreover, focusing on best practices will generate an important potential for learning by other Dutch care groups, and, given the Netherlands' long experience in integrated care and status as a pioneer [42, 43], also for other European and non-European countries. Despite the popularity and widespread use of best practices research, its use in scientific research is controversial, most notably due to

the limited external validity of this case-based approach [44, 45]. Therefore, it should be noted that the authors define best practices as “best practices for the process of planning for most appropriate interventions for the setting and population” [44]. This definition entails that the envisaged outcome of best practices is not a generalisable plan, but a generalisable process for planning [44]. The following criteria will be pivotal in the selection of the care groups: nomination as national best practices by leading health research institutions, participation in previous (diabetes) research, involvement in care innovation pilots such as those recently selected by the Dutch Minister of Health, Welfare and Sport to be closely followed in the upcoming years [46].

Data Collection

Data from the two case sites will be collected by means of a document review, semi-structured interviews, and routine health care data.

Document Review. The documents will be provided by the two case sites’ respective contact persons. Initially, the interviewers will request documents that cover the whole cycle of implementation, from the initial idea via planning, implementation, evaluation and adaptations to the current state of affairs. At a later stage, additional documents will be requested for those phases not adequately covered by the initial set of documents. The documents to be collected include regional policy documents, performance evaluation reports, annual reports, focus group reports, improvement plans, educational programmes, and other documentation. The main purpose of the document review is as preparation for the interviews, to serve as illustration and for the triangulation of the interview results.

Interviews. In addition to the document study and the collection of routine health care data, 25 interviews will be conducted for each case site. Interviews will be chosen as main method of data collection because their purpose is to gain an overview of the variations in perspectives and opinions and the circumstances that play a role [47]. In addition, interviews are the preferred method of data collection when the research question refers to opinions and experiences (as opposed to actions) which only the interviewee can access [48], which is applicable to this case, especially regarding the barriers and facilitators encountered during the implementation process. Of the 25 interviews to be conducted per care group (50 in total), 10 will be held with diabetes patients; the other 15 with care group directors, managers and staff as well as health care providers involved in the organisation and delivery of integrated diabetes care, including general practitioners, internists, diabetes nurse specialists, practice nurses, dieticians, pharmacists, optometrists, podiatrists, and pedicurists. Precisely which persons and professions will be approached, will be decided in consultation with the care group contact persons. We expect that a heterogeneous sample including patients as well as all relevant health professions and care group staff involved in diabetes care will create as complete a picture as possible, consisting of many diverse perspectives, experiences and opinions.

Interviewees will be requested to sign an informed consent form, indicating that he or she has read the information leaflet and had the opportunity to ask questions, that he or she understands that the participation in the research is on a voluntary basis and can be revoked at any time, that he or she agrees to participate in the research and with the interview being audio-taped. All interviews will be

audio-recorded and transcribed. During the interviews, the interviewers will use a topic list to help the interviewer steer the conversation via predefined topics and initial questions [47]. The topic list for the health professionals will focus on the areas of integrated care in general and in the interviewee's institution, implementation of integrated care, information technology, finance, and sustainability of integrated care. As previous research with patients suffering from chronic disease has shown the importance of giving patients the opportunity to tell their illness narratives [49-51], the patients' topic list will focus on the patients' personal experiences with their disease, their knowledge and experiences about integrated care and the care group they are a part of, the barriers and facilitators they encountered to their care as well as the health outcomes they achieved and how the former may have affected the latter. While establishing rapport between the interviewer and interviewee is important in all individual interviews, it is especially so for the more vulnerable target groups such as (elderly) patients. Therefore, the four stages of building rapport, namely apprehension, exploration, co-operation and participation, will be given special emphasis in the patient interviews [52].

In both cases, the number and nature of the sub-questions can vary, as can the pre-defined topics if considered necessary during the research process [47]. Additional and follow-up interviews will be conducted until saturation is achieved regarding the scope and the detail of the research. To assure the quality of the interviews conducted a member check will be performed by sending a one page summary of each interview to the interviewees who will then be asked whether this summary reflects their point of view and statements made during the interview. In case of negative feedback by the interviewee, a follow-up interview will be scheduled for clarification.

Routine health care data: To measure health outcomes, diabetes type 2 patients' routine health care data will be collected. These will be provided by the care groups participating in the case study. They have access to the data from all diabetes type 2 patients in treatment by general practitioners who are members of the care group as the collection of these data in a common information technology system is a requirement for membership of the care group. Data will be collected for the period from 2008 (start of systematic data collection by the care groups via the electronic medical record) to 2014 (start of data collection by the researchers). The collected data include intermediate clinical outcome measures (e.g. glycated haemoglobin, low-density lipoprotein, systolic blood pressure and body mass index) as well as process outcome measures (measurements of glycated haemoglobin, low-density lipoprotein, systolic blood pressure and body mass index) [31, 53].

Data analysis

For the analysis of the interviews, the audio-recordings will be transcribed verbatim and coded independently by two researchers. Given the inherently iterative nature of qualitative research [54], the coding of the interview transcripts will be performed in three phases, namely open coding, axial coding and selective coding [54, 55]. In the open coding phase, which is characterised by its exploratory nature [54], two researchers will label fragments of the text material with descriptive as well as interpretive codes based on the interviewees' own wording (in vivo codes) and prominent concepts from the literature study described above (constructed codes) [56, 57]. The second phase, axial coding, involves finding and describing important concepts and making a distinction between the more or less

relevant codes so as to reduce the amount of material [55, 57]. In the selective coding phase the researchers will start searching for explanations of the phenomena that were found as well as the relationships between different categories [55, 58]. All coding activities described above will be performed independently by two researchers. This will help to limit bias and assure the quality of the analysis as well as enable the development of a well-structured coding system [55]. In addition, it helps to improve the validity and objectivity of the results [58]. Disagreement will be resolved by consensus through bilateral discussions. All coding and analysis activities will be performed in Atlas.ti 6. Furthermore, as for the literature review, also for the case study, the implementation model by Grol and Wensing will be used for the categorisation of the context factors identified [39].

For the quantitative data, statistical analyses will be performed in SPSS 19. Multi-level analyses will be performed to describe the development of process and intermediate patient outcomes over time at baseline (t0) and yearly intervals until 2014 (t6). Moreover, the intermediate and process outcomes for each care group will be compared using analysis of variance. Sex, age, diabetes type and diabetes duration will be included as potential confounders. As mentioned above, special emphasis will be put on the integration of qualitative and quantitative data, by comparing quantitative clinical data to qualitative patient stories and explaining how they relate to each other. Moreover, the results from the analysis of the interviews and document study will be triangulated with the results from the literature review. This entails that the results from the literature review will provide a context for interpretation of the case study results by providing the basis for the coding process of the interviews. This will enable us to give a combined answer to the same research questions, based on different sources of knowledge.

Discussion

This paper presents the design of a mixed methods study to be conducted on the implementation of integrated care for type 2 diabetes. The chosen combination of methods of data collection and analysis will enable a thorough study of the mechanisms by which and contexts in which integrated care for type 2 diabetes has been implemented, which outcomes have been achieved and how the former affected the latter. Especially the combination of the international literature review and the national case study will provide added value through the triangulation of results and the provision of an international embedding of national research.

An important strength of this article is its grounding in different conceptual models, including Pawson and Tilley's realistic evaluation framework, the chronic care model and the implementation model, which all adopt a holistic approach to implementation analysis. While realistic evaluation makes it possible to study the links between the intervention, its implementation and outcomes achieved, the six chronic care model components and implementation model levels, respectively, make it possible to capture the whole range of inner local/organisational factors as well as outer national/regulatory factors. This is especially important given the Netherlands' national set-up of integrated care via care groups and bundled-payment contracts which are implemented differently per local context. The authors believe that the interviewees to be selected for this study will be able to identify and elaborate

on the links between the national/regulatory and local/organisational factors and connect them to the likelihood of a successful implementation in practice.

There are also some limitations to this prospective study which need to be taken into consideration. First, the decision to link the definition of integrated care to the chronic care model might blind the researchers to aspects of care integration that are not described by the chronic care model. The choice of the chronic care model, however, is based on its acceptance and use in the international literature as well as national practice, assuming that this indicates the model's scientific and societal relevance and applicability. The second limitation concerns the decision to focus the literature search only on the four core elements of the chronic care model. By not actively searching for health system and community interventions, the search might miss publications of potential added value to the research. However, given the study's explicit focus on the implementation of programmes and interventions, the researchers feel the necessity to limit the search to the most tangible of interventions. It is likely that the programmes identified through the literature search will often also include aspects of the health system and community components even if they are not actively searched for. The third limitation lies in the study's focus on best practices. Despite the many advantages this entails, focusing on best practices only means that the results from the prospective study will not provide any information about average Dutch diabetes care. By not including other care groups in the research, it will also not be possible to report the exact aspects in which the two selected case sites differ from other Dutch care groups and whether these differences might limit the external validity as well as applicability of the results to other care groups. The literature review, however, applies an international perspective and balances the focused perspective of the case study.

Conclusion

Systematic investigation of the implementation of integrated care is insufficiently highlighted. This research fills the gap in knowledge on how to best implement integrated care for type 2 diabetes, taking into account the specific mechanisms and contexts that affect the outcomes to be achieved. In doing so, this study will form the basis of tangible recommendations to health practitioners, managers and policy makers as to what can or should be implemented in which circumstances and what the expected results can be. Insights from this study could be applied to other settings as well as other chronic conditions to strengthen the evidence on the implementation of integrated care.

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Appendix

Table 1: Operationalisation of the four core chronic care model components

Chronic Care Model component	Intervention	Source
Self-management support	Information Provision	[29]
	Patient education – general	[28]
	Patient education – disease education	[32]
	Patient education – self-management education	[32]
	Provision of self-management tools	[32]
	Patient-centeredness / active patient involvement, e.g. in development of care plan and goal setting	[28, 30]
	Behavioural support / motivational support	[29]
	Other	
Delivery system design	Team-based care provision	[29-31]
	Structured care	[31]
	Individualised care	[28]
	Medicines management	[28]
	Follow-up	[28, 30, 32]
	Case management	[28, 30]
	Nurse-led care	[32]
	Health literacy	[30]
	Cultural sensibility	[30]
	Advanced access to medical care for participants	[29]
	Other	
Decision support	Evidence-based guidelines	[28-32]
	Provider education	[28, 30, 32]
	Access to / integration of specialist expertise	[28, 29]
	Non-automated performance monitoring	[30, 32]
	Feedback	[28-30]
	Non-automated clinician reminders	[30]
	Non-automated patient reminders	[30]
	Other	
Decision support	Patient reminder system	[28-30]
	Provider reminder system	[28-30]
	(Electronic) Patient registry	[29]
	(Electronic) Disease registry	[28, 32]
	Electronic performance monitoring	[28, 30, 32]
	Electronic medical record	[32]
	Use of electronic / ICT devices	[32]
	Other	

Table 2: Four groups of search terms

Group	Search terms
Health condition	diabetes, diabetes type 2, diabetes mellitus, DMT2, diabetes mellitus type 2
Intervention type	integrated care, disease management, disease state management, comprehensive healthcare, complex interventions, multifactoral lifestyle interventions, shared care, chronic care model, care transition, transitional care, intermediate care, case management
Chronic care model component	<p>Self-management support: self-management, self-care, self-management support, patient-centeredness, patient-centred care, behavioural support, motivational support</p> <p>Delivery system design: delivery system design, care pathway, critical pathway, individualised care plan, clinical case management services, medicines management, co-morbidities management, health literacy, cultural sensibility, practice nurse counseling, team-based care provision</p> <p>Decision support: decision support, clinician reminders, patient reminders, reminder systems, provider education, specialty expertise integration, individualised care plans</p> <p>Clinical information system: clinical information system, clinical registry, population information database, shared information system, health information systems, health information technology, electronic registry, clinical reminder, patient reminder, clinician reminder, provider feedback, performance monitoring, ICT devices, patient portal, telemonitoring, telehealth, teleassistance, telehomecare, videoconferencing, mobile phone, electronic health record, patient-held record</p>
Implementation	Implementation

Table 3: Tabular overview of the mixed methods appraisal tool [34]

Type of research	Focus
All	Clear research question and/or objective?
	Do collected data allow answering the research question?
Qualitative	Relevant data sources for research question?
	Relevant data analysis process for research question?
	Findings related to research context?
	Findings related to researcher's influence?
Quantitative randomised controlled trials	Description of randomisation?
	Description of allocation concealment?
	Completion rate?
	Withdrawal rate?
Quantitative non-randomised	Participants recruited with selection bias?
	Appropriate measurements?
	Comparability between participants in different groups?
	Appropriate completion rate?
	Appropriate withdrawal rate?
Quantitative descriptive	Appropriate follow-up rate?
	Relevant sampling strategy for research question?
	Representative study population?
	Appropriate measurements?
Mixed methods	Acceptable response rate?
	Relevant research design for research question?
	Relevant integration of qualitative and quantitative data or findings?
	Consideration of the limitations of above integration?



CHAPTER 3

Intervention types and outcomes of integrated care for diabetes mellitus type 2: a systematic review

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Abstract

Rationale, aims and objectives: The delivery of integrated care is a priority in many countries' efforts to improve health outcomes for people at risk of or with diabetes. This study aims to provide an overview of the different types of integrated care interventions for type 2 diabetes and to report their outcomes.

Methods: A systematic literature search was conducted in PubMed and Cochrane for the period 2003-2013. Article selection and data extraction were performed independently by three researchers and results were discussed together. The chronic care model (CCM) was used to describe intervention types.

Results: Forty-four articles met the inclusion criteria. Most interventions included all CCM components and a variety of sub-components. Most studies reported positive patient, process and health service utilization measures. The information on costs was limited and inconsistent. The low number of articles reporting comparable outcome measures made it difficult to make meaningful statements about an association between intervention type and outcomes.

Conclusions: Future research would benefit from a more uniform understanding of integrated care as well as intermediate outcome measurements that allow for the establishment of a chain of evidence from specific intervention types to specific outcomes achieved. It is expected that such a comprehensive approach will reveal important insights as to which integrated care intervention types and settings are most conducive to successful implementation and would thereby be of relevance to policymakers and practitioners involved in the financing, management and delivery of integrated care.

Introduction

The delivery of integrated care is a priority in many countries' efforts to improve health outcomes for people at risk of or with chronic illness. The World Health Organization has described integrated care as "the management and delivery of health services such that people receive a continuum of health promotion, health protection and disease prevention services, as well as diagnosis, treatment, long-term care, rehabilitation, and palliative care services through the different levels and sites of care within the health system and according to their needs" [1]. Previous reviews of integrated care for type 2 diabetes have shown mixed effects on processes as well as patient outcomes [2-6]. Several of these reviews investigated the relative effectiveness of different types of integrated care interventions and were partly able to explain why some types of interventions were more effective than others [2, 5-7]. However, different definitions and operationalizations of integrated care as well as different typologies of interventions and/or intervention components were used in these reviews. This makes it difficult, if not impossible, to compare results and draw generalizable conclusions. Consequently, it is important to find an operational definition of integrated care that allows for the systematic and reliable identification and categorization of different types of integrated care interventions.

To this purpose several reviews have linked their definition of integrated care to the chronic care model (CCM) which postulates that improving integrated chronic care requires changes in four components: self-management support, delivery system design, decision support and clinical information system [6, 8-10]. These reviews operationalized integrated care as including at least two CCM components and categorized intervention types by the number of CCM components the interventions included (2, 3 or 4) [6, 8, 9]. Using this approach for a systematic literature review on type 2 diabetes, Elissen et al. [6] found that intervention type explained approximately 10% of the diversity between studies regarding measured changes in HbA1c and systolic blood pressure. Moreover, interventions with more components yielded better results than those with fewer components [6]. We built on this approach by linking our operational definition of integrated care to the CCM in the same way as described above. Moreover, we further developed this approach by providing and applying a detailed operationalization of the four core CCM components into CCM sub-components that allows for a more uniform and reliable application of the CCM and a more detailed typology of the different integrated care interventions [11]. For example, self-management support was operationalized, among others, into information provision, patient education (general, disease-related or self-management-related), and a patient-centered approach. Examples of the operationalization of the delivery system design component include team-based care provision, case management and nurse-led care. In doing so, the objective of this study was to provide a systematic overview of the different types of integrated care interventions for type 2 diabetes found in the international scientific literature and to report their outcomes. The results of this study can be used by research and practice as a tool for the systematic classification of integrated care interventions and thereby facilitate analyses of the effectiveness of different types of integrated care interventions and their relative impact on outcomes achieved.

This systematic review focusses specifically on integrated care interventions for type 2 diabetes. Diabetes is one of the chronic health care problems addressed most frequently by means of integrated

care interventions [12, 13]. Moreover, the condition has a major societal impact: In 2010, 285 million people aged 20-79 years were living with diabetes (representing 6.4% of the world population in this age group [14]), almost four million deaths were attributable to diabetes [15], and 12% of global health expenditure was allocated to diabetes care [16]. With changing lifestyle factors and an ageing world population, the number of people with diabetes worldwide is expected to increase by approximately 50% between 2011 and 2030 [17]. This study is part of Project INTEGRATE on "Benchmarking Integrated Care in Chronic and Age-related Conditions in Europe", financed by the European Commission (project reference 305821). Project INTEGRATE aims to investigate the leadership, management and delivery of integrated care to help European care systems responding to the challenges of an ageing population and the increasing number of people living with chronic conditions [18, 19].

Methods

In August 2013, a systematic literature review was conducted in PubMed and Cochrane. The methods of this review have been described in detail elsewhere [11].

Concepts and definitions

We linked our definition of integrated care to the CCM. In line with previous research we considered an intervention integrated care if it targeted at least two CCM components [6, 8, 9]. We further developed this approach by providing and applying a previously published operationalization of the CCM components by CCM sub-components [11], based on a checklist used by the European DISMEVAL project [20] and complemented by other examples of CCM sub-components from the literature [21-24] (see Table 1, online appendix¹). By 'intervention' we mean a combination of tangible actions directed at change. 'Intervention type' is defined by the number of CCM components the intervention targets (2, 3, or 4) as well as its complexity, that is, the number of CCM sub-components. By 'outcomes' we mean the intentional and unintentional effects of the intervention. We distinguish between patient, process, health service utilization and cost measures.

Literature search and study selection

In order to locate relevant articles, four groups of search terms were created, relating to the health condition, type of intervention, CCM components and implementation. Between September 2013 and January 2014, LB, KL and AE performed three selection rounds based on title, abstract and full text. In each round, two researchers independently assessed the article's compliance with the selection criteria. Results were discussed in pairs until consensus could be reached. To guarantee a homogenous selection procedure, a checklist consisting of the CCM operationalization and a set of inclusion criteria was used by all researchers. The following inclusion criteria were applied: concerning the implementation of an integrated care intervention, focusing on type 2 diabetes, and published between 2003 and 2013. Articles were excluded when written in a language other than English, German, Dutch, Spanish or Swedish (i.e. other than Project INTEGRATE languages), when the target population

¹ <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/full>

consisted exclusively of children, adolescents, prisoners or homeless persons (i.e. populations different from Project INTEGRATE target populations), or when they did not concern empirical research. Systematic reviews and meta-analyses were also excluded since they generally base their findings on interventions that would not necessarily (all) fit our definition of integrated care.

Data extraction and quality assessment

The data extraction was performed between September 2013 and January 2014 by LB, KL, and AE using a common data extraction table completed independently by two researchers and then compared in pairs. The following information was extracted from the articles: author, publication year, title, data collection methods, type of data, data collection setting, follow-up period, population, participants, researcher's influence, data analysis, research questions and/or article objective, study limitations, intervention name, purpose, CCM sub-components, and outcomes [25]. The methodological quality was assessed using the Mixed Methods Appraisal Tool (MMAT), a unified quality assessment tool for the appraisal of qualitative, quantitative and mixed methods studies [25, 26]. It includes questions such as "Are there clear qualitative, quantitative or mixed methods research questions (or objectives)?" or "Do the collected data address the research question (or objective)?" These criteria can be fulfilled, unfulfilled or unmentioned. All criteria were assessed independently by three researchers (LB, KL and AE) during the data extraction phase. Results were discussed in pairs until consensus was reached.

Data analysis

Integrated care interventions were categorized according to the above operationalization of the CCM components (see Table 1, online appendix²). Outcomes were reported as patient, process, health service utilization and cost measures. In line with previous reviews on the effectiveness of integrated care interventions, we decided not to use pooled analyses given the large differences between the included studies regarding interventions, settings and patient populations [2, 7]. In addition to reporting the different intervention types and their outcomes, we also tried to examine the association between intervention type and outcomes. First, we examined the association between the number of CCM components targeted and the achievement of positive outcomes. Because the CCM components are not implemented separately but combined to mutually reinforce each other, we hypothesized that a higher number of CCM components included in an integrated care intervention would be associated with better outcomes of the intervention. Second, we looked at the association between inter-component complexity (the number of sub-components targeted within each CCM component) and the achievement of positive outcomes. The articles reported up to 20 sub-components, which were divided into four equal groups: 1-5, 6-10, 11-15 and 16-20 sub-components. Based on the same reasoning as above, we hypothesized that a higher inter-component complexity in an integrated care intervention would be associated with better outcomes of the intervention. Cross tables were created and chi-square tests were performed to test the above hypotheses. All but two chi-square tests did not fulfil the assumption that all expected cell values E must be equal to or higher than 1. For those two tests that did fulfil the assumptions (patient outcomes for glycemetic control by number of CCM components and patient outcomes for glycemetic control by number of CCM sub-components), the outcome of the chi

² <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/full>

square test was not significant. Because it was consequently not possible to make statements about the relationship between the variables, the frequencies (absolute counts) of reported outcomes by the number of CCM components and sub-components are reported instead.

Results

Figure 1 depicts a flowchart showing the complete selection process. The final selection for research objective one consisted of 44 studies, including eight qualitative studies, 10 randomized controlled trials, five non-randomized quantitative studies, 15 descriptive quantitative studies and six mixed method studies. Two (qualitative) studies did not report outcomes and were therefore excluded for the second research objective [27, 28].

Quality assessment

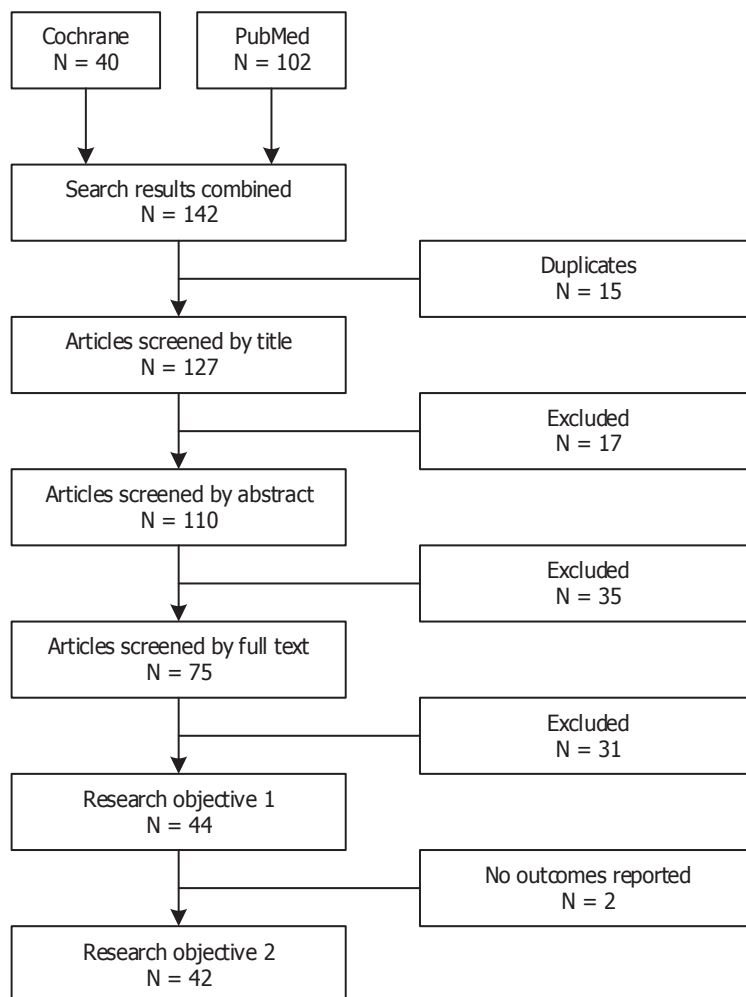
Of the 44 articles, 15 studies in total fulfilled all quality criteria applicable to their respective study type, including six randomized controlled trials [29-34], four qualitative [27, 28, 35, 36], three quantitative descriptive [37-39] and two quantitative non-randomized studies [40, 41]. All mixed methods studies had at least two unfilled and one unmentioned criterion. None of the mixed methods studies gave appropriate, if any, consideration to the limitations associated with the integration of quantitative and qualitative data [42-47]. In general, it was difficult to decide whether unmentioned criteria were an indication of substandard methodological quality or concise reporting. Finally, it was decided that studies fulfilling only two quality criteria or less warranted caution and were therefore marked with an asterisk (*) in the remainder of the article. Moreover, no examples from these articles are used.

Study characteristics

The objective, follow-up period (in months), setting and population of the 44 studies are portrayed in Table 2 (see online appendix³). Thirty studies assessed the impact of integrated care interventions on pre-specified diabetes-related outcome measures and 17 studies extracted lessons from the implementation process by describing successful interventions, highlighting barriers and facilitators and reporting patient and provider experiences. The follow-up periods of the studies ranged between 1 and 96 months (median = 15). A total of 29 studies were conducted in the United States, while 12 studies were set in the European Union, including Germany, Italy, Spain, Belgium, the Netherlands and England. Three studies took place elsewhere (Japan, Canada and Israel). Twenty-seven studies focused on interventions implemented in the primary care sector or small (family) practice settings, while 18 studies focused on hospitals, medical centers and community-based centers or practices. Several studies (n = 15) were implemented in regions with populations characterized by socio-economic disadvantages, low levels of education, ethnic diversity (including predominantly Hispanic, African American and Chinese populations), health un-insurance or low (health) literacy.

³ <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/supinfo>

Figure 1: Flowchart portraying the literature review selection process



Intervention types

Table 1 (see online appendix⁴) provides an overview of the CCM components and sub-components of the integrated care interventions. Twenty-three studies concerned all CCM components, 15 studies focused on three components and four studies targeted two components. Two studies used practice implementation of the CCM as dependent variable without reporting specific sub-components. Within the self-management support component, patient self-management education was included most often ($n = 25$), followed by patient disease education ($n = 20$). Generally, both forms of patient education were delivered one-on-one or in group sessions, by a nurse case manager or a diabetes nurse

⁴ <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/full>

specialist, via written print-outs, audio-visual materials or the internet. Sometimes, a computer was installed at the practice setting or patients were provided with laptops to use at home. General patient education and patient centeredness/involvement were each included 17 times. Within the delivery system design component, 26 studies focused on team-based care provision. Often these teams consisted of multidisciplinary staff with different educational backgrounds and areas of expertise. Twenty-four studies included structured care and 14 studies involved follow-up of patients over time. Within the decision support component, 28 studies included provider education, often on evidence-based guidelines, self-management support or more in depth diabetes knowledge. Providers were also educated on the theoretical model behind the integrated care intervention or trained to work with a new health IT system or database. Twenty-three studies used evidence-based guidelines and 10 included feedback provision. Finally, within the clinical information system component, 16 studies included automated performance monitoring. Often this entailed automated generation of patient or provider outcome reports from data registered in the patient or disease registry. Mostly, these reports were used for peer-to-peer comparisons between providers and to identify improvement plans. Thirteen studies included patient registries and 12 used ICT devices, often mobile phones or laptops.

Outcomes

The outcomes reported in the studies are summarized in Table 2 (see online appendix⁵).

Patient measures

Thirty-five articles reported patient measures. Of these, 22 studies reported positive effects on intermediate clinical outcome measures, including improvements in glycaemic control, blood pressure, cholesterol levels, and body mass index (BMI). Sixteen studies reported that these positive effects were statistically significant. The clinical relevance of statistically significant results was often not specifically discussed in the studies included in this review. However, Bellazzi et al. stated that their rather preliminary data was not sufficient to draw conclusions on the clinical impact of the intervention [48]. Borgermans et al. report a relative absence of clinically significant differences between the two intervention arms of their study, which may be related to the limited use of additional interventions provided to doctors and patients [29]. Eight studies reported no statistically significant improvements to glycaemic control, blood pressure, cholesterol levels, or BMI. No studies reported worsening of intermediate clinical outcome measures. Twelve studies reported improvements in (self-reported) patient outcome measures such as patient satisfaction, diabetes and lifestyle knowledge, self-management behavior, (mental) health status, self-efficacy, and diabetes-related distress. Four studies on the other hand reported no improvements in self-efficacy, diabetes knowledge, or health behavior. No studies reported worsening of patient outcomes measures.

Process measures

While patient measures refer to the values of certain measurements (e.g. whether the values have improved, worsened or stayed the same), process measures refer to the frequency of certain measurements, that is, how often or regularly they were performed. Process measures were reported in

⁵ <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/supinfo>

24 studies. Of these, 20 studies reported improvements in process measures such as the frequency of glycaemic control measurements, foot examinations, cholesterol testing, and eye examinations. On the other hand, six studies reported a reduced frequency of glycaemic control measurements or decreased likelihood of annual lipid profile, or found no difference in the frequency of cholesterol measurements, micro-albuminuria testing, ophthalmologist visits, annual creatinine testing or foot exams.

Health services utilization

Eleven studies reported information on health services utilization. Of these, eight studies reported positive changes in health services utilization, including a reduced number of days spent in hospital, lower diabetes-related hospital admission rates, and lower extremity amputation rates. Two studies reported no improvements in health services utilization measures such as number of patients seen and number of patient phone calls received. One study reported low utilization of educational resources by doctors, including continuing medical education sessions and CD-ROMs that were made available to them for voluntary use. Another study reported increased hospital admissions.

Costs

Ten studies provided information on measures of cost. Regarding the costs of the intervention itself, three studies reported low intervention costs, while two studies reported high intervention costs. As regards the effect of the intervention on health costs, four studies reported reduced health costs as effect of the intervention, whereas one study reported increased health costs as effect of the intervention and another study reported no effect on health costs as effect of the intervention.

Interventions and outcomes

We present the frequency (absolute counts) of studies reporting outcome measures by the number of CCM components (Figure 2) and the number of CCM sub-components (Figure 3), respectively (see online Appendix⁶). Data on costs were not considered as they were too scarce and inconsistent to be operationalized into the categories used (not reported, negative, neutral, and positive). Figures 2 and 3 show the high number of articles not reporting specific outcome measures. Moreover, it can be seen that only very few negative or neutral outcomes are reported. The figures also show that the evidence on interventions with a low number of CCM components or CCM sub-components is especially scarce. Finally, the figures confirm that because of the low number of articles reporting the same outcome measures it is not possible to make statements about the relationship between intervention type and outcomes.

Discussion

This paper presented a systematic literature review of the intervention types and outcomes of integrated care for type 2 diabetes. We followed the approach of previous reviews to systematically classify integrated care and its different intervention types by linking our definition of integrated care to the CCM. We further developed this approach by providing and applying a detailed operationalization of

⁶ <http://onlinelibrary.wiley.com/doi/10.1111/jep.12478/full>

the CCM components into sub-components. This allowed us to classify the integrated care interventions of the included studies according to CCM components and CCM sub-components. However, because of the low number of comparable outcome measures, we were not able to study the relationship between intervention type and outcomes. Thereby, our study highlights the current challenges in integrated care evaluation.

We found that most studies included all four CCM components and targeted a variety of sub-components. This is in contrast to a previous review by Elissen et al. [6] which found only relatively few studies involving all CCM components. One explanation for this difference could lie in the fact that there is only an overlap of two studies between our review and Elissen et al.'s [48, 49], probably because Elissen et al. used rather generic search terms related to integrated care, whereas we combined these generic search terms with specific search terms describing the sub-components of the interventions we were aiming to find. This probably led us to retrieve more complex interventions, often including all four CCM components. Moreover, we used a detailed and systematic checklist based on the operationalization of the CCM to check the studies for examples of the CCM components. This probably helped us to discover more aspects of the CCM components that could otherwise more easily have been overlooked or depended on the researchers' subjective understanding of the CCM.

Another explanation could lie in the fact that Elissen et al.'s review included studies from the early years of the development of integrated care. These early studies might cover less complex interventions than those implemented in the later years. Specifically, Elissen et al. included studies published between 1995 and 2011, while our cut-off years were 2003 and 2013. Of the 21 empirical studies included in Elissen et al.'s review published before 2003, only six targeted all CCM components (29%), while of the 40 empirical studies published 2003 and later, 15 targeted all CCM components (38%), suggesting a move towards more four-component interventions in the more recent years. However, of the 35 studies included in our review that were published in the same period (between 2003 and 2011), 20 targeted all CCM components (57%), suggesting that changes over time are probably not the only difference. Operationally linking the concept of integrated care to the CCM and applying a detailed operationalization of the four core CCM components as suggested in this paper is likely to increase the comparability and reliability of research findings.

Within the self-management support component of the CCM, patient self-management and disease education were included most often. Within the delivery system design component most studies focused on team-based care and structured care provision. Within the decision support component, most studies included provider education and the use of evidence-based guidelines. Within the clinical information system component, most studies included automated performance monitoring and the use of patient registries. This is in line with the review by Elissen et al. [6] which also often found self-management support to include patient education, delivery system design to include multidisciplinary care teams, decision support to include guidelines, and clinical information system to include (shared) computerized patient databases.

In a recent study on diabetes care in the Netherlands, three of the most-implemented sub-components found in our review, namely use of an electronic patient registry, patient education (leaflets) and provider (nurse) education were found to have a significant positive impact on different outcome measures (HbA1c, systolic blood pressure control and cholesterol control, respectively) [50]. We tried to compare the most-implemented sub-components to other reviews evaluating the relative effectiveness of different types of integrated care but due to differing definitions of integrated care and/or intervention typologies used in these studies this was not possible [2, 5, 7]. Again, if future research was to link its definition of integrated care to the CCM and apply a detailed operationalization of its components in a systematic and rigorous way, this would likely benefit the comparability of results and researchers' ability to interpret their findings in the light of other research.

With regard to outcome measures, most studies reported improved patient, process and health service utilization measures. This is in line with previous reviews of integrated diabetes care [4-6]. The information on costs was limited and mixed, which is in line with a recent review on the economic impact of integrated care which found mixed evidence that was difficult to interpret [51]. According to the authors, this was at least in part due to the polymorphous nature of the concept of integrated care which made a systematic evaluation of the included interventions very challenging. Despite the use of a detailed typology of integrated care interventions in the present study, it was still not possible to make statements about the relationship between intervention type and outcomes achieved, mainly due to the low number of articles reporting comparable outcome measures.

This study is subject to methodological limitations that should be taken into consideration. First, while the MMAT is a comprehensive quality assessment tool that caters to the need of simultaneously assessing qualitative, quantitative and mixed method studies [25], it proved to be insufficient in determining whether unfulfilled or unmentioned criteria were due to substandard methodology or concise reporting. However, the information reported by the four studies with only two fulfilled criteria or less did not differ from the information reported by the other articles. Therefore, we do not think that the inclusion of these studies biased the findings of this paper. Second, given the various definitions of integrated care currently in use, operationalizing integrated care as interventions targeting at least two CCM components is not an undisputed approach. However, in addition to providing us with the basis for a uniform checklist used by all researchers to assess whether an intervention indeed concerned integrated care, it also allowed us to check whether interventions that were classified as integrated care by study authors indeed fit our definition. Moreover, this approach has been used previously in the international scientific literature [6, 8, 9], and was confirmed by the Scientific Committee of Project INTEGRATE. Still, related to this is the concern that linking integrated care exclusively to CCM components – and choosing search terms accordingly – might have led us to overlook relevant studies on integrated care that did not use the same approach. However, most studies identified through our approach did not actually use the CCM as a framework themselves. We can therefore assume that our search strategy identified a broad range of studies not limited to studies adopting a CCM approach, mainly because of the use of specific search terms based on a detailed operationalization of the CCM.

Herein lies the main strength and added value of the present review: its understanding of integrated care as a combination of CCM components and sub-components. Through the provision and application of a detailed operationalization of CCM components, we developed an ordering principle for the different types of integrated care interventions and the (sub-) components they consist of. In doing so, different intervention types of integrated care for type 2 diabetes – and other chronic conditions – can be systematically identified and categorized. By adapting an approach that has been used previously in the literature and that can be applied relatively easily and consistently by others in the future, we contribute to the increased comparability and generalizability of results in this field.

Given the low number of articles reporting comparable outcome measures, which prevented us from making statements about the relationship between intervention type and outcomes, it seems reasonable to call for more studies to report those outcomes. For each type of integrated care intervention (e.g. with two, three or four components or a certain number of sub-components), there would then be enough outcome measurements to make these kinds of statements. Alternatively, however, one could also call for studies to report more intermediate outcome measures. Measuring intermediate outcomes that are closer to the intervention makes it more feasible to capture the complexity of an intervention. For example, when one implements an intervention with a team-based care component and evidence-based guidelines, it would be relevant to know how this affects, for example, staff satisfaction, patient satisfaction or disease knowledge, before starting to measure how these changes influence clinical outcomes. Measuring intermediate outcomes, especially when including in depth qualitative measures, enables the creation of a chain of evidence from the intervention via intermediate outcomes to clinical outcomes.

Another important feature of this chain of evidence is that it does not exist in isolation but in a complex social system. Traditional quantitative evaluations are rather simplistic in their focus on two specific points in time, namely before and after the intervention. In order to increase the ability to attribute the differences observed post-intervention to the intervention itself, most factors expected to have a confounding effect on the causal relationship are stripped away. However, especially for complex interventions such as integrated care interventions, it is often precisely those factors left out of the equation which hold the most valuable information [52, 53]. Measuring the effectiveness of integrated care interventions should therefore take into account context factors such as barriers and facilitator to their implementation. Consequently, we recommend a whole systems approach that measures intermediate outcomes that are closer to the intervention and thereby allows for the establishment of a chain of evidence that links specific intervention types to specific outcomes achieved. This chain of evidence should also include the assessment of barriers and facilitators to the implementation of an intervention that shape the trajectory from intervention to outcomes. It is expected that this comprehensive approach will reveal important insights as to which integrated care intervention types and settings are most conducive to successful implementation and would thereby be of relevance to policymakers and practitioners involved in the financing, management and delivery of integrated care.

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CHAPTER 4

Context, mechanisms and outcomes of integrated care for diabetes mellitus type 2: a systematic review

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Abstract

Background: Integrated care interventions for chronic conditions can lead to improved outcomes, but it is not clear when and why this is the case. This study aims to answer the following two research questions: First, what are the context, mechanisms and outcomes of integrated care for people with type 2 diabetes? Second, what are the relationships between context, mechanisms and outcomes of integrated care for people with type 2 diabetes?

Methods: A systematic literature search was conducted for the period 2003-2013 in Cochrane and PubMed. Articles were included when they focussed on integrated care and type 2 diabetes, and concerned empirical research analysing the implementation of an intervention. Data extraction was performed using a common data extraction table. The quality of the studies was assessed with the Mixed Methods Appraisal Tool. The CMO model (context + mechanism = outcome) was used to study the relationship between context factors (described by the barriers and facilitators encountered in the implementation process and categorised at the six levels of the Implementation Model), mechanisms (defined as intervention types and described by their number of Chronic Care Model (sub-)components) and outcomes (the intentional and unintentional effects triggered by mechanism and context).

Results: Thirty-two studies met the inclusion criteria. Most reported barriers to the implementation process were found at the organisational context level and most facilitators at the social context level. Due to the low number of articles reporting comparable quantitative outcome measures or in-depth qualitative information, it was not possible to make statements about the relationship between context, mechanisms and outcomes.

Conclusions: Efficient resource allocation should entail increased investments at the organisational context level where most barriers are expected to occur. It is likely that investments at the social context level will also help to decrease the development of barriers at the organisational context level, especially by increasing staff involvement and satisfaction. If future research is to adequately inform practice and policy regarding the impact of these efforts on health outcomes, focus on the actual relationships between context, mechanisms and outcomes should be actively incorporated into study designs.

Background

With health systems facing the burden of an ageing society, finding sustainable solutions for the increasing number of people with chronic conditions has become an urgent task for health practitioners and policymakers around the globe. Integrated care has been suggested as one of the solutions. The World Health Organization has described integrated care as “the management and delivery of health services such that people receive a continuum of health promotion, health protection and disease prevention services, as well as diagnosis, treatment, long-term care, rehabilitation, and palliative care services through the different levels and sites of care within the health system and according to their needs” [1]. While previous research has shown that integrated care initiatives can lead to improved outcomes for chronic conditions [2-5], this is not always the case and it is often not clear when or why certain interventions are effective [6, 7]. However, not knowing which intervention types or settings are conducive to successful implementation makes it difficult to adequately inform policymakers and practitioners regarding their choices for efficient allocation of scarce health resources. As a solution to this, researchers have called for an increased focus on examining the implementation process of integrated care interventions and its relationship to the outcomes achieved, instead of a narrow focus on outcomes only [8-10]. It is assumed that integrated care is a form of social change, for whose evaluation the “context + mechanism = outcome model” (CMO model) has been suggested [11]. The CMO model proposes that interventions only have successful outcomes when they introduce appropriate mechanisms in the appropriate social and cultural contexts.

This study builds on a previous systematic literature review using the same search, which reported on the different types of integrated care interventions for type 2 diabetes, the outcomes achieved and the relationship between intervention type and outcomes [12]. For the purpose of this review, the concept of integrated care was linked to the Chronic Care Model (CCM), which postulates that improving integrated chronic care requires changes in four components: self-management support, delivery system design, decision support and clinical information system [13]. Intervention type was then defined as the number of CCM components included in the intervention as well as the number of subcomponents as defined by a detailed operationalisation of the four CCM components (see Table 1, Appendix). The review found that most interventions included all CCM components as well as a variety of subcomponents. Moreover, most studies reported positive patient, process and health service utilisation measures. The information on costs was limited and inconsistent. Because of the low number of articles reporting effects on comparable outcome measures, no statements could be made regarding the association between intervention type and outcomes. The authors concluded that future research should focus on gaining insights into the relationships between intervention type and outcomes as well as the context factors influencing these relationships. Based on these results, the objective of the present study is to provide a systematic overview of the contexts in which integrated care for type 2 diabetes was implemented and to provide insights into the relationship between mechanisms, contexts and outcomes. Therefore, the review aims to answer the following two research questions:

1. What are the contexts, mechanisms and outcomes of integrated care for people with type 2 diabetes?
2. What are the relationships between context, mechanisms and outcomes of integrated care for people with type 2 diabetes?

This study is part of Project INTEGRATE, which aims to investigate the leadership, management and delivery of integrated care to help European health care systems responding to the challenges of an ageing population and the increasing number of people living with chronic conditions.

Methods

The methods of this literature review have been described in detail in a study protocol [14].

Concepts and definitions

In line with previous research, interventions were identified as integrated care interventions when they included two or more of the four core CCM components [2, 3, 5, 15]. The four CCM components were further operationalised into four sets of subcomponents (Table 1, Appendix). The CMO model was used to study implementation by distinguishing between mechanism, context and outcomes [11, 16, 17]. We operationalised the concepts as follows: "Mechanism" is understood to mean the different types of integrated care, defined by the number of CCM components and subcomponents they target. "Context" is defined as the setting in which the mechanisms are brought into practice. This setting can be described using the Implementation Model (IM) by Grol and Wensing, which specifies six levels of health care at which barriers and facilitators to change can occur: innovation (advantages in practice, feasibility, credibility, accessibility, attractiveness), individual professional (awareness, knowledge, attitude, motivation to change, behavioural routines), patient (knowledge, skills, attitude, compliance), social context (opinion of colleagues, culture of the network, collaboration, leadership), organisational context (organisation of care processes, staff, capacities, resources, structures) and economic and political context (financial arrangements, regulations, policies) [18]. We describe the context by detailing the barriers and facilitators to change that occur at the six levels of the IM. By "outcomes" we mean the intentional and unintentional effects triggered by mechanism and context.

Literature search and study selection

The Cochrane and PubMed databases were searched for the period 2003-2013 using the following four groups of search terms: 1. health condition; 2. intervention type; 3. CCM components; and 4. implementation. Table 2 (Appendix) shows the complete search terms and search string.

Between September 2013 and January 2014 articles were selected in three rounds based on their title, abstract and full text version. Articles were assessed independently and results were discussed in pairs (LB and KL; LB and AE) until consensus was reached. To ensure a homogenous selection procedure, all researchers were required to use a checklist specifying in- and exclusion criteria. Articles were included when they were published between 2003 and 2013, concerned integrated care, focussed on type 2 diabetes, and concerned empirical research analysing the implementation of an intervention. They were

excluded when written in a language other than English, German, Dutch, Spanish or Swedish (i.e. other than Project INTEGRATE languages), targeted populations consisting exclusively of children, adolescents, prisoners or homeless persons (i.e. populations different from Project INTEGRATE target populations), or when they did not concern empirical research. Systematic reviews and meta-analyses were excluded as well because they generally base their findings on interventions that would not necessarily all fit our definition of integrated care. For the first research question, studies had to report barriers or facilitators encountered in the implementation of the integrated care interventions. For the second research question, studies had to report barriers or facilitators as well as outcomes of the intervention.

Data extraction and quality assessment

Data extraction was performed between September 2013 and January 2014 by LB, KL and AE using a common data extraction table specifying the following information: author, publication year, title, data collection methods, type of data, data collection setting, follow-up period, population, participants, researcher's influence, data analysis, research questions and/or article objective, study limitations, intervention name, purpose, CCM subcomponents, barriers, facilitators and outcomes [14, 19]. For each included study, the data extraction table was completed by two researchers independently and results were discussed in pairs until consensus was reached (LB and KL; LB and AE). The Mixed Methods Appraisal Tool (MMAT), which is a unified quality assessment tool for the appraisal of qualitative, quantitative and mixed methods studies, was used to assess the methodological quality of the papers, [19, 20]. Despite its relative novelty, the MMAT has been used as a comprehensive quality assessment tool in various systematic reviews in the health sciences [21-23]. Its criteria can be fulfilled, unfulfilled or unmentioned. For each study, two researchers performed the appraisal independently and results were discussed in pairs (LB and KL; LB and AE).

Data analysis

Barriers and facilitators were analysed based on the IM [18]. Moreover, we examined the relationships between mechanisms and context; context and outcomes; and context, mechanism and outcomes. Mechanisms were operationalised as the intervention's number of CCM components (2, 3 or 4) and the number of CCM subcomponents (1-5, 6-10, 11-15 or 16-20). Context was operationalised as the number of barriers/facilitators encountered (0-2, 3-5, 6-8 or 9-11) and the number of IM levels at which barriers/facilitators were encountered (0, 1-3 or 4-6). Outcomes included patient measures (glycaemic control, blood pressure, cholesterol), process measures (measurements of glycaemic control, blood pressure, cholesterol, foot examinations, eye examinations) and health service utilisation, which could be worsened, neutral or improved. In line with previous reviews on the effectiveness of integrated care interventions, we decided not to use pooled analyses given the large differences between the included studies regarding interventions, settings and patient populations [7, 24]. We created cross tables and performed chi-square tests to test for statistically significant relationships between the above variables. For all but three chi-square tests, the assumption that all expected cell values E must be equal to or higher than 1 was not fulfilled. For those three tests that did fulfil the assumptions (patient outcomes for cholesterol by number of barriers; patient outcomes for glycaemic control by number of implementation levels at which barriers were reported; and patient outcomes for cholesterol by number

of implementation levels at which barriers were reported), the outcome of the chi-square test was not significant. Consequently, we opted for a more qualitative approach and examined what the studies themselves specified in terms of information on the relationships between context, mechanism and outcomes.

Results

Figure 1 depicts a flow chart portraying the selection process. The final selection consisted of 32 studies for research objective one (to provide a systematic overview of the contexts in which integrated care for type 2 diabetes was implemented) and 30 for research objective two (to provide insights into the relationship between mechanisms, contexts and outcomes). See Additional file 1: Table S1 (online appendix⁷) for an overview of the study objective, follow-up period, setting, population, and outcomes of the included studies. Generally, studies assessed the impact of integrated care interventions on pre-specified diabetes-related outcome measures or extracted lessons from the implementation process by describing successful interventions, highlighting barriers and facilitators and reporting patient and provider experiences. Follow-up periods ranged between 1 and 96 months (median = 18). A total of 22 studies were conducted in the United States, whereas 8 studies were set in the European Union, including Germany, Belgium, the Netherlands and the United Kingdom. Two studies took place elsewhere (Canada and Israel). Additional file 2: Table S2 (online appendix⁸) shows the intervention types of the included studies. Nineteen studies included all CCM components [25-43], 10 studies concerned 3 components [44-53] and 2 studies targeted 2 components [54, 55]. One study used practice implementation of the CCM as the dependent variable without reporting specific subcomponents (indicated as empty cells in Additional file 2: Table S2, online appendix⁹) [56].

Quality assessment

Of the 32 articles, 10 studies in total fulfilled all quality criteria applicable to their respective study type. Generally, it was difficult to assess whether unmentioned criteria were due to lower methodological quality or concise reporting. The three studies only fulfilling two quality criteria or less are marked with an asterisk (*) in the remainder of the article and no examples from these articles were used.

Context

Tables 3 and 4 (see online Appendix¹⁰) present the barriers and facilitators encountered in the included studies, categorised at the six levels of the IM [18].

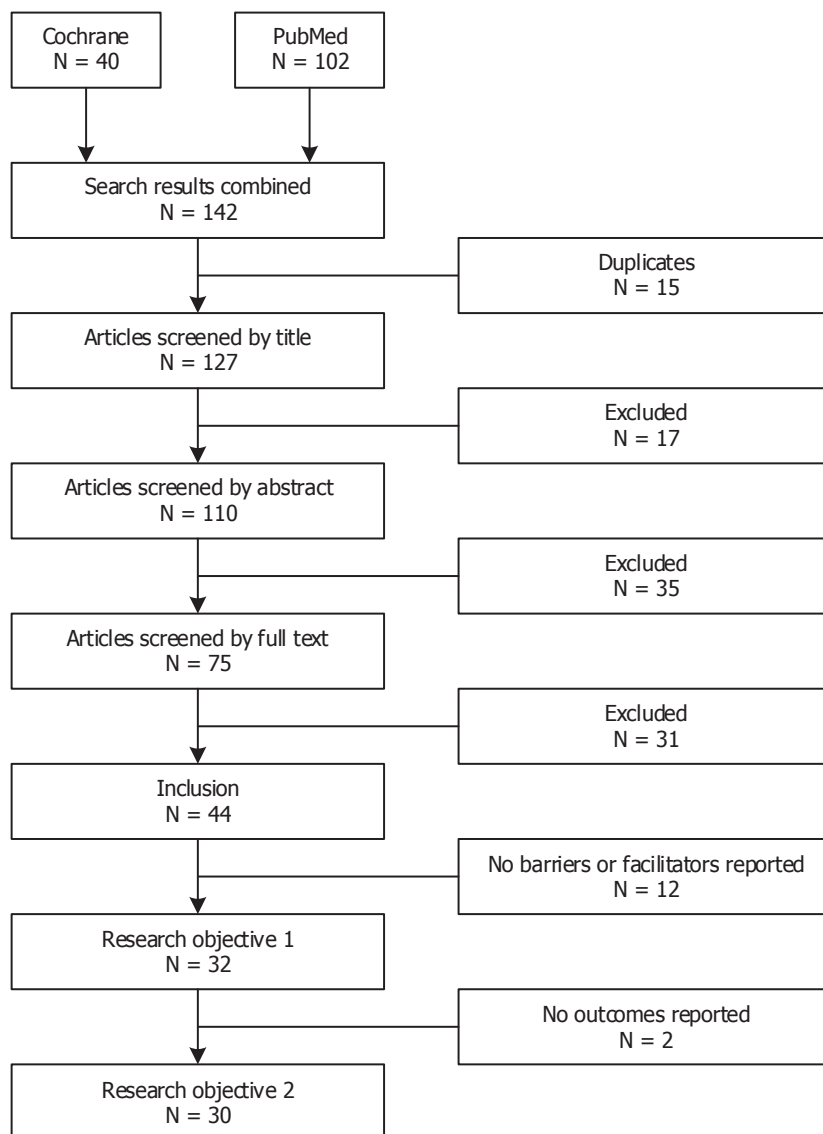
⁷ <http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1231-3>

⁸ <http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1231-3>

⁹ <http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1231-3>

¹⁰ <http://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-1231-3>

Figure 1: Flowchart portraying the literature review selection process



Barriers

A recurring topic at the innovation level was difficulties relating to the database or electronic medical record used for the innovation, either because there was no such health IT in place, because the implementation of the health IT was problematic or because the system did not generate useful outcome data. At the individual professional level, reluctance to discharge patients or share care as well as general low provider engagement were often mentioned. Also, provider incapability or reluctance to use IT systems were often reported. Finally, lack of diabetes- or self-management-related provider expertise was also mentioned as a barrier at the individual professional level. At the patient level, several barriers related to the IT system and patients' difficulties using the system. Other barriers related to patients' unwillingness to be discharged, their lack of motivation or knowledge, and their medically, socially or economically complicated backgrounds. Social context barriers included competing staff priorities, changing the culture at the workplace and suboptimal leadership. Difficult areas such as unsafe neighbourhoods or ethnically diverse settings were also among the social context barriers. Most barriers at the organisational context level related to workflow changes due to the introduction of an innovation, logistical barriers and problems relating to staff turnover or limited staff capacity. Economic and political context barriers mostly related to concerns regarding funding and the (financial) sustainability of an innovation, but one barrier also related to legal requirements hindering an innovation.

Facilitators

Facilitators at the innovation level included the use of bilinguals, translations and pictures as well as database availability and certain database features such as generation of useful outcome data. Most individual professional facilitators focussed on guidelines and disease- or self-management-related provider education. Other facilitators related to the providers' ability to engage with patients, their motivation and the use of reminders. Patient-level facilitators included provision of patient education and peer support. Several of the social context facilitators related to the involvement of staff in decision-making and planning, the ability to find committed staff and generate staff buy-in, good leadership and intra- as well as inter-practice resource-sharing and cooperation. The practice's culture and openness to change were also facilitators at the social context level. Organisational context-level facilitators mostly related to multidisciplinary teamwork and workflow changes. Economic and political facilitators related to the low costs of the intervention and the availability of national task profiles.

Context + mechanism = outcome

Even though the literature review identified a substantial evidence base on the separate components of the CMO model, only a very limited number of studies reported the actual relationships between the intervention type implemented, barriers and facilitators encountered and outcomes achieved. Thirteen studies provided information on the impact of the barriers and facilitators on intermediate output variables or other variables, but not on the outcome indicators measured in the respective studies [25-30, 43, 48-52, 55]. For example, several studies mentioned how a certain facilitator improved communication or office workflow, but not how these in turn led (or did not lead) to improved patient outcome indicators as measured within the scope of the same study.

Eight studies specified the way in which barriers and facilitators encountered affected the outcomes measured. With regard to the effect of facilitators, the study by Borgermans et al. found that interdisciplinary diabetes care teams were associated with significant improvements in HbA1c, LDL-cholesterol as well as increased statin and anti-platelet therapy use. According to the authors, these positive results can be explained by the quality task orientation of the team and the fact that there was shared leadership with shared group goals [31]. Gabbay et al. found that nurse case management led to reduced blood pressure mainly because the intervention was multifaceted, consisting of components such as patient education, behavioural goal setting, therapeutic adjustments and close follow-up [32]. Lemay et al. reported that a community health centre collaborative could not have led to increased patient self-management without changing the health centre philosophy towards more patient centeredness and empowerment [33]. Rothe et al. attributed the success of the Saxon Diabetes Management Program in improving A1C and blood pressure to timely referral of patients to the specialised diabetes practitioners, and to the enhanced competences of general practitioners. Moreover, they claimed that the collective discussion about quality management data between health care providers from different levels of health care was pivotal for the success of the programme [34]. The low health literacy and culturally sensitive diabetes education programme studied by Swavely et al. led to significant improvements in patient knowledge, self-care behaviour, self-efficacy and A1C, and high patient, provider and staff satisfaction. According to the authors, this could not have been achieved without the creation of a non-intimidating environment [44]. Finally, Yu and Beresford found three critical success factors for their chronic illness model that led to improvements in HbA1C, blood pressure, LDL and urine albumin-to-creatinine ratio, namely leadership commitment to change, increased clinical staff involvement and residents acting as change agents [35].

Two studies reported how barriers inhibited programme success. While the web-based diabetes intervention for physicians studied by Estrada et al. was associated with an increase in A1C and LDL assessments, it did not lead to improvements in A1C control, blood pressure control or LDL control. The authors explained this lack of improvement in patient outcomes by a high attrition rate as well as low provider web engagement [36]. Sanchez found that the implementation of a diabetes self-management education programme in primary care using shared medical appointments did not lead to improvements in A1C, blood pressure and body mass index. The study found that patients without motivation for self-management tended to have a higher A1C level and were less likely to return to a follow-up shared medical appointment [37].

Discussion

This paper has presented a literature review of the context, mechanisms and outcomes of integrated care for type 2 diabetes identified in the international literature. Most reported barriers to the implementation process were related to the organisational context level, including workflow changes due to the introduction of the integrated care initiative and logistical barriers and problems relating to staff turnover or limited staff capacity. Most facilitators to the implementation process were found at the social context level, including involvement of staff in decision-making and planning, the ability to find committed staff and generate staff buy-in, good leadership and intra- and inter-practice resource-

sharing and cooperation. It is difficult to say whether these findings are in line with previous reviews of integrated care for type 2 diabetes as these have typically focussed on the effect of the intervention on outcomes, sometimes assessing the relative effectiveness of different intervention components [3, 24, 57-59]. None of these reviews, however, focussed on barriers and facilitators to the implementation process and/or their potential mediating effect on the relationship between interventions and outcomes. A previous review by Renders identified barriers to change in diabetes care, which included a lack of guideline acceptance, a lack of diabetes knowledge, poor staff member cooperation, poor quality care documentation, guideline complexity and a lack of information needed to incorporate these guidelines into practice, non-attendance and poor patient compliance [7]. However, these were barriers identified prior to the implementation of the intervention instead of barriers encountered during the implementation process, as was the focus of the present study.

Our findings regarding the occurrence of most barriers at the organisational context level suggest that if targeted policy programmes and quality improvement strategies are to yield the most significant impact, efficient allocation of health resources should entail more resources allocated to the organisational context to provide additional support in those areas where most obstacles are expected to occur. At the same time, this should not occur at the expense of investments at the social context level because although most facilitators to the implementation process were encountered at this level, investments for sufficient resources are needed to benefit optimally from those factors that help the implementation process to develop relatively smoothly. It is also likely that investments in the social context level to increase staff involvement and satisfaction will decrease the development of barriers at the organisational context level, such as staff turnover and limited staff capacity. Our ability to make statements about the relationships between context, mechanisms and outcomes was severely impeded by the low number of articles reporting comparable quantitative outcome data as well as the small amount of articles reporting in-depth qualitative information on the relationships between context, mechanisms and outcomes. Only eight studies qualitatively described the interplay between context, mechanisms and outcomes, but due to the lack of previous reviews focussing on barriers and facilitators to the implementation process, we cannot say how these findings relate to previous research on integrated care for type 2 diabetes.

There are several limitations associated with this study that should be taken into consideration. First, there are various definitions and conceptualisations of integrated care and the decision to link integrated care to the CCM is therefore not undisputed. However, for the specific purpose of this review, an operational definition was needed that could be applied structurally and uniformly to the identification of integrated care interventions from the literature. As mentioned above, the CCM has been used to this end repeatedly in the literature [2-5, 60]. The question was also posed to an expert committee from Project INTEGRATE, but its members could not provide a feasible alternative operational definition and eventually consensus was reached for our approach. The second limitation relates to the quality assessment instrument. The MMAT is a comprehensive quality assessment tool that allows for the simultaneous assessment of qualitative, quantitative and mixed methods studies [19]. However, based on the MMAT it was often not possible to determine whether unfulfilled or unmentioned criteria were a sign of substandard methodology or concise reporting. Fortunately, the

information reported by the three studies with only two fulfilled criteria or less did not differ from the information reported by the other articles. Therefore, it is unlikely that the inclusion of these studies biased the findings of this paper. The third limitation concerns the data extraction for the barriers and facilitators. The authors chose to only include information on those barriers and facilitators that were explicitly identified as such by the authors of the included studies. Of course, different authors may have been more or less exhaustive in explaining the reasons for the success or failure of their interventions and our findings may be biased accordingly. Nevertheless, most authors did encounter barriers and facilitators and chose to report those most pertinent to their findings. Therefore, the choice was made to consider the studies' authors as experts of their own study and to follow their observations as the most reliable source of information on barriers and facilitators.

The strength of this article lies in its embeddedness in three robust and widely used theoretical models. The CMO made it possible to look at the context, mechanisms and outcomes of integrated care as separate elements as well as a complex, collective web of interrelationships between the three separate elements. The CCM helped to identify and categorise different types of integrated care interventions despite the lack of a common conceptual definition of integrated care and the use of different operational definitions of integrated care in the included studies. With the IM a diverse array of barriers and facilitators could be categorised and analysed. However, the very low number of articles reporting comparable outcome measures made it difficult to statistically analyse the relationship between context, mechanism and outcomes, and while the qualitative insights provided in the studies are informative, they remain extremely limited. This means that while we do know in which areas most barriers and facilitators can be expected to occur, we do not know their expected impact on health outcomes. Nor do we know whether certain intervention types make it more likely that certain barriers or facilitators will (or will not) be encountered or what their combined effect on outcomes would be. This means that while there is ample separate information on the context, mechanisms and outcomes of integrated care for type 2 diabetes, there is neither enough of the same quantitative information to statistically analyse the relationships between these parts, nor is there enough qualitative information to provide meaningful insights into how the separate parts are linked. Consequently, more CMO-informed focus on the actual relationships between context, mechanisms and outcomes must be actively incorporated into study designs if future research is to adequately inform practitioners and policymakers regarding their choices on efficient resource allocation for integrated care interventions.

Conclusions

This systematic review of the context, mechanisms and outcomes of integrated care interventions for type 2 diabetes found most reported barriers to the implementation process to be related to the organisational context and most facilitators to be related to the social context level. Based on the insights of this review it is suggested that efficient allocation of health resources should entail more resources allocated to the organisational context to provide additional support in those areas where most obstacles are expected to occur. Moreover, it is likely that investments at the social context level, especially to increase staff involvement and satisfaction, will also help to decrease the likelihood of barriers occurring at the organisational context level. Due to the limited number of studies reporting

comparable outcomes measures as well as the low number of articles reporting relevant qualitative information, it was not possible to make statements about how the context and mechanisms of the integrated care interventions for type 2 diabetes influenced outcomes achieved. As retrospectively linking the separate elements of the CMO model is therefore not possible, future research should be conducted with the CMO model incorporated into study designs so as to gain insights into the relationships between the context, mechanisms and outcomes of integrated care.

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Appendix

Table 1: Operationalisation of the four CCM components adapted from Busetto et al. 2014

CCM component	CCM subcomponents
Self-management support	Information provision
	Patient education – general
	Patient education – disease education
	Patient education – self-management education
	Provision of self-management tools
	Patient-centredness / Active patient involvement, e.g. in development of care plan and goal setting
	Behavioural support / motivational support
	Other
Delivery system design	Team-based care provision
	Structured care
	Individualised care
	Medicines management
	Follow-up
	Case management
	Nurse-led care
	Health literacy
	Cultural sensibility
	Advanced access to medical care for participants
	Other
Decision support	Evidence-based guidelines
	Provider education
	Access to / integration of specialist expertise
	Non-automated performance monitoring
	Feedback
	Non-automated clinician reminders
	Non-automated patient reminders
	Other
Clinical information system	Patient reminder system
	Provider reminder system
	(Electronic) Patient registry
	(Electronic) Disease registry
	Electronic performance monitoring
	Electronic medical record
	Use of electronic / ICT devices
	Other

Table 2: Search terms and search string

#	Group	Search terms
#1	Diabetes	Diabetes OR DMT2
#2	Integrated Care	Integrated care OR disease management OR disease state management OR comprehensive healthcare OR complex interventions OR multifactorial lifestyle interventions OR shared care OR chronic care model OR care transition OR transitional care OR intermediate care OR case management
#3	Chronic Care Model – Self-management support	Self-management support OR self-care OR self-management OR patient-centeredness OR patient-centred care OR behavioural support OR motivational support
#4	Chronic Care Model – Delivery system design	Delivery system design OR care pathway OR critical pathway OR individualised care plan OR clinical case management services OR medicines management OR co-morbidities management OR health literacy OR cultural sensibility OR practice nurse counselling OR team-based care provision
#5	Chronic Care Model – Decision support	Decision support OR clinician reminders OR patient reminders OR provider education OR reminder systems OR specialty expertise integration OR individualised care plans
#6	Chronic Care Model – Clinical information system	Clinical information system OR clinical registry OR population information database OR shared information system OR health information systems OR health information technology OR electronic registry OR clinical reminder OR patient reminder OR clinician reminder OR provider feedback OR performance monitoring OR ICT devices OR patient portal OR telemonitoring OR telehealth OR teleassistance OR telehomecare OR videoconferencing OR mobile phone OR electronic health record OR patient-held record
#7	Implementation	Implementation
#8	Complete search string	Diabetes AND ((integrated care OR (self-management support AND delivery system design) OR (self-management support AND decision support) OR (self-management support AND clinical information system) OR (delivery system design AND decision support) OR (delivery system design AND clinical information system) OR (decision support AND clinical information system)) AND implementation #1 AND ((#2 OR (#3 AND #4) OR ((#3 AND #5) OR ((#3 AND #6) OR (#4 AND #5) OR (#4 AND #6) OR (#5 AND #6)) AND #7



CHAPTER 5

Implementation of integrated care for diabetes mellitus type 2 by two Dutch care groups: a case study

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Abstract

Background: Even though previous research has demonstrated improved outcomes of integrated care initiatives, it is not clear why and when integrated care works. This study aims to contribute to filling this knowledge gap by examining the implementation of integrated care for type 2 diabetes by two Dutch care groups.

Methods: An embedded single case study was conducted including 26 interviews with management staff, care purchasers and health professionals. The Context + Mechanism = Outcome Model was used to study the relationship between context factors, mechanisms and outcomes. Dutch integrated care involves care groups, bundled payments, patient involvement, health professional cooperation and task substitution, evidence-based care protocols and a shared clinical information system. Community involvement is not (yet) part of Dutch integrated care.

Results: Barriers to the implementation of integrated care included insufficient integration between the patient databases, decreased earnings for some health professionals, patients' insufficient medical and policy-making expertise, resistance by general practitioner assistants due to perceived competition, too much care provided by practice nurses instead of general practitioners and the funding system incentivising the provision of care exactly as described in the care protocols. Facilitators included performance monitoring via the care chain information system, increased earnings for some health professionals, increased focus on self-management, innovators in primary and secondary care, diabetes nurses acting as integrators and financial incentives for guideline adherence. Economic and political context and health IT-related barriers were discussed as the most problematic areas of integrated care implementation. The implementation of integrated care led to improved communication and cooperation, but also to insufficient and unnecessary care provision and deteriorated preconditions for person-centred care.

Conclusions: Dutch integrated diabetes care is still a work in progress, in the academic and the practice setting. This makes it difficult to establish whether overall quality of care has improved. Future efforts should focus on areas that this study found to be problematic or to not have received enough attention yet. Increased efforts are needed to improve the interoperability of the patient databases and to keep the negative consequences of the bundled payment system in check. Moreover, patient and community involvement should be incorporated.

Background

Previous research has shown that integrated care initiatives can lead to improved processes and patient outcomes [1-4]. However, this is not always the case and there is a lack of evidence regarding the reasons why and in which cases integrated care works [5, 6]. Consequently, researchers have called for increased emphasis on the implementation process and its relationship to outcomes [7-9]. To this purpose, Pawson and Tilley suggest the "Context + Mechanism = Outcome Model" (CMO Model), stipulating that interventions only have successful outcomes when they introduce appropriate mechanisms in appropriate contexts [10].

Two recent literature reviews examining 44 studies on the implementation of integrated care for diabetes attempted to analyse the effectiveness of integrated care in light of the CMO Model [11, 12]. These reviews found that most integrated care interventions included all components of the Chronic Care Model (CCM) and reported improved patient, process and health service utilisation measures. Moreover, most barriers were related to the organisational context, while most facilitators were related to the social context. However, given the lack of comparable outcome measures as well as in depth qualitative data, it was not possible to make statements about the relationship between context, mechanisms and outcomes. It was suggested that more research with the CMO Model in mind is needed. This study aims to contribute to filling this knowledge gap by conducting research on the context, mechanisms and outcomes of integrated care for type 2 diabetes.

This study is part of Project INTEGRATE, financed by the European Commission, studying geriatric conditions, chronic obstructive pulmonary disease (COPD), mental health problems and type 2 diabetes. The current study describes a case study on two care groups providing integrated care for people with type 2 diabetes in the Netherlands and aims to find out how mechanisms and context have influenced the outcomes of integrated care for type 2 diabetes as implemented by the two care groups. Care groups are legal entities that establish contracts with health insurers and health professionals in order to coordinate the so-called 'care chain' of chronic care from diagnosis to after care [13]. Integrated care for chronic conditions has been in the process of development in the Netherlands since the 1980s. Today, integrated care is characterised by care groups and the bundled payment system, patient involvement, provider cooperation and substitution, evidence-based care protocols and the use of a shared clinical information system (see Table 1, Appendix). The remainder of the article will outline the study methods, present and discuss the study's findings and end with a conclusion including recommendations for further research.

Methods

This study adopts an embedded single case design with two units of analysis. This case study is based on a protocol described in detail elsewhere [14].

Case selection

The two care groups invited to participate were selected as best practices based on the following criteria: nomination as national best practices by leading health research institutions, participation in previous (diabetes) research, and involvement in care innovation pilots [14, 15]. Best practice research is a popular approach but controversial, mostly due to problematic external validity [16, 17]. However, focusing on best practices is expected to generate an important potential for learning by other Dutch care groups, and, given the Netherlands' long experience in integrated care and its status as a pioneer, also for other European and non-European countries [18, 19].

Concepts

We distinguished between context, mechanisms and outcomes according to the CMO Model which states that interventions have successful outcomes only when they are introduced by appropriate mechanisms in the appropriate context [10, 20, 21]. 'Context' was understood as the setting in which the mechanisms are brought into practice and described by outlining the barriers and facilitators to change encountered in the implementation process. Barriers and facilitators were categorised and analysed using the Implementation Model (IM) by Grol and Wensing, which specifies six levels of health care at which barriers and facilitators to change can occur, i.e. innovation (advantages in practice, feasibility, credibility, accessibility, attractiveness), individual professional (awareness, knowledge, attitude, motivation to change, behavioural routines), patient (knowledge, skills, attitude, compliance), social context (opinion of colleagues, culture of the network, collaboration, leadership), organisational context (organisation of care processes, staff, capacities, resources, structures) and economic and political context (financial arrangements, regulations, policies) [22]. 'Mechanisms' were defined as the different elements of integrated care and categorised according to the CCM by Wagner [23]. The CCM states that improvements in integrated care for chronic conditions require changes in six components (health system, self-management support, delivery system design, decision support, clinical information system and community [24]). Generally, interventions targeting at least two of these components are considered integrated care [1, 2, 4]. As indicated earlier, Dutch integrated care is characterised by care groups and the bundled payment system, patient involvement, health professional cooperation and task substitution, evidence-based care protocols and the use of a shared clinical information system (see Table 1, Appendix). We mapped these elements to five of the six CCM components as shown in Table 2. No aspects of integrated care relating to the community component (i.e. mobilising community resources to meet the needs of patients) have been found in the relevant literature and documents, including national diabetes care standards and a previous major evaluation of current Dutch integrated care [25, 26]. 'Outcomes' were defined as the effects triggered by mechanism and context. In our analysis, we used quality of care as the main outcome variable as this was the type of outcome discussed most frequently by the interviewees. Our understanding of quality of care was informed by the WHO's operational definition spanning six dimensions of quality including effective, efficient, accessible, patient-centred, equitable and safe health care [27].

Table 2: Dutch integrated care for type 2 diabetes by CCM components

Dutch integrated care for type 2 diabetes	CCM component
Care groups and bundled payment system	Health system
Patient involvement	Self-management support
Health professional cooperation and task substitution	Delivery system design
Evidence-based care protocols	Decision support
Shared clinical information system	Clinical information system
	Community

Data collection

Data were collected from the case sites by means of semi-structured interviews. Initial contact between research team and interviewees was established via the case sites' contact persons. The response rate was 96%. In total 26 interviews (13 per care group) were conducted between May 2013 and January 2014 with care group managers and staff, care purchasers as well as health care professionals such as general practitioners (GPs), internists, diabetes nurse specialists (DNSs), practice nurses (PNs), dieticians, optometrists, podiatrists, pedicurists and pharmacists. All interviewees signed an informed consent form, and all interviews were audio-taped and transcribed verbatim. The interviewers used a topic list to steer the conversation. Member checks were performed by sending a one-page summary to each interviewee to confirm the interpretation of their statements. In a reminder, interviewees were informed that a lack of response would be interpreted as agreement with the summary. Nineteen interviewees replied to the member check, of which 13 confirmed the summary without comment (or only minor textual adjustments) and six commented on the member check or provided an adapted version. These comments and changes were taken up in the analysis of the interview results. Dutch law does not require medical or ethical reviews for interviews with health care professionals. Confidentiality was ensured by not disclosing the names or regions of the care groups and only referring to the interviewees by their functions.

Data analysis

We chose a case-oriented approach to data analysis because of its suitability to studying "complex, context-bound, or context-sensitive" phenomena [28]. Using Atlas.ti 6, a sub-sample of the interview-transcripts was coded independently by two researchers (LB, KL) and the rest by one researcher (LB). A coding list was based on the conceptual models and topic list and further adapted in an iterative coding process. To ensure a homogeneous interpretation of the interviews, a content check was performed for a heterogeneous sub-sample of interviews. Two researchers (KL, HV) checked ten interviews independently and compared them to the preliminary results provided by a third researcher (LB). The researchers (LB, KL, HV) discussed the results together until consensus was reached.

Results

Table 3 presents an overview of the barriers and facilitators per IM level. In the following section, we present the results for each CCM component and IM level to adequately reflect the complex

relationships between context, mechanisms and outcomes. For each section, we present the relationships between the CCM component, barriers and facilitators, and outcomes as explained by the interviewees. In general, the economic and political context barriers were the topics discussed most saliently as the most problematic areas for implementing integrated care, followed by barriers relating to the patient databases. Patient involvement received very little attention, and community involvement was mentioned just once and only as a goal for future efforts.

Table 3: Overview of barriers and facilitators to the implementation of integrated care per IM level

IM level	Barriers	Facilitators
Innovation	<ul style="list-style-type: none"> • Disease-specific care management • Insufficient integration between the various patient databases 	<ul style="list-style-type: none"> • Performance monitoring via the care chain information system
Individual professional	<ul style="list-style-type: none"> • Decreased earnings • Too many innovations • Resistance by GPs 	<ul style="list-style-type: none"> • Increased earnings • GP support
Patient	<ul style="list-style-type: none"> • Patients' insufficient medical and policy-making expertise 	<ul style="list-style-type: none"> • Increased focus on self-management
Social context	<ul style="list-style-type: none"> • Resistance by GP assistants due to perceived competition 	<ul style="list-style-type: none"> • Innovators in primary and secondary care • Tradition of transmutal cooperation
Organisational context	<ul style="list-style-type: none"> • Lack of qualified PNs • Too much care provided by PNs 	<ul style="list-style-type: none"> • Care group management and support • PNs and DNSs acting as integrators
Economic and political context	<ul style="list-style-type: none"> • The negative role of some health insurers • Yearly changes in insurance policies • The funding system incentivising the provision of care exactly as described in the care protocols 	<ul style="list-style-type: none"> • Financial incentives for care innovations • Health insurer cooperation • Financial pressure in the health sector • Financial incentives for guideline adherence

Health System

Individual Professional

Interviewees reported that earnings of some care chain partners such as the dieticians, podiatrists and pedicurists had decreased with the introduction of the new funding system, which led to dissatisfaction among these groups. On the other hand, three interviewees indicated that integrated care had brought financial benefits for health care professionals, including certain care chain partners but especially GPs, and that this led to increased provider satisfaction. Six interviewees indicated that when too many innovations were introduced too fast, health care professionals became tired and reluctant to implement changes. Care group staff were aware of this danger:

"I think we're less good at maintaining what's there because we are so focussed on new developments and innovating all the time that we forget that we have a basis who we continually burden with

everything we introduce and that for this some kind of support is very important and this should sometimes be at the expense of the time you invest in new developments.”

Care group B, staff

Organisational Context

Many interviewees pointed out the pivotal role of the care group in supporting the health care professionals. It was also mentioned that it was helpful that the care group had multiple mutual obligations with the health insurer because these interdependencies increased the pressure for both parties to reach mutually acceptable agreements. Moreover, higher quality of care was facilitated by the existence of certain quality requirements which care chain partners had to fulfil to begin cooperating with a care group. Finally, the care purchasers pointed out that the care group was a helpful access point to introduce new innovations via established channels.

Economic and Political Context

Eight interviewees pointed out the dominant, powerful and sometimes even obstructive role of the health insurers during the negotiations with the care groups. One interviewee lamented that health care professionals were trying to improve the quality of care in spite of the health insurers, as a result of the health insurers' focus on keeping the costs of care as low as possible. Many interviewees indicated that health insurers differed considerably with regard to their focus on costs vis-à-vis quality of care, and all interviewees who saw this difference said that health insurer X was also interested in quality, while health insurer Y tended to focus mainly on costs. This impression was confirmed by the purchasers from health insurer X. Related to this is the major barrier that the Dutch insurance law allows people to choose new health insurance every year. Consequently, every year health insurers determine a new policy of what they are willing to finance. The frequency of these changes caused a lot of frustration in the care group and among the health care professionals:

“We have to negotiate the price for our efforts every year. Every year again. It's crazy in the long run and a lot of wasted energy. It's terrible (...). The moment you sign an agreement you're basically already negotiating for the next year.”

Care group B, GP

Despite the care group's efforts it was not always possible to implement all changes before 1 January, the date on which new insurance policies take effect. This caused additional confusion and uncertainty because care was already provided while there were no definitive contracts and reimbursement rates were still unknown. Three interviewees explained that the current funding system involved financial incentives to provide care exactly as described in the protocols. However, at times this meant that patients received too much or too little care. Several interviewees worried that this financing based on evidence-based care protocols might have been taken too far and now constituted a barrier to person-centred and high quality care. On the upside, interviewees appreciated that the new funding system included financial incentives for new developments such as the care chain information system, online patient platforms, patient education courses, individualised health care and provider education. Moreover, it was pointed out that financial incentives to provide care as described in evidence-based

care protocols led to a more efficient care delivery and higher overall quality of care. Five interviewees pointed out the role of one particular health insurer as a facilitating one. Care group A's director explained that the care group had a very good working relationship with health insurer X. Interviewees also pointed out that the financial pressure in the national health sector made cooperation more urgent and therefore easier to accomplish, amongst other things, because financial constraints motivated people to become more innovative.

Self-Management Support

Patient

Two interviewees mentioned an increased focus on self-management and a change in health care professionals' attitudes towards more patient-centeredness:

"And the most important thing, I believe, is what changed towards the patient, that the health care professionals started to realise that if the patient is not motivated, you will never ever succeed. (...) The idea that you can leave the patient just as he is and then you have to try to limit the damage with some kind of chemical warfare, that's just... You need patient participation."

Care group A, specialist

Both care groups indicated that there were attempts and experiences regarding structural patient involvement in the organisation of care, but often patients were only involved on an incidental basis. Care group A used to involve patient representatives in the development of care programmes but this ended because patients themselves felt that the working groups required a level of policy making and medical expertise they did not have. Care group B structurally involves a patient advisory board in certain trajectories and developments of new projects. However, one interviewee pointed out that, while she thought that co-consultation with the patients was ensured, she doubted whether there was actual co-decision making as the patient advisory board was not represented in the body making the final decisions.

Delivery System Design

Innovation

At the level of the innovation itself, several interviewees indicated that, with so many diabetes patients suffering from multi-morbidity, disease-specific care management sometimes caused problems in practice. For example, care group A's PN sometimes had to refer patients to the GP or a different PN for non-diabetes related questions. This resulted in confusion in the patients and the need for more complex planning by the PNs. Moreover, health care professionals were uncertain about data administration and invoicing when patients suffered from more than one medical condition.

Individual Professional

When integrated care was first implemented, many GPs resisted its introduction because of the perceived loss of autonomy resulting from becoming part of a care group, which involved relatively

strict care protocols, internist-supervision, PNs taking over a large part of diabetes care and increased transparency due to performance monitoring. Moreover, new developments around integrated care required the GPs to become managers of their own enterprises and to manage an increasing number of staff, for several of whom they became financially responsible. Not all GPs were equally capable or willing to assume this extended role. Still, it was important for GPs to be convinced that integrated care would improve quality of care in order for them to become supportive of the integrated care intervention. It was also important for them to recognise the DNSs' expertise which helped them to accept the DNSs as partners. This also led the GPs to recommend the DNSs to their colleagues.

Social Context

When PNs were first introduced in general practice, the GPs' assistants perceived them as a threat because they feared that PNs would take tasks away from them. However, eventually they realised that PNs took on new tasks relating to the management of chronically ill patients, while the assistants kept providing administrative support to the GP's practice. Interviewees from both care groups pointed out innovators in the primary as well as secondary care sector who initiated and advanced the implementation of integrated care in the region. Several interviewees reported that also after this initial phase, there was always a group of innovators to drive the developments. Five interviewees from region A mentioned the rich and longstanding tradition of transmural cooperation in the region which resulted in a good basis for building and further developing integrated care.

Organisational Context

When the expanded role of the PN was introduced, it was difficult to find a sufficient number of qualified personnel. Until a structured training programme could be set up, personnel were enticed away from home care organisations. Two interviewees expressed their worry that, today, the substitution of care from GP to PN might have been taken too far and that now too much care was provided by the PN instead of the GP which impeded the quality of care provided. By facilitating the cooperation between the GPs and care chain partners, both the PNs and the DNSs were reported as important actors in a truly integrated approach to health care provision and helped to ensure increased continuity of care for the patients. It was also pointed out that knowing the other partners personally and knowing everyone's contribution to the patient's care, improved cooperation. Mostly, these personal contacts were organised between the PN and the other health care professionals.

Economic and Political Context

In region A, four interviewees specifically emphasised the good atmosphere of cooperation between GPs and medical specialists across care sectors. One important reason for this good cooperation was thought to be the fact that the specialists were employed at an academic hospital where specialists receive a regular salary independent of the number of patients treated, as opposed to regular hospitals with a fee-for-service structure. This was assumed to remove financial competition from the relationship when the number of patients treated in primary instead of secondary care began to increase. Together these factors led to improved cooperation and a successful shift of stable diabetes patients from secondary to primary care.

Decision Support

Innovation

Three interviewees indicated that the reporting of protocol based care provision in the care chain information system allowed for performance monitoring, which, in combination with quality audits, helped to provide health care professionals with insights into their own performance and to compare them to their colleagues in the region. It also provided the basis for targeted plans for improvement and helped in demonstrating the positive outcomes achieved for diabetes care. This positive view was shared by the care purchasers who believed that performance monitoring increased the transparency and quality of care.

Organisational Context

As explained above, financial compensation is based on health professionals' adherence to the care group's care protocols. On the one hand, this has led to clear guidelines for individual health care professionals as well as a clear division of tasks and responsibilities among several health care professionals cooperating around a specific patient. On the other hand, however, several interviewees thought that, due to the obligatory use of care protocols, some patients received more and others less care than necessary:

"You are bound to a set of rules, which is good on the one hand, that you have certain guidelines to provide care, that they say: We expect you to do this for each patient every year. But given that the population is so diverse, not everyone needs the same kind of care and it has become more difficult to keep this personalised. What used to be easier before has changed now because I have to deliver certain outputs which are expected of me. And I think that some people receive more care than they actually need, but I also see other patients to whom I would have preferred to give more."

Care group B, podiatrist

Another interviewee explained how strictly protocol-based care provision led to a one-size-fits-all approach to care delivery, which in turn, stood in the way of high quality, person-centred care:

"If you have a meat chopper and you put meat in it, it doesn't matter what you put in it, you will always get minced meat. So in the past we might have had nothing, that's true, so I think that the quality of care has improved. Back then maybe we had nothing, but now we turn everyone into minced meat. And that's not fair to the patient because every patient gets the same standard product and very little profiling takes place because the financing and accounting culture and the current indicator-mania make this impossible."

Care group A, specialist

Clinical Information System

Innovation

Interviewees indicated insufficient integration between the various electronic databases used by GPs, PNs, care chain partners and hospitals. As mentioned above, within the care group, GPs often use their own GP information system (HIS), practice nurses and care chain partners use the care chain information system (KIS), and care chain partners also use their own profession-specific databases. Hospitals also use their own system, which is separate from the systems used in primary care. In care group A, not all HISs were integrated with the care group's KIS, and hence, in these cases, PNs had to enter patient data twice. In care group B, the HIS and KIS were integrated to the extent that data entered in one system were automatically displayed in the other system. However, extracting data from the system for purposes of performance monitoring resulted in faulty or incomplete reports because the data originated from two different sources. In both care groups, most care chain partners cooperated with multiple care groups in the same region, which meant that they had to work with several care chain information systems in addition to their own administrative system. One dietician explained that some of her colleagues worked with up to six different systems, especially when they also worked in the hospital. For PNs and care chain partners alike, this double data entry took longer, increased the likelihood of incorrect and incomplete data and led to staff dissatisfaction. Moreover, interviewees pointed out that sometimes the registration and data entry took up so much of the consultation time that it impeded on the time spent with the patient:

"You have to enter things twice and that takes a lot of time. I think it's a pity we spend a lot of time on IT now and registering things. Even though I understand that it needs to be done, it all needs to be transparent and clear, but because of this we sometimes have too little time to really provide care and I think... The patient is much more important to me... capturing data should be a minor matter but because you have two systems, well, it just takes a lot of time."

Care group A, PN

Finally, when patients were referred to hospital, they disappeared from the primary care information systems until they returned to primary care, because the primary and secondary care information systems were incompatible. In those periods, the internist could access the care chain information system on a read-only basis.

Organisational Context

Six interviewees pointed out the usefulness of the shared care chain information system, especially because it provided access to the patient's electronic medical record to all involved health care professionals:

"So the whole idea of cooperating around a patient and making sure that you do it in a coherent way has been helped a lot by the possibility to register everything in one place so that you could see and read what everyone registered."

Care group B, director

Most notably, this meant that, at the first point of contact between a care chain partner and the patient, the health care professional had access to the patient's electronic medical record, a source of information considerably richer than the paper-based referral or the patient's memory. Moreover, it became clearer who the patient's primary health care professional was and who bore responsibility for which aspects of the patient's care.

Discussion

The above presented an exploratory study on the implementation of integrated care for type 2 diabetes by two Dutch care groups, examining how the context and mechanisms of the intervention affected its outcomes. Regarding mechanisms, our mapping of current core elements of Dutch integrated care to CCM components showed Dutch integrated care to reflect five of the six CCM components, namely health system (care groups and bundled payment system), self-management support (patient involvement), delivery system design (cooperation and substitution), decision support (evidence-based care protocols) and clinical information system (shared clinical information system). Aspects related to the community component were not found. The fact that integrated care touches upon almost all CCM components shows that many different aspects are being taken into account which is appropriate for a complex intervention. At the same time this means that efforts are divided over several focal points and therefore not implemented equally well in all areas. At the moment emphasis is mostly put on the health system, delivery system design, decision support and clinical information system. Self-management support is receiving much attention in the care standards but this has not been translated into the practice setting yet. Moreover, the fact that the community component has not yet been incorporated into the intervention underscores that integrated care is still in development.

Barriers were found at all levels of the IM and included insufficient integration between the various patient databases (innovation), decreased earnings for some health professionals (individual professional), patients' insufficient medical and policy-making expertise (patient), resistance by GP assistants due to perceived competition (social context), too much care provided by PNs instead of GPs (organisational context) and the funding system incentivising the provision of care exactly as described in the care protocols (economic and political context). Facilitators were also found at all levels of the IM and included performance monitoring via the care chain information system (innovation), increased earnings for some health professionals (individual professional), increased focus on self-management (patient), innovators in primary and secondary care (social context), PNs and DNSs acting as integrators (organisational context) and financial incentives for guideline adherence (economic and political context). These findings show that the implementation of a complex intervention is complex in itself, too: various factors impact on different outcomes in different ways. The fact that the economic and political context as well as health IT-related barriers were discussed most frequently by the interviewees points towards those obstacles that are currently problematic. The fact that patient level barriers and/or facilitators have hardly been discussed at all points towards the need for increased focus on these stakeholders in practice as well as future research.

According to the interviewees, integrated care has led to perceived improvements in certain aspects of quality of care such as improved communication and cooperation, but also to perceived deteriorations in others such as insufficient and unnecessary care provision and the preconditions for person-centred care. However, with so many diverse factors impacting on outcomes achieved, respondents' opinions varied on whether, overall, integrated care had led to improved or deteriorated quality of care. This finding is in line with the findings of a large-scale evaluation of the bundled payment system three years after its introduction which also found small improvements to processes as well as some outcome indicators, but concluded that it was not clear what these meant for overall quality of care [26]. A report on the status-quo of health IT use in Dutch integrated care also concluded that an overall health IT system has not been fully implemented yet and that often parts of the system are incompatible with each other and consequently cause problems in other areas as well [29].

There are several limitations associated with this study. First, there is no uniform way of describing or analysing the implementation of integrated care. Our interpretation of the CMO Model, defining mechanisms as the different aspects of the integrated care intervention, context as the barriers and facilitators encountered during the implementation, and outcomes as quality of care, is probably not the only way this could be done. However, we believe that this study's approach, being embedded in three internationally accepted and widely-used conceptual models, is a valuable starting point for a more tangible way of evaluating integrated care interventions using the CMO approach. Second, despite the importance attributed to the role of patients in integrated care, our study has found very little evidence on patient-level barriers and facilitators. This is probably at least partially due to the lack of patient interviews included in this research. However, it should be emphasised that all interviewees were specifically asked for their opinion about patient perspectives on integrated care. The lack of patient-related context information could therefore also be a sign of a limited focus on this issue by the health care professionals and thereby be a result in itself, reflecting the need for increased emphasis of the patient's perspective. This would correspond to the findings of a study on the effects of care standards for vascular risk management which found self-management support and patient involvement to be lacking [30]. Third, being a single-case study design our study is case- and context-specific and cannot claim generalisability to other settings or conditions. Nevertheless, we think that the experiences and examples provided help organisations wishing to implement integrated care interventions in their own settings. Above all, the added value lies in pointing out potential speed bumps as well as solutions and where these can be expected.

Conclusions

Barriers and facilitators were found at all levels of the Implementation Model, with economic and political context and health IT-related barriers discussed most frequently by the interviewees. On the one hand, the implementation of integrated care led to improved communication and cooperation, but on the other hand also to insufficient and unnecessary care provision and deteriorated preconditions for person-centred care. These findings show that Dutch integrated care is still in development and that its implementation has not realised its full potential yet. Future efforts should therefore focus on actively developing all areas of integrated care. However, the most problematic areas (such as financial and

health IT issues) or those that have not received enough or any attention yet (such as patient and community involvement) seem to warrant the most urgent attention. To achieve generalisability, future research should also focus on the development of an integrated framework for analysing the implementation of integrated care interventions for people with chronic conditions, focusing on the different mechanisms by which and context in which these are implemented and explicitly linking those factors to the outcomes achieved.

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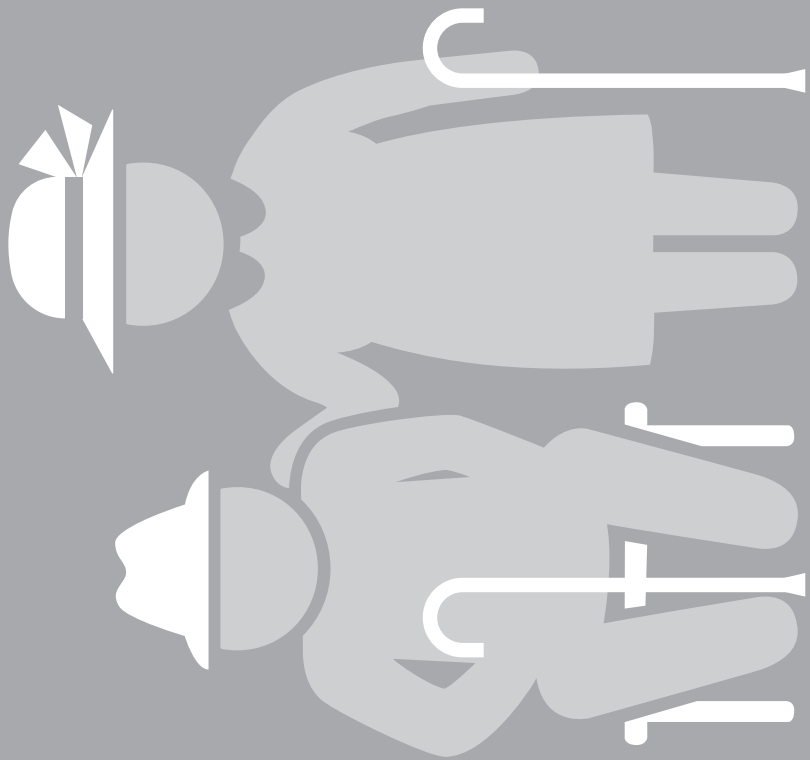
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Appendix

Table 1: Core elements of integrated care for type 2 diabetes in the Netherlands

Element	Description
Care groups and bundled payment system	Dutch integrated care for type 2 diabetes is organised via so-called care groups, legal entities that “establish contracts with health insurers in order to coordinate and execute chronic care in a specified region, with the aim of improving the quality of care” [13]. The legal form of these organisations varies but, in most cases, general practitioners (GPs) are (co-) owners [26]. In 2010, there were approximately 100 care groups offering integrated care for diabetes, many of which were also offering programmes for other chronic conditions such as COPD and vascular risk management [26]. In the funding framework introduced in 2007, the so-called bundled payment system, care groups act as intermediaries between health insurers and health care professionals by negotiating the content and price of a comprehensive package of diabetes care, the resulting agreements of which are captured in bundled payment contracts [26]. These contracts make it possible to buy care as if it were one single product, even though it consists of many components delivered by a diverse group of health care professionals often in more than one setting [26]. For those health care services not provided by GPs and practice nurses (PNs), care groups enter contracts with care chain partners such as dieticians, podiatrists or pedicurists, depending on the chronic condition.
Evidence-based care protocols	In the Netherlands, care provision for type 2 diabetes is based on national evidence-based care standards describing norms of high quality chronic care for specific chronic diseases, such as the diabetes care standard [25]. Based on the negotiations between care groups, health care professionals and health insurers, these standards are translated into specific care protocols, based on which, care is delivered and reimbursed. Negotiations do not only take place between one care group and one health insurer or one care group and one health care professional, but each care group enters into contracts with potentially all health insurers and all relevant health care professionals in a given region and vice versa [31, 32].
Health professional cooperation and task substitution	The delivery of diabetes care is performed by a group of health care professionals involved in the care for a specific chronic disease. The core of diabetes care includes GPs, PNs, diabetes nurse specialists (DNSs) and internists. The former two are located in general practice, whereas internists are located at the hospital, and DNSs are dispatched from hospital to general practice and are therefore present at both locations [33, 34]. It should be noted that, while internists are involved in the provision of integrated diabetes care, whether they are reimbursed via the bundled payment contract differs per region and care group. At the periphery, dieticians, podiatrists, pedicurists, optometrists and other medical specialists are also involved [25, 26]. Dutch integrated care is based on the assumption that substitution of professional roles and tasks will lead to more cost-efficient care. Horizontal substitution means the transition of patients from secondary to primary care, where stable diabetes patients as a default should be treated by the GP instead of the internist. Vertical substitution means that certain tasks traditionally performed by the GPs or internists are now performed by PNs and DNSs, respectively [13, 34].
Patient involvement	Involvement of patients both during consultations and in the organisation of health care is an important strategy in the Dutch approach to integrated care for type 2 diabetes [25]. One example of the former is shared patient-doctor goal-setting, mostly realised via

	<p>individual care plans which, as opposed to general treatment plans, consist of precise and feasible goals that are set in a shared decision-making process between patient and health care professional. An approach to involving patients in the organisation of diabetes care is the consultation with patient advisory boards. With Dutch integrated care still being in development, both aspects of patient involvements are not yet fully implemented in practice [26].</p>
Shared clinical information system	<p>The electronic administration and exchange of data for patients with type 2 diabetes treated within the bundled payment framework is an important requirement for integrated care [25]. However, the number and type of electronic databases used in practice differs per region and care group. Often, GPs use their own GP information system (HIS) and practice nurses and care chain partners use a care chain information system (KIS). Care chain partners also use their own profession-specific electronic medical record systems. The HISs are commercial systems that can be chosen freely according to the GP's own preferences. A KIS, on the other hand, is generally chosen by the care group, and every GP practice and care chain partner working with a certain care group must work with this specific KIS [26].</p>



CHAPTER 6

Implementation of integrated geriatric care at a German hospital: a case study to understand when and why beneficial outcomes can be achieved

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Implementation of integrated geriatric care at a German hospital:
a case study to understand when and why beneficial outcomes can be achieved.

Abstract

Integrated care is seen as a promising approach for geriatric patients, whose conditions often fall outside the scope of traditional, disease-focussed systems. This study aims to analyse the implementation of integrated care at a German geriatric hospital and explore whether the use of a CMO (context + mechanisms = outcomes)-based model provides insights into when and why beneficial outcomes can be achieved. We conducted 15 semi-structured interviews with health professionals employed at the geriatric hospital. Mechanisms were defined as the different components of the integrated care intervention, context as the barriers and facilitators encountered in the implementation process, and outcomes as effects triggered by mechanisms and context. The integrated care intervention consisted of three main components: a specific reimbursement system called “early complex geriatric rehabilitation”, multidisciplinary cooperation, and comprehensive geriatric assessments. The reimbursement system was financially advantageous for the geriatric hospital, but its inflexibility regarding the obligatory number of treatment sessions as well as its focus on the length of stay contributed to less care delivered to the patient, overuse, underuse and misuse of health services, less focus on the patient’s needs, a revolving door effect, and frustration among staff. Multidisciplinary cooperation was mainly impeded by high workload, but also facilitated by informal cooperation structures. This contributed to frustration among staff, waste in workflows, and less family involvement, but also to faster information exchange and more focus on the patient’s needs. Comprehensive geriatric assessments were enhanced by family member involvement and contributed to a more holistic view of the patient and a decreased likelihood of adverse events. We recommend that the negative aspects of the reimbursement system should be adapted or counter-balanced with appropriate quality measures. The workload and administrative obligations of the health professionals should be lessened or distributed so as not to impede multidisciplinary cooperation. Overall, we recommend an increased focus on trying to understand how intervention components interact with context factors and, combined, lead to positive and/or negative outcomes. Our CMO-based approach has proven to be a useful instrument for these types of evaluations.

Introduction

Over the past decade, many health systems have implemented integrated care as an alternative approach to health care delivery that is more appropriate for patients with complex, long-term needs. The World Health Organization (WHO) defines integrated care as “the management and delivery of health services such that people receive a continuum of health promotion, health protection and disease prevention services, as well as diagnosis, treatment, long-term care, rehabilitation, and palliative care services through the different levels and sites of care within the health system and according to their needs” [1]. As such, integrated care interventions often include changes to the health system, use of community resources, patient-provider relationships, care process design, communication infrastructures and the ways in which health professionals deliver care [2-4]. This is expected to lead to improved population health, patient experiences and cost-efficiency [5-8], a trio of goals commonly referred to as the Triple Aim [9].

When persons fall ill at an old age, they are often referred to as geriatric patients, even though exact definitions differ. Generally speaking, geriatric patients suffer from geriatric conditions, that is, a collection of signs and symptoms which are common in older patients [10, 11]. These often include incontinence, falls, malnutrition or low body mass index, dehydration, constipation, depression, pressure ulcers, mobility disability, dizziness, vision impairment, hearing impairment, cognitive impairment, delirium, insomnia, and polypharmacy [10, 12-17]. As these conditions are often not associated with a specific disease and therefore fall outside the scope of traditional disease-focussed models of care delivery, it has been argued that integrated care interventions are especially important for this target population [11-13, 18]. However, so far the evidence on the effectiveness of integrated care for people with geriatric conditions has been mixed. While some interventions were found to have contributed to a reduction in symptoms, emergency department visits, acute hospital admissions and hospital bed days [19, 20], other interventions showed no improvements in length of hospital stay, use of care, prevention of adverse outcomes, health status and costs [20-25]. In addition to this heterogeneity in outcomes, there was also a considerable variation in the interventions themselves, which ranged from telehealth education, discharge planning and community support, and multidisciplinary pathways to integration of the cure, care and welfare sector.

Rather than assessing whether integrated care for geriatric conditions “works”, it should be explored why and in which cases some interventions do, while others do not. This requires a focus on the implementation of an intervention, including which type of intervention is implemented, how it is affected by the context in which it is implemented, and to which outcomes it contributes [26-28]. In order to gain more insights into the implementation of integrated care for people with geriatric conditions, the first objective of our study is to describe the implementation of an integrated geriatric care intervention at a German geriatric hospital. This case was selected as case study of integrated care implementation within the scope of a comparative European project [29]. To facilitate the analysis of the case study, we make use of a CMO (context + mechanisms = outcomes)-based model, which assumes that interventions have beneficial outcomes when they introduce appropriate mechanisms in the appropriate social and cultural contexts [27, 30]. The second objective of this study is to explore

whether the application of this model provides insights into when and why beneficial outcomes can be achieved.

Methods

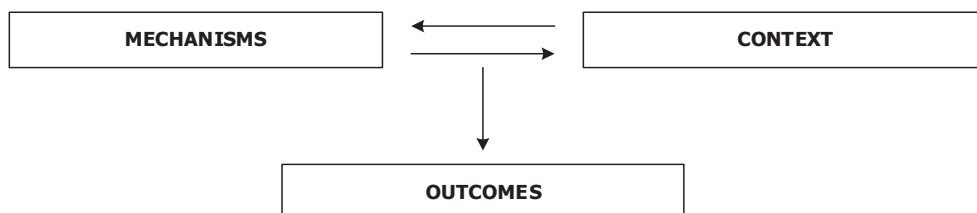
Case selection

Within the scope of a European research project, a German geriatric hospital was identified as a case study of integrated care implementation for patients with geriatric conditions. Within the project, four case studies were conducted on integrated care for two specific chronic conditions (i.e. diabetes and chronic obstructive pulmonary disease) and two groups of conditions (i.e. mental and geriatric condition), with the aim of identifying what constitutes good quality integrated care provision [31]. The German case site was one of the first geriatric hospitals in Germany intentionally organised as a multidisciplinary hospital with an integrated care approach. It includes a geriatric hospital with more than 150 beds, a day clinic and a nursing home specialised in dementia care. In this article, we focus specifically on the geriatric hospital. Its patient population consists of patients with complex, multiple age-related conditions that are in temporary need of acute care before they can be discharged or transferred to a long-term care facility [32]. Care for geriatric patients is delivered by a geriatric team led by a geriatric physician, who have weekly team meetings and perform standardised comprehensive geriatric assessments. Patients stay at the hospital for up to 21 days, depending on their health status and potential for rehabilitation. Subsequently, they are discharged to their home setting or transferred to a nursing home for long-term care.

CMO-based approach

As research informed by the CMO Model is best equipped to answer 'how' and 'why' questions in combination with 'what has been achieved' questions, we use the CMO Model as an umbrella framework for the collection, analysis and interpretation of data [27]. It should be noted that even though the CMO Model suggests the order "context, mechanisms, outcomes", in the following we will discuss the elements in the order "mechanisms, context, outcomes". The reason for this is that in our understanding, the mechanisms of an intervention are introduced, then they encounter barriers and facilitators in a specific setting, which combined with the mechanisms, lead to certain outcomes. This relationship is shown in Figure 1.

Figure 1: Relationship between mechanisms, context and outcomes



Mechanisms were defined as the different components of the integrated care intervention and categorised according to Wagner's Chronic Care Model (CCM). According to the CCM, improvements in integrated care for chronic conditions require changes in six components (health system, self-management support, delivery system design, decision support, clinical information system and community [4]. Interventions targeting at least two of these components are generally considered integrated care [3, 30, 33-36]. Context is understood as the setting in which the mechanisms are brought into practice and described by the barriers and facilitators encountered in the implementation process. We define barriers and facilitators as those factors that either hinder or foster the implementation of integrated care interventions in practice. These were categorised according to the six levels of Grol and Wensing's Implementation Model (IM): innovation, individual professional, patient, social context, organisational context and economic and political context [37]. During the analysis, the level "health system context" was added and the level "economic and political context" was changed to "economic, political and legal context" to make it more explicit that the legal/regulatory dimension was also covered. Outcomes are defined as the effects triggered by mechanisms and context. These were categorised according to the six dimensions of quality of care as defined by the WHO, namely effectiveness, efficiency, accessibility, patient-centeredness, equity and safety [38]. We added satisfaction as additional dimension, which can refer to staff and patient satisfaction.

Data collection and analysis

After receiving approval by the ethical review committee of the Charité Universitätsmedizin Berlin, potential interviewees were contacted personally by one of the researchers (JK). In order to ensure diversity in professional backgrounds and include different perspectives on the integrated care intervention, we aimed to include at least two interviewees from each professional group represented in the multidisciplinary team (i.e. medical doctors, occupational therapists, neuropsychologists, physical therapists, nurses, speech therapists and social workers). The response rate was 75%. Those who declined to participate did so mainly due to high workload. Eventually, 15 interviews of approximately one hour were conducted with four medical doctors, four occupational therapists, three neuropsychologists, two physical therapists and two nurses. Speech therapists and social workers were not represented in the sample. During the interviews, a topic list was used that focussed on the various components of the integrated care intervention, the barriers and facilitators to its implementation, and the outcomes achieved because of the intervention. This topic list had been developed by a consortium of researchers involved in the European comparative project and tested and used in a similar case study on integrated diabetes care in the Netherlands [30]. All interviews were audio-taped and transcribed verbatim afterwards. Due to the strict anonymity requirements by the ethical review committee, there were no records of the interviewees' identities, and it was therefore not possible to perform member checks as a quality assurance measure.

Data analysis was performed by two researchers (JK, LB). JK had conducted the interviewees and knew the interviewees and their work environment well. LB was an outsider who had not met the interviewees and was not familiar with their work environment. The initial coding list was an adapted version of the coding list from the Dutch case study on integrated diabetes care and included codes related to the different CCM components, the role of the interviewee, the patient population, the

implementation of the intervention (including the foundation of the hospital, changes over time, barriers and facilitators to the execution of the intervention), transfers to and from the geriatric hospital, and middle and senior management and leadership. Paper-based coding of the interview transcripts was performed independently by two researchers (LB, JK). After five interviews, the sections for which a certain code was identified, were summarised and translated from German to English. The translated summaries were transferred to a tabular form of the coding list (i.e. the coding table). The coding table was compared to and adapted according to the second researcher's (JK) paper based coding. The adapted coding table was complemented by the next five interviews' paper based codes. This was repeated a third time until all paper based coding was summarised in the coding table. Throughout this process, the list of available codes was adapted when necessary after discussion among the two coders (LB, JK). Based on the information summarised in the coding table, the main mechanisms, context factors and outcomes were identified, described and visualised according to the CMO-based model described above. This resulted in an overview of the mechanisms, context factors and outcomes, as well as three clusters of their interrelationships described around the three main intervention components.

Results

We found the integrated care intervention to consist of three main components, namely a specific reimbursement system (called "early complex geriatric rehabilitation), multidisciplinary cooperation and comprehensive geriatric assessments (see Table 1).

Table 1: Overview of the mechanisms of the integrated care intervention

CCM component	Mechanisms
Health system	Early complex geriatric rehabilitation
Self-management support	
Delivery system design	Multidisciplinary cooperation
Decision support	Comprehensive geriatric assessment
Clinical information system	
Community	

The implementation of these components was hindered by barriers such as a sub-optimal documentation system, patients with increasingly complex conditions, high workload, lack of inter-organisation infrastructure, and administrative obligations. The implementation was facilitated by family member involvement, informal cooperation structures, and also administrative obligations (Table 2).

Table 2: Overview of the context of the integrated care intervention

IM Level	Barriers	Facilitators
Innovation	Documentation system	
Individual professional		
Patient	Increasingly complex conditions	Family member involvement
Social context		
Organisational context	High workload	Informal cooperation structures
Health system context	Lack of inter-organisational infrastructure	
Economic, legal and political context	Administrative obligations	Administrative obligations

In combination, mechanisms and context factors contributed to negative outcomes such as less care provided to patients, overuse, underuse and misuse of health services, unnecessary incurrence of costs, waste in workflows, less focus on the patient instead of administrative obligations, less family involvement, increased likelihood of adverse events or medical mistakes, revolving door effect and frustration among staff. Positive outcomes included better understanding of colleagues' expertise, continuity in care provision, more care provided to patient, financially advantageous reimbursements, faster information exchange, more focus on patient instead of administrative obligations, holistic view of the patient, improved transparency, decreased likelihood of adverse events or medical mistakes, appreciation by staff, and appreciation by patients (Table 3).

Table 3: Overview of the outcomes of the integrated care intervention

WHO dimension	Negative outcomes	Positive outcomes
Effectiveness	<ul style="list-style-type: none"> Less care provided to patients 	<ul style="list-style-type: none"> More care provided to patients Better understanding of colleagues' expertise Continuity in care provision
Efficiency	<ul style="list-style-type: none"> Overuse, underuse, misuse Waste in workflows 	<ul style="list-style-type: none"> Financially advantageous reimbursements Faster information exchange
Accessibility		
Patient-centeredness	<ul style="list-style-type: none"> Less family member involvement Less focus on patient instead of administrative considerations 	<ul style="list-style-type: none"> More focus on patient instead of administrative considerations Holistic view of the patient
Equity		
Safety	<ul style="list-style-type: none"> Revolving door effect Increased likelihood of adverse events or medical mistakes 	<ul style="list-style-type: none"> Decreased likelihood of adverse events or medical mistakes Improved transparency
Satisfaction	<ul style="list-style-type: none"> Frustration among staff 	<ul style="list-style-type: none"> Appreciation by staff Appreciation by patients

In the following section, we describe the interplay of these factors by presenting clusters of mechanisms, context factors and outcomes. For increased clarity, we ordered the clusters around the intervention components, i.e. Cluster 1 around the reimbursement system, Cluster 2 around multidisciplinary cooperation and Cluster 3 around comprehensive geriatric assessments.

Cluster 1: Early complex geriatric rehabilitation

The care patients receive at the geriatric hospital is reimbursed as “early complex geriatric rehabilitation” (in German: geriatrische frührehabilitative Komplexbehandlung (GFK)) (mechanism). This is a technical term that describes a specific reimbursement option within the German system of disease related groups (G-DRG) [39-42]. The G-DRGs are an obligatory classification system used by hospitals to receive bundled reimbursements for the treatment of similar groups of patients. Patients are classified into specific DRGs based on demographic data, primary and secondary diagnoses and so-called medical procedures. The procedure applicable to geriatric care is the GFK which is applicable for geriatric patients in temporary need of acute care (OPS 8-550). In order to be eligible for reimbursement under the GFK framework, the geriatric hospital must fulfil certain criteria. Amongst others, they must show that the patient is a geriatric patient (i.e. multimorbid, often 70 years and older), care must be provided by a geriatric team led by a geriatric physician, and standardised comprehensive geriatric assessments as well as weekly team meetings must take place. Additionally, patients staying at the geriatric hospital for a certain number of days must receive a certain number of therapy sessions. For example, patients staying 14 days need to receive 20 therapy sessions, and patients staying 21 days require 30 therapy sessions. If the patient does not need complex care, they can be discharged earlier without the number of required therapy units. In this case, the GFK framework does not apply and the patient is classified according to his or her primary condition within the G-DRG system. However, for the geriatric hospital, reimbursements as GFK are financially advantageous compared to the regular rates (outcome).

One of the characteristics of the GFK is its inflexibility regarding the number of treatment sessions that have to be provided to each patient. Given the vast differences in rehabilitation potential of the patients, this standardisation leads to overuse of services by some patients, and under- and misuse of services by others (outcome). This leads to frustration when the health professionals feel that treatments are provided to patients who cannot benefit much from these treatments, at the expense of other patients who could benefit greatly but who have reached their maximum number of treatments (outcome). As mentioned above, the GFK framework offers advantageous reimbursement rates when patients stay at the geriatric hospitals for a minimum of 14 days and receive 20 therapy sessions, or 21 days and 30 therapy sessions. However, day 14 and 21 are cut-off points, and there is no financial incentive for hospitals to keep patients for more than 14 days (but less than 21), or more than 21 days when the required number of therapy sessions has been provided. Instead, when patients stay longer than these cut-off days, hospitals incur the costs of having patients at the hospital without receiving an additional reimbursement. As a consequence, interviewees noticed a change in the care planning approach. One example given in this context was that even if all health professionals agreed that a few more therapy units would greatly improve the patient’s health status, the patient still would have to be discharged at the end of the 21 day period. As a result, the patients’ needs and wishes were less

decisive for their care trajectories, and patients received less or even insufficient care (outcome). The latter contributed to a revolving door effect, meaning that patients were re-admitted soon after discharge. This transfer to and from different settings was potentially dangerous to patient health, especially for frail older people (outcome). The negative effects of the increased focus on the length of stay were further exacerbated by the fact that the patient population in the geriatric hospital was characterised by more and increasingly complex conditions (context). This made it less likely that an appropriate amount of care could be realised within the same timeframe (outcome).

Another characteristic of the GFK is the fact that it is not a full-range treatment on its own, but an intermediate stop between a previous location (home or care facility) and the next location (also home or care facility). However, there is a lack of a general infrastructure (including IT infrastructure) to support inter-organisational cooperation between the geriatric hospital and referring/admitting institutions and the ambulatory sector (context). For example, sometimes patients arrive at the geriatric hospital without the necessary information on their medical condition:

"Patients arrive without a letter of referral. That's an absolute no-go, it must not happen, even if it's only a short letter with the most essential diagnoses. But it should never happen that a multimorbid patient arrives here without a referral letter, with only a short consultation between the nurses. Well, what can you do? You pick up the phone and call a number only to hear that your colleague is currently in surgery and there's no one available to give at least a short summary of the patient. That's bad style, but it happens on a daily basis. The time we spend on the phone, to get to know at least something, it's terrible."

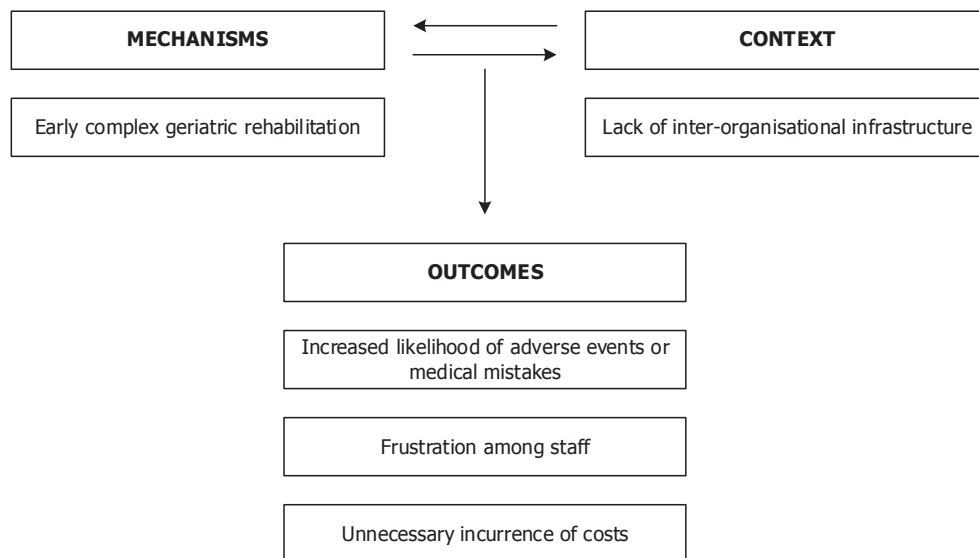
This lack of information is time-consuming and frustrating for health professionals (outcome). Moreover, it is potentially dangerous for the patients, since health professionals have to rely on incomplete information to make medical decisions (outcome). Another example of the problematic inter-organisational infrastructure is the fact that patients should not be discharged from the geriatric hospital on a Friday because it is not often clear how they will get their medicines until Monday or how they are otherwise supported at their homes. Often this entails a longer length of stay at the geriatric hospital over the weekend and thereby increased costs for the hospital, without adding any benefit for the patient who does not receive additional treatment sessions in the weekends (outcome). As an example of the interplay between mechanism, context and outcomes in Cluster 1, the influence of the lack of inter-organisational infrastructure is portrayed in Figure 2.

Cluster 2: Multidisciplinary cooperation

The geriatric hospital has multidisciplinary staff consisting of doctors, nurses, occupational therapists, physical therapists, speech therapists, neuropsychologists and social workers (mechanism). Depending on the patient's needs, different combinations of health professionals work together. For example, physical therapists perform certain measures that make it possible for occupational therapists to mobilise that part of the patient's body. For stroke patients with cognitive impairments, it makes sense for the occupational therapists to cooperate primarily with the neuropsychologists. As one interviewee put it:

"Basically it's a whole network of staff from different professional groups who are linked to one another and who communicate so that the patient is cared for in an optimal way."

Figure 2: Example of the interplay between mechanism, context and outcomes in Cluster 1



The multidisciplinary team meets regularly during daily morning meetings and weekly team meetings. During the daily morning meetings, new patients are introduced by the doctor and nurses from the night shift describe whether there were any events during the past shifts. The weekly team meetings are obligatory under the GFK framework and are led by the ward doctor. Here, the patients' advances during the past week are discussed from the professional groups' different perspectives. At the end of the discussion a therapy plan for the patient for the next week is agreed on and the possibilities for discharge or transfer to a nursing home are discussed. Interviewees have indicated that they enjoyed the multidisciplinary cooperation, mainly because the flat hierarchical structures led to a lot of independence and accountability of each member of the team (outcome). Formal meetings were seen as an important factor in improving the efficiency of the information exchange and thereby saving time for the health professionals (outcome). Moreover, interviewees indicated that because of the team meetings, health professionals already had a lot of information about the patients and therefore did not need to ask the same questions several times, which otherwise would have led to frustration among the patients and providers (outcome). An additional benefit was seen in the deeper understanding of the other health professionals' perspectives and work with the patient, including the interpretation of assessments (outcome).

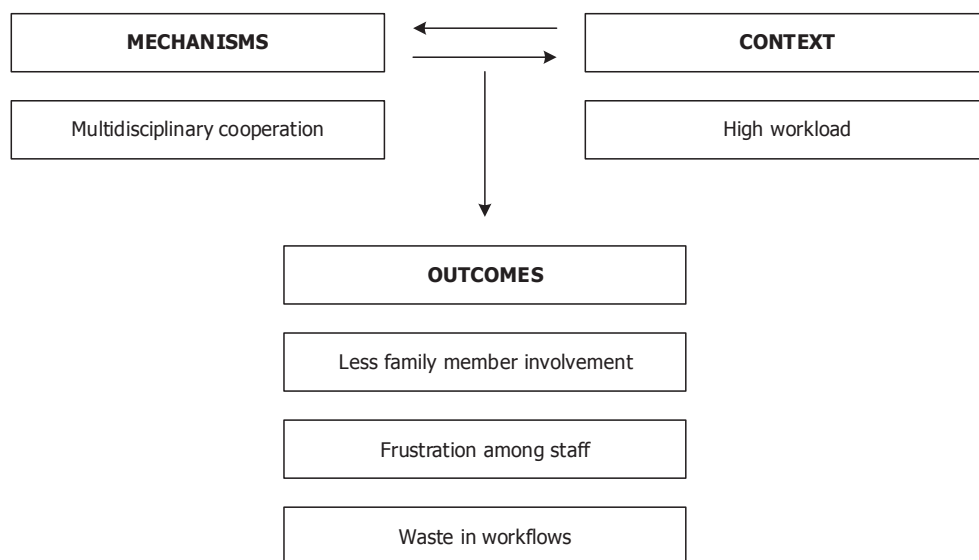
However, interviewees indicated that the current documentation system acted as a barrier to their cooperation (context). They indicated that the documentation system was too old, too slow, and too

unreliable, because it broke down frequently. Moreover, not all health professionals could see all data produced by the other professions, and not all relevant information could be documented with the system. Overall, these problems resulted in considerable frustration among staff and waste in workflows (outcome). Over time, many informal cooperation structures were established at the geriatric hospital as a workaround to the limited number of weekly team meetings and impediments due to the lack of a proper IT system (context). For example, direct communication in passing between health professionals effectively replaced the gathering of information via the patient record. Furthermore, it made it possible to re-adjust strategies in between the weekly team meetings. As such, informal cooperation led to faster information exchange (outcome). Moreover, interviewees indicated that team meetings often centred on organisational issues for fulfilling prerequisites of the GFK framework. The informal cooperation allowed the health professionals to discuss the patient instead of administrative obligations (outcome).

Interviewees indicated that they experienced a high workload at the geriatric hospital (context). This meant that they did not have enough time to talk to their colleagues, which led to the fact that the treatment approaches of the different health professionals were not always well coordinated and aligned to one another, which contributed to waste in workflows (outcome). Moreover, staff felt that they did not spend enough time with the patient either, which led to frustration (outcome). High workload was also seen as a major barrier to increased family involvement and information provision (outcome). As an example of the interplay between mechanism, context and outcomes in Cluster 2, the influence of a high workload on multidisciplinary cooperation shown in Figure 3.

Moreover, interviewees reported that administrative obligations multiplied over the past 10-15 years (context). This contributed to a shift of focus during the team meetings, away from discussing the patients as a multidisciplinary team, and towards making sure that patients received the obligatory number of sessions or that length of stay would not be exceeded (outcome). Interviewees realised that documentation was important in terms of transparency (outcome). However, as long as this increasing imbalance towards documentation was not compensated by more staff to spend time with the patient, less care would be provided to the patients (outcome). This also led to frustration by staff who felt that their time is not spent on what should be their most important task, namely taking care of their patients (outcome). Finally, interviewees reported that when family members were included in the care process and educated on how to take care of the patient (context), this helped to decrease the workload of the nurses, which meant that they could better cooperate with their colleagues and deliver more care to the patient (outcome). Family member involvement also enabled them to continue the care once the patient was discharged (outcome).

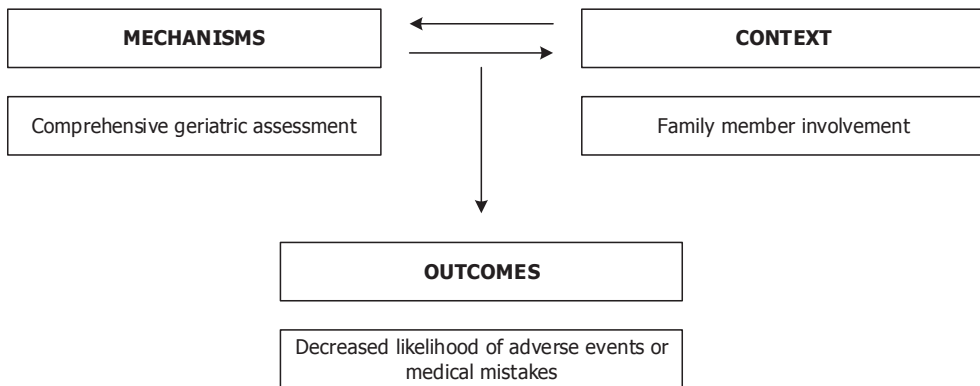
Figure 3: Example of the interplay between mechanism, context and outcomes in Cluster 2



Cluster 3: Comprehensive geriatric assessments

At the geriatric hospital, each patient is assessed by all health professionals during in-take and before discharge (mechanism). Certain parts of these assessments are obligatory, while others depend on the mobility or cognitive abilities of the patient. All assessments are documented in the documentation system, which is a necessary condition for receiving reimbursements via the GFK framework. They are also used as a basis for the discussions in the team meetings and further care planning. Interviewees indicated that the comprehensive geriatric assessments made it possible to include various perspectives and thereby different interpretations of the patient's situation. In doing so, they were seen as an enabler of a holistic view of the patient as a whole person instead of separate parts of the body or illnesses that must be treated (outcome). Moreover, interviewees pointed out that this type of cooperation between all health professionals compensated for the loss of the patient as information carrier (e.g. due to cognitive or speech impairments) and thereby helped to prevent adverse events or medical mistakes (outcome). The involvement of family members made it possible to complement the comprehensive geriatric assessments with other sources of information (context). This was necessary because these assessments can never capture all relevant information, and they are sometimes invalidated by the patients themselves who are not entirely honest or try to embellish their situation. Especially in the case of chronically ill patients, family members hold valuable information which often helps to prevent mistakes or adverse events from (re-)occurring (outcome). As an example of the interplay between mechanisms, context and outcomes in Cluster 3, the influence of family member involvement on the comprehensive geriatric assessments is presented in Figure 4.

Figure 4: Example of the interplay between mechanism, context and outcomes in Cluster 3



Missing CCM components

Based on the interviews, we did not find self-management support, a clinical information system and use of community resources to be part of the intervention. The interviewees rarely mentioned self-management support as a topic, even though some health professionals described a patient-centred approach to care planning for their own therapy sessions. For example, one occupational therapist described how he discusses goals and priorities with the patients to determine the care plan. However, no structured programs or approaches to self-management support or the involvement and training of family members existed. The IT system used in the geriatric hospital was generally seen as a digital documentation system or administrative tool rather than a real-time information system from which information was actively accessed. Some health professions stated that the system was mainly used to fulfil the documentation requirements for the reimbursement within the GFK framework. With regard to the use of community resources, most interviewees were aware that in the discharge of the patient from the geriatric hospital to the patient's home setting, there are different actors who play a role and who can be involved to optimise the patient's situation. However, we found no evidence of how community resources were mobilised or linked with the hospital to this purpose.

Discussion

This study presented an analysis of the implementation of integrated geriatric care at a German geriatric hospital by identifying the main intervention components, how they were affected by the context in which they were implemented, and to which outcomes they contributed. We made use of a CMO-based model to create clusters describing the interplay of mechanisms, context factors and outcomes.

We found the integrated care intervention at the geriatric hospital to consist of three main components, namely a specific reimbursement system, multidisciplinary cooperation and comprehensive geriatric assessments. Reimbursements as GFK (health system) are financially advantageous for the geriatric hospital (efficiency). Moreover, the inflexibility of the GFK framework regarding the obligatory number

of treatment sessions as well as its focus on the length of stay contributed to less care delivered to the patient (effectiveness), overuse, underuse and misuse of health services (efficiency), less focus on the patient instead of administrative obligations (patient-centeredness), a revolving door effect (safety), and frustration among staff (satisfaction). This was further exacerbated by a patient population with increasingly complex conditions (patient). The execution of the GFK framework in practice was impeded by the lack of inter-organisational infrastructure (health system context), which contributed to unnecessary incurrence of costs (efficiency), an increased likelihood of adverse events or medical mistakes (safety), and frustration among staff (satisfaction). These findings resonate with Kolb et al.'s evaluation of the GFK 10 years after its inception, from the perspectives of the German Federal Association of Geriatrics (BVG), the German Health Insurance Medical Service (MDK) and the National Association of Statutory Health Insurance Funds (GKV Spitzenverband) [32]. The authors also found evidence of a lacking inter-organisational structure, which was not in line with the overarching goals of comprehensive geriatric care, namely a transsectoral, interlinked, and therefore holistic approach to geriatric care. Moreover, they found the financial disincentives inherent to the GFK framework to have led to an increased focus by hospitals and financiers on the cut-off points for eligibility. On the one hand, they saw financial incentives for hospitals to keep patients for longer than 14 days to be eligible for the financially advantageous framework. But at the same time there were financial incentives for the financiers to dispute the necessity for ambulatory care for longer than 14 days so as to make hospitals ineligible for the framework, which is financial disadvantageous to the financiers. Kolb et al. also found that hospitals tended to limit their services to the minimum requirements stipulated in the framework. The authors criticised that there is currently no quality system to counter-balance this trend. Additionally, they raised doubts about whether the decision which and how much care is delivered to the geriatric patients was determined by their need or rather the wish by the hospital to optimise the reimbursements. This is in line with our finding that certain aspects of the GFK framework contribute to the over- and under-provision of health services to the patients and increased focus on administrative obligations at the expense of patient-centeredness.

Multidisciplinary cooperation (delivery system design) contributed to a better understanding of other health professionals' expertise (effectiveness), faster information exchange (efficiency), and appreciation by staff and patients (satisfaction). On the one hand, the execution of multidisciplinary cooperation in practice was impeded by the documentation system (innovation), high workload (organisational context), and administrative obligations (economic, legal and political context). These barriers contributed to less care provided to the patients (effectiveness), waste in workflows (efficiency), less focus on the patient instead of administrative considerations, less family member involvement (patient centeredness), and frustration among staff (satisfaction). On the other hand, multidisciplinary cooperation was facilitated by family member involvement (patient), informal cooperation structures (organisational context), and administrative obligations (economic, legal and political context). These positive context factors contributed to a better understanding of one's colleagues' expertise, continuity in care, more care provided to the patients (effectiveness), faster information exchange (efficiency), more focus on the patient instead of administrative considerations (patient-centeredness), improved transparency (safety), and appreciation by staff and patients (satisfaction). It is difficult to compare these findings to other studies on multidisciplinary cooperation

within integrated geriatric care interventions, as these are sparse, especially comprehensive qualitative ones. A review of multidisciplinary collaboration within the scope of collaborative care management models found mixed results for mortality, clinical, functional and social outcomes, utilisation of medical services, quality of life, activities in daily living and satisfaction with care. However, the authors concluded that relationships between teamwork and patient outcomes were difficult to assess with randomised controlled trials (RCT) [43]. A qualitative study on interdisciplinary team collaboration during discharge of depressed older persons identified the lack of effective team leadership, the need to change the delivery system, and enhancing self-management support including family member involvement as important context factors. However, the impact of these context factors on specific outcomes was not explicitly studied or discussed [44]. A qualitative study on integrated end of life care for people with advanced dementia did explicitly focus on the context, mechanisms and outcomes of the intervention, but used a different operationalisation of the concept. Their study underscored the importance of multidisciplinary cooperation in integrated care and the danger of weighing financial efficiency over person-centeredness [45].

Comprehensive geriatric assessments (decision support) contributed to a holistic instead of disease-focused view of the patient (patient-centeredness) and a decreased likelihood of adverse events or medical mistakes (safety). The achievement of the latter outcome was further enhanced by family member involvement (patient). As in the case of multidisciplinary cooperation, (qualitative) research on comprehensive geriatric assessments within the scope of integrated care interventions is still relatively sparse. A recent scoping review of interdisciplinary geriatric consultation teams in acute care hospitals found that the structure and processes of care provided by these teams were highly heterogeneous [46]. However, the relationship of these different intervention types to context factors or outcomes was not studied or discussed. A qualitative study on the facilitating and impeding factors to the implementation of geriatric assessment and decision support in residential care homes found positive opinions of staff and management, continuing support of staff and the availability of sufficient computer equipment to be necessary conditions for intervention adoption [47]. However, the study did not link the intervention itself and the context factors affecting its implementation to outcomes achieved, which again makes it difficult to compare findings. A systematic review of in-patient comprehensive geriatric assessments found positive outcomes, including an increased chance of patients living at home in the long term, especially for ward-based management units [48]. Another review of effectiveness of gerontologically informed nursing assessment and referral interventions for older persons in the emergency department reported mixed results for patient and health systems outcomes. Here, too, the authors stressed that testing of complex interventions in RCTs was inherently problematic [49].

We concluded that evidence of the self-management support component was largely absent at the geriatric hospital. A mixed methods study among older people with long-term conditions found self-management support to be associated with continued active participation and completion of a strength and balance intervention [50]. However, in their study among chronically ill older adults with complex medical needs, Gerber et al. cautioned that effective self-management support should be attuned to the older people's ability to self-manage, which may be hindered by factors such as depression, health literacy, or hearing impairments [51]. We found no clinical information system at the geriatric hospital.

In their 2003 study on medical informatics in geriatrics, Nebeker, Hurdle and Bair predicted that barriers to information exchange would decrease while the quality and relevance of exchanged information would increase [52]. Ten years after this prediction we would have to conclude that this may have been too optimistic, at least for the German healthcare sector in which barriers to (electronic) information exchange between organisations, providers and/or patients continue to abound [53-56]. At the time of writing, however, a new digital information system has been implemented at the geriatric hospital which would provide an interesting case for further investigation in light of these barriers as well as the findings of the current study. Finally, we did not find evidence of the use of community resources, but this could be due to the fact that no social workers were interviewed, i.e. the group responsible for discharge arrangements. In general, the use of community resources might be impeded by the difficult regulatory framework for cross-sectoral health care in Germany [56-59].

Appraisal of the CMO-based model

In this study, we explored the usefulness of our CMO-based approach for studying when and why an intervention “works”. Our analysis has shown how certain components of the intervention itself have contributed to negative or positive outcomes, and how in other cases, the execution of specific components of the intervention was facilitated or hindered by context factors exterior to the intervention. We believe that this approach indeed allows for more targeted improvements than only investigating whether certain outcomes have improved or not. First, because it allows for the finding of positive as well as negative results, even for the same category, rather than an aggregate estimate or net effect of the intervention. For example, we found more and less focus on patients instead of administrative obligations as outcomes for patient-centeredness, and more and less care provided to patients as outcomes for effectiveness. It is more useful to know both the negative and positive side of these outcomes, rather than knowing that overall, there is neither a significant positive or negative effect of the intervention. Second, our approach makes the reasons for the achievement of positive and negative outcomes visible. For example, it was shown that due to the high workload, the members of the multidisciplinary team did not have time to truly cooperate with each other, which prevented positive outcomes and contributed to negative ones. Knowing these intricacies is more useful for designing plans for improvement than having to conclude that the multidisciplinary approach did not lead to improved outcomes. A third advantage of our CMO-based approach is that the model helps to not only come up with a list of isolated barriers and facilitators, but instead, to consider their interplay with the mechanism and outcomes, e.g. with which aspects of the integrated care intervention do they interact, which do they impede or enhance, and to which outcomes does this lead. In doing so, our CMO-based approach has proven to be a valuable instrument for answering questions of when, why and how an intervention can contribute to positive outcomes.

Limitations

Our study is subject to several limitations which should be taken into consideration. First, our findings are based on a convenience sample which did not include patients or their family members, speech therapists and social workers, as well as other stakeholder groups from outside the multidisciplinary team, such as IT experts, hospital administrators or financiers. Including patients in our interviews would have given us the opportunity to evaluate the intervention directly from patients’ perspective

rather than relying on what the health professionals thought the patients' evaluation would be. Moreover, our findings show the involvement of family members as a facilitator for multidisciplinary cooperation as well as the lack of family member involvement as a negative consequence of multidisciplinary cooperation when it is not well-executed. The family members' perspective on how and to what extent they are (or wish to be) involved would provide valuable additional insights to our findings. The inclusion of social workers in our sample could have provided more insights into the use of community resources, or confirmed our impression that this component was largely absent from the integrated care intervention. Additionally, the inclusion of other professional stakeholders from outside the multidisciplinary team would have enabled us to analyse outside perspectives on salient topics such as the financing of the hospital, regulatory frameworks and personnel distribution. Second, the CMO-based model used in the collection, analysis and interpretation of data assumes that complex, intricate social phenomena and processes can be neatly categorised as either mechanisms, context factors or outcomes. Additionally, the model assumes a linearity and chronology of events that represents a simplification of reality which is not accurate. Instead, a certain factor might be an intervention component which acts as a barrier to the execution of other intervention components, and certain positive outcomes can act as facilitators to other intervention components. However, simplification can be a necessary and useful step when trying to understand the complexities of the real world and thereby making them manageable. Third, being based on the analysis of one case study, our findings are context-specific and cannot be transferred as is to other health systems, cultural backgrounds, care sectors or chronic conditions. However, some of the intervention components and context factors might be similar in other cases and given the detailed explanations of the setting provided here, we believe our results to hold much learning potential for other organisations currently implementing or planning to implement integrated care interventions for geriatric and other chronic conditions. This is especially relevant given the fact that many studies on integrated geriatric care stem from the Dutch context and insights from other settings are still relatively sparse [21-23].

Implications

The current study has identified the main components of an integrated geriatric care intervention at a German geriatric hospital. Moreover, it has traced the relationships between these components, various context factors and the positive and negative outcomes that were achieved. With regard to this specific case, we recommend for policy-makers to reconsider the financial disincentives of the funding system, with specific emphasis on how these can be curtailed or at least counter-balanced with appropriate quality assurance measures. In the meantime, we would recommend for managers and practitioners to explore context factors at the organisational, social context or individual professional level that could help to keep the negative consequences found in this study in check. In general, we recommend for academics as well as practitioners, managers and policy-makers involved in the evaluation of complex interventions such as integrated care to broaden their focus from merely trying to determine whether an intervention works or not. Given the heterogeneity in outcomes, we should try to understand how the different components of an intervention interact with context factors and, combined, lead to positive and/or negative outcomes. This in depth understanding of the complex and intricate interplay between mechanisms, context and outcomes is a necessary precondition for targeted improvements that can result in real benefits for real people.

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PART B

Workforce changes in integrated care interventions



CHAPTER 7

The development, description and appraisal of an emergent multimethod research design with multiphase combination timing

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The development, description and appraisal of an emergent multimethod research design with multiphase combination timing.

Abstract

In this paper, we provide a detailed and explicit description of the processes and decisions underlying and shaping the emergent multimethod research design of our study on workforce changes in integrated chronic care. The study was originally planned as mixed method research consisting of a preliminary literature review and quantitative check of these findings via a Delphi panel. However, when the findings of the literature review were not appropriate for quantitative confirmation, we chose to continue our qualitative exploration of the topic via qualitative questionnaires and secondary analysis of two best practice case reports. The resulting research design is schematically described as an emergent and interactive multimethod design with multiphase combination timing. In doing so, we provide other researchers with a set of theory- and experience-based options to develop their own multimethod research and provide an example for more detailed and structured reporting of emergent designs. We also argue that the terminology developed for the description of mixed methods designs should also be used for multimethod designs such as the one presented here.

Background

Health services research is increasingly concerned with the study of complex interventions that include multiple components, target multiple levels and contribute to multiple outcomes [1]. By combining more than one method of research within the same study, multimethod research is considered especially appropriate for the study of complex interventions [2-5]. Multimethod research designs may be the outcome of prescriptive planning (i.e. enacted) or an unfolding, evolutionary, pragmatic research process (i.e. emergent) [3]. The latter, more flexible approach, refers to designs whose detailed frameworks emerge during the study, depending on the data and the researchers' interpretation thereof [6]. A defining characteristic of emergent designs is that they are flexible by allowing for interaction between different strands of data at different points of time during the research [7]. For example, one can use the preliminary findings from one data collection as a basis for the next data collection or as a framework for its analysis.

The choice for an emergent design can be a conscious one at the outset of the research to let the data guide the next steps of the research [8], but it is also possible that the decision is necessitated at some point during the project at which the research is moving in a different way than originally anticipated [6, 9, 10]. In both cases it would be useful to learn which choices were made by researchers in particular situations and why, or which difficulties were encountered and how they were overcome. Unfortunately, detailed accounts of emergent research processes in scientific papers are rare. Instead, most readers have to contend with the simple notion that an emergent design was used and the presentation of the route that "worked" [9]. As a remedy, scholars have argued that there should be more focus on the actual research process, in particular on the actual integration of multiple methods, rather than the "reconstructed logic" of published designs and methods [11]. In order to better understand how and to what end multiple methods were integrated, Maxwell et al. have urged researchers to write about their experiences with integrated approaches and methods [11]. The first aim of this paper is therefore to provide a detailed and explicit description of the process and decisions underlying and shaping the emergent multimethod research design of our study of a complex intervention, namely integrated care for people with chronic conditions.

However, even when detailed descriptions are available, these tend to concern retrospective accounts of one specific research project as well as the problems encountered and solutions found for this specific context only [6, 8, 9, 12]. While this is certainly useful, it does not necessarily help other researchers challenged with similar problems in other settings. It would be more useful to characterise the research design as a specific type of multimethod design and thereby provide researchers with a more general set of theory- and experience-based options that can be followed throughout an emergent research process and labelled as such in its description [11]. Leeman et al. have added that graphic presentations of the approaches used are especially useful for multimethod research [1]. The second aim of this study is therefore to schematically display the interdependencies of the different data strands included in the design and thereby identify the type of multimethod design that was used.

In the following, the research topic for which this research design was developed is outlined. This is followed by a detailed description of the different steps of the data collection and analysis process and the decisions that shaped this process, including a reflective commentary [13]. Next, a graphic display of the research design is presented. We end with a discussion of the limitations, strengths and implications for further research.

Integrated chronic care as an example of a complex intervention

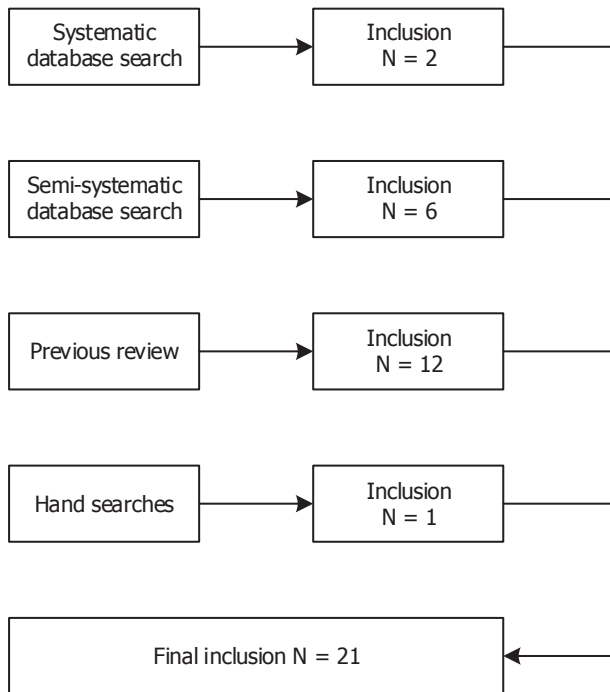
The demand for health care is on the rise and changing from acute, short-term care to chronic, long-term care [14, 15]. This is mainly due to population ageing, increased prevalence of lifestyle factors conducive to chronic disease and a change in the definition of illness to include also those at risk of disease [14-16]. Integrated care has been suggested as a means to approach these challenges and its delivery is a priority in many countries' efforts to improve health outcomes for people at risk of or with chronic illness [16-18]. Integrated care is an approach that seeks to improve the quality of care for patients with long-term illness by ensuring that services are well-coordinated around their needs [19]. Generally, integrated care concerns complex interventions which include changes to patient-provider relationships, care process designs, communication infrastructures and to how health professionals deliver care. Given health professionals' involvement in all aspects of integrated care, it is assumed that changes to the health workforce affect the implementation of integrated care profoundly. Our objective was to investigate (1) the workforce changes implemented as part of integrated care interventions for people with chronic conditions, (2) the barriers and facilitators to their implementation, as well as (3) their outcomes [20].

Initial data collection and analysis

In order to achieve this objective, we planned to conduct a systematic literature review followed by a Delphi panel. The purpose of the combination of the two methods was triangulation for the convergence and corroboration of findings [3]. First, the data collection for the literature review was to be conducted, followed by the data analysis and interpretation of results. Based on the literature review, we envisaged to find a list of workforce changes, several barriers and facilitators, and positive and/or negative outcomes of these workforce changes. We planned to use these findings as the basis for the data collection of the Delphi panel by using them as input for the items to be confirmed, rated or commented upon by the experts within the scope of the Delphi panel. The first step of the research was to design a literature review strategy and to conduct the database searches. We employed the following four-step approach for the literature search: (a) systematic database search; (b) semi-systematic database search; (c) secondary analysis of a previous literature review; and (d) unsystematic hand search. Three groups of search terms were used in the search, relating to chronic conditions, intervention type, and workforce. All articles were subjected to title, abstract and full text scans, performed individually by three researchers (LB, SC, LG) and then discussed together until consensus was reached. Figure 1 depicts the selection process of the four stages of the literature review. The final selection consisted of 21 studies. Initially, we only analysed the workforce changes that were found in the articles included in the literature review. A list of common workforce changes

was compiled from the literature by one researcher (LB) and checked independently by two researchers (SC, LG). The list was discussed and adapted until all researchers agreed that all workforce changes from the included studies were covered and there were no redundancies in the list.

Figure 1: Flowchart of the literature review selection process



Revision of the research plan

At this point of the research, we considered it necessary to re-evaluate the original research plan. As Figure 1 shows, only two studies were identified from the initial, systematic literature search. Adding additional steps made it possible to retrieve more articles and, eventually, to identify a set of workforce changes. But given the fact that most articles were retrieved through the unsystematic searches, it was not clear to what extent these findings could be generalised and whether they were complete. It was therefore decided that a quantitative validation of this list via a Delphi panel would not be a productive approach. Instead, we chose to continue our qualitative exploration of the topic, specifically by conducting a qualitative expert questionnaire and secondary analysis of two case reports of best practice integrated care implementation. The purpose of the combination of multiple methods changed from triangulation for convergence and corroboration to complementarity for elaboration and enhancement of findings [3].

Between January and April 2015, we administered a qualitative exploratory questionnaire to experts in the fields of integrated care, chronic care, and health human resource management. We included experts with academic or policy backgrounds as well as 'field experts' (i.e. health professionals or managers of organisations involved in the provision of integrated care). Experts were identified using the snowball method and had to be proficient in English or in one of the three languages in which translations of the English questionnaire were available (i.e. Dutch, Italian and Spanish). In total, the questionnaire was sent to 91 experts, of which 25 completed and returned the questionnaire, resulting in an overall response rate of 28%. Experts were asked to indicate which of the workforce changes from the literature review they recognised from their own experience and which were missing. Moreover, they were requested to describe an integrated care intervention, the workforce changes included in this integrated care intervention, the barriers and facilitators to the implementation of the workforce changes, and the outcomes of the workforce changes. Apart from the information from the literature review and expert questionnaires, we wanted to know whether the same or possibly more workforce changes, barriers, facilitators and outcomes could be found when looking in detail at several best practices of integrated care implementation. We had access to two detailed case reports that included information on a specific integrated care intervention including workforce changes and the barriers and facilitators to their implementation. The case reports were written as part of [Project blinded]. The data extraction of these reports was sent to the authors for their confirmation and feedback. All changes and comments provided were taken up in the analysis of the case reports. One of the case reports has been published elsewhere [Reference blinded].

We also decided that we would not complete the analysis for one data source and then move on to the next data source, and so on. Instead, we decided to perform the data analysis for each research objective separately, i.e. first for the workforce changes, second for the barriers and facilitators, and third for the outcomes. This choice was based on the decision to use the CMO Model (context + mechanisms = outcomes) as umbrella framework for our research. The CMO Model states that interventions only have successful outcomes when they introduce the appropriate mechanisms in the appropriate context. By focusing on the intervention (workforce changes), the implementation process (barriers and facilitators) as well as the outcomes, the CMO Model is especially appropriate to investigating complex interventions such as integrated care [21-23]. Following from this, it was necessary to study the elements of the CMO Model in coherence with each other.

Workforce changes

The data analysis of the workforce changes from the expert questionnaires was performed by four researchers (LB, KL, SC, LG). We used the list obtained from the literature review as initial coding list for the coding of the questionnaire workforce changes. The coding list could be expanded and adapted when necessary. For the case report workforce changes, a secondary analysis was performed in which the workforce changes described in the case reports were mapped against the coding list identified from the literature review described above. When the analyses of the workforce changes from the literature review, expert questionnaires and case reports were finalised, we compared the workforce changes that were reported in both case reports or among those mentioned by most studies and

experts as evidenced by their belonging to the three highest percentages per data source. This resulted in a list of seven workforce changes.

Barriers and facilitators

After the analysis and interpretation of the workforce changes was completed, we turned to the barriers and facilitators. We started by analysing the data on the expert questionnaire barriers and facilitators because these were found to be richer in volume and content than the data on barriers and facilitators collected through the literature review or available in the case reports. An open coding approach was used which meant that two researchers (LB, KL) independently created a coding list and then compared and consolidated the coding lists together. To build on the coding process conducted for the expert questionnaire barriers and facilitators, the data from the literature were coded based on the coding lists resulting from the expert questionnaire. When the data did not fit the categories of the coding lists, the list was adapted accordingly. The case report barriers and facilitators were coded using the adapted coding list from the expert questionnaire and literature review. Finally, we compared the barriers and facilitators that were reported in both case reports or among those mentioned by most studies and experts as evidenced by their belonging to the three highest percentages per data source. This resulted in six categories of facilitators and six categories of barriers to the implementation of workforce changes.

Outcomes

After the data collection, analysis and interpretation for the barriers and facilitators was completed, we turned to the outcomes of the workforce changes. We started by analysing the data from the expert questionnaires because the questionnaires already included a list of outcome categories which could be used as a basis for the coding list. Four researchers were involved in the data extraction and analysis (LB, KL, SC, LG). For the literature review outcomes, the data were coded based on the coding list resulting from the expert questionnaire. When the results from the literature review did not fit into the categories of this coding list, the list was adapted accordingly. The case report outcomes were coded using the adapted coding list from the expert questionnaire and literature review. As the case reports did not report outcomes of the interventions, this data strand was not included. Finally, we compared the outcomes that were among those mentioned by most experts or studies, as evidenced by their belonging to the three highest percentages per data source. Positive and negative outcomes were found for five different categories.

Transcending the particular

After the finalisation of these steps, we had collected, analysed and interpreted data from three different sources. In order to turn our own experience in a useful learning opportunity for ourselves and others, we decided to describe the research design that resulted from this process in a schematic way. In the following we present a graphic display of the research design including the sequencing and (in-)dependencies of the data strands as regards the collection, analysis and interpretation of data in the adapted research design. Figures 2-4 show how our emergent multimethod research design combined different data strands in an interactive manner with multiphase combination timing. By data strands we

refer to the processes of data collection, analysis and interpretation. Interactive designs are characterised by direct interaction between the different data strands, for example when the results of one data collection are used as basis for another data collection. Multiphase combination timing combines concurrent timing (when the data strands are carried out during a single phase of the study) and sequential timing (when the data strands are carried out in two distinct phases, and one strand is carried out after the other) [7]. Figure 2 concerns the workforce changes, Figure 3 the barriers and facilitators and Figure 4 the outcomes.

Figure 2: Adapted research design: workforce changes

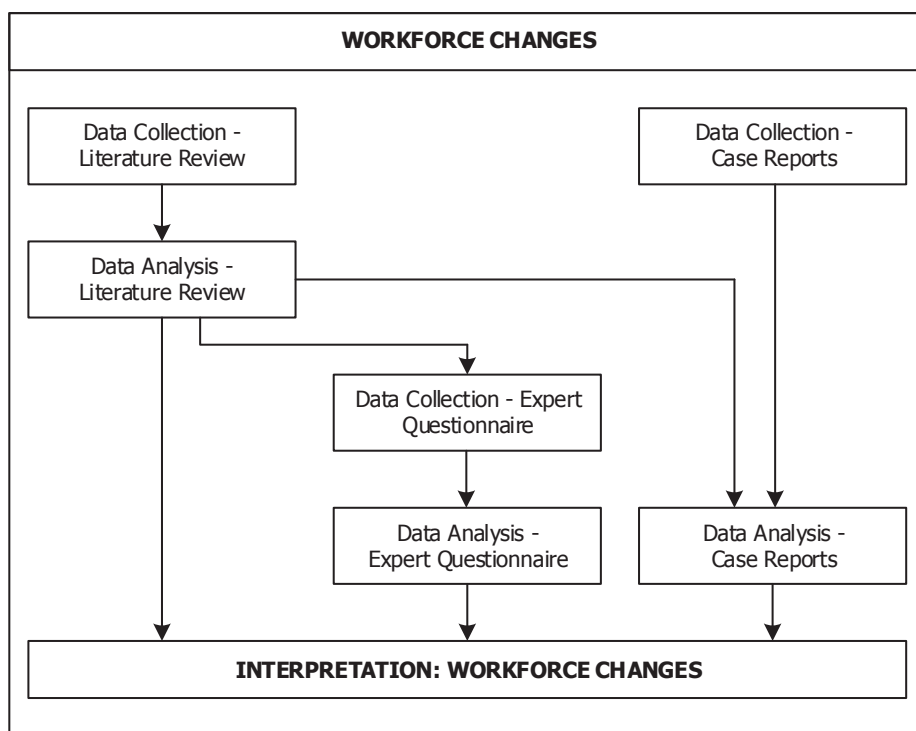
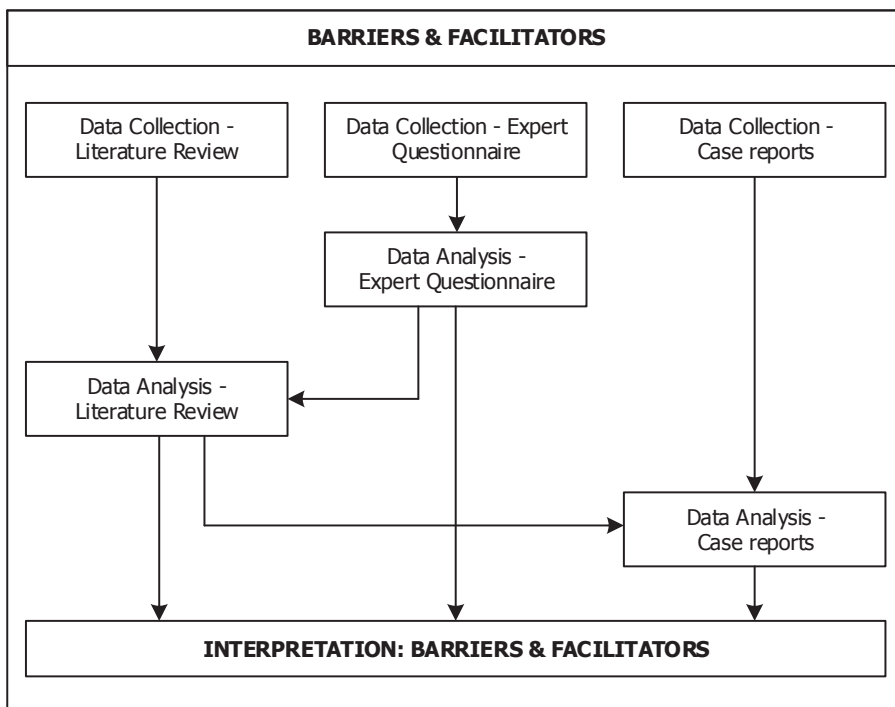


Figure 2 describes the data collection and analysis to identify workforce changes by means of a literature review, expert questionnaires and case reports. Here, the data collection for the expert questionnaire was dependent on and sequential to the data collection and analysis of the literature review, because the list of workforce changes from the literature review was incorporated into the data collection for the expert questionnaire by asking experts to confirm and/or complete the list workforce changes. The data analysis of the workforce changes for the expert questionnaire and the secondary analysis of the case reports were both dependent on and sequential to the data collection and analysis of the literature review, because the results from the literature review were also used for data analysis of the expert questionnaires by serving as coding list to analyse and categorise the experts' descriptions of the workforce changes in the integrated care interventions. The same holds true for the secondary

analysis of the case reports, where the list from the literature review also served as a coding list for the workforce changes described in the case reports. However, the data collection for the case reports was carried out concurrently and independently of the data collection and analysis for the literature review. The results from all three data strands were combined in the end at the stage of interpretation.

Figure 3 describes the data collection and analysis for the barriers and facilitators to the implementation of workforce changes. Here, the data collection for the literature review, expert questionnaires and case reports were carried out concurrently and independently of each other. It might seem contradictory that Figure 2 seems to show the data collection for the expert questionnaire to have taken place after the data collection for the case reports, while Figure 3 seems to show all data collections to have taken place at the same time. However, this would be a misunderstanding of the difference between the actual timing of a specific activity (i.e. the day/month/year it was carried out) and the sequencing of a specific activity (i.e. whether it was carried out independently or dependently of a previous activity).

Figure 3: Adapted research design: barriers & facilitators

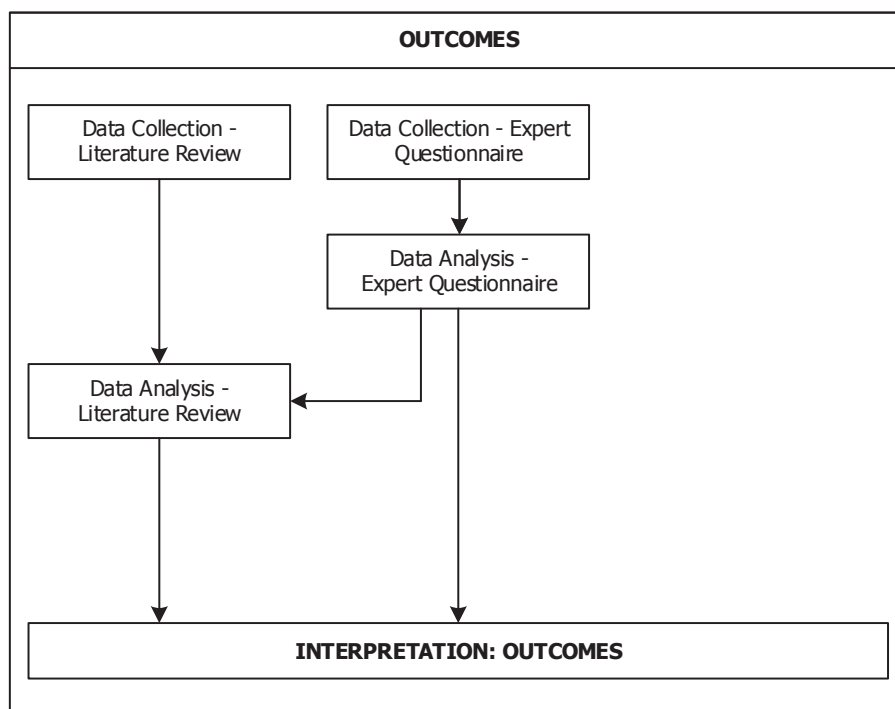


To use a specific example, the data collection for the literature review was carried out in August/September 2014 and the data collection for the expert questionnaire between January and April 2015. In the case of the workforce changes, the actual timing is relevant because the data collection for the expert questionnaire was dependent on the data collection and analysis of the literature review, which means that the data collection for the expert questionnaire had to take place after the data

collection and analysis of the literature review. However, even though the timing is relevant, it should be noted that Figure 2 (as do Figures 3 and 4) shows the sequencing of the activities, i.e. the fact that the data collection for the expert questionnaire was sequential to the data collection and analysis for the literature review. As regards the barriers and facilitators, the timing of the data collection for the literature and expert questionnaire is not relevant because the two activities were carried out independently of each other. This means that it does not matter that the actual timing of the data collection was approximately half a year apart, because the data collection activities were carried out concurrently.

Figure 4 describes the data collection and analysis for the outcomes of workforce changes. Again, the data collection for the literature review, expert questionnaires and case reports were carried out concurrently and independently of each other. As a next step, the data analysis for the expert questionnaires was carried out by using a coding list based on the specific answer categories used in the questionnaire. This coding list was used for and adapted based on the coding of outcomes from the literature review. As in the two previous cases, the results from the two data strands were combined at the final stage of interpretation.

Figure 4: Adapted research design: outcomes



Discussion and appraisal

This paper described the development of an emergent and interactive multimethod design with multiphase combination timing to investigate the workforce changes implemented as part of integrated care interventions for people with chronic conditions, the barriers and facilitators to their implementation, as well as their outcomes. The original research plan foresaw an initial investigation of the workforce changes, their barriers and facilitators, and their outcomes as described in the international scientific literature. We planned to confirm these findings quantitatively via a Delphi panel among an international group of experts in the field of integrated chronic care and health human resource management. However, when the systematic literature review yielded only a very small number of studies, we decided to continue the qualitative exploration of the topic instead of aiming for a quantitative confirmation of first results, whose generalisability and completeness were in doubt. Consequently, the Delphi study was replaced by a qualitative expert questionnaire and two qualitative case reports of best practice examples of integrated care implementation.

Glavare, Löfgren and Schult [24] describe an emergent design used in a qualitative study on the experience of unemployed long-term pain sufferers. As they only used one method of data collection (interviews), the emergent nature of their design lay in the use of preliminary topics resulting from the coding of early interviews for the adaptation of the topic list used in later interviews. Other studies describe similar uses of emergent designs within the framework of one method of data collection [25-27]. In their study on the management of spinal cord injury neuropathic pain, Norrbrink & Löfgren [28] used an emergent design that started with focus groups among patients. When the preliminary findings from these focus groups indicated the need to involve the health care perspective, individual interviews were conducted with physicians. The interview guide for these interviews was based on the first results of the focus group analysis, which were also used for the analysis of the physician interviews. This process is similar to the interaction between data collection and analysis that we described for the analysis of workforce changes in the literature review that was used in the data collection for the expert questionnaires as well as for the analysis of workforce changes from the expert questionnaires and case studies. Apart from these examples, little has been published in scientific journals on the topic of emergent designs. As mentioned earlier, those studies that do employ emergent designs tend to offer only very limited descriptions or else detailed descriptions that only apply to their own specific circumstances.

While we deemed a change of plans necessary in our particular situation, this was not without drawbacks, the main one being that we were not able to perform a quantitative analysis of our qualitative findings. Ideally, we would have wanted to perform more qualitative research first, and then return to the original plan of quantitative conformation of the qualitative results. However, conducting qualitative research is time-consuming and adding not one but two additional qualitative elements to our design meant that this was really an either-or-decision instead of an add-on to the original plan, at least within the scope of this particular project. Given this limitation, we recommend further quantitative exploration of our research findings for future research, for which we believe our qualitative research provides a much stronger basis than the original research design would have allowed. A second

disadvantage of the adapted research design is related to the decision to focus on the three research objectives (workforce changes, barriers and facilitators, and outcomes) separately. Given this specific set-up, we were able to collect, analyse and interpret data for each research objective separately, but not in combination. This means that while the research design allowed us to gain insights on the different types of workforce changes, the barriers and facilitators, and outcomes separately, it does not allow us to find out which types of workforce changes are generally encountered by which barriers and facilitators or related to which positive or negative outcomes, which would be valuable information for practitioners and policy-makers in the field of integrated care. However, this type of detailed information might not be a realistic goal for an exploratory study as described here. Instead, we are confident that our findings will provide detailed and evidence-based input for more detailed quantitative and qualitative investigations of the relationships between the workforce changes, the barriers and facilitators to their implementation, as well as the outcomes achieved. This could be done in combination with further quantitative exploration of our findings.

Despite these drawbacks, there were also several important advantages resulting from the change of research design. One of the main advantages is the fact that it allowed us to make use of the data gathered via the literature review, which contributes to the study's information-richness [29]. As explained earlier, when the initial systematic search only led to the inclusion of two studies, we added unsystematic steps which resulted in the inclusion of 19 additional studies which held rich and relevant results for our research questions. However, since these results were for the largest part not based on a systematic search, it was impossible to know to what extent the findings are complete or whether they only paint a partial picture. Confirming this potentially partial picture quantitatively did not seem like a worthwhile option. Of course, this did not mean that the review findings said nothing; it just meant that we did not know whether they said enough. Switching to a different multimethod approach allowed us to still make use of the information we had from the literature review by using it as input for further data collection, as coding lists for data analysis and point of reference for the interpretation of overall results. As Daly et al. [30] point out, literature reviews are generally the starting point for more complex and more advanced studies.

This relates to a second strength of the new study design: its flexibility. Switching from a fixed design to a flexible one allowed us to combine different data strands at different points of time during data collection and analysis. As Archibald et al. pointed out in their review of current mixed methods practices in qualitative research, 98% of the studies they reviewed mixed data at the interpretation stage only [31]. In our study, however, we combined different methods during all stages of the research, which made it possible to build upon and triangulate insights gained from earlier data strands and further explore concepts that became apparent during early data collection and analysis phases. The combination of different methods remedies their respective limitations while at the same time enhancing their respective advantages and thereby contribute to the credibility of the study [3, 13, 32]. Additionally, this triangulation improved the confirmability of our study by limiting investigator bias inherent to qualitative research [13, 32]. Furthermore, our study design combines in depth data from the case reports with a broad scope of data from the literature review and expert questionnaire. It also includes very local data from the case reports with regional and national data from the literature review,

while the expert questionnaires provided local, regional and national data. Including data from different environments contributes to the transferability of study findings to other settings [13].

The most compelling argument in favour of the adapted research design presented here is the fact that it allowed us to still achieve our research objectives. We were able to identify seven types of workforce changes implemented as part of integrated care interventions for people with chronic conditions, 17 categories of barriers and facilitators to the implementation of workforce changes, as well as five categories of negative and positive outcomes. We are convinced that this would not have been possible by staying with the original research plan. Furthermore, we were able to retrospectively describe the multimethod design that emerged over the course of the research in a schematic way and label it as an emergent and interactive research design with multiphase combination timing. In doing so, we transcend the particulars of our own study and make our strategies and options accessible for future projects by other researchers. To use Shenton et al.'s [13] words, we created a "prototype model" of a research design which allows for theoretical or actual repetition of our work and which thereby contributes to the dependability of our study.

The terminology used to label the different parts and processes of the emergent design in this paper was originally developed for, and is currently used to describe, mixed methods research, that is, the combination of quantitative and qualitative methods [7, 33, 34]. However, we recommend that this terminology – and the ideas and concepts it describes – should be used for any design that combines different data strands, whether they be quantitative, qualitative or a mix of both. The common denominator is that one has to be clear and specific about the choices that were made in the combination of these data strands, at which points they took place and what consequences they had for the overall research objective. Because, as Fossey et al. [29] explain, this "enables the reader to understand the intentions of the study and evaluate the congruence (fit) between these intentions and subsequent choices". By providing detailed insights into the processes and decisions regarding the collection, analyses and interpretation of data, including both the road that did and did not work, this paper contributes to increased transparency and transferability of methods to be used in complex study designs. By outlining and labelling the options available in the course of an emergent design, we expect our account to be of assistance to researchers planning or presently conducting multimethod research. We also hope that our account can act as an example for a more detailed and structured reporting of emergent research designs.

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CHAPTER 8

Exploration of workforce changes in integrated chronic care: findings from an interactive and emergent research design

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Exploration of workforce changes in integrated chronic care:
findings from an interactive and emergent research design.

Abstract

Background: Integrated care interventions applied in response to the increased demand for long-term care entail profound changes to the health workforce. This exploratory study aims to provide an overview of the workforce changes implemented as part of integrated chronic care interventions.

Methods: An interactive and emergent research design was used consisting of a literature review, qualitative expert questionnaires and case reports. We defined integrated care as interventions targeting at least two of the six Chronic Care Model components (i.e. health system, self-management support, delivery system design, decision support, clinical information system and community). Workforce changes were defined as those changes experienced by clinical and non-clinical staff responsible for public and individual health intervention.

Results: Seven workforce changes were identified: (1) nurse involvement in the delivery of care; (2) multidisciplinary staff including health professionals from different disciplines; (3) multidisciplinary protocols/pathways involving tasks for health professionals from different disciplines; (4) provider training such as on-the-job training or educational seminars or materials for health professionals; (5) involvement of a case manager/care coordinator role in the delivery of care; (6) regular team meetings to discuss a patient's treatment; and (7) the creation of a new position, role or function specifically to deliver integrated chronic care. Most interventions contained more than one of these workforce changes.

Conclusions: The results of this study provide detailed insights into the current implementation of workforce changes in integrated care interventions and thereby pave the way for further investigations into the relative effectiveness of different workforce changes within the scope of complex interventions. Moreover, our findings can serve as a menu of potential workforce changes to pick from for health systems planning to implement integrated care. Advancing knowledge in this area is essential for fostering health systems' capacity to cope with the challenges related to the current demographic and epidemiological trends.

Background

Integrated care is a means to deliver high quality long-term care to people with chronic conditions [1, 2]. It concerns complex interventions including changes to the health system, use of community resources, patient-provider relationships, care process design, communication infrastructures and to how health professionals deliver care [3-5]. As the demand for health care is on the rise and changing from acute, short-term to chronic, long-term care [6, 7], the implementation of integrated care has become a priority in various countries. Given health professionals' involvement in all aspects of integrated care delivery, changes to the health workforce affect the implementation of integrated care profoundly. Bodenheimer and Sinsky even propose to include the health workforce in the Quadruple Aim, which is an extension of the traditional Triple Aim focusing on enhancing patient experience, improving population health, and reducing costs [8]. Given the symbiotic relationship between providers and recipients of health care, it can be argued that the workforce is a prerequisite for improving patient outcomes [8, 9].

Previous studies on the health workforce have investigated health workforce planning [10, 11], assessed present and future health workforce needs [12], and predicted trends for specific sectors or groups of health professionals [13, 14]. Other studies have investigated specific types of changes for the health workforce such as skill mix or team work [15, 16]. However, none of these studies were conducted specifically on integrated care interventions for chronic diseases. This is problematic for two reasons. First, chronic care with its focus on long-term management of illness differs considerably from acute care with its focus on episodic treatment of illness. Second, when workforce changes are not implemented as single interventions, but as part of integrated care interventions, they are implemented in combination with changes targeting the other areas of integrated care delivery described above.

Studying workforce changes as part of complex, multifaceted interventions requires the use of study designs that can capture this complexity. Because of their multifaceted nature, complex interventions must be studied from different angles, which requires the use of different data sources. However, the data collection and analysis from each of these sources might develop in unforeseen ways and their combination may therefore require changes to the research design throughout the different stages of its execution (L. Busetto, K.G. Lujkx, S. Calciolari, L.G. González Ortiz, H.J.M. Vrijhoef, unpublished). These changes can be accommodated most appropriately within the scope of a flexible and emergent design, that is, a design that evolves throughout its different stages and allows for the interaction between different strands of data at different points of time during the research [17]. This makes it possible to use preliminary findings from one data source as a basis for the subsequent data collection or as a framework for data analysis or interpretation.

As a contribution to the field of integrated chronic care, the aim of the current exploratory study is to provide an overview specifically of those workforce changes that have been implemented as part of integrated care interventions for people with chronic diseases. Within the scope of a flexible and emergent research design, data were collected from a literature review, expert questionnaires and case reports. This study is part of Project INTEGRATE "Benchmarking Integrated Care in Chronic and Age-

related Conditions in Europe”, financed by the European Commission (project reference 305821). Within the scope of this project, we also investigated the barriers, facilitators and outcomes of the workforce changes implemented as part of integrated care interventions. These findings are reported elsewhere [18].

Methods

This study employed an emergent and interactive research design that included a literature review, empirical research via a qualitative expert questionnaire, and secondary analysis of two case reports. The research design has been described in detail elsewhere (L. Busetto, K.G. Luijkx, S. Calciolari, L.G. González Ortiz, H.J.M. Vrijhoef, unpublished).

Definitions

In line with previous research, we defined integrated care as interventions targeting at least two of the six Chronic Care Model (CCM) components (i.e. health system, self-management support, delivery system design, decision support, clinical information system and community) [4, 5, 19]. (Health) workforce changes were defined as those changes experienced by clinical and non-clinical staff responsible for public and individual health intervention [20].

Data collection and analysis

Dutch law does not require ethical approval for data collection among health professionals and experts.

Literature Review

Between July and October 2014, a literature search was conducted using a four-step approach including a (1) systematic database search, (2) semi-systematic database search, (3) secondary analysis of a previous literature review, and (4) unsystematic hand searches. The systematic literature search was performed in PubMed/Medline, CINAHL, Science Direct, and Business Source Premiere. Three groups of search terms relating to chronic diseases, intervention type, and workforce were combined. Three selection rounds based on title, abstract and full text were performed individually by three researchers (LB, SC, LG) and then discussed together until consensus was reached. Articles were included when they focused on the health workforce, integrated care and chronic diseases/care and were published after 2000, given the increased focus on integrated care over the past 15 years [2]. Articles were excluded when they were published in a language other than English, Dutch, German, Italian or Spanish, were conducted in a developing country or concerned non-empirical research. Systematic reviews and meta-analyses were excluded because experience with a previous review showed that the majority of reviews and meta-analyses based their findings on interventions that did not (all) fit our definition of integrated care.

The initial, limited output of the systematic database search was reported to the scientific committee of Project INTEGRATE, consisting of senior researchers from eight different European countries, who provided us with another set of health workforce related search terms. These search terms were combined in the previously used search string with the integrated care and chronic care related search

terms and the search was repeated in PubMed, CINAHL and ScienceDirect. We did not conduct an additional search in Business Source Premier because of the very low number of relevant articles resulting from the initial search. The results of the search were assessed in a semi-systematic way based on the in- and exclusion criteria described earlier. As a third step, we re-assessed a previous literature review on integrated care for type 2 diabetes that followed a similar approach to the current review [21]. All articles included in the previous review focused on integrated care and a chronic disease. Articles were checked for a focus on health workforce changes and were included if applicable. Finally, all researchers conducted unsystematic hand searches of the reference lists of articles obtained from the previous search steps and via Google. Articles suggested for inclusion were assessed and discussed by three researchers (LB, SC, LG) until consensus was reached.

The data extraction was performed between September 2014 and October 2014 independently by two researchers and then compared in pairs (LB and SC, LB and LG, SC and LG). A list of common workforce changes was compiled by one researcher (LB) and checked independently by two researchers (SC, LG). The list was discussed and adapted until all researchers agreed that all workforce changes from the included studies were covered and there were no redundancies in the list. It was not possible to provide comprehensive definitions of the workforce changes based on the limited information available in the studies. Instead, we provided a succinct description for each type of workforce change in order to ensure a uniform understanding and application of the respective concepts.

Expert questionnaires

Between January and April 2015, a qualitative exploratory questionnaire was sent to experts on integrated care, chronic care, and health human resource management. Respondents were recruited using the snowball method, including experts with academic or policy backgrounds as well as field experts (i.e. health professionals or managers of organisations involved in the provision of integrated care). Experts had to be proficient in one of the languages in which the questionnaire was available (i.e. English, Dutch, Italian and Spanish). Experts were asked to describe an integrated care intervention and the workforce changes included in this intervention. These descriptions were mapped by the authors to the 11 workforce changes coded in the literature review. In a separate question, the experts were requested to indicate which of the workforce changes from the literature review they recognised from their own experience. The English questionnaire was translated to three target languages (Dutch, Italian, and Spanish) according to the languages in which at least one of the authors of this article is a native speaker. Based on a feasible adaption of recommendations provided in the relevant scientific literature [22-25], we opted for the following pragmatic multi-step approach: (1) original English questionnaire checked by a native speaker of English; (2) forward translations by native speakers of the target language; (3) back translations to English by a researcher proficient in English; and (4) discussion of English versions (original and back translation). The translation of "workforce changes" was a problematic issue because no precise or unambiguous translation could be agreed upon in Dutch, Spanish, and Italian. Eventually, the researchers agreed on using the best available approximate translation and adding several examples of workforce changes to further clarify the concept. These examples were the same in all translations. The coding was performed by four researchers (LB, KL, SC, LG). The list obtained from the literature review was used as initial coding list for the coding of the

workforce changes. The coding list was expanded and adapted when necessary after discussion among the coders.

Case reports

Two detailed reports of case studies conducted from September 2012 to March 2014 as part of Project INTEGRATE, were available for secondary analysis. The first case report described the implementation of integrated care for geriatric conditions at a German geriatric hospital [26]. This hospital consists of five wards, each organised in independent multidisciplinary teams consisting of doctors, physiotherapists, occupational therapists, nurses and neuropsychologists [26]. A scientific paper based on this report is to be submitted for publication elsewhere (L. Busetto, J. Kiselev, K.G. Luijkx, E. Steinhagen-Thiessen, H.J.M. Vrijhoef, unpublished). The second case report concerned the implementation of integrated care for type 2 diabetes mellitus by two Dutch care groups. Care groups are legal entities that establish contracts with health insurers and health professionals in order to coordinate the so-called 'care chain' of chronic care from diagnosis to after care [27]. A scientific paper based on the detailed report was published elsewhere [28]. The workforce changes described in the case reports were mapped by one researcher (LB) to the coding list identified from the literature review described above. The data extraction and the mapping of workforce changes were sent to the authors of the German case report for feedback. Changes and comments were taken up in the analysis of the case reports. This check was not performed for the Dutch case since the authors of the Dutch case are also the authors of the current study.

Results

General Information

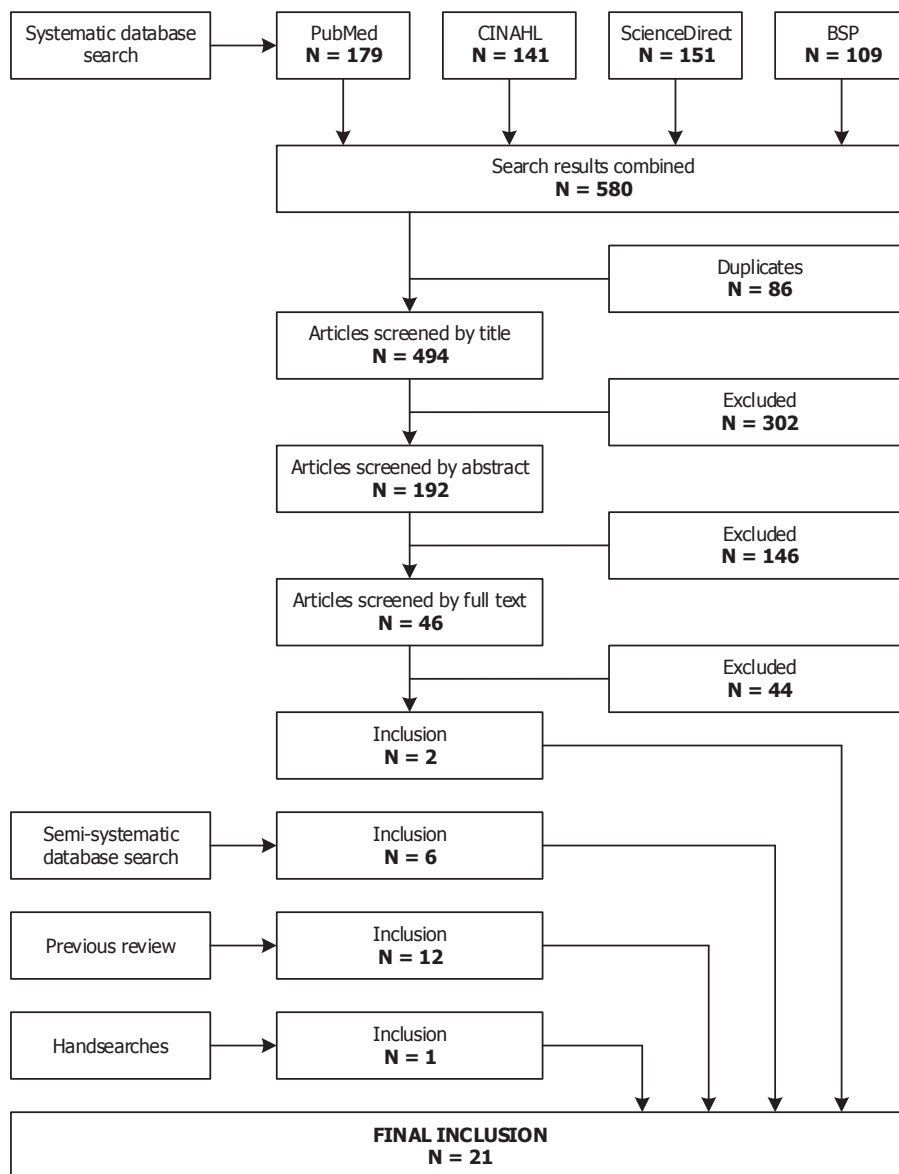
Literature review

Figure 1 depicts the selection process of the four phases of the literature review. The final selection consisted of 21 studies. The interventions described in the studies were implemented in seven countries, including the United States (N=10), the Netherlands (N=4), the United Kingdom (N=2), Canada (N=2), Belgium (N=1), Austria (N=1), and Germany (N=1). Interventions were implemented for patients with diabetes (N=16), patients with chronic diseases (N=3), older patients with dementia and/or depression (N=1), and patients with rheumatoid arthritis (N=1).

Expert questionnaires

The questionnaire was sent to 91 experts, of which 25 completed and returned the questionnaire, resulting in an overall response rate of 28%. The interventions described by the respondents were implemented in 12 different countries, including Belgium (N=8), Spain (N=5), Estonia (N=2), Italy (N=2), the Netherlands (N=2), the United Kingdom (N=2), Australia (N=1), Czech Republic (N=1), Germany (N=1), Greece (N=1), Norway (N=1), and Switzerland (N=1). Most often, interventions were implemented for patients with any type of chronic/long-term illnesses (N=5), patients with diabetes (N=5), COPD patients (N=4), people with cardiovascular disease (N=2), and all patients (N=2).

Figure 1: Flowchart of the literature review selection process



Workforce changes

Literature review

The following eleven workforce changes were identified from the included articles:

- *Nurse-led care/nurse as main care provider*: a nurse is the main care provider for the patient and/or the team is led by the nurse;
- *Multidisciplinary protocols/pathways*: care is delivered according to protocols or pathways that involve tasks for health professionals from different disciplines or with different medical specialties;
- *Multidisciplinary staff*: care is delivered by a team that includes health professionals from different disciplines or with different medical specialties;
- *Nurse involvement*: a nurse is involved in the delivery of care;
- *Pharmacist involvement*: a pharmacist is involved in the delivery of care;
- *Team meetings*: a care team that works around a patient or group of patients meets on a regular basis to discuss the patients' treatment;
- *Case manager/care coordinator*: a case manager or care coordinator or someone assuming a similar role is involved in the delivery of care;
- *Provider training*: on-the-job training or educational seminars or materials are provided to health professionals;
- *New position*: a new position, role or function is created specifically to deliver integrated chronic care;
- *Task re-distribution*: the tasks of health professionals involved in the delivery of care are re-distributed;
- *Shared medical appointments*: consultations are delivered by different health professionals during the same appointment.

Table 1 (Appendix) shows an overview of the workforce changes described in the respective studies. A mean number of 2.81 workforce changes was described per study ($M=2.81$; $SD=1.17$). In two studies, only one workforce change was included. Nurse involvement is the workforce change described most frequently in the literature ($N=19$; 91%), followed by multidisciplinary staff ($N=11$; 52%). They are also often implemented in combination ($N=10$; 48%). Nurse-led care/nurse as main care provider was always described together with nurse involvement, but not the other way around, which means that not all nurses involved had a leading role. Team meetings were mentioned only once, even though multidisciplinary staff and protocols were mentioned much more frequently (11 and six times, respectively). Multidisciplinary staff and protocols/pathways were described together five times, but no study mentioned these two changes and team meetings together. Both times the introduction of a new position was described, task-redistribution was described as well. Case managers/care coordinators were only once described in combination with the introduction of a new position, and also only once in combination with task-redistribution. This suggests that the other four times case managers/care coordinators were described, other workforce changes were insufficiently described, because, logically, either the introduction of a new position or the re-distribution of tasks must have taken place along with

the introduction of a care manager/care coordinator role, but neither was described explicitly in those studies.

Expert questionnaires

Table 2 (Appendix) shows which workforce changes were described by the respondents (the numbers in the second row indicate the 25 experts). The experts described interventions with a mean number of 1.72 workforce changes per intervention ($M=1.72$; $SD=0.84$). This is lower than the number of workforce changes per integrated care interventions described in the studies. Multidisciplinary staff ($N=11$; 44%), provider training ($N=8$; 32%), multidisciplinary protocols/pathways ($N=5$; 20%), and creation of a new position ($N=5$; 20%) were described most often by the respondents. In addition to the workforce changes presented in Table 2, seven respondents described other approaches, tools and guidelines to support the delivery of care that did not fit a common category. Again, nurse-led care/nurse as main care provider was always described together with nurse involvement, but not the other way around. And again, team meetings were mentioned only once, even though multidisciplinary staff and protocols were mentioned much more frequently (11 and five times, respectively). Multidisciplinary staff and protocols/pathways were described together less frequently than in the studies (only twice), and again, no study mentioned these two changes and team meetings together. Of the four times case managers/care coordinators were described, they were described only once in combination with the creation of a new position and never in combination with task-redistribution, again suggesting an under-reporting of workforce changes. Provider education was described more often by the experts (32%) than in the studies (10%). Shared medical appointments were described only once in the studies, but not at all by the experts.

As previously mentioned, the respondents were also presented with the 11 workforce changes identified in the literature review and asked which of these changes they recognised from their own expertise or experience. Table 3 (Appendix) shows which workforce changes were confirmed by the experts (the numbers in the second row indicate the 25 experts). The experts confirmed a mean number of 6.36 workforce changes per expert ($M=6.36$; $SD=3.17$). The average number of workforce changes confirmed per expert is much higher than those described per study or expert because in the former case the experts were asked about all workforce changes they were familiar with in general, while in the latter case workforce changes were described per intervention. Multidisciplinary protocols/pathways were confirmed by most experts ($N=21$; 84%), followed by team meetings ($N=20$; 80%), multidisciplinary staff ($N=19$; 76%), and nurse involvement ($N=19$; 76%). Again, nurse involvement was confirmed more often than nurse-led care/nurse as main care provider. Shared medical appointments and team meetings which were described in the studies and by the experts only zero or one time, were now confirmed ten and 20 times, respectively. There were three experts who confirmed all 11 workforce changes. Two experts recognized all workforce changes except for provider education and pharmacist involvement, respectively. Respondent 16 did not confirm any of the workforce changes, despite having described two workforce changes in response to the first question (see Table 2).

Case reports

A secondary analysis was performed for the German and Dutch case reports described above. The workforce changes in the integrated care interventions described in the reports case were mapped to the list of 11 workforce changes from the literature review. Table 4 shows which case studies incorporated which of the workforce changes identified in the literature review. Multidisciplinary staff and nurse involvement were present at both case sites (N=2; 100%). The Dutch case report mentioned nurse-led care/nurse as main care provider, multidisciplinary protocols/pathways, case managers/care coordinators, provider training, new position and task-redistribution (N=1; 50%). The German case report mentioned team meetings (N=1; 50%). Shared medical appointments were present in neither of the cases (N=0; 0%). Pharmacist involvement was planned in the Netherlands but had not yet been implemented at the time the case study was conducted.

Table 4: Overview of workforce changes per case report and number and percentage of case reports mentioning the respective changes

Workforce changes	Case reports			
	Germany	Netherlands	n	%
Nurse-led care/main care provider		x	1	50
Multidisciplinary protocols/pathways		x	1	50
Multidisciplinary staff	x	x	2	100
Nurse involvement	x	x	2	100
Pharmacist Involvement			0	0
Team meetings	x		1	50
Case managers/care coordinators		x	1	50
Provider training		x	1	50
New position		x	1	50
Task re-distribution		x	1	50
Shared medical appointments			0	0

Notes: X indicates that the workforce change was present in the respective case report. Empty cells indicate that the workforce change was not present in the respective report. Abbreviations: n = number of case reports, % = percentage of case reports.

Synthesis

We compared the workforce changes that were among those mentioned by most studies, experts or cases. For the literature review and expert questionnaires, this was evidenced by their belonging to the three highest percentages per data source. Given the low number of case reports and consequent distribution of percentages, we only included those workforce changes that were present in both case reports. Table 5 presents an overview of the workforce changes that were among those mentioned by most studies, experts or cases. Nurse involvement and multidisciplinary staff were mentioned in both case reports and among the highest percentages in the literature review and expert questionnaires. Multidisciplinary protocols/pathways were among the highest three percentages in the literature review and expert questionnaire (both described and confirmed). Provider training, case

managers/coordinators, team meetings and new position were among the three highest percentages in either the literature review or the expert questionnaires.

Table 5: Overview of the workforce changes among the highest three percentages in the literature review or expert questionnaires, or present in both case reports

Workforce changes	Literature Review	Case Reports	Expert Questionnaire Description	Expert Questionnaire Confirmation
Nurse involvement	91%	100%	20%	76%
Multidisciplinary staff	52%	100%	44%	76%
Multidisciplinary protocols/pathways	29%	50%	20%	84%
Provider training	10%	50%	32%	60%
Case managers/care coordinators	29%	50%	16%	56%
Team meetings	5%	50%	4%	80%
New position	10%	50%	20%	40%

Notes: Percentages in bold print indicate that the respective workforce change was among the highest three percentages in the literature review or expert questionnaires, or present in both case reports. Percentages in normal print indicate that the respective workforce change was present in both case reports or among the three highest percentages in one of the other data sources.

After combining the results from the three different data sources, we arrive at a list of seven workforce changes that were among those mentioned by most studies, experts or cases:

- Nurse involvement;
- Multidisciplinary staff;
- Multidisciplinary protocols/pathways;
- Provider training;
- Case manager/care coordinator;
- Team meetings;
- New position.

Discussion

The aim of this study was to provide an overview of the workforce changes implemented as part of integrated care interventions for people with chronic diseases. To this purpose, three methods of data collection were combined, namely a literature review, expert questionnaires and case reports.

This study identified seven workforce changes that were implemented as part of integrated care interventions for people with chronic diseases. These included (1) nurse involvement in the delivery of care; (2) multidisciplinary staff including health professionals from different disciplines; (3)

multidisciplinary protocols/pathways involving tasks for health professionals from different disciplines; (4) provider training such as on-the-job training or educational seminars or materials for health professionals; (5) involvement of a case manager/care coordinator role in the delivery of care; (6) regular team meetings to discuss a patient's treatment; and (7) the creation of a new position, role or function specifically to deliver integrated chronic care. In practice, these workforce changes are often related to one another and implemented in combination.

Two related changes, namely team care and role change, were also identified by a recent literature review to construct a typology of workforce models used by primary care practices [29]. The authors concluded that primary care, where integrated care often takes place, would have to be team care and that workforce innovation required new human resources. The creation of new roles was also identified by a recent study on effective workforce practice in integrated health care as well as a scoping study by the British National Health Service (NHS) on best practices for integrated care for older adults [30, 31]. A global shift towards team care was also found by an international expert consultation involving experts from the United States, Canada, Australia, England, Germany and the Netherlands [32]. The same study found nurses to be the main non-physician health professionals working along doctors in primary care. Provider education was described as a facilitator in a systematic review that also reported that inter-organisational and inter-sectoral multidisciplinary provider education was necessary to underpin integrated clinical care [33]. Moreover, a recent WHO report stressed the importance of initial as well as ongoing multidisciplinary education in strengthening the future integrated care workforce [9]. This also shows the connection between the seven workforce changes which are seldom implemented in isolation, a finding that was also confirmed by other studies [6, 31]. Finally, the involvement of case managers or case coordinators was also found by the NHS scoping review mentioned earlier [31].

Some workforce changes are implemented together so often that it becomes difficult to disentangle them. This might explain why team meetings are *confirmed* by 80% of the experts but only *described* by 4%. The latter percentage may not necessarily mean that only 4% of the interventions described by the experts included team meetings, but most likely that the experts did not explicitly mention this workforce change because the concept is so similar that one might assume that it is already implicitly covered by, for example, multidisciplinary staff. Based on this reasoning we might assume that the average number of workforce changes per intervention described in studies and by experts is probably an underestimation of the real number, with the most obvious ones not having been mentioned explicitly. In the case of the descriptions by the experts this underreporting was possibly even further exacerbated by having to write down everything in detail, sometimes not even in one's mother tongue. However, based on these findings, researchers might conclude that team meetings are only rarely implemented in practice even though the very opposite could be the case. To prevent this, it would be necessary to have a common terminology with clear distinctions between and descriptions of its categories. Future research should focus on increased standardisation in the terminology regarding workforce changes to generate further knowledge in this research field and to make useful recommendations for the practice setting.

The current lack of a common terminology related to workforce changes was the reason for one of the main limitations of this study. In the case of the literature review, we were surprised by the extremely low number of studies found via the systematic search (N=2), despite our use of a rather extensive list of search terms. It is not clear whether this paucity of research found reflects a real paucity of research on the topic or whether the research that does exist is too difficult to find. The latter scenario might be due to a limitation that is specific to research on integrated care: there is no common definition or understanding of what constitutes integrated care [34, 35]. We identified an intervention as integrated care when it included at least two CCM components. However, this approach might have led us to exclude interventions which could have constituted integrated care but could not be categorised as such based on the limited information provided. For example, self-management interventions might be internet- or mobile device based (and therefore also target the clinical information system component) or be initiated only after the providers themselves were trained on the topic (and thereby also target the decision support component). But if this is not explicitly mentioned, it is not possible to identify the intervention as integrated care. However, currently, this approach seems to be the best available option, as evidenced by its use in the literature [21, 36-38] and confirmation by the Scientific Committee of Project INTEGRATE. On the upside, the approach ensured that no false-positives were included in our study. Moreover, we were able to use the approach for all three data sources, which ensured consistency.

Even though the inclusion of additional, mostly nurse-related, search terms led to the retrieval of several additional articles, most articles were found via the previous diabetes review which was conducted without specific focus on workforce related search terms. It was therefore difficult to gauge to what extent the list of workforce changes we found in the literature was coincidental, representative or complete. It should also be mentioned that we did not conduct a quality assessment of the methodology of the studies included in the review. This was mainly due to the difficulty in comparatively assessing the methodological quality of studies whose research designs and scopes differed considerably one from another. However, given the exploratory nature of this research, it seemed more important to find as many relevant studies as we could, rather than applying a strict but probably inconsistent quality tool. To remedy the above shortcomings, we conducted more research on the original list of workforce changes via the expert questionnaire and case studies. This showed that the list from the literature review was a good starting point for further research but indeed needed further exploration. Further quantitative investigation of the topic could provide more insights into the frequency with which the workforce changes are implemented and which of them are associated with better health outcomes.

The current study is also characterised by several strengths, the first being its interactive and emergent design, which allowed us to combine different data strands at different points of time in the data collection and analysis. This made it possible to build upon insights gained from earlier data strands and further explore concepts that became apparent during early data collection and analysis phases. The use of multiple methods of data collection mitigates their respective limitations while reinforcing their strengths [39]. Another strength of the study lies in its international scope. Our dataset includes countries that are not often represented in studies on integrated care such as Estonia, Czech Republic,

Greece and Norway. Moreover, only about a third of the data were collected from the United States, the United Kingdom, Canada and Australia, which are countries that are typically over-represented in these types of studies [30]. Finally, over the past 1.5 years, the methods and results of this study were regularly fed back to and commented on by the scientific committee and advisory board members of Project INTEGRATE, which improved the quality of the study and ensured that its focus stayed in line with the current needs of the academic and practice fields of integrated chronic care.

A source of tension throughout the whole study was the dilemma between on the one hand wanting to disentangle a complex intervention such as integrated care into its components, but on the other hand to still consider the workforce changes as only a part of a bigger intervention. The former step is necessary to be better able to analyse, identify and categorise integrated care and its components, but the latter step is also essential because integrated care as a whole is assumed to be more than the sum of its disentangled parts. In the current study, our focus was mainly on the first part, that is, to zoom into one component and gain detailed insights. In this aim we were successful, but we had to discover that this happened to a certain extent at the expense of losing sight of the bigger picture. Zooming back out is not a straightforward option because one lacks the necessary information to connect the dots between those aspects of integrated care that were studied and those that were not. An issue that further complicates this conundrum is the fact that even though we disentangled integrated care and focussed on the health workforce aspects only, it turned out that health workforce interventions are also complex in their own right, as evidenced by the existence of at least seven different workforce changes, of which on average two are implemented per integrated care intervention. This makes their implementation even more complicated, as well as the evaluation thereof. Promising approaches to address these challenges include complex typologies that are explicit about the constituent components of the overarching intervention [40] or comprehensive analytical approaches that investigate the impact of an overall intervention as well as its components [28]. This appears to be one of the most important areas for future research, namely to address the tension of needing to zoom into one specific aspect in order to know what exactly one studies but at the same time to zoom out in order to not lose sight of the bigger picture. Finding a solution to these challenges is a prerequisite for the investigation of the effectiveness of integrated care as a whole as well as its single parts in relation to each other and in relation to the whole intervention.

Conclusion

This study provided an overview of the workforce changes implemented as part of integrated care interventions for people with chronic diseases. Generally, seven workforce changes have been implemented, namely nurse involvement, multidisciplinary staff, multidisciplinary protocols/pathways, provider training, case manager/care coordinator, team meetings and the creation of new positions. On average, integrated care interventions included two workforce changes, and possibly even more when taking into account underreporting. Certain combinations of workforce changes are implemented together more often than others, such as multidisciplinary staff and multidisciplinary protocols. The results of this study provide a solid basis for further investigations of the relative effectiveness of different workforce changes within the scope of complex interventions. Overall, it was found that

research on workforce changes is difficult to access and not yet described in the literature in a systematic way. This seems to be in stark contrast with the relevance attributed to this field by the international research and practice community of chronic and integrated care. The development of a uniform and well-described terminology related to workforce changes in integrated care interventions is therefore recommended. Advancing knowledge in the area of workforce changes in integrated care interventions would help decision makers to design more appropriate integrated care interventions and foster nations' health systems' capacity to cope with the challenges associated with the current demographic and epidemiological trends.

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Appendix

Table 1: Overview of workforce changes per included study and number and percentage of studies mentioning the respective changes

Workforce changes	Studies																					n	%
	[41]	[42]	[43]	[44]	[45]	[46]	[47]	[48]	[49]	[50]	[51]	[52]	[53]	[54]	[55]	[56]	[57]	[58]	[59]	[60]	[61]		
Nurse-led care/nurse as main care provider	x									x						x				x	x	5	24
Multidisciplinary protocols/pathways		x							x	x	x				x				x			6	29
Multidisciplinary staff		x	x	x					x	x	x	x				x	x		x		x	11	52
Nurse involvement	x	x	x	x	x	x		x	x	x		x	x	x	x	x	x	x	x	x	x	19	91
Pharmacist involvement				x								x										2	10
Team meetings				x																		1	5
Case managers/care coordinators								x			x					x	x		x	x		6	29
Provider training					x				x													2	10
New position								x		x												2	10
Task re-distribution								x		x					x						x	4	19
Shared medical appointments																					x	1	5

Notes: X indicates that the workforce change was mentioned in the respective study. Empty cells indicate that the workforce change was not mentioned in the respective study. Abbreviations: n = number of studies, % = percentage of total number of studies.



CHAPTER 9

Barriers and facilitators to workforce changes in integrated care

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Barriers and facilitators to workforce changes in integrated care.

Abstract

Purpose: To investigate the barriers and facilitators to the implementation of workforce changes implemented as part of integrated chronic care interventions.

Methodology: We used a qualitative multimethod design that combined expert questionnaires, a systematic literature review, and secondary analysis of two case reports. Twenty-five experts, twenty-one studies and two case reports were included in the study.

Findings: Most barriers related to problematic delivery structures, health professionals' skills and enthusiasm, IT, funding, culture and cooperation and communication. Most facilitators related to health professionals' motivation and enthusiasm, good delivery structures, communication and cooperation, IT, patients, leadership and senior management. Overall, similar categories of barriers and facilitators were found.

Research implications: We recommend that future research focusses on more complex designs including multiple data sources, as these are better able to capture the complexity of interventions such as integrated care.

Practical implications: We recommend that health managers and policy-makers should invest in delivery structures and skills and motivation of health professionals to improve the implementation of workforce changes in integrated chronic care interventions.

Value: The added value of the present study lies in its provision of information on which factors might mitigate the success of an intervention, which helps to prevent premature conclusions of ineffectiveness for complex interventions.

Introduction

Health systems are faced with an ageing population and an increase in chronic conditions. These challenges require more appropriate approaches than the current largely single-disease and acute-care focussed health care systems. Integrated care is seen as one of the most promising of these approaches by targeting the health system, patient-provider relationships, care process design, communication infrastructures, community resources, and how care is delivered by health professionals [1-4]. In doing so, integrated care is expected to improve population health, patient experiences and cost-efficiency [5-8], a trio of goals commonly referred to as the Triple Aim [9]. Given health professionals' involvement in all aspects of integrated care delivery, changes to the health workforce affect the implementation of integrated care profoundly. It has therefore been argued that the health workforce should be included as a fourth aspect in the Triple Aim, thereby extending it to a Quadruple Aim of healthcare improvement [10].

In a previous study on the outcomes of integrated care interventions including workforce changes, we found improvements in quality of care (including clinical patient outcomes and process measures), patient satisfaction and staff satisfaction [11]. However, improvements were not always found and it was not clear when and why successful outcomes could be achieved. We therefore called for more attention to the setting in which integrated care interventions are implemented. This requires the use of complex research designs that focus on the barriers and facilitators to the implementation of an intervention, instead of simply focusing on observations before and after the introduction of the integrated care intervention and stripping away those factors expected to have a confounding effect on the causal relationship between input and output [12-14]. Additionally, complex designs should incorporate multiple data sources in order to include different perspectives of stakeholders to a specific intervention and triangulate results in explicit ways, which contributes to the methodological quality of the research [15-17].

The aim of this study was therefore to investigate the barriers and facilitators to the implementation of workforce changes implemented as part of integrated care interventions for people with chronic conditions. To this purpose, we used a qualitative interactive design with multiphase combination timing including a qualitative expert questionnaire, systematic literature review, and secondary analysis of two case reports.

Methods

We used an interactive multimethod design with multiphase combination timing, which is characterised by direct interaction between different data strands and a combination of concurrent and sequential timing [18]. Specifically, data collection took place concurrently, data analysis sequentially, and the results of the analysis one data source was used as the basis for the analysis of the next data source. Ethical approval was not required under Dutch law.

Definitions

In line with previous research, interventions were considered integrated care when targeting more than one Chronic Care Model (CCM) component (i.e. health system, self-management support, delivery system design, decision support, clinical information system and community) [2, 19-21]. (Health) workforce changes were defined as those changes experienced by clinical and non-clinical staff responsible for public and individual health intervention [22]. By barriers and facilitators we mean those factors that either hinder or foster the implementation or execution of integrated care interventions in practice. It should be noted that these factors can act as both barriers and facilitators [23].

Data collection and analysis

When implemented as part of integrated care interventions, workforce changes are not an independent intervention, but one aspect of a complex intervention that also includes other aspects. This means that barriers and facilitators can be reported specifically for the workforce changes included in the integrated care intervention, or for the overall integrated care intervention that includes workforce changes. The distinction is that the former approach focusses specifically on one aspect of a complex intervention, namely workforce changes, whereas the latter focusses on the complex intervention as a whole, namely integrated care. We combined both of these approaches in this study: via expert questionnaires, we measured the factors affecting the workforce changes, via a literature review the factors affecting the overall intervention, and via case reports the factors affecting the overall intervention but with specific focus on workforce-related issues.

Expert questionnaires

Between January and April 2015, we administered a qualitative exploratory questionnaire to experts in the fields of integrated care, chronic care, and health human resource management. The questionnaire was translated from English to Dutch, Italian, and Spanish, based on a feasible adaption of recommendations provided in the relevant scientific literature [24-27], including a check by an English native speaker, forward translations by native speakers of the target language, back translations to English by a researcher proficient in English, and a discussion of the English versions. Experts were recruited using the snowball method. In the questionnaire, experts were asked to describe an integrated chronic care intervention, the workforce changes implemented as part of this intervention as well as the barriers and facilitators encountered in the implementation of these workforce changes. These were open questions to which free-text answers were expected. During an open coding phase, two researchers (LB, KL) independently created coding lists. During the subsequent axial and selective coding phases, the coding lists were compared and consolidated after discussion among the researchers (LB, KL). Examples based on the data were added for each code.

Literature Review

Between July and October 2014, a literature search was conducted, including a systematic database search, a semi-systematic database search, unsystematic hand searches and secondary analysis of a previous literature review [1]. First, in the systematic database search, articles were assessed individually by three researchers (LB, SC, LG) and then discussed together until consensus was reached. As a second step, after the systematic database search yielded only a limited number of studies (N=2),

another set of health workforce related search terms was added to the search. The new results were assessed in the semi-systematic way, meaning that one researcher performed the title and abstract selection, but full-text versions suggested for inclusion were discussed by three researchers (LB, SC, LG). As a third step, studies from a previous review on type 2 diabetes were checked for a focus on health workforce changes by one researcher (LB) and included if applicable. Fourth, hand-searches were conducted on reference lists and via Google searches. Studies were included when they focused on the health workforce and integrated chronic care and when they were published after 2000. Studies were excluded when published in a language other than English, Dutch, German, Italian or Spanish, conducted in a developing country, or when concerning non-empirical research, systematic reviews and meta-analyses.

The data extraction was performed independently by three researchers (LB, SC, LG) and compared in pairs of two until consensus was reached (LB and SC, LB and LG, SC and LG). While in the expert questionnaires, experts were asked specifically about the workforce changes included in the integrated care interventions, for the studies data was extracted on the barriers and facilitators to the overall intervention because the studies reported integrated care interventions without specific focus on the workforce changes. The data were coded based on the coding lists resulting from the analysis of the expert questionnaires. Two researchers (KL, LB) performed the coding independently and discussed the results together until consensus was reached. When the data did not fit the categories of the coding lists, the lists could be adapted accordingly.

Case reports

Two detailed case reports of integrated care interventions implemented in the Netherlands and Germany were available for secondary analysis [28, 29]. Both case reports provided data on barriers and facilitators, but these were not specifically linked to the workforce changes of the integrated care intervention. This additional step was performed by one researcher (LB) during the secondary analysis. The barriers and facilitators described in the case reports were coded using the coding lists from the analysis of the expert questionnaires and literature review. The coding was performed independently by two researchers (LB, KL) and discussed in pairs until consensus was reached. When the data did not fit the categories of the coding lists, the lists could be adapted accordingly.

Synthesis

After analysing the barriers and facilitators per data source, we compared those barriers and facilitators that were among those mentioned by most experts, studies or cases. For the literature review and expert questionnaires, we included barriers and facilitators that belonged to the three highest percentages per data source. Given the low number of case reports, we only included those barriers and facilitators that were present in both case reports.

Results

We first present general information for each data source, before presenting the results on the barriers and facilitators.

General information

Expert questionnaires

The questionnaires were sent to 91 experts and returned by 25, resulting in a response rate of 28%. Examples of integrated care interventions included the integration of primary, community and social care services, multidisciplinary teams, comprehensive geriatric assessments, provider education in self-management support, and comprehensive care trajectories. Interventions were implemented in 12 different countries, including Belgium (N=8), Spain (N=5), Estonia (N=2), Italy (N=2), the Netherlands (N=2), the United Kingdom (N=2), Australia (N=1), Czech Republic (N=1), Germany (N=1), Greece (N=1), Norway (N=1), and Switzerland (N=1).

Literature review

The final selection consisted of 21 studies [30-50]. Examples of integrated care interventions included patient education by specialist nurses, structured patient-oriented care coordination, the use of a patient registry to support multidisciplinary team work and practice nurse involvement in shared medical appointments. The studies described interventions implemented in seven countries, including the United States (N=10), the Netherlands (N=4), the United Kingdom (N=2), Canada (N=2), Belgium (N=1), Austria (N=1), and Germany (N=1).

Case reports

The German case study was conducted at a geriatric hospital where each ward is organised in independent interprofessional teams consisting of doctors, physiotherapists, occupational therapists, nurses and neuropsychologists. A scientific paper based on this report is submitted for publication elsewhere (reference blinded). The Dutch case study was conducted among two care groups implementing integrated care for people with type 2 diabetes. Care groups are legal entities that establish contracts with health insurers and health professionals to coordinate the so-called 'care chain' of chronic care from diagnosis to after care [51]. A scientific paper based on the detailed report is published elsewhere [52].

Barriers & Facilitators

Expert questionnaire

Barriers and facilitators to the implementation of the workforce changes were found for the following 17 categories (in alphabetical order):

- Communication and cooperation
- Competition, priority, pressure
- Complexity
- Culture
- Delivery structures
- Funding
- Health and social care

- Health professionals
- Implementation support
- Incentives
- Information technology (IT)
- Leadership and senior management
- Patients
- Political and health system
- Primary and secondary care
- Time
- Other

The barriers mentioned by most respondents related to delivery structures and health professionals (N=11; 44%), followed by culture (N=10; 40%), and funding (N=8; 32%). Delivery structure barriers related to nurse-led care, guidelines and checklists, staffing and delineation of responsibilities. As regards the delineation of responsibilities, examples of barriers included arguments about the responsibilities of primary vs. hospital care and the lack of clarity of who should execute the intervention (general practitioner (GP), nurse, or someone else). With regard to staffing, barriers related to the number of specialised geriatric doctors or nurses, the difficulty of attaining and maintaining a sufficient number of staff and a high staff turnover. Health professional barriers related to their lack of knowledge, skills and expertise, education, enthusiasm and support, and other factors. Examples included the lack of knowledge on how to execute the intervention, worries around competencies and abilities, lack of engagement, worries about an additional (administrative) burden, the fear of change, and the fear of making mistakes or having them made public.

The facilitators mentioned by most respondents related to health professionals (N=13, 52%), followed by leadership and senior management (N=10; 40%), and delivery structures, patients, and communication and cooperation (N=7; 28%). With regard to health professional facilitators, most respondents mentioned facilitators related to their enthusiasm and support, including examples such as enthusiastic professionals and volunteers, existence of a health professional championship to raise confidence for the program, and the fact that staff involvement led to enthusiasm which led to more cooperation and better implementation. Provider education facilitators included examples such as management involvement in the process to send staff to courses, education of interprofessional teams, and the existence of two regional laws that promote education activities. Facilitators related to leadership and senior management included strong and committed leadership, support from senior management, and good communication with hospital management.

Literature Review

Barriers and facilitators to the implementation of integrated care interventions including workforce changes were found for 14 of the 17 categories from the expert questionnaire. The three categories for which the studies did not report barriers and facilitators were complexity of the intervention, primary and secondary care, and health and social care. It was not necessary to adapt the coding lists.

The barriers described in most studies related to delivery structures (N=7; 34%), health professionals (N=6; 29%), IT (N=5; 24%) and communication and cooperation (N=5; 24%). Most delivery structure barriers related to staffing and included examples such as insufficient staff capacity, high staff turnover, cost of hiring sufficient staff, and an appropriate salary. Most barriers within the category health professionals related to health professionals' knowledge, skills and expertise and included perceived lack of expertise, problematic understanding and implementation of diabetes education, and the fact that doctors were uncomfortable with computers and e-communication. Communication and cooperation barriers included drawbacks to standardised communication (e.g. the risk that the context of the data collection is lost from view and that the tone of the communication is misconstrued), perceived unwillingness to share care, and barriers to building a registry (e.g. multiple data sources, inconsistent formatting, unwillingness to share data).

The facilitators described in most studies related to delivery structures (N=6; 29%), health professionals (N=6; 29%), IT (N=5; 24%), and patients (N=4; 19%). Examples of facilitators relating to delivery structures included the use of a multidisciplinary team, systematic identification and assignment of patients and weekly case conferences. Within the category health professionals, most facilitators related to provider education and included continuous education efforts, extended training periods and participatory methods, and offering staff continuous education credit. Examples of IT facilitators included a registry, a social networking module that allowed participants to connect with each other, and mandatory, pre-structured patient files on the internet. Patient facilitators related to patient centeredness and involvement and support, awareness and motivation. Examples included the collaborative development of self-care plans reflecting both treatment indications and patient preference, a home visit tutorial conducted by the project staff, less formal diabetes education, and behavioural goal setting.

Case reports

Barriers and facilitators were found for 13 categories. The coding list did not need to be adapted. Both case reports reported barriers for the categories delivery structures, health professionals and IT (N=2; 100%). Delivery structure barriers included staff shortages, strict guidelines that gave health professionals very little room to adapt the requirements to the specific needs of the patients, and the fear that tasks would be taken away when new professional roles were introduced. Most health professional barriers related to their lack of enthusiasm and support and included examples such as resistance to the introduction to integrated care by GPs and frustration caused by too many innovations within a short time frame. IT barriers included strict data protection frameworks and the separation of data systems between different health sectors or primary and secondary care.

Facilitators were reported in both case reports for the categories delivery structures, health professionals, IT and communication and cooperation (N=2; 100%). Examples of delivery structure facilitators included the facilitating role of a practice nurse in the cooperation between the GP and other health professionals, and organisational workarounds to compensate for the lack of official structures and tools to support multidisciplinary care delivery. Health professional facilitators included the personal experience and competences of the clinical leader and founder of a geriatric hospital, the existence of a

group of innovators to drive innovations, and the increased conviction by health professionals that integrated care helps to improve the quality of care.

Synthesis

Table 1 shows the barriers that were mentioned most often. Delivery structure and health professional barriers were among the three highest percentages in the expert questionnaire and literature review, and mentioned in both case reports. IT barriers were among the three highest percentages in the literature review and mentioned in both case reports. Funding and culture barriers were among the three highest percentages in the expert questionnaires and communication and cooperation barriers among the three highest percentages in the literature review.

Table 1: Overview of the barriers mentioned by most experts, studies or cases

Barriers	Expert Questionnaire (N = 25)	Literature Review (N = 21)	Case Reports (N = 2)
Delivery structures	44%	34%	100%
Health professionals	44%	29%	100%
IT	16%	24%	100%
Funding	32%	14%	50%
Culture	40%	10%	0%
Communication and cooperation	4%	24%	0%

Note: Percentages in bold print indicate that the respective barrier was among the three highest percentages in the expert questionnaire or literature review, or mentioned in both case reports. Percentages in normal print indicate that the respective barrier was among the three highest percentages in the expert questionnaire or literature review, or mentioned in both case reports.

Table 2 shows the facilitators that were mentioned most often. Facilitators related to health professionals and delivery structures were among the three highest percentages in the expert questionnaires and literature review, and reported in both case reports. Facilitators relating to the communication and cooperation, IT and patients were mentioned most often in two of the three data sources. Leadership and senior management facilitators were among the three highest percentages in the expert questionnaires.

Table 2: Overview of the facilitators mentioned by most experts, studies or cases

Facilitators	Expert Questionnaire (N = 25)	Literature Review (N = 21)	Case Reports (N = 2)
Health professionals	52%	29%	100%
Delivery structures	28%	29%	100%
Communication and cooperation	28%	14%	100%
IT	8%	24%	100%
Patients	28%	19%	0%
Leadership and senior management	40%	5%	50%

Note: Percentages in bold print indicate that the respective facilitator was among the three highest percentages in the expert questionnaire or literature review, or mentioned in both case reports. Percentages in normal print indicate that the respective facilitator was among the three highest percentages in the expert questionnaire or literature review, or mentioned in both case reports.

Discussion

This study has described the barriers and facilitators to the implementation of workforce changes in integrated chronic care interventions. To this purpose, three methods of data collection were combined, namely expert questionnaires, a literature review and case reports.

We found most barriers to the implementation process to be related to delivery structures, including problematic staffing and delineation of responsibilities. Health professionals' lack of skills and enthusiasm were also perceived as problematic. Barriers related to IT, funding, culture and communication and cooperation were also reported. Barriers such as high costs, problematic funding, lack of health professionals' motivation and technical barriers were also reported in a recent European study on the continuous professional development of different health professions [53]. Furthermore, a study on team training and organisational change in the Canadian context found barriers relating to the resistance to share care, high costs, and staffing problems [54]. A review exploring the characteristics of effective workforce practice in integrated health and social care services found difficulties in information sharing to be an important barrier [55]. Finally, a scoping study by the British National Health Service (NHS) also found gaps in the skills of staff who provide integrated care for older adults [56].

Most facilitators were related to health professionals' motivation and enthusiasm. Good delivery structures including a sufficient number of staff and nurse-led care also helped the implementation process. Other facilitators concerned communication and cooperation, IT, patients and leadership and senior management. Health professionals' motivation was also identified as a facilitator in a review on the changing skill-mix of the health workforce [57]. A study on multidisciplinary meetings in geriatric assessment units found nurse involvement to be a facilitator of multidisciplinary collaboration [58]. The study on team training and organisational change in the Canadian context referenced above found

leadership support and health professionals' willingness to change to be important facilitators for workforce change. Good leadership was also identified as important facilitator by the review on characteristics of effective workforce practice in integrated health and social care services mentioned above, together with provider education, a clear understanding of different roles and responsibilities, and good communication between professionals [55]. A recent European study on new professional roles in health care found established health professionals' willingness to change and new roles that emphasise patient-centred care to be important facilitators as well [59]. The importance of staff engagement in the implementation of workforce changes was also outlined in a recent study from England [60]. Additionally, patient engagement was identified by the NHS as a facilitator for responsive and adaptive integrated care services [56]. Finally, the use of IT systems was identified as an important facilitator for better health human resource utilisation and empowerment of elderly patients [61].

As mentioned above, when implemented as part of integrated care interventions, workforce changes are not an independent intervention, but only one aspect in a complex intervention. Because of these different emphases on one aspect of an intervention as opposed to the overall intervention, one would expect the literature review to reveal barriers and facilitators for the highest number of different categories, because of its broad focus on the overall intervention, as opposed to the expert questionnaire, which had a more narrow focus on the workforce changes within the overall intervention. However, as mentioned above, the experts reported barriers and facilitators for 17 categories, while the studies only reported 14 categories, leaving out the categories complexity of the intervention, primary and secondary care, and health and social care. This difference may be explained by the fact that especially the latter two categories can be more easily witnessed by an expert observer than systematically measured as would be appropriate for published academic literature. Another reason could be that these factors have received attention in academic publications only relatively recently and might therefore not come to the fore in systematic reviews of the literature. The case reports form an exception because they focussed on only one intervention each. Therefore, it is not surprising that the case reports only found barriers and facilitators for 13 categories, even though they had a relatively broad focus on the overall intervention with a focus on workforce-related issues. Despite these differences, the 17 categories found via the expert questionnaire did not need to be extended for the literature review and case reports. This shows that, overall, the three approaches yielded similar findings.

It is also noticeable that similar categories of barriers and facilitators were found. This points towards the fact that most factors can act as facilitators as well as barriers, depending on whether they are present or absent or how well they are implemented. For example, the lack of an IT system can be a huge barrier to efficient care delivery, but so can an IT system that creates more problems than it was intended to solve. Faced with such a problematic IT system, the lack or circumvention of an IT system would be a facilitator, but of course, so would be an IT system that works well. In this sense, barriers and facilitators are often two sides of the same coin. Additionally, barriers and facilitators are often causes and consequences of one another. To use the previous example, a health IT system might be implemented to facilitate the communication between health professionals working at different locations and to standardise information exchange. However, when replacing face-to-face or phone contact,

digitalised and standardised communication can act as a barrier to good working relationships between the different health professionals. This might lead to the implementation of new solutions which, in turn, might cause new problems. This interrelatedness of barriers and facilitators reflects the complexity that is inherent to integrated care interventions and shows that the implementation of most complex interventions is never really complete. More attention should therefore be paid to the interplay between different factors as well as the levels at which this interplay occurs. A useful framework for these types of analyses is the PARIHS framework for promoting action on research implementation in health services [62, 63].

There are methodological limitations to this study which should be taken into consideration. First, the interpretation of answers to the expert questionnaire was sometimes ambiguous. While some answers were very detailed and informative, others were too short to make sense of or were so ambiguous that they generated more questions than they answered. When one of those answers (e.g. "IT" or "no money") matched a category rather clearly (e.g. the categories "IT" or "Funding"), we mapped the answer to the respective category. However, when there was no clear link between a short or ambiguous answer and an already existing category, the answer was excluded from the analysis. Second, the systematic part of our literature review identified only a very small evidence base on workforce changes. This is in line with previous studies on health workforce changes [55-57]. We tried to alleviate this shortcoming by adding semi- and unsystematic searches as well as consulting a previous literature review on diabetes. The latter revealed a rich evidence base on workforce changes in integrated care interventions even though its search strategy was not primarily concerned with workforce related search terms. This shows that not being able to find a large evidence base does not necessarily mean that it does not exist, but that it is not easily accessible. This could be the case because those who contribute to creating the scientific evidence on the topic might not realise that they are doing so because they are only focusing on a specific professional field or disease. The field would benefit from a common and clearly described terminology for workforce changes, but also from increased attention to a cross-cutting issue such as workforce changes that transcends those diverse and much specialised fields of interest.

One of the main strengths of this study lies in its international scope by including data from 15 different countries. This is especially relevant because there is no consensus definition of integrated care and the concept often has different meanings in different countries or health systems [64, 65]. Moreover, the research plan as well as preliminary findings were regularly fed back to the scientific committee of Project Integrate, which enhanced the methodological quality of the study and ensured its relevance for the international academic and practice community [66]. Finally, the study combined three different methods of data collection in an interactive design with multiphase combination timing, which enabled the triangulation of findings. The added value of the present study lies in its provision of information on which factors might mitigate the success of an intervention, which helps to prevent premature conclusions of ineffectiveness due to inappropriate research designs for complex interventions [67, 68]. Moreover, knowing which factors are conducive to successful implementation makes it possible to adequately inform policy-makers and practitioners regarding their choices for efficient allocation of

scarce health resources. In the long run, this is expected to benefit the population with or at risk of chronic conditions as well as the health workforce caring for them.

We recommend that future research focusses on more complex designs including multiple data sources, as these are better able to capture the complexity of interventions such as integrated care. Furthermore, we recommend that researchers and practitioners pay more attention to context factors in evaluations of complex interventions, rather than focussing on outcomes only [62, 63]. This would yield valuable information on the strengths and weaknesses of the execution of an intervention in a specific real-world setting and thereby increase the likelihood of implementing interventions successfully. Finally, we recommend for health managers and policy-makers to allocate significantly more resources to improving delivery structure and work environments of health professionals, as most barriers as well as facilitators were related to the number of health professionals, their skills, enthusiasm and division of tasks. These long-term investments into the health workforce, rather than short-term cost-cutting measures at the expense of the health workforce, are expected to contribute to the health and experiences of the population.

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CHAPTER 10

Outcomes of integrated chronic care interventions including workforce changes

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Abstract

Background: Integrated care is seen as a promising approach to deal with the current mismatch between people's increasing demand for complex, long-term and person-centred care and a traditional supply of acute, episodic and single-disease-focused care. Given the involvement of health professionals in all aspects of integrated care delivery, changes to the health workforce are seen as a key enabler of integrated health services delivery.

Objectives: The first aim of this study was to investigate the outcomes of integrated care interventions for people with chronic conditions that included workforce changes. The second aim was to develop preliminary insights into the relative benefits of measuring the outcomes of *workforce changes that are part of integrated care interventions* as opposed to measuring *integrated care interventions that included workforce changes*.

Method: Data were collected by means of an expert questionnaire and a literature review. While the expert questionnaire investigated the outcomes of the workforce changes that were part of an integrated care intervention, the literature review investigated the outcomes of integrated care interventions that included workforce changes.

Results: Overall, both approaches found positive outcomes, in particular for quality of care (including clinical patient outcomes and process measures), patient satisfaction and staff satisfaction. Outcomes were reported for the same categories in the studies as in the questionnaires.

Conclusion: We recommend for health managers and policy makers to invest in workforce changes and to (re-)consider strategies that may be detrimental to the health workforce and thereby adversely affect patient health and patient experiences of care.

Introduction

Current demographic and epidemiological trends are characterized by an ageing population and an increase in chronic conditions [1-3]. These developments challenge today's and tomorrow's health systems as they create a mismatch between people's increasing demand for complex, long-term and person-centred care on the one hand and a traditional supply of acute, episodic and single-disease-focused care on the other hand [2, 4]. This chasm can lead to fragmented, duplicative, unsafe and poorly coordinated health services, especially for people with chronic conditions [2, 3]. Scholars have argued that solutions to these problems must entail holistic approaches that target all aspects of a given health system [1, 2]. Today, integrated care is seen as one of the most promising of these approaches [2, 5-7]. Integrated care entails comprehensive interventions targeting the health system, use of community resources, patient-provider relationships, care process design, communication infrastructures and the ways in which health professionals deliver care [5, 8, 9]. In doing so, it is expected to lead to improved quality of care and health outcomes [10-16], better patient experiences [10, 11, 14-16] and increased (cost) efficiency [10, 12-17], representing the three pillars of the Triple Aim [18]. However, currently, a debate is developing on the relevance of the workforce for achieving these outcomes. Specifically, Bodenheimer and Sinsky have proposed to include the health workforce as a fourth aspect in the Triple Aim, thereby extending it to a Quadruple Aim focusing on the health workforce, costs reductions, improved population health and enhanced patient experiences of care [19].

Given the involvement of health professionals in all aspects of integrated care delivery, this discussion is especially relevant for integrated care interventions. Moreover, changes to the health workforce are seen as a key enabler of integrated health services delivery [20]. Previous studies have been conducted on health workforce planning [21, 22], present and future health workforce needs [23], and trends for specific sectors or groups of health professionals [24, 25]. Other studies have examined specific types of changes for the health workforce such as skill mix or team work [26, 27]. However, none of these studies were conducted specifically on integrated care interventions for chronic diseases, which means that we do not know whether workforce changes embedded in these types of interventions lead to improved outcomes. The first aim of this study is therefore to investigate the outcomes of workforce changes implemented as part of integrated care interventions for people with chronic conditions. To this purpose, we conducted a qualitative survey study among experts and a literature review.

However, it is not clear how one specific aspect of a complex intervention, such as workforce changes, contributes to the achievement of certain outcomes. It is not clear, either, how this one aspect of the complex intervention relates to other aspects of the intervention that are not being studied or to the intervention as a whole. For example, previous studies have looked at the effectiveness of payment mechanisms or patient involvement in integrated care interventions [7, 28]. But the authors did not discuss these aspects in relation to the other aspects of the integrated care intervention or the intervention as a whole. It is generally assumed that integrated care is more than the sum of its components but this claim is difficult to underpin, especially because it is not clear how this should be done in terms of methodological approaches. In other words, it is not clear how to study the impact of one aspect of a complex intervention without losing sight of the impact of the overall intervention as

well as the other aspects this intervention entails. Given these methodological challenges, it was not clear whether we should measure the outcomes of *workforce changes that are part of integrated care interventions* or the outcomes of *integrated care interventions that included workforce changes*. We therefore combined both approaches by having the expert questionnaire focussing on the first approach and the literature review on the latter one. We hypothesised that measuring outcomes of integrated care interventions including workforce changes might lead to more varied outcome categories due to its broader focus, compared to measuring the outcomes of workforce changes within integrated care interventions, which zooms into the workforce changes more narrowly. The second objective of this study was to develop some very preliminary insights on the relative benefits of these two approaches.

Methods

Definitions

In line with previous research, we considered an intervention integrated care if it targeted more than one Chronic Care Model (CCM) component (health system, self-management support, delivery system design, decision support, clinical information system and community) [9, 29-31]. We defined health workforce as “the different kinds of clinical and non-clinical staff responsible for public and individual health intervention” [32] and workforce changes as the changes that the health workforce experiences. Outcomes were categorised as positive and negative outcomes for the following outcome measures: quality of care, patient satisfaction, staff satisfaction, productivity, cost containment, (in)appropriate visits or diagnoses and accessibility of care. When an intervention did not yield any positive changes, this was also counted as a negative outcome.

Data collection and analysis

Data were collected by means of an expert questionnaire and a literature review. According to Dutch law, data collection among health professionals does not require ethical approval.

Expert questionnaires

Between January and April 2015, we administered a qualitative exploratory questionnaire to experts in the fields of integrated care, chronic care and health human resource management who were proficient speakers of English, Dutch, Italian or Spanish. The original English questionnaire was translated to these languages based on recommendations provided by the literature [33-36]. We contacted experts using the snowball method starting with the members of the Project INTEGRATE scientific committee and ending when no additional names were provided. In the questionnaire, experts were asked to describe (in free text) an integrated care intervention as well as the workforce changes it included. Moreover, they were asked to indicate which positive and/or negative outcomes of the workforce changes were measured for seven pre-specified outcome categories (quality of care, patient satisfaction, staff satisfaction, productivity, cost containment, inappropriate visits or diagnoses, accessibility of care). Additional outcome categories could be added by the respondents. The data extraction was performed by two researchers (SC, LG) and checked by a third (LB).

Literature Review

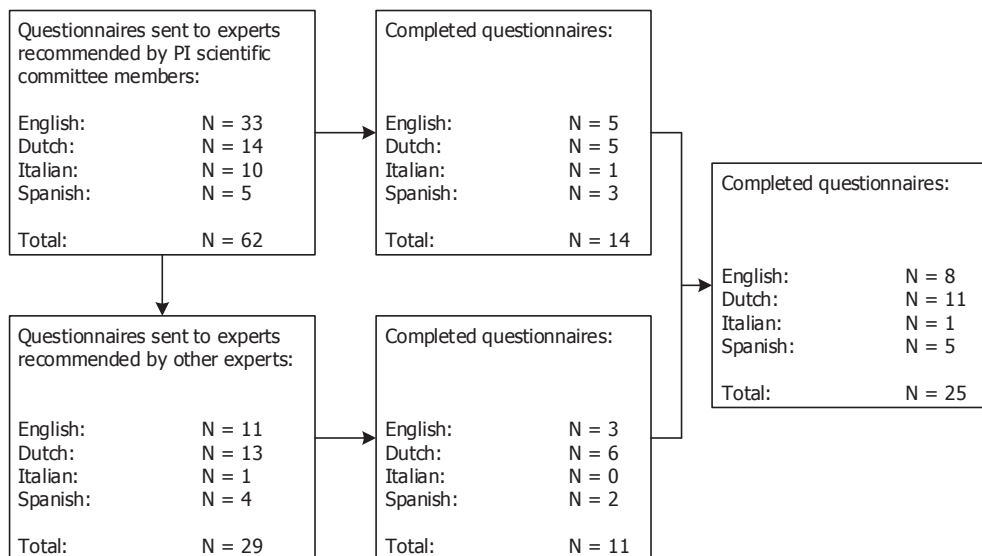
Between July and October 2014, we searched the international scientific literature on integrated care interventions for people with chronic conditions that included workforce changes. The search was conducted in four steps. First, a systematic search was conducted in four databases and articles were assessed individually by three researchers (LB, SC, LG) and then discussed together until consensus was reached. Second, after the systematic review only led to the inclusion of two studies, a semi-systematic search with new workforce-related search terms was conducted, in which one researcher performed the title and abstract selection, and suggestions for inclusion were discussed by three researchers (LB, SC, LG). Third, a previous systematic review on type 2 diabetes was re-examined for studies focusing on workforce changes. Finally, unsystematic hand-searches via Google and references lists were conducted. Two researchers (SC, LG) performed the data extraction. The data extraction for the articles included via the previous diabetes review was re-assessed by one researcher (LB). Data were extracted for the outcomes of the integrated care interventions. For the data analysis, two researchers (LB, KL) independently coded the data based on the coding list which resulted from the expert questionnaire. When the results from the literature review did not fit into the categories of this coding list, the list was adapted.

Results

Expert questionnaires

The questionnaire was sent to 91 experts. Twenty-five experts completed and returned the questionnaire, which resulted in a response rate of 28%. Figure 1 shows a flowchart of the questionnaire respondents.

Figure 1: Flowchart of questionnaire respondents



The languages in the flowchart (English, Dutch, Italian, and Spanish) refer to the language in which the questionnaire was provided to the experts, not the nationalities of the experts, e.g. Dutch questionnaires were sent to Dutch and Belgian experts, etc. Examples of integrated care interventions included the integration of primary, community and social care services, multidisciplinary teams, comprehensive geriatric assessments, provider education in self-management support, and comprehensive care trajectories. The interventions described by the respondents were implemented in Belgium (N=8), Spain (N=5), Estonia (N=2), Italy (N=2), the Netherlands (N=2), the United Kingdom (N=2), Australia (N=1), Czech Republic (N=1), Germany (N=1), Greece (N=1), Norway (N=1), and Switzerland (N=1). The target groups of the interventions included patients with any type of chronic/long-term illnesses (N=5), patients with diabetes (N=5), Chronic Obstructive Pulmonary Disease patients (N=4), people with cardiovascular disease (N=2), and all patients (N=2).

Table 1 reports the positive and negative outcomes for seven outcome categories as indicated by the questionnaire respondents. As stated earlier, this refers to the outcomes of the workforce changes implemented as part of integrated care interventions (as opposed to the outcomes of integrated care interventions including workforce changes).

Table 1: Overview of outcomes from the expert questionnaire (number and percentage of experts reporting the respective outcomes)

Category	Negative		Positive	
	n	%	n	%
Quality of care	4	16	13	52
Patient satisfaction	2	8	11	44
Staff satisfaction	2	8	11	44
Productivity	0	0	3	12
Cost containment	0	0	6	24
Inappropriate visits or diagnoses	1	4	4	16
Accessibility of care	0	0	2	8

Notes: n = number of respondents, % = percentage of respondents.

The negative outcomes indicated by most experts were related to quality of care (N=4; 18%), patient satisfaction (N=2; 8%), staff satisfaction (N=2; 8%) and inappropriate visits or diagnoses. For example, with regard to negative outcomes for quality of care one respondent indicated that in some regions, geriatric assessments were rather formal with no big added value as perceived by the service providers. Regarding patient and staff satisfaction, respondents indicated that the intervention was not well known yet among the patients and that in some regions staff just did their work and had an indifferent attitude towards the specific service.

The positive outcomes indicated by most experts were related to quality of care (N=13; 52%), patient satisfaction (N=11; 44%), staff satisfaction (N=11; 44%), and cost containment (N=6; 24%). For example, with regard to positive outcomes for quality of care, improvements in care processes were indicated, as well as better compliance and decreased re-admission rates. With regard to positive outcomes for patient satisfaction, one respondent indicated that patients felt more supported and less anxious and that they were pleased with the range of support that was offered. Regarding positive outcomes for staff satisfaction, the same respondent indicated that the GPs especially valued nurse support through knowledge about referral processes and other relevant information provided to them by the nurses. Other respondents indicated high staff attendance rates for trainings and general positive evaluations by the staff.

Additionally, one respondent indicated mixed results for patient satisfaction and staff satisfaction. Other outcomes indicated by the experts included a lower risk of burnout in health professionals, better coordination of the care process, recovery of the functional ability of the patients involved, and a better work environment. These outcomes were each reported by one respondent.

Apart from the numbers and percentages themselves, it is also interesting to look at the combinations of reported positive outcomes of workforce changes included in integrated care interventions: eight respondents reported improvements in both patient and staff satisfaction; seven respondents reported improvements in both staff satisfaction and quality of care; nine respondents reported improvements in both patient satisfaction and quality of care, and seven respondents reported improvements in patient satisfaction, staff satisfaction and quality of care. This suggests that workforce changes tend to influence several types of outcome categories. For the negative outcomes the total number of respondents was too low to make these kinds of comparisons.

Literature Review

The final selection consisted of 21 studies [37-57]. Examples of integrated care interventions included patient education by specialist nurses, structured patient-oriented care coordination, the use of a patient registry to support multidisciplinary team work and practice nurse involvement in shared medical appointments. These interventions were implemented in the United States (N=10), the Netherlands (N=4), the United Kingdom (N=2), Canada (N=2), Belgium (N=1), Austria (N=1), and Germany (N=1). The interventions were targeted at patients with diabetes (N=16), patients with chronic conditions (N=3), older patients with dementia and/or depression (N=1), and patients with rheumatoid arthritis (N=1).

Table 2 provides an overview of the negative and positive outcomes of integrated care interventions including workforce changes as found in the literature review. Outcomes were found for the same categories as in the expert questionnaire, where the outcomes of workforce changes included in integrated care interventions were measured.

Table 2: Overview of outcomes from the literature review (number and percentage of studies reporting the respective outcomes)

Category	Negative		Positive	
	n	%	n	%
Quality of care	4	19	14	67
Patient satisfaction	1	5	5	24
Staff satisfaction	1	5	5	24
Productivity	0	0	2	10
Cost containment	1	5	0	0
Inappropriate visits or diagnoses	1	5	5	24
Accessibility of care	0	0	0	0

Notes: n = number of studies, % = percentage of studies.

The negative outcomes described in most studies related to the category quality of care (N=4; 19%). This included no or negative changes to clinical patient outcomes such as glycated haemoglobin, low density lipids and weight as well as no or negative changes to process measures such as a reduced frequency of regular glycated haemoglobin checks and low use of educational sessions and CD-ROMs by doctors. Negative outcomes for patient satisfaction, staff satisfaction, cost containment and inappropriate visits or diagnoses were each reported in one study (N=1; 5%). Negative outcomes for staff satisfaction included high physician drop-out and negative outcomes for cost containment were higher costs for the intervention. For quality of care, productivity and accessibility of care no negative outcomes were reported.

Positive outcomes for the category quality of care were described in most studies (N=14; 67%), including improved clinical patient outcomes and improved process outcomes. The former included, for example, improved glycaemic control, blood pressure, lipid level control and body mass index, while the latter included increased screening and identification rates, but also decreased hospital (re-) admission rates and length of stay. Positive outcomes for the categories patient satisfaction, staff satisfaction, and inappropriate visits or diagnoses were each reported in five studies (N=5; 24%). Patient satisfaction included both improved patient satisfaction and improved patient-provider relationship. Examples of positive outcomes for staff satisfaction included high staff satisfaction and improved patient-provider or nurse-GP relationships. Positive outcomes for productivity were described in two studies (N=2; 10%). No studies described positive outcomes for the categories cost containment and accessibility of care.

It is interesting to look at the combinations of studies reporting positive outcomes of integrated care interventions including workforce changes. One study reported positive outcomes for quality of care, patient satisfaction, staff satisfaction and productivity. Two studies reported positive outcomes for quality of care, patient satisfaction and staff satisfaction. One study reported positive outcomes for patient satisfaction and staff satisfaction, another for patient satisfaction and productivity and another one for quality of care and inappropriate visits or diagnoses. This seems to suggest that integrated care

interventions including workforce changes also tend to influence several types of outcome categories, but to a lesser extent than witnessed in the expert questionnaire. For the negative outcomes the total number of studies was too low to make these kinds of comparisons.

Combination

Overall, more positive than negative outcomes were found. First, experts reported positive outcomes for all seven categories, as opposed to negative outcomes for only four categories. In the studies, negative and positive outcomes were each reported for five categories. Second, for all but two categories described above more positive than negative outcomes were measured, in the expert questionnaire as well as the literature review. The first exception is accessibility of care, for which no negative nor positive outcomes were reported in the studies. The second exception is the category cost containment, as one study reported negative outcomes for cost containment, while no study reported positive outcomes for this category. However, in the expert questionnaire this trend was reversed: while six experts reported positive outcomes for cost containment, none reported negative outcomes for the same category.

Discussion

The aim of this study was to investigate the outcomes of workforce changes implemented as part of integrated care interventions for people with chronic conditions. To this purpose, two methods of data collection were combined, namely an expert questionnaire and a literature review. Moreover, two approaches to measuring outcomes were applied. While the expert questionnaire investigated the outcomes of the workforce changes that were part of an integrated care intervention, the literature review investigated the outcomes of integrated care interventions that included workforce changes.

Overall, we found positive outcomes, especially related to quality of care (including clinical patient outcomes and process measures), patient satisfaction and staff satisfaction. This is partially in line with previous research on the outcomes of workforce changes, but overall, findings are mixed. For example, in their systematic review of substitution of doctors by nurses in primary care, Laurant et al. found no differences between care provided by doctors and nurses regarding clinical patient outcomes, process outcomes, resource utilisation and costs. Only for the specific case when nurses were responsible for first contact care for patients wanting urgent consultations, patient satisfaction was higher when care was provided by the nurses [58]. In their review of skill mix changes between general practitioners, pharmacists and practice nurses in the care of elderly people, Dennis et al. found improved clinical patient and process outcomes, but no reduction in health service utilisation [59]. In their review of the outcomes of skill mix change, Sibbald et al. conclude that there is a dearth of research, especially regarding members of the workforce other than doctors or nurses, cost-effectiveness and overall impact on the health care system [60]. Overall, available research on the topic is limited and findings are inconsistent, which calls for better accessibility to previous research and makes new research necessary.

We found more positive than negative outcomes for all categories except cost containment and accessibility to care. Regarding cost containment, this may be due to the fact that it is more difficult to measure costs in a way that is suitable for scientific publication, as this usually requires a societal perspective to cost measurements [18]. Experts may also be more inclined to consider an integrated care intervention on its own, while academic publications require a more comprehensive perspective beyond the intervention, which might lead to different conclusions. The same might hold true for accessibility to care for which no outcomes were measured in the studies, but for which two experts indicated positive outcomes. Measuring accessibility to care also often requires a look beyond a specific intervention, for example when it is applied in one area but its impact is expected to reach also into other areas of health care delivery. It is also possible that the confirmation by the experts regarding costs was more of a feeling that the workforce changes led to cost-efficiency rather than based on hard evidence, reflecting the general expectation that integrated care will lead to cost reductions, even though this has not been confirmed by the literature [61]. On the other hand, some experts referred to as of yet unpublished results, so it might also be an indication of more research conducted in the recent years to which the published literature has not yet caught up.

Measuring outcomes of complex interventions

In general, outcomes were reported for the same categories in the literature as by the experts. This finding is not in line with our expectation that using different approaches to measuring outcomes would lead to the measurement of different types of outcomes. Specifically, we had expected that measuring outcomes of integrated care interventions including workforce changes would lead to more varied outcome categories due to its broader focus, compared to measuring the outcomes of workforce changes within integrated care interventions. This hypothesis was actually supported by the fact that the additional outcomes indicated by the experts that did not fit a specific category were for the most part closely related to the workforce, including for example burnout, care process coordination and the work environment. However, on a larger scale, this difference was not seen, even though experts were free to indicate additional outcome categories, which could have been expected if there had been other major types of outcomes related specifically to workforce changes.

This begs the question whether there really were two different approaches to outcome measurement as intended at the outset of the study. In other words, did the experts really only indicate the outcomes of the workforce changes or did they rather indicate the outcomes of the overall integrated care intervention, as was the case in the studies? There are two arguments in support of the latter scenario. First, when asked about rather broad outcome categories that are not specifically related to workforce changes, the focus of the experts may have shifted from the workforce changes only to the integrated care intervention as a whole. For example, one respondent indicated comprehensive geriatric assessment as the integrated care intervention, and teamwork and provider training in geriatric care as the workforce changes as part of the overall integrated care intervention. But when asked about the outcomes of the workforce changes, the same respondent indicated that the geriatric assessment, instead of the teamwork or provider training, was appreciated highly, showing that the respondent referred to the outcomes of the overall integrated care intervention rather than the workforce changes. This discrepancy could also be related to a different understanding of the output (i.e. direct products of

program activities) as opposed to the outcomes (i.e. specific changes in program participants' behaviour, knowledge, skills, status and level of functioning) of an intervention [62]. Workforce changes may have produced specific direct outputs, but when asked about the more fundamental outcomes, the respondents may have referred to the overall intervention instead.

The second argument relates to the question whether it is even possible for the experts to know the outcomes of the workforce changes only. One could argue that the experts cannot possibly know which outcomes were due to the workforce changes because the workforce changes were implemented together with the other aspects of an integrated care intervention. Put differently, to measure the impact of workforce changes specifically, one would want to isolate them from the other components of an integrated care intervention, but, once isolated, the workforce changes alone would not constitute integrated care anymore. This, in turn, relates to the question whether the concept "workforce changes as part of an integrated care intervention" as was measured in the expert questionnaire, really exists. This is one of the main disadvantages of zooming into one aspect of a complex intervention only, namely that the demarcation line that one draws around this aspect creates a simplification of reality that is inherently artificial. However, as Valentijn argues, simplification does have considerable benefits as an analytical tool and may play an important role in developing more complex concepts in the long run that are much closer to reality [2]. Moreover, the respondents are experts of the interventions they describe and may be able to understand complex mechanisms linking workforce changes to specific outcomes. In doing so, it is possible that they have pointed us in relevant directions and towards what's most likely, even though one cannot be completely sure. The second approach to measuring outcomes is not without drawbacks either: measuring integrated care including workforce changes measures the outcomes of the whole intervention, which means that we do not know the role of the workforce changes in the interventions vis-à-vis the other components. But despite not knowing the exact role of the workforce changes in achieving the outcomes, we do know that they were part of it, and that, combined, they led to positive outcomes such as improved quality of care, patient satisfaction and staff satisfaction. In the end, both approaches may have measured the outcomes of integrated care interventions including workforce changes, rather than measuring the outcomes of workforce changes only. But this is what we set out to measure, namely the outcomes of a complex intervention.

Strengths and limitations

In addition to these considerations, this study is subject to several methodological limitations which should be taken into account. First, there is no commonly accepted definition of integrated care and the operationalisation of integrated care as at least two CCM components is neither perfect nor undisputed. However, this approach has been used previously in the international scientific literature and proven to be useful in this study for the assessment of interventions described in the studies as well as to explain consistently to the experts what we meant by integrated care. Second, we performed no quality assessment of the studies included in the literature review, mainly due to the difficulty of assessing studies with very varied methodological designs. However, given the exploratory nature of our study, it seemed more important to find as many relevant studies as possible rather than apply strict quality criteria. Third, we did not check whether the experts included in the study were really experts in the field of integrated chronic care. Instead, we relied on appropriate identification of experts by their

colleagues via the snowball method as well as self-exclusion. Self-exclusion did indeed take place by several experts who indicated that they were no expert in this specific area and therefore declined to complete the questionnaire. It should be noted that it took a considerable amount of time to complete the questionnaire, which leads us to assume that the topic must have been relevant to those experts who did complete the questionnaire. Moreover, the inclusion of appropriate experts was evidenced by the quality and detail of their answers. Finally, we did not distinguish between the output, outcomes or even impact (i.e. the fundamental intended or unintended change occurring in organizations, communities or systems as a result of program activities) of an intervention [62]. As mentioned above, this may have contributed to a better understanding of what has been achieved due to the workforce changes vis-à-vis the overall integrated care intervention.

This study also has several strengths. First, the study has a broad international scope by including data from 14 different countries. Moreover, while the included studies are mostly from countries such as the United States, United Kingdom and the Netherlands, which are often overrepresented in these types of studies [63], the interventions described by the experts were conducted in countries that are represented less often in research on integrated care such as Belgium, Spain, Estonia, Czech Republic, Greece and Norway. Second, our study combines two different methods of data collection. If we had only asked experts, we could not have been sure if their answers were accurate or possibly overstatements of what they felt were outcomes of the intervention. Similarly, if we had only looked at the published literature, our findings may have suffered from publication bias and a lack of the most recent, not yet published, scientific insights. This shows that triangulating results from different methods of data collection enhances the methodological quality of the study by contributing to the study's information-richness and providing a remedy to the different methods' respective weaknesses while at the same time enhancing their respective strengths [64, 65]. Third, our study represents a qualitative exploration of what is usually measured quantitatively, which is more suitable for exploratory research, especially when also paying attention to different methodological approaches [66]. Finally, our study includes many different integrated care interventions rather than zooming into only one. This is especially important given the lack of a common understanding of integrated care, as explained above.

Implications

The findings of this study underscore the importance of integrated care interventions including workforce changes which have been shown to lead to positive outcomes. This is not only promising for people with or at risk of chronic conditions, but also shows the relevance of the workforce for improving patient outcomes, as expressed in the Quadruple Aim [19]. However, in some cases, our findings also show negative outcomes of integrated care interventions including workforce changes. The question remains when and why interventions are successful and when and why they are not. We therefore recommend future research to pay specific attention to the barriers and facilitators influencing the implementation and thereby the outcomes of integrated care interventions including workforce changes. They may prove to be successful in experimental settings or pilot studies, but if the workforce is not able or willing to implement them in a real word setting, they are unlikely to succeed. Argued the other way around, this would mean that knowing which factors are conducive to successful implementation, or which factors need special attention, would increase the likelihood of implementing interventions

with a real world benefit for patients with chronic conditions as well as the health workforce caring for them. A good starting point might be approaches such as the evidence-based Workforce Change Checklist developed by Nancarrow et al. to guide workforce change projects [67]. As regards the practice setting, we recommend that the findings of our study be considered by managers and policymakers who might consider cutting costs at the expense of the very workforce that is needed to improve patient outcomes. Even though the health workforce represents one of the main determinants of health costs, this strategy may turn out to be detrimental to the success of integrated care interventions, and ultimately, achieving improved patient health and experiences in the long run.

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PART C

**Methodological tools for the comprehensive
evaluation of integrated care**



CHAPTER 11

Development of the COMIC Model for the comprehensive evaluation of integrated care interventions

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Abstract

Objective: To develop a model for the comprehensive evaluation of integrated care interventions that provides insights into when, why and how successful outcomes can be achieved.

Methods: A preliminary model was developed based on the CMO ("context + mechanism = outcome model") Model and further developed based on its application to a literature review, two case studies and an expert questionnaire. The COMIC Model for studying the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions assumes that an intervention is introduced using certain mechanisms (categorised according to the Chronic Care Model), which are met with particular context factors (described by barriers and facilitators and categorised according to the Implementation Model), which combined, contribute to specific outcomes (categorised by the WHO dimensions of quality of care).

Results: Application of the COMIC model to the literature review and expert questionnaires did not allow for statements to be made about the relationships between mechanisms, context and outcomes. Application to the two case studies made it possible to (1) comprehensively analyse the mechanisms, context and outcomes of the specific case, (2) to make the relationships between the mechanisms, context and outcomes within each case visible, and (3) to compare the two cases to each other in a systematic way that added value to the analysis.

Discussion: Using the COMIC Model makes it possible to comprehensively study the interplay of the mechanisms, context and outcomes of integrated care interventions and thereby provides insights into when, why and how integrated care contributes to improved outcomes.

Introduction

Finding sustainable approaches to managing the increasing demand for complex long-term care has become an urgent task for health systems around the globe. Currently, integrated care (IC) is seen as one of the most promising of these approaches by targeting the health care system, patient-provider relationships, care process design, communication infrastructures, community resources, and how care is delivered by health professionals [1-4]. In doing so, IC is expected to contribute to the Triple Aim, i.e. improved quality of care and health outcomes, better patient experiences, and increased cost effectiveness [5-9]. However, so far, findings have been mixed. Recent studies have shown IC to have contributed to reduced hospital (re-) admissions, adherence to treatment guidelines, lower caregiver stress, better patient experiences and quality of life [10-13]. But at the same time, mixed results or no improvements were found for mortality, hospitalisation, emergency department visits, medication adherence, patient satisfaction, emotional well-being, quality of life and cost-effectiveness [2, 4, 10, 12, 14-17].

It has been argued that effectiveness reviews and primary studies of the randomised controlled trial (RCT) variety, use a reductionist logic that is inappropriate for the evaluation of complex interventions such as IC [18-20]. In contrast to conceptually simple interventions (e.g. new drugs), complex interventions include multiple components, target multiple levels, contribute to multiple outcomes, and are generally implemented in complex systems [18, 19, 21]. By neglecting the context in which interventions are implemented, reductionist approaches fail to take these complexities into account and therefore typically result in inconsistent findings or the assertion that nothing works [19]. Moreover, even if results are significantly negative or positive, the methods used would not allow us to gain insights into whether this is due to certain active intervention components, interaction between different components, interaction between components and context factors, or context factors that act independently of the intervention. Yet this is precisely the information that is needed for targeted improvements and transfers of successful interventions to other settings [18-20, 22, 23]. Given the inconclusiveness of previous effectiveness reviews of IC as well as the methodological difficulties in evaluating complex interventions using reductionist approaches, it has been argued that rather than asking whether IC contributes to better outcomes, there should be a shift in focus towards understanding when, why and how some interventions do, while others do not [19, 20, 22, 24, 25].

Answering these types of questions requires a focus on the implementation of an intervention, including which type of intervention was implemented, how the setting in which the intervention was implemented affected its implementation, and which outcomes were achieved [18, 19, 26, 27]. While there have been numerous previous attempts to evaluate IC interventions holistically, there are currently no models to guide these types of comprehensive evaluations. This does not only impede a better understanding of the implementation of specific interventions, but also the comparison of findings across interventions. As a remedy, the objective of the current study is to develop a model for the comprehensive evaluation of IC interventions which guides the collection, analysis, interpretation and reporting of data. This model is expected to enable the systematic and detailed study of the

intervention type, setting, and outcomes of IC interventions, as well as the interplay of these elements, and thereby provide insights into when, why and how successful outcomes can be achieved.

Methods

We developed a preliminary model which was applied to and further developed based on three different types of studies previously conducted by us: a literature review [1, 28], two case studies [29] (L. Busetto, J. Kiselev, K.G. Luijckx, E. Steinhagen-Thiessen, H.J.M. Vrijhoef, unpublished) and an expert questionnaire [30] (L. Busetto, K.G. Luijckx, S. Calciolari, L.G. González Ortiz, H.J.M. Vrijhoef, unpublished). These insights were combined in the COMIC Model for studying the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions.

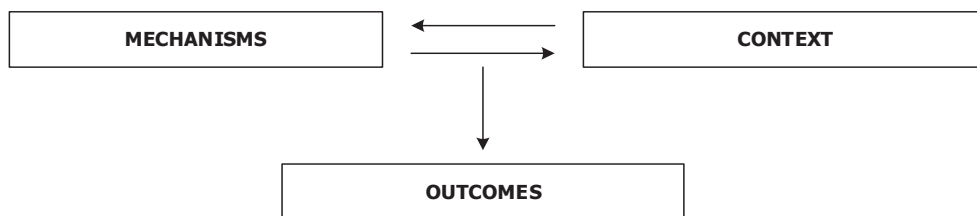
Terminology

In the following, we will use the term "element" when we refer to the different categories of the COMIC Model (i.e. mechanisms, context and outcomes), the term "components" to describe and categorise mechanisms, "factors" when we refer to the context (i.e. barriers and facilitators), and "dimensions" to describe outcome categories.

Preliminary model

The importance of the context in which interventions are implemented has been described most appropriately by Pawson and Tilley in their realist evaluation approach [27]. Their Context + Mechanism = Outcome Model (CMO Model) proposes that interventions only have successful outcomes when they introduce appropriate mechanisms in the appropriate social and cultural contexts. Given its holistic approach and frequent use in previous evaluation studies [31-35], we used the CMO Model as the basis for our own model. Our interpretation of the CMO Model assumes that an intervention is introduced using certain mechanisms, which are met with particular context factors, which combined, contribute to specific outcomes (Figure 1).

Figure 1: Relationship between mechanism, context and outcomes in the preliminary model



However, while the CMO Model provides guidance on which aspects should be taken into consideration when performing comprehensive evaluations, it does not offer, and there is currently no agreement on, the definition and operationalisation of its three elements [36, 37]. This is not only problematic for the consistent application of the model to the collection and analysis of empirical data, but also for the comparison of findings from different studies. We therefore added definitions and operationalisations of

the mechanisms, context and outcomes to our preliminary model. 'Mechanisms' were defined as the different components of IC interventions and categorised according to the Chronic Care Model (CCM) by Wagner [38]. The CCM assumes that improved chronic care delivery requires changes in six interrelated components: health system, self-management support, delivery system design, decision support, clinical information system and community [39]. The CCM was chosen because, as one of the most influential models for integrated chronic care delivery [7], it has been used in numerous studies on (integrated) chronic care [2, 4, 14, 40, 41], and informed healthcare redesign in various countries [7, 42-44]. We defined 'context' as the setting in which the mechanisms are brought into practice and described it by outlining the barriers and facilitators to change encountered in the implementation process. Barriers and facilitators were categorised using the Implementation Model (IM), which specifies six levels of healthcare at which barriers and facilitators to change can occur, namely innovation, individual professional, patient, social context, organisational context and economic and political context [45]. One of the distinctive features of the IM is that it encompasses a whole range of factors from inner local/organisational factors to outer national/regulatory factors [46, 47]. The IM was chosen because various previous studies have shown it to be a useful framework for the classification of barriers and facilitators to the implementation of healthcare innovations [48-52]. Outcomes were defined as the effects triggered by mechanisms and context, but were not yet linked to a specific model. As these effects may not equal the outcomes reported in traditional types of evaluation studies, we chose to study those outcomes that were indicated as such by respondents or reported in studies, before providing a more detailed operationalisation [18, 21].

Application of the preliminary model

To explore the usefulness of the preliminary model and to further develop it based on lessons learned from the application process, we applied it to three different types of studies: (1) a systematic literature review on the implementation of IC for people with type 2 diabetes, (2) two case studies on the implementation of integrated diabetes and geriatric care interventions, and (3) a qualitative expert questionnaire on the implementation of workforce changes within the scope of IC interventions. These three types of studies were not chosen at the outset of the development of the model, but were added as consecutive steps in an iterative process. Specifically, difficulties in applying the COMIC Model to the literature review led to the application of the model to the case studies, and the successful but relatively time-intensive application of the model to the case studies made us look for a faster route in the form of a qualitative expert questionnaire. These choices will be explained in more detail in the following sections.

Results

In the following sections, we provide short summaries of the studies conducted, explain how the preliminary model was used, and, if applicable, how it was extended or adapted.

Systematic review of the international literature

First, the preliminary model was used in a systematic review in which we examined 44 studies on the implementation of IC for people with type 2 diabetes. The search strategy, data extraction and data analysis used in this review, as well as a complete overview of our findings, are reported in detail elsewhere [1, 28]. We found that most interventions included all components of the CCM. Moreover, most barriers were related to the innovation and organisational context level and included problematic health IT systems, workflow changes due to the introduction of the IC intervention and logistical barriers relating to staff turnover or limited staff capacity. Most facilitators related to the innovation and social context level and included the availability of translations, health IT systems, involvement of staff in decision-making and planning, the ability to find committed staff and generate staff buy-in, good leadership and resource-sharing and cooperation. Regarding outcomes, improved patient, process and health service utilisation measures were reported.

We concluded that while the model made it possible to gather and classify detailed information on the separate elements of the model (i.e. the mechanism, context and outcomes), it was not possible to make statements about their interplay. This was mainly the case because there was not enough information on the same intervention types, context factors and outcome measures to allow for quantitative analysis [1, 28]. There were several options to move on from this point, for example to gather more information on the same intervention types, context factors and outcomes measures. However, we considered it relatively unlikely to come by enough data from a sufficient number of studies, as most studies do not report enough data, neither in terms of depth nor in terms of scope, as the literature review showed. Therefore, instead of exploring which data (and how much of it) would be needed to enable these types of quantitative analyses, we opted to move in the direction of qualitative research in order to understand the interplay between context, mechanisms and outcomes, rather than to quantify it. This qualitative approach via case study research is described in the next section.

Case studies of Dutch and German IC interventions

As a second step, we applied the preliminary model to two case studies of IC implementation. The first case study concerned the implementation of integrated diabetes care by two Dutch care groups [29]. Care groups are legal entities that establish contracts with health insurers and health professionals in order to coordinate the so-called 'chain' of chronic care from diagnosis to after-care [53]. The second case study was conducted on the implementation of an integrated geriatric care intervention at a German hospital where care is provided by a geriatric team whose members have weekly team meetings and perform comprehensive geriatric assessments (L. Busetto, J. Kiselev, K.G. Luijkx, E. Steinhagen-Thiessen, H.J.M. Vrijhoef, unpublished). Detailed descriptions of the data collection, analysis and interpretation as well as the complete results are reported elsewhere [29] (L. Busetto, J. Kiselev, K.G. Luijkx, E. Steinhagen-Thiessen, H.J.M. Vrijhoef, unpublished).

Mechanisms

We mapped the components of the IC interventions in the Dutch and German case to the six CCM components (Table 1). While the preliminary model as used in the literature review only focused on the core CCM components (i.e. self-management support, delivery system design, decision support and

clinical information system), in the case studies it became necessary to also add the two peripheral components (i.e. health system and community).

Table 1: Mechanisms of the IC intervention by CCM component

CCM component	Dutch case	German case
Health system	Care groups and bundled payment system	Early complex geriatric rehabilitation
Self-management support	Patient involvement	-
Delivery system design	Health professional cooperation and task substitution	Multidisciplinary cooperation
Decision support	Evidence-based care protocols	Comprehensive geriatric assessments
Clinical information system	Shared information system	-
Community	-	-

Notes: Dashes indicate that no examples of a specific category were found.

For example, under the health system component, both interventions involved complex funding frameworks. In the Dutch case, this referred to a nation-wide bundled payment system, in which health insurers and care groups negotiate one price for a whole diabetes care package per patient per year. Bundled payments are predetermined payments to healthcare providers that are related to the expected costs of a bundle of healthcare services [54]. In the German case, this referred to a specific reimbursement option (called “early complex geriatric rehabilitation”) within the German system of disease related groups. Under this option, geriatric hospitals can be eligible for financially advantageous reimbursements if they provide care according to certain criteria.

Context

For both cases, the barriers and facilitators to the implementation process were identified and mapped to the six levels of the IM. In the analysis of the German case study, the level “health system context” was added to describe the intermediate level between the organisation under study and the wider economic and political context. Furthermore, the level “economic and political context” was changed to “economic, political and legal context” to make it more explicit that legal or regulatory aspects are also covered. Table 2 presents one barrier per IM level to give an example of the findings.

Table 2: Barriers to the implementation of the IC interventions by IM level

IM level	Dutch case	German case
Innovation	Insufficient database integration	Problematic documentation system
Individual professional	Decreased earnings	-
Patient	Patients' insufficient expertise	Increasingly complex conditions
Social context	Resistance by general practitioner assistants	-
Organisational context	Too much care provided by practice nurses	High workload
Health system context	-	Lack of inter-organisational infrastructure
Economic, political and legal context	Financial disincentives	Administrative obligations

Notes: Dashes indicate that no examples of a specific category were found.

At the innovation level, the Dutch case reported insufficient database integration, while the German case reported problems with the documentation system. Dutch IC involves a shared clinical information system to which all health professionals have access. However, this system existed in parallel to other IT systems such as the general practitioners' information system and hospital systems, which meant that data had to be entered for each system separately. In the German case, a documentation system was in place in which assessments and the patients' progress had to be recorded. However, due to frequent breakdowns and a lack of necessary functionalities, the health professionals could not use it as an information system.

Outcomes

In the Dutch case, interviewees indicated improved communication and cooperation as positive outcomes of the IC interventions. However, as negative outcomes they indicated insufficient and unnecessary care provision and deteriorated preconditions for person-centred care in terms of a relatively standardised (as opposed to individualised) care product that each patient received. During the analysis of the German case study, an operationalisation of the outcomes was added to the model to bring more structure into the variety of outcomes reported and thereby enable comparisons across cases. Specifically, we used the six dimensions of quality of care as defined by the World Health Organization (WHO), namely effectiveness, efficiency, accessibility, patient-centeredness, equity and safety [55]. This operationalisation was chosen because it is in line with the six aims for improvement defined in the Institute of Medicine's (IOM) landmark report "Crossing the Quality Chasm" [56, 57]. We added (care provider and patient) satisfaction as an additional dimension. For all dimensions we aimed to extract qualitative "judgments" by the interview respondents. Table 3 shows some of the negative and positive outcomes of the implementation of the German IC intervention by quality of care dimension.

Table 3: Outcomes of the implementation of the German IC intervention by quality of care dimensions

Dimensions	Negative outcomes	Positive outcomes
Effectiveness	Less care provided to patients	Better understanding of colleagues' expertise
Efficiency	Overuse, underuse and misuse	Faster information exchange
Accessibility	-	-
Patient-centeredness	Less family involvement	Holistic view of the patient
Equity	-	-
Safety	Increased likelihood of adverse events or medical mistakes	Decreased likelihood of adverse events or medical mistakes
Satisfaction	Frustration among staff	Appreciation by staff

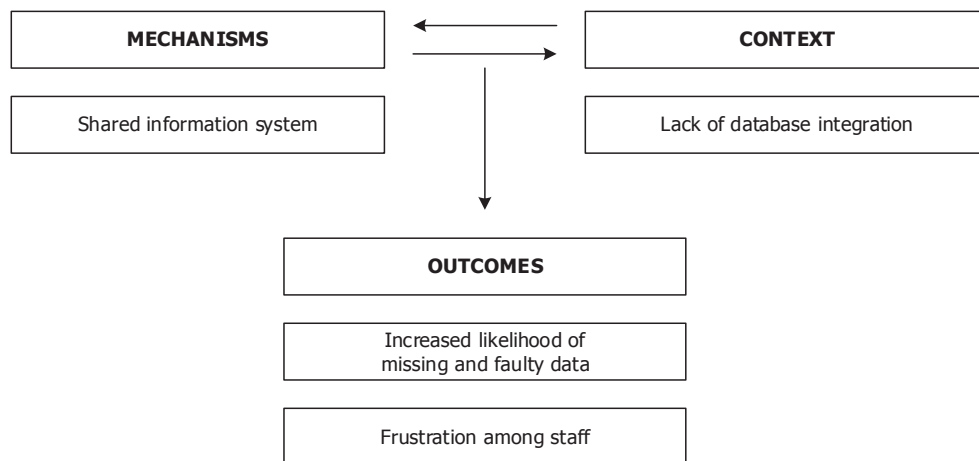
Notes: Dashes indicate that no examples of a specific category were found.

Both cases found instances of insufficient and unnecessary care provision, which is also referred to as overuse, underuse and misuse [58]. In the Dutch case, this was often referred to when stable diabetes patients had to undergo four routine check-ups per year even though they themselves as well as their health professionals felt that this was unnecessary. On the other hand, health professionals found that other types of care, such as consultations at the podiatrists' or pedicurists', were reduced to an almost unacceptable extent. In the German case, the funding system determined that in order to be eligible for reimbursement, each patient must receive a minimum number of therapy sessions. However, the health professionals complained that patients with a limited revalidation potential received the same number of therapy sessions as those with a more promising potential.

Relationship between mechanisms, context and outcomes

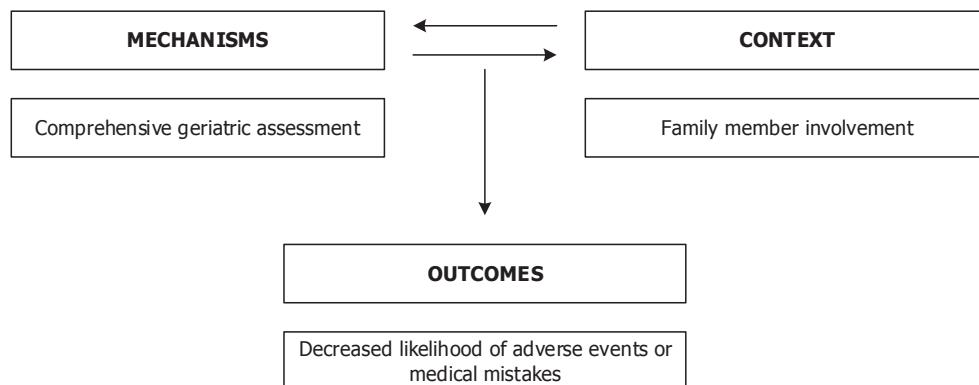
Examples of the interplay between mechanisms, context and outcomes in the Dutch and German case studies are shown in Figure 2 and 3, respectively. The Dutch shared information system (mechanism) was implemented, but not integrated with other databases (context). This meant that data had to be entered into more than one system, which led to an increased likelihood of missing and faulty data and frustration among staff (outcome). This example shows that the shared information system in itself did not result in staff dissatisfaction, but the fact that it was not integrated with other databases did. Whereas traditional approaches to studying intervention effectiveness might only have found worsened outcomes and concluded that the shared information system did not work, our approach reveals the "true culprit" and thereby a direction to identifying a solution. One could even argue that it would not have mattered how good an information system was implemented, it would not have resulted in improved outcomes with the barrier of lacking database integration in place. In this sense, the COMIC Model supports the process of deduction during data analysis. In particular, by structuring complex information, it becomes easier to recognise interrelationships between mechanisms, context factors and outcomes. Moreover, even before that, using the COMIC Model helps to explicitly gather data on the interplay between these factors. If not asked for, these relationships cannot be discovered later on in the analysis.

Figure 2: Example of the interplay between the mechanisms, context and outcomes in the Dutch case



In the German case, we found that comprehensive geriatric assessments (mechanism) were complemented by information provided by family members (context), which contributed to a decreased likelihood of adverse events or medical mistakes (outcome). Again, it was not only the intervention itself that contributed to improved outcomes, but its combination with a facilitator. However, traditional approaches would have only focused on the positive outcomes, concluded that the intervention was successful and implemented the intervention in different settings, where family members may not be asked for additional information, and positive outcomes might not have been achieved.

Figure 3: Example of the interplay between the mechanisms, context and outcomes in the German case



Qualitative expert questionnaires on workforce changes in IC interventions

As a third step, we applied the preliminary model to a qualitative expert questionnaire on workforce changes implemented in IC interventions [30]. We aimed to explore whether there was a “short-cut” to the detail of the above case study analyses. As mentioned above, the literature review showed that it

was not possible to use our model for aggregation of findings from studies that were conducted without a CMO approach in their designs. We wanted to see whether this would change when specifically asking respondents about all elements of the preliminary model. We did not use the detailed operationalisations of the mechanisms, context and outcomes, but the logic of the preliminary model (Figure 1), due to the slight shift in focus from IC interventions in general to workforce changes in IC interventions. Moreover, given the exploratory nature of the study, we wanted the data collection and analysis to remain relatively unrestricted by detailed models and categories. We asked experts to describe an IC intervention they were familiar with as well as the workforce changes included in this intervention (mechanisms), the barriers and facilitators to their implementation (context) as well as their outcomes. Details of the data collection and analysis are reported elsewhere [30] (L. Busetto, K.G. Luijkx, S. Calciolari, L.G. González Ortiz, H.J.M. Vrijhoef, unpublished).

Instead of a rich description of one case, we now had short descriptions of the mechanisms, context and outcomes for 25 cases from 12 different countries, including Belgium (N=8), Spain (N=5), Estonia (N=2), Italy (N=2), the Netherlands (N=2), the United Kingdom (N=2), Australia (N=1), Czech Republic (N=1), Germany (N=1), Greece (N=1), Norway (N=1), and Switzerland (N=1). The interventions were implemented for target groups with any type of chronic/long-term illnesses (N=5), diabetes (N=5), COPD (N=4), cardiovascular disease (N=2), and all patients (N=2) [30]. The information from these descriptions could be aggregated for each element (i.e. mechanisms, context and outcomes) separately. However, we were not able to make statements about the relationships between these elements. As expected, we did not have enough information to allow for quantitative analysis. However, this time we had expected to be able to link the mechanisms, context and outcomes to each other qualitatively, based on the information provided by the experts. But given the general lack of detail of the information provided, as well as lack of detail on the links between the separate elements, it was not possible to create the types of clusters as we did for the case studies. On the one hand this showed us that, instead of asking three consecutive but separate questions about the mechanisms, context and outcomes, we should have explicitly asked about the interplay of these elements. On the other hand, we suspected that even if we had done so, we would probably still not have had enough information, nor the necessary understanding of the background story. Overall, we concluded that aggregating less detailed qualitative information even with a specific focus on mechanisms, context and outcomes, was not a viable short-cut for the information-richness of case study analyses.

COMIC Model

The above findings and insights were combined into the COMIC Model to study the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions (Figure 4). Data collection should take place by means of semi-structured interviews, as this type of in-depth qualitative method of data collection does not separate the collection of information on mechanisms, context and outcomes. Instead, it allows for the elicitation of information on the interplay, relationships and links between these elements. Methods of data collection that do extract information separately on the different elements of the COMIC Model, such as literature reviews and questionnaires, should not be used, as they do not provide information on the interplay between the elements. In future research, it can be explored whether focus groups and

observations are viable alternative options as they do not seem to necessitate the separate collection of information and therefore seem to be promising alternatives. If not offered by the respondents themselves, information should be elicited specifically on the interplay between the mechanisms, context and outcomes, as perceived by the respondents. We strongly recommend the inclusion of health practitioners, managers and patients as interviewees. If applicable, financiers such as health insurers, or policy-makers may be relevant informants as well. Data should be analysed using appropriate qualitative analysis techniques, including co-coding by at least two independent coders and making use of member checks [59-61]. Findings may be visualised as clusters of mechanisms, context factors and outcomes (see Figure 2 and 3), but should always be explained using detailed descriptions.

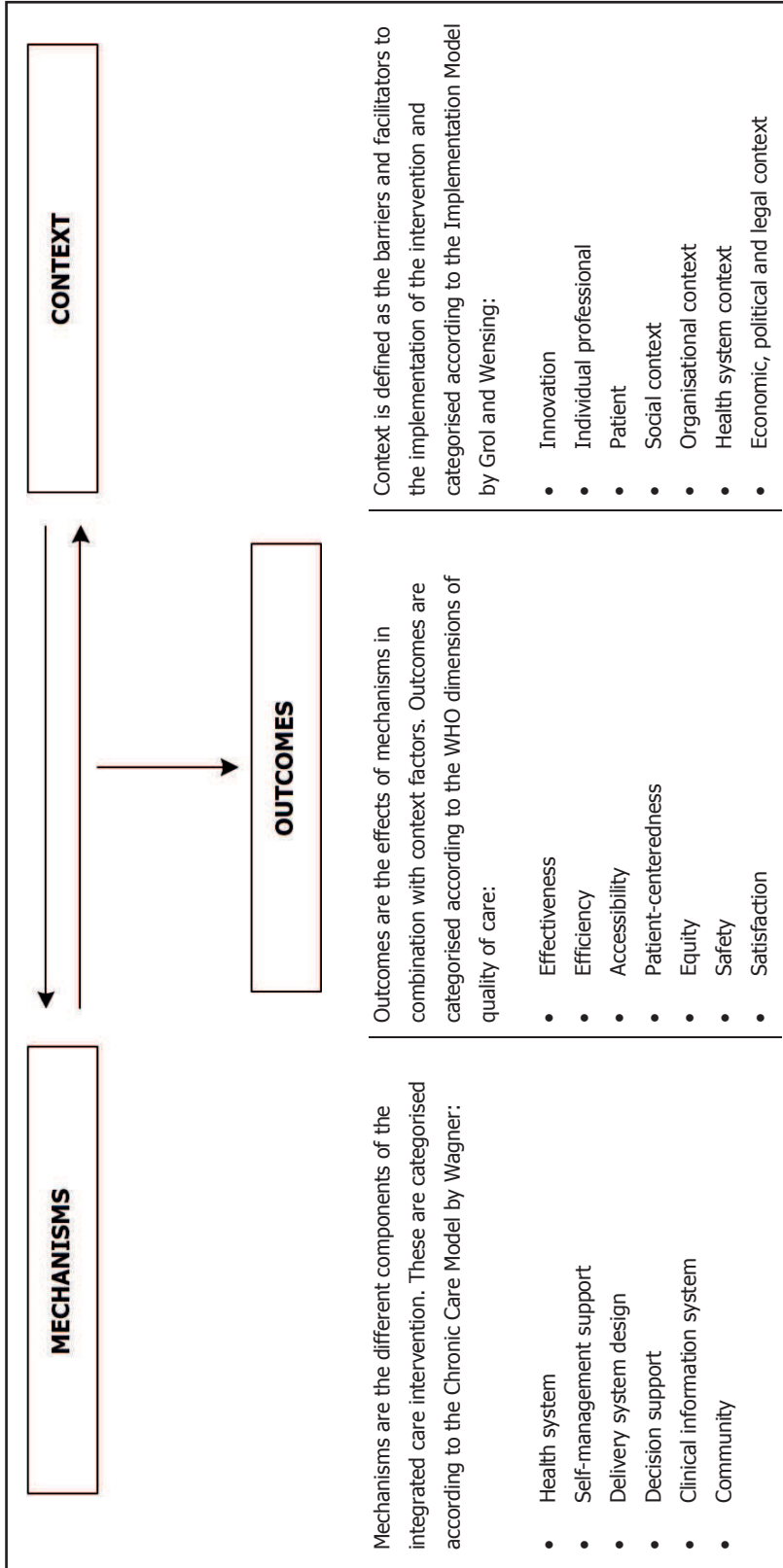
Discussion

In this study, we described the development of the COMIC Model as well as the first steps towards its validation. The purpose of the COMIC Model is to systematically and comprehensively study the different intervention types, settings, and outcomes of integrated chronic care interventions, as well as the interplay of these elements, and thereby allows for comprehensive evaluations of when, why and how IC can contribute to successful outcomes. The preliminary version of the model was based on the CMO Model, with detailed operationalisations of the mechanisms, context and outcomes added during a process of applications to different types of studies, including a systematic literature review, two detailed case studies and a qualitative expert questionnaire.

The systematic review revealed relevant information on the separate elements of the preliminary model (mechanisms, context and outcomes) but no statements could be made about the relationships between these elements. The two case studies showed the full potential of the model which made it possible to (1) comprehensively analyse the mechanisms, context and outcomes of the specific case, (2) to make the relationships between the mechanisms, context and outcomes within each case visible, and (3) to compare the two cases to each other in a systematic way that added value to the analysis. The application of the model to aggregated findings from a qualitative expert questionnaire showed the same limitation as the literature review, namely that these types of aggregate studies do not lend themselves to the examination of the interplay between the mechanisms, context and outcomes. In this sense, they are not viable short-cuts for detailed case study analyses.

We are aware of other comprehensive models that support complex healthcare improvement, one of which is the Behaviour Change Ball (BCB), which is also concerned with IC and visualises the complex relationships between the elements that should be taken into account in the development and implementation of integrated public health policies [62]. However, as a tool intended to guide the development of interventions, it is concerned with the situation before implementation, as opposed to the COMIC Model which is concerned with the situation after implementation. The fact that the BCB guides the development of interventions also shows that it is a prescriptive model that indicates which steps should be taken and which actions are more desirable than others [47].

Figure 4: COMIC Model: Context, Outcomes and Mechanisms of Integrated Care interventions



Notes: Based on the CMO Model by Pawson and Tilley [27], Chronic Care Model by Wagner [38], Implementation Model by Grol and Wensing [45], and the WHO dimensions of quality of care [55].

The COMIC Model, on the other hand, does not in itself propose “what works” but makes it possible for people involved in the implementation of IC to find the answer to what works, when and why themselves. Since the COMIC Model supports comprehensive and explicit descriptions of how specific context factors shaped the implementation of an intervention, evaluations conducted in one setting are likely to also provide lessons learned that are of added value to other organisations in other settings.

Another relevant approach is the recently developed Monitoring and Assessment Framework for the European Innovation Partners on Active and Healthy Ageing (MAFEIP), which is a web-based tool to estimate the health and economic outcomes of innovations in the health care sector, including integrated care interventions [63]. Given its explicitly European scope, the tool takes into account contextual variation in terms of population, intervention and assessment methods. However, the tool consists of a quantitative measurement of effects on pre-specified outcome measures or indicators, rather than aiming at a profound understanding of why these outcomes are achieved. Using the terminology introduced earlier, the MAFEIP tool measures the what, while the COMIC Model measures the when, why and how – which, on a side note, would make a combination of both these approaches an especially interesting case.

A third approach to assessing healthcare improvement concerns the so-called Logic Models, which are visual representations of how an intervention is expected to lead to desired outcomes by specifying the paths between input, intervention components, activities, outputs, outcomes and ultimate outcomes [64, 65]. While Logic Models have been applied to various areas of healthcare [65-68], they were not specifically developed for this purpose. More importantly, while Logical Models specify context factors perceived as relevant to the pathways, these are not explicitly linked to the intervention types and outcomes. This means that their effect on the different intervention components, and how this influences outcomes achieved, is not described. It is, maybe above all else, this ability to extract and visualise how the interaction between context and intervention shapes the achievement of certain outcomes that sets the COMIC Model apart from previous approaches to assessing the results of health care improvement efforts.

Limitations and strengths

Our study is subject to several limitations. First, our definition of mechanisms is different from the original definition by Pawson and Tilley, in which mechanisms are hidden and do not equal the intervention itself [27, 36]. However, there is a huge variation in interpretation of the concept of mechanisms [36], and even the definitions and explanations offered by Pawson and Tilley themselves are not always clear-cut [37]. We found that operationalising mechanisms as different intervention components makes them more tangible and thereby easier to observe, measure and describe. Second, our definition of context is different from the original definition or the general use in the international literature, where context is usually described as a static a priori setting in which the intervention is implemented [18, 27]. We, on the other hand, describe the barriers and facilitators encountered during the implementation and execution of the intervention in practice. We assume that if static a priori factors are indeed relevant, they will hinder or further the implementation and therefore be considered as barriers and facilitators in our approach. Third, there was no involvement of patients in the

development of the model. This should be remedied in future applications which must include patient interviews along with practitioner and other stakeholder interviews. Finally, despite its comprehensiveness, the COMIC Model is still a simplification that often does not realistically reflect the complexities and chaos of the real world. It also presupposes that all factors fit one exact category while in reality they may fit more than one and it is just a question of choosing one over the other. For example, the lack of integration between the different patient databases we described as a barrier in the Dutch case, could also have been described as part of the intervention. After all, connectivity to other systems can be seen as an IT system feature and therefore as part of the intervention. While this is a viable option, we understood the lack of integration not only as an inner technical issue, but an outside issue that characterised other databases as much as the specific database that was part of the intervention. What we want to stress is that the COMIC Model is a description that tries to approximate reality in a way that makes it more comprehensible, but it cannot capture reality as is.

Our study is also characterised by several strengths. First, the COMIC model is embedded in four robust and widely-used theoretical models. The CMO Model makes it possible to look at the context, mechanisms and outcomes of IC as separate elements as well as a complex, collective web of inter-relationships. The CCM helps to identify and describe IC interventions despite the lack of a common definition. With the IM a diverse set of reported barriers and facilitators can be categorised and analysed spanning the whole range of inner local/organisational and outer national/regulatory factors. The WHO dimensions of quality of care reflect a global consensus on the areas of improvement that healthcare innovations should aim at. Second, the preliminary model was used in three different types of studies and further developed based on the insights gained. It therefore holds the potential to become not only a theory- but also an evidence-based model. Moreover, the repeated use of the model for different chronic conditions and health systems means that it was elevated from a highly context-specific model to one with more generic applicability. Finally, the COMIC Model was specifically developed for the healthcare setting and IC interventions. While this is indeed a strength of the model, it should also be pointed out that the connection of the COMIC Model to IC is anchored only in the operationalisation of the mechanisms. The operationalisations of context and outcomes are applicable to healthcare in general. This means that if the operationalisation of mechanisms were to be replaced by a different one (e.g. for acute emergency care), the COMIC Model could also be applied to other areas of healthcare delivery in the future.

Implications

By providing guidance on how to conduct comprehensive evaluations, the COMIC Model supports the shift in the academic community from assessing whether an intervention works, towards evaluating when, why and how interventions can contribute to improved outcomes. Moreover, we expect the COMIC Model to contribute to more systematic and consistent evaluations of IC interventions and thereby improved comparability of findings across different interventions or studies using the COMIC methodology. We also expect the COMIC Model to contribute to improved efficiency at the organisational level by enabling a better understanding of the ways in which an intervention was (un)successful and, based on these insights, the improvement of existing interventions instead of incurring implementation costs for new interventions. These insights can also support organisations in

their reporting towards financiers. While this study has outlined the first applications of the COMIC Model to different types of studies and research methodologies, further validation is needed. On the one hand, it is necessary to conduct more studies using similar research methodologies as the ones we used in this study and for which we concluded that they were not a good match for the COMIC Model. This is necessary in order to find out whether there is really a problem with the fit between the model and the methodology, rather than the model and the methodology as we used it in our specific study. On the other hand, it would be interesting to see whether it is possible to apply the COMIC Model to research methodologies other than the ones we have used so far, including qualitative methodologies such as focus groups or (participatory) observation, but also innovative quantitative approaches such as big data. In conclusion, the COMIC Model is expected to be of relevance to practitioners and patients involved in the delivery, implementation and receipt of integrated health services. These user groups experience the enormous complexity of health service innovations in their daily professional and personal lives. The COMIC Model can be an important supporting tool to structure this complexity and thereby make it manageable. However, in the form in which it is presented here, the COMIC Model is mainly targeted at scientists and therefore requires translation to a practice tool to be used by practitioners and patients in their own practice setting. Future research is needed to explore how a practice version of the COMIC Model can be made more accessible to practitioners and patients, for example by using appropriate language, including relatable examples and adopting a different format than a scientific publication.

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CHAPTER 12

Advancing integrated care and its evaluation by means of a universal typology

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Key messages

- Rather than agreeing on one definition of integrated care, a universal typology of integrated care interventions should be developed to enable the comparison of interventions that are based on different understandings of integrated care.
- This universal typology should combine rankable and intangible components with unrankable and intangible sub-components, and be conceptually sound and flexible.
- The content of the typology should be developed by an international consortium of relevant stakeholders.

Many health systems have endorsed integrated care in response to an increasing demand for complex long-term care. However, while there seems to be an almost universal consensus on expecting that integrated care will contribute to improved population health, patient experiences and cost-efficiency, there is a huge variation in opinions about what integrated care actually is or should be, often depending on the specific research focus, cultural or professional backgrounds, or the timing of the research. For example, in the United Kingdom the so-called integrated care pilots concern the integration of health and social care services [1], whereas the so-called vanguard sites target integrated primary and acute care systems, enhanced health in care homes, and multispecialty community provider systems [2]. Other examples include population health management pilots in the Netherlands [3], selective health insurance contracts for providers from different sectors in the German health system [4], and next generation accountable care organisations in the United States [5]. We argue that rather than aiming for agreement on one definition of integrated care, which is unlikely, we are in need of a typology that allows for the description of all of these different interventions that are considered integrated care by different stakeholder groups, while respecting local colour. This would enable the comparison and aggregation of findings from a diverse set of experiences, which is a necessary step to move integrated care and its evaluation forward.

A brief history of existing typologies

There have been many attempts at taxonomies or typologies of integrated care in the literature whereby authors used different labels to refer to the different types or components of integrated care interventions. A commonly used label is type of integration which is, for example, used by Shaw et al. to distinguish between systemic, normative, organisational, administrative, and clinical integration [6]. Valentijn et al. use a similar distinction (i.e. system, organisational, professional, clinical, functional, and normative integration) but refer to it as dimensions of integration [7]. So do Rosen et al. by distinguishing between clinical, informational, organisational, financial, administrative, and normative integration, but they use the label groups of integrative processes [8]. Van der Klauw et al. use the label objectives of integrated care to distinguish between functional, organisational, professional, and service/clinical integration [9]. Lloyd & Wait use the same distinction but refer to it as levels (at which integration can occur) [10]. The label level is also used to distinguish between linkage, coordination, and full integration [11], which has also been referred to as degree [12, 13] or type of integration [14]. The label breadth has been used to refer to vertical, horizontal, and sometimes virtual integration [12, 15], a distinction that has also been referred to as form of integration [14]. Other labels include (but are not limited to) processes of integration (cultural, social, structural, systemic) [12], key elements of integrated care (horizontal, vertical, system, organisational, professional, clinical, functional, and normative integration)[7], perspectives of integrated healthcare delivery (patient, organisational and management, logistic, policy, economic, clinical practice, and public health) [14], means of integration (joint planning, training, decision making, instrumentation, information systems, purchasing, screening and referral, care planning, benefit coverage, service delivery, monitoring, and feedback) [11], concepts of integration (virtual, vertical, horizontal, functional, clinical, and physician) [16], models of integration (system level, program/service level, progressive, and sequential) [16], and mechanisms of integration (degree, patient-centeredness, and normative) [9].

Typologies of integrated care can be typologised themselves according to the rankability and tangibility of their components. Tangible components are empirically measurable or implementable in practice (e.g. multidisciplinary protocols), as opposed to intangible components which are theory-based, non-empirical or not directly implementable in practice (e.g. system integration). Rankable components can be ranked in a meaningful way (e.g. from less integration to more integration or from the micro to the macro level), as opposed to unrankable components for which this is not possible (e.g. vertical and horizontal integration). For example, Leutz described an intangible and rankable typology by describing the three theoretical concepts linkage, coordination and full integration representing an increasing degree of integration along a continuum [11]. The distinction between real and virtual integration [13] represents an example of a typology whose components are intangible and unrankable. Lloyd & Wait provide an example of a tangible and unrankable typology by describing five models of integration including shared information among professionals from different sectors, standardised communication protocols and formats, single assessment processes incorporating multi-disciplinary assessment, defined pathways of care and single access points to care [10]. There are also more comprehensive typologies such as the ones put forward by Kodner and Spreeuwenberg [17] and Valentijn et al. [18] that combine intangible and rankable components with tangible and unrankable sub-components.

Using a specific typology generally reflects a specific understanding of integrated care as well as an intention to describe an intervention that fits this understanding. For example, if we want to compare whether one health system is less or more integrated than another, we would choose a typology that allows for rankability. In that case, a distinction between linkage, coordination and full integration would be more useful than one between horizontal and vertical integration. If we want to compare a national bundled payment system to the cooperation between two health care provider organisations, and to multidisciplinary geriatric assessments at a hospital ward, we would need a typology that at least describes the system, inter-organisational and intra-organisational level. However, if we want to compare three different multidisciplinary geriatric assessment interventions to each other, the distinction between the system, inter-organisational and intra-organisational level would be less useful because all three interventions act at the same level and no useful distinctions can be made to inform the comparison. In this case, we would need a more detailed typology for the intra-organisational level that would let us describe more tangible components such as whether standardised communication protocols or single access points to care have been used.

Developing a universal typology of integrated care interventions

These considerations provide insights into the usability of a specific typology for a specific type of intervention or evaluation purpose. However, if we choose typologies according to the type of intervention we want to describe, we cannot compare or aggregate findings from studies describing different types of integrated care, precisely because they use different typologies. As with the discussion about the definition of integrated care, choosing “the best” of existing typologies is not worthwhile, not the least because the former choice will probably inform the latter. We do not argue in favour of discarding existing typologies such as the ones described above, but rather suggest that a

combination of their advantages can be used as a basis to inform a typology that enables the description of the versions of integrated care that they are able to describe and that is thereby able to encompass the diverse definitions of integrated care currently in use.

We aim for a typology of integrated care interventions that enables the description of them all. Such a typology should have the following attributes. First, the main components should be rankable from the macro to the micro level in order to have a meaningful ordering principle that reflects the level at which an intervention is implemented. The macro level should reflect the system (or national/policy/legislative/regulatory) level and the micro level should reflect the level of the patient (or person at risk of illness or in need of care). As mentioned above, it is also possible for a typology to be rankable from less to more integration, but this option should be explored with caution, given that the typology should enable the comparison of a diverse set of interventions, for which more or less integration might hold different meanings. Second, the components should be intangible, as these components are often theory-based and can therefore make a typology more theoretically robust. For example, they could be based on the Chronic Care Model, which specifies areas for improvement for chronic illness care [19]. Moreover, conceptual typologies tend to be more encompassing because they cover all categories that are theoretically relevant instead of only those that can be or were observed in practice. For example, it is apparent that when one describes horizontal integration, there should also be the conceptual opposite, namely vertical integration, which is not as apparent for non-conceptual examples such as multidisciplinary teams or feedback. This will increase the likelihood that all relevant levels between the macro and micro level are included in the typology. Third, these intangible and rankable main components should be operationalised into or include examples of tangible sub-components or sub-categories as this makes it easier to apply the typology to practice examples of integrated care interventions. For example, it is easier to determine whether an intervention includes evidence-based guidelines than whether it concerns functional integration. Fourth, these sub-components should be unrankable because otherwise it would not be possible to list all the tangible examples observed in practice. Fifth, the typology should be conceptually sound, that is, not include context factors or intended outcomes as intervention components. For example, 'client satisfaction' or 'reliable behaviour' might be goals or factors that, if present, would facilitate implementation, but they do not constitute specific activities that are part of an intervention. If we want to conduct comprehensive evaluations that take into account how the context in which an intervention is implemented affects the outcomes achieved, we need to be clear about what is what. Sixth, the typology should be flexible enough to allow for new sub-components to be added in case new approaches or technologies are developed.

Moving forward

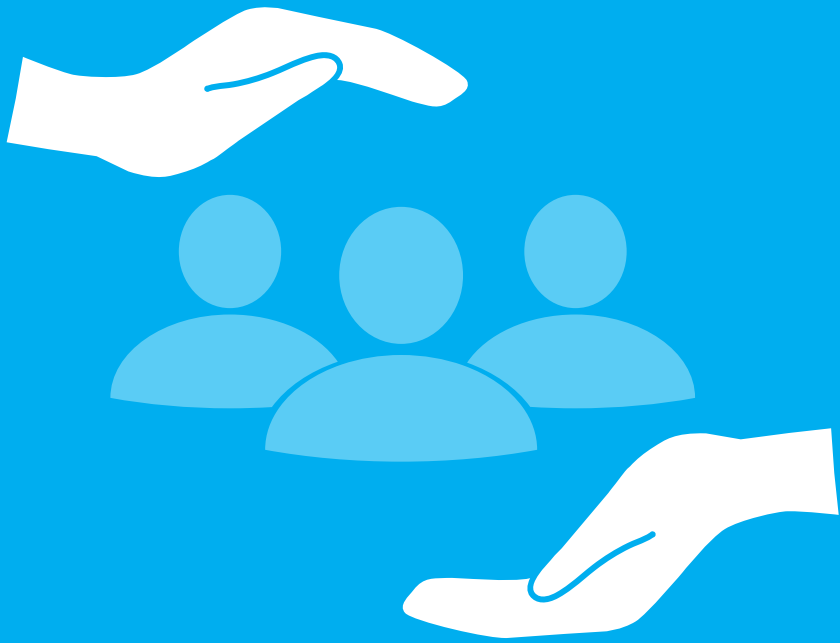
We have argued for the need to develop a typology that encompasses the variation in definitions of and shapes and sizes in which integrated care appears, rather than trying to find a definitive answer to what integrated care is or should be. We believe this to be a necessary tool to make integrated care interventions and their components observable, identifiable, measurable and therefore comparable. We have outlined the main characteristics such a typology should exhibit, which mainly pertain to the form

of the typology. The content of the typology should be developed and validated in an international effort spanning different countries, cultures, health systems, professions and life experiences. A typology in itself is not an endpoint, but should be incorporated into more appropriate and comprehensive research designs which take into account the context of an intervention and its influence on outcomes achieved, so as to arrive at targeted recommendations for improvement, that will hopefully indeed contribute to improved population health, patient experiences and cost-efficiency. Given the early stage of large scale evaluations of integrated care in various countries, we believe that this is the moment to join forces.

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CHAPTER 13

GENERAL DISCUSSION

Background

Integrated care is seen as one of the most promising approaches to providing appropriate care to people with (multiple) chronic conditions. There are great expectations regarding the outcomes integrated care is supposed to achieve, including improved quality of care and health outcomes, better patient experiences and increased cost efficiency, representing the three pillars of the Triple Aim. However, so far, findings have been mixed, with some studies indicating improved outcomes [1-4] and others pointing towards mixed evidence or no improvements [1, 3, 5-10]. It has been argued that effectiveness reviews, which have a reductionist focus on outcomes only, are inappropriate for the evaluation of complex interventions such as integrated care [11-13]. Therefore, rather than focussing on whether integrated care contributes to better outcomes, we should focus on trying to understand when, why and how some interventions do, while others do not [11, 14-17]. This requires a focus on the implementation of an intervention, including which type of intervention was implemented, how the setting in which the intervention was implemented affected its implementation, and which outcomes were achieved [11, 18, 19]. We used a broad understanding of implementation that spans the initial implementation of the intervention as well as the execution of the intervention from that period on [13, 20]. The objective of this dissertation was to answer the question:

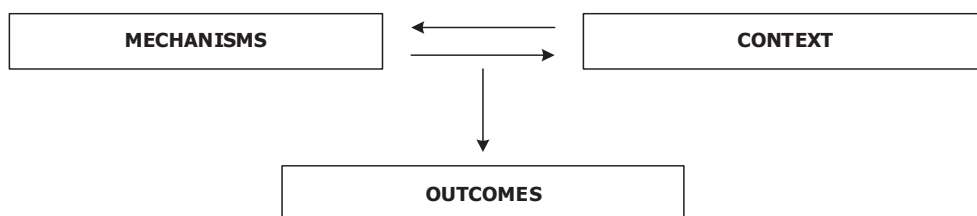
How is integrated care implemented and to which outcomes does it contribute?

We approached this question from two different angles. In Part A of the dissertation, we studied the implementation of integrated care interventions for two different (groups of) chronic conditions, namely type 2 diabetes and geriatric conditions. In Part B, we studied a specific aspect of integrated care, namely workforce changes, implemented as part of integrated care interventions. In both cases, we used the Context + Mechanisms = Outcomes (CMO) Model as an umbrella framework for the collection, analysis, interpretation and reporting of data. The CMO Model postulates that interventions only have successful outcomes when they introduce appropriate mechanisms in the appropriate social and cultural contexts [19]. However, throughout the research process it became clear that the CMO Model in itself was not sufficient, mainly due to a lack of clear definitions and operationalisations of its three elements, as well as a missing explicit link between the CMO Model and integrated care [21, 22].

In Part C of the dissertation, we therefore aimed to develop methodological tools to support comprehensive evaluations of when, why and how integrated care interventions can contribute to improved outcomes. This process started with a preliminary model, based on the CMO Model, that was further developed and adapted based on its application to the studies conducted in Part A and B. The preliminary model assumed that when mechanisms are introduced, they are met with certain context factors, which combined, contribute to certain outcomes (Figure 1). Mechanisms were defined as intervention types and categorised as Chronic Care Model (CCM) components [23]; context was

described as barriers and facilitators to the implementation of the mechanisms and categorised according to the Implementation Model [24]; and outcomes were defined as effects triggered by mechanisms and context, but not yet linked to a specific model. We aimed to further develop this preliminary model into a model to support comprehensive evaluations of integrated care interventions by providing insights into when, why and how successful outcomes can be achieved. Furthermore, given the lack of consensus on one definition of integrated care, we aimed to start the discussion about the necessity of a universal typology of integrated care interventions. The aim of such a typology would be to allow for systematic and consistent descriptions of integrated care interventions despite the lack of a common definition, and thereby allow for comparisons of different types of interventions.

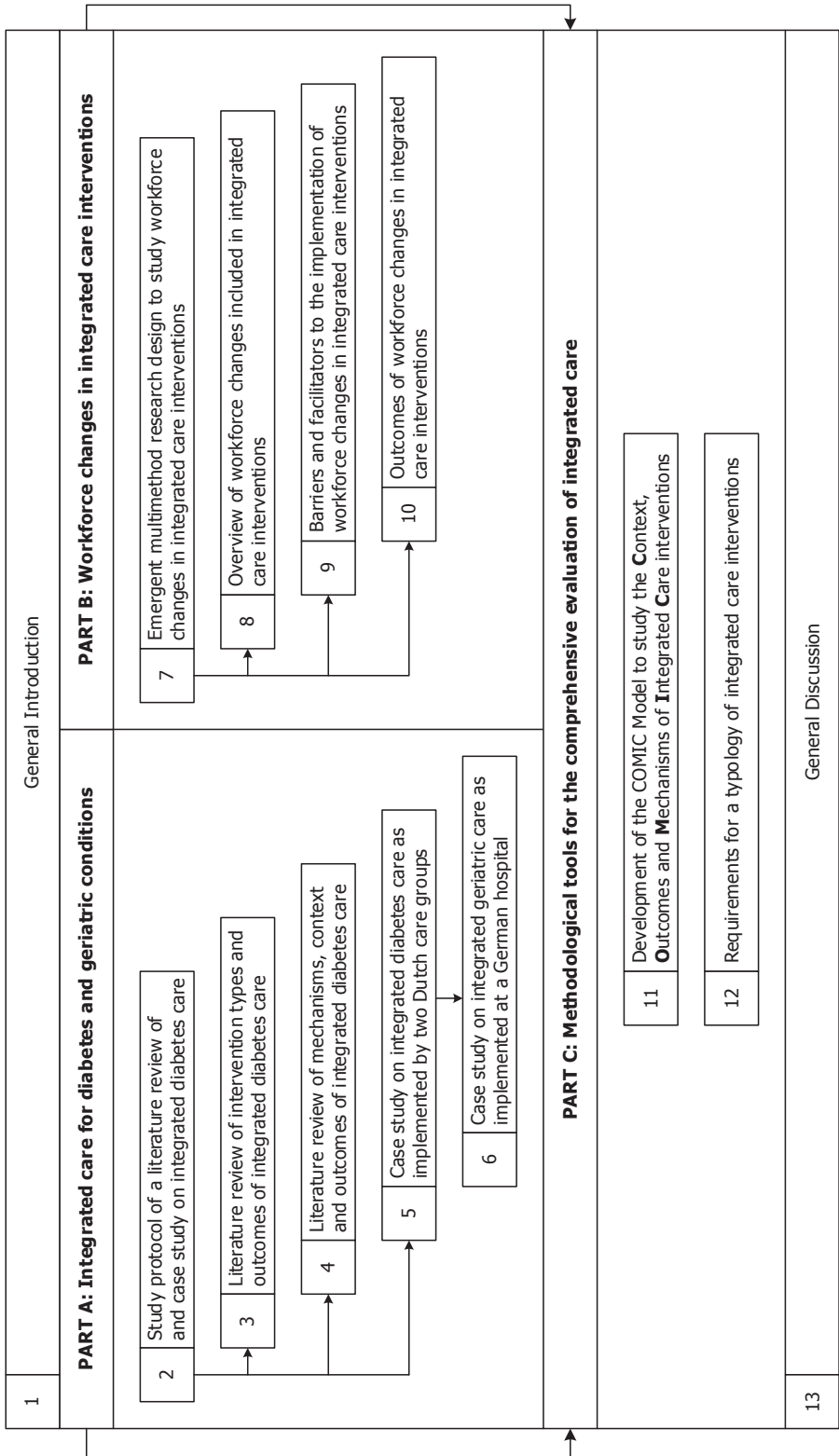
Figure 1: Interplay between mechanisms, context and outcomes in the preliminary model



The different studies included in this dissertation are summarised in Figure 2. The studies are numbered according to the respective chapters of the thesis in which they are presented, starting with the General Introduction in Chapter 1 and ending with this General Discussion in Chapter 13. Arrows indicate that studies are based on insights presented or methodologies developed in previous studies.

We first present the interpretation of main findings from Part A, B, and C of the dissertation and discuss the modifications that were made to the preliminary model throughout this process. We will then outline the limitations and strengths of the dissertation and provide 10 recommendations for research, policy and practice. We will end with a conclusion.

Figure 2: Overview of the dissertation



General Discussion

13

Interpretation of main findings

Part A: Integrated care for diabetes and geriatric conditions

In Part A, we studied the implementation of integrated care interventions for diabetes and geriatric conditions. To this purpose, we applied a convergent parallel mixed methods research design (Chapter 2), including a systematic review of the international literature on the implementation of integrated care for type 2 diabetes (Chapter 3 and 4) as well as a case study on two Dutch best practices on integrated care for type 2 diabetes in the primary care setting (Chapter 5). A second case study was conducted on the implementation of integrated geriatric care at a German geriatric hospital (Chapter 6). Forty-four studies were included in the literature review. The Dutch case study was based on 26 interviews with care group staff, care purchasers and health professionals involved in the provision of diabetes care, including general practitioners, internists, practice nurses, diabetes nurse specialists, optometrists, dieticians, podiatrists, pedicurists and pharmacists. For the German case study, 15 interviews were conducted with multidisciplinary team members involved in the provision of integrated geriatric care, including medical doctors, nurses, occupational therapists, neuropsychologists and physical therapists. In the following, we discuss the mechanisms, context and outcomes of integrated diabetes and geriatric care based on the literature review and the two case studies.

Mechanisms of integrated care for diabetes and geriatric conditions

We mostly found interventions that included three or more CCM components, indicating the complexity or multi-facetedness of integrated care interventions. Specifically, most studies selected for the literature review included three or four CCM components, the Dutch case was characterised by five CCM components, and the German case by three. There were differences regarding what exactly the CCM components entailed. The health system component was included in both case studies. In the Dutch case, it included the organisation of integrated care via care groups and the funding via a national bundled payment system. In the German case, it included a specific reimbursement option for geriatric patients in need of short-term acute care. The delivery system design component, which was found in the literature review and both case studies, was mostly characterised by multidisciplinary cooperation, team-based care provision and task substitution. Decision support, which was also found in the literature review and both case studies, included provider education, the use of evidence based guidelines or protocols and comprehensive geriatric assessments.

In the Dutch case, the clinical information system component involved a shared information system used by all care group staff and associated health professionals. In the literature review, it most often included automated performance monitoring and the use of patient registries. In the German case, the clinical information system was considered to be largely absent, because only a documentation system was in place, which functioned sub-optimally. Self-management support was the component included most often in the literature review studies. It was only partially present in the Dutch case, where it took the form of patient involvement during consultations and in the organisation of health care, but both aspects had not yet fully been implemented in practice. In the German case, self-management support was largely absent, especially on a structural basis. What strikes the eye is that the self-management

component was mentioned most often in the studies included in the review, while it was only partially included in the Dutch case and largely absent in the German case. This difference may be explained by the fact that we applied a stricter assessment criterion in the case studies than in the literature review. When study authors reported instances of self-management, we took this as the truth, mainly for lack of knowing better. But in the case studies, we were able to ask more questions about the form and extent of self-management support and conclude for ourselves that it was largely absent or not fully implemented yet. We did not find evidence of community involvement, except that it was discussed by a care group manager in the Dutch case, but had not yet been implemented. It may not be surprising that the community component has not (yet) received much attention in practice, given that it requires the involvement of other sectors than the health sector, which might be new territory for many health innovators.

In practice, intervention components are generally not as distinct from one another as they might seem in the rather abstract descriptions presented in scientific papers (including our own). For example, in the Dutch case, the care groups have a prominent role in the bundled payment system and the shared information system is implemented and managed by the care groups. Moreover, the general practitioners who provide care to diabetes patients are sometimes also co-owners of the care groups and therefore more or less directly involved in the negotiations about the price and content of the yearly diabetes care package. In the German case, we saw that the comprehensive geriatric assessments and the multidisciplinary cooperation are compulsory requirements of the reimbursement framework, and the latter component therefore shapes how the former two are executed in practice. This inter-relatedness makes it all the more important to consider complex interventions in their entirety and in relation to the context in which they are implemented.

Another observation concerns the fact that in the studies included in the literature review, intervention components were described as part of a specific intervention that was intentionally developed and implemented as one whole intervention. Typically, this entailed that the intervention had one discrete starting point (or several consecutive ones when a stepped approach was used), and that the effect of the intervention as a whole was measured. In the case studies, on the other hand, we described which components were present at the time of data collection, even though the total of these components did not necessarily equal what was considered as one intervention. Rather, it represented the result of separate interventions that had been implemented over time, but not as part of a bigger overall intervention. For example, in the Netherlands the introduction of national care standards for diabetes care pre-dated the introduction of care groups by several years, which in turn, pre-dated the introduction of the national bundled payment system by another few years. There was no clear and unambiguous start of “the intervention”, but at the time of data collection there was clear evidence of certain CCM components to be found in practice. In the German case, there was no clear discernible intervention either. The geriatric hospital itself with its multidisciplinary approach might be considered as the intervention, but the foundation of the hospital pre-dated the introduction of the reimbursement system, which is now maybe the core element of the integrated care approach. These differences can be understood in light of our broad understanding of implementation as also including the execution of the intervention in practice, rather than only the narrow definition of implementation as the initial phase

of bringing a theoretical idea into practice. The execution of intervention components in practice is longer lasting and therefore likely to coincide with new initiatives. Of course, this is not to say that the separate interventions or components are independent of each other. On the contrary, later interventions were often implemented as (additional) solutions to shortcomings of earlier interventions and, when executed concurrently, they tended to develop interrelated effects.

Contexts of integrated care for diabetes and geriatric conditions

As regards the context in which integrated care interventions for diabetes and geriatric conditions were implemented, barriers and facilitators were found at all levels of the IM. Barriers at the innovation level mostly related to databases or electronic medical records, either because there was no such system in place or because the implementation of the system was problematic. At the level of the individual professional, barriers often related to health professionals' reluctance to (actively) participate in the intervention. In the Dutch case, decreased earnings of some health professionals were also reported as a barrier. Patient level barriers included their insufficient expertise or motivation and complicated socio-economic or medical conditions. At the social context, barriers were found related to competing staff priorities, changing the culture at the workplace, suboptimal leadership as well as challenging neighbourhoods. Organisational context barriers related to workflow changes due to the introduction of an intervention, logistical barriers and problems relating to staff turnover, limited staff capacity and high workload. In the Dutch case, interviewees perceived that too much care was provided by practice nurses instead of general practitioners. In the German case, the high workload was perceived as a barrier by health professionals, especially the nurses. At the economic, legal and political context level, barriers related to funding systems, health insurer requirements and financial disincentives. In the German case, the health system level was added, for which the lack of an infrastructure between the geriatric hospital and other health care organisations and the ambulatory sector was reported.

Facilitators at the innovation level included the use of bilinguals, translations and pictures as well as the availability of databases and electronic medical records. Individual professional facilitators focussed on the use of guidelines and reminders, provider education, health professionals' expertise and motivation, as well as increased earnings. At the patient level, facilitators included increased focus on self-management and family member involvement. Social context facilitators included good working relationships between staff and leadership. Innovators as well as the organisation's openness to and tradition of innovation were also reported. Facilitators at the organisational context included multidisciplinary teamwork, workflow changes including informal cooperation, the support by management organisations (i.e. the Dutch care groups) and advanced nurses acting as integrators. At the economic, legal and political context level, facilitators related to administrative obligations and financial incentives and pressures.

In general, barriers and facilitators often seemed interrelated by being two sides of the same coin, depending on whether a factor was present or absent, or how well it was executed in practice. For example, in the Dutch case decreased earnings for some health professionals acted as a barrier to the implementation of the integrated care intervention, while increased earnings for other health professionals acted as a facilitator. Moreover, the bundled payment system was found to incentivise the

provision of care according to the national care standards. On the one hand, this was perceived as a facilitator, because it encouraged the provision of care according to guidelines of good practice care delivery for type 2 diabetes. On the other hand, it was perceived as a barrier when this influenced the treatment choices to such an extent that it prevented the provision of tailored, person-focussed care and instead provided all patients with more or less the same care product regardless of their individual needs. Barriers and facilitators also sometimes seemed interrelated by being problems and solutions to one another. For example, based on the literature review we concluded that investments at the social context level to increase staff involvement and satisfaction could help decrease the likelihood of barriers developing at the organisational context level, such as high staff turnover and limited staff capacity.

Outcomes of integrated care for diabetes and geriatric conditions

In the literature review, we distinguished between process measures, patient outcomes, health service utilisation and costs. For all categories, positive and negative/unchanged outcomes were found, but for all categories except costs, more positive than negative/unchanged outcomes were found. The information on costs was limited and mixed.

For the Dutch case, we focussed on what the interviewees felt were the most important outcomes of the intervention. Overall, they reported that integrated care had contributed to improvements in certain aspects of quality of care such as improved communication and cooperation but also to perceived deteriorations in others such as insufficient and unnecessary care provision and the preconditions for person-centred care. We approached the German case the same way as the Dutch one, by following the interviewees' opinions and experiences on how they perceived the impact of the integrated care intervention. But to facilitate the analysis, we chose to report outcomes for six dimensions of quality of care and (patient and provider) satisfaction [25]. Negative outcomes were reported for the dimensions effectiveness (less care provided to patient), efficiency (overuse, underuse and misuse, unnecessary incurrence of costs and waste in workflows), patient-centeredness (less focus on the patient instead of administrative obligations and less family involvement), safety (increased likelihood of adverse events or medical mistakes and revolving door effect) and satisfaction (frustration among staff). Positive outcomes were found for the same dimensions: effectiveness (better understanding of colleagues' expertise, continuous care and more care provided to patients), efficiency (faster information exchange), patient-centeredness (more focus on patient instead of administrative obligations and holistic view of the patient), safety (improved transparency and decreased likelihood of adverse events or medical mistakes) and satisfaction (appreciation by staff and patients).

Outcomes were not reported for accessibility and equity. Accessibility in terms of geographic proximity was probably not an important topic given the location of the geriatric hospital in an urban, metropolitan area. However, issues relating to possible difficulties to be admitted to this specific hospital if patients wished so, might not have come to the fore given the lack of patient interviews. The same might hold true for equity, even though we also believe that this could be due to the German health insurance system, which, at least in theory, is the same for every patient regardless of socio-economic background or other factors.

The types of outcomes that were studied and reported in the literature review differed from those in the case studies. For example, in the studies included in the literature review, the focus was on the improvement of clinical processes as intermediate outcomes and on improvements in patient health, health services utilisation and costs as long-term outcomes or envisaged end-points of the intervention. The case studies focussed on intermediate outcomes (or outputs), that were closer to the intervention, and that sometimes contributed themselves to other intermediate effects in a longer chain of outcomes. Despite the focus on longer-term outcomes in the literature review studies, these were generally measured in the relative short-term, namely on average 15 months after the implementation of the intervention. For some components in the case studies, on the other hand, measurement took place more than 10 years after initial implementation. It is also noticeable that the outcomes reported in the studies included in the literature review mostly concerned rather objective, hard evidence, whereas the case study outcomes were characterised by relative subjectivity, both in terms of which outcomes were reported as well as whether they were perceived to have improved or worsened.

Another difference between the types of outcomes measured in the literature review as opposed to those measured in the case studies, is that the former were generally reported as aggregates or “net effect” of the intervention, whereas the latter could be reported as both negative and positive outcomes for the same category. For example, in the Dutch case both positive and negative effects in terms of quality of care were reported, and in the German case, both increased and decreased likelihood of adverse events or medical mistakes were reported as outcomes in terms of safety. The latter option has the advantage of providing more insights into the reasons why certain negative or positive outcomes were found and to which (combinations of) mechanisms and context factors they can be traced back.

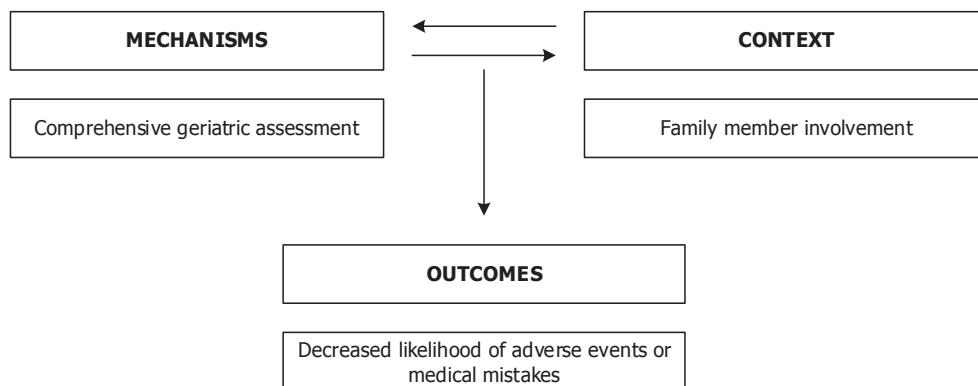
Finally, the studies included in the literature review measured patient outcomes directly from the patients, whereas the case studies did not include patients and therefore had to rely on the perceptions of the health professionals. However, it is not clear how statistically significant improvements in certain aspects of patient health, such as blood sugar levels or Body Mass Index (BMI), relate to how patients perceived these improvements. Nor do they provide information about whether patient satisfaction improved along with the clinical outcomes, or maybe even suffered in consequence. While still one step removed from asking the patients themselves, interviewing health professionals revealed how they thought certain outcomes related to the patients. For example, in the German case, health professionals indicated that they thought that being asked too many of the same questions by different health professionals would cause frustration among the patients.

Interplay of mechanisms, context and outcomes

For the literature review, it was not possible to make statements about the interplay between the mechanisms, context and outcomes of integrated care interventions, neither quantitatively nor qualitatively. This was mainly due to the low number of articles reporting comparable quantitative outcome measures or in depth qualitative information on the relationship between mechanisms, context and outcomes. In the case studies, it was possible to outline how barriers and facilitators had influenced the relationship between mechanisms and outcomes. For example, we found that the Dutch case included a shared information system for all involved health professionals (mechanism). However,

other IT systems such as the general practitioners' information system and the hospital system were being used in parallel to the new system, which meant that patient data had to be entered twice (context). This caused frustration and increased the likelihood of faulty or missing data (outcomes). In the German case, we found that comprehensive geriatric assessments (mechanism) were complemented by information provided by family members (context), which contributed to a decreased likelihood of adverse events or medical mistakes (outcome). The latter example is shown in Figure 3.

Figure 3: Example of the interplay between the mechanisms, context and outcomes in the German case



In both case studies, the use of our preliminary model for data collection and analysis proved to be of added benefit. The Dutch example showed that the shared information system in itself did not lead to frustration among staff or increased likelihood of missing and faulty data, but the fact that it was not integrated with other databases did. It might not even have mattered how appropriate the information was, as long as the barrier of lacking system integration remained in place. The German example showed that the comprehensive geriatric assessments were not sufficient in themselves, but when complemented with additional information by the family members, they contributed to improved safety. Again, traditional approaches might only have found positive outcomes and, based on these insights, concluded that comprehensive geriatric assessments were associated with decreased likelihood of adverse events or mistakes. This apparently successful intervention could then have been transferred to other settings where family members were not asked for additional information, and positive outcomes might not have been achieved. As these example demonstrate, a comprehensive CMO-based approach allows researchers to understand the influence of the different intervention components, how these are affected by different barriers and facilitators during their implementation, and how – combined – they affect the outcomes that can be achieved.

Part B: Workforce changes in integrated care interventions

In Part B, we aimed to study the workforce changes implemented as part of integrated chronic care interventions. To this purpose, we applied an emergent and interactive multimethod design with multiphase combination timing (Chapter 7). This design combined a literature review, qualitative expert questionnaire and secondary analysis of case reports at different stages of the research to provide an overview of the workforce changes implemented as part of integrated care interventions (Chapter 8), the barriers and facilitators to their implementation (Chapter 9) as well as their outcomes (Chapter 10). Twenty-one studies from seven countries were included in the literature review, 25 experts from 12 countries in the questionnaire, and the detailed reports of the Dutch and German case studies described above were available for secondary analysis. Workforce changes were defined as those changes experienced by clinical and non-clinical staff responsible for public and individual health intervention [26].

Mechanisms of workforce changes in integrated care interventions

We identified seven workforce changes, namely (1) nurse involvement in the delivery of care; (2) multidisciplinary staff including health professionals from different disciplines; (3) multidisciplinary protocols/pathways involving tasks for health professionals from different disciplines; (4) provider training such as on-the-job training or educational seminars or materials for health professionals; (5) involvement of a case manager/care coordinator role in the delivery of care; (6) regular team meetings to discuss a patient's treatment; and (7) the creation of a new position, role or function specifically to deliver integrated chronic care. Most interventions included more than one of these workforce changes and some workforce changes were implemented together so often that it became difficult to disentangle them. For example, team meetings might be so similar to multidisciplinary staff, that we suspected that study authors or expert respondents did not specifically mention one or the other when asked to describe the workforce changes of an intervention. Based on this reasoning, it might even be the case that the average number of workforce changes per intervention described in the studies and by the experts is an underestimation of the real number. A source of tension when analysing workforce changes as part of integrated care interventions was the dilemma between wanting to disentangle a complex intervention into its components, but to still consider the workforce changes as only one part of a whole intervention.

Contexts of workforce changes in integrated care interventions

When workforce changes are implemented within the scope of an integrated care intervention, they are one aspect of a complex intervention that also includes other aspects. This means that barriers and facilitators can be reported specifically for the workforce changes included in the integrated care intervention, or for the overall integrated care intervention that includes workforce changes. While the former approach focusses specifically on one aspect of a complex intervention, namely workforce changes, the latter focusses on the integrated care intervention as a whole. We combined these two approaches by measuring the context factors affecting workforce changes via the expert questionnaires, the factors affecting the overall intervention via the literature review, and the factors affecting the overall intervention, but with specific focus on workforce-related issues, via the case reports. We found

that most barriers to the implementation process were related to delivery structures, including problematic staffing and delineation of responsibilities. Health professionals' lack of skills and enthusiasm were also perceived as barriers to the implementation process. Other barriers related to IT, funding, culture and communication and cooperation. Most facilitators related to health professionals' motivation and enthusiasm. Delivery structures such as a sufficient number of staff and nurse-led care also facilitated the implementation process. Other facilitators included communication and cooperation, IT, patients and leadership and senior management. Given the broad focus of the literature review on the overall intervention, we expected this part of the study to reveal barriers and facilitators for the highest number of different categories, compared to the expert questionnaire, which had a more narrow focus on the workforce changes. This was not confirmed by our findings, as overall, the three approaches yielded similar findings. It was noticeable that, overall, the same categories of barriers and facilitators were found. This may suggest that certain factors can act as facilitators as well as barriers, depending on whether they are present or absent or how well they are implemented. Additionally, barriers and facilitators were often causes and consequences of one another, for example when solutions were found to initial barriers, which then gave rise to new barriers or other facilitators. This interrelatedness of barriers and facilitators reflects the complexity that is inherent to integrated care interventions and shows that the implementation of most complex interventions remains an ongoing process that is never really complete.

Outcomes of workforce changes in integrated care interventions

As mentioned above, we combined different approaches to measuring one aspect of an intervention as opposed to the overall intervention. As was the case for the barriers and facilitators, we measured the outcomes of the workforce changes via the expert questionnaire and the outcomes of the overall intervention via the literature review. The case reports did not report outcome measures and were therefore not included in this part of the study. Again, our hypothesis was that measuring outcomes of integrated care interventions including workforce changes might lead to more varied outcome categories due to its broader focus, compared to measuring the outcomes of workforce changes within integrated care interventions, which zooms into the workforce changes more narrowly. Overall, we found positive outcomes, in particular for quality of care (including process measures and clinical patient outcomes), patient satisfaction and staff satisfaction. Improved process measures included increased screening and identification rates as well as decreased re-admission rates. Positive outcomes for clinical patient outcomes included improved glycaemic control, blood pressure, lipid level control and body mass index. Improved patient satisfaction included improved patient-provider relationships and improved staff satisfaction included improved relationships between different groups of providers. Negative outcomes were found for the same categories as the positive outcomes, but to a much lesser extent. In general, outcomes were reported for the same categories in the literature as by the experts. This finding is not in line with our expectation that using different approaches to measuring outcomes would lead to the measurement of different types of outcomes. We concluded that, in the end, both approaches may have measured the outcomes of integrated care interventions including workforce changes, rather than measuring the outcomes of workforce changes only. Unfortunately, this means that we do not know the exact role of workforce changes in the achievement of improved outcomes.

We do know, however, that when they are implemented as part of integrated care interventions, they can contribute to improved quality of care and patient and staff satisfaction.

Interplay between mechanisms, context and outcomes

As described in Part A, the diabetes literature review showed that it was not possible to use our preliminary model to analyse aggregated findings from studies that were conducted without a CMO approach in their designs. We thought that this could be remedied by specifically asking respondents about all elements of the CMO Model. This approach yielded short descriptions of the mechanisms, context and outcomes for a number of different integrated care interventions, instead of a rich description of one case. This information could be aggregated for each element separately, as shown above. However, we were not able to make statements about the interplay between these elements. As expected, we did not have enough information for the same outcomes categories to allow for quantitative analyses, and given the general lack of detail of the information provided, as well as lack of detail on the links between the separate elements, it was not possible either to create the types of clusters as we did for the case studies in Part A. On the one hand this showed us that, instead of asking three consecutive but separate questions about the mechanisms, context and outcomes, it would have been necessary to specifically ask about the interplay of these elements. On the other hand, we believe that even if we had done so, we would probably not have had the necessary understanding of the background story. We concluded that aggregating less detailed qualitative information even with a specific focus on mechanisms, context and outcomes, could not be used as short-cut to detailed case study analyses.

Part C: Methodological tools for the comprehensive evaluation of integrated care

Throughout the research conducted for Part A and B, two main obstacles to the evaluation of integrated care became visible. First, there was no model to guide comprehensive evaluations of integrated care interventions that would provide insights into when, why and how integrated care can contribute to improved outcomes. Second, in line with the lack of consensus on one definition of integrated care, there was also no typology to describe the different types of integrated care interventions that are based on a different understanding of what integrated care is or should be. Given these obstacles, we aimed to develop a model to guide the comprehensive evaluation of integrated care interventions (Chapter 11), and argued for the development of a universal typology of integrated care interventions (Chapter 12).

Development of the COMIC Model

As explained earlier, comprehensive evaluations of integrated care interventions that aim to answer the when, why and how of successful outcomes must focus on the interplay between mechanisms, context and outcomes. The importance of the context in which interventions are implemented has been described most appropriately in the CMO Model. However, there is no consensus on the definition and operationalisation of what exactly is meant by the concepts "context", "mechanisms" and "outcomes". Additionally, the CMO Model does not have a specific link to integrated care, which is problematic given the lack of consensus on what integrated care actually is. In response to these challenges, we

developed a preliminary model that provided definitions and operationalisation of these elements, as well as a visualisation of the interplay between these elements (Figure 1, see above). However, as we had never used this model, we were in the dark about its usefulness for the collection, analysis and reporting of data. Moreover, while outcomes were defined as effects triggered by mechanisms and context, the concept had not yet been linked to a specific model, as we were unaware about the appropriateness of the types of outcomes reported in traditional evaluation studies. Given these considerations, the preliminary model was applied to the literature review and case studies described in Part A as well as to the workforce studies described in Part B.

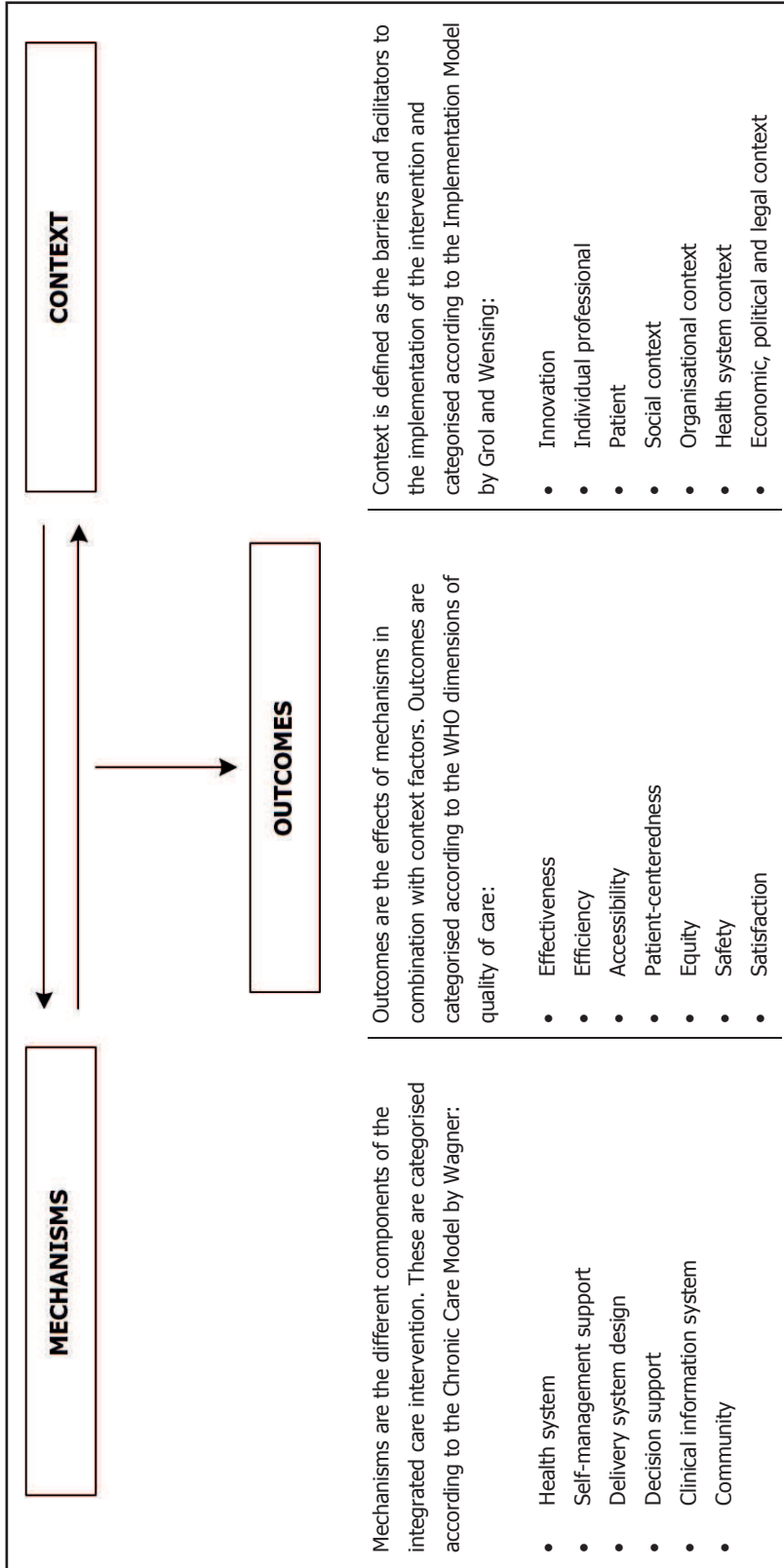
When applied to the literature review on the different intervention types, contexts and outcomes of integrated diabetes care (Chapter 3 and 4), the preliminary model made it possible to gather and structure detailed information on the mechanisms, context and outcomes, separately. However, neither quantitative nor qualitative analysis of the interplay between these three elements were possible. We thought that this challenge might be remedied by incorporating an explicit focus on CMO-thinking in research designs of future studies. As a next step, we applied our preliminary model to the case study on integrated diabetes care as implemented by two Dutch care groups (Chapter 5). We concluded that the preliminary model was useful in gathering and structuring information on the mechanisms, context and outcomes separately as well as on the interplay of these elements. However, the outcomes had not yet been structured and we had not yet been able to visualise our findings in a way that mirrored the logic of our preliminary model as presented in Figure 1. We therefore applied the preliminary model to another case study, namely on the implementation of integrated geriatric care at a German geriatric hospital (Chapter 6). During the data analysis process, we adapted the levels of the IM used for the description of the barriers and facilitators to the implementation of intervention components. First, the level "health system context" was added to describe the intermediate level between the organisation under study and the wider economic and political context. Second, the level "economic and political context" was changed to "economic, political and legal context" to make the legal or regulatory dimension more visible. Additionally, an operationalisation of outcomes was added to the preliminary model, namely according to the six dimensions of quality of care as defined by the World Health Organization (i.e. effectiveness, efficiency, accessibility, patient-centeredness, equity and safety) [25]. As in the Dutch case, the preliminary model made it possible to make statements on the interplay between the mechanism, context and outcomes, but in the German case we could now also structure the outcomes and add visualisations of the interplay (Figure 3, see above). Based on the experiences from both case studies, we concluded that our model indeed made it possible to comprehensively analyse the mechanisms, context and outcomes of one specific case, make the interplay between the mechanisms, context and outcomes within this case visible, and compare different cases in a systematic way that adds value to the analysis.

We also applied the preliminary model to our multimethod study on workforce changes (Chapter 7-10). Given the slight shift in focus to workforce changes in integrated care interventions, we did not use the detailed operationalisations of the mechanisms, context and outcomes, but only the logic of the preliminary model as presented in Figure 1. However, we soon ran into similar challenges as encountered in the literature review on type 2 diabetes, namely that it was not possible to make

statements on the interplay between the mechanisms, context and outcomes. We had thought to have addressed the shortcoming of the literature review by incorporating an explicit focus on CMO-thinking in our research design. For example, we asked experts to describe the workforce changes included an integrated care intervention they were familiar with (mechanisms), the barriers and facilitators to their implementation (context) as well as their outcomes. However, we had to conclude that asking three consecutive but separate questions did not substitute for specifically asking about the interplay between these elements, nor did the concise information reported by the expert respondents substitute for the detailed background stories of the case studies. The main challenge with these types of studies that report aggregated findings is that they separate certain pieces of information from their context, by using data extraction forms or, as we did, by asking for separate pieces of information in distinct questions [12]. Unfortunately, this separation of information causes its decontextualisation. As our experience showed, it was not possible to put back the separate parts, neither quantitatively nor qualitatively. We therefore suggested that the separation should not be performed in the first place, and that instead, the interplay between mechanisms, context and outcomes should be understood against the background of the entirety of the case for which they are being studied.

Eventually, all insights gained throughout the previous studies were combined in the final COMIC Model to study the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions (Figure 4). The COMIC Model is appropriate for detailed, qualitative case study research rather than aggregated findings within the scope of reviews or questionnaires. Moreover, when using the COMIC Model, it is essential to incorporate a focus on the mechanisms, context and outcomes of integrated care interventions, as well as their interplay, into study designs, data collection, analysis, interpretation and reporting. We recommend that patients, practitioners, managers and other relevant stakeholders should be included as interviewees. In our analyses of the Dutch and German cases, we first coded the interviews based on the interviewees' own wording (in vivo codes) and prominent concepts from the literature, that is, independently of the operationalisations of the COMIC Model. As a second step, the codes resulting from this preliminary process were mapped to the CCM components, IM levels and WHO dimensions of quality of care. It can be explored whether it is also possible to base the coding directly on the concepts included in the COMIC Model, but measures should be taken to ensure that relevant findings are not missed when not explicitly covered by the COMIC Model. Findings may be visualised as clusters of mechanisms, context factors and outcomes as shown in Figure 3, but should always be explained using detailed descriptions.

Figure 4: COMIC Model: **C**ontext; **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions



Notes: Based on the CMO Model by Pawson and Tilley [19], Chronic Care Model by Wagner [23], Implementation Model by Grol and Wensing [24], and the WHO dimensions of quality of care [25].

The need for a universal typology of integrated care interventions

Integrated care research and practice is currently characterised by a huge diversity in understanding of what integrated care is or should be, often depending on the specific research focus, cultural or professional background, or timing of the research. This diversity makes it difficult to compare and aggregate insights from interventions that are based on different definitions of integrated care. For over a decade, the academic community has been trying to resolve this issue by developing different definitions of integrated care and striving for agreement on “the best” of these. However, the diversity in integrated care interventions can also be seen as strength of the field, which should be embraced. Rather than agreeing on one definition, we have argued for the development of a universal typology of integrated care that enables the description and comparison of all interventions considered integrated care by relevant stakeholder groups, while allowing for local colour. We identified six attributes such a universal typology should possess. First, the main components should be rankable from the micro level (i.e. person at risk of illness or in need of care) to the macro level to reflect the level at which an intervention is implemented. Second, these components should be intangible (i.e. theory-based, non-empirical or not directly implementable in practice) so that they can cover all categories that are theoretically relevant instead of only those that can be or were observed in practice. Third, the main components should be operationalised into tangible sub-components so that the typology can be applied more easily to practice examples of integrated care interventions. Fourth, these sub-components should be unrankable because otherwise it would not be possible to list all the tangible examples observed in practice. Fifth, the typology should be conceptually sound by only including mechanisms, not context factors or intended outcomes. Sixth, the typology should be flexible enough to be adapted when new approaches or technologies are developed. While these requirements mainly pertain to the form of the typology, its content should be developed and validated by an international consortium that includes different countries, cultures, health systems, professions and life experiences. We believe a universal typology to be a necessary tool to make integrated care interventions and their components observable, identifiable, measurable and therefore comparable. Eventually, the universal typology should be incorporated in comprehensive evaluations of integrated care interventions such as the COMIC Model.

Limitations and strengths

This dissertation is characterised by a number of limitations and strengths. Its main limitation is the lack of patient involvement. In the study protocol described in Chapter 2, we set out to include patients as interviewees in the Dutch case study. However, this was not realised mainly due to the relatively short timeline of the European project in which the data collection took place. The lack of patient involvement may have led to a relative overemphasis of the areas of delivery system design, health system and decision support (mechanisms) and the individual professional, social context, organisational context and political, legal and economic context levels (context). It has probably also led to a relative underemphasis of the areas of self-management support (mechanisms), the patient level (context) and patient satisfaction (outcomes). When applying the COMIC Model to evaluations of integrated care interventions, researchers must make sure to also include patients as informants, in order to make sure that interventions are evaluated comprehensively. As we will argue in more detail later, we believe that

a practice version of the COMIC Model should be developed that is more accessible and usable for practice settings. When using this practice version of the COMIC Model, we recommend that patients (or their representatives) are not only included as informants, but as active users, who in cooperation with health professionals, managers, funders and other relevant stakeholders, are responsible for the evaluation of integrated care interventions in their own practice settings.

Another limitation of the current thesis concerns the decision to operationally link integrated care to the CCM by defining integrated care as interventions targeting two or more CCM components. This means that, for example, an intervention including a website for patients (clinical information system) with information on a specific disease (self-management support) would be classified as integrated care because it targets two CCM components. It is true that this intervention would not constitute a connection of the health system with other human service systems [27], or a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels [28]. But while this could indeed happen, our experience with the literature review on integrated diabetes care has shown that most interventions in fact included three or more CCM components. We found that rather than being too inclusive, we even had to exclude several interventions classified as integrated care by study authors, but for which we only found evidence of less than two CCM components, although we do not know whether this was due to the actual lack of complexity in the intervention or concise reporting. Overall, despite the limitations associated with this approach, we did not find a feasible alternative that would allow for the systematic identification and description of integrated care interventions, especially given their diversity and the lack of a common understanding of what actually constitutes integrated care. We emphasise that our approach concerns an operational definition that we found to be the most useful of available approaches. However, as argued previously, we believe that the way to move forward is the development of a universal typology of integrated care interventions to support the navigation of the diversity of interventions referred to as integrated care.

The third limitation concerns the exploratory and preliminary status of the workforce studies included in this dissertation. These studies were originally planned as mixed method design consisting of a qualitative literature review on the implementation of workforce changes, and a quantitative check of these findings via a Delphi study. However, via the systematic literature review, we could only identify two studies that focussed on integrated care, chronic care and workforce changes. When we added additional search terms, six additional studies could be added. However, most of the studies that were eventually included in the final selection were found via the previous literature review on diabetes care, which did not incorporate a specific focus on workforce changes in its search terms. We therefore decided to continue the qualitative exploration of the topic instead of aiming for a quantitative confirmation of first results, whose generalisability and completeness were in doubt. While the new qualitative multimethod research design had many advantages, we still would have liked to return to the original plan of quantitative confirmation of the qualitative results. However, conducting qualitative research is time-consuming and adding not one but two additional qualitative elements to our design meant that adding a quantitative step was not a feasible option within the scope of this project. As regards the limited results of the systematic review, we do not know whether this paucity of research found reflects a real paucity of research on the topic or whether the research does exist, but is difficult

to find. The latter scenario might be approached by the development of a common terminology with regard to integrated care as well as workforce changes. With regard to the former scenario, it could be that the relative lack of research came as a surprise to us because as a research team from the Netherlands we are most familiar with the Dutch setting, where a focus on workforce changes has been an integral part of disease management and integrated care efforts for the past few decades [29-31]. Similar approaches such as the inclusion of advanced nurse practitioners also hold a prominent role in integrated care efforts in the United Kingdom [32, 33]. However, it might well be the case that these are the exceptions rather than the rule and that in most countries, traditional workforce research remains relatively separate from the field of integrated care. For example, a recent report by the European Observatory on Health Systems and Policies on the changing role of nursing mentions integrated care only once, despite the prominent role nurses can and do play in integrated care interventions [34]. Given the key role of the health workforce in all aspects of integrated care delivery, both the lack of research as well as the problematic accessibility of existing research form impediments to the implementation of integrated care as a whole and should therefore be prioritised in future research.

A fourth limitation of the current thesis concerns the use of an evolving model for the collection and analysis of data, which was subject to change throughout the different phases of the research. For example, for the diabetes literature review we only focused on the four core CCM components; the health system and community components were only added after they were found to be necessary for the description of the Dutch case. In the German case study, we added one IM level (health system level) and changed the economic and political context level to economic, legal and political context. We also added the operationalisation of outcomes as dimensions of quality of care and patient and provider satisfaction. These changes made it rather difficult to compare all findings from all studies in this dissertation. Moreover, the application of the (different versions of the) model in itself was a trial-and-error process. For example, only in using the model for the study on the workforce changes we could find out that this was not a perfect match. At the time, we were confident that the model would be useful for this type of analysis, but the actual use of the model showed us that it did not allow for statements on the interplay between mechanisms, context and outcomes. Moreover, applying the model meant learning how to apply the model, and if we re-applied the COMIC Model in its current form to the same studies again, the new data collection and analysis would probably differ from the current one.

Despite the difficulties associated with the use of an evolving model, we also consider it an important strength of the present thesis. First and foremost, because it has allowed us to make mistakes, extract lessons learned from these mistakes and to further develop the model based on these lessons. If this had not been the case, all our studies would have suffered from the same limitations as the earlier studies, such as the lack of an appropriate operationalisation of the outcomes or a lack of focus on the health system and community component. Additionally, having applied the model to different types of studies has provided us with insights into how and for which studies the COMIC Model should (not) be used. Moreover, using the preliminary model in two detailed case studies contributed to increased conceptual clarity on the differences between mechanisms and context factors, how they relate to

outcomes achieved, and how this interplay can be adequately visualised to facilitate the analysis as well as reporting of findings. Its repeated use also means that the COMIC Model is not only a theory-, but also an evidence based model. Finally, the use of the model in different settings also helped to transform a highly context-specific instrument into a generic instrument with broader applicability [35, 36].

The second strength of this dissertation concerns its international scope. Part A includes data from 10 different countries, and Part B from 15 different countries. This also includes countries that are represented less often in research on integrated care such as Estonia, Czech Republic, Greece, Norway and Israel. The international scope of the thesis is especially relevant given the lack of a consensus definition of integrated care, which means that the concept often has different meanings in different countries or health systems [28, 37]. Moreover, our study was embedded in the European Project INTEGRATE, which means that methods and preliminary findings were regularly fed back to and commented on by the scientific committee of Project INTEGRATE as well as its advisory board. This helped to ensure that the focus of our research stayed in line with and was relevant for the current needs of the international and European academic and practice fields of integrated chronic care. This, too, is necessary given the different traditions of what is seen as integrated care.

Another strength of this dissertation is its explicit focus on developing appropriate research designs for a given research question, instead of basing this decision on a hierarchy of evidence which sees RCTs and similar designs as inherently superior to others [38-40]. For example, we prioritised qualitative over quantitative research, because it is more appropriate to generating in depth understanding of a given situation [16, 18, 41]. In our studies on workforce changes, this was further necessitated by the exploratory nature of the study and the preliminary nature of the early findings which were not appropriate for quantitative confirmation. The importance of qualitative research itself, as well as the importance of using qualitative research when this is the most appropriate approach to answering a research question, was recently highlighted by 76 senior researchers from 11 countries in an open letter to the editors of the British Medical Journal [18]. Furthermore, we chose to embed these qualitative methods in complex multimethod designs. By combining more than one method of research within the same study, these designs are considered especially appropriate for the study of complex interventions, such as integrated care [17, 42, 43]. In Part A, we reported different studies on the same topic, but in Part B the different data sources were consciously and explicitly combined in an interactive multimethod research design. The combination of different data sources allowed for triangulation of findings, which improved the confirmability of our study by limiting the investigator bias inherent to qualitative research [44, 45]. Moreover, it contributed to information-richness and thereby transferability of our study findings to other settings [44, 46]. It has also been argued that the combination of different methods remedies their respective limitations and enhances their respective strengths [42, 44, 45].

Finally, this dissertation is characterised by a high degree of innovativeness. As mentioned earlier, evaluations of integrated care have so far typically focussed on quantitative net effectiveness reviews. Other studies have used qualitative case study designs, but have not focussed on the comparability of their case-specific findings to other research. In the form of the COMIC Model, this dissertation presents

an innovative approach to the evaluation of integrated care that allows for the in-depth context-specificity of qualitative case study research, but at the same time it structures this research in a way that makes the findings comparable to other, equally context-specific, research. Furthermore, the innovativeness of this dissertation can also be witnessed in its exploration of workforce changes, which is still a relatively novel focal area of integrated care research, which, despite its apparent relevance, has not received sufficient attention yet. Finally, to our knowledge, we are the first to argue for the development of a universal typology of integrated care interventions, rather than the agreement on one definition of integrated care, and to specify a set of requirements regarding the form of such a typology.

Recommendations

Based on the insights gained in this dissertation, we have formulated the following ten recommendations for future healthcare research, practice and policy:

1. Be explicit about what integrated care means

This recommendation has several dimensions. The first is being explicit about what integrated care means in a specific case. This entails that we need to accept that there is no integrated care as such, but a multitude of different versions of integrated care. Being explicit about what exactly the integrated care intervention in question entails makes it possible to compare different experiences and learn from each other. Second, we need to be explicit about the outcomes the specific integrated care intervention is expected or supposed to achieve. Integrated care is currently often seen as the magic bullet to solve the puzzle of the Triple or even Quadruple Aim - if only we find and implement the "right" integrated care. However, it is more realistic to assume that some integrated care interventions are more likely to achieve certain outcomes than others, even before factoring in the impact of the context. For example, if an intervention focusses on delivery system design, it seems realistic to aim for improvements in terms of provider satisfaction and more efficient workflows, but not necessarily improvements in patient satisfaction or costs (even though these still might occur as unanticipated side effects). It might also be helpful to remember that not all types of outcomes have to be achieved all at once, but that one might aim for increased provider satisfaction first, as this might also help to improve patient satisfaction at a later stage. Third, it is important to distinguish between the first point and the second, i.e. what the intervention consists of and the outcomes it is supposed to achieve. Integrated care is often defined by the outcomes it is supposed to achieve, for example to improve clinical outcomes, satisfaction and efficiency [27], or to achieve seamless and continuous care [47]. The same holds true for context factors, which are also sometimes seen as part of the intervention [48]. But this is conceptually confusing and opens the door for circular reasoning. If comprehensive evaluations are to take into account the mechanisms, context and outcomes of an intervention, we need to be clear and explicit about what is what. This includes being explicit about those cases when we are not sure about whether something is part of the intervention or the context in which it is implemented, or when a factor seems to fall into more than one category.

2. *Focus on prevention*

An area that should be further developed is prevention, which is often seen as an essential part of integrated care. As such, it is anchored in several definitions of integrated care and part of the underlying reasoning why integrated care is expected to contribute improved cost-efficiency [49-51]. However, despite its importance, we have not come across this issue in our studies. One reason for this might be the fact that integrated care interventions are generally implemented in health care settings, which means that the target groups of these interventions are usually already diagnosed with a specific chronic condition or the risk factors for the development thereof. A related difficulty lies in the fact that it is not clear when the appropriate prevention period should start. In a rather narrow sense, self-management support and obligatory regular visits at the GP's are already prevention activities, specifically prevention of exacerbations when the chronic disease has already manifested. In a broader sense, prevention can be understood as the prevention of the onset of chronic disease, or the prevention of the onset of risk factors for chronic disease. Recent studies have even pointed towards links between experiencing adverse events in childhood and the onset of (mental and/or somatic) chronic disease in adulthood [52-55]. However, investments in the health promotion of children might take half a decade before benefits become visible and financial profits are returned. Not only are these long-term incentives not well-aligned with organisational or public budgets, but investments in early-life health promotion will probably have to be made by the social care sector, while the benefits are reaped by the health care sector. These challenges underscore the necessity of large-scale system redesign towards systems that are inherently more appropriate to health promotion and thereby make investments in prevention more feasible and attractive.

3. *Focus on those components of integrated care that have not received (enough) attention yet*

We have witnessed a relative complexity of integrated care interventions in terms of the number of CCM components they involved as well as the form that these components took in the specific intervention under study. This shows that many different aspects are currently being taken into account, which is appropriate for complex interventions such as integrated care. But this also means that efforts are divided over several focal points and may therefore not be implemented equally well in all areas. In line with this observation, we have seen that some components, such as delivery system design or decision support, have received more attention than others, such as self-management support and community resources. It seems that a pattern is discernible in the sense that so far, interventions have focussed more on the professional arenas than the private (patient) ones, and that top-down approaches have been used more than bottom-up ones. This is understandable, as the former areas are generally better organised and structures for change management are already in place or can be implemented more easily. Following the same reasoning, it is also understandable why one focusses on integration within the health sector first, before aiming for integration between different sectors. However, while it may not be surprising that those areas that are easier to manage have received more attention so far, it is necessary to move forward from here and invest more in those parts that have not received attention yet. Above all, these include truly patient-centred approaches and cooperation beyond organisational and health sector boundaries, including the mobilisation of community resources.

4. Invest in areas where barriers occur, but also in the strengthening of facilitators

Our studies have shown barriers and facilitators to occur at all levels of the IM and to often appear as two sides of the same coin. It might be helpful to imagine barriers and facilitators as the two ends of a continuum of factors that play a role when implementing integrated care, including for example health professional expertise, patient motivation, financial incentives or IT systems. Depending on how (well) these factors are executed, they are likely to hinder or further the implementation of an intervention. However, it is not sufficient, and probably not even helpful, to identify an isolated list of these factors that have been found to play a role in previous cases. What is really needed is an improved understanding of how these factors affected the specific intervention implemented and thereby changed the trajectory of events compared to how they were envisaged beforehand, in a negative or positive way. Learning from other settings is only possible if we understand the meaning of what was found elsewhere and how these lessons learned can be transferred to our own setting. Moreover, there must also be attention to how these diverse factors, whether they appear as barriers or facilitators, influence each other. This is also important for understanding how these factors can be used to steer future implementation trajectories. For example, our findings from the diabetes literature review suggested that investments in the social context to increase staff involvement and satisfaction may decrease the development of barriers in the organisational context, such as staff turnover and limited staff capacity. Using the COMIC Model for these types of analyses is expected to support researchers in mapping and understanding these interdependencies.

5. Improve the "fit" between mechanisms and context

In our studies, we have analysed and described how the combination of certain mechanisms with certain context factors has contributed to certain outcomes. For example, in the German case study we have seen an example of how high workload acted as a barrier to the multidisciplinary approach of the geriatric hospital, which led to the fact that the treatment approaches of the different health professionals were not always well coordinated and aligned to one another, which contributed to waste in workflows. As a next step, this retrospective focus on understanding a situation in the past should be turned into a prospective focus on improving this interaction between mechanisms and context factors in the future. Chambers et al. have argued for the need to improve the "fit" between the context and the intervention in a continuous improvement effort so as to arrive at better outcomes and improve the sustainability of interventions over time [13]. This idea underscores the necessity of not only focusing on the intervention to be implemented, but also on making sure that the circumstances are right for the intervention to be carried out – also in the long run after the initial implementation and evaluation have taken place. We expect that the COMIC Model can assist researchers and practitioners in finding current mismatches between context and mechanisms and thereby point towards solutions to achieve a better fit between these aspects in the future.

6. See outcomes as indicators and opportunities for improvement

The good news is that integrated care interventions have been shown to be able to contribute to improved outcomes. Optimism seems to be warranted, as do further investments (financial or intellectual) in this area. However, negative outcomes and no improvements have been found as well and it seems naïve to think that if only we found the perfect intervention, the occurrence of negative

outcomes could be prevented. Instead, it is more likely that any complex intervention will contribute to positive as well as negative outcomes, and the main question should therefore be how to curtail the negative and boost the positive ones. This entails that we see outcomes not as endpoints of an evaluation, but indicators of how an intervention can be improved and opportunities to actually do so. This, in turn, means that we need to know all outcomes to which an intervention contributes, even the unanticipated ones, and to understand their meaning. Once we know to which negative and/or positive changes the intervention has contributed, we can focus on understanding why this was the case and how this can be changed. A broader focus on outcome measurement also makes it possible to be more transparent about the choices we can make. Integrated care can contribute to the three pillars of the Triple Aim, but probably not all at the same time, which creates room for strategic prioritisation. For example, if we aim for improved cost-efficiency in the short-term, we will probably have to abandon some aspirations for quality improvement measures. But investing in quality improvement and more integration now may make it possible to focus on cost-efficiency in the long-run without as many limitations on the quality of care. Using the COMIC Model for comprehensive evaluations of integrated care interventions can be an important tool in mapping outcomes and understanding their meaning, which allows for targeted improvements.

7. Aim for intervention improvement rather than "accreditation"

Throughout this dissertation, we have argued for a shift in focus from whether an intervention works, towards when, why and how it can contribute to improved outcomes. The aim of such efforts is to gain insights into how existing interventions can be improved, either by improving the intervention itself, the context in which it is implemented, or the fit between intervention and context. It cannot be stressed enough that this is not the aim of (nor can it be achieved by) evaluations with a reductionist focus on the net effectiveness of an intervention. As Bonell et al. have argued, the purpose of these types of evaluations is the generation of evidence to support the "accreditation" of interventions [39]. Similarly, Chambers et al. have argued that these approaches place a premium on creating and "freezing" interventions, as well as the way in which they are implemented [13]. As argued earlier, this is highly problematic because of the disregard of these approaches for the context in which interventions are implemented. But is also counter-intuitive to assume that the first version of an intervention that is implemented in practice will be the best we can achieve and should therefore not be changed once it is "proven" to contribute to improved outcomes. As Chambers et al. have further argued, there is no reason why health services research should not use continuous improvement cycles as the ones used for software development, which aim for improved versions 2.0 and higher [13]. Comprehensive evaluations of the initial implementation of interventions can yield useful information on which areas need to be improved and in which ways this can be realised. We believe that this would be a much more worthwhile effort for providers, recipients, funders and scholars of health services alike.

8. Cooperate with the different research fields that touch upon integrated care

Moving beyond sectors is not only relevant for health care practice, but also research focusing on integrated care, as many issues that integrated care touches upon are also fields of expertise in their own right. This holds true for workforce changes or health human resource management, but also the other cross-cutting issues brought to the fore by Project INTEGRATE, including financial flows, IT, care

process design and patient involvement. It may be helpful to remember that integrated care is concerned with the connection of different parts or functions of a given system, not with reinventing them. It therefore seems necessary to make better use of these existing fields of expertise in order for integrated care research to stand on the proverbial shoulders of giants. This would require openness and awareness in terms of prioritisation of such collaborations in research projects but also possibilities to disseminate such findings. For example, we felt that our combined focus on integrated care and the health workforce made it relatively difficult to find appropriate academic journals to publish our findings. But if research on integrated care is mainly published in journals on coordinated or integrated care and research on workforce changes in health human resource journals, insights from one field are less likely to reach the other. Moreover, focussing on areas such as workforce or IT in isolation only is likely to reinforce those barriers and boundaries that integrated care is trying to bring down. An increased focus on interdisciplinary research could be supported by policy-makers and funders who require research consortia or networks to consist of a cluster of researchers from different academic backgrounds who approach a given challenge in a multidisciplinary but common effort.

9. Strengthen the use of qualitative and multimethod designs

Joan Eakin has described the medical and health sciences as “a land in which the randomized controlled trial (RCT) is considered the apex of the methodological food chain” [41]. RCTs are indeed still often seen as the “gold standard” that one should approximate as closely as possible insofar as practical circumstances allow [13, 41]. Over the past years, however, voices have become more prominent about the inappropriateness of these research designs, in particular for complex interventions. The tenor of these voices is that in determining whether an RCT should be conducted, the match with the research question should be decisive, not its practical feasibility. Relevant research questions in the field of integrated care may call for the prioritisation of qualitative over quantitative methods (especially RCTs), multimethod over single method designs, process evaluations over outcome evaluations, and comprehensive evaluations over effectiveness reviews. While this may indeed be a relatively novel insight for health services research, other fields have developed differently and might offer more appropriate similarities to look at than medicine. For example, Nilsen et al. have traced the similarities and differences between implementation research in the health sciences and policy implementation research and concluded that both fields are concerned with the translation of intentions into actual changes and that policy implementation research has much to offer for health implementation research to learn from, especially regarding the importance attributed to research designs other than RCTs [38]. However, while an increasing number of scholars is already driving this development, support is also needed from the relevant funders, publishers, peers and educators, as several scholars before us have already argued [16, 18, 41, 43, 56, 57]. The above is not to say that qualitative or multimethod research is inherently better than quantitative or single method research, but it should be clear that the reverse is not the case either. With regard to integrated care, being a complex intervention and being studied in a research environment that tends to over-prioritise quantitative, single-method, outcome-focussed and RCT-type research, we do think that a much stronger emphasis on qualitative, multimethod and process- and context-focused research is warranted. This development can be driven by an increased demand for this type of research by practitioners and policy-makers. However, for this to occur, practitioners and policy-makers must acquire a sufficient understanding of which research

designs are able to generate answers to which types of questions. For example, if policy-makers want to gain insights into favourable contexts for the implementation of integrated care interventions, they must learn to contradict researchers who propose conducting an RCT to answer this question.

10. Use the COMIC Model in research and practice settings

Using the COMIC Model makes it possible to comprehensively study the interplay of the mechanisms, context and outcomes of integrated care interventions and thereby provides insights into when, why and how integrated care contributes to improved outcomes. Specifically, the COMIC Model makes it possible to comprehensively analyse mechanisms, context and outcomes within a given case, to visualise the relationships between the mechanisms, context and outcomes within a given case, and to compare several cases to each other in a systematic way that adds value to the analysis. However, the uptake of these types of scientific insights in practice settings is usually low, mainly due to their limited accessibility and suitability to the needs of their intended users [58-60]. For example, while the detailed operationalisations and explanations of the three elements of the COMIC Model are essential for in depth scientific investigations, they may not lend themselves to the use in fast-paced and results-driven environments. We therefore propose that the COMIC Model should eventually be translated into a practice tool to be used by health practitioners and patients for the evaluation of integrated care interventions in their own practice setting. While the evidence base of the scientific COMIC Model as well as its embeddedness in four robust theoretical models must remain the basis for a practice version, its accessibility, form and usability can be adapted to the specific needs of this target group. We can imagine that this may take the form of a web application to be run on computers or mobile devices, which would offer many opportunities in terms of dissemination, flexibility to incorporate changes, customisation, or language features. Apart from the form of the tool, it will also be necessary to ensure that the tool is relevant to its intended target group. It is therefore imperative to include the future users of the tool in co-designing its conception, implementation and evaluation. We expect that involving patients as equal partners in the use of the practice version of the model will contribute to more patient-centeredness and patients as active agents in their own care. We also expect the use of a practice version to contribute to more staff satisfaction by making sure that health professionals' voices are heard during the evaluation process. Moreover, we expect the COMIC Model to contribute to improved efficiency at the organisational level by providing organisations with better insights into what works and why, which allows organisations to improve the implementation of existing interventions instead of incurring implementation costs for new interventions [13, 16]. These insights can also support organisations in their reporting towards financiers, and vice versa.

Conclusion

This dissertation has investigated the question of how integrated care is implemented and to which outcomes it contributes. Of course, an improved understanding of the implementation of integrated care is not an aim in itself, but stems from the desire to implement better interventions, and to implement them better, in order to achieve better outcomes, and to do so more consistently. We expect that the insights from this dissertation, and in particular the COMIC Model to study the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions, will support future comprehensive

evaluations of integrated care interventions. By focusing on the implementation of an intervention, including which type of intervention was implemented, how the setting in which the intervention was implemented affected its implementation, and which outcomes were achieved, these evaluations are expected to contribute to improved outcomes for people with or at risk of chronic disease. This is not a ready-made solution, but an instrument to be put in the hands of researchers, policy-makers, practitioners and patients.

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SUMMARY

English summary

Nederlandse samenvatting

Deutsche Zusammenfassung

Sintesi in italiano

Resumen en español

English summary

Great expectations: the implementation of integrated care and its contribution to improved outcomes for people with chronic conditions

While there are great expectations regarding the role of integrated care in providing appropriate care to people with (multiple) chronic conditions, the evidence regarding its contribution to improved outcomes is mixed. In this dissertation, we aimed to understand when, why and how some integrated care interventions contribute to improved outcomes, while others do not. Specifically, we aimed to answer the research question: *How is integrated care implemented and to which outcomes does it contribute?* The dissertation consists of three parts. In Part A, we studied the implementation of integrated care interventions for two different (groups of) chronic conditions, namely type 2 diabetes and geriatric conditions. In Part B, we studied a specific aspect of integrated care, namely workforce changes, implemented as part of integrated care interventions. In Part C, we focussed on the development of methodological tools to comprehensively evaluate integrated care interventions.

Part A: Integrated care for diabetes and geriatric conditions

Chapter 2 described the study protocol of a review of the international scientific literature on integrated care for type 2 diabetes and a case study on Dutch integrated care for type 2 diabetes. Specifically, these studies were combined in a convergent parallel mixed methods research design. The aim of the proposed research was to investigate the mechanisms by which and the context in which integrated care for type 2 diabetes was implemented, which outcomes were achieved and how the context and mechanisms affected the outcomes. To this purpose, we made use of the CMO Model (context + mechanisms = outcomes) by Pawson and Tilley, which specifies that both the context in which an intervention is implemented as well as the mechanisms by which it is implemented will affect the outcomes that can be achieved. We operationalised *mechanisms* as the different types of integrated care interventions, which we described by means of the Chronic Care Model (CCM) by Wagner. In line with previous research, it was decided that if an intervention targeted at least two CCM components, the intervention was to be considered integrated care. We operationalised *context* as the barriers or facilitators to the implementation of the intervention, which we described by means of the Implementation Model (IM) by Grol and Wensing. We operationalised *outcomes* as the intended and unintended consequences of mechanism and context, but we did not link this to a specific model yet. The above interpretation and operationalisation of the CMO Model constituted the first version of our preliminary model to support comprehensive evaluations of integrated care intervention. This preliminary model was applied to and further developed based on the studies conducted within the scope of Part A and B of this dissertation. The final model is presented in Part C.

Chapter 3 described the intervention types and outcomes of integrated care for diabetes mellitus type 2 based on a systematic review of the international scientific literature. Forty-four articles met the inclusion criteria. Most interventions included all four core CCM components (i.e. self-management support, delivery system design, decision support and clinical information system) as well as a variety of

sub-components. Most studies reported positive patient, process and health service utilization measures, but the information on costs was limited and inconsistent. The low number of articles reporting comparable outcome measures made it difficult to make meaningful statements about an association between intervention type and outcomes. We concluded that future research would benefit from a more uniform understanding of integrated care as well as intermediate outcome measurements that allow for the establishment of a chain of evidence from specific intervention types to specific outcomes achieved.

In *Chapter 4*, the context, mechanisms and outcomes of integrated care for diabetes mellitus type 2 were examined, based on the same literature search as in Chapter 3. Thirty-two studies met the inclusion criteria. Most reported barriers to the implementation process were related to the innovation level and organisational context, including difficulties regarding databases or electronic medical records, workflow changes due to the introduction of the integrated care initiative and logistical barriers and problems relating to staff turnover or limited staff capacity. Most facilitators to the implementation process related to the innovation level and social context, including the availability of databases and electronic medical records, involvement of staff in decision-making and planning, the ability to find committed staff and generate staff buy-in, good leadership and intra- and inter-practice resource-sharing and cooperation. Our ability to make statements about the relationships between context, mechanisms and outcomes was impeded by the low number of articles reporting comparable quantitative outcomes data as well as the low number of articles reporting in-depth qualitative information on the relationships between context, mechanisms and outcomes. We recommended that efficient resource allocation should entail increased investments at the organisational context level where most barriers are expected to occur. We concluded that, if future research is to adequately inform practice and policy regarding the impact of these efforts on health outcomes, focus on the actual relationships between context, mechanisms and outcomes must be actively incorporated into study designs.

In *Chapter 5*, a Dutch case study on integrated care for people with type 2 diabetes in the primary care setting was reported. Dutch integrated diabetes care includes care groups, bundled payments, patient involvement, health professional cooperation, task substitution, evidence-based care protocols and a shared clinical information system. We mapped these elements to five of the six CCM components, namely health system, self-management support, delivery system design, decision support and clinical information system. Barriers to the implementation of the integrated care intervention included insufficient integration between the patient databases, decreased earnings for some health professionals, patients' insufficient medical and policy-making expertise, resistance by general practitioner assistants due to perceived competition, too much care provided by diabetes nurses instead of general practitioners and the funding system incentivising the provision of care exactly as described in the care protocols. Facilitators included performance monitoring via the care chain information system, increased earnings for some health professionals, increased focus on self-management, innovators in primary and secondary care, diabetes nurses acting as integrators and financial incentives for guideline adherence. The implementation of integrated care led to perceived improved communication and cooperation but also to perceived insufficient and unnecessary care provision and

perceived deteriorated preconditions for person-centred care. We concluded that Dutch integrated diabetes care is still a work in progress. Specifically, increased efforts are needed to improve the interoperability of the various patient databases and to keep the negative consequences of the bundled payment system in check. Moreover, patient and community involvement should be incorporated.

Chapter 6 reported a German case study on integrated care for geriatric conditions in a secondary care setting. Here, integrated care included a specific reimbursement system called “early complex geriatric rehabilitation”, multidisciplinary cooperation and comprehensive geriatric assessments. The reimbursement system was financially advantageous for the geriatric hospital, but its inflexibility regarding the obligatory number of treatment sessions as well as its focus on the length of stay contributed to less care delivered to the patient, overuse, underuse and misuse of health services, less focus on the patient’s needs, a revolving door effect, and frustration among staff. Multidisciplinary cooperation was mainly impeded by high workload, but also facilitated by informal cooperation structures. This contributed to frustration among staff, waste in workflows, and less family involvement, but also to faster information exchange and more focus on the patient’s needs. Comprehensive geriatric assessments were enhanced by family member involvement and contributed to a more holistic view of the patient and a decreased likelihood of adverse events. We recommended that the negative aspects of the reimbursement system should be adapted or counter-balanced with appropriate quality measures, and that the workload and administrative obligations of the health professionals should be lessened or distributed so as not to impede multidisciplinary cooperation.

Part B: Workforce changes in integrated care interventions

Chapter 7 introduced the research design which connects the studies on workforce changes. Specifically, we provided a detailed and explicit description of the processes and decisions underlying and shaping the emergent multimethod research design of our study on workforce changes in integrated chronic care. The study was originally planned as mixed method research consisting of a preliminary literature review and quantitative check of these findings via a Delphi panel. However, when the findings of the literature review were not appropriate for quantitative confirmation, we chose to continue our qualitative exploration of the topic via qualitative questionnaires and secondary analysis of two best practice cases. The resulting research design was schematically described as an emergent and interactive design with multiphase combination timing. In doing so, we provided other researchers with a set of theory- and experience-based options to develop their own emergent research and provided an example for a more detailed and structured reporting of emergent designs.

In *Chapter 8*, we described seven workforce changes that were implemented as part of integrated chronic care interventions, based on a literature review, qualitative expert questionnaires and case reports. Workforce changes were defined as those changes experienced by clinical and non-clinical staff responsible for public and individual health intervention. The following workforce changes were identified: (1) nurse involvement in the delivery of care; (2) multidisciplinary staff including health professionals from different disciplines; (3) multidisciplinary protocols/pathways involving tasks for health professionals from different disciplines; (4) provider training such as on-the-job training or

educational seminars or materials for health professionals; (5) involvement of a case manager/care coordinator role in the delivery of care; (6) regular team meetings to discuss a patient's treatment; and (7) the creation of a new position, role or function specifically to deliver integrated chronic care. Most interventions contained more than one of these workforce changes. The results of this study provided detailed insights into the current implementation of workforce changes in integrated care interventions and thereby paved the way for further investigations into the relative effectiveness of different workforce changes within the scope of complex interventions.

Chapter 9 described the barriers and facilitators to the implementation of workforce changes, implemented as part of integrated chronic care interventions, based on a literature review, qualitative expert questionnaires and case reports. The barriers mentioned by most respondents related to delivery structures, health professionals, culture, and funding. The facilitators mentioned by most respondents related to health professionals, leadership and senior management, delivery structures, patients, and communication and cooperation. It was noticeable that, overall, the same categories of barriers and facilitators were found. This pointed towards the fact that most factors can act as facilitators as well as barriers, depending on whether they are present or absent or how well they are implemented. Additionally, barriers and facilitators were often causes and consequences of one another. Often, solutions are found to initial barriers, which then act as facilitators for the initial barrier but, at the same time, may give rise to new barriers or other facilitators. We recommended that future research focusses on more complex designs including multiple data sources, as these are better able to capture the complexity of interventions such as integrated care. Furthermore, we recommended for health managers and policy-makers to allocate more resources to improving delivery structures and work environments of health professionals, as most barriers as well as facilitators were related to the number of health professionals, their skills, enthusiasm and division of tasks.

Chapter 10 described the outcomes of the workforce changes, based on an expert questionnaire and a literature review, and discussed the differences between focussing on outcomes of workforce changes in integrated care interventions, as opposed to studying the outcomes of integrated care interventions that include workforce changes. Both approaches found positive outcomes, in particular for quality of care (including clinical patient outcomes and process measures), patient satisfaction and staff satisfaction. Improved process measures included increased screening and identification rates as well as decreased re-admission rate. Positive outcomes for clinical patient outcomes included improved glycaemic control, blood pressure, lipid level control and body mass index. Improved patient satisfaction included improved patient-provider relationships and improved staff satisfaction included improved relationships between different groups of providers. Negative outcomes were found for the same categories as the positive outcomes, but to a much lesser extent. In general, outcomes were reported for the same categories in the studies as in the questionnaires. We recommended for health managers and policy makers to invest in workforce changes and to (re-)consider strategies that may be detrimental to the health workforce and thereby adversely affect patient health and patient experiences of care.

Part C: Methodological tools for the comprehensive evaluation of integrated care

Chapter 11 described the COMIC Model for the comprehensive evaluation of integrated care interventions that provides insights into when, why and how successful outcomes can be achieved. As mentioned earlier, a preliminary model was developed based on the CMO Model and further developed based on its application to the above studies. The resulting COMIC Model (to study the **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions) assumes that an intervention is introduced using certain mechanisms, which are met with certain context factors, which combined, contribute to certain outcomes. Mechanisms are defined as the different components of an integrated care intervention and categorised according to the CCM. Context is defined as the setting in which mechanisms are brought into practice, described by barriers and facilitators and categorised according to the IM. Outcomes are defined as effects triggered by mechanism and context and categorised by the World Health Organization's six dimensions of quality of care. When using the COMIC Model, a focus on the mechanisms, context and outcomes of integrated care interventions, as well as their interplay, must be incorporated into study designs, data collection, analysis, interpretation and reporting. Data collection should take place by means of in-depth qualitative methods of data collection rather than studies that aggregate findings, such as literature reviews or questionnaires. We found that the COMIC Model made it possible to comprehensively study the interplay of the mechanisms, context and outcomes of integrated care interventions and thereby provided insights into when, why and how integrated care contributes to improved outcomes. We recommended that health practitioners, managers and patients and other relevant stakeholders should be included as informants. We also recommended the development of a practice version of the COMIC Model so as to make it more directly accessible and useful to providers and recipients of care.

In *Chapter 12*, we argued for the development of a universal typology of integrated chronic care interventions. We observed that the current diversity in understanding of what integrated care is or should be makes it difficult to compare and aggregate insights from interventions that are based on different understandings of integrated care. However, rather than resolving this issue by agreeing on one definition, we argued for the development of a universal typology of integrated care that enables the description and comparison of all interventions considered integrated care by relevant stakeholder groups. Moreover, we identified six characteristics such a universal typology should possess. 1. The main components should be rankable from the micro level (i.e. person at risk of illness or in need of care) to the macro level (i.e. system/national/policy/legislative/regulatory) to reflect the level at which an intervention is implemented. 2. These components should be intangible (i.e. theory-based, non-empirical or not directly implementable in practice) so that they can cover all categories that are theoretically relevant instead of only those that can be or were observed in practice. 3. The main components should be operationalised into tangible sub-components so that the typology can be applied more easily to practice examples of integrated care interventions. 4. These sub-components should be unrankable because otherwise it would not be possible to list all the tangible examples observed in practice. 5. The typology should be conceptually sound by only including mechanisms, not context factors or intended outcomes. 6. The typology should be flexible enough to be adapted when new approaches or technologies are developed. While these requirements mainly pertain to the form of

the typology, its content should be developed and validated in an international effort spanning different countries, cultures, health systems, professions and life experiences.

Nederlandse samenvatting

Hoge verwachtingen: de bijdrage van integrale zorg aan het verbeteren van uitkomsten voor mensen met chronische aandoeningen

Ondanks de toename van het aantal mensen met chronische aandoeningen ligt in de meeste zorgsystemen de nadruk op episodische, acute en ziektespecifieke zorg in plaats van langdurige, chronische en mensgerichte zorg. Integrale zorg wordt gezien als een veelbelovende manier om de zorg voor chronisch zieken beter te organiseren, o.a. door zelfmanagement te bevorderen, de verschillende onderdelen van het zorgproces beter op elkaar af te stemmen, het werken in multidisciplinaire teams te verbeteren en slimmere ICT oplossingen te benutten. De verwachtingen omtrent de potentiële bijdrage van integrale zorg aan betere uitkomsten zijn hoog, maar tot op heden is het wetenschappelijk bewijs hiervoor verdeeld. In dit proefschrift hebben wij onderzocht wanneer, waarom en hoe sommige integrale zorg interventies bijdragen aan betere uitkomsten, terwijl anderen dit niet doen. In het bijzonder hebben wij een antwoord gezocht op de onderzoeksvraag: Hoe wordt geïntegreerde zorg geïmplementeerd en aan welke uitkomsten draagt het bij?

Methoden

Het onderzoek is gebaseerd op twee internationale literatuuronderzoeken, een Nederlandse en een Duitse case studie (diabetes en ouderenzorg) en een internationaal vragenlijstonderzoek. Het onderzoek maakt deel uit van Project INTEGRATE, een door de EU gesubsidieerd wetenschappelijk onderzoek.

Resultaten

Integrale zorg kan bijdragen aan verbeterde uitkomsten voor mensen met chronische aandoeningen. Dit betreft klinische uitkomsten (zoals verbeterde bloedsuikerwaarden of cholesterol), maar ook een hogere patiënttevredenheid, een hogere tevredenheid onder zorgverleners en verbeterde samenwerking van zorgverleners. Echter, er zijn ook negatieve uitkomsten gevonden, zoals het verlenen van onvoldoende en onnodige zorg. Het behalen van positieve of negatieve uitkomsten is mede afhankelijk van de context of setting waarin de interventie wordt geïmplementeerd.

Omdat traditionele onderzoeksmethoden hiermee onvoldoende rekening houden, hebben wij het COMIC Model ontwikkeld¹¹. Het COMIC Model gaat ervan uit dat niet alleen de interventie zelf bepalend is voor het behalen van verbeterde uitkomsten, maar dat het hierbij om de combinatie van interventie en context gaat. Uit de Nederlandse case studie is bijvoorbeeld gebleken dat een keteninformatiesysteem (onderdeel van de interventie) onvoldoende gekoppeld was aan bestaande databases, zoals het huisartseninformatiesysteem (context). Daardoor moesten dezelfde patiëntengegevens dubbel ingevuld

¹¹ De afkorting COMIC staat voor **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions.

worden, wat leidde tot frustratie onder zorgverleners en minder volledige en betrouwbare gegevens (uitkomsten). Traditionele modellen die alleen kijken naar interventie en uitkomsten, hadden op basis van de negatieve uitkomsten waarschijnlijk geconcludeerd dat het keteninformatiesysteem niet werkt. Daarentegen concluderen wij dat het meest geavanceerde keteninformatiesysteem pas zijn vruchten afwerpt indien interventie en context op de juiste manier op elkaar afgestemd zijn. Deze inzichten zijn ook belangrijk als een interventie die eerder succesvol is gebleken in een andere setting geïmplementeerd wordt.

Conclusies

Integrale zorg interventies kunnen bijdragen aan verbeterde uitkomsten voor mensen met chronische aandoeningen, maar dit is niet altijd het geval. Evaluaties die gebruik maken van het COMIC Model houden rekening met de context waarin een interventie wordt geïmplementeerd en kunnen zodoende inzicht geven in waarom een interventie (niet) werkt en hoe de interventie en/of de context verbeterd kunnen worden om betere uitkomsten te behalen.

Deutsche Zusammenfassung

Große Erwartungen: Die Implementation integrierter Versorgungsstrukturen und deren Beitrag zur Verbesserung von Behandlungsergebnissen bei Patienten mit chronischen Erkrankungen

Trotz der steigenden Zahlen von Patienten mit chronischen Erkrankungen sind die meisten Gesundheitssysteme auf eine episodische und krankheitszentrierte Akutmedizin, statt einer langfristigen und ganzheitlichen Versorgung von Patienten mit chronischen Beschwerden, ausgerichtet. Die Idee der integrierten Versorgung gilt hierbei als vielversprechendes Konzept zur angemessenen Versorgung von Patienten mit (multiplen) chronischen Erkrankungen, beispielsweise durch die Förderung von Selbst-Management-Fähigkeiten, eine bessere Koordination der einzelnen Versorgungsprozesse, die Zusammenarbeit in multidisziplinären Teams und die Nutzung intelligenter Informationstechnologien. Große Erwartungen werden an die integrierte Versorgung auch in Bezug auf verbesserte Behandlungsergebnisse gestellt, bislang ist jedoch hierzu die Evidenz uneinheitlich. In dieser Dissertation wurde versucht zu verstehen, warum, wann und wie einige Formen der integrierten Versorgung in der Lage sind, solche verbesserten Behandlungsergebnisse zu erzielen, während andere dazu nicht in der Lage sind. Im besonderen Fokus stand dabei die Forschungsfrage: Wie wird integrierte Versorgung implementiert und auf welche Ergebnisparameter kann sie Einfluss nehmen?

Methoden

Die vorliegenden Ergebnisse basieren auf zwei systematischen Literaturanalysen, zwei Analysen integrierter Versorgungsdienstleister in den Niederlanden und in Deutschland sowie einem internationalen Expertensurvey. Die Arbeiten fanden im Rahmen des von der Europäischen Union geförderten Forschungsprojekts „Project INTEGRATE“ statt.

Ergebnisse

Integrierte Versorgung kann dazu beitragen, die Versorgung von Patienten mit chronischen Erkrankungen zu verbessern. Dies trifft sowohl für klinische Parameter zu (wie beispielsweise verbesserte Blutzucker- oder Cholesterinwerte) als auch für Faktoren wie Patientenzufriedenheit, Zufriedenheit der Berufsangehörigen oder verbesserte Kooperation zwischen den einzelnen Berufsgruppen in der Versorgung. Demgegenüber wurden aber auch negative Faktoren, wie beispielsweise die Bereitstellung unzureichender oder unnötiger Therapien, gefunden. Die Frage, ob integrierte Versorgung mit positiven oder negativen Ergebnissen einhergeht, ist dabei abhängig vom Kontext, in dem die integrierte Versorgung implementiert wurde.

Bestehende Untersuchungsmethoden beziehen den Kontext nicht ausreichend ein. Aus diesem Grund wurde das COMIC Modell¹² entwickelt. Das COMIC Modell basiert auf der Annahme, dass nicht nur die

¹² COMIC ist eine Abkürzung für **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions.

Intervention entscheidend ist für ein verbessertes Behandlungsergebnis, sondern auch die gegenseitige Beziehung zwischen Intervention und Kontext. So konnte beispielsweise in der Untersuchung des deutschen Standorts festgestellt werden, dass einerseits ein multidisziplinäres geriatrisches Team vorhanden war (Intervention), dieses aber aufgrund der hohen Arbeitsbelastung keine ausreichende Zeit für eine tiefergehende Kooperation hatte (Kontext). Dies führte zu ineffizienten Arbeitsabläufen, Frustration in den einzelnen Berufsgruppen und einer geringeren Einbindung der Familienangehörigen von Patienten in den pflegerischen Prozess (Ergebnis). Herkömmliche Bewertungsmethoden wären an dieser Stelle zu dem Schluss gekommen, dass die multidisziplinäre Zusammenarbeit nicht effektiv sei. Unsere Untersuchungen kamen hingegen zu dem Schluss, dass auch ein gutes multidisziplinäres Team mit dem bestmöglichen Skill-Mix nur dann effektiv zusammenarbeiten kann, wenn die dazu notwendigen Kontextfaktoren erfüllt sind. Ein solches Verständnis ist auch dann wichtig, wenn erfolgreiche Interventionen an anderen Standorten implementiert werden sollen.

Schlussfolgerung

Integrierte Versorgung kann zu verbesserten Interventionsergebnissen in der Versorgung von Menschen mit chronischen Erkrankungen beitragen. Evaluationen solcher Programme mit Hilfe des COMIC Modells beziehen den Kontext, in dem solche Interventionen stattfinden, ein und ermöglichen so Einblicke in die Gründe, warum bestimmte Interventionen (nicht) effektiv sind und wie entweder die Intervention oder der Kontext so angepasst werden muss, dass positive Effekte erzielt werden können.

Sintesi in italiano

Grandi aspettative: l'implementazione di cure integrate ed il contributo al miglioramento degli outcome per persone con malattie croniche

Nonostante il numero crescente di persone affette da malattie croniche, molti sistemi sanitari si focalizzano su un approccio alle cure di tipo episodico anziché di lungo termine e centrato sulla patologia anziché sulla persona. L'integrazione delle cure è considerata uno dei più promettenti approcci per l'erogazione di cure appropriate a persone affette da patologie croniche (multiple), poichè, per esempio, promuovono l'auto-cura, un miglior allineamento dei diversi attori coinvolti nel processo di cura, il lavoro in gruppi multidisciplinari, e l'uso intelligente di soluzioni tecnologiche (IT). Vi sono grandi aspettative riguardo al potenziale contributo dell'integrazione delle cure per migliorare gli outcome, ma al momento si registrano evidenze contrastanti. In questa tesi, si è cercato di capire perchè, quando e come alcuni interventi di integrazione delle cure contribuiscono o meno a migliorare gli outcome. In particolare, si è affrontata la seguente domanda di ricerca: Come si implementa l'integrazione delle cure e a quali outcome conducono?

Metodi

La ricerca si basa su due review della letteratura, un caso di studio olandese ed uno tedesco (rispettivamente, riguardante il diabete e condizioni geriatriche) ed un sondaggio rivolto ad esperti internazionali. L'attività di ricerca è stata condotta nell'ambito del progetto Europeo "INTEGRATE", finanziato dall'Unione Europea.

Risultati

L'integrazione delle cure può contribuire a migliorare gli outcome per persone affette da patologie croniche. Questo vale per gli outcome clinici (ad esempio: migliori livelli di zucchero nel sangue o di colesterolo), ma anche per una più alta soddisfazione del paziente e dei professionisti, e una migliore cooperazione tra questi ultimi. Tuttavia, si riscontrano anche outcome negativi, come l'erogazione di cure insufficienti o non necessarie. Il fatto che si ottengano outcome negativi o positivi dipende dal contesto in cui un intervento è implementato.

Poichè i metodi tradizionali di ricerca non considerano sufficientemente il contesto, si è sviluppato il modello COMIC¹³. Questo modello assume che non solo l'intervento in sè è decisivo per il conseguimento degli outcome, ma anche l'interazione tra intervento e contesto. Ad esempio, il caso di studio tedesco mostra che nonostante vi fosse un team geriatrico multidisciplinare (intervento), i membri del gruppo avevano un tale livello di sovraccarico lavorativo da non avere tempo per cooperare effettivamente l'uno con l'altro (contesto). Questa situazione generava flussi di attività inefficienti,

¹³ COMIC è una abbreviatura di **C**ontesto, **O**utcomes e **M**eccanismo di Interventi di **I**ntegrazione delle Cure.

frustrazione tra i professionisti sanitari e limitato coinvolgimento della famiglia (outcomes). Questi risultati indicano che i tradizionali modelli concentrati solo sugli outcome avrebbero condotto alla conclusione che la collaborazione multidisciplinare non funziona. Mentre il presente lavoro indica che un team multidisciplinare, anche se dispone del migliore mix di competenze possibile, può migliorare gli outcome solo se opera in un adeguato contesto. Questo aspetto è importante anche quando un intervento risulta di successo ma è implementato in un contesto diverso.

Conclusioni

Gli interventi di integrazione delle cure possono contribuire a migliorare gli outcome per persone affette da malattie croniche, anche se non sempre. Le valutazioni basate sul modello COMIC tengono in considerazione il contesto dove l'intervento è implementato e possono dunque fare luce sul perché un intervento funziona o meno e come l'intervento o il relativo contesto possono essere cambiati per migliorare gli outcome.

Resumen en español

Grandes expectativas: la implementación de atención integrada y la contribución al mejoramiento de resultados para personas con enfermedades crónicas

A pesar del incremento del número de personas con enfermedades crónicas, la mayoría de los sistemas de salud aún se focalizan en episodios agudos en vez de crónico, o en la enfermedad en vez de centrar la atención en la persona. La atención integrada es considerada uno de los enfoques más prometedores para proveer atención adecuada a las personas con (múltiples) enfermedades crónicas, por ejemplo promoviendo el autocuidado, un mejor alineamiento de las diferentes partes del proceso de atención, mejorando el trabajo de equipos multidisciplinarios, y haciendo uso de soluciones tecnológicas (IT) más sofisticadas. Existen grandes expectativas acerca de la potencial contribución de las intervenciones de atención integrada al mejoramiento de resultados, pero hasta ahora la evidencia no es muy clara. La presente tesis tiene como objetivo comprender por qué, cuándo y cómo algunas intervenciones de atención integrada contribuyen a mejorar los resultados, mientras otras no. En particular, se aborda la siguiente pregunta de investigación: ¿Cómo es implementada la atención integrada y cuáles son los resultados sobre los que ésta incide?

Métodos

La investigación está basada en dos revisiones de la literatura internacional, en un caso holandés y un alemán (sobre diabetes y síndromes geriátricos, respectivamente), y una encuesta en la que participaron expertos de varios países. El estudio ha sido realizado como parte de proyecto europeo INTEGRATE, financiado por la Unión Europea.

Resultados

Se encontró que la atención integrada puede contribuir a obtener mejores resultados en personas con enfermedades crónicas. Esto no sólo es válido para resultados clínicos (tales como mejores niveles de glucosa en la sangre o de colesterol), sino también para mayores niveles de satisfacción del paciente y de los profesionales de salud, así como para mejorar la cooperación entre éstos últimos. Sin embargo, también se observaron resultados negativos como la provisión de atención insuficiente e innecesaria. La obtención de resultados positivos o negativos depende del contexto en el cual una intervención es implementada.

Como los métodos tradicionales no toman suficientemente en cuenta el contexto, se desarrolló el modelo COMIC¹⁴. Este modelo asume que no sólo la intervención es decisiva para alcanzar mejores resultados, sino también la interacción entre la intervención y el contexto. Por ejemplo, el estudio de caso alemán mostró que, a pesar de que había un equipo geriátrico multidisciplinario en el lugar

¹⁴ COMIC es una abreviatura de Contexto, Resultados y Mecanismo de Intervenciones de Atención Integrada; en inglés: **C**ontext, **O**utcomes and **M**echanisms of **I**ntegrated **C**are interventions.

(intervención), los miembros del equipo experimentaban tal carga de trabajo que no tenían tiempo para colaborar realmente con los demás (contexto). Esto contribuyó a un flujo de trabajo ineficiente, frustración entre los profesionales de la salud, y menor participación de la familia (resultados). En base a estos hallazgos, los modelos tradicionales que se focalizan sólo en resultados habrían concluído que la colaboración multidisciplinaria no funciona. Sin embargo, el presente estudio concluye que un equipo multidisciplinario, aun contando con el mayor mezcla de competencias posible, puede contribuir a mejorar los resultados sólo si se logra un buen ajuste con el contexto. Este aspecto también es importante cuando una intervención que resulta exitosa es implementada en un contexto diverso.

Conclusiones

Las intervenciones de atención integrada pueden contribuir a mejorar los resultados en salud de las personas con enfermedades crónicas, aunque no siempre es así. Las evaluaciones que utilizan el modelo COMIC toman en cuenta el contexto en el cual una intervención es implementada y, de este modo, pueden dar indicios del porqué una intervención funciona o no, y de cómo la intervención y/o el contexto pueden ser cambiados para obtener mejores resultados.

