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Abbreviations

ACIC	Assessment of Chronic Illness Care
CCM	Chronic Care Model
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
COSMIN	COnsensus-based Standards for the selection of health Measurement Instruments
DALYs	Disability Adjusted Life Years
EHR	Electronic Health Record
EU	European Union
FRASIK	Frankfurt Patient Safety Climate Survey
GDP	Gross Domestic Product
HIT	Health Information Technology
IOM	Institute of Medicine
NCDs	Noncommunicable Diseases
NPSA	National Patient Safety Agency
OECD	Organisation for Economic Co-operation and Development
PACIC	Patient Assessment of Chronic Illness Care
PREMs	Patient-Reported Experience Measures
PREOS-PC	Patient Reported and Outcomes of Safety in Primary Care
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta- Analyses
QOF	Quality and Outcomes Framework
QALYs	Quality Adjusted Life Years
RMSEA	Root Mean Square Error of Approximation
ROI	Return on Investment
SAQ	Safety Attitude Questionnaire
SCOPE-PC	SCOPE-Primary Care

SRMR	Standardised Root Mean Square Residual
STROBE	STrengthening the Reporting of Observational studies in Epidemiology
TLI	Tucker Lewis Index
VAS	Visual Analogue Scale
WHO	World Health Organization
YLDs	Years Lived with Disabilities

Chapter 1

General Introduction and Thesis Outline

Healthcare is changing. The combination of technological advancements, demographic changes (e.g., growing number of elderly people), new disease patterns, and the associated rising healthcare costs lends urgency for healthcare systems around the globe to adapt.

Tremendous progress has been made in healthcare as a result of advances in medical knowledge and innovation. This resulted in large falls of death rates for many life-threatening conditions such as HIV/AIDS, heart attacks, and strokes. Consequently, life expectancy at birth globally increased. According to the latest Lancet *Global Burden of Disease Study* in 2015, the world population has gained more than 10 years of life expectancy since 1980, rising to 69.0 years for men and 74.8 years for women in 2015 [1]. Life expectancy across the European Union (EU) countries has increased by more than six years since 1990, rising from 74.2 years to 80.9 years in 2014 [2]. Hence, the share of population aged over 65 years in EU countries has increased from 10% in 1960 to almost 20% in 2015 and is projected to increase to nearly 30% by 2060 [2]. Although quality of care has generally improved in most EU countries, one must note that inequalities still persist, both across and within countries.

The progress in healthcare is worthy of praise, however the future sustainability of healthcare systems is jeopardised. Although *overall* life expectancy has increased by 10.1 years between 1980 and 2015, *healthy* life expectancy has increased steadily by 6.1 years, resulting in more years of life with illness and disability [1]. In other words, an illness which was once fatal has now become a chronic condition that the patient can live with for many years. For instance, a French study of 417.000 new adult cancer cases diagnosed between 1989 and 2004 showed significant improvements in survival rates for most cancers and especially for prostate cancer [3]. Similar improvements were found for AIDS patients [4]. These chronic diseases - also referred to as noncommunicable diseases (NCDs) - are defined as conditions of long duration and generally slow progression [5]. The rise of NCDs is not only driven by an ageing population, but also by globalisation, urbanisation, and traditional risk factors such as smoking, high blood pressure, and unhealthy diet [6].

CHRONIC DISEASE BURDEN

The burden of chronic diseases is rapidly increasing worldwide. According to the aforementioned *Global Burden of Disease Study* (2015), NCDs are now responsible for approximately 50% of the world's burden of disease, with cardiovascular conditions, cancers, and respiratory diseases as the most common causes of death [7]. Between 2008 and 2030, the annual number of deaths from chronic conditions is projected to further increase from 36 million to 52 million around the globe [5]. It is often assumed that chronic disease deaths are restricted to older people. However, approximately 16 million chronic disease deaths occur each year in people under 70 years of age, especially in low and middle-income countries [8]. One must also note that there is a progressive trend in earlier onset of chronic diseases [8].

Furthermore, the rising chronic care needs also resulted in an estimated 1%-5% reduction in Gross Domestic Product (GDP) between 2005 and 2015 across all EU countries [2]. The World Health Organization (WHO) estimated that each 10% increase in working-age mortality rates of chronic diseases results in a decrease of the economic growth rates by close to 0.5% [9]. Additionally, the EU will witness an increase in healthcare expenditures from 6% of the GDP in 2010 to 9.5% in 2060 [2].

Currently, around 50 million EU citizens are estimated to suffer from two or more chronic conditions and this number is expected to increase in the coming years [1]. In Belgium, the top five leading causes of years lived with disability (YLDs) are low back pain, major depressive disorders, falls, neck pain, and other musculoskeletal disorders [10]. The top three causes of disability adjusted life years (DALYs) are heart diseases, low back pain, and cerebrovascular diseases [10]. In 2015, Belgium devoted 10.4% of its GDP on healthcare, which is higher than the EU average of 9.9% [2].

LACK OF CARE COORDINATION AND THE IMPACT ON PATIENT SAFETY

Healthcare systems are still ill-equipped to deal with the aforementioned demographic transformation. The management of chronic care is often complex, both clinically and on the organisational level. It is the sum of different care needs, usually answered by more varied health and social care services. However, chronic care has been developed in ways that have tended to fragment care delivery - within and between healthcare settings - and which is largely built around the long-standing acute and episodic model of care provision [11]. Patients are often sent from pillar to post and sometimes forced to repeat their story numerous times. Consequently, some components of care may be duplicated, whereas others may be overlooked.

As the number of healthcare professionals (often from different settings) involved in the patient's care increases, effective coordination of care becomes highly important. Poorly coordinated care for people with chronic conditions is frequently implicated in studies of unsafe care. A lack of integration and coordination may lead to suboptimal care and may endanger patient safety in terms of preventable hospitalisation or adverse drug events [12]. In a major nationwide study of 506.376 participants in the USA, chronically ill patients - whose primary care professionals offer fragmented care - had higher chances of departure from clinical best practices, had higher rates of preventable hospitalisations, and were associated with higher healthcare-associated expenditures [13].

Coordination of care is even more difficult for individuals with multiple chronic conditions [12] and particularly at the interface between secondary and primary care, with about half of adults experiencing a medical incident after hospital discharge and 19%-23% suffering an adverse event [14-18]. A mixed methods analysis of 598 patient safety incident reports in England and Wales from hospital discharge furthermore identified specific errors in discharge communication (54% causing harm), errors in referral to community care (73% causing harm), errors in medication (87% causing harm), and lack of provision of care adjuncts (94% causing harm) as the main causes of adverse events [19].

However, patient safety incidents in primary care are not always directly transferable from hospital care. In a recent retrospective review study of 600 patient records, Schildmeijer *et al*. concluded that 76.1% of safety incidents in primary care were related to home healthcare, 12.4% to in-hospital care, 6.5% to social care, and 3.4% to outpatient care [20]. Indeed, fragmentation of care also exists within primary care [21] or (for example) between hospitals and nursing homes [22].

Hence, fragmentation of care poses major challenges for today's chronic care delivery. Yet, chronic patients are in high need of a broad range of professionals and skills from different healthcare settings and practices, which are offered as integrated and coordinated services, embedded within a system that promotes patient empowerment. In other words, patients need the right care, at the right time, and in the right place. Research indicated that higher levels of continuity of care are associated with a lower likelihood of hospitalisation [23,24], better patient experiences [25], and improved patient adherence [26].

PATIENT SAFETY

As the complexity of care delivery increases, interaction between multiple healthcare professionals from different settings (i.e., home healthcare, specialist care, social care, …) is critical for patient safety. As outlined before, new hazards arise if communication and coordination of care is deficient. In addition, evolutions in healthcare - even in the form of organisation - inevitably bring new risks for patients. In an economic landscape where healthcare systems have to achieve more with less, the safety of care delivery is now more than ever a central concern.

In the light of the increasing number of chronic patients, Amalberti *et al*. once stated: '*patient safety incidents no longer relate only to episodic errors and failures in procedures at specific times, but also to cumulative failures throughout a patient's journey within a health system*' [27].

The Origin of Human Error and Patient Safety

Anecdotes such as the Tenerife runway collision in 1977, the Three Mile Island crisis in 1979, the Bhopal methyl isocyanate disaster in 1984, the Chernobyl explosion in 1986, the King's Cross tube station fire in 1987, and the Piper Alpha oil platform explosion in 1988 led to a collective impetus on addressing error [28]. High-reliability environments deal with safety risks and hazards on a daily basis. Aforementioned safety incidents were not the result of employees' lack of sophistication or desire to do the right thing. They were caused by a variety of factors that employees cannot control, such as lack of standardised approaches or outdated work systems. In a landmark publication, James Reason developed a model for dynamics of accident causation, often referred to as the *Swiss Cheese Model* [28]. The model describes how safety incidents are frequently the result of multiple smaller errors within a failed system.

Reason identified the - what he describes as *latent failures* - and the trajectory of error opportunity as a result of the alignment of holes in the slices of Swiss cheese: '*(…) whose adverse consequences may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defences (…). Latent error (…) are most likely to be spawned by those whose activities are removed in both time and space from the direct control interface: designers, high-level decision makers, construction workers, managers, and maintenance personnel*'.

People make errors, regardless of their intelligence, experience, motivation, or vigilance. Humans are somehow destined to make mistakes and therefore no system can produce perfect results. Employees cannot control the system they work in and therefore cannot be held responsible for possible safety incidents as a result of system failings. Rather than punishing, employees should be consoled and supported. Originally defined by Reason as '*a collective understanding of where the line should be drawn between blameless and blameworthy actions'*, this organisational fairness has been imbedded in high-risk industries of aviation, train transportation, and nuclear power [28,29].

The Patient Safety Challenge

Since the release of the *Harvard Medical Practice Study* in 1991 and the Institute of Medicine's (IOM) report *To Err is Human: Building a Safer Health System* in 2000, widespread public attention was drawn to the importance and magnitude of patient harm from medical incidents [30,31]. The IOM report estimated that more people in the USA were dying as a result of adverse events than from road traffic accidents. Following the aforementioned IOM report, the number of patient safety publications has been continuously increasing [32]. Incident rates from medical record review studies were reported for Australia [33], New-Zealand [34], Denmark [35], Canada [36], France [37], Tunisia [38], Spain [39], Italy [40], the UK [41], Portugal [42], the Netherlands [43], and Belgium [44]. Moreover, the economic burden of adverse events is substantial. A literature-based evaluation of 30 EU countries estimated the annual cost of preventable adverse events to be in the range of €17–38 billion [45].

In literature, many definitions of *patient safety* are mentioned. In its simplest, it can be defined as '*the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of healthcare'* [46]. A *patient safety incident* is defined as '*an unintended event during the care process that resulted, could have resulted, or still might result in harm to the patient*' and an *adverse event* is defined as '*an unintended injury or complication, leading to prolonged hospital stay, disability at the time of discharge or death, and are due to healthcare management rather than to the patient's underlying disease*' [47]. According to the IOM, safe care is one of the critical components of the delivery of high-quality care [48]. Other elements include effectiveness, patient-centredness, timeliness, efficiency, and equitability. Recently, the Strategic Advisory Board for Welfare, Health and Family Policy (*Strategisch Adviesraad voor Welzijn, Gezondheid en Gezin*) of the Flemish Government (Belgium) added two more components, namely continuity and integration of care [49].

Patient Safety Culture

The National Patient Safety Agency (NPSA) identified seven crucial steps to improve patient safety [50]. One of the key conditions is creating a sustainable and supportive patient safety culture in order to identify possible weaknesses and to develop improvement strategies so recurrence of safety incidents can be minimised [30]. Safety culture is only one aspect of the wider organisational culture and originated from other industries such as the nuclear industry, aviation, and the petrochemical industry [51]. Within the healthcare sector, patient safety culture is widely accepted in safety improvements. The IOM report *To Err is Human: Building a Safer Health System* highlighted the importance of safety culture: '*organisations must develop a culture of safety such that an organisation's care processes and workforce are focused on improving the reliability and safety of care for patients*' [30]. Moreover, several international healthcare organisations such as the WHO, the Organisation for Economic Cooperation and Development (OECD), and the EU included safety culture in patient safety programs [50]. In addition, a small number of theories suggest that organisations and teams can contribute to minimising the risk of incidents by assessing safety culture perceptions [52].

Internationally, the commonly used definition for the term *patient safety culture* is: '*the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*' [53]. Measuring patient safety culture may act as a diagnostic learning tool by identifying perceived areas of patient safety weakness. Additionally, it enables the monitoring and benchmarking of scores for important patient safety dimensions. Reason identified four characteristics of a positieve patient safety culture: [1] a *reporting* culture (i.e., a context in which employees have enough confidence to report patient safety concerns), [2] a *just* culture (i.e., a context in which employees are encouraged and supported to be fair), [3] a *flexible* culture (i.e., a context in which the organisation and employees are capable of effectively adapting to changing demands), and [4] a *learning* culture (i.e., a context in which the organisation is able to learn from mistakes) [54].

In literature, the terms *climate* and *culture* are often used interchangeably. However, the exact meanings of both terms are different. According to Schein, *culture* manifests itself in deeper levels of unconscious assumptions whereas *climate* refers to the visible manifestation or measurable components of culture [51]. In other words, climate provides a snapshot of culture by examining its measurable aspects [55].

Patient Safety in Primary Care

As a lot of care for (chronic) conditions is provided in primary and community care settings, a different vision of patient safety is required. Heretofore, the vast majority of research almost exclusively focused on hospital care for various reasons; that is the perception that primary care is a low technology environment where patient safety is not perceived as a major issue and the multiplicity of sites where primary care is delivered [56]. Far less is known about the nature, causes, and consequences of patient safety incidents in primary care settings where the vast majority of patient-professional encounters take place. Safety issues in primary care may differ from inpatient settings in several ways; that is differences in the type of patient safety incidents, patient-professional encounters, and organisational structures. However, one must note that some safety incidents and patient-professional characteristics are common in both home healthcare and hospital care [20].

The WHO established a *Safer Primary Care Working Group* to study patient safety in primary care by expanding knowledge on the risks, nature, and magnitude of adverse events due to unsafe practices. In 2012, the group launched a consensus statement on the need to address this research gap [57]. These commitments emphasise a shift in prioritisation of patient safety towards primary care. Ten years after the report *To Err is Human: Building a Safer Health System*, a review of patient safety in primary care revealed major gaps in the understanding and improvement of primary care safety [58]. Most published research on patient safety in primary care originated from the USA or the UK and often addresses the themes of medication incidents, safety culture, and incident reporting [59]. To date, prevalence rates for patient safety incidents in primary care vary widely.

A large medical record review study of 1.000 patients in the Netherlands found 211 patient safety incidents across a period of one year of which 58 incidents affected patients and seven were associated with hospital admission [60]. In England, a random sample of 74.763 medical records revealed an incident rate of eight adverse events per 10.000 consultations [61]. The aforementioned studies provide heterogeneous results due to definitional challenges, differences in organisational structures of primary care, and the restricted use of only one information source. Moreover, two recent Canadian studies in home care that used almost identical sampling and data collection methodology reported incidence rates of 13.2% [62] and 10.1% [63]. Home care patients with higher instrumental activities of daily living dependency or a higher number of diagnoses were found to have higher odds for experiencing an incident [64].

FRAMEWORKS FOR IMPROVING CHRONIC CARE DELIVERY

In short, current models of care delivery are unsustainable and the pressure for change will only increase. Chronic diseases demand long-term care and constant follow-up. Secondary care cannot remain the main provider of healthcare. Care will often move outside the hospital with a consequential new vision on (community-based) primary care. More integrated, seamless, and person-centred services for patients living with long-term conditions are required for patients to live independently, mitigate risk, and have a good quality of life [2].

Across the world, compelling demands can be found for a fundamental shift in the organisation of health and social care for better prevention and more effective management of chronic diseases. For instance, the WHO calls for a fundamental shift in the way healthcare services are delivered to more '*integrated people-centred health services that puts the needs of people and communities at the centre of health systems and empowers people to take charge of their own health*' [65].

The Chronic Care Model

There are several organisational models for the care of chronic diseases [66]. The *Chronic Care Model* (CCM) - developed in the late 90s in California by a group of researchers from the MacColl Institute for Healthcare Innovation - is one of the most well-known and applied models (see Figure 1) [67]. The CCM was developed as an outcome of extensive systematic literature review. In 2003, the CCM model was refined by incorporating additional themes such as patient safety, cultural competency, care coordination, community policies, and case management. This international reference model provides a comprehensive framework for the organisation of healthcare services and aims at improving outcomes for chronic patients. Moreover, the CCM brings together evidence-based components that encourage high-quality chronic disease care that have a positive impact on patient outcomes, quality of care, and cost savings [68-71]. For example, a recent systematic review reported that CCM-based integrated care models for diabetes type 2 patients resulted in positive effects on intermediate clinical outcome measures, including improvements in glycaemic control, blood pressure, cholesterol levels, and body mass index [72].

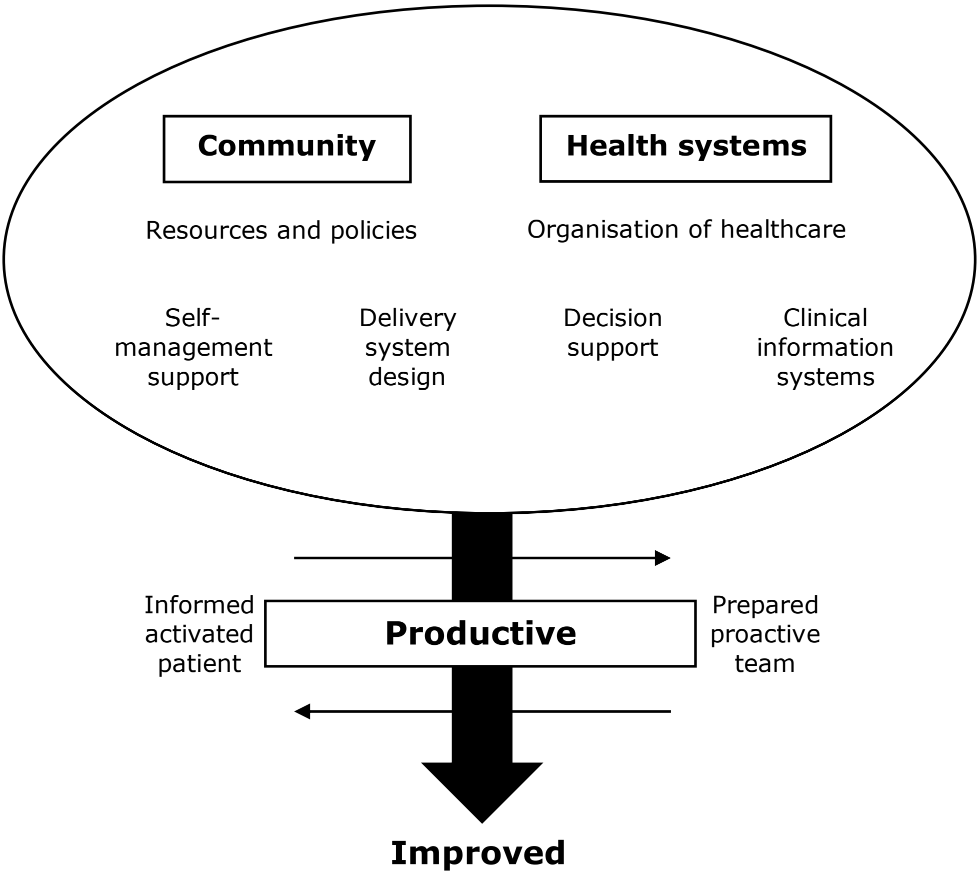

Figure 1 The Chronic Care Model

The CCM is based on six key issues [67]:

1. The **community**: mobilise community resources to meet the needs of patients by encouraging patients to participate in community programs, forming partnerships with community organisations, and advocating for policies to improve patient care;
2. The **health system**: create a culture, an organisation, and mechanisms that promote safe, high quality care by supporting improvement at all levels of the organisation, promoting effective improvement strategies, encouraging open and systematic handling of errors, providing incentives based on quality of care, and developing agreements that facilitate care coordination;
3. **Self-management support**: empower and prepare patients to manage their health and healthcare by emphasising the patient's central role, using effective self-management support strategies, and organising internal and community resources;
4. **Delivery system design**: assure the delivery of effective, efficient clinical care, and self-management support by defining roles and distribute tasks among team members, using planned interactions to support evidence-based care, providing clinical case management services, ensuring regular follow-up, and giving care that patients understand and that fits with their cultural background;
5. **Decision support**: promote clinical care that is consistent with scientific evidence and patient preferences by embedding evidence-based guidelines into daily clinical practice, sharing evidence-based guidelines and information with patients, using proven provider education methods, and integrating specialist expertise and primary care;
6. **Clinical information systems**: organise patient and population data to facilitate efficient and effective care by providing timely reminders for providers and patients, identifying relevant subpopulations for proactive care, facilitating individual patient care planning, sharing information with patients and providers to coordinate care, and monitoring performance of practice teams and care system.

Other Well-known Frameworks

In the meantime, several CCM-modifications have been developed such as the WHO's *Innovative Care for Chronic Conditions Framework* [73] and the *Expanded Chronic Care Model* [74]. Additionally, other frameworks have been designed to integrate care for chronic patients at the individual (e.g., case management, individual care plans, Patient-centred Medical Home Model, or personal health budgets), disease-specific (e.g., disease management or managed clinical networks/pathways), and population level (e.g., Kaiser Permanente or Veterans Health Administration). Below, a short overview of the most well-known models is provided [66]:

- **Patient-centred Medical Home**: a model for transforming the organisation and delivery of primary care. The PCMH framework is a holistic approach to manage chronic patients by offering a comprehensive model of personalised primary care where patients are assigned to particular medical homes and healthcare professionals;
- **Kaiser Permanente**: a model that is based on stratification of the population and supplying different services according to the needs. The model is presented in the Kaiser Pyramid. The general population receives promotion and prevention to control exposure to risk factors. The majority of chronic patients (70%-80%) receives support for self-management of their illness. High-risk patients (15%) and a small group of patients with severe complications (5%) receive disease and case management;
- **The Rainbow Model of Integrated Care**: a conceptual framework for integrated care from a primary care perspective. The model defines several dimensions of integrated care for chronic patients; that is [1] system integration at a macro level, [2] professionals (i.e., partnerships between healthcare professionals) and organisational (e.g., network-like governance mechanisms) integration at a meso level, and [3] clinical (i.e., the coordination of person-focused care in a single process across time, place, and discipline) integration at a micro level [75].

This dissertation will only use the CCM as conceptual framework for it has been implemented in different healthcare setting - including Belgium [76] - and as a basis for other chronic care models.

MAIN OBJECTIVES OF THE DISSERTATION

While a great deal of progress has been made in understanding adverse events in the hospital setting, research regarding patient safety in primary care is recent and still in an early stage of development. Despite, broad consensus exists that re-balancing care between primary and secondary care settings is one of the keys to the future organisation of chronic care delivery that is more continuous, comprehensive, and coordinated [2]. Healthcare systems that are dominated by secondary, tertiary, and emergency care are often fragmented, discontinuous, and costly as they do not meet the rising chronic care needs. Many patients attending the hospital can be much better treated either in their homes or in primary care settings.

There is widespread belief that moving care away from costly inpatient services will deliver the *Triple Aim* of improving population health and the quality of patient care whilst reducing costs [11]. The 1978 *Alma-Ata Declaration* envisaged primary care as '*the first level of contact of individuals, the family and community with the national health system bringing healthcare as close as possible to where people live and work, and constituting the first element of a continuing healthcare process*' [77]. Comprehensive research demonstrated that strong primary care systems deliver better population health outcomes at lower costs and play an important role in reducing social health inequalities [78,79]. Furthermore, greater availability of primary care has also been associated with lower infant mortality, fewer years of life lost due to suicide, and higher life expectancy [78,79].

The aim of the dissertation is twofold; first to give a scientific overview of patient safety in primary care and second to understand the current underlying discontinuity and fragmentation of healthcare in Belgium (Flanders) in order to define key conditions of new care delivery models that meet the rising chronic care needs and prevent patient safety incidents in the future. The following research questions were addressed:

1. **What is the best available scientific evidence on patient safety in primary care and the potential economic impact of integrated care models for patients with chronic diseases (PART I)?**

2. **How do chronic patients perceive the quality and safety of today's chronic care delivery (PART II)?**

3. **How do healthcare professionals perceive the safety of today's chronic care delivery (PART III)?**

This research was part of project CORTEXS (*Care Organisation: a Re-Thinking EXpedition in search for Sustainability*), running from November 2013 to October 2017. Project CORTEXS was an extensive multidisciplinary research project in Belgium (Flanders), that studied integrated care from the micro-level of care recipients and their caregivers, over the meso-level of intra- and inter-organisational processes, to the macro-level of legal and financial frameworks [80]. Consequently, this dissertation has an empirical focus on community-based primary care in Flanders (Belgium).

OUTLINE OF THE DISSERTATION

The different chapters - starting with this General Introduction in **Chapter 1** and ending with the General Discussion in **Chapter 9** - are written as separate articles and can be read independently. Inevitably, the content of the chapters may show some overlap, especially regarding used methods and instruments.

PART I: Evidence on Patient Safety in Primary Care

The first part of the doctoral thesis addresses the first research question regarding the available evidence on patient safety in primary care and the potential economic impact of integrated care models for patients with chronic diseases.

Chapter 2 presents the results of the narrative literature review that focused on patient safety in primary care. After all, a clear understanding is needed about the epidemiology and type of patient safety incident that occur in primary care settings. The review is based on four conditions - proposed by Shojania *et al*. - that must be fulfilled to improve patient safety; that is [1] identifying patient safety risks, [2] developing effective interventions to reduce these risks, [3] implementing these interventions in practice, and finally [4] defining useful indicators to measure any improvements [81]. It is only by understanding why and how patient safety incidents in primary care occur that learning can be derived.

When talking about the quality and safety of care, one must also consider the financial aspects of healthcare delivery. In times of financial pressure, policy makers often focus more on achieving a financial balance rather than on quality indicators. Since integrated care receives a more prominent role in healthcare delivery, **Chapter 3** aims at assessing the potential economic impact of integrated care models for patients with chronic diseases; that is patients with diabetes mellitus type 2, schizophrenia, and multiple sclerosis respectively. The PRISMA-statement (*Preferred Reporting Items for Systematic reviews and Meta-Analyses*) was applied to report the results of the systematic review [82].

PART II: Patient-Perceived Quality and Safety of Chronic Care

In the years following the IOM report *To Err is Human: Building a Safer Health System*, patient safety research mainly focused on the perspectives of healthcare professionals, which are - while important - an incomplete vision. There is now growing international consensus that patients can play a more active role in improving healthcare as they increasingly recognise the defects in their care [83]. The integration of patients' perspectives has the potential to enhance care quality. They have been shown in a number of studies to willingly report patient safety incidents accurately and to participate in prevention strategies [83]. Patients will have an increasingly important role in maintaining safety as they are the only one who are present throughout the full continuum of care. This is increasingly important for patients with chronic conditions where outcomes are not measured by cure rates, but rather determined by adherence to long-term treatment regimes [84]. While research has reiterated the need to put patients first, patients themselves and their experiences still seems to be missing, referred by Wachter as a '*troubling gap*' [85].

Consequently, the second part of the dissertation will cover chronic patients' perceptions of the quality and safety of today's chronic care delivery. **Chapter 4** assesses chronic patients' perceptions of the quality of care delivery or - more specifically - the alignment with the CCM. A cross-sectional survey study design was applied by using the *Patient Assessment of Chronic Illness Care* (PACIC) survey that provides a patient perspective on receipt of CCM-related chronic illness care [86].

Given the aforementioned substantial shift of chronic care delivery and the relatively lack of research on patient safety in primary care, the study in **Chapter 5** sought to explore chronic patients' perceptions of the safety of today's chronic care delivery in community-based primary care. Again, an observational cross-sectional study design was applied by using existing validated metrics and self-formulated questions.

PART III: A Healthcare Professional Perspective on the Safety of Primary Care

The third part of the dissertation provides a healthcare professional perspective on the safety of primary care. An important condition of patient safety management is a supportive patient safety culture in order to identify possible weaknesses and to develop improvement strategies so recurrence of incidents can be minimised [30]. The importance of considering safety culture in patient safety improvements is widely accepted within healthcare. Despite this awareness, most tools to measure and strengthen patient safety culture have been developed and tested within hospitals.

As a consequence, research gaps remain in the understanding of patient safety culture in primary care. **Chapter 6** provides a systematic and psychometric review of self-reported instruments to assess patient safety culture in primary care in order to identify the most appropriate measurement instrument. The instrument was chosen by using the four-point rating scale COSMIN (*Consensus-based Standards for the selection of health status Measurement INstruments*) checklist [87]. The checklist is a standardised tool to evaluate the methodological quality of the instruments' validation process. Based on the review, the SCOPE-Primary Care (SCOPE-PC) instrument was chosen as the most appropriate instrument.

Furthermore, **Chapter 7** builds further on chapter 6 and is aimed at testing the psychometric properties (i.e., confirmatory factor analysis, Cronbach's alphas, and inter-correlations between the seven safety dimensions as well as with the patient safety grade) of the SCOPE-PC instrument in a single home care organisation. Finally, **Chapter 8** presents the results of a large-scale study regarding patient safety culture in community-based primary care.

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PART I

Evidence on Patient Safety in Primary Care

‘Knowledge is proud that he has learned so much;

wisdom is humble that he knows no more.’

- William Cowper -

Chapter 2

Patient Safety in Primary Care: A State of the Art

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SUMMARY

Echoing the increasing burden of chronic diseases, a considerable part of healthcare delivery continues to shift from secondary towards primary care. At the same time, patient safety in primary care has been barely addressed and the risks have not been fully articulated, although this form of healthcare delivery is growing rapidly. Consequently, the present narrative review sought to present the current state of the art on patient safety in primary care.

According to the (limited) scientific research, patient safety incidents in primary care do occur: the median incidence rate is two to three incidents for every 100 consultations of which 4% may result in actual patient harm (*identifying patient safety risks*). Improving patient safety is the next logical step after analysing safety risks. A considerable number of interventions have been developed, but most evidence on their impact remains largely mixed if not unknown (*developing effective interventions*). Additionally, the implementation of improvement strategies has shown to be difficult in various settings within healthcare, which emphasises the importance of a thoughtful implementation process. Every new implementation creates uncertainty and raises questions among healthcare professionals (*implementing interventions in practice*). Finally, quality indicators for primary care have been developed in a few European countries. The *Quality and Outcomes Framework* from England is the most advanced monitoring system for primary care across European countries (*defining useful indicators*).

In conclusion, gaps remain in the knowledge of patient safety in primary care. A better understanding is needed on the epidemiology of patient safety incidents and the contributory factors so reoccurrence can be minimised. Research and policy must now take advantage of what is learned in the hospitals, while remembering that primary care is a different setting.

Many patients are harmed by care that is intended to help them. Consequently, healthcare is held to be a paradox itself: it is supposed to do good, but it is also accused of doing harm. Over the past two decades, researchers have gathered evidence on the epidemiology, causes, and consequences of patient safety incidents in hospitals. Between 3%-17% of patients admitted to the hospital may experience a safety incident [1]. Additionally, 10% of hospitalised patients are inadvertently harmed [2]. Following the IOM report *To Err is Human: Building a Safer Health System*, patient safety gained widespread attention, which is reflected in the increasing number of patient safety-related publications [3,4].

Echoing the increasing burden of chronic diseases, a considerable part of healthcare delivery continues to shift from secondary towards primary care [5]. The global drive towards primary care-based models is furthermore spurred by the increasing demand to reduce the number of hospital beds, facilitate earlier hospital discharge, improve quality of care, and the need to decrease healthcare-associated costs [6]. Primary care is the cornerstone of healthcare delivery and is defined by the Expert Panel on Effective Ways of Investing in Health as '*the provision of universally accessible, integrated person-centred, comprehensive health and community services provided by a team of professionals accountable for addressing a large majority of personal health needs. These services are delivered in a sustained partnership with patients and informal caregivers, in the context of family and community, and play a central role in the overall coordination and continuity of people's care. The professionals active in primary care teams include dentists, dieticians, general practitioners/family physicians, midwives, nurses, occupational therapists, optometrists, pharmacists, physiotherapists, psychologists, and social workers*' [7]. Primary care promotes a more holistic approach to health with an equal focus on prevention and cure over longer periods of time [8].

At the same time, innovations in healthcare delivery towards primary care may introduce new kinds of patient safety risks. Whilst millions of interactions occur every day throughout the world, the absolute burden of patient safety incidents in primary care may increase. And when patients move between secondary and primary care settings, the potential for patient safety risks further increases.

OBJECTIVES

Patient safety in primary care has been barely addressed and the risks have not been fully articulated. Therefore, it is crucial to identify factors which contribute or create unsafe practices so that the aforementioned shift of healthcare delivery can proceed in a safe and sustainable manner. Accordingly, the present narrative review sought to present the current state of the art on patient safety in primary care.

IMPROVING PATIENT SAFETY

The ultimate goal is to improve patient safety by minimising the risks and reducing the number of patient safety incidents. To achieve meaningful improvement, four conditions must be fulfilled [9]:

1. Identifying patient safety risks;
2. Developing effective interventions to reduce these risks;
3. Implementing these interventions in practice;
4. Defining useful indicators to show any improvements.

Patient Safety Risks

An effective safety improvement strategy is partly founded on the understanding of the contributory factors, causes, frequency, and severity of patient safety incidents. The NPSA also emphasised the necessity to describe '*things that may go wrong*' in their seven crucial steps to improve patient safety in primary care [10].

Recently, Panesar *et al*. conducted a systematic review to investigate how often patient safety incidents occur in primary care and how often these were associated with patient harm. The aggregated median - derived from population-based review studies - was two to three incidents for every 100 consultations of which 4% may result in actual patient harm [11]. Considering the high utilisation rates, the absolute burden of iatrogenic harm in primary care is large. Extrapolated to Belgium, 25 adverse events would occur each day in general practices only [12].

When considering other areas of primary care, harm would be appreciably higher. The great majority of patient safety incidents can be classified in the following domains: administrative or communication incidents, diagnostic incidents, and medication management incidents [11].

First, most of the administration incidents are related to inefficient documentation, inappropriate monitoring of laboratory tests, or suboptimal communication between healthcare professionals and also with patients. Additionally, specific information hazards arise in primary care and may reduce the safety and quality of care delivered; that is information overload (i.e., when there are too many data), information underload (i.e., when necessary information is lacking), information scatter (i.e., when information is located in multiple places), information conflict (i.e., when healthcare professionals are unable to determine which data are correct), and erroneous information (i.e., when information is wrong) [13]. Separately or together, these information hazards increase the risk of patient safety incidents. Second, common diagnostic incidents are related to wrong, delayed, or missed diagnoses, which may lead to harm or sub-standard treatment. According to a recent IOM report, most people will likely be confronted with a diagnostic error once in their lifetime [14]. However, diagnostic errors are difficult to study as they are hard to define and not directly observable. Take for example a cancer patient who visits his general practitioner at least three times before referral [15].

Third, the median preventable adverse drug event rates in ambulatory care-based studies is 16.5% [16]. A high incidence of adverse drug events results from the growing number of chronic patients and the consequential increase in medication use. Multiple chronic diseases affects 50%-70% of individuals over the age of 70 [17]. As a result, more patients are exposed to polypharmacy; that is a daily intake of five or more medicines. The frequency of non-evidence based medicines, dosing errors, and potential interactions between drugs is alarmingly high. In a descriptive study of 169 patients with polypharmacy in Austria, a mean of 2.7 adverse drug events per patient occurred with at least one dosing error in 56.2% of all patients [18].

Interventions to Improve Patient Safety

Improving patient safety is the next logical step after analysing safety problems. The sheer volume of patient-professional contacts in primary care and the consequential high number of patients being avoidably harmed, brings pressure on the development and implementation of improvement strategies. A considerable number of strategies have been developed, but most evidence on their impact remains largely mixed if not unknown [19]. After all, limited evidence on safety incidents in primary care and their impact hinders the development of strategies to improve patient safety. Improvement strategies also need to consider the specific characteristics of primary care, including the broad diversity of patients and conditions and the high number of patient-professional contacts. By consulting a European international panel of primary healthcare professionals, Gaal *et al*. identified several strategies to improve patient safety in primary care [20]. Strategies that yielded the highest scores included an adequate medical record system, good telephone access, standards for record keeping, a learning culture, vocational training on patient safety, and the presence of a patient safety guideline. In what follows, three well-known improvement strategies are briefly discussed; that is incident reporting, health information technology (HIT), and patient safety culture.

Incident reporting is probably the most studied strategy in the field of patient safety [21]. Reporting systems play an important role in improving patient safety by providing not only a means to determine the incidence rate of adverse events and near-misses, but also for healthcare professionals to reflect on care processes they might need to modify [22]. Literature has pointed towards what are believed to be characteristics of successful reporting systems; that is nonpunitive, confidential, independent of any authority, analysed by experts, timely in reporting, focused on systems and processes rather than individuals, and responsive to needs for information [23].

In addition, improving medication safety has become an important topic in primary care patient safety research due to the high frequency of drug prescriptions and the high number of adverse drug events resulting in avoidable hospital admissions [24].

In a literature review of randomised controlled trials, computerised prescriber order entry systems with clinical decision support and involvement of pharmacists were found to be the most effective in improving medication safety [25]. Furthermore, prospective risk analyses may also be particularly useful as a patient safety improvement strategy by proactively evaluating healthcare processes so patient safety incidents can be detected and intercepted before causing harm [26].

Since 2000, it has often been claimed by policymakers that health information technology may address many quality and safety concerns in today's healthcare [2]. Information technology and electronic health records (EHRs) are designed to facilitate data entry and to contribute to more timely and available information. They furthermore assist and support medical decision making and prescribing, allow healthcare professionals to check test results, give patients access to their health-related information, and enhance cooperation between healthcare professionals [19]. Nevertheless, the rapid uptake of HIT may result in unintended consequences. New types of error may result from computerised provider order entry, alarm fatigue arising from proliferation of well-intended safety alerts, and problems with poor interoperability of different health record systems [27]. Consequently, the effective use of HIT largely depends on consistent deployment and associated training (see Additional Paper).

Patient safety will not be achieved unless the culture within a healthcare organisation is supportive. Patient safety culture assessments provide valuable information on how patient safety is viewed and handled within a healthcare organisation and have been observed to positively affect patient safety since healthcare professionals report five times more incidents due to risk awareness [28]. In primary care, organisations with a positive patient safety culture are characterised by communication based on mutual trust and openness, shared perceptions of the importance of safety, confidence in the efficacy of preventive safety measures, organisational learning, committed leadership and executive responsibility, and a no blame and non-punitive approach to incident reporting and analyses [29]. Notwithstanding the lack of research on patient safety in primary care, numerous studies have been conducted on patient safety culture in primary care facilities (see Chapter 6).

The number of valid and reliable surveys is however limited. Additionally, the relationship between a well-developed patient safety culture and patient outcomes remains to be established [30].

The Implementation Problem

The implementation of improvement strategies has shown to be difficult in various settings within healthcare, which emphasises the importance of a thoughtful implementation process [31,32]. Every new implementation creates uncertainty and raises questions among healthcare professionals. Caregivers work in specific social, organisational, and structural settings in which several factors may contribute to the supporting or hindering of change. Literature identified several factors that may hinder the implementation of patient safety improvement strategies, namely the characteristics of healthcare professionals and patients, teamwork, the organisation of care processes, and finally available time, staffing, and leadership [33].

Take for example the implementation of incident reporting systems in primary care. General practitioners have a positive attitude towards incident reporting as it can enhance their awareness of the importance of patient safety [34], but only if the system granted legal and administrative protection [35]. Additionally, the most commonly raised barriers relating to incident reporting concerns the heavy workload, fear of embarrassment or blame, and lack of feedback [36]. Cultural and legal preconditions must be satisfied for reporting systems to be effectively implemented; that is non-punitive, in an open and supportive environment with respect for professional accountability, supported by strong leadership throughout the practice or organisation, and in a shared understanding of what a patient safety incident is [37].

Patient Safety Indicators

The measurement and monitoring of patient safety continues to be a challenge, but many progress has been made in developing reliable safety indicators [38,39]. Quality indicators are measured aspects of healthcare delivery and are more likely to be effective if they are derived from rigorous scientific evidence.

In many European countries, quality indicators for primary care have been developed such as the *Dutch Practice Accreditation Scheme* [40] and the *Quality and Outcomes Framework* (QOF) in England [41]. The QOF is one of the most advanced monitoring systems for primary care across OECD countries. It is an incentive scheme with more than 80 indicators. For 2015/16, the QOF awards practices achievement points for three domains (see Table 1): [1] managing some of the most common chronic diseases (e.g., diabetes), [2] managing major public health concerns (e.g., smoking), and [3] implementing preventative measures (e.g., regular blood pressure checks). Each domain consists of a set of achievement measures - known as indicators - against which practices score points according to their level of achievement. The 2015/16 QOF measures achievement in primary care against 77 indicators, grouped into 25 categories. Practices score points on the basis of achievement against each indicator, up to a maximum of 559 points. The QOF is especially relevant given the huge challenges (primary) care is facing. After all, compelling demands around the globe can be found for a fundamental shift in the organisation of health and social care for better prevention and more effective management of chronic diseases. Two categories in this framework '*managing some of the most common chronic diseases*' and '*implementing preventative measures*' are therefore very valuable.

Frigola-Capell *et al*. also presented an international framework for patient safety indicators in primary care [42]. Four domains were specified: [1] leadership that promotes a culture of quality and safety, [2] people management that ensures up-to-date knowledge and skills of healthcare professionals and promotes the individual well-being of these professionals, [3] partnerships with other practices and available resources in the practice, and [4] clinical processes which are distinguished in overall organisational structures, treatment protocols, and patient safety procedures (see Table 2).

DISCUSSION

The demand for primary-based care is driven by a combination of both population and health system characteristics that includes demographic changes, financial constraints, and consumer preferences. Healthcare has brought extraordinary benefits, but every encounter may introduce new risks of various kinds. Patient safety in primary care is an under-researched issue. Nevertheless, the increased complexity of patients' needs and the large number of consultations lend urgency to better understand patient safety in this setting. Consequently, the present review sought to present the current state of the art on patient safety in primary care.

The paper of Panesar *et al*. makes major contributions to the patient safety field by providing an overview of the burden of patient safety incidents in primary care [11]. However, the analysis is probably an underestimate due to definitional challenges and the use of only one ascertainment method (e.g., the review only counted events where the wrong thing was done and did not include events where the right thing was not done) [43]. In addition, most of the included papers conducted a record review study. Only a few used incident reporting systems or questionnaires. Considering the limitations of each ascertainment method, the included studies most likely under-represent the frequency of patient safety incidents in primary care. In addition, the estimated incidence of patient safety incidents in primary care settings is lower than the estimated 10% in hospitals. Although safety incidents in primary care do not seem to carry the same urgency as adverse events in hospitals, the sheer volume of healthcare delivery in this setting emphasises the public health burden. Moreover, patient safety in primary care cannot be managed in the same way as patient safety in the hospital setting, owing to differences in the nature of medical incidents, nature of patient-professional relationships, respective environments, and patients' characteristics [44].

Research on patient safety improvements is still limited. Incident reporting and patient safety culture assessments are two methods that are frequently used, but have unknown effects on patient safety. It remains to be determined which strategies are most effective.

Interventions to improve patient safety must however consider the variety of patients and clinical conditions, the vast array of healthcare professionals, and the diversity of primary care settings. While awaiting the scientific evidence of patient safety improvement strategies, several toolkits are already developed and available for use. The Royal College of General Practitioners has launched an online *Patient Safety Toolkit*, allowing general practitioners to look at different aspects of patient safety (e.g., safe systems, safety culture, communication, patient-reported problems, diagnostic safety, and prescribing safety) in order to make quality improvements [45]. Additionally, quality indicators have a crucial role in programmes to assess and improve healthcare. The present paper suggested the QOF from England as it is the most advanced monitoring system for primary care across OECD countries.

This comprehensive literature review indicates the need to extend the patient safety agenda more explicit towards primary care and consequently proposes several recommendations. First, a clear and detailed clarification of core concepts relating to safety in primary care is required. In literature, many definitions of *patient safety*, *harm* and *preventability* are used, possibly hampering comparison between studies and the development of improvement strategies [46]. Consequently, the research field urgently needs (to follow) a unique international terminology and classification system. Second, prospective mixed-methods approaches are promoted to identify the underlying causes of patient harm in primary care by triangulating evidence from different sources; that is healthcare professionals' feedback, medical records, and patient-reported information (see Chapter 4 and 5). Therewith, it is acknowledged that more accurate assessments of the number and severity of patient safety incidents are needed. Third, classification systems as descriptive tools allow appropriate analysis of safety incidents so safe and effective improvement strategies can be developed. Classification systems integrate patient safety data from different sources such as incident reporting, survey data, and chart reviews. For example, the *Patient Safety Incident Classification for Primary Care* by the LINNEAUS Collaboration offers researchers and practitioners the opportunity to learn from medical incidents [47].

Fourth, the integration of patient safety in the educational curricula of (future) healthcare professionals is possibly the most promising approach to improve patient safety. A survey of primary healthcare professionals and researchers identified education and training as an important strategy to improve patient safety [20]. Additionally, educational programmes regarding patient safety are also essential to inform, motivate, and train individual healthcare professionals to incorporate prevailing evidence in their daily work. In the qualitative evaluation of a collaborative learning programme regarding patient safety in primary care, Bowie *et al*. concluded that the majority of participants referred to gaining new theoretical and experiential safety knowledge and skills [48].

CONCLUSIONS

Traditionally, research on patient safety mainly focused on hospitals-based care delivery and a great deal of progress has been made to understand adverse events in acute care settings. Gaps remain in the knowledge of patient safety in primary care. A better understanding is needed on the epidemiology of safety incidents and the contributory factors so reoccurrence can be minimised. Research and policy must now take advantage of what is learned in the hospitals, while remembering that primary care is a different world as it poses different kinds of challenges, types of safety incidents, and improvement strategies.

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Table 1 Quality and Outcomes Framework for Measuring and Monitoring Patient Safety

Indicator group	Example indicator description
Managing some of the most common chronic diseases	
Atrial fibrillation	The contractor establishes and maintains a register of patients with atrial fibrillation.
Secondary prevention of coronary heart disease	The percentage of patients with coronary heart disease in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less.
Heart failure	The percentage of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2006) which has been confirmed by an echocardiogram or by specialist assessment 3 months before or 12 months after entering on to the register.
Hypertension	The percentage of patients with hypertension in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less.
Peripheral arterial disease	The percentage of patients with peripheral arterial disease with a record in the preceding 12 months that aspirin or an alternative anti-platelet is being taken.
Stroke and transient ischaemic attack	The percentage of patients with a stroke or TIA (diagnosed on or after 1 April 2014) who have a record of a referral for further investigation between 3 months before or 1 month after the date of the latest recorded stroke or the first TIA.
Asthma	The percentage of patients with asthma aged 14 or over and who have not attained the age of 20, on the register, in whom there is a record of smoking status in the preceding 12 months.
Chronic obstructive pulmonary disease	The percentage of patients with COPD who have had influenza immunisation in the preceding 1 August to 31 March.
Cancer	The percentage of patients with cancer, diagnosed within the preceding 15 months, who have a patient review recorded as occurring within 6 months of the date of diagnosis.
Chronic kidney disease	The contractor establishes and maintains a register of patients aged 18 or over with CKD with classification of categories G3a to G5.
Diabetes mellitus	The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months.
Palliative care	The contractor has regular (at least 3 monthly) multi-disciplinary case review meetings where all patients on the palliative care register are discussed.

Indicator group	Example indicator description
Dementia	The percentage of patients diagnosed with dementia whose care plan has been reviewed in a face-to-face review in the preceding 12 months.
Depression	The percentage of patients aged 18 or over with a new diagnosis of depression in the preceding 1 April to 31 March, who have been reviewed not earlier than 10 days after and not later than 56 days after the date of diagnosis.
Epilepsy	The contractor establishes and maintains a register of patients aged 18 or over receiving drug treatment for epilepsy.
Learning disabilities	The contractor establishes and maintains a register of patients with learning disabilities.
Mental health	The percentage of patients with schizophrenia, bipolar affective disorder, and other psychoses who have a record of blood pressure in the preceding 12 months.
Osteoporosis: secondary prevention of fragility fractures	The percentage of patients aged 75 or over with a record of a fragility fracture on or after 1 April 2014 and a diagnosis of osteoporosis, who are currently treated with an appropriate bone- sparing agent.
Rheumatoid arthritis	The percentage of patients with rheumatoid arthritis, on the register, who have had a face-to-face review in the preceding 12 months.
Managing major public health concerns	
Blood pressure	The percentage of patients aged 45 or over who have a record of blood pressure in the preceding 5 years.
Cardiovascular disease - primary prevention	In those patients with a new diagnosis of hypertension aged 30 or over and who have not attained the age of 75, recorded between the preceding 1 April to 31 March (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an assessment tool agreed with the NHS CB) of ≥20% in the preceding 12 months: the percentage who are currently treated with statins.
Obesity	The contractor establishes and maintains a register of patients aged 18 or over with a BMI ≥30 in the preceding 12 months.
Smoking	The contractor supports patients who smoke in stopping smoking by a strategy which includes providing literature and offering appropriate therapy.

Indicator group	Example indicator description
	Implementing preventative measures
Cervical screening	The contractor has a policy for auditing its cervical screening service and performs an audit of inadequate cervical screening tests in relation to individual sample-takers at least every 2 years.
Contraception	The percentage of women, on the register, prescribed emergency hormonal contraception one or more times in the preceding 12 months by the contractor who have received information from the contractor about long acting reversible methods of contraception at the time of or within 1 month of the prescription.

Table 2 Framework of Safety Indicators for Primary Care by Frigola-Capell *et al*.

Domain	Description
Leadership	Working towards a culture of quality and safety.
People management	The health centre has a training plan for its staff's continuing professional development.
Partnerships and resources	Professionals of the health centre know the referral facilities. Efficacy and quality of the non-healthcare providers' services employed by the health centre. Safety and suitability of the health centre. Effectiveness, safety, and use of technical support resources.
General organisational structures	The health centre has a database that contains the personal data of its patients. Use of the electronic medical records. Management of urgent requests for assistance. Home care for chronic conditions. Clinical decision tools are present.
Treatment protocols	Treatment protocols for cardiopulmonary emergencies and cardiovascular risk factors. Treatment protocols for acute and infectious diseases, management of cancer, chronic respiratory diseases, and mental diseases. Treatment protocols for suspected cases of abuse and end of life care.

Domain	Description
Patient safety procedures	Detection of patient safety incidents and sentinel events. Processes in place to ensure the effectiveness, efficiency, and safe use of medicines. Safe processes for the prescription of medicines. Safeguard professionals and the public from infections. Guaranty of continuity of care between primary care and emergency medical services, specialists, and long-term care services. Safety mechanisms and procedures for blood sample collection. Research activities of the health centre safeguard safety of participants and follow research ethics. Appointments delays of patients with their allocated clinician.

Chapter 3

Economic Impact of Integrated Care Models for Patients with Chronic Diseases: A Systematic Review

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SUMMARY

The fast-growing scientific knowledge and rapid technological innovation, the fragmentation of care, as well as the rapidly aging population and increasing numbers of patients with (multiple) chronic diseases represent major challenges for healthcare systems worldwide. Currently, integrated care receives increasing attention as it is considered an appropriate answer in reducing the fragmentation of care, improving the quality of patient care, and controlling healthcare-related costs. However, the current body of literature is inconclusive about the potential economic impact of integrated care models. Consequently, the present systematic review aimed to assess the costs and potential financial benefit of integrated care for patients with chronic diseases; that is type 2 diabetes mellitus, schizophrenia, and multiple sclerosis respectively.

Out of 575 articles, 26 were included. Most studies examined integrated care models for patients with type 2 diabetes mellitus (n=18) and to a lesser extent for patients with schizophrenia (n=6) or multiple sclerosis (n=2). Across the three disease groups, the incremental cost per patient per year ranged from – €3,860 to + €613.91 ($\bar{x}$= – €533.61, SD=€902.96). The incremental cost for type 2 diabetes mellitus ranged from – €1,507.49 to + €299.20 ($\bar{x}$= – €518.22, SD=€604.75), for schizophrenia from – €3,860 to + €613.91 ($\bar{x}$= – €677.21, SD=€1,624.35), and for multiple sclerosis from – €822 to + €339.43 ($\bar{x}$= – €241.29, SD=€821.26). The vast majority of studies (22/26, 84.6%) reported a positive economic impact of integrated care models, respectively for type 2 diabetes mellitus (16/18, 88.9%), schizophrenia (4/6, 66.7%), and multiple sclerosis (1/2, 50.0%).

In conclusion, the vast majority of studies reported a beneficial economic impact of integrated care models. However, in order to support well-considered decision-making, there is still a high need for well-designed health economic evaluations of integrated care models.

The fast-growing scientific knowledge and rapid technological innovation, the fragmentation of care, as well as the rapidly aging population and increasing numbers of patients with (multiple) chronic diseases represent major challenges for healthcare systems worldwide. At the same time, one must guard the primary goal of healthcare; that is to provide high quality of care. Nevertheless, the significant rise of people with chronic diseases jeopardises the financial sustainability of healthcare systems and therefore the efficiency of healthcare. Total healthcare costs for chronic diseases in Europe are estimated at €700 billion annually [1]. For patients with type 2 diabetes mellitus, schizophrenia, and multiple sclerosis, annual healthcare costs in Europe are estimated at €90 billion, €94 billion, and €15 billion respectively [1].

Healthcare systems are facing the challenge of efficiently meeting the complex care needs of the chronically ill, while historically being organised to respond to acute diseases. Currently, integrated care receives increasing attention as it is considered an appropriate answer in reducing the fragmentation of care, improving the quality of patient care, and controlling healthcare-related costs [2]. Moreover, it is considered a new innovative strategy to overlap the existing care gaps and to help changing healthcare systems into more '*demand-driven, client-centred, and cost-conscious systems*' [3]. The WHO defined integrated care as: '*the management and delivery of health services such that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation, and palliative care services, through the different levels and sites of care within the health system, and according to their needs throughout the life course'* [4]. Integrated care is driven by the so-called *Triple Aim* approach; that is a simultaneous focus on cost-savings, better patient care experiences, and improved health outcomes [5]. Different terms are used for labelling particular models of integrated care such as *disease management* [6], *case management* [7], *continuous care* [8], *care pathways* [9], and *integrated delivery networks* [10]. Hence, integrated care is an umbrella term of various alternative forms rather than an exact definition.

Although there is a widespread belief that integrated care can control or even reduce healthcare-related costs, relatively few studies evaluated the economic impact of integrated care models so far and the current body of literature is thus inconclusive [5]. In their literature review, Ofman *et al*. reported that one article out of seven (14.3%) showed a positive economic impact of integrated care [11]. Ouwens *et al*. found that four out of seven articles (57.1%) showed a financial benefit [5]. In a recent literature review conducted by de Bruin *et al*., 13 articles out of 21 (61.0%) reported cost-savings [12]. Specifically for type 2 diabetes mellitus [12] and schizophrenia [13], scientific literature is inconclusive.

OBJECTIVES

Since integrated care models receive a more prominent role in healthcare and limited evidence is available on the potential financial benefit, the present systematic review aimed at assessing the economic impact of integrated care models for patients with chronic diseases; that is type 2 diabetes mellitus, schizophrenia, and multiple sclerosis respectively.

METHODS

Design

A systematic review was carried out according to the *Cochrane Handbook for Systematic Reviews* and the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) guidelines to assess the economic impact of integrated care models for patients with chronic diseases [14,15].

Eligibility Criteria

The eligibility criteria for the present review were a priori decided. First and in line with two basic approaches to economic evaluations, included designs were randomised controlled trials, non-randomised controlled trials, before-after studies (i.e., trial-based studies), or observational studies and modelling studies [16]. Consequently, editorials, opinion papers, and descriptive papers were excluded. Second, this systematic review included studies that conducted a cost analysis to assess the potential financial benefit of integrated care models.

Third, articles were included if they specifically dealt with type 2 diabetes mellitus (i.e., one of the most common chronic diseases), schizophrenia (i.e., representing a mental disease of which the impact is likely to considerably increase in the future), or multiple sclerosis (i.e., a chronic disease with different phases of severity), together covering a broad range of chronic illness consequences. Fourth and in line with previous research, integrated care models were categorised according to the six components of the CCM [17-20]. Hence, the models were considered *integrated care* if they targeted two or more CCM components. Finally, the presence of an alternative type of care - typically usual or standard care - was required in order to assess the positive or negative economic impact of a given integrated care model.

Search Strategy

A systematic literature review was conducted in the 50th week of 2014, searching the electronic peer-reviewed databases Medline, Web of Science, and Embase. The search was performed using the following queries: ('integrated delivery system' [MeSH] OR 'integrated care' OR 'disease management' [MeSH] OR 'case management' [MeSH] OR 'patient care management' [MeSH] OR 'patient-centred care' [MeSH] OR 'managed care' OR 'transmural care' OR 'coordinated care' OR 'seamless care' OR 'continuity of patient care' [MeSH] OR 'clinical pathways' OR 'patient care planning' [MeSH] OR 'patient care team' [MeSH]) AND ('cost analysis' [MeSH] OR 'economic evaluation' OR 'economic impact' OR 'cost-minimisation analysis') AND ('diabetes mellitus type 2' [MeSH] OR 'schizophrenia' [MeSH] OR 'multiple sclerosis' [MeSH]). Since different terms are used for labelling particular models of integrated care, broad search terms were applied without date restrictions in order to make the search strategy as sensitive as possible. In addition, bibliographies of included articles were hand searched for other relevant papers.

Study Selection and Data Abstraction

After removal of duplicates, the first selection of articles was made based on title and abstract. Papers selected for full-text review were screened according to the eligibility criteria. Two reviewers (MD and DV) independently investigated the relevance and methodological quality of the extracted papers. In case of inconclusiveness, a third researcher (SV) helped to obtain consensus. For each of the studies found eligible for the systematic review, study characteristics (i.e., authors, year, country, study design, study period, usual care condition, and term used for the integrated care model), characteristics of the integrated care models (i.e., components of the CCM included in the intervention), characteristics of the cost analysis (i.e., type of costs and viewpoint of the analysis), and study outcomes (i.e., incremental cost, return on investment, and clinical outcomes) were extracted. A data abstraction form (see Appendix I) was created to collect and catalogue the relevant data. Assessment for risk of bias was conducted using the *Cochrane Collaboration Tool for Assessing Risk of Bias* (see Appendix II) which recommends addressing the following domains: sequence generation and allocation concealment, blinding of participants, personnel and assessors, incomplete outcome data, and selective outcome reporting [14].

Data Analysis

All relevant data (study characteristics, characteristics of the integrated care models, characteristics of the cost analysis, and study outcomes) were tabulated and/or graphed. Due to heterogeneity in study data, a descriptive and narrative synthesis of the data was undertaken by adopting a textual approach to the process of synthesising the research findings from the included studies. The CCM components for each study were ascertained from the described intervention. The main outcome for this systematic review was the incremental cost which can be defined as the difference in healthcare costs between the integrated care model and the usual care conditions. The incremental cost (reported per patient per year) can be either negative or positive. A negative incremental cost implies that healthcare costs in the integrated care model are lower as compared to usual care. The incremental cost was either drawn directly from the articles or calculated from data provided in the papers.

Where possible, this systematic review also reported the return on investment (ROI), comparing cost-savings with implementation and operational costs of the integrated care model. A ROI greater than 1 indicates a profitable investment of the model. Again, the ROI was either drawn directly from the articles or calculated from data provided in the papers. The standard deviation and/or confidence interval of the incremental cost was rarely reported. As a consequence, it was not appropriate to undertake a meta-analysis. In order to facilitate comparison, all amounts were converted to euro 2015 (conversion rate 0,89). In addition, this systematic review also tried to examine the association between the number of CCM components and the incremental cost on the one hand and the association between the study period and the incremental cost on the other hand. After all, the current review did not only expect a positive economic impact of integrated care models, it also hypothesised greater cost-savings for models with a higher number of included CCM components [18] and greater cost-savings for studies with a longer follow-up period as implementation and operational costs decrease [21].

RESULTS

Results of the Search

The literature search yielded 575 potentially relevant studies after duplicates being removed: 456 for type 2 diabetes mellitus, 76 for schizophrenia, and 43 for multiple sclerosis respectively. On the basis of title and abstract, 56 articles were selected for full-text screening. The screening process resulted into 19 articles: 14 for type 2 diabetes mellitus, four for schizophrenia, and one for multiple sclerosis. By screening the reference lists of the included studies, seven additional papers were included. Finally, a total of 26 articles were included in the present literature review (see Figure 1). The most relevant reasons for exclusion were: the model did not specifically focus on type 2 diabetes mellitus, schizophrenia, or multiple sclerosis, the model did not meet the definition of integrated care, and/or the article was a review or theoretical analysis (see Appendix IV).

Assessment of Risk of Bias

All studies were prone to bias due to methodological decisions (see Appendix III). Most of the papers reported the results of non-randomised studies, resulting in potential selection bias. In addition, the methodological information was often difficult to find and therefore many questions concerning bias remained unanswered. It is therefore not feasible to make a selection of studies for further inclusion based on the methodological assessment. However, the following potential types of bias could be generalised. The first bias concerns the method of concealment. Four studies [22-25] allocated participants based on medical data and six studies [26-31] on a voluntary basis, resulting in potential selection and/or volunteer bias. Unlike allocation concealment, blinding is not always possible, especially for studies in this systematic review. Participants in the integrated care model were aware of the intervention they receive. However, it is desirable to at least mask participants' treatment status from people collecting outcome data and from other clinicians providing normal care. However, insufficient information was provided to make a judgement, resulting in potential performance and/or detection bias. In addition, four studies had high risk of bias due to inadequately addressed incomplete outcome data [24,32-34]. Finally, all studies were free of suggestion of selective outcome reporting.

Study Characteristics

Table 1 summarises the study characteristics of the included articles. Out of 26 articles, 18 [22-32,35-41] focused on type 2 diabetes mellitus, six [33,42-46] on schizophrenia, and two [34,47] on multiple sclerosis. Most studies originated from the USA (n=13), followed by Germany (n=3) and the UK (n=2). Other studies originated from France, China, Austria, Singapore, New-Zealand, the Netherlands, Taiwan, and Italy (n=1). Regarding study design, 12 randomised controlled trials, six before-after studies, six retrospective studies, and two prospective studies were included. Across all studies, the sample size varied from 16 to 67.080 patients. Duration of the studies was mostly limited to one (n=14), two (n=5), or three (n=4) years. Three studies had a study period of four years.

Additionally, the most common terms for labelling particular models of integrated care (see Table 1) were *disease management* (n=13), followed by *community care* (n=3), *integrated care* (n=3), *home-based care* (n=2), and *team-based care* (n=2). The other alternative terms were: *managed care*, *chronic care clinics*, and *care management* (n=1). Disease management was mainly used for type 2 diabetes mellitus (n=13). For schizophrenia, most articles focused on community or home-based care. In all studies, the economic impact of integrated care was compared to usual care. Finally, provided information about the usual care conditions was mostly limited to the descriptions *usual care*, *hospital care*, or *routine care*.

Characteristics of the Integrated Care Models

Table 2 presents the included CCM components in all articles. As mentioned, all studies had to include at least two components of the CCM in order to be defined as *integrated care*. Eight articles [24-28,30,35,42] enclosed three elements and four articles [23,33,36,40] included four elements. With exception of five articles [34,39,43,45,46], all integrated care models included the component 'self-management support'. The components 'delivery system design' and 'decision support' were also frequently enclosed in the integrated care models.

In all but one article [39], the integrated care models for type 2 diabetes mellitus included the component 'self-management support' through educational materials and equipment for self-monitoring. Furthermore, most studies also used the clinical *American Diabetes Guidelines*. Seven studies used a clinical information system [23,30,35,36,39-41]. All studies for schizophrenia emphasised the component 'community resources and policies'. Three articles [33,42,44] included the component 'self-management support' and no study used a clinical information system. For multiple sclerosis, one study included 'self-management support' and 'delivery system design' [47]. The other study also included 'community resources and policies' [34].

Characteristics of the Cost Analyses

Table 3 presents the characteristics of the cost analyses. In all but one study [41], direct healthcare costs (e.g., costs of hospitalisation, medication, and consultation) were included. Three studies considered indirect costs; that is productivity losses due to morbidity or mortality [23,41,43]. Two articles considered both cost aspects [23,43]. Out of eight articles [26-29,34,35,39,42] that included implementation and operational costs of the integrated care model, three articles [26,27,48] also reported the ROI. Ten studies reported the viewpoint of the analysis [23,32,34,37,39,41,43-46].

For type 2 diabetes mellitus, two articles [23,41] considered indirect costs and six studies [26,27,29,39,48] considered implementation and operational costs. Out of those six studies, three calculated the ROI [26,27,48]. Furthermore, two studies [23,37] performed the cost analysis from the third-party payer perspective and one from the patient [39], professional organisation [32], or employer [41] perspective. For schizophrenia, one article considered indirect costs [43] and implementation and operational costs [42]. Two studies performed the cost analysis from the third-party payer [43,45] or patient [44,46] perspective. Finally, only direct costs were considered in the studies for multiple sclerosis. One study considered implementation and operational costs [34] and one study performed the cost analysis from the third-party payer perspective [49].

Study Outcomes

Figure 2 displays the incremental cost per patient per year for all studies. Each bar represents a study. Across the three disease groups, the incremental cost ranged from – €3,860 to + €613.91 ($\bar{x}$= – €533.61, SD=€902.96). Four articles concluded a positive incremental cost [32,33,38,39].

The incremental cost for type 2 diabetes mellitus varied from – €1,507.49 up to + €299.20 ($\bar{x}$= – €518.22, SD=€604.75). Two studies published a positive incremental cost of respectively + €42.42 and + €299.49 [32,39]. Five studies found no difference in healthcare costs between integrated care and usual care [23,36,40,41,47]. The other eleven studies reported a negative incremental cost of – €98.21 up to – €1,507.49.

Six studies considered implementation and operational costs of integrated care [26-28,30,39,48]. With exception of one article [39], the incremental cost remained negative. Three studies calculated the ROI, respectively 2.30 [26], 4.34 [27], and 3.37 [35]. Four studies also reported significant improvements in clinical outcomes such as lower glycaemia, blood pressure, and cholesterol level [27,30,32,48]. The incremental cost for schizophrenia varied from – €3,860 up to + €613.91 ($\bar{x}$= – €677.21, SD=€1,624.35). Three articles found no significant difference in healthcare costs between integrated and usual care [43,45,46]. Two articles concluded a negative incremental cost of – €817.18 and – €3,860 [42,44]. One article reported a positive incremental cost of + €613.91 [33]. Moreover, one article considered implementation and operational costs [42]. The ROI could not be calculated since the amount of those costs was not reported. The incremental cost for multiple sclerosis was – €822 and + €339.43 ($\bar{x}$= – €241.29, SD=€821.26). One study considered implementation and operational costs [34]. The ROI could not be calculated since the amount of those costs was also not reported.

Figure 3 and 4 displays the association between the number of CCM components in the integrated care model and the incremental cost and the association between the study period and the incremental cost. Figure 3 suggests that implementing four CCM components does not result in higher cost-savings compared to integrated care models with two or three CCM components. Figure 4 illustrates that the incremental cost does not decrease when the follow-up period extends.

DISCUSSION

Within the context of the increasing prevalence of chronic diseases, policy makers are constantly searching for structural alternatives that can ensure qualitative - including financial - sustainability of healthcare systems. Currently, integrated care receives increasing attention as it is considered an appropriate answer in reducing fragmentation of care, improving quality of patient care, and controlling healthcare-related costs. However, limited evidence is available on the potential financial benefit. Consequently, the present systematic review aimed at assessing the economic impact of integrated care models for patients with chronic diseases; that is type 2 diabetes mellitus, schizophrenia, and multiple sclerosis respectively.

Twenty-six studies were included: 18 for type 2 diabetes mellitus, six for schizophrenia, and two for multiple sclerosis. In more than half of the included studies (14/26, 53.8%), integrated care models were found to be associated with lower healthcare expenditures: 11 articles for type 2 diabetes mellitus, two for schizophrenia, and one for multiple sclerosis. It should be noticed that an incremental cost of 0 is also considered a favourable outcome. In a systematic review, Hisashige showed considerable evidence on the effectiveness and efficiency of integrated care models in process, health services, and quality of life [50]. Therefore, implementing these models without an additional cost must be seen as a positive phenomenon. From this point of view, the vast majority of studies (22/26, 84.6%) reported a positive economic impact of integrated care models, respectively for type 2 diabetes mellitus (16/18, 88.9%), for schizophrenia (4/6, 66.7%), and for multiple sclerosis (1/2, 50.0%). A second favourable outcome was that seven out of eight articles that considered implementation and operational costs reported a negative incremental cost. Consequently, cost-savings were higher than the investment of the integrated care model. Furthermore, five studies found that the observed savings were accompanied by significantly fewer hospital admissions and fewer inpatient days [26,28,35,42,44]. No explanations were reported in case of positive incremental costs. Compared with previous reviews [5], the current systematic review showed that the economic impact of integrated care models might be positive. Especially for type 2 diabetes mellitus, the results of this systematic review were more favourable. It should be noticed however that de Bruin *et al.* applied a time limit (2007-2009) and also included studies that did not compare integrated care with standard or usual care [12].

This systematic review identified a wide range of integrated care models. For type 2 diabetes mellitus, disease management was primarily used. Disease management is a programmatic approach of a chronic disease where early detection and self-management are central. Especially self-management and self-monitoring are very important in the treatment of type 2 diabetes mellitus [49]. This is also highlighted in the included articles: with exception of one article [39], all studies on type 2 diabetes mellitus included the component 'self-management support' of the CCM. Articles on schizophrenia focused especially on the community or home-based care.

In 1960, a policy was introduced in which patients with mental disorders should be treated in their community instead of a conventional psychiatric hospital [51]. This community approach can also be identified in the articles: all studies included the component 'community resources and policies' of the CCM. Finally, it is hard to establish how many CCM components an integrated care model should include in order to obtain cost-savings. Consequently, no association could be found between the number of CCM components targeted and the (potential negative) incremental cost. Furthermore, no trend could be found between the study follow-up period and the (potential negative) incremental cost.

This systematic review has several limitations. Although the definition of integrated care in this review is based on the CCM, the term is still very broad and definitional challenges remain. Therefore, results might depend on the operational definition. The lack of a clear definition forms a barrier to evaluate and promote integrated care overall. Due to the differences among populations, evaluation tools, and the content of integrated care models, it is also probable that some models might be more effective than others. Second, many instruments for assessing the methodological quality of non-randomised trials have been created. However, none were suitable for different study designs. This systematic review used the *Cochrane Collaboration Tool for Assessing Risk of Bias*, because it can also be used for cohort studies. Associated with the previous, another persistent limitation is the methodological design that is used in the articles. Fourteen studies that used a non-randomised design might as a result increase the risk of potential selection bias. The use of a historical control group or administrative data may also influence the results when data are incorrect or incomplete. Fourth, publication bias - as with all systematic reviews - may be present, whereby certain types of studies may be more likely to be published. Fifth, this systematic review yielded few studies with a follow-up period of more than one year. Therefore, the evidence on the long-term effect of integrated care models is limited. In addition, it is currently unknown whether the integrated care models were correctly implemented and fully adopted by patients and healthcare professionals. Therefore, the results might depend on the level of implementation of integrated care models. Seventh, only few studies (even after personal contact with the authors) provided the necessary statistical data for a meta-analysis.

Finally, the current study only focused on costs. In order to be labelled as a full economic evaluation, healthcare effects (i.e., clinical and non-clinical outcomes) must also be considered since the main goal of healthcare systems remains the preservation of health. Therefore, all dimensions of quality of care should be assessed.

The main strength of the current study is that new information about the circumstances under which integrated care models might be most effective is provided. Nevertheless, future research should more thoroughly describe the definition and content of integrated and usual care, the level of implementation, and the components of the interventions in order to understand, compare, and evaluate integrated care models. Second, randomised controlled trials and/or mixed methods designs are needed to enhance the empirical evidence on the potential effects of integrated care in daily practice with particular focus on the health economic impact, assessing costs and health consequences of integrated care models. Third, studies comparing the economic effect of integrated care models with usual care are particularly recommended since findings of such studies provide payers and governments better insights in how to spend the available resources in the most efficient way. Finally, future research must also better describe the point of view from which the economic evaluation is performed and has to include indirect costs.

CONCLUSIONS

Healthcare systems worldwide are facing the rising prevalence of chronic diseases and their financial burden. Although there is widespread belief that integrated care might reduce healthcare expenditures, relatively few studies have evaluated the economic impact of integrated care models. This systematic review presented the results of cost analyses of integrated care models for type 2 diabetes mellitus, schizophrenia, and multiple sclerosis. The vast majority of studies reported a beneficial economic impact of integrated care models. However, in order to support well-considered decision-making, there is still a high need for well-designed health economic evaluations of integrated care models.

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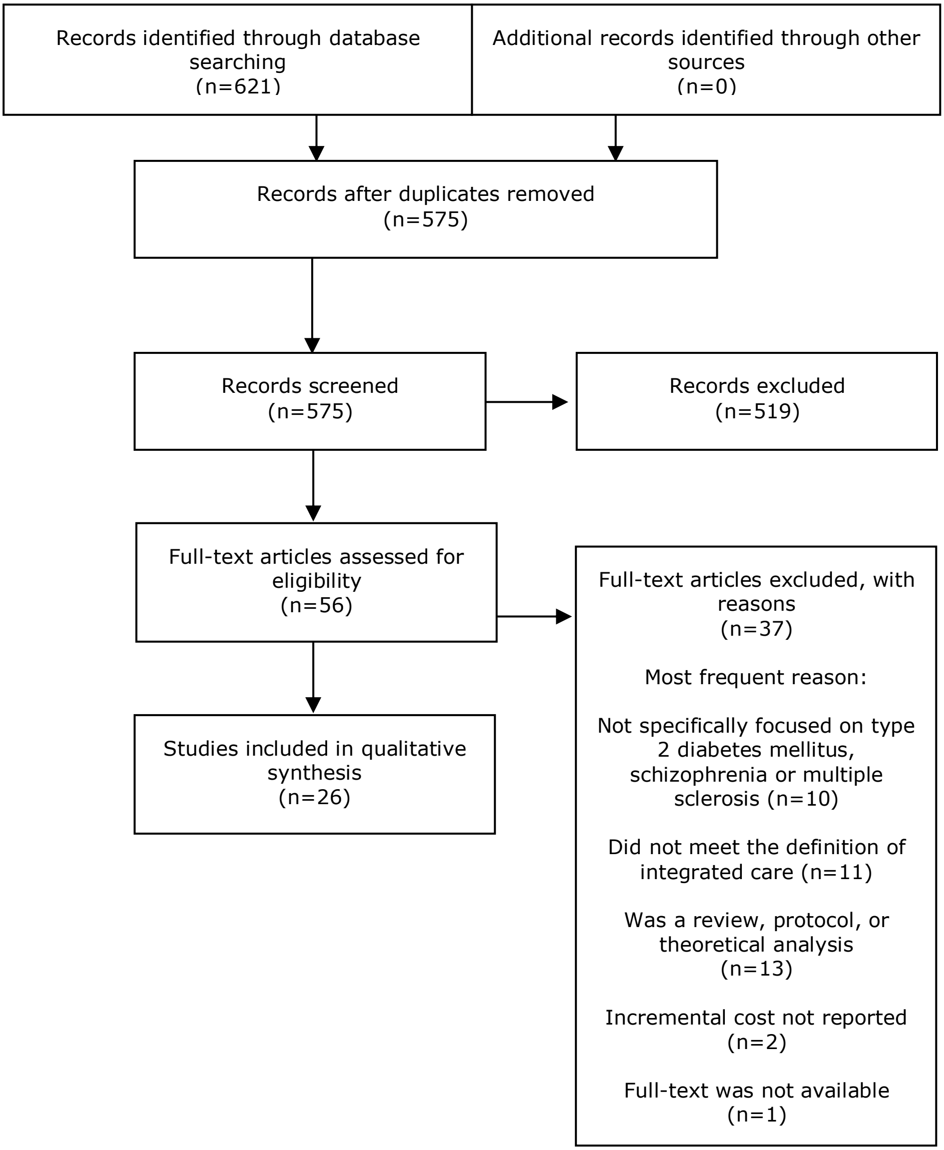

Figure 1 PRISMA Flow Diagram Showing Selection of Articles for Review

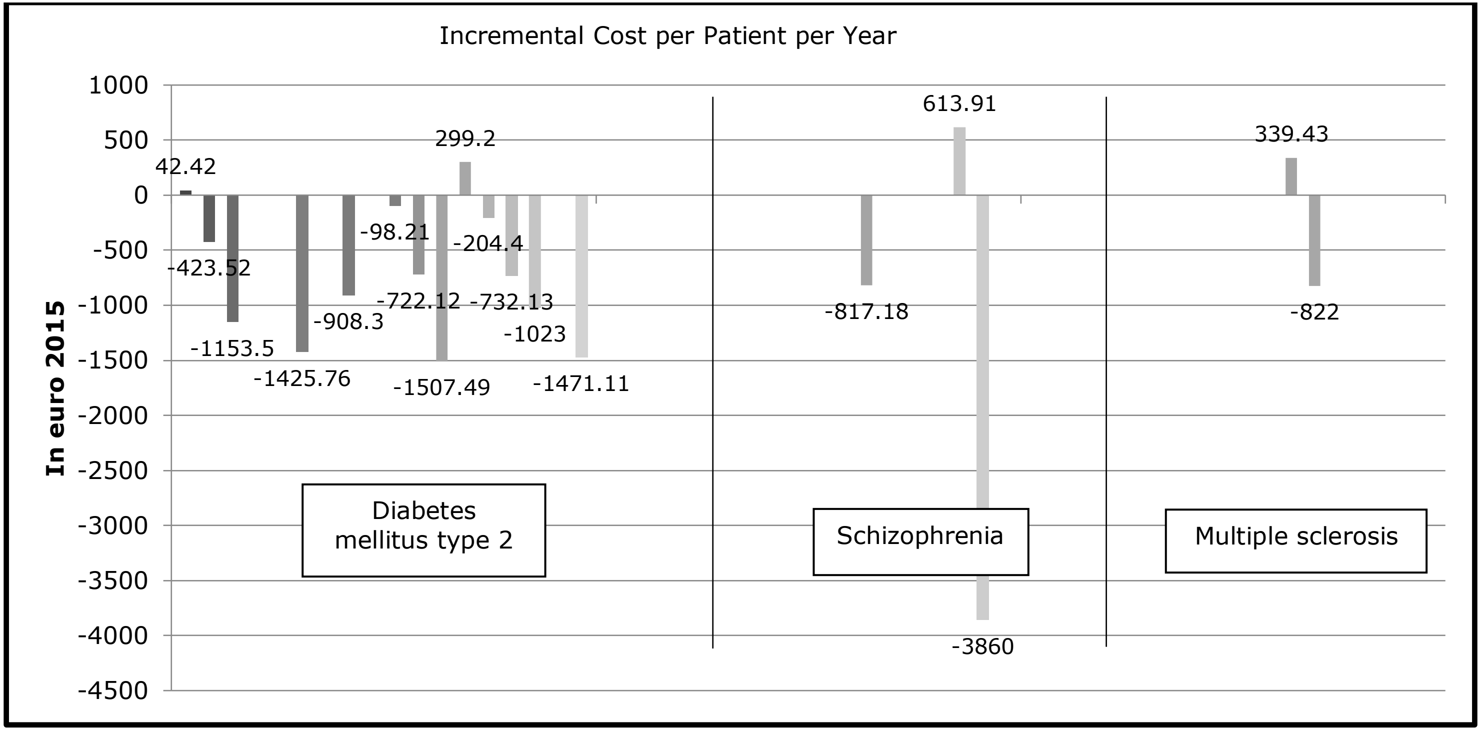

Figure 2 Incremental Cost per Patient per Year of Integrated Care Models

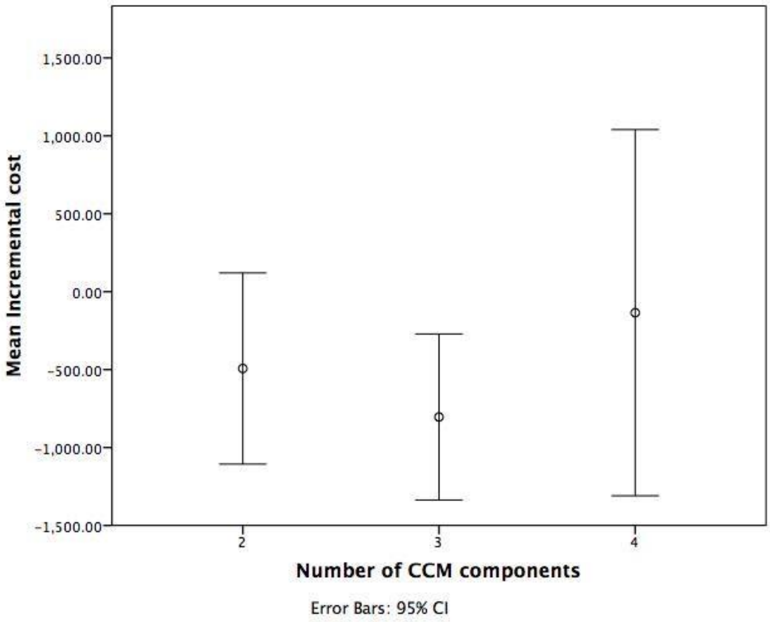

Figure 3 Association Between Number of CCM Components and Incremental Costs

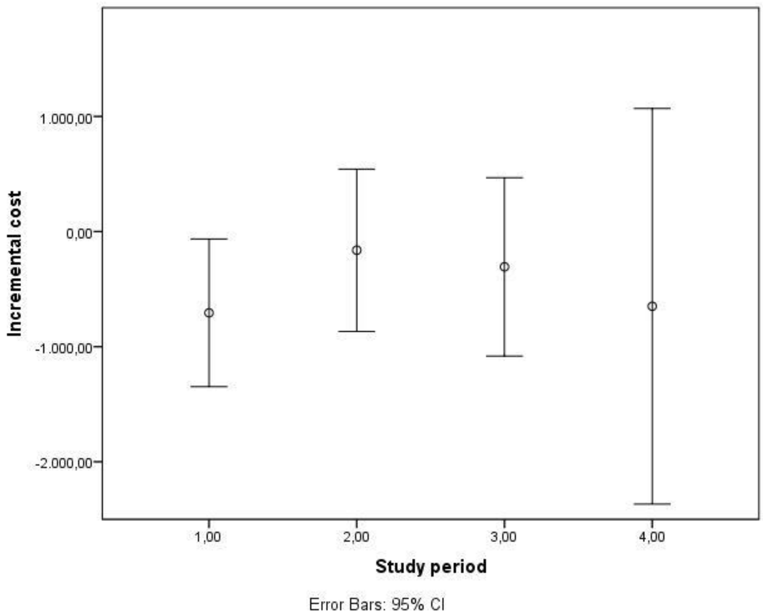

Figure 4 Association Between Study Period and Incremental Costs

Table 1 Characteristics of the Studies Included in the Systematic Review

	Author (year)	Country	Study design	Study period (years)	Usual care (comparator)	Integrated care
Type 2 diabetes mellitus	Naji (1994)	USA	RCT	2	Conventional care	Integrated care
	Berger *et al*. (2001)	USA	Before-after	4		Disease management
	Sidorov *et al*. (2002)	USA	Retrospective	2		Disease management
	Wagner *et al*. (2001)	USA	RCT	2	Usual care	Chronic care clinics
	Berg & Wadhwa (2002)	USA	Before-after	1		Disease management
	Snyder *et al*. (2003)	USA	Before-after	4		Disease management
	Villagra & Ahmed (2004)	USA	Before-after	1		Disease management

Author (year)	Country	Study design	Study period (years)	Usual care (comparator)	Integrated care
Boyer *et al*. (2008)	France	Before-after	3		Managed care
Scanlon *et al*. (2008)	USA	Retrospective	1		Team-based care
Stock *et al*. (2010)	Germany	RCT	4	Routine care	Disease management
Dall *et al*. (2010)	USA	Prospective	1		Disease management
Rosenzweig *et al*. (2010)	USA	Prospective	1		Disease management
Ko *et al*. (2011)	China	RCT	2	Usual care	Team-based care
Drabik *et al*. (2012)	Germany	Retrospective	3		Disease management

	Author (year)	Country	Study design	Study period (years)	Usual care (comparator)	Integrated care
	Dall *et al*. (2011)	USA	Retrospective	1		Disease Management
	Ostermann *et al*. (2012)	Austria	Retrospective	3		Disease management
	Adepoju *et al*. (2014)	USA	RCT	1	Usual care	Disease management
	Tan *et al*. (2014)	Singapore	Before-after	3		Disease management
Schizophrenia	Reynolds & Hoult (1984)	New-Zealand	RCT	1	Hospital care	Community care
	Wiersma *et al*. (1995)	The Netherlands	RCT	2	Hospital care	Community care
	Burns & Raftery (1991)	United Kingdom	RCT	1	Hospital care	Home-based care

	Author (year)	Country	Study design	Study period (years)	Usual care (comparator)	Integrated care
	Gater *et al*. (1997)	United Kingdom	RCT	1	Hospital care	Community care
	Tzeng *et al*. (2007)	Taiwan	RCT	1	Hospital care	Integrated care
	Schmidt-Kraepelin *et al*. (2009)	Germany	RCT	1	Hospital care	Integrated care
Multiple sclerosis	Tan *et al*. (2010)	USA	Retrospective	1		Care management
	Pozzili *et al*. (2014)	Italy	RCT	1	Hospital care	Home-based care

Table 2 Characteristics of the Integrated Care Models Included in the Systematic Review

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Type 2 diabetes mellitus						
Naji (1994)					Clinical guidelines for testing	Electronic registration system
Berger *et al*. (2001)			Patient education through telephone and mailing		*American Diabetes Guidelines*	
Sidorov *et al*. (2002)			Patient education and self-monitoring	Nurse as case manager	Promoting clinical guidelines	
Wagner *et al*. (2001)			Patient education through individual and group sessions	Multidisciplinary team of diabetologists and diabetes specialist nurse	Clinical guidelines for testing	Electronic registration system

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Berg & Wadhwa (2002)			Patient education and self-monitoring	Multidisciplinary team with nurse as case manager	*American Diabetes Guidelines*	
Snyder *et al*. (2003)			Patient education through telephone and group sessions	Making individual care goals		Digitising medical records, test results, and prescriptions
Villagra & Ahmed (2004)			Patient education through mailing, telephone, educational material, and equipment for self-monitoring	Making individual care goals	*American Diabetes Guidelines*	
Boyer *et al*. (2008)			Patient education	Optimising coordination and communication between professionals	Clinical guidelines	Digitising medical records

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Scanlon *et al*. (2008)			Self-management is important	Multidisciplinary team with nurse as care manager, doctor, medical assistant, and social worker	Evidence-based treatment protocols	*Primary Health Care-provided Patient Evaluation and Care System*
Stock *et al*. (2010)			Patient education is important	Making individual care goals	Evidence-based guidelines	
Dall *et al*. (2010)			Patient education through newsletters and online educational material	Making individual care goals		
Rosenzweig *et al*. (2010)			Patient education (*Joslin Diabetes Center* + newsletters) + self-monitoring	Nurse as care manager and making individual care goals	Protocols for discharge	

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Ko *et al*. (2011)			Patient education is important	Multidisciplinary team with diabetes specialist nurse as case manager		
Drabik *et al*. (2012)			Patient education is important		Clinical guidelines	Technological support
Dall *et al*. (2011)			Patient education is important	Multidisciplinary team with case manager		
Ostermann *et al*. (2012)			Patient education is important		Evidence based pathways and clinical guidelines	
Adepoju *et al*. (2014)			Patient education and self-monitoring are important			Diabetes pilot software

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Tan *et al*. (2014)			Patient education (toolkits) and self-monitoring are important		Clinical guidelines for referral	
Schizophrenia						
Reynolds & Hoult (1984)	Community care		Patient education is important	*Community Treatment Team* and making individual care goals		
Wiersma *et al*. (1995)	Home visits			Multidisciplinary team		
Burns & Raftery (1991)	Home visits			Multidisciplinary team with psychiatrist, social worker, and psychiatric nurse		

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Gater *et al*. (1997)	Home visits and close collaboration with community services			Multidisciplinary team		
Tzeng *et al*. (2007)	Close collaboration with community services		Patient education is important	Multidisciplinary team	Decision support system based on therapeutic protocols	
Schmidt-Kraepelin *et al*. (2009)	Home visits and support for family member		Patient education through individual and group session			

	Community resources and policies	Healthcare organisation	Self-management support	Delivery system design	Decision support	Clinical information system
Multiple sclerosis						
Tan *et al*. (2010)			Patient education is important	Nurse as case manager		
Pozzili *et al*. (2014)	Home visits and close collaboration with community services			Multidisciplinary team + making individual care goals		

Table 3 Characteristics and Outcomes of the Cost Analyses Included in the Systematic Review

	Costs	Viewpoint	Incremental cost (euro) per patient per year	Return on investment	Clinical outcomes
Type 2 diabetes mellitus					
Naji (1994)	Direct costs	Patient	+42.42		
Berger *et al*. (2001)	Direct costs		−423.52		
Wagner *et al*. (2001)	Direct costs		0		
Sidorov *et al*. (2002)	Direct costs		−1,153.50	2.30:1	
Berg & Wadhwa (2002)	Direct costs		−1,507.49	4.34:1	Lower blood sugar level and blood pressure
Snyder *et al*. (2003)	Direct costs		−1,425.76	3.37:1	Lower HbA1c level
Villagra & Ahmed (2004)	Direct costs		−1,471.11		

	Costs	Viewpoint	Incremental cost (euro) per patient per year	Return on investment	Clinical outcomes
Boyer *et al*. (2008)	Direct and indirect costs	Third-party payer	0		
Scanlon *et al*. (2008)	Direct costs		0		
Stock *et al*. (2010)	Direct costs		−98.21		
Dall *et al*. (2010)	Direct costs		−722.12		
Rosenzweig *et al*. (2010)	Direct costs		−908.30		
Ko *et al*. (2011)	Direct costs	Professional organisation	+299.20		Lower blood pressure and HbA1c level
Drabik *et al*. (2012)	Direct costs		−204.4		Lower blood sugar level, blood pressure, and cholesterol level
Dall *et al*. (2011)	Direct costs		−732.13		

	Costs	Viewpoint	Incremental cost (euro) per patient per year	Return on investment	Clinical outcomes
Ostermann *et al*. (2012)	Direct costs	Third-party payer	−1,023.00		
Adepoju *et al*. (2014)	Indirect costs	Employer	0		
Tan *et al*. (2014)	Direct costs		0		
Schizophrenia					
Reynolds & Hoult (1984)	Direct costs		−817.18		
Wiersma *et al*. (1995)	Direct costs	Third-party payer	0		
Burns & Raftery (1991)	Direct costs	Patient	0		
Gater *et al*. (1997)	Direct and indirect costs	Third-party payer	0		

	Costs	Viewpoint	Incremental cost (euro) per patient per year	Return on investment	Clinical outcomes
Tzeng *et al*. (2007)	Direct costs		+613.91		
Schmidt-Kraepelin *et al*. (2009)	Direct costs	Patient	−3,860.00		
Multiple sclerosis					
Tan *et al*. (2010)	Direct costs		+339.43		
Pozzili *et al*. (2014)	Direct costs	Third party payer	−822		

APPENDIX I – EXAMPLE OF DATA ABSTRACTION FORM

Item	Reported data
Author(s)	Wagner *et al*.
Year	2001
Journal	Diabetes Care
Country	USA
Type of integrated care model	Chronic care clinics
Target population	Type 2 diabetes mellitus
Study perspective	/
Type of costs	Direct costs
Time horizon	2 years
Comparators	Usual care
Methods	Randomised controlled trial
Components of the CCM	Patient education through individual and group sessions Multidisciplinary team: diabetologists and diabetes specialist nurse Clinical guidelines Electronic registration system
Incremental cost	0 euro
Return on investment	/

APPENDIX II – EXAMPLE OF THE ASSESSMENT OF RISK OF BIAS IN INCLUDED STUDIES

Article: Wagner *et al*. (2001) Chronic Care Clinics for Diabetes in Primary Care

Domain	Review authors' judgement
Sequence generation	**UNCLEAR**: Patients were randomly allocated to usual care or to integrated care. Nevertheless, there was insufficient information about the sequence generation process.
Allocation concealment	**UNCLEAR**: The method of allocation concealment is not described.
Blinding of participants, personnel and outcome assessors	**UNCLEAR**: Insufficient information to permit judgement.
Incomplete outcome data	**LOW RISK OF BIAS**: No missing outcome data.
Selective outcome reporting	**LOW RISK OF BIAS**: The study protocol is available.
Other sources of bias	**LOW RISK OF BIAS**: The study appears to be free of other sources of bias.

APPENDIX III – SUMMARY OF THE ASSESSMENT OF RISK OF BIAS

	Sequence generation	Allocation concealment	Blinding of participants, personnel, and outcome	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Diabetes mellitus type 2						
Naji (1994)						
Berger et al. (2001)						
Sidorov et al. (2002)						
Wagner et al. (2001)						
Berg & Wadhwa (2002)						
Snyder et al. (2003)						
Villagra & Ahmed (2004)						
Boyer et al. (2008)						
Scanlon et al. (2009)						
Stock et al. (2010)						
Dall et al. (2010)						
Rosenzweig et al. (2010)						
Ko et al. (2011)						
Drabik et al. (2012)						
Dall et al. (2011)						
Ostermann et al. (2012)						
Adepoju et al. (2014)						
Tan et al. (2014)						
Schizophrenia						
Reynolds & Hoult (1984)						
Burns & Raftery (1991)						
Wiersma et al. (1995)						
Gater et al. (1997)						
Tzeng et al. (2007)						
Schmidt-Kraepelin et al. (2009)						
Multiple sclerosis						
Tan et al. (2010)						
Pozzili et al. (2014)						

APPENDIX IV – LIST OF EXCLUDED STUDIES

Article	Reason for exclusion
Rubin *et al*. (1998). Clinical and economic impact of implementing a comprehensive diabetes management program in managed care.	Not specifically for diabetes mellitus type 2
Hussey et al. (2014). Continuity and the costs of care for chronic disease.	The model did not meet the definition of integrated care
Hong *et al*. (2010). Continuity of care for elderly patients with diabetes mellitus, hypertension, asthma, and chronic obstructive pulmonary disease in Korea.	The model did not meet the definition of integrated care
Gador-Whyte *et al*. (2014). Cost of best-practice primary care management of chronic disease in a remote Aboriginal community.	The model did not meet the definition of integrated care
Cousins (2003). Cost savings for a preferred provider organization population with multi-condition disease management: evaluating program impact using predictive modelling with a control group.	Not specifically for diabetes mellitus type 2
Gilmer (2011). Costs of chronic disease management for newly insured adults.	Not specifically for diabetes mellitus type 2
Lairson *et al*. (2008). Economic evaluation of an intensified disease management system for patients with type 2 diabetes.	The model did not meet the definition of integrated care
Rasekaba *et al*. (2012). Effect of a chronic disease management service for patients with diabetes on hospitalization and acute care costs.	The model did not meet the definition of integrated care
Conti (2013). Effect of Medicaid disease management programs on emergency admissions and inpatient costs.	Not specifically for diabetes mellitus type 2
Albisser *et al*. (2001). The impact of initiatives in education, self-management training, and computer-assisted self-care on outcomes in diabetes disease management.	Not specifically for diabetes mellitus type 2
Furler *et al*. (2014). Can primary care team-based transition to insulin improve outcomes in adults with type 2 diabetes: the stepping up to insulin cluster randomized controlled trial protocol.	Trial protocol
Tsiachristas *et al*. (2014). Changes in costs and effects after the implementation of disease management programs in the Netherlands: variability and determinants.	Not specifically for diabetes mellitus type 2
Lynne (2004). Diabetes disease management in managed care organizations.	Not specifically for diabetes mellitus type 2
Clancy *et al*. (2008). Do Diabetes Group Visits Lead to Lower Medical Care Charges?	The model did not meet the definition of integrated care
Flamm *et al*. (2012). Impact of a randomized control group on perceived effectiveness of a Disease Management Programme for diabetes type 2	Incremental cost was not reported
Klonoff & Schwartz (2000). An economic analysis of interventions for diabetes.	Review
Palmas *et al*. (2010). Medicare payments, healthcare service use, and telemedicine implementation costs in a randomized trial comparing telemedicine case management with usual care in medically underserved participants with diabetes mellitus (IDEATel).	The model did not meet the definition of integrated care
Freund *et al*. (2011). Primary care practice-based care management for chronically ill patients (PraCMan): study protocol for a cluster randomized controlled trial.	Trial protocol

Article	Reason for exclusion
Gagliardino *et al*. (2006). PROPAT: a study to improve the quality and reduce the cost of diabetes care.	The model did not meet the definition of integrated care
McCall *et al*. (2011). Results of the Medicare Health Support disease-management pilot program.	Not specifically for diabetes mellitus type 2
Linder *et al*. (2011). The benefit and efficiency of the disease management program for type 2 diabetes.	Incremental cost was not reported
Linden (2006). What will it take for disease management to demonstrate a return on investment? New perspectives on an old theme.	Theoretical analysis
Marshall *et al*. (2011). WITHDRAWN: Case management for people with severe mental disorders.	Review
Dieterich *et al*. (2010). Intensive case management for severe mental illness.	Not specifically for schizophrenia
Chatterjee *et al*. (2011). Collaborative community based care for people and their families living with schizophrenia in India: protocol for a randomized controlled trial.	Trial protocol
Scott & Dixon (1995). Assertive community treatment and case management for schizophrenia.	Review
Marshall *et al*. (2000). Case management for people with severe mental disorders.	Theoretical analysis
Kashner *et al*. (2006). An empirical analysis of cost outcomes of the Texas Medication Algorithm Project.	The model did not meet the definition of integrated care
Rosenheck (1995). Multisite experimental cost study of intensive psychiatric community care	The model did not meet the definition of integrated care
Tyrer *et al*. (1998). Randomized controlled trial of two models of care for discharged psychiatric patients.	Not specifically for schizophrenia The model did not meet the definition of integrated care
Nielsen (2000). Case management in psychiatric disability.	Not available
Bandari *et al*. (2012). Evaluating risks, costs, and benefits of new and emerging therapies to optimize outcomes in multiple sclerosis.	Review
Wynia *et al*. (2010). Design of a Randomized Controlled Trial (RCT) on the effectiveness of a Dutch patient advocacy case management intervention among severely disabled Multiple Sclerosis patients.	Trial protocol
Sperandeo *et al*. (2011). Managed approaches to multiple sclerosis in special populations.	Theoretical analysis
Lad *et al*. (2010). Socioeconomic trends in hospitalization for multiple sclerosis	The article is not about integrated care
Morrow (2007). The costs and consequences of multiple sclerosis relapses: a managed care perspective.	Theoretical analysis
Burks (1998). Multiple sclerosis care: an integrated disease-management model.	Theoretical analysis

PART II

Patient-Perceived Quality and Safety of Primary Care

'Could a greater miracle take place than for us to look

through each other's eyes for an instant?'

- Henry David Thoreau -

Chapter 4

Seen Through the Patients' Eyes: Assessing Congruency of Chronic Care Delivery with the Chronic Care Model

Presented in part at the 2nd *International Scientific Nursing and Midwifery Congress*, Antwerp (Belgium), February 2017.

Presented in part at the 17th *International Conference on Integrated Care*, Dublin (Ireland), May 2017.

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SUMMARY

Most well-developed healthcare systems are facing the challenge of managing the increasing prevalence of patients with chronic diseases. Improving the quality of care for chronic patients is an important aim, both for healthcare professionals and policy makers. In contrast with the increasing burden of chronic diseases, today's care delivery often remains acute disease-driven in many healthcare settings and practices. Comprehensive frameworks - such as the Chronic Care Model - receive widespread acceptance for improving care processes, clinical outcomes, and healthcare-associated costs. Consequently, the aim of the present study was to assess the quality of chronic care delivery or the alignment with the Chronic Care Model among patients living in Belgium (Flanders).

An observational, cross-sectional study design was applied and participants were recruited from the Flemish Patients' Platform. An online questionnaire was designed to assess chronic patients' socio-demographic characteristics, medical consumption, quality of life (EQ-5D survey), and perspectives on the quality of chronic care delivery (PACIC survey). The mean overall PACIC score was 2.87 (SD=0.93) on a maximum score of 5. The highest mean score for the PACIC subscales was found for 'patient activation' ($\bar{x}$=3.26, SD=1.12), followed by 'delivery system design/decision support' ($\bar{x}$=3.23, SD=0.99), 'problem-solving/contextual counselling' ($\bar{x}$=2.86, SD=1.17), 'goal setting/tailoring' ($\bar{x}$=2.70, SD=1.00), and 'follow-up/coordination' ($\bar{x}$=2.59, SD=1.03). Quality of life - as measured by the EQ-5D Visual Analogue Scale - had a significantly positive correlation with the mean PACIC score (r=0.153, P=0.005).

The Chronic Care Model is considered an important step towards improved care for patients with chronic diseases. However, the findings of the present study showed that several elements from the model have not yet been fully implemented. Aspects such as dealing with problems that may interfere with achieving predefined care goals, helping patients to set specific goals in their care delivery, and arranging follow-up meetings are less common in today's chronic care delivery.

Due to increases in population numbers and ageing, most well-developed healthcare systems are facing the challenge of managing the increasing prevalence of patients with chronic diseases. According to the latest Lancet *Global Burden of Disease Study* (2015), people are living more years with illness and disability, which is associated with a high burden on individuals' quality of life [1]. It is estimated that around 50 million European citizens are suffering from two or more chronic conditions and most of these people are over 65 years old [2]. Consequently, the premature deaths of working-age people across the EU cost around €115 billion or 0.8% of the GDP annually and the burden of ill-health on social benefit expenditures is huge with 1.7% of the GDP annually [3].

Improving the quality of care for patients with chronic diseases is an important aim, both for healthcare professionals and policy makers. Current delivery of care is often fragmented and largely built around the long-standing acute and episodic model of care, although solid evidence showed that a more integrated and proactive approach helps to reduce the burden of many chronic diseases [4]. Comprehensive frameworks - such as the CCM - increasingly receive widespread acceptance for improving care processes, clinical outcomes, and healthcare-associated costs [5]. The CCM is an evidence-based framework to guide chronic care delivery that supports patient self-management. The framework is structured around integrated healthcare teams and incorporates clinical information systems to facilitate productive patient-professional relationships and to enhance chronic care [6]. The CCM describes six elements of a healthcare system that collaboratively encourage high-quality chronic care delivery: [1] 'health system', [2] 'clinical information systems', [3] 'delivery system design', [4] 'decision support', [5] 'self-management support', and [6] 'community' [6]. Implementation of the CCM has been found to improve patient outcomes and reduce healthcare-associated costs [7-9].

Furthermore, there is growing consensus that patients can play a more active role in improving healthcare as they increasingly recognise the defects in their care. Indeed, patient experience is an important component of patient-centred quality of care and is defined as '*perceptions and feelings of patients after interactions, occurrences, and events that happen independently and collectively throughout the care process*' [10].

Devkaran distinguishes 13 domains of patient experience, including consistency and coordination of care [11]. There are specific handbooks and guidelines to measure patients' experiences. In addition, a special survey with questions about patients' experiences regarding continuity of chronic care exists [12]. The *Patient Assessment of Chronic Illness Care* (PACIC) survey is proven to be an effective instrument to measure the alignment of chronic care delivery with the CCM; that is measuring care that is patient-centred, proactive, planned, and includes collaborative goal setting, problem-solving, and follow-up support [13].

OBJECTIVES

Given the rising burden of chronic diseases and the consequential need to reform today's healthcare delivery, it is essential to evaluate the quality of chronic care from the patients' perspectives to ensure that both care and quality improvements align with their needs and expectations. Consequently, the aim of the present study was to assess the quality of chronic care delivery among patients living in Belgium (Flanders). Since previous research indicated that patients' assessments may depend on socio-demographic or disease-related characteristics, relationships between the mean PACIC score and possible aforementioned predictors were also explored [14].

METHODS

Design and Recruitment

An observational, cross-sectional study design was applied by using an online questionnaire. Participants were recruited from the Flemish Patients' Platform (*Vlaams Patiëntenplatform*), an independent organisation founded in 1999 and which unites more than 100 patient associations. The main goal of the organisation is to defend patients' rights and to strive for more care quality and an active role for patients within health policy. Sampling was opportunistic, based on opting-in and within the constraints of the following inclusion criteria: all participants were over 18 years of age, were able and willing to provide informed consent to participate, and could fully understand and express themselves in Dutch.

Several steps were taken to mitigate the risk of common method bias, both ex-ante remedies as well as statistical controls after the questionnaires were returned (e.g., during design and administration stage of the survey, respondents were assured of confidentiality of the study and that there were no right or wrong answers) [15]. The questionnaires were distributed through an online platform (Qualtrics) between April and September 2016, using the mailing list of the Flemish Patients' Platform. A general reminder was send four weeks after initial announcement.

Questionnaire Development

In order to safeguard the relevance of the questions and maintain understandable language, the questionnaire was developed in conjunction with two staff members of the Flemish Patients' Platform. The survey included existing validated metrics and self-formulated questions.

The final questionnaire consisted of the following four parts: [1] socio-demographic characteristics, [2] medical consumption, [3] the EuroQol 5D-5L survey, and [4] the PACIC survey. First, selected patient characteristics included age, gender, educational level, and number plus type of chronic conditions. The second part contained questions about the patients' medical consumption. Participants were asked to indicate the number of contact moments (including visits and consultations) with general practitioners, medical specialists, allied healthcare professionals, family caregivers, and informal caregivers during the last six months. To assess respondents' quality of life perception, the EuroQol Group's EQ-5D 5L dimensions and Visual Analogue Scale (VAS) were used in part three [16]. The EQ-5D 5L has five dimensions: [1] 'mobility', [2] 'self-care', [3] 'usual activities', [4] 'pain/discomfort', and [5] 'anxiety/depression', each of which was reported in five levels (i.e., 'no problems', 'slight problems', 'moderate problems', 'severe problems', and 'extreme problems'). The EQ VAS allowed respondents to mark their perceived health status on a scale, ranging from 0 ('worst imaginable health status') to 100 ('best imaginable health status'). Finally, the PACIC instrument was used to assess the quality of chronic care from the patients' perspectives [12].

The PACIC survey is a 20-item validated questionnaire, assessing the following five scale constructs: [1] 'patient activation' (3 items), [2] 'delivery system design/decision support' (3 items), [3] 'goal setting/tailoring' (5 items), [4] 'problem-solving/contextual counselling' (4 items), and [5] 'follow-up/coordination' (5 items). Respondents were asked to evaluate chronic care delivery (received during the last six months) on a five-point Likert scale, ranging from 1 ('none of the time') to 5 ('always'), with higher scores indicating better patient-assessed quality of chronic care and greater alignment with the CCM.

Statistical Analyses

Analyses were performed using SPSS software version 23. The significance level α was set at 0.05 and all *P*-values were two-sided. The analyses and descriptions followed the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) guidelines for cross-sectional studies [17]. Since all questionnaires were completely filled out, imputation of missing data was not necessary. First, descriptive statistics (including proportion, mean, standard deviation, median, and range) were used to determine the sample's characteristics, medical consumption, and quality of life. The EQ-5D-5L levels were dichotomised into 'no problems' (level 1) and 'problems' (levels 2 to 5) as suggested by the EuroQol User Guide EQ-5D [18].

The PACIC survey has been translated and validated in several studies [19-35]. However, validation studies showed mixed evidence regarding data quality and psychometric properties of the PACIC scales [22,25-27,29,31-33]. Therefore, the present study sought to conduct a confirmatory factor analysis (CFA) to test the hypothesised factor structure of the PACIC survey before interpreting the 20-item scale in a Belgian population. The five-domain structure of the PACIC survey was explored by conducting a CFA using R: A Language and Environment for Statistical Computing version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria) [36]. Bartlett's Test of Sphericity ($P<0.05$) and the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (>0.60) were performed to establish the adequacy of the sample for factor analysis [37].

Afterwards, a set of goodness-of-fit indices was used: the X^2 with an associated *df* and probability, Comparative Fit Index (CFI), Tucker Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA), and Standardised Root Mean Square Residual (SRMR). A non-significant X^2 means that the discrepancies between the hypothesised model and the empirical data are negligibly small and thus indicate a good fit. The other parameters measure how well the empirical model approaches the theoretical model. A CFI and TLI value between 0.90 and 0.95, a RMSEA value of $\leq$0.06, and a SRMR value of $\leq$0.08 are considered a close fit of the model [38]. Construct validity of the PACIC survey was further assessed by using Standardised Path Coefficients ($\geq$0.50) [39].

Finally, each PACIC subscale was scored by averaging items completed within the scale and the overall PACIC score as an average across all 20 items [12]. Analyses of differences in mean PACIC score were performed with the Independent Sample T test and the One-Way ANOVA test. The Spearman Correlation test was conducted to calculate bivariate correlations.

Ethical Consideration

Participants were informed that the collected information would be kept confidential and that the questionnaire was anonymous. There were no incentives provided for completing the questionnaire. The institutional ethics committees of Hasselt University and Ghent University reviewed and approved the study (ref. CME2016/0122).

RESULTS

Respondents' Characteristics

A total of 339 questionnaires were returned. Table 1 presents sample characteristics. The mean age for the entire sample was 55.80 years (SD=11.76) and the majority of respondents were female (n=221, 65.2%). More than half of respondents hold a college or university degree (n=183, 54.0%). The median number of chronic conditions was two, ranging from one to nine chronic conditions. The top five most prevalent chronic conditions were chronic back pain (n=106, 31.3%), multiple sclerosis (n=91, 26.8%), chronic neck pain (n=79, 23.3%), osteoarthritis (n=77, 22.7%), and hypertension (n=53, 15.6%).

Medical Consumption

Table 2 displays respondents' medical consumption. Aggregated for general practitioner, medical specialist, allied healthcare professional, and home care nurse, respondents had five monthly contacts (range=0 to 95) during the last six months. Monthly visits to a general practitioner and a medical specialist (median=1, range= 0 to 12) were most prevalent. Related to the frequent reported chronic conditions, the following medical specialists were visited most prevalent: neurologist (n=149, 36.2%), rheumatologist (n=55, 13.3%), and pulmonologist (n=49, 11.9%). The majority of patients with home care, received care for more than one year (n=95, 28.0%) and mainly hygienic care (n=48, 37.2%), followed by injections (n=27, 20.9%), wound care (n=19, 14.7%), managing and administering medication (n=16, 12.4%), help with transfers (n=14, 10.9%), and catheter care (n=5, 3.9%). Finally, a wide hour range of family and informal care was found, ranging from no care to receiving 672 hours per month of additional care.

Quality of Life

Regarding quality of life, the median EQ 5D-5L VAS score was 60 (range=0 to 95). Respondents experienced most problems with pain/discomfort (n=294, 86.7%), followed by usual activities (n=273, 80.5%), mobility (n=222, 65.5%), self-care (n=163, 48.1%), and anxiety/depression (n=156, 46.0%). Details are provided in Table 2.

Confirmatory Factor Analysis of the PACIC Survey

Bartlett's Test was significant (*P*<0.003) and the Kaiser-Meyer-Olkin Measure was 0.94, indicating that the dataset was appropriate for factor analysis. The indices for model fit indicated that the data fitted well for the proposed model [38,40,41]: CFI=0.902, TLI=0.887, RMSEA=0.085, and SRMR=0.060. However, the Chi-square Statistic test was significant (*P*<0.001). Nevertheless, it tends to result in a rejection of the model in large samples (over 200 cases) and is therefore sensitive to sample size [42]. The CFA (see Appendix I) showed high factor loadings for items in the scales 'patient activation' (range=0.66 to 0.84), 'delivery system design/decision support' (range=0.62 to 0.80) and 'problem-solving/contextual counselling' (range=0.75 to 0.89). The remainders of the PACIC scales included items with both moderate and high loadings: 'goal setting/tailoring' (range=0.57 to 0.80) and 'follow-up/coordination' (range=0.59 to 0.80). In conclusion, all factor loadings were above the 0.50 cut-off value [39].

PACIC Overall and Subscales Scores

Table 3 presents descriptive statistics for scores on the PACIC subscales. The mean overall PACIC score was 2.87 (SD=0.93) on a maximum score of 5. The highest mean score for the PACIC subscales was found for 'patient activation' ($\bar{x}$=3.26, SD=1.12), followed by 'delivery system design/decision support' ($\bar{x}$=3.23, SD=0.99), 'problem-solving/contextual counselling' ($\bar{x}$=2.86, SD=1.17), 'goal setting/tailoring' ($\bar{x}$=2.70, SD=1.00), and 'follow-up/coordination' ($\bar{x}$=2.59, SD=1.03).

Quality of life - as measured by the EQ-5D VAS - was found to have a significantly positive correlation with the mean PACIC score (*r*=0.153, *P*<0.005). Details are provided in Table 4. The following characteristics were not associated with a significant difference in mean PACIC score: age, number of chronic conditions, number of contact moments with the healthcare team, number of professionals in the healthcare team, and number of hours family and informal care.

DISCUSSION

The rising prevalence of patients with chronic diseases represents substantial challenges in delivering high-quality care. As the IOM's *Crossing the Quality Chasm: A New Health System for the 21st Century* report concluded: '*the current care system cannot do the job. Trying harder will not work. Changing systems of care will*' [43]. Consequently, integrated and patient-centred strategies are crucial to improve chronic care delivery. A critical step in developing these new and innovative strategies is assessing the needs and preferences of chronic patients. Indeed, there is growing consensus that patients can play a more active role in defining and reforming healthcare. Therefore, the current study used the PACIC survey to explore patients' perspectives on today's chronic illness care or the alignment with the CCM.

A total of 339 chronic patients completed the survey. The top five most prevalent chronic conditions were chronic back pain, multiple sclerosis, chronic neck pain, osteoarthritis, and hypertension. Consequently, the study population reflected the top five leading causes of YLDs in Belgium; that is low back pain, cerebrovascular diseases, falls, neck pain, and other musculoskeletal diseases [3]. Additionally, the current study found a mean PACIC score of 2.87 (SD=0.93) on a maximum score of 5. The highest PACIC subscale scores were found for 'patient activation' and 'delivery system design/decision support', suggesting that chronic patients are generally active patients who are well supported and motivated by their healthcare professionals. Lowest PACIC subscale scores were found for 'goal setting/tailoring' and 'follow-up/coordination', indicating that chronic patients experience a lack of setting specific goals in their care delivery and in arranging follow-up meetings. Furthermore, no relationship was observed between the mean PACIC score and patients' socio-demographic characteristics, medical consumption, and quality of life (EQ-5D) dimensions. However, quality of life - as measured by the EQ-5D VAS - had a significantly positive correlation with the mean PACIC score. This finding - supported by Randell *et al*. and Schmittdiel *et al*. - suggests that implementing quality improvements in chronic care may benefit the perceived health status of patients with chronic diseases [33,44].

Given that Quality Adjusted Life Years (QALYs) are the main measure of benefit in cost-effectiveness models, the authors have chosen the VAS scale as it is the most regular and user-friendly tool for eliciting preferences. Results of the present study are in line with previous research [33,45-47], however inferior to the mean PACIC score of Glasgow *et al*. and Balbale *et al*. [48,49]. Differences in mean PACIC scores may be attributable to the fact that some studies focused on specific chronic conditions [14,44,46,48,49] or healthcare settings [33,45]. Houle *et al*. evaluated chronic illness care among Canadian patients and obtained a mean PACIC score of 2.80, indicating that CCM-concordant care occurred '*a little or some of the time*' [45]. Petersen *et al*. described how older patients with multimorbidity assessed routine chronic care in Germany and found an overall mean PACIC score of 2.40 [14]. Furthermore, the mean PACIC score for seven Kaiser Permanente regions in the USA was 2.70 [33] and 3.05 among American veterans with multiple chronic conditions [49]. Finally, the mean PACIC score in a large inflammatory bowel disease cohort [44], for diabetic patients [48], and for patients with osteoarthritis [46] was 2.40, 3.20, and 2.79 respectively.

Chronic patients are in high need of long-term care that brings together a broad range of professionals and that moreover integrates and coordinates services along the continuum of care. As a result, integrated care has gathered momentum to correct the deficiencies - such as lack of care coordination - in current chronic care delivery [50]. A transformation of healthcare is required to overcome these deficiencies. As mentioned, integrated care receives increasing attention as it is considered an appropriate answer in potentially reducing the fragmentation of care, improving the quality and safety of care, and controlling healthcare-associated costs [7,9,51]. Consequently, there has been an increase in initiatives to encourage professional partnerships, such as *Integrated Care Strategies* in Australia [52], *New Care Models and Integrated Care Pioneers* in England [53], and *Population Health Management Pilots* in the Netherlands [54]. In Belgium, a large national program on integrated care was launched, called *Integrated Care for a Better Health* [55]. Within this program, 20 pilot projects were selected for further conceptualisation.

These projects may also use the PACIC survey or the results of the present study to define their innovative and integrated care models, with special attention to the patients' needs and expectations such as better goal setting and follow-up.

The results of the present study have to be interpreted carefully. First, the current study was limited by a cross-sectional study design that prevents examining causality and therefore determining direction of the observed association between the EuroQol VAS and the mean PACIC score. In addition, the questionnaire approach generates low response of patients with complex needs who often do not have enough energy to fill out a survey. Moreover, qualitative descriptions of patients' experiences in the form of focus groups or in-depth interviews may offer additional information about the structural and incidental factors that influence the quality of care delivery [56]. Third, the sample consisted largely of members of patient organisations, enclosing dedicated and committed individuals within a strong involvement in their care. This could explain the high score on the subscale 'patient activation'. Moreover, the five PACIC subscales do not perfectly map onto the six CCM components. According to the developers of the PACIC instrument, most chronic patients may not be aware of some aspects of their care such as clinical information systems [12]. Fifth, the present study should also assess depressive symptoms and the severity of chronic diseases since previous research indicated that PACIC scores may be associated with depression and the chronic disease burden [47]. Finally, it is of great importance to assess both patients' and healthcare professionals' perspectives when evaluating quality of chronic illness care, as the ACIC (*Assessment of Chronic Illness Care*) and PACIC scales appear to provide complementary information [57].

This study also has some important strengths. First, a mixed sample of chronic conditions was included. Furthermore, patients' perspectives on chronic illness care in Belgium (Flanders) has - to the best of the authors' knowledge - not yet been published in scientific literature. Finally, the present study conducted a CFA to test the hypothesised factor structure of the PACIC instrument in a Belgian population. The indices for model fit showed that the data fitted well and the CFA showed high to moderate factor loadings on the five PACIC subscales.

CONCLUSIONS

Long-term, structured, and proactive approaches of care may help to reduce the increasing burden of chronic diseases. The CCM is considered an important step towards improved care for chronic patients. Findings of the present study showed that CCM elements have not yet been fully implemented in today's chronic illness care. Elements such as dealing with problems that may interfere with predefined care goals ('problem-solving/contextual counseling'), helping patients to set specific goals ('goal setting/tailoring'), and arranging follow-up meetings ('follow-up/coordination') are less common in today's care for chronic patients. These findings highlight important areas for future research and chronic care improvements.

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Table 1 Respondents' Characteristics (n=339)

Characteristics	Mean (SD) N (%) Median (range)
Age (yrs), mean (SD)	55.80 (11.76)
Gender, n (%)	
Female	221 (65.2%)
Male	118 (34.8%)
Educational level, n (%)	
Less than high school	22 (6.5%)
High School	134 (39.5%)
College	134 (39.5%)
University	49 (14.5%)
Number of chronic conditions, median (range)	2.00 (1-9)
Five most prevalent chronic conditions, n (%)	
Chronic back pain	106 (31.3%)
Multiple sclerosis	91 (26.8%)
Chronic neck pain	79 (23.3%)
Osteoarthritis	77 (22.7%)
Hypertension	53 (15.6%)

Table 2 Respondents' Medical Consumption and Quality of Life (n=339)

Medical consumption	N (%) Median (range)
Visits healthcare team aggregated (monthly), median (range)	5.00 (0-95)
Most prevalent visits to or contacts with, median (range)	
General practitioner (monthly)	1.00 (0-12)
Specialist (monthly)	1.00 (0-12)
Number of professionals in healthcare team, median (range)	2.00 (0-8)
Duration of home care, n (%)	
No home care	201 (59.4%)
Less than 6 months	31 (9.1%)
Between 6 months and 1 year	12 (3.5%)
More than 1 year	95 (28.0%)
Most prevalent types of care received, n (%)	
Toilet and hygienic care/washing and dressing	48 (37.2%)
Injections	27 (20.9%)
Wound care	19 (14.7%)
Managing and administering medication	16 (12.4%)
Help in and out of bed/help with transfers	14 (10.9%)
Catheter care	5 (3.9%)
Hours family/informal care (monthly), median (range)	0.00 (0-672)
Problems Quality of Life (EQ-5D) dimensions, n (%)	
Mobility	222 (65.5%)
Self-care	163 (48.1%)
Usual activities	273 (80.5%)
Pain/discomfort	294 (86.7%)
Anxiety/depression	156 (46.0%)
Quality of Life (EQ-5D) VAS, median (range)	60.00 (0-95)

Table 3 Score Distributions of the PACIC Subscales (n=339)

PACIC scores	Mean (SD)	95% CI
Overall PACIC score	**2.87 (0.93)**	**2.77-2.96**
Patient activation	3.26 (1.12)	3.14-3.38
Delivery system design/decision support	3.23 (0.99)	3.12-3.34
Goal setting/tailoring	2.70 (1.00)	2.59-2.80
Problem-solving/contextual counselling	2.86 (1.17)	2.73-2.98
Follow-up/coordination	2.59 (1.03)	2.47-2.70

Table 4 Correlations between PACIC Scores and Possible Predictors

Characteristics	PACIC Subscales					
	Patient activation	**Delivery system design Decision support**	**Goal setting**	**Problem-solving Contextual counselling**	**Follow-up Coordination**	**Overall**
Age*	-0.079	0.042	0.100	-0.019	-0.030	0.011
Number of chronic conditions	-0.021	-0.043	-0.001	-0.084	-0.050	-0.068
Number of contact moments with healthcare team	-0.025	-0.041	-0.058	-0.064	-0.035	-0.057
Number of professionals in healthcare team	-0.032	-0.066	-0.045	-0.073	-0.035	-0.059
Number of hours family and informal care	-0.041	-0.079	-0.011	-0.017	-0.047	-0.039
QoL VAS	0.124**	0.122**	0.103**	0.142**	0.146**	0.153**

* Pearson Correlation

** Significant at the 0.01 level (2-tailed)

APPENDIX I – FACTOR LOADINGS OF THE PACIC INSTRUMENT

Item	Description	F1	F2	F3	F4	F5
Patient activation						
A1	Asked for my ideas when we made a treatment plan	0.83				
A2	Given choices about treatment to think about	0.84				
A3	Asked to talk about any problems with my medicines or their effects	0.66				
Delivery system design/decision support						
A4	Given a written list of things I should do to improve my health		0.72			
A5	Satisfied that my care was well organised		0.62			
A6	Shown how what I did to take care of myself influenced my condition		0.80			
Goal setting/tailoring						
A7	Asked to talk about my goals in caring for my condition			0.80		
A8	Helped to set specific goals to improve my eating or exercise			0.74		
A9	Given a copy of my treatment plan			0.63		
A10	Encouraged to go to a specific group or class to help me cope with my chronic condition			0.57		
A11	Asked questions, either directly or on a survey, about my health habits			0.66		
Problem-solving/contextual counselling						
A12	Sure that my doctor or nurse thought about my values, beliefs, and traditions when they recommended treatments to me				0.77	
A13	Helped to make a treatment plan that I could carry out in my daily life				0.88	
A14	Helped to plan ahead so I could take care of my condition even in hard times				0.89	
A15	Asked how my chronic condition affects my life				0.75	
Follow-up/coordination						
A16	Contacted after a visit to see how things were going					0.59
A17	Encouraged to attend programs in the community that could help me					0.67
A18	Referred to a dietician, health educator, or counsellor					0.68
A19	Told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment					0.80
A20	Asked how my visits with other doctors were going					0.74

Chapter 5

Seen Through the Patients' Eyes: Adverse Medical Events in Primary Care

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SUMMARY

There has been insufficient recognition of patients' experiences and expertise of safety incidents in healthcare. Patients and their caregivers however can provide useful information, correct inaccurate data, and identify inefficiencies in their care, which may be the missing evidence in order to fully understand patient safety incidents and their impact on patients' health and welfare. Particularly in chronic care delivery, acknowledging and discussing patients' experiences reinforce patient-centred care delivery. Consequently, the present study sought to explore perceptions of the safety of chronic care delivery among patients living in Belgium (Flanders).

An observational, cross-sectional study design was applied and participants were recruited from the Flemish Patients' Platform. An online questionnaire was designed to assess chronic patients' socio-demographic characteristics, medical consumption, perceptions of the quality (PACIC survey) and safety of chronic illness care, as well as experiences of patient safety incidents in community-based primary care. In general, respondents (n=339) had positive perceptions of the safety of chronic care delivery as they indicated to receive safe care at home (68.1%), receive enough care support at home (70.8%), and experience good communication between their healthcare professionals (51.6%). Additionally, almost one quarter of respondents experienced a patient safety incident, mainly related to self-reported fall incidents (50.4%), wrong diagnoses or treatments (37.8%), and adverse drug events (11.8%). Finally, more than half of respondents who experienced an incident, indicated that poor communication between their healthcare professionals was the main cause.

Information on patients' experiences is critical to identify patient safety incidents and to ultimately reduce patient harm by developing and implementing appropriate quality and safety initiatives. Currently, integrated care has great potential to redesign care around patients' needs and to improve quality and safety of chronic care delivery. Finally, more research is needed in order to better understand and improve patient safety in primary care.

One of the biggest challenges most healthcare systems globally are facing is the increasing burden of chronic conditions [1]. In practice, the care for chronic patients is mainly provided in primary care. At the same time, the demand for home and community services is increasing substantially to reduce the number of hospital beds, facilitate earlier hospital discharge, improve quality of care, and decrease healthcare-associated costs [2,3]. Consequently, a considerable part of chronic care will continue to shift from secondary to primary care, and home care settings [4].

In accordance with the publication of the IOM's 2000 report *To Err is Human: Building a Safer Health System*, patient safety is widely acknowledged as an important health issue and it is considered indistinguishable from the delivery of high-quality care [5]. Despite the growing importance of primary care, concerns about the safety of patients in hospital settings have thus far driven most research in the field. As a result, the knowledge base about patient safety in primary care is still scarce, although numerous studies have revealed that patient safety incidents in primary care do occur (see Chapter 2). The median incident rate – derived from population-based record review studies - was two to three incidents for every 100 consultations of which 4% of these incidents may be associated with severe harm to the patient [6]. These incidents are mainly related to insufficient communication between healthcare professionals, administrative inefficiencies, medication errors, and diagnostic failures [6,7].

Patient safety data can be collected with information from several methods, such as retrospective medical records, incident reports by healthcare professionals, and patient-reported information. Medical records and incident reports are the most utilised information sources, but can be unreliable as they might suffer from underreporting or incomplete documentation due to the culture of blame or resistance to excessive administrative duties [7]. Additionally, chronic patients have multiple healthcare professionals from different settings involved in their care. Healthcare professionals will only have a partial view of the patient journey, which is incomplete given the particularly high-risk process of care transitions. At the same time, there has been insufficient recognition of patients' experiences and expertise of patient safety incidents.

Nevertheless, patients and their caregivers can provide useful information, correct inaccurate data, and identify inefficiencies in their care, which may be the missing evidence in order to fully understand patient safety incidents and their impact on patients' health and welfare [7-9]. In a number of studies, patients have been shown to report medical incidents and adverse events accurately and to provide additional information, specifically regarding breakdowns in the continuity of care, medication errors, and communication inefficiencies [10]. Studying patients' perceptions of safety is important for several reasons [10]. First, healthcare policy increasingly encourages patients to take a proactive role in their care. Second, patients' experiences can influence other outcomes such as patient adherence, clinical processes, and safety culture. Finally, patients' perspectives can provide an additional lens for viewing complex systems and processes for continuous quality improvement efforts, as endorsed by the WHO Alliance for Patient Safety [11].

OBJECTIVES

Given the aforementioned substantial shift of chronic care delivery and the relatively lack of research concerning patient safety in primary care, the present study sought to explore perceptions of the safety of chronic care delivery in community-based primary care among patients living in Belgium (Flanders).

METHODS

Design and Recruitment

An observational, cross-sectional study design was applied by using an online questionnaire. Participants were recruited from the Flemish Patients' Platform (*Vlaams Patiëntenplatform*), an independent organisation founded in 1999 which unites more than 100 patient associations. The main goal of the organisation is to defend patients' rights and to strive for more care quality and an active role for patients in health policy. Sampling was opportunistic, based on opting-in and within the constraints of the following inclusion criteria: all participants were over 18 years of age, were able and willing to provide informed consent to participate, and could fully understand and express themselves in Dutch.

Several steps were taken to mitigate the risk of common method bias, both ex-ante remedies as well as statistical controls after the questionnaires were returned (e.g., during design and administration stage of the survey, respondents were assured of confidentiality of the study and that there were no right or wrong answers) [12]. The questionnaires were distributed through an online platform (Qualtrics) between April and September 2016, using the mailing list of the Flemish Patients' Platform. A general reminder was send four weeks after initial announcement.

Questionnaire Development

In order to safeguard the relevance of the questions and maintain understandable language, the questionnaire was developed in conjunction with two staff members of the Flemish Patients' Platform. The survey included existing validated metrics and self-formulated questions.

The final questionnaire consisted of five parts: [1] socio-demographic characteristics, [2] medical consumption, [3] the PACIC survey, [4] perceptions of the safety of chronic care delivery in primary care, and [5] experiences of patient safety incidents in primary care. The first part contained items exploring socio-demographic characteristics of the respondents, including age, gender, educational level, and number plus type of chronic conditions. The second part contained items exploring participants' medical consumption. Participants were asked to indicate the number of contact moments (including visits and consultations) with general practitioners, medical specialists, allied healthcare professionals, family caregivers, and informal caregivers during the last six months. The next part assessed respondents' perceptions of the quality of chronic illness care by using the PACIC survey. The PACIC instrument is a 20-item validated questionnaire, assessing the alignment of chronic care with the CCM (see Chapter 4) [13,14]. The fourth part contained three items exploring patients' perceptions of the safety of chronic care delivery in primary care. Each item was phrased as a statement: '*I receive safe care at home*', '*I receive enough care support*', and '*I experience good communication between my healthcare professionals*'.

Participants responded by using a five-point Likert scale ranging from 'strongly disagree' to 'strongly agree', with a neutral mid-point. The final part explored respondents' experiences of patient safety incidents in primary care. Respondents were asked to indicate whether they experienced an incident, which type of incident occurred (e.g., fall incident, adverse drug event, wrong diagnosis, …), and whether or not the incident was caused by poor communication between their healthcare professionals.

The following definition of a patient safety incident was used: *'an unintended event during the care process that resulted, could have resulted, or still might result in harm to the patient'* [15]. It was further agreed that the term *error* should be avoided, because of its rather negative connotation.

Statistical Analyses

Analyses were performed using SPSS software version 23. The significance level α was set at 0.05 and all *P*-values were two-sided. The analyses and descriptions follow the STROBE guidelines for cross-sectional studies [16]. Since all questionnaires were completely filled out, imputation of missing data was not necessary. Univariate analyses were conducted to describe respondents' socio-demographic characteristics, medical consumption, perceptions of the quality (PACIC) and safety of chronic care delivery, and their experiences of patient safety incidents. The overall PACIC score was calculated by averaging scores across all 20 items [13].

Bivariate correlations of covariates with the perceptions of the safety of chronic care delivery and the experiences of incidents were tested using the Chi-squared test. To assess predictive factors, logistic regression models were utilised. The covariates included age, gender, level of education, number of chronic conditions, number of contact moments with the healthcare team, hours of family and informal care, number of professionals in the healthcare team, duration of home care, and perceptions of the quality of chronic illness care (mean PACIC score). The healthcare team was ex post defined when the patient received care from at least two different healthcare professionals.

Ethical Consideration

Participants were informed that the collected information would be kept confidential and that the questionnaire was anonymous. There were no incentives provided for completing the questionnaire. The institutional ethics committees of Hasselt University and Ghent University reviewed and approved the study (ref. CME2016/0122).

RESULTS

Respondents' Characteristics

A total of 339 questionnaires were returned. Table 1 presents sample characteristics. The mean age for the entire sample was 55.80 years (SD=11.76) and the majority of respondents were female (n=221, 65.2%). More than half of respondents hold a college or university degree (n=183, 54.0%). The median number of chronic conditions was two, ranging from one to nine chronic conditions. The top five most prevalent chronic conditions were chronic back pain (n=106, 31.3%), multiple sclerosis (n=91, 26.8%), chronic neck pain (n=79, 23.3%), osteoarthritis (n=77, 22.7%), and hypertension (n=53, 15.6%).

Medical Consumption and Overall PACIC Score

Table 2 displays respondents' medical consumption and assessment of chronic illness care (PACIC) score. Aggregated for general practitioner, medical specialist, allied healthcare professional, and home care nurse, respondents had five monthly contacts (range=0 to 95) during the last six months. Monthly visits to a general practitioner and a medical specialist (median=1, range=0 to 12) were most prevalent. In general, respondents had two professionals (range=0 to 8) in their healthcare team. The majority of patients with home care, received care for more than one year (n=95, 28.0%). Furthermore, a wide hour range for family and informal care was found, ranging from no care to receiving 672 hours per month of additional care. Finally, the mean PACIC score was calculated at 2.87 (SD=2.90) on a maximum score of 5, indicating low to moderate quality of care from the patients' perspectives (see Chapter 4) [17-19].

Perceptions of the Safety of Chronic Care Delivery

Table 3 shows respondents' perceptions of the safety of chronic care delivery in their home environment. The majority of respondents (n=231, 68.1%) reported to either 'strongly agree' (n=131, 38.6%) or 'agree' (n=100, 29.5%) to the statement '*I receive safe care at home*'. In line with this positive perception of safe chronic care, 70.8% (n=240) reported to either 'strongly agree' (n=142, 41.9%) or 'agree' (n=98, 28.9%) to the statement '*I receive enough care support at home*'. Only half of respondents (n=175, 51.6%) reported to either 'strongly agree' (n=74, 21.8%) or 'agree' (n=101, 29.8%) to the statement '*I experience good communication between my healthcare professionals*'.

Multivariate (ordinal) logistic regression analyses (see Table 5) were performed with respondents' socio-demographic characteristics, medical consumption, and mean PACIC score as covariates, predicting perceptions of the safety of chronic care delivery. The findings show that older age (OR=1.10, 95% CI=0.03-0.16, *P*=0.006), a higher PACIC score (OR=9.61, 95% CI=1.25-3.27, *P*<0.001), more contact moments with the healthcare team (OR=1.05, 95% CI=0.01-0.10, *P*=0.040), more hours of family and informal care (OR=1.02, 95% CI=0.01-0.04, *P*=0.030), and receiving more than one year of homecare (OR=5.26, 95% CI=0.09-3.24, *P*=0.039) made respondents more likely to agree with the statement '*I receive safe care at home*'. However, respondents with multiple chronic conditions (OR=0.61, 95% CI=0.81-0.18, *P*=0.002) and more professionals in the healthcare team (OR=0.50, 95% CI=1.25-0.12, *P*=0.017) were less likely to agree with the same statement. As for the statement '*I receive enough care support at home*', respondents with a higher PACIC score (OR=4.63, 95% CI=0.78-2.28, *P*<0.001) were more likely to agree. Once again, having multiple chronic conditions (OR=0.59, 95% CI=0.82-0.23, *P*<0.001) and more professionals in the healthcare team (OR=0.62, CI 95%=0.94-0.01, *P*=0.048) made respondents less likely to agree. Finally, respondents with a higher PACIC score (OR=9.90, 95% CI=1.58-3.01, *P*<0.001) were more likely to agree with the statement *'I experience good communication between my healthcare professionals'*. On the contrary, having more professionals in the healthcare team (OR=0.64, 95% CI=0.82-0.07, *P*=0.020) made respondents less likely to agree with the same statement.

Respondents' Experiences of Patient Safety Incidents

Respondents were asked to indicate whether they experienced an incident outside the hospital, which type of incident occurred, and whether or not the incident was caused by insufficient communication between their healthcare professionals. In total, 22.7% (n=77) experienced a patient safety incident. The median number of incidents experienced was one, ranging from zero to four incidents. The most frequent reported incidents were fall-related incidents (n=132, 50.4%), followed by wrong diagnoses (n=50, 19.1%), wrong treatments (n=49, 18.7%), and adverse drug events (n=31, 11.8%). Of the 77 respondents who experienced an incident, 64.9% (n=50) indicated that insufficient communication between their healthcare professionals was the main cause. A detailed overview of the results can be found in Table 4.

Logistic regressions show that respondents with two or more chronic conditions were more likely to experience two or more incidents (OR=3.40, 95% CI=1.22-9.46, P=0.019) and were more likely to agree with the statement that the incident was caused by insufficient communication between their healthcare professionals (OR=5.74, 95% CI=1.47-22.40, P=0.012). Furthermore, respondents who received less than one year of homecare were more likely to experience two or more incidents (OR=4.17, 95% CI=1.39-12.48, P=0.011) and female respondents were more likely to agree with the statement that the incident was caused by poor communication between their healthcare professionals (OR=4.55, 95% CI=1.06-19.45, P=0.041). Details are provided in Table 6.

DISCUSSION

Primary care entails a greater likelihood of causing unintentional harm to patients due to - inter alia - early discharge from hospitals, the pressure of short consultations, and the fragmented nature of care services [20]. In addition, the increasing prevalence of chronic patients tends to shift the balance of care delivery from secondary to primary care, and home care settings [4]. Nevertheless, major gaps remain in the understanding of patient safety in this setting [21]. A growing body of evidence suggests that patients and their caregivers can recognise inefficiencies in healthcare and could operate as an extra source of learning [22]. Therefore, the current study explored the perceptions of chronic patients on the safety of chronic care delivery in community-based primary care.

In general, the findings of the present study suggest that patients with chronic diseases have positive perceptions of the safety of chronic care delivery in their home environment. The majority indicated to receive safe care at home, receive enough care support at home, and experience good communication between their healthcare professionals. However, it is remarkable that patients with more than two healthcare professionals involved in their care delivery were less likely to agree with the aforementioned statements, which may indicate that continuity of care among healthcare professionals is perceived as not consistent and coherent [23]. One might expect that patients would feel more supported when they are surrounded by numerous healthcare professionals, but findings of the present study thus indicate otherwise. Furthermore, almost one quarter of respondents experienced a patient safety incident. These incidents are mainly related to self-reported fall incidents, wrong diagnoses or treatments, and adverse drug events. Particularly, higher rates of adverse events were reported with multiple chronic diseases. Moreover, insufficient communication between healthcare professionals was perceived as the main cause in more than half of the reported incidents. Aforementioned findings are noteworthy in light of previous research. Recently, Lang *et al*. conducted a systematic review to produce a comprehensive summary of the published literature assessing patients' views on adverse events in primary care [24].

The authors concluded that most of the problems identified were concerns about communication and limitations in coordination or access to healthcare, which is consistent with findings of the present study. However, comparison between studies is compromised due to the absence of an international terminology and a classification system.

As the present study indicated, communication and coordination among healthcare professionals and organisations remain complex issues. Care delivery is often developed in ways that have tended to fragment care. Patients with chronic diseases often receive treatment from many healthcare professionals, working in different locations and parts of the healthcare system. Coulter and Amalberti recently identified a clear need for further research on capturing patient experiences when transitioning care between different organisations or settings; that is the so-called *patient journey* [25,26]. Patients may experience harm during an episode of care (e.g., mistaken identity in the hospital) or later, after some time has passed (e.g., adverse drug event at home due to inefficient patient handover after hospital discharge). This will especially become important given the substantial shift of chronic care delivery from secondary to primary and homecare settings and the resulting focus on transmural care. Within this context, policy makers are constantly searching for structural alternatives to ensure innovative, qualitative, and safe healthcare. Currently, integrated care has great potential to redesign care around patients' needs and it is considered an appropriate answer in potentially reducing the fragmentation of care, improving quality and safety of care, and controlling healthcare-associated costs [27-29]. In response to these emerging challenges posed by chronic diseases, several countries are experimenting with new models of care delivery. In Belgium a large national program on integrated care was launched, called *Integrated Care for a Better Health* [30]. Within this program, 20 pilot projects were selected for further conceptualisation. It is advised that these projects pay explicit attention to patient safety as this study indicated that incidents in primary care do occur.

The results of the present study have to be interpreted carefully. First, respondents consisted largely of members of patients' organisations, comprising dedicated and committed individuals with a strong involvement in their care. This could result in a more critical attitude towards patient safety. Nevertheless, the present study is the first to examine in detail the influence of socio-demographic characteristics on patient reports [24]. Furthermore, capturing patients' experiences of safety incidents is challenging due to the lack of an adequate definition of the term *patient safety incident* and the difficulty to identify and recruit patients who have experienced an incident. Third, no single validated tool currently captures patients' experiences of possible safety incidents [7,31]. A systematic review of methods to identify incidents in healthcare concluded that '*the available methods have widely differing purposes, strengths, and weaknesses and must be considered as complementing each other by providing different levels of qualitative and quantitative information*' [32]. Hence, mixed methods approaches or a triangulation of approaches are proposed to identify patient safety incidents and to focus more on their impact on patients and their caregivers [7,33]. Classification systems may contribute to the integration of patient safety data from numerous sources such as incident reporting, chart reviews, and survey data [34]. Fourth, the degree to which patients can play an active role in their care depends on patients' willingness and ability [22]. Engaging patients does not mean that they should carry the ultimate responsibility for the safety of their care. Moreover, patient participation in safety will depend on a complex interplay of patient-related (e.g., differences in health literacy levels), healthcare professional-related (e.g., beliefs regarding patient participation), healthcare setting-related (e.g., patients experience greater difficulty communicating with hospital staff than with their general practitioner), and task-related factors (e.g., patients are more involved in aspects of their care that do not require medical knowledge) [35]. Finally, there is still no agreement about the best way to assess patients' perspectives nor on the applicability and advantages of these patient reports in daily healthcare [24].

This study also has some important strengths. First, a mixed sample of chronic conditions was included. Furthermore, patients' perspectives of the safety of chronic illness care in Belgium (Flanders) has - to the best of the authors' knowledge - not yet been published in scientific literature.

CONCLUSIONS

Information on patients' experiences is critical to identify safety incidents and to ultimately reduce patient harm. Patients have a key role in their care and must be part of the patient safety discourse. The present study showed that the majority of chronic patients have positive perceptions on the safety of community-based primary care. However, incidents do occur and are mainly related to wrong diagnoses, inappropriate treatments, adverse drug events, and insufficient communication between healthcare professionals. Addressing patient safety in primary care requires a rethinking of guiding frameworks that have been used to examine patient safety in institutional healthcare settings.

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Table 1 Respondents' Characteristics (n=339)

Characteristics	Mean (SD) N (%) Median (range)
Age (yrs), mean (SD)	55.80 (11.76)
Gender, n (%)	
Female	221 (65.2%)
Male	118 (34.8%)
Educational level, n (%)	
Less than high school	22 (6.5%)
High school	134 (39.5%)
College	134 (39.5%)
University	49 (14.5%)
Number of chronic conditions, median (range)	2.00 (1-9)
Five most prevalent chronic conditions, n (%)	
Chronic back pain	106 (31.3%)
Multiple sclerosis	91 (26.8%)
Chronic neck pain	79 (23.3%)
Osteoarthritis	77 (22.7%)
Hypertension	53 (15.6%)

Table 2 Respondents' Medical Consumption and Mean PACIC Score (n=339)

Medical consumption	Mean (SD) N (%) Median (range)
Visits healthcare team aggregated (monthly), median (range)	5.00 (0-95)
Most prevalent visits to or contacts with, median (range)	
General practitioner (monthly)	1.00 (0-12)
Specialist (monthly)	1.00 (0-12)
Neurologist, n (%)	149 (36.2%)
Rheumatologist, n (%)	55 (13.3%)
Pulmonologist, n (%)	49 (11.9%)
Number of professionals in healthcare team, median (range)	2.00 (0-8)
Duration of home care, n (%)	
No home care	201 (59.4%)
Less than 6 months	31 (9.1%)
Between 6 months and 1 year	12 (3.5%)
More than 1 year	95 (28.0%)
Hours family/informal care (monthly), median (range)	0.00 (0-672)
Overall PACIC score, mean (SD)	2.87 (0.93)

Table 3 Respondents' Perceptions of the Safety of Chronic Illness Care (n=339)

Statements	Strongly disagree n (%)	Disagree n (%)	Neither agree or disagree n (%)	Agree n (%)	Strongly agree n (%)
'I receive safe care at home'	37 (10.9%)	25 (7.4%)	46 (13.6%)	100 (29.5%)	131 (38.6%)
'I receive enough care support at home'	32 (9.4%)	23 (6.8%)	44 (13.0%)	98 (28.9%)	142 (41.9%)
'I experience good communication between my healthcare professionals'	49 (14.5%)	44 (13.0%)	71 (20.9%)	101 (29.8%)	74 (21.8%)

Table 4 Respondents' Experiences of Patient Safety Incidents (n=339)

Experiences	N (%) Median (range)
Experienced an incident, n (%)	
Yes	77 (22.7%)
No	262 (77.3%)
Number of incidents experienced	1 (0-4)
Most prevalent incidents, n (%)	
Fall-related incident	132 (50.4%)
Wrong diagnosis	50 (19.1%)
Wrong treatment	49 (18.7%)
Adverse drug event	31 (11.8%)
Caused by poor communication, n (%)	
Yes	50 (64.9%)
No	27 (35.1%)

Table 5 Ordinal Logistic Regression Analyses

Statements	Characteristics		Odds ratio (95% CI)
'I receive safe care at home'	**Age**	years	1.10 (0.03-0.16)**
	Number of chronic conditions	#conditions	0.61 (0.81-0.18)**
	PACIC score	score	9.61 (1.25-3.27)**
	Number of contact moments with healthcare team	#contacts	1.05 (0.01-0.10)*
	Number of hours family and informal care	#hours	1.02 (0.01-0.04)*
	Number of professionals in healthcare team	#caregivers	0.50 (1.25-0.12)*
	Duration of homecare	> 12 months	5.26 (0.09-3.24)*
		< 6 months	Reference

Statements	Characteristics		Odds ratio (95% CI)
'I receive enough care support at home'	**Number of chronic conditions**	#conditions	0.59 (0.82-0.23)**
	PACIC score	score	4.63 (0.78-2.28)**
	Number of professionals in healthcare team	#caregivers	0.62 (0.94-0.01)*
'I experience good communication between my healthcare professionals'	**PACIC score**	score	9.90 (1.58-3.01)**
	Number of professionals in healthcare team	#caregivers	0.64 (0.82-0.07)*

* Significant at the 0.05 level (2-tailed)

** Significant at the 0.01 level (2-tailed)

Table 6 Logistic Regression Analyses

Experiences	Characteristics		Odds ratio (95% CI)
Experienced an incident	**Number of chronic conditions**	1 condition	Reference
		≥ 2 conditions	2.93 (1.154-7.438)*
Number of incidents experienced	**Number of chronic conditions**	1 condition	Reference
		≥ 2 conditions	3.40 (1.218-9.464)*
	Duration homecare	< 1 year	4.17 (1.390-12.476)*
		> 1 year	Reference
Caused by poor communication	**Gender**	Male	Reference
		Female	4.55 (1.063-19.446)*
	Number of chronic conditions	1 condition	Reference
		≥ 2 conditions	5.74 (1.471-22.397)*

* Significant at the 0.05 level (2-tailed)

PART III

A Healthcare Professional Perspective on the Safety of Primary Care

'I suggested that the biggest challenge to moving to a safer healthcare system is changing the patient safety culture from one in which individuals are blamed for errors to one in which errors are treated as opportunities to improve the system and prevent harm.'

- Linda Kohn -

Chapter 6

Systematic Psychometric Review of Self-Reported Instruments to Assess Patient Safety Culture in Primary Care

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SUMMARY

A key condition for improving patient safety is creating a sustainable and supportive patient safety culture in order to identify possible weaknesses and to develop improvement strategies so recurrence of incidents can be minimised. However, most tools to measure and strengthen patient safety culture have been developed and tested in hospitals. Nevertheless, primary care is facing greater risks and a greater likelihood of causing unintentional harm to patients. Consequently, the aim of the present review was to give an overview of empirical studies using self-reported instruments for assessing patient safety culture in primary care.

Notwithstanding the relevant lack of research on patient safety in primary care, many studies have been conducted on patient safety culture in this setting. Resulting from the literature search, 14 published studies were identified, mostly originated from Western high-income countries. As these studies come with great diversity in tools used and outcomes reported, comparability of the results is compromised. Moreover, psychometric properties of many patient safety culture tools are subject to criticism. Based on the psychometric review, the SCOPE-Primary Care instrument was chosen as the most appropriate instrument to measure patient safety culture in primary care as the instrument had excellent internal consistency with Cronbach's alphas ranging from 0.70 to 0.90 and item factor loadings ranging from 0.40 to 0.96, indicating a good structural validity.

The number of valid and reliable surveys related to patient safety culture in primary care is limited. A standard and widely validated survey is needed in order to increase generalisability and comparability. In conclusion, the findings of the present systematic and psychometric review suggest that the SCOPE-Primary Care instrument is the most appropriate tool to assess patient safety culture in primary care. Nevertheless, further psychometric techniques are now essential to ensure that the instrument provides meaningful information regarding patient safety culture.

Patient safety is a key aspect of healthcare quality and has been defined as the '*avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare*' [1]. To date, primary care is facing greater risks and a greater likelihood of causing unintentional harm to patients due to - inter alia - early hospital discharges, time pressure of shorter consultations, the fragmented nature of care services, and the fundamental shift of chronic care from secondary to primary care services [2,3]. Numerous studies have revealed that patient safety incidents in primary care do occur (see Chapter 2): the median incident rate - derived from population-based record review studies - was two to three incidents for every 100 consultations of which 4% of these incidents may be associated with severe harm [4]. These incidents are mainly related to poor communication between healthcare professionals, administrative inefficiencies, medication incidents, and diagnostic failures [4]. However, the amount of incidents in primary care is often difficult to estimate as it depends on incident standardisation and the accuracy of monitoring the quality of care provision [5]. Therefore, aforementioned statistic on patient safety incidents in primary care is probably a gross underestimation.

A key condition for improving patient safety is creating a sustainable and supportive patient safety culture in order to identify possible weaknesses and to develop improvement strategies so recurrence of incidents can be minimised [6]. Patient safety culture is defined as '*the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*' [7]. Measuring perceptions of safety culture is already established in high-risk industries such as aviation, nuclear energy, and oil-drilling industry [8-10]. Patient safety culture assessments typically require healthcare and non-healthcare staff to complete self-reported questionnaires anonymously on a periodic basis. These surveys are useful tools to monitor healthcare professionals' attitude towards patient safety issues, to identify areas requiring urgent attention, and to motivate interventions that reduce the risk of medical incidents.

These measurements provide valuable information on how patient safety is viewed and handled within an organisation. Furthermore, safety culture assessments have been observed to positively affect patient safety since healthcare professionals report five times more incidents due to risk awareness [11].

Primary care is gaining importance due to the increasing prevalence of chronic patients and the associated shift of healthcare delivery [3]. Moreover, the importance of considering safety culture in patient safety improvement strategies is widely accepted within healthcare [12,13]. Despite these awarenesses, most tools to measure and strengthen patient safety culture have been developed and tested in hospitals [14-16]. As a consequence, research gaps remain in the understanding of patient safety culture in primary care.

OBJECTIVES

The aim of the present review was twofold. First, an overview of empirical studies using self-reported instruments for the assessment of patient safety culture in primary care was provided. Second, psychometric properties of these instruments were determined and synthesised in order to identify the most appropriate instrument to measure safety culture in primary care.

METHODS

Design

A systematic and psychometric review was carried out according to the protocol for systematic reviews of measurement properties recommended by the *COnsensus-based Standards for the selection of health Measurement INstruments* (COSMIN) panel [17] and the PRISMA reporting guidelines [18].

Eligibility Criteria

Cross-sectional studies that conducted a patient safety culture assessment in primary care were included. More specifically and in line with previous research and recommendations, studies that used a questionnaire approach were considered eligible [19,20]. Consequently, qualitative approaches, editorials, and opinion papers were excluded. Furthermore, only articles published in English or Dutch were included. Searches were not restricted by country or publication date.

Search Strategy

A comprehensive literature search was conducted, searching the electronic databases Medline, Web of Science, and Embase. The search strategy was divided into two categories: [1] primary care (i.e., general or family practice, ambulatory care, community care, and generalist care) and [2] patient safety culture. The search strategy combined selected MeSH terms and free text terms to identify quantitative studies on patient safety culture assessments in primary care. The search was performed using the following queries: ('primary care safety' OR 'primary care' OR 'primary care setting' OR 'primary healthcare' [MeSH]) AND ('culture of safety' OR 'patient safety culture' OR 'safety climate'*)*. One must note that there is a difference between *safety culture* and *safety climate*. According to Schein, *culture* manifests itself in deeper levels of unconscious assumptions whereas *climate* refers to the visible manifestation or measurable components of culture [21]. In other words, climate provides a snapshot of culture by examining its measurable aspects. In literature however, the terms *climate* and *culture* are often used interchangeably. Therefore, the authors chose to include the term *climate* as well in the search strategy.

During preparation of the manuscript, the search strategy was repeated weekly in order to identify potentially new relevant publications. Additionally, bibliographies of included articles were hand searched for other relevant papers. Finally, the authors reviewed key texts, reports, and policy documents related to patient safety culture in primary care. A bibliographical database was created using the database Papers[3] to store and manage the retrieved references [22].

Study Selection and Data Abstraction

After removal of duplicates, the first selection of articles was made based on title and abstract. Papers selected for full-text review were screened according to the eligibility criteria. Two reviewers (MD and DV) independently investigated the relevance and methodological quality of the extracted papers. In case of inconclusiveness, a third researcher (JB) helped to obtain consensus. Researchers designed, piloted, and used structured forms to extract and record data from the studies (see Appendix I). The items of the forms included study characteristics (i.e., author, year, journal, country, methods, sample size, and respons rate), used definitions plus dimensions of *patient safety culture*, and characteristics plus results of the patient safety culture assessments (i.e., questionnaire, psychometric properties, target population, and overall result). Data on psychometric properties were preferably extracted from a preliminary validation study report. If no validation study was conducted, data on measurement properties were extracted from the study.

Data Analyses

First, all relevant data were tabulated. Due to heterogeneity in study data, a descriptive and narrative synthesis of the data was undertaken by adopting a textual approach to the process of synthesising the research findings from the included studies. The COSMIN quality ratings for each study were tabulated to illustrate the methodological quality of each study on psychometric properties.

Quality Appraisal

The most appropriate instrument to assess patient safety culture in primary care was chosen by using the four-point rating scale COSMIN checklist [17]. The checklist is a standardised tool to evaluate the methodological quality of the instrument's validation process. The measurement properties assessed by the checklist are: internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity, and responsiveness.

Each measurement property is described by 5 to 18 items that identify specific quality standards. Each item was scored on a four-point Likert scale (i.e., 'excellent', 'good', 'fair', or 'poor'). The overall score for each measurement property was obtained by considering the lowest rating assigned to any item in the checklist. For example, if one item in the checklist related to internal consistency is scored poor, the overall methodological quality for internal consistency is rated poor. Two reviewers (MD and DV) independently evaluated the psychometrics properties. Any discrepancy was resolved by discussion and a third reviewer (JB) was consulted if necessary.

RESULTS

Results of the Search

The literature search yielded 360 potentially relevant studies after duplicates being removed. Based on reviewing titles and abstracts, 29 articles were selected for in-depth screening. Twelve relevant papers were retained. By screening reference lists of the included studies, two additional papers were enclosed. Finally, a total of 14 articles was included in the present review. The COSMIN flow diagram - showing selection of articles - is presented in Figure 1 [18]. Three studies were excluded as the patient safety culture assessment was conducted in a hospital setting. This was the most frequent reason for exclusion (see Appendix II).

Study Characteristics

Characteristics of the included studies are presented in Table 1. Resulting from the literature search, 14 published studies on patient safety culture in primary care were identified. Most studies (n=8) originated from Western high-income countries [23-30]. Five studies [31-35] assessed primary care patient safety culture in the Eastern Mediterranean Region of which four [31,33-35] in an Arabic population. With the exception of two studies [23,31], all papers were published between 2012 and 2016. All studies conducted a cross-sectional anonymous survey with a sample size varying between 78 [35] and 4.344 [29] respondents. The respons rate varied between 23.6% [27] and 99.4% [36].

Safety Culture Definitions and Dimensions

An overview of the definitions and dimensions for *patient safety culture* in primary care are presented in Table 2. The most commonly used definition was the one - or a derivative from - the nuclear industry: '*the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*' [37]. However, seven studies used another patient safety culture definition [23,25,27,28,31,32,35]. Frequently enclosed safety culture dimensions were 'leadership' [24,28-30,35], 'staffing' [23,29,30,32,34,35], 'organisational learning' [23,27,29,30,32,34,35], 'communication' [23,24,27-30,32,34,35], and 'teamwork' [23-25,27-30,32-36].

Characteristics and Results of the Safety Culture Assessments

A full overview of the characteristics and results of the patient safety culture assessments is presented in Table 3. A wide range of questionnaires was used. Three studies developed a questionnaire based on the Hospital Survey on Patient Safety Culture [23,32,34] or on the Medical Office Survey [29,30,35]. The Safety Climate Survey and the Safety Attitude Questionnaire (SAQ) - both initially developed for the hospital setting - were also used [31,36]. Five studies used a newly developed survey, respectively the PC-Safequest [24,28], the Frankfurt Patient Safety Climate Questionnaire (FRASIK) [25], the Attitude to Patient Safety Questionnaire-III [33], and the SCOPE-PC instrument [27]. One study combined the SAQ, PC-Safequest, and FRASIK [26]. Regarding psychometric properties, four studies used a survey instrument from the hospital setting without proper re-evaluation of its suitability in primary care [23,31,32,34]. Al-Khaldi used a questionnaire that was validated for use among students and tutors [33]. The remaining nine studies used a patient safety culture survey that was validated for use in primary care settings, either in a separate validation study [24,25,27-29] or in the included safety culture study [26,30,35,36].

All studies conducted the survey to measure patient safety culture among primary healthcare professionals as proposed in the eligibility criteria. Physicians and nurses were frequently invited to participate in the studies [23-26,29-36], followed by technical and administrative staff [23,24,29,31,34,35], healthcare assistants/workers [25,30,32,35], and managers [24,31,32]. To a lesser extent, midwives [23,32,35], pharmacists [24,31], phlebotomists [24], dentists [32], nutritionists [30], and psychologists [30] participated in the studies. One study did not specify which healthcare professionals completed the survey and only made a distinction between clinical and non-clinical staff [28]. Another study administered the survey according to the primary care setting; that is dental care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy, and speech therapy [38].

Results of the patient safety culture assessments ranged from 3.72 [29] to 4.64 [26] on a possible score of 5 and from 36.0% [31] to 69.0% [34]. Three studies reported a mean score on a maximum of 7, respectively 5.48 [24], 4.90 [33], and 5.10 [28]. However, it is impossible to compare these results as different questionnaires were used. Due to the heterogeneity in used surveys and the reporting of outcomes, comparison between studies on perceived patient safety culture in primary care is thus difficult.

Psychometric Review

Evidence on the psychometric properties of eight instruments was obtained, but limited to internal consistency, content validity, and construct validity [24-28,30,35,36]. Five studies [24,25,27-29] used a self-reported questionnaire that was validated in a separate study, respectively the PC-Safequest [39], FRASIK [40], SCOPE-PC [41], and the Medical Office Survey [42]. Internal consistency was assessed in all eight studies, with respectively two studies obtaining an excellent score [26,27] and three studies obtaining a faire [24,28,36] or poor score [25,30,35]. Content validity was assessed in three studies, all obtaining a poor score [24,28,36]. Finally, construct validity was assessed in six studies [24-28,36]. One study obtained an excellent score [27]. Additionally, two studies obtained a good score [25,26] and three studies obtained a fair score [24,28,36]. A full overview is provided in Table 4 and Appendix III.

DISCUSSION

It seems intuitive that the use of patient safety culture assessments may provide insight in healthcare professionals' attitude or that it will help practices in the improvement of the culture of safety. Moreover, measurement of safety culture is believed to facilitate the identification of high-risk situations or increased risks for adverse events. In primary care, healthcare organisations with a positive safety culture are characterised by communication based on mutual trust and openness, shared perceptions of the importance of safety, confidence in the efficacy of preventive safety measures, organisational learning, committed leadership and executive responsibility, and finally a no blame and non-punitive approach to incident reporting and analyses [43]. Notwithstanding the relevant lack of research on patient safety in primary care, many studies have been conducted on patient safety culture in this setting [44]. Therefore, an overview of empirical studies using self-reported instruments for the assessment of patient safety culture in primary care was provided. Additionally, psychometric properties of these instruments were also reported.

Resulting from the present literature review, 14 published studies were identified, mostly originated from Western high-income countries. All surveys addressed certain patient safety dimensions that might be considered core dimensions of safety culture such as communication, teamwork, leadership, and organisational learning [45]. One commonality is that the included studies come with great diversity in tools used and outcomes reported. Some studies adapted and validated existing questionnaires and others developed new surveys. While translating and/or validating a particular survey - that is often originated from secondary care - modifications through the addition or elimination of items were often done. Consequently, alterations in an instrument can have an impact on the ability to benchmark results against those from other healthcare settings, practices, or countries. As a result, psychometric properties of many patient safety culture instruments are subject to criticism [46].

As Martinez *et al*. said: '*implementation science faces the risk of constructing a magnificent house without bothering to build a solid foundation*' [47]. A paradox has emerged whereby researchers often use existing instruments that are not psychometrically sound due to lack of time or expertise. When selecting the most appropriate measurement instrument, comprehensive literature reviews are critically important for gathering research evidence [48]. Therefore, a systematic approach was applied to review the psychometric properties of the included questionnaires. As a result, the SCOPE-PC instrument was chosen as the most appropriate instrument to measure safety culture in primary care as the questionnaire had excellent scores on the COSMIN scales. In particular, the SCOPE-PC questionnaire had excellent internal consistency with Cronbach's alphas ranging from 0.70 to 0.90 [41,49]. Moreover, explanatory factor analysis showed the best fit of the SCOPE-PC instrument with seven dimensions, including item factor loadings ranging from 0.40 to 0.96 [41,50]. The SCOPE-PC tool is also very similar to the MaPSaF tool [43]. The MaPSaF has been endorsed by the UK's NPSA to assess and strengthen safety culture in UK Primary Care Trusts. The tool can be used to facilitate discussion regarding patient safety issues during team-based and self-reflection workshops and received the most favourable ratings in two consensus-based studies [51]. Furthermore, the SCOPE-PC questionnaire can be used both in small (<8 employees) and large (>8 employees) facilities [52]. Finally, the SCOPE-PC instrument pays particular attention to the theme 'handover and teamwork', which is of great importance in the context of more integration and coordination of care [53].

This particular selected tool also has some limitations [41]. First, selection bias could not be excluded in the original validation study as more innovative practices probably were more enthusiastic about the topic and more willing to participate in the study. Second, the response rate in the validation study of the SCOPE-PC instrument (38.4% for individual questionnaires) was not very high. However, with a total of 615 valid questionnaires, the rule of 10 respondents per instrument item was met. A third and general limitation is the remaining concern whether self-reported surveys are appropriate to measure safety culture as they provide only a snapshot at a certain point in time which may be a simplified, superficial, and partial description.

Trbovich and Griffin highlight the need to move beyond surveying and recommend the triangulation of both quantitative and qualitative methods to attain a more in-depth assessment of culture and its underlying aspects [54].

The results of the present review have to be interpreted carefully. Since the main electronic databases were searched, papers published in other databases may have been missed. Second, only articles published in English and Dutch were selected, possibly resulting in overlooking instruments that were developed and evaluated in other languages and cultures. Third, the method of quality appraisal was based on the COSMIN criteria. Researchers assigned a quality score based on their subjective understanding. Therefore, caution is required when interpreting these quality assessments. Finally, data extraction by using the established COSMIN tool was ambitious as important information on measurement properties was mostly not reported.

The major strength of the present systematic review is the provision of the first overview of self-reported questionnaires to assess patient safety culture in primary care. Moreover, the present review also critically appraised all safety culture instruments by using a systematic approach (COSMIN scale).

CONCLUSIONS

Healthcare can cause avoidable harm to patients. Primary care is not an exception and the relative lack of research in this area lends urgency to a better understanding of patient safety and the development of primary care-oriented safety programs. In addition, the number of valid and reliable surveys related to patient safety culture for primary care services is limited. A standard and widely validated survey is needed in order to increase generalisability and comparability. In conclusion, the findings of the present systematic and psychometric review suggest that the SCOPE-PC tool is the most appropriate instrument to assess safety culture in primary care. Nevertheless, further psychometric techniques are now essential to ensure that the instrument provides meaningful information regarding patient safety culture (see Chapter 7).

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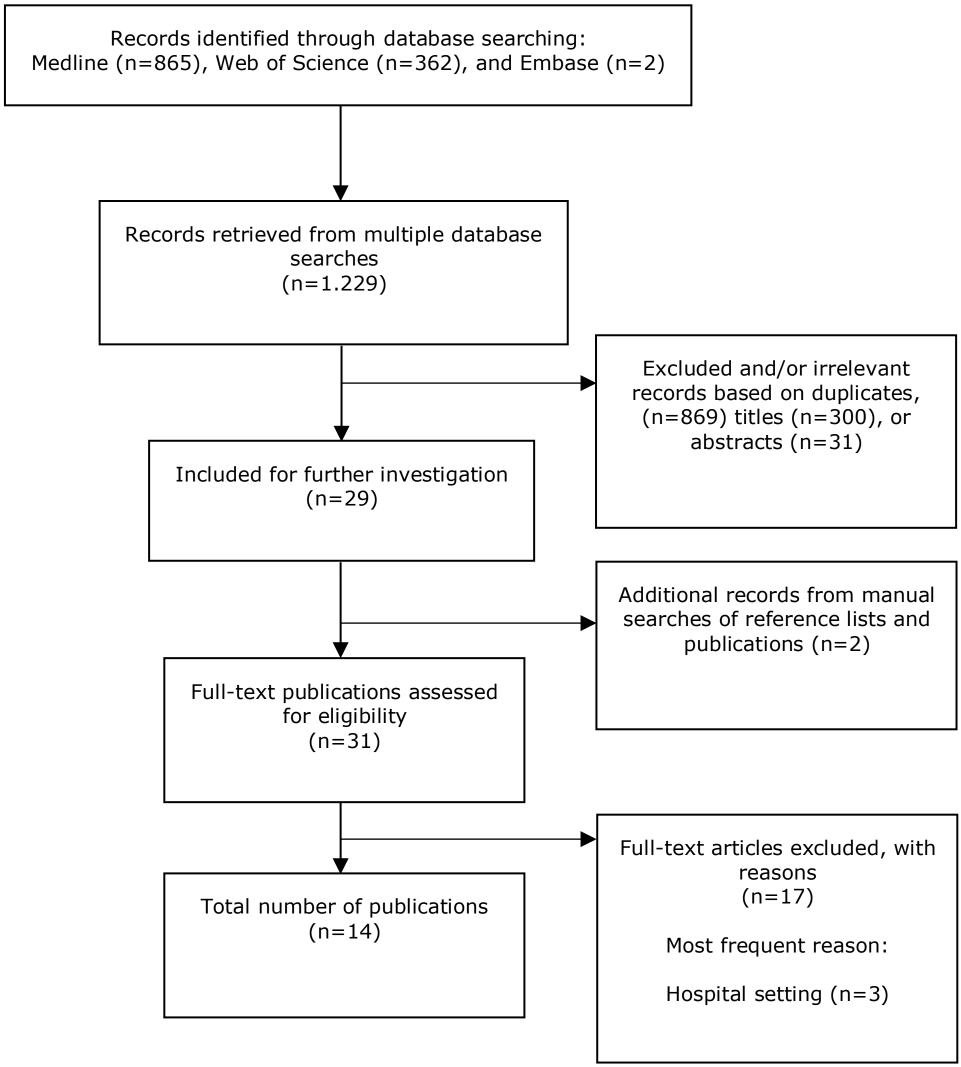

Figure 1 COSMIN Flow Diagram Showing Selection of Articles for Review

Table 1 Characteristics of the Studies Included in the Systematic Review

Authors	Publication date	Country	Methods	Sample size	Respons rate
Nabhan & Ahmed-Tawfik	2007	Egypt	Cross-sectional study design	600	92.0%
Bodur & Filiz	2009	Turkey	Cross-sectional study design	180	85.0%
de Wet *et al*.	2012	Scotland	Cross-sectional study design	563	84.4%
Tabrizchi & Sedaghat	2012	Iran	Cross-sectional study design	100	83.3%
Hoffmann *et al*.	2013	Germany	Cross-sectional study design	2.111	58.5%
Gehring *et al*.	2013	Switzerland	Cross-sectional study design	630	50.0%
Al-Khaldi	2013	Saudi Arabia	Cross-sectional study design	228	65.0%
Verbakel *et al*.	2014	The Netherlands	Cross-sectional study design	625	23.6%
Ghobashi *et al*.	2014	Kuwait	Cross-sectional study design	276	74.8%
Webair *et al*.	2015	Yemen	Cross-sectional study design	78	71.0%

Authors	Publication date	Country	Methods	Sample size	Respons rate
Bell et al.	2015	United Kingdom	Cross-sectional study design	335	29.0%
Astier-Peña *et al*.	2015	Spain	Cross-sectional study design	4.344	56.2%
Gabrani *et al*.	2016	Albania	Cross-sectional study design	523	99.4%
Ornelas *et al*.	2016	Madeira Island	Cross-sectional study design	483	52.0%

Table 2 Used Definitions and Dimensions of the Term *Patient Safety Culture* Included in the Systematic Review

Authors	Definition	Dimension
Nabhan & Ahmed-Tawfik		
Bodur & Filiz	*'The common values, beliefs, behaviours, perceptions, and attitudes of the staff in a healthcare center'*	Manager expectations and actions promoting safety Organizational learning Teamwork within units Communication openness Feedback and communications about errors Non-punitive response to errors Staffing Management support for patient safety Teamwork across units Handoffs and transitions Overall perceptions of safety Frequency of event reporting

Authors	Definition	Dimension
de Wet *et al*.	*'The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine a team or organization's commitment to safety management'*	Leadership Teamwork Communication Workload and safety systems
Tabrizchi & Sedaghat	'*Organizational safety culture means that everyone knows the safety as his most important concern in the organization. Patient safety culture means as acceptance and actions of patient safety as the first priority in the organization'*	Teamwork across units of health centres Head of center support for patient safety Staffing Non-punitive response to error Feedback and communication about error Communication openness Teamwork within units Organisational learning Head of center expectations and actions Frequency of events reported Overall perception of safety

Authors	Definition	Dimension
Hoffmann *et al*.	'*Shared employee perceptions of the priority of safety … at their organization*'	Teamwork climate and job satisfaction Perception of causes of error Safety of clinical processes Safety of practice structure Receptiveness to healthcare assistants and patients Staff perception of management and error management Quality and safety of medical care
Gehring *et al*.	'*The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management*'	Office climate Team-based error prevention Assignment of responsibilities Rules and risks

Authors	Definition	Dimension
Al-Khaldi		Patient safety training received Errors reporting confidence Working hours as error cause and error inevitability Professional incompetence as error cause Disclosure responsibility and team functioning Patient involvement in reducing errors Importance of patient safety in curriculum
Verbakel *et al*.	*'The shared values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice'*	Open communication and learning from error Handover and teamwork Adequate procedures and working conditions Patient safety management Support and fellowship Intention to report events Organisational learning

Authors	Definition	Dimension
Ghobashi *et al*.	'*The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management*'	Non-punitive response to error and staffing Communication openness Supervisor expectations and actions promoting safety Feedback and communication about error Organisational learning continuous improvement Teamwork within center units Center handoffs and transitions Teamwork across all PHC center units Center management support for patient safety Frequency of event reporting among all staff Overall perceptions of safety

Authors	Definition	Dimension
Webair *et al*.	*'A true safety culture is one in which every person in the organization recognizes their responsibilities in regard to patient safety and works to improve the care they deliver'*	Teamwork and staff training Work pressure and pace Office processes and standardization Communication openness and about error Patient care tracking/follow up Leadership support and organisational learning Overall perceptions of patient safety and quality
Bell *et al*.	*'Safety culture, in turn, determines how safety is managed by a team or organization. The attitudes, values, perceptions, and behaviours, which help to shape the team or organization's commitment to safety, collectively form the team's safety culture'*	Workload Communication Leadership Teamwork Safety systems

Authors	Definition	Dimension
Astier-Peña *et al*.	'*The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management*'	Patient safety and quality issues Information exchange with other setting Teamwork Work pressure and pace Staff training Office processes and standardization Communication openness Patient care tracking/follow up Communication about error Leadership support for patient safety Organisational learning Overall perceptions of patient safety and quality Overall score on patient safety

Authors	Definition	Dimension
Gabrani *et al*.		Stress recognition Working conditions Safety climate Perceptions of management Job satisfaction Teamwork climate
Ornelas *et al*.	'*The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*'	Teamwork Organizational learning Overall perceptions of patient safety and quality Patient care tracking/follow-up Staff training and work pressure + pace Office processed and standardization Communication openness and about error Owner/leadership support for patient safety List of patient safety and quality issues

Table 3 Characteristics and Results of the Safety Culture Assessments Included in the Systematic Review

Authors	Questionnaire	Psychometric properties	Target population	Result
Hoffmann *et al*.	Frankfurt Patient Safety Climate Questionnaire	Reliability Construct validity Discriminant validity	Healthcare assistants and physicians	Mean score=4.22/5
Nabhan & Ahmed-Tawfik	Safety Climate Survey	Validated in hospitals	Managers, physicians, nurses, pharmacists, and technicians	Mean score=3.89/5 Mean positive dimensional score=36.0%
Bodur & Filiz	AHRQ Hospital Survey on Patient Safety Culture	Validated in hospitals	General practitioners, nurses, midwives, and health officers	Mean positive dimensional score=46.0%
de Wet *et al*.	PC-Safequest	Content validity Reliability Construct validity	General practitioners, practice managers, reception/administrators, nurses, health visitors, pharmacists, and phlebotomists	Mean score=5.48/7

Authors	Questionnaire	Psychometric properties	Target population	Result
Tabrizchi & Sedaghat	AHRQ Hospital Survey on Patient Safety Culture	Validated in hospitals	Head of centres, dentists, health workers, midwives and physicians	Mean positive dimensional score=57.0%
Gehring *et al*.	Safety Attitude Questionnaire Ambulatory Version, PC-QUEST, and Frankfurt Patient Safety Climate Questionnaire	Reliability Construct validity	Physicians and nurses	Mean score=4.64/5
Al-Khaldi	Attitude to Patients Safety Questionnaire-III	Validated for use among students and tutors	Physicians	Mean score=4.90/7

Authors	Questionnaire	Psychometric properties	Target population	Result
Verbakel *et al*.	SCOPE-PC	Reliability Construct validity	Dental care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy, speech therapy, and supporting staff	Mean score=4.03/5
Ghobashi *et al*.	AHRQ Hospital Survey on Patient Safety Culture	Validated in hospitals	Physicians, nurses, technical, and administrative staff	Mean positive dimensional score=69.0%
Webair *et al*.	AHRQ Medical Office Survey on Patient Safety Culture	Reliability	Physicians, nurses, medical assistants, midwives, and non-clinical staff	Mean positive dimensional score=67.0%

Authors	Questionnaire	Psychometric properties	Target population	Result
Bell *et al*.	PC-Safequest	Content validity Reliability Construct validity	Clinical and non-clinical staff	Mean score=5.1/7
Astier-Peña *et al*.	AHRQ Medical Office Survey on Patient Safety Culture	Validation study available in Spanish	Physicians, nurses, and non-healthcare professionals	Mean score=3.72/5
Gabrani *et al*.	Safety Attitude Questionnaire Long Ambulatory Version	Content validity Reliability Construct validity	Physicians and nurses	Mean positive dimensional score=60.0%
Ornelas *et al*.	AHRQ Medical Office Survey on Patient Safety Culture	Reliability	Medical specialists, physicians, nurses, operating and technical assistants, …	Mean positive dimensional score=52.0%

Table 4 Quality Appraisal of the Included Studies in the Systematic Review by Using the COSMIN Checklist

Authors	Psychometric properties	Quality score	Questions for each property													
			1	2	3	4	5	6	7	8	9	10	11	12	13	14
Nabhan & Ahmed-Tawfik																
Bodur & Filiz																
de Wet *et al.*	Internal consistency	Fair		Excellent	Fair	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Excellent			
	Content validity	Poor	Excellent	Poor	Fair	Poor	Excellent									
	Construct validity	Fair		Excellent	Fair	Excellent	Excellent	Excellent								

Authors	Psychometric properties	Quality score	Questions for each property													
			1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Tabrizchi & Sedaghat																
Hoffmann *et al*.	Internal consistency	Poor			Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Poor		
Gehring *et al*.	Internal consistency	Excellent			Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Excellent		
	Construct validity	Good			Excellent	Excellent	Excellent	Excellent	Good							

Authors	Psychometric properties	Quality score	Questions for each property													
			1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Al-Khaldi																
Verbakel *et al*.	Internal consistency	Excellent			Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Excellent		
Verbakel *et al*.	Internal consistency	Excellent			Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Excellent		
	Construct validity	Excellent			Excellent	Excellent	Excellent	Excellent	Excellent							
Ghobashi *et al*.																

Authors	Psychometric properties	Quality score	Questions for each property													
			1	2	3	4	5	6	7	8	9	10	11	12	13	14
Bell et al.	Internal consistency	Fair				Excellent	Fair	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		
	Content validity	Poor				Excellent	Poor	Fair	Poor	Excellent						
	Construct validity	Fair				Excellent	Fair	Excellent	Excellent	Excellent						

Authors	Psychometric properties	Quality score	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Astier-Peña et al.	Construct validity	Fair			Excellent	Fair	Excellent	Excellent	Excellent							
Gabrani et al.	Internal consistency	Fair			Good	Fair	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent		Excellent		
	Content validity	Poor			Fair	Poor	Fair	Poor	Excellent							
	Construct validity	Fair			Good	Fair	Excellent	Excellent	Excellent							
Ornelas *et al.*	Internal consistency	Poor			Excellent	Fair	Excellent	Poor	Excellent	Excellent	Excellent	Excellent		Poor		

APPENDIX I – EXAMPLE OF DATA ABSTRACTION FORM

Item	Reported data
Author(s)	Verbakel *et al*.
Year	2014
Journal	International Journal for Quality in Health Care
Country	The Netherlands
Questionnaire	SCOPE-PC
Target population	Dental care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy, speech therapy, and supporting staff
Methods	Cross-sectional study design
Sample size	625
Response rate	23.6%
Safety culture definition	'*The shared values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice*'
Psychometric properties	Validation study provided[1] Reliability: Cronbach's alpha from 0.70 to 0.90 Construct validity: • EFA: Factor loadings from 0.40 to 0.96 • Pearson correlations from 0.34 to 0.55
Safety culture dimensions (result)	Open communication and learning from error (4.25) Handover and teamwork (3.99) Adequate procedures and working conditions (4.14) Patient safety management (3.79) Support and fellowship (4.26) Intention to report events (3.73) Organisational learning (3.98)
Overall result	Mean score on a maximum of 5=4.03

[1] Verbakel NJ., Zwart DLM., Langelaan M., *et al*. Measuring safety culture in Dutch primary care: psychometric characteristics of the SCOPE-PC questionnaire. *BMC Health Serv Res* 2013; 13:354.

APPENDIX II – LIST OF EXCLUDED STUDIES

Article	Reason for exclusion
Gonzáles-Formoso et al. (2011). Adverse events analysis as an educational tool to improve patient safety culture in primary care: a randomized trial.	Study protocol.
Mira *et al*. (2015). Interventions in health organisations to reduce the impact of adverse events in second and third victims.	Impact of interventions on second and third victims rather than a safety culture measurement.
Bondevik *et al*. (2014). Patient safety culture in Norwegian primary care: a study in out-of-hours casualty clinics and GP practices.	Study aimed to assess the variations in safety attitudes, related to profession, age, gender, and clinical setting.
Hovik *et al*. (2009). What is most important for safety climate: the company belonging or the local working environment? A study from the Norwegian offshore industry.	The aim of the study was to examine health and safety climate in the petroleum industry.
Gallego *et al*. (2012). Investigating patient safety culture across a health system: multilevel modelling of differences associated with service types and staff demographics.	The aim of the study was to investigate whether safety culture varies according to the type of service in a large healthcare system.
McGuire *et al*. (2012). Patient safety perceptions of primary care providers after implementation of an electronic medical record system.	The study focused on changes in perceptions of patient safety.
Frankel *et al*. (2008). Revealing and resolving patient safety defects: the impact of leadership walkrounds on frontline caregiver assessments of patient safety.	Hospital setting.
Verbakel *et al*. (2015). Effects of patient safety culture interventions on incident reporting in general practice.	The aim of the study was to assess the effects of patient safety culture assessments on risk awareness.
Alameddine *et al*. (2015). Assessing health-care providers' readiness for reporting quality and patient safety indicators at primary health-care centres in Lebanon: a national cross-sectional survey.	No safety culture assessment included.
Pohl *et al*. (2013). Use of a comprehensive patient safety tool in primary care practices.	The tool used in the study was to measure the extent to which patient safety practices were rigorously and systematically implemented.
Ulrich & Kear (2014). Patient safety culture in nephrology nurse practice settings: initial findings.	Hospital setting.
Randmaa *et al*. (2014). SBAR improves communication and safety climate and decreases incident reports due to communication errors in an anaesthetic clinic: a prospective intervention study.	Hospital setting.
Gaal *et al*. (2010). Patient safety in primary care: a survey of general practitioners in the Netherlands.	The purpose of the study was to gain better insight into what GP's consider unsafe practices and what they judge to be risk factors for patient safety in primary care.
Modak *et al*. (2007). Measuring safety culture in the ambulatory setting: The Safety Attitudes Questionnaire-ambulatory version.	The purpose of the study was to determine reliability of the SAQ-AV.

APPENDIX III – SUMMARY OF THE QUALITY APPRAISAL OF THE INCLUDED STUDIES

	BOX A	BOX B	BOX C	BOX D	BOX E	BOX F	BOX G	BOX H	BOX I
	Internal consistency	Reliability	Measurement error	Content validity	Structural validity	Hypothesis testing	Cross-cultural validity	Criterion validity	Responsiveness
Nabhan & Ahmed-Tawfik									
Bodur & Filiz									
de Wet *et al*.	Fair			Poor	Fair				
Tabrizchi & Sedaghat									
Hoffmann *et al*.	Poor				Good				
Gehring *et al*.	Excellent				Good				
Al-Khaldi									
Verbakel *et al*.	Excellent				Excellent				
Ghobashi *et al*.									
Webair *et al*.	Poor								
Bell *et al*.	Fair			Poor	Fair				
Astier-Peña *et al*.									
Gabrani *et al*.	Fair			Poor	Fair				
Ornelas *et al*.	Poor								

Chapter 7

The SCOPE-PC Instrument for Assessing Patient Safety Culture in Primary Care: A Psychometric Evaluation

Presented in part at the 13th *Knowledge for Growth Conference*, Ghent (Belgium), May 2017.

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SUMMARY

Primary care differs from hospitals in terms of - inter alia - organisational structure. Therefore, patient safety culture could differ between these settings. Various instruments have been developed to measure collective attitudes of personnel within a primary care organisation. However, the number of valid and reliable instruments is limited. Consequently, psychometric properties of the SCOPE-Primary Care instrument were tested to examine the instrument's applicability in home care services.

A cross-sectional study was conducted by administering the SCOPE-Primary Care questionnaire in a single home care service organisation with more than 1.000 employees, including nurses, midwives, healthcare assistants, diabetes educators, and nursing supervisors. First, a confirmatory factor analysis was performed to test whether the observed dataset fitted to the proposed seven-factor model of the SCOPE-Primary Care instrument. Second, Cronbach's alphas were calculated to examine internal consistency. Finally, inter-correlations between the seven dimensions as well as with the patient safety grade were examined. In total, 603 questionnaires were retained for further analysis, representing an overall response rate of 43.9%. Most respondents were nursing staff, followed by healthcare assistants and nursing supervisors. The results of the confirmatory factor analysis satisfied the chosen cut-offs, indicating an acceptable to good model fit. With the exception of the dimension 'organisational learning' (α=0.58), Cronbach's alpha scores of the SCOPE-scales indicated a good level of internal consistency: 'open communication and learning from error' (α=0.86), 'handover and teamwork' (α=0.78), 'adequate procedures and working conditions' (α=0.73), 'patient safety management' (α=0.81), 'support and fellowship' (α=0.75), and 'intention to report events' (α=0.85). Moreover, inter-correlations between the seven dimensions as well as with the patient safety grade were moderate to good.

In conclusion, the present study indicated that the SCOPE-Primary Care instrument has good psychometric properties for home care services in Belgium. No modifications are required to the original survey to allow benchmarking between primary care settings.

Since the publication of the report *To Err is Human: Building a Safer Health System* by the IOM in 2000, patient safety became a global health topic [1]. The IOM report triggered researchers to develop new systematic approaches to improve patient safety in healthcare settings. Patient safety culture has gained much interest and is one of the main focuses in patient safety research [1]. It refers to '*the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*' [2]. The concept of *safety culture* originated outside healthcare, in studies of high reliability organisations (i.e., organisations that consistently minimise adverse events despite carrying out intrinsically complex and hazardous work). These organisations maintain a commitment to safety at all levels; that is from frontline providers to managers and executives. This commitment establishes a culture of safety, which is associated with higher employee safety compliance and better organisational performance [3]. A positive patient safety culture is important in the context of safe care as it entails an atmosphere of open communication, learning from incidents, and mutual trust.

Due to an aging population and medical progresses, a considerable part of healthcare delivery continues to shift from secondary to primary care [4]. At the same time, the demand for home and community services is increasing substantially in order to reduce the number of hospital beds, facilitate earlier hospital discharge, improve quality of care, and decrease healthcare-associated costs [5,6]. Moreover, primary healthcare professionals are encouraged to work together in broad healthcare centres, to collaborate in disease management programs, and to consult each other in managing patient care. This reflects the move to a more integrated primary care through collaborative partnerships across multidisciplinary teams [7]. Despite these awarenesses, most tools to measure and strengthen patient safety culture have been developed and tested in the hospitals setting [8-10]. Moreover, the number of valid and reliable instruments for primary care is limited. Nevertheless, a generic patient safety culture instrument is needed to enable comparison between different primary care settings and to facilitate exchange of learning and improvement strategies.

Based on a review of the literature (see Chapter 6), the SCOPE-PC instrument was chosen as the most appropriate questionnaire to measure safety culture in primary care as the instrument has good psychometric properties and has been validated in the Netherlands for several primary care facilities [26]. However, the instrument was not validated for home care services. Moreover, cultural differences between healthcare environments within or between countries may weaken the validity of the instrument. Therefore, it is important to carefully test the SCOPE-PC instrument before using the questionnaire and interpreting its results in a Belgian primary care setting.

OBJECTIVES

Taking into consideration the cultural differences in measuring patient safety culture in primary care and to allow national and international comparison of research findings, psychometric properties of the SCOPE-PC instrument were tested to examine the instrument's applicability in home care services in Belgium (Flanders).

METHODS

SCOPE-Primary Care Instrument

The original SCOPE instrument is a modification of the Dutch *Hospital Survey on Patient Safety Culture* and was developed in 2011 for general practices only [27]. In 2013, the SCOPE instrument was also validated for dietetics, occupational therapy, physiotherapy, midwifery, skin therapy, speech therapy, dental care, exercise therapy, and anticoagulation clinics [26]. Verbakel *et al*. adjusted the original SCOPE questionnaire through an iterative process. First, a research team revised the terminology of the questionnaire. Second, professionals from all primary care professions assessed the instrument individually on clarity and applicability to their own setting. Adjustments were limited to a few changes of terminology.

The final SCOPE-PC instrument - an acronym in Dutch for *Systematic Culture Inquiry on Patient Safety in Primary Care* - consists of 41 items, clustered in seven patient safety culture dimensions: [1] 'open communication and learning from error' (8 items), [2] 'handover and teamwork' (7 items), [3] 'adequate procedures and working conditions' (9 items), [4] 'patient safety management' (5 items), [5] 'support and fellowship' (5 items), [6] 'intention to report events' (3 items), and [7] 'organisational learning' (3 items). With Cronbach's alphas ranging from 0.70 to 0.90, internal consistency of the SCOPE-PC instrument is excellent. Moreover, the questionnaire has good construct validity [26]. In the SCOPE-PC questionnaire, respondents address over 40 safety culture items by means of a five-point Likert scale, ranging from 1 ('strongly disagree' or 'never') to 5 ('strongly agree' or 'always'). In addition, two questions regarding the frequency of incident reporting within the last 12 months and a patient safety grade ranging from 1 ('failing') to 5 ('excellent') are included. Finally, some background questions address demographic and work-related information of the respondents such as profession and working experience.

Data Collection

A cross-sectional study was conducted. This study used a convenience sample and administered the SCOPE-PC questionnaire in a single home care organisation in Belgium's Flemish region (White-Yellow Cross West-Flanders) with more than 1.000 employees, including nurses, midwives, healthcare assistants, diabetes educators, and nursing supervisors. Data collection occurred between September and November 2016 through the online platform Qualtrics. The electronic survey targeted all healthcare professionals, supervisors, managers, and administrators who had direct or indirect interaction with patients. All healthcare and non-healthcare professionals received an invitation by e-mail. Two reminders were sent with an interval of two weeks. In addition, several steps were taken to mitigate the risk of common method bias, both ex-ante remedies as well as statistical controls after the questionnaires were returned (e.g., during design and administration stage of the survey, respondents were assured of confidentiality of the study and that there were no right or wrong answers) [28].

Participants were informed about the purpose of the study and their participation was anonymous, voluntarily, and confidential. The home care organisation received a feedback report regarding staff perceptions of patient safety issues, medical incidents, and event reporting.

Statistical Analyses

All analyses were performed using R: A Language and Environment for Statistical Computing version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria) [29]. Regarding the rule of thumb of 10 respondents per instrument item, at least 410 completed questionnaires were needed [30]. Respondents with more than 50% missing values were excluded from analyses. Item analyses was performed in order to identify problematic items with high missingness (i.e., 35% or more) or with a highly skewed distribution (i.e., 85% or more of the respondents answered on the same side of the response scale). Negatively worded items were reverse-coded so that a higher score would indicate a more positive attitude. Finally, listwise deletion of incomplete data was used.

As this study used an existing questionnaire, a CFA was performed to test whether the observed dataset fitted to the proposed seven-factor model of the SCOPE-PC instrument [30]. Bartlett's Test of Sphericity ($P<0.05$) and the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (>0.60) were performed to establish the adequacy of the sample for factor analysis [31]. Afterwards, a set of goodness-of-fit indices was used: the X^2 with an associated *df* and probability, CFI, TLI, RMSEA, and SRMR. A non-significant X^2 means that the discrepancies between the hypothesised model and the empirical data are negligibly small and thus indicate a good fit. The other parameters measure how well the empirical model approaches the theoretical model. A CFI and TLI value between 0.90 and 0.95, a RMSEA value of $\leq$0.06, and a SRMR value of $\leq$0.08 is considered a close fit of the model [32]. Furthermore, internal consistency of the factors was measured using Cronbach's alphas (α) which is - like other reliability coefficients - interpreted as a normal range of values between 0.00 and 1.00, with higher values reflecting higher internal consistency [30]. A positive rating for internal consistency is met when Cronbach's alphas are equal or greater than 0.60, indicating that the different items measure the same concept [33].

Cronbach's alphas were calculated for each scale of the SCOPE-PC instrument. Moreover, inter-correlations between dimensions were examined to assess construct validity. Additionally, correlations between the seven safety culture dimensions and the patient safety grade were computed. Inter-correlations between dimensions were calculated with the Pearson Correlation coefficient. Correlations between 0.30 and 0.70 are often recommended [30].

Finally, results of the patient safety culture assessment were also reported. First, positive dimensional scores (percentage of positive responses) were calculated. Answers above 3 ('agree/strongly agree' or 'most of the time/always') were considered as positive towards patient safety. Strengths were defined when ≥75% of respondents answered positive. Areas with potential for improvement were identified as items with <50% of respondents answered positively [34].

Ethical Consideration

Participants were informed that the collected information would be kept confidential and that the questionnaire was anonymous. There were no incentives provided for completing the questionnaire. The institutional ethics committee of Hasselt University approved the study (ref. CME2016/641).

RESULTS

In total, 665 individual questionnaires were returned from 1.375 employees. Sixty-two surveys were omitted from the study because participants did not fill out at least 50% of the items. Finally, 603 questionnaires were retained for further analyses, representing an overall response rate of 43.9%. Consequently, the rule of thumb of 10 respondents per instrument item was met. The response rate was markedly lower for non-healthcare assistants (20.7%) than for healthcare assistants (38.7%), nurses (42.4%), managers (53.3%), and nursing supervisors (54.8%). Overall, missingness was low with the highest proportion of 20.9% for item B4 ('*My supervisor/manager overlooks patient safety problems that happen over and over*'). In addition, there were no items with extreme skewness. Furthermore, Bartlett's Test was significant ($P<0.001$) and the Kaiser-Meyer-Olkin Measure was 0.90, indicating that the dataset was appropriate for factor analysis.

Respondents' Characteristics

Characteristics of respondents are listed in Table 1. Most of the respondents were female (n=555, 92.0%). The median age was 41 years, with a range from 20 to 64 years. Most respondents were nursing staff (n=481, 79.8%), followed by nursing assistants (n=43, 7.1%) and nursing supervisors (n=23, 3.8%). Almost 50% of the sample had worked between 1 and 10 years in the home care organisation (n=281, 46.5%). Most of the respondents had direct interaction or contact with patients (n=555, 92.0%).

Psychometric Properties

Results of the CFA satisfied the chosen cut-offs, indicating an acceptable to good model fit (see Table 2): CFI=0.930, TLI=0.916, RMSEA=0.058, and SRMR=0.063. However, the Chi-square Statistic was significant (X^2=7441.996, *df*=780, and *P*<0.001). Nevertheless, it tends to result in a rejection of the model in large samples (over 200 cases) and is therefore sensitive to sample size [35]. Furthermore, all items showed factor loadings higher than the chosen 0.50 cut-off value, indicating an acceptable allocation of the 41 items in the proposed seven factors.

With the exception of the dimension 'organisational learning' (α=0.58), Cronbach's alpha scores of the SCOPE-scales indicated a good level of internal consistency (see Table 2). The Cronbach's alpha was 0.86 for 'open communication and learning from error', 0.78 for 'handover and teamwork', 0.73 for 'adequate procedures and working conditions', 0.81 for 'patient safety management', 0.75 for 'support and fellowship', and 0.85 for 'intention to report events'. Table 3 shows the correlations between the seven safety culture dimensions as well as with the patient safety grade. Overall, inter-correlations were moderate to good. The highest correlations were found between 'patient safety management' and 'open communication and learning from error' (*r*=0.65), 'patient safety management' and 'adequate procedures and working conditions' (*r*=0.50) and finally 'patient safety management' and 'support and fellowship' (*r*=0.51). However, none of the correlations were extremely high (>0.70), indicating that none of the seven safety culture dimensions needed to be combined.

Remarkable, the dimension 'intention to report events' did not correlate with other dimensions (*r*=0.10 - 0.27). Additionally, correlations with the patient safety grade were also moderate to good, with positive correlations ranging from 0.35 to 0.51, except for the dimension 'intention to report events' (*r*=0.20).

Positive Dimensional Scores

Table 4 presents item scores and overall positive dimensional scores. The highest percentages of positive responses were found for 'organisational learning' (71.7%), 'support and fellowship' (63.5%), 'patient safety management' (60.3%), and 'open communication and learning from error' (57.6%). Three dimensions scored below 50%: 'intention to report events' (48.5%), 'adequate procedures and working conditions' (43.4%), and 'handover and teamwork' (43.0%). Additionally, 60.7% (n=366) of the employees graded patient safety in their organisation as *good* and 30.3% (n=183) *never* reported an incident within the last 12 months (see Table 5).

DISCUSSION

Organisations with a positive patient safety culture are more likely to learn openly and effectively from failure. Safety culture measurements mainly rely on a quantitative method, using individual and self-administered questionnaires. Survey scores are aggregated to provide a measure of those dimensions known to be important markers of patient safety culture. However, an instrument can only be applied to measure patient safety when the different dimensions are correctly assessed. The data presented in this study are part of a larger study regarding patient safety culture assessments in primary care in the Dutch speaking part of Belgium (see Chapter 8). In this study, a database containing over 600 responses was used to assess psychometric properties of the SCOPE-PC instrument in a single home care organisation in Belgium (Flanders).

Overall, psychometric properties of the SCOPE-PC instrument proved satisfactory and the results of the validation work support the seven-factor and 41-item model. The fit indices of the model were acceptable and the items showed moderate to high factor loadings. Moreover, Cronbach's alpha scores indicated good internal consistency for all dimensions and inter-correlations between the seven dimensions as well as with the patient safety grade were also moderate to good. Consequently, no changes were made to the safety culture instrument. The findings were comparable to the original SCOPE-PC validation study in the Netherlands [26]. However, caution must be taken when comparing validation results across studies since a different use of samples and data collection methods are reported. Furthermore, in order to identify areas of weaknesses and strengths in patient safety, positive dimensional scores were calculated. This study indicated some areas for improvement in patient safety, especially regarding 'handover and teamwork', 'intention to report events', and 'adequate procedures and working conditions'. Improvements may be realised through open communication, non-punitive policies with respect to incident reporting, and staffing improvements.

With regard to limitations, a first limitation concerns the relatively low internal consistency of the dimension 'organisational learning' (α=0.58). However, as the alpha value is influenced by the number of items in a scale, the low value of the Cronbach's alpha could be a consequence of the inclusion of only three items [36]. Therefore, it is advised that the items within this dimension should not be deleted since they signify important aspects of patient safety. Second, the absence of correlations between the dimension 'intention to report events' and other dimensions is remarkable. Verbakel *et al*. proposed two main explanations, namely the facts that incident reporting is still uncommon in primary care and that the questions regarding incident reporting relate to actual steps to be undertaken rather than how the respondents feel or think of the culture in their organisation [26]. Third, the present study focused on a quantitative approach to assess patient safety culture. A questionnaire approach is desirable considering the high-volume patient throughput and limited opportunities for collective learning. It is an economical method - both in time and money - when conducting large-scale studies, but questionnaires only provide a snapshot at a single point of time.

A qualitative approach is recommended and one such method has been developed for primary care in the UK [11]. It is advised to use both quantitative and qualitative approaches to obtain more breadth and depth of understanding patient safety culture in primary care. Fourth, Blegen *et al*. questioned the meaning of identifying high and low scoring dimensions as the latter might be a reflection of the negatively worded items rather than a weakness of safety culture [37]. Fifth, wide variations in the perceptions of safety culture can exist within a single organisation [10]. Future research must therefore use multilevel analyses to measure variations in safety culture perceptions within primary care settings, relating to individual and practice characteristics (see Chapter 8). Finally, the SCOPE-PC instrument was tested in a specific primary healthcare organisation. Hence, caution is required when generalising safety culture perceptions between and within different types of healthcare settings given their context-specific nature. Therefore, it is recommended that patient safety culture instruments are validated before their use in a specific healthcare context.

Nevertheless, the current study presents the results of the first patient safety culture assessment in a community-based primary care setting in Belgium (Flanders). Moreover, the SCOPE-PC instrument was carefully chosen, based on a systematic and psychometric review (see Chapter 6).

CONCLUSIONS

Validation of the SCOPE-PC instrument was performed using the same strategy as the original questionnaire. In conclusion, the present study indicated that the SCOPE-PC questionnaire has good psychometric properties to assess patient safety culture in home care services. Although the dimension 'organisational learning' was measured with a too low level of internal consistency, it is suggested that no modifications are required to the SCOPE-PC instrument in order to allow benchmarking between different primary care settings. Still, caution must be taken when generalising safety culture perceptions between different types of healthcare settings given their context-specific nature. It is therefore recommended that safety culture instruments are validated before their use. The next step is to explore the current safety culture in primary care and to identify possible differences between professions.

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Table 1 Respondents' Characteristics (n=603)

Characteristics	N (%) Median (range)
Age (yrs), median (range)	41 (20-64)
Gender, n (%)	
Male	21 (3.5%)
Female	555 (92.0%)
Missing	*27 (4.5%)*
Profession, n (%)	
Nurse	481 (79.8%)
Nursing assistant	43 (7.1%)
Nursing supervisor	23 (3.8%)
Non-healthcare assistant	17 (2.8%)
Manager	8 (1.3%)
Midwife	1 (0.2%)
Diabetes educator	1 (0.2%)
Missing	*29 (4.8%)*
Professional experience in organisation, n (%)	
Less than 1 year	39 (6.5%)
1 to 5 years	159 (26.3%)
6 to 10 years	122 (20.2%)
11 to 15 years	46 (7.6%)
16 to 20 years	48 (8.0%)
21 years or more	154 (25.6%)
Missing	*35 (5.8%)*

Characteristics	N (%) Median (range)
Overall professional experience, n (%)	
Less than 1 year	75 (12.4%)
1 to 5 years	94 (15.6%)
6 to 10 years	82 (13.6%)
11 to 15 years	43 (7.1%)
16 to 20 years	67 (11.1%)
21 years or more	209 (34.7%)
Missing	*33 (5.5%)*
Working time (hours), n (%)	
Less than 20 hours	167 (27.7%)
21 to 30 hours	154 (25.5%)
31 to 40 hours	224 (37.1%)
Missing	*58 (9.7%)*
Working shift, n (%)	
Mornings	301 (49.9%)
Days	240 (39.8%)
Evenings	29 (4.8%)
Nights	6 (1.0%)
Missing	*27 (4.5%)*
Interaction with patients, n (%)	
Yes	555 (92.0%)
No	21 (3.5%)
Missing	*27 (4.5%)*

Table 2 Factor Loadings and Reliability Coefficients of the SCOPE-PC Instrument in a Belgian Population

Item	Description	F1	F2	F3	F4	F5	F6	F7	α
Open communication and learning from error									**0.86**
C1	We are given feedback about changes put into place based on event reports	0.67							
C2	Staff will freely speak up if they see something that may negatively affect patient care	0.73							
C3	We are informed about errors that happen in this practice	0.72							
C4	Staff feel free to question the decisions or actions of those with more authority	0.69							
C5	In this practice, we discuss ways to prevent errors from happening again	0.80							
C6	Professionals discuss errors that occurred with each other	0.59							
C8	We are given personal feedback about our own event reports	0.61							
B4n	My supervisor/manager overlooks patient safety problems that happen over and over	0.58							

Item	Description	F1	F2	F3	F4	F5	F6	F7	α
Handover and teamwork									**0.78**
F1n	Problems often occur in the exchange of information across disciplines in our practice		0.53						
F2n	The fact that patients are treated by different professionals in our practice is causing problems		0.64						
F3n	Disciplines in the practice that we co work with do not coordinate well with each other		0.63						
F4	There is a good exchange of information between professionals in this practice		0.56						
F5	There is a good exchange of information between supporting staff in this practice		0.55						
F6n	Things fall between the cracks when transferring patients between different disciplines in this practice		0.64						
F7n	Important patient care information is often lost because patients see different professionals		0.62						

Item	Description	F1	F2	F3	F4	F5	F6	F7	α
Adequate procedures and working conditions									**0.73**
A5n	It is just by chance that more serious mistakes don't happen around here			0.68					
A7n	We use more agency/temporary staff than is best for patient care			0.58					
A8n	Staff feel like their mistakes are held against them			0.59					
A10n	In this practice, we work longer hours than is best for patient care			0.68					
A12n	When an event is reported, it feels like the person is being written up, not the problem			0.60					
A13n	We work in crisis mode trying to do too much, too quickly			0.77					
A14n	Staff worry that mistakes they make are kept in their personnel file			0.56					
A15n	We have patient safety problems in this practice			0.69					
B3n	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts			0.57					

Item	Description	F1	F2	F3	F4	F5	F6	F7	α
Patient safety management									**0.81**
B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures				0.67				
B2	My supervisor/manager seriously considers staff suggestions for improving patient safety				0.72				
B5	My supervisor/manager provides a work climate that promotes patient safety				0.73				
B6	The actions of my supervisor/manager show that patient safety is top priority				0.74				
B7n	My supervisor/manager seems interested in patient safety only after an adverse event happens				0.61				

Item	Description	F1	F2	F3	F4	F5	F6	F7	α
Support and fellowship									**0.75**
A1	People support one another in this practice					0.65			
A2	We have enough staff to handle the workload					0.77			
A3	When a lot of work needs to be done quickly, we work together as a team to get the work done					0.63			
A4	In this practice, people treat each other with respect					0.67			
A11	When someone in this practice gets really busy, others help out					0.70			
Intention to report events									**0.85**
D2	When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?						0.71		
D3	When a mistake is made, but has no potential to harm the patient, how often is this reported?						0.93		
D4	When a mistake is made that could harm the patient, but does not, how often is this reported?						0.81		
Organisational learning									**0.58**
A6	We are actively doing things to improve patient safety							0.66	
A9	Mistakes have led to positive changes here							0.61	
A16	Our procedures and systems are good at preventing errors from happening							0.51	

Table 3 Correlations with Patient Safety Grade and Inter-Correlations Between the Seven Safety Culture Dimensions

Dimensions	Patient Safety Grade	1	2	3	4	5	6
Open communication and learning from error	0.51*						
Handover and teamwork	0.35*	0.36*					
Adequate procedures and working conditions	0.36*	0.44*	0.38*				
Patient safety management	0.51*	0.65*	0.39*	0.50*			
Support and fellowship	0.43*	0.47*	0.31*	0.38*	0.51*		
Intention to report events	0.20*	0.27*	0.16*	0.18*	0.25*	0.10*	
Organisational learning	0.46*	0.48*	0.34*	0.39*	0.49*	0.48*	0.17*

* Correlation is significant at the 0.01 level (2-tailed)

Table 4 Positive Dimensional Scores and Item Scores (n=603)

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Open communication and learning from error=57.6%					
We are given feedback about changes put into place based on event reports	603	3.65 (0.98)	60.2%	-0.540	-0.031
Staff will freely speak up if they see something that may negatively affect patient care	603	3.84 (0.86)	68.1%	-0.455	-0.365
We are informed about errors that happen in this practice	603	3.57 (0.97)	57.0%	-0.431	-0.229
Staff feel free to question the decisions or actions of those with more authority	603	3.23 (0.97)	41.7%	-0.239	-0.385
In this practice, we discuss ways to prevent errors from happening again	603	3.85 (0.86)	72.1%	-0.732	0.651
Professionals discuss errors that occurred with each other	603	3.64 (0.87)	61.5%	-0.524	0.124
We are given personal feedback about our own event reports	603	3.36 (1.01)	48.2%	-0.342	-0.366
My supervisor/manager overlooks patient safety problems that happen over and over*	477	3.61 (0.91)	64.9%	-0.789	0.429

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Handover and teamwork=43.0%					
Problems often occur in the exchange of information across disciplines in our practice*	574	2.79 (1.01)	21.4%	0.654	0.650
The fact that patients are treated by different professionals in our practice is causing problems*	586	3.06 (0.97)	39.5%	-0.287	-0.782
Disciplines in the practice that we co work with do not coordinate well with each other*	581	3.36 (0.87)	50.7%	-0.443	0.143
There is a good exchange of information between professionals in this practice	583	3.88 (0.82)	75.3%	-0.639	0.660
There is a good exchange of information between supporting staff in this practice	581	3.84 (0.84)	72.9%	-0.566	0.686
Things fall between the cracks when transferring patients between different disciplines in this practice*	569	2.74 (1.01)	15.2%	0.803	1.444
Important patient care information is often lost because patients see different professionals*	581	2.73 (1.08)	28.2%	0.254	-0.572

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Adequate procedures and working conditions=43.4%					
It is just by chance that more serious mistakes don't happen around here*	601	3.46 (1.08)	51.1%	-0.125	-0.052
We use more agency/temporary staff than is best for patient care*	601	3.57 (1.22)	47.2%	0.149	-0.256
Staff feel like their mistakes are held against them*	601	3.61 (1.01)	61.3%	-0.641	0.697
In this practice, we work longer hours than is best for patient care*	601	2.79 (1.09)	24.9%	0.303	-0.169
When an event is reported, it feels like the person is being written up, not the problem*	601	3.60 (0.96)	61.4%	-0.523	0.400
We work in crisis mode trying to do too much, too quickly*	601	2.46 (1.09)	18.1%	0.599	0.057
Staff worry that mistakes they make are kept in their personnel file*	601	2.88 (1.03)	27.8%	0.118	-0.249
We have patient safety problems in this practice*	601	3.65 (0.88)	64.9%	-0.528	1.226
Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts*	477	3.41 (0.93)	53.2%	-0.388	-0.494
Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts*	477	3.41 (0.93)	53.2%	-0.388	-0.494

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Patient safety management=60.3%					
My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	479	3.23 (1.04)	47.8%	-0.428	-0.588
My supervisor/manager seriously considers staff suggestions for improving patient safety	478	3.63 (0.82)	67.3%	-1.016	1.240
My supervisor/manager provides a work climate that promotes patient safety	476	3.63 (0.78)	65.7%	-0.875	0.988
The actions of my supervisor/manager show that patient safety is top priority	479	3.57 (0.78)	58.2%	-0.626	0.880
My supervisor/manager seems interested in patient safety only after an adverse event happens*	479	3.63 (0.90)	62.6%	-0.585	0.173
Support and fellowship=63.5%					
People support one another in this practice	603	4.28 (0.79)	89.3%	-1.230	2.211
We have enough staff to handle the workload	603	2.65 (1.01)	23.2%	0.272	-0.690
When a lot of work needs to be done quickly, we work together as a team to get the work done	603	3.49 (1.06)	54.8%	-0.198	-0.215
In this practice, people treat each other with respect	603	4.05 (0.78)	82.0%	-0.796	0.880
When someone in this practice gets really busy, others help out	603	3.74 (0.96)	70.0%	-0.651	0.016

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Intention to report events=48.5%					
When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	603	3.17 (1.22)	41.4%	-0.056	-1.004
When a mistake is made, but has no potential to harm the patient, how often is this reported?	603	3.27 (1.17)	42.6%	-0.109	-0.850
When a mistake is made that could harm the patient, but does not, how often is this reported?	603	3.71 (1.10)	61.5%	-0.564	-0.451
Organisational learning=71.7%					
We are actively doing things to improve patient safety	598	4.10 (0.72)	83.8%	-0.549	0.739
Mistakes have led to positive changes here	598	3.81 (0.80)	69.3%	-0.155	0.732
Our procedures and systems are good at preventing errors from happening	598	3.70 (0.77)	63.7%	-0.347	0.533

* Items are reverse scored

Table 5 Patient Safety Grade and Numbers of Events Reported (n=603)

Outcome Questions			
Patient safety grade	**N (%)**	**Number of events reported**	**N (%)**
Poor	2 (0.3%)	None	183 (30.3%)
Moderate	42 (7.0%)	1 to 2	144 (23.9%)
Acceptable	160 (26.5%)	3 to 5	70 (11.6%)
Good	366 (60.7%)	6 to 10	41 (6.8%)
Excellent	33 (5.5%)	11 to 20	16 (2.7%)
		More than 20	6 (1.0%)
		Missing	*143 (23.7%)*

Chapter 8

Exploring and Evaluating Patient Safety Culture in a Community-Based Primary Care

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SUMMARY

Community-based primary care will become an important setting for healthcare delivery, but is delivered differently and in a less structured manner compared to acute care. In addition, an open and fair patient safety culture is essential to ensure incident reporting from which lessons can be learned and improvement strategies can be developed. Multiple tools have been developed and evaluated to assess patient safety culture. However, nearly all of these tools are hospital-based. The primary aim of the present study was to measure patient safety culture in two home care services in Belgium (Flanders). Additionally, variability based on respondents' profession was examined.

A cross-sectional study was conducted by administering the SCOPE-Primary Care questionnaire in two home care service organisations. In total, 1.875 valid questionnaires were returned from 2.930 employees, representing a response rate of 64.0%. The highest mean patient safety culture score was found for 'organisational learning' ($\bar{x}$=3.81, SD=0.53), followed by 'support and fellowship' ($\bar{x}$=3.76, SD=0.61), 'open communication and learning from error' ($\bar{x}$=3.73, SD=0.64), and 'patient safety management' ($\bar{x}$=3.71, SD=0.60). The lowest mean scores were found for 'handover and teamwork' ($\bar{x}$=3.28, SD=0.58) and 'adequate procedures and working conditions' ($\bar{x}$=3.30, SD=0.56). Moreover, managers/supervisors scored significantly higher on the dimensions 'open communication and learning from error', 'adequate procedures and working conditions', 'patient safety management', 'support and fellowship', and 'organisational learning' compared to clinical and non-clinical staff.

In conclusion, organisational learning is perceived as most positive. However, large gaps remain in the continuity of care as 'handover and teamwork' is perceived as the most negative safety culture dimension. With knowledge of the current patient safety culture, organisations can redesign processes or implement improvement strategies to avoid patient safety incidents and patient harm in the future.

Over the past 20 years, secondary care settings have become the main focus of research assessing and improving patient safety [1]. Nevertheless, primary care faces major challenges. In the last 15 years, patients with chronic conditions are more often treated in primary care rather than in a hospital [2]. And when patients move between the secondary-primary care interface, the risks for patient safety incidents further increases [3,4]. In particular, community-based primary care will become an important setting for healthcare delivery, but care is delivered differently and in a less structured manner compared to acute care [5]. Patients are much more autonomous and coordination between healthcare professionals is more difficult. Additionally, healthcare professionals are witnessing multiple patient safety risks such as lack of knowledge, fall-inducing obstacles, and unpackaged medications. For example, Blais *et al*. found that 4.2% (95% CI 3.0%-5.4%) of home care patients experienced injuries due to fall-related incidents, wound infections, and medication errors within a 12-month period after hospital discharge, [6].

Echoing the recommendations in the IOM report *To Err is Human: Building a Safer Health System*, healthcare organisations began the process of improving deficits in patient safety, including a widespread focus on patient safety culture [7]. Fifteen years after the aforementioned report, the National Patient Safety Foundation emphasised in their *Free from Harm* report the development and sustainability of an open patient safety culture in which incidents or service failures can be reported and discussed [8]. Following the nuclear industry definition, patient safety culture refers to '*the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management*' [9]. An open and fair patient safety culture is essential to ensure incident reporting from which lessons can be learned and improvement strategies be developed. Assessing healthcare professionals' perceptions and attitudes towards communication and handover, experienced workload, degree of involvement and commitment, and working conditions are crucial research areas as they might result in either more or less safety for the patient.

Multiple tools have been developed and evaluated to assess patient safety culture. Nearly all of these tools cover relevant dimensions such as communication and handover, but most of the instruments are hospital-based [9,10]. Few studies have been conducted on patient safety culture in primary care and - to date - none in Belgium (Flanders) [11-24].

OBJECTIVES

The objective of the present study was twofold. The primary aim was to measure patient safety culture in two home care service organisations in Belgium (Flanders). As research in other healthcare settings reports wide variety in patient safety culture perceptions [18,25,26], variability in safety culture based on respondents' profession was also examined.

METHODS

SCOPE-Primary Care Instrument

The SCOPE-PC instrument is a multi-item questionnaire, assessing seven patient safety culture dimensions: [1] 'open communication and learning from error' (8 items), [2] 'handover and teamwork' (7 items), [3] 'adequate procedures and working conditions' (9 items), [4] 'patient safety management' (5 items), [5] 'support and fellowship' (5 items), [6] 'intention to report events' (3 items), and [7] 'organisational learning' (3 items) [27]. All patient safety items use five-point Likert response scales of agreement from 'strongly disagree' (score 1) to 'strongly agree' (score 5) or response scales of frequency from 'never' (score 1) to 'always' (score 5). In some cases, there is also the option 'not applicable'. In addition, the instrument includes two questions regarding the frequency of incident reports within the last twelve months and an overall patient safety grade from 'failing' to 'excellent'. Finally, some background questions address demographic and work-related information such as profession and working experience.

Recently, the SCOPE-PC instrument was validated for use in home care services [28]. The instrument showed good psychometric properties with Cronbach's alphas ranging from 0.58 to 0.86 and moderate to good inter-correlations between the seven safety culture dimensions as well as with the overall patient safety grade.

Data Collection

A cross-sectional survey study design was applied. This study used a convenience sample and administered the SCOPE-PC questionnaire in two home care organisations in Belgium (Flanders) with each more than 1.000 employees, including nurses, nursing assistants, midwives, healthcare assistants, and nursing supervisors. These two organisations - out of five regional associations - are autonomous, offering different kinds of home care services. At the same time, there is also an umbrella federation that carries out the interests of these five regional associations.

Data collection occurred between September and December 2016 through the online platform Qualtrics. The electronic questionnaire targeted all healthcare professionals, supervisors, managers, and administrators who had direct or indirect interaction with patients. All healthcare and non-healthcare professionals received an invitation by e-mail. Two reminders were sent with an interval of two weeks. Moreover, several steps were taken to mitigate the risk of common method bias, both ex-ante remedies as well as statistical controls after the questionnaires were returned (e.g., during design and administration stage of the questionnaire, respondents were assured of confidentiality of the study and that there were no right or wrong answers) [29]. Participants were informed about the purpose of the study and their participation was anonymous, voluntarily, and confidential. The home care organisations each received a feedback report with staff perceptions on patient safety issues, medical incidents, and event reporting.

Statistical Analyses

All analyses were performed using R: A Language and Environment for Statistical Computing version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria) [30]. The significance level α was set at 0.05 and all *P*-values were two-sided. As defined in the SCOPE-PC manual, questionnaires with >50% missing values or >50% scoring 'not applicable' on patient safety items were excluded from further analyses [31]. Negatively worded items were reverse-coded so that a higher score would indicate a more positive attitude. Finally, pairwise deletion of incomplete data was used.

Descriptive statistics - including frequency distribution for qualitative variables and means (SD) or medians (range) for quantitative variables - were computed for demographic characteristics of the sample and each item on the SCOPE-PC instrument. For each patient safety culture dimension, scale scores were calculated by summing item scores for each dimension and dividing it by the number of completed items, with a score of four or higher representing a positive attitude [18]. Afterwards, positive dimensional scores (percentage of positive responses) were also calculated. Answers above 3 ('agree/strongly agree' or 'most of the time/always') were considered as positive towards patient safety. Strengths were defined when ≥75% of respondents answered positive. Areas with potential for improvement were identified as items with <50% of respondents answered positively [31].

When using patient safety culture questionnaires in healthcare, mean scores or percentage positive scores (i.e., averaging culture scores) are typically reported, which may paint an inaccurate picture. A large body of organisational research considers consensus or agreement among individuals in a group as a prerequisite to accurately aggregate and analyse culture at a group level [32]. Consequently, the Rwg(j) measure of agreement was calculated to measure *culture* (or *climate*) *strength* [33]. The Rwg(j) assesses the extent of consensus/agreement within a single case; that is in this study the two home care organisations and different professions. Rwg(j) values between 0.51 and 0.70 indicate moderate agreement and values ≥0.71 suggest high agreement (i.e., *strong climate/culture*) and thus justifies aggregation [34]. At the same time, simple histograms of all patient safety culture items are recommended in order to visually show the pattern of safety culture scores and yield more diagnostic information (see Appendix I) [33,35].

Taking potential predictors from literature into account, analyses of variance (Kruskal-Wallis test) were conducted to test for differences in mean dimensional scores between professions. All professions were grouped into three categories; that is [1] managers/supervisors, [2] clinical staff, or [3] non-clinical staff.

Ethical Consideration

Participants were informed that the collected information would be kept confidential and that the questionnaire was anonymous. There were no incentives provided for completing the questionnaire. The institutional ethics committee of Hasselt University approved the study (ref. CME2016/641).

RESULTS

In total, 1.875 valid questionnaires were returned from 2.930 employees, representing a response rate of 64.0%. Organisation A had a higher response rate compared to organisation B, with respectively 79.5% and 46.5%. For most dimensions, missing data rates were low (<6.0%). For the dimension 'patient safety management', the missing rate was relatively higher with 10.7%, which resulted from the number of respondents not having formal management (n=341, 18.2%) and therefore not able to respond to the items within this dimension.

Respondents' Characteristics

Table 1 shows respondents' characteristics. Most of the respondents were female (n=1.648, 87.8%). The median age was 41 years, with a range from 20 to 65 years. The majority of respondents were nursing staff (n=1.380, 73.6%), followed by nursing assistants (n=96, 5.1%) and managers (n=70, 3.7%). Most of the respondents worked between 1 to 5 years (n=397, 21.2%) or 21 years and more (n=448, 23.9%) in their organisation. Almost 87.0% (n=1.629) of the sample had direct interaction or contact with patients.

Patient Safety Culture Scores

The mean (SD) dimension and item scores are presented in Table 2 and 3 respectively. Table 2 also shows that median Rwg(j) values approach or exceed 0.70 for all seven patient safety culture dimensions, suggesting a good level of inter-rater agreement which justifies the aggregation of individual scores.

In general, none of the seven dimensions scored above four. The highest mean patient safety culture score was found for 'organisational learning' ($\bar{x}$=3.81, SD=0.53), followed by 'support and fellowship' ($\bar{x}$=3.76, SD=0.61), 'open communication and learning from error' ($\bar{x}$=3.73, SD=0.64), 'patient safety management' ($\bar{x}$=3.71, SD=0.60), and 'intention to report events' ($\bar{x}$=3.61, SD=0.99). The lowest mean scores were found for 'handover and teamwork' ($\bar{x}$=3.28, SD=0.58) and 'adequate procedures and working conditions' ($\bar{x}$=3.30, SD=0.56).

With regard to the dimension 'adequate procedures and working conditions', the items '*In this practice, we work longer hours than is best for patient care*' (A10), '*We work in crisis mode trying to do too much, too quickly*' (A13), and '*Staff worry that mistakes they make are kept in their personnel file*' (A14) scored remarkably lower with 3.04 (SD=1.14), 2.66 (SD=1.12), and 3.01 (SD=1.06) respectively. With regard to the dimension 'handover and teamwork', the items '*Problems often occur in the exchange of information across disciplines in our practice*' (F1), '*Things fall between cracks when transferring patients between different disciplines in this practice*' (F6), and '*Important patient care information is often lost because patients see different professionals*' (F7) scored remarkably lower with 2.88 (SD=1.00), 2.98 (SD=1.01), and 3.01 (SD=1.08) respectively. Appendix I provides an example of histograms for the aforementioned patient safety culture items. Furthermore, positive dimensional scores range from 46.9% ('handover and teamwork') to 70.8% ('organisational learning'). Additionally, 63.5% (n=1.191) of the employees graded patient safety in their organisation as *good* and 35.8% (n=671) *never* reported an incident within the last twelve months (see Table 4).

Differences Between Professions

Table 5 shows that median Rwg(j) values by profession again approach or exceed 0.70 for all seven patient safety culture dimensions. Analyses of variance tests were conducted to test for differences in mean dimension scores between professions. There were significant differences at the $P<0.05$ level for the dimensions 'open communication and learning from error' ($X^2=11.477$, $df=2$, and $P=0.003$), 'adequate procedures and working conditions' ($X^2=53.641$, $df=2$, and $P<0.001$), 'patient safety management' ($X^2=27.278$, $df=2$, $P<0.001$), 'support and fellowship' ($X^2=34.241$, $df=2$, and $P<0.001$), and 'organisational learning' ($X^2=11.628$, $df=2$, $P=0.003$).

Post hoc comparisons showed that managers/supervisors scored significantly higher on the dimensions 'open communication and learning from error' (3.96 vs 3.74 and 3.73), 'adequate procedures and working conditions' (3.69 vs 3.28 and 3.41), 'support and fellowship' (4.11 vs 3.76 and 3.87), and 'organisational learning' (3.99 vs 3.82 and 3.75) compared to clinical and non-clinical staff. Moreover, managers/supervisors scored significantly higher on the dimension 'patient safety management' than clinical staff (4.04 vs 3.72). Results are presented in detail in Table 5.

DISCUSSION

The demand for home and community services has increased substantially in recent years. Despite the increasing shift of healthcare from hospitals to community-based primary care, literature on patient safety continues to focus primarily on institutionalised settings. To assess the current culture and to develop improvement strategies, healthcare organisations in primary care are interested in patient safety culture as well. Consequently, the present study aimed at assessing patient safety culture in two home care services in Belgium (Flanders).

The response rate of the participating practices was 64.0%. The highest mean patient safety culture score was found for 'organisational learning' ($\bar{x}$=3.81, SD=0.53), followed by 'support and fellowship' ($\bar{x}$=3.76, SD=0.61). The lowest mean scores were found for 'handover and teamwork' ($\bar{x}$=3.28, SD=0.58) and 'adequate procedures and working conditions' ($\bar{x}$=3.30, SD=0.56). Despite good teamwork, respondents often experience a heavy workload and inefficient patient handovers between different healthcare professionals. These are areas with potential for improvement. For example, health information technology is very important for patient safety as it facilitates tracking patients and follow-up [36]. Furthermore, managers/supervisors scored significantly higher on the dimensions 'open communication and learning from error', 'adequate procedures and working conditions', 'support and fellowship', and 'organisational learning' compared to clinical and non-clinical staff. A large study with responses from 15.523 primary healthcare professionals also indicated that management has significantly more positive perceptions [37]. One possible explanation is that negative information does not always reach managers as they are detached from front-line operations. To build a strong patient safety culture, it is however essential for the differences to be acknowledged and perceptions of all healthcare professionals to be aligned.

Because of heterogeneity in applied questionnaires and the reporting of outcomes, comparison with other studies on patient safety culture is difficult. Nevertheless, remarkable consistencies exist. The low scores on the dimensions 'adequate procedures and working conditions' and 'handover and teamwork' are also reported in other studies on patient safety culture in primary care where workload and patient follow-up are considered least positive [12-14,19-24]. The WHO has found that heavy workloads are a common concern among healthcare professionals, which may contribute to lower performance [38]. Appropriate redistribution of workload is therefore necessary. Furthermore, teamwork and organisational learning are frequently reported as positive patient safety culture dimensions [12-14,19-21,23,24]. As mentioned, real comparison with other studies on patient safety culture in primary care is difficult due to heterogeneity in applied questionnaires. However, the study of Verbakel *et al*. in the Netherlands also used the SCOPE-PC instrument, but the results of the present study are inferior to the ones from the Dutch study (range=3.73-4.26) [18].

The results of the present study have to be interpreted carefully. First, respondents may not have felt comfortable enough to express their safety concerns about the organisations although the risk was minimised by expressing confidentiality. Second, other control variables were not disposed in the analyses such as practice size and type of ownership. Third, questions still remain whether self-reported questionnaires are appropriate to measure patient safety culture as they provide only a snapshot of the culture at a certain point in time which may be a simplified, superficial, and partial description. Trbovich and Griffin highlight the need to move beyond surveying and recommend the triangulation of both quantitative and qualitative methods to attain a more in-depth assessment of culture and its underlying aspects [39]. Fourth, limited evidence is available on the relationship between safety culture and patient outcomes [40], although some studies indicate that safety culture assessments foster communication around the topic and increase the number of incidents reported [41,42]. Evidence on the relationship between patient safety culture and patient outcomes exists at the hospital and nursing unit level. However, the number of studies finding statistically significant correlations is limited [43]. Consequently, more effort should be expended on examining and understanding the relationship between safety culture and patient outcomes such as hospitalisations, emergency department visits, and mortality.

CONCLUSIONS

The present study was the first step in approaching patient safety issues in a community-based primary care setting in Belgium (Flanders) by using a validated questionnaire. In conclusion, organisational learning is perceived as most positive. However, large gaps remain in the continuity of care as the safety culture dimension 'handover and teamwork' is perceived as the most negative one. With knowledge of the current patient safety culture, organisations can now redesign processes or implement improvement strategies for the prevention of patient safety incidents and ultimately patient harm in the future.

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Table 1 Respondents' Characteristics (n=1.875)

Characteristics	N (%) Median (range)
Age (yrs), median (range)	41 (20-65)
Gender, n (%)	
Male	92 (4.9%)
Female	1.648 (87.8%)
Missing	*135 (7.3%)*
Profession, n (%)	
Nurse	1.380 (73.6%)
Nursing assistant	96 (5.1%)
Manager/supervisor	70 (3.7%)
Administrative assistant	47 (2.5%)
Polyvalent assistant	34 (1.8%)
Midwife	25 (1.3%)
Nursing supervisor	23 (1.2%)
Staff member	16 (0.9%)
Logistics assistant	12 (0.6%)
Dietician	10 (0.5%)
Interior assistant	8 (0.4%)
Podologist	3 (0.2%)
Missing	*151 (8.1%)*

Characteristics	N (%) Median (range)
Professional experience in organisation, n (%)	
Less than 1 year	101 (5.4%)
1 to 5 years	397 (21.2%)
6 to 10 years	345 (18.4%)
11 to 15 years	143 (7.6%)
16 to 20 years	138 (7.4%)
21 years or more	448 (23.9%)
Missing	*303 (16.1%)*
Overall professional experience, n (%)	
Less than 1 year	84 (4.5%)
1 to 5 years	333 (17.8%)
6 to 10 years	295 (15.7%)
11 to 15 years	142 (7.6%)
16 to 20 years	191 (10.2%)
21 years or more	563 (30.0%)
Missing	*267 (14.2%)*
Working time (hours), n (%)	
Less than 20 hours	62 (3.3%)
20 hours	382 (20.4%)
24 hours	210 (11.2%)
28.5 hours	261 (13.9%)
32 hours	404 (21.5%)
38 hours	414 (22.1%)
Missing	*142 (7.6%)*

Characteristics	N (%) Median (range)
Working shift, n (%)	
Mornings	1.111 (59.2%)
Days	570 (30.4%)
Evenings	41 (2.2%)
Nights	17 (0.9%)
Missing	*136 (7.3%)*
Interaction with patients, n (%)	
Yes	1.629 (86.8%)
No	114 (6.1%)
Missing	*132 (7.1%)*

Table 2 Dimension Scores (n=1.875)

Dimension	Mean score (SD)	% Positive	Median Rwg(j)	Range Rwg(j)
Open communication and learning from error	3.73 (0.64)	65.6%	0.92	0.91-0.94
Handover and teamwork	3.28 (0.58)	46.9%	0.90	0.89-0.91
Adequate procedures and working conditions	3.30 (0.56)	48.6%	0.88	0.87-0.89
Patient safety management	3.71 (0.60)	68.9%	0.91	0.89-0.93
Support and fellowship	3.76 (0.61)	69.3%	0.88	0.87-0.89
Intention to report events	3.61 (0.99)	57.8%	0.63	0.59-0.68
Organisational learning	3.81 (0.53)	70.8%	0.87	0.86-0.87

Table 3 Item Scores (n=1.875)

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Open communication and learning from error					
We are given feedback about changes put into place based on event reports	1.843	3.69 (0.95)	63.4%	-0.567	-0.011
Staff will freely speak up if they see something that may negatively affect patient care	1.843	4.00 (0.83)	76.8%	-0.675	-0.348
We are informed about errors that happen in this practice	1.843	3.65 (0.93)	61.6%	-0.491	-0.089
Staff feel free to question the decisions or actions of those with more authority	1.843	3.44 (0.92)	51.2%	-0.405	-0.055
In this practice, we discuss ways to prevent errors from happening again	1.843	4.01 (0.79)	79.2%	-0.756	0.879
Professionals discuss errors that occurred with each other	1.843	3.76 (0.84)	67.2%	-0.222	0.193
We are given personal feedback about our own event reports	1.843	3.63 (0.93)	60.4%	-0.541	-0.114
My supervisor/manager overlooks patient safety problems that happen over and over*	1.660	3.70 (0.87)	68.0%	-0.740	0.462

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Handover and teamwork					
Problems often occur in the exchange of information across disciplines in our practice*	1.779	2.88 (1.00)	23.2%	0.077	-0.641
The fact that patients are treated by different professionals in our practice is causing problems*	1.779	3.22 (0.97)	43.3%	-0.397	-0.568
Disciplines in the practice that we co work with do not coordinate well with each other*	1.778	3.41 (0.87)	50.1%	-0.560	-0.101
There is a good exchange of information between professionals in this practice	1.779	3.93 (0.79)	76.0%	-0.653	0.722
There is a good exchange of information between supporting staff in this practice	1.779	3.85 (0.78)	72.3%	-0.599	0.663
Things fall between the cracks when transferring patients between different disciplines in this practice*	1.779	2.98 (1.01)	22.5%	-0.027	-0.384
Important patient care information is often lost because patients see different professionals*	1.779	3.01 (1.08)	35.4%	-0.092	-0.883

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Adequate procedures and working conditions					
It is just by chance that more serious mistakes don't happen around here*	1.875	3.56 (1.08)	54.5%	-0.483	-0.322
We use more agency/temporary staff than is best for patient care*	1.875	3.76 (1.22)	47.3%	-0.379	-0.303
Staff feel like their mistakes are held against them*	1.875	3.67 (0.98)	61.9%	-0.813	0.704
In this practice, we work longer hours than is best for patient care*	1.875	3.04 (1.14)	31.3%	-0.131	-0.686
When an event is reported, it feels like the person is being written up, not the problem*	1.875	3.57 (0.96)	56.8%	-0.645	0.212
We work in crisis mode trying to do too much, too quickly*	1.875	2.66 (1.12)	21.8%	0.195	-0.784
Staff worry that mistakes they make are kept in their personnel file*	1.875	3.01 (1.06)	26.8%	0.004	-0.426
We have patient safety problems in this practice*	1.875	3.77 (0.86)	66.0%	-0.801	1.084
Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts*	1.664	3.52 (0.91)	58.8%	-0.492	-0.275

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Patient safety management					
My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	1.673	3.55 (0.93)	61.3%	-0.690	0.177
My supervisor/manager seriously considers staff suggestions for improving patient safety	1.666	3.81 (0.72)	76.3%	-1.035	2.142
My supervisor/manager provides a work climate that promotes patient safety	1.662	3.78 (0.69)	74.4%	-0.911	1.783
The actions of my supervisor/manager show that patient safety is top priority	1.666	3.70 (0.73)	65.6%	-0.550	0.812
My supervisor/manager seems interested in patient safety only after an adverse event happens*	1.661	3.73 (0.86)	67.7%	-0.650	0.392
Support and fellowship					
People support one another in this practice	1.875	4.29 (0.76)	89.1%	-1.175	2.027
We have enough staff to handle the workload	1.875	2.91 (1.06)	32.3%	0.102	-0.841
When a lot of work needs to be done quickly, we work together as a team to get the work done	1.875	3.66 (0.97)	61.7%	-0.577	-0.038
In this practice, people treat each other with respect	1.875	4.17 (0.75)	86.7%	-0.905	1.318
When someone in this practice gets really busy, others help out	1.875	3.87 (0.90)	73.4%	-0.791	0.476

	N	Mean (SD)	% Positive	Skewness	Kurtosis
Intention to report events					
When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	1.788	3.42 (1.20)	50.6%	-0.288	-0.892
When a mistake is made, but has no potential to harm the patient, how often is this reported?	1.788	3.51 (1.13)	53.5%	-0.361	-0.714
When a mistake is made that could harm the patient, but does not, how often is this reported?	1.786	3.90 (1.04)	69.4%	-0.761	-0.059
Organisational learning					
We are actively doing things to improve patient safety	1.875	4.12 (0.73)	83.0%	-0.633	1.066
Mistakes have led to positive changes here	1.875	3.72 (0.85)	59.3%	-0.433	0.433
Our procedures and systems are good at preventing errors from happening	1.875	3.73 (0.78)	65.3%	-0.496	0.459

* Items are reverse scored

Table 4 Patient Safety Grade and Numbers of Events Reported (n=1.875)

Outcome Questions			
Patient safety grade	**N (%)**	**Number of events reported**	**N (%)**
Poor	8 (0.4%)	None	671 (35.8%)
Moderate	80 (4.3%)	1 to 2	207 (11.0%)
Acceptable	391 (20.8%)	3 to 5	126 (6.7%)
Good	1.191 (63.5%)	6 to 10	54 (2.9%)
Excellent	131 (7.0%)	11 to 20	22 (1.2%)
Missing	*74 (4.0%)*	More than 20	6 (0.3%)
		Missing	*789 (42.2%)*

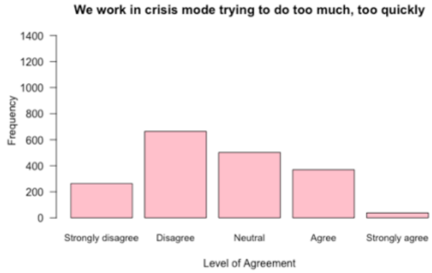
Table 5 Mean Dimension Scores by Profession

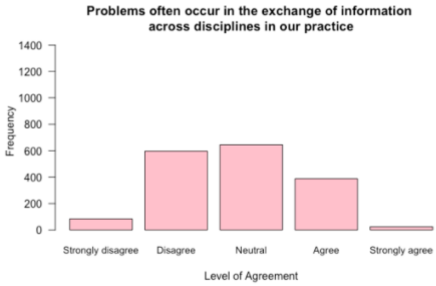
Patient safety culture dimension	Median Rwg(j) (range)	Mean (SD)			P-value
		Managers/supervisors	Clinical staff	Non-clinical staff	
Open communication and learning from error	0.93 (0.91-0.94)	3.96 (0.52)	3.74 (0.62)	3.73 (0.61)	0.003*
Handover and teamwork	0.90 (0.86-0.90)	3.35 (0.55)	3.28 (0.58)	3.31 (0.57)	0.394
Adequate procedures and working conditions	0.89 (0.81-0.90)	3.69 (0.48)	3.28 (0.55)	3.41 (0.68)	<0.001*
Patient safety management	0.92 (0.92-0.92)	3.99 (0.58)	3.71 (0.59)	3.85 (0.66)	<0.001**
Support and fellowship	0.89 (0.86-0.91)	4.11 (0.59)	3.76 (0.60)	3.87 (0.62)	<0.001*
Intention to report events	0.63 (0.62-0.64)	3.69 (0.99)	3.61 (0.98)	3.57 (1.00)	0.684
Organisational learning	0.86 (0.80-0.88)	3.99 (0.56)	3.82 (0.52)	3.75 (0.63)	0.003*

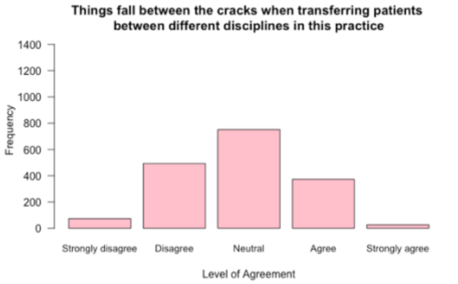
* Managers/supervisors scored significantly higher than clinical and non-clinical staff

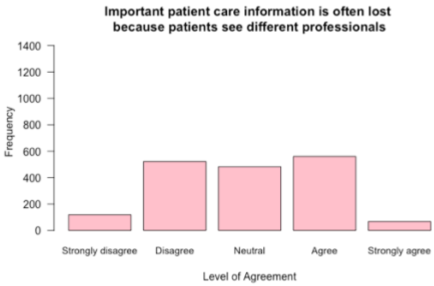
**Managers/supervisors scored significantly higher than clinical staff

APPENDIX I – EXAMPLE OF HISTOGRAMS









Chapter 9

General Discussion

The ageing population, urbanisation, and globalisation of unhealthy lifestyles undermines the future sustainability of healthcare systems worldwide. Due to their fragmented nature, healthcare systems are unable to respond to the rising chronic care needs, which jeopardises the provision of equitable, high-quality, and economically sustainable care. Consequently, there is a high need for healthcare systems to adapt [1].

Patients with chronic care needs expect a healthcare system that meets their expectations in a more holistic, integrated, and patient-centred way with efficient communication between healthcare professionals at crucial care transition points. Moreover, the needs of people with chronic conditions range from minimal personal assistance to total everyday care [2]. Interventions to meet these needs are offered in a variety of settings, including the patient's home and community environment [2]. Evidence shows that healthcare systems based on a strong primary care, delivers better population health outcomes at lower costs [3]. Primary care is therefore an important growing segment of healthcare delivery [4]. This may lead to concerns regarding the quality and safety of care provision. A patient safety agenda in community-based primary care needs to consider a different kind of workplace, including the isolation from other healthcare professionals and supervisors, the unique characteristics of each home setting, and the disjuncture in communication between colleagues [5]. Patient safety in community-based primary care cannot be managed in the same way as in the hospital as care delivery is influenced by the characteristics of the patient, physical environment, characteristics of the healthcare professionals, and the availability of family and other caregivers [6].

Hence, the present dissertation focused on patient safety in primary care. By means of seven separate studies, this dissertation presents a research overview on patient safety in primary care and tries to understand the current underlying discontinuity and fragmentation of healthcare in order to define key conditions of new care delivery models to meet the rising chronic care needs.

The following research questions were addressed:

1. **What is the best available scientific evidence on patient safety in primary care and the potential economic impact of integrated care models for patients with chronic diseases (PART I)?**

2. **How do chronic patients perceive the quality and safety of today's chronic care delivery (PART II)?**

3. **How do healthcare professionals perceive the safety of today's chronic care delivery (PART III)?**

In this closing chapter, empirical findings of each study are summarised. Following this, limitations and strengths of the studies are discussed. Next, implications for practice and healthcare policy are provided. Finally, recommendations and suggestions for further research are discussed.

OVERVIEW OF EMPIRICAL FINDINGS

RQ1: Evidence on Patient Safety in Primary Care

Chapter 2. Every day, millions of interactions occur in primary care and most patients receive safe care. However, two to three incidents for every 100 consultations occur of which 4% may lead to actual patient harm [7]. Most healthcare encounters occur in primary care, yet there has been the assumption that primary care is a low technology environment where harm is less significant. Though, primary care is complex and diverse and so patient safety in primary care cannot be managed in the same way as patient safety in the hospital. In primary care, patients are seen over longer periods of time and are often dealing with complex conditions or comorbidities. Moreover, research on patient safety improvement strategies in primary care is still limited. It remains to be determined which strategies are most effective. Incident reporting and patient safety culture assessments are two topics that are frequently studied, but have unknown impact on patient safety. On the other hand, primary care also has unique advantages in promoting patient safety.

Healthcare professionals have longitudinal relationships with their patients who are more likely to take an active role in improving their own care. Nevertheless, there is high need for clear and detailed clarification of core concepts relating to patient safety in primary care, prospective mixed-methods approaches to identify underlying causes of patient harm, and clarification systems to analyse safety incidents so effective improvement strategies can be developed.

Chapter 3. As mentioned before, healthcare systems are often organised to respond to acute diseases. However, chronic patients are in need of long-term care which brings together a broad range of professionals, that above integrates and coordinates services along the continuum of care. Hence, healthcare systems are facing the challenge of meeting the complex care needs of the chronically ill in an effective manner. Hereto, integrated care received increasing attention as it is considered an appropriate answer in reducing the fragmentation of care, improving the quality of patient care, and controlling healthcare-associated costs. Nevertheless, the current body of literature is inconclusive about the potential economic impact of integrated care. This dissertation provides a systematic literature review, where a vast majority of studies (22/26, 84.6%) reported a positive economic impact, respectively for type 2 diabetes mellitus (16/18, 88.9%), schizophrenia (4/6, 66.7%), and multiple sclerosis (1/2, 50.0%). Moreover, seven out of eight articles that considered implementation and operational costs of the integrated care models, reported a negative incremental cost. Cost savings were thus higher than the investment of the models. The observed savings were mostly accompanied by significantly fewer hospital admissions and fewer inpatients days. Nevertheless, in order to support well-considered decision-making, there is a high need for well-designed health economic evaluations of integrated care.

RQ2: Patient-Perceived Quality and Safety of Primary Care

Chapter 4. With the expansion of integrated care initiatives, there is an increasing emphasis on patient-centricity. Patients' insights have extraordinary potential to enhance transparency, accountability, and care quality [8]. However, much patient-reported feedback remains underutilised [9]. Given the need to reform today's healthcare systems, it is nevertheless essential to evaluate the quality of chronic care from the patients' perspectives to ensure that both care and quality improvements align with their needs and expectations. In a cross-sectional study using the *Patient Assessment of Chronic Illness Care* survey, chronic patients' perspectives on today's care delivery and the alignment with the Chronic Care Model were explored. The study found a mean PACIC score of 2.87 on a maximum score of 5. The highest PACIC subscale scores were found for 'patient activation' and 'delivery system design/decision support', suggesting that chronic patients are generally active patients who are well supported and motivated by their healthcare professionals. Lowest PACIC subscale scores were found for 'goal setting/tailoring' and 'follow-up/coordination', indicating that chronic patients experience a lack of setting specific goals in their care delivery and in arranging follow-up meetings. Hence, chronic patients experience uncoordinated services. Especially the communication between primary and secondary care is perceived as disjointed and not coherent.

Chapter 5. At the same time, research on patients' experiences of safety incidents is little studied. Nevertheless, numerous studies have shown that patients report medical incidents and adverse events accurately and provide additional information, specifically regarding breakdowns in the continuity of care, medication management, and communication inefficiencies [10]. Information on patients' experiences is critical to identify incidents and to ultimately reduce patient harm. Patients have a key role in their care and must therefore be part of the patient safety discourse. In a cross-sectional study, patients with chronic diseases indicated to have positive perceptions on the safety of chronic care delivery in their home environment. The majority indicated to receive safe care at home, receive enough care support at home, and experience good communication between their healthcare professionals.

However, it is remarkable that patients with more than two healthcare professionals involved in their care provision were less likely to agree with the aforementioned statements. This may indicate that continuity of care among healthcare professionals is perceived as not consistent and coherent. Furthermore, almost one quarter of respondents experienced a patient safety incident. These incidents are mainly related to self-reported fall incidents, wrong diagnoses or treatments, and adverse drug events. Insufficient communication between healthcare professionals was perceived as the main cause in more than half of the reported incidents.

RQ3: A Healthcare Professional Perspective on the Safety of Primary Care

Chapter 6. One of the challenges is to engage all healthcare professionals to an agenda that explicitly address issues related to patient safety. In 2001, the Institute of Medicine recommended healthcare organisations to enhance their patient safety culture [11]. Consequently, there has been an increasing focus on assessing patient safety culture in the hospital environment and this is also building momentum in primary care. Notwithstanding the relevant lack of research on patient safety in primary care, many studies have been conducted on patient safety culture in primary care facilities. In a systematic and psychometric review, an overview of empirical studies using self-reported instruments for assessing patient safety culture in primary care was provided. Moreover, psychometric properties of these instruments were determined and synthesised in order to identify the most appropriate measurement instrument. As these studies come with great diversity in tools used and outcomes reported, comparability of the results is compromised. Moreover, psychometric properties of many patient safety culture tools are subject to criticism. Based on a psychometric review, the SCOPE-Primary Care instrument was chosen as the most appropriate tool to measure patient safety culture in primary care as the questionnaire had excellent scores on the COSMIN scales, is very similar to the MaPSaF tool, can be used both in small (<8 employees) and large (>8 employees) primary care facilities, and pays particular attention to the theme 'handover and teamwork' which is of great importance in the context of integration and coordination of care [12].

Chapter 7. However, the SCOPE-PC instrument was not validated for home care services. Moreover, it is possible that cultural differences exist between healthcare environments within or between countries which may weaken the validity of the instrument. Therefore, it is important to carefully test the instrument before using the questionnaire and interpreting its results in a Belgian (Flemish) primary care setting. In a validation study, psychometric properties of the SCOPE-Primary Care instrument were tested. The results of the confirmatory factor analysis satisfied the chosen cut-offs, indicating an acceptable to good model fit. Moreover, Cronbach's alpha scores of the SCOPE scales indicated a good level of internal consistency and inter-correlations between the seven dimensions as well as with the overall patient safety grade were also moderate to good, indicating a good construct validity. Hence, no modifications were required to the original survey. This allows benchmarking between different primary care settings.

Chapter 8. In a large cross-sectional study, patient safety culture in two Belgian (Flemish) home care service organisations was measured by using the validated SCOPE-PC instrument. The highest mean patient safety culture score was found for 'organisational learning', followed by 'open communication and learning from error'. The lowest mean scores were found for 'adequate procedures and working conditions' and 'handover and teamwork'. Moreover, managers/supervisors often scored significantly higher on the dimensions than clinical and non-clinical staff.

In conclusion, results of the present dissertation indicate (both from the patients' as well as from the healthcare professionals' perspective) a lack of care coordination in today's chronic care delivery in Belgium (Flanders). Especially the communication between primary and secondary care is perceived as disjointed and not coherent, leading to possible patient safety incidents and patient harm. Hence, Belgium (Flanders) is facing the challenge of meeting the complex care needs of the chronically ill in an effective manner. Hereto, integrated care received increasing attention as it is considered an appropriate answer in reducing the fragmentation of care, improving the quality of patient care, and controlling healthcare-associated costs. The large national program on integrated care, called *Integrated Care for a Better Health*, may use the results of the present study to define their innovative and integrated care models, with special attention to the patients' needs and expectations such as better goal setting and follow-up.

LIMITATIONS AND STRENGHTS OF THE RESEARCH

Methodological limitations of the individual studies are addressed in the respective chapters. Here, some general considerations of limitations and restrictions of the dissertation are discussed. First, this dissertation does not include any qualitative research. It would however be valuable to assess the underlying aspects of patient safety culture by conducting in-depth interviews or organising group workshops. For example, the MaPSaF - originally developed for use in primary care in the UK – encourages reflection on safety culture and the development of interventions to change its culture by means of workshops [13]. In the meantime, the MaPSaF has been validated for use in Germany (the *Frankfurt Patient Safety Matrix*), resulting in a better reporting of safety incidents [14]. Second, all studies in the dissertation are questionnaire-based. Although all surveys were anonymous, respondents may have given socially desirable answers. Third, all studies provide results which reflect the Belgian - or even by restriction the Flemish - situation which may hamper generalisability of research findings and practical recommendations.

One of the major strengths of the dissertation is the use of different study designs, including a narrative and systematic review, cross-sectional patient experience studies, a psychometric review, a validation study, and a large-scale patient safety culture assessment. Especially the conduction of two systematic reviews, provides a complete and exhaustive summary of the current scientific literature. A second strength is that large samples of healthcare professionals and patients were included in the explorative studies, allowing for robust findings and conclusions. Third, new information about patient safety in primary care and the circumstances under which integrated care models might be most effective is provided. A fourth strength is the inclusion of a mixed sample of chronic conditions in the cross-sectional patient experience studies. Furthermore, this dissertation validated the *Patient Assessment of Chronic Illness Care* survey in a Belgian (Flemish) population. Finally, the present dissertation is the first to document patient safety culture in a community-based primary care setting in Belgium (Flanders) and across the globe. An overview and critical appraisal of self-reported questionnaires and the psychometric testing of the SCOPE-Primary Care instrument methodologically support the large-scale patient safety culture assessment in two home care services.

IMPLICATIONS FOR PRACTICE AND HEALTH POLICY

Like most improvements in healthcare delivery, improving patient safety in primary care will probably be a slow process. This dissertation sets out some new fundamentals in how care and outcomes for chronic patients can be realised in a safe manner.

Further Promote Incident Reporting in Primary Care

Incident reporting is widely acknowledged as a key method to improve patient safety in healthcare and many countries or organisations established an incident reporting system. When more incidents are reported, and thus more information is available about what went wrong in the organisation, adequate actions can be taken to make healthcare delivery safer. That is why it is important that staff - both clinical and non-clinical - are confident enough to report all patient safety incidents. In its seven crucial steps to improve patient safety in primary care, the National Patient Safety Agency gives several tips to increase incident reporting: make it simple to report and communicate about incidents, ensure timely and valuable feedback, provide ongoing training sessions to explain the importance of incident reporting, inform all new staff, disseminate safety information, disseminate success stories, and ensure leadership support [15].

At the same time, there is an ongoing debate about the value of incident reporting systems and the need to shift the goal of reporting from outcome to learning [16]. To date, reporting systems are overwhelmed with reports, resulting in a lack of defining improvement strategies. Moreover, it is of key importance to engage all healthcare professionals in analysing incidents as it may change the way they think about safety risks and increase their vigilance [17].

Stimulate a Nonpunitive Approach to Incident Reporting

The aforementioned National Patient Safety Agency has identified seven crucial steps as a guide to improve patient safety in primary care [15]. These steps are founded on a thorough review of the literature from across the world. The first recommendation to improve safety in primary care is to build a positive patient safety culture in which every person recognises their responsibilities to patient safety. Patient safety is increasingly viewed as a failure of systems rather than of humans. There isn't a universally accepted definition of *patient safety culture* and discussions remain regarding the difference between *culture* and *climate*, making the concept difficult to understand. Nevertheless, patient safety culture assessments can provide useful information regarding inefficiencies in the organisation of care from which lessons can be learned to minimise incidents recurring.

When a patient safety incident occurs, staff is often afraid of being blamed or punished, which can influence their openness and thus the validity of their reports. Rather than punishing, employees should be consoled and supported (*psychological safety*). In other words, it is important not to look for an individual to blame, but to understand why and how the safety incident occurred in order to prevent recurrence and possible injuries in the future. Consequently, an essential condition for healthcare organisations is to be open and fair about incidents so lessons can be learned and patient safety be improved. An open and fair safety culture means that people are open and able to talk about incidents in a context where they are treated fairly and supported. When an incident occurs, a positive patient safety culture - in which leaders play an essential role - does not focus on the individual to blame, but rather on what went wrong in the system (i.e., systems approach) [18]. However, one must note that implementing a non-punitive approach does not mean that employees are dismissed from accountability. Some patient safety incidents do warrant individual accountability and justify punitive actions (e.g., errors made under the influence of drugs or alcohol).

Reduce Complexity and Move Towards More Integrated Care

Communication and coordination between healthcare professionals and settings remain complex issues which are especially vulnerable at the interfaces along the continuum of care. While the focus of this dissertation is on patient safety in primary care, the impact of transitions between the hospital and primary care settings cannot be overlooked. Indeed, patients are much more vulnerable when they move between different parts of the healthcare system, including transitions between the home environment, hospital, residential care settings, and consultations with different healthcare professionals from out-patient facilities [6]. Effective transitions from primary care to the hospital and vice-versa is essential, but are recognised as high-risk situations for patient safety and may result in an increase in mortality, morbidity, delays in receiving the appropriate treatment, emergency department visits, duplicated tests, and preventable readmissions to the hospital [19]. Additionally, elderly with complex health issues are at higher risk for safety incidents as they undergo multiple transitions of care [20]. Better continuity of care is therefore essential.

In the UK, a large study on 230.472 patient records found that patients who experienced higher continuity of care in general practice tended to experience fewer hospital admissions; that is a decrease of 6% in hospital admissions if these patients saw their general practitioner two or more times out of every ten consultations [21]. Studies also show a link between continuity of care and patient satisfaction [22]. Continuity of care has been shown to correlate with certain outcomes such as better adherence to medication, better control of blood sugar levels, and reduced emergency department visits [23-25].

Patient safety may also improve through the reorganisation of healthcare systems towards a more holistic, continuous, and patient-centred approach. Consequently, new and innovative approaches to care are needed to simultaneously improve quality of care, support financial sustainability, and respond to the increasing chronic care needs. Integrated care is one such solution. In a 24-month, multicentre, pragmatic cluster randomised controlled trial of 1.086 patients with chronic obstructive pulmonary disease, the PACIC 'follow-up/coordination' scale remained significantly higher in the integrated disease management program than in the control group [26].

Overall, a meta-review of systematic reviews and meta-analyses of integrated care programs for chronic conditions found beneficial effects of integration, including reduced hospital admissions and readmissions, improved adherence to treatment guidelines, and better perceived quality of life [27].

Despite increasing interest for integrated care, a widely accepted definition is lacking. A comprehensive review identified close to 180 definitions of terms and concepts that are relevant to one or several aspects of integrated care [28]. This situation has been described as '*the imprecise hodgepodge of integrated care*' [29]. Integrated care is an umbrella term, covering a variety of different concepts and programs that aim at fostering more coordination and continuity within and between healthcare services. The World Health Organization defined *integrated care* as: '*the management and delivery of health services such that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation, and palliative care services, through the different levels and sites of care within the health system, and according to their needs throughout the life course'* [30].

While one size will not fit all, evidence from countries with strong integrated care models show that healthcare services are more efficient; that is the likelihood of service duplication and hospital use is reduced, while patients' experiences and quality of life are improved [31]. However, strong commitment and involvement from all stakeholders - including hospitals - are required. Against a background of demographic changes and global economic pressures, it is abundantly clear that all healthcare systems need to invest in more integrated care. Hospitals will also play an important, but a fundamentally different role by providing services through horizontal networks with other hospitals, developing integrated care service models beyond the hospital boundaries, and working closely with local primary and community care facilities through vertical networks with a shared vision and strategy. Most case studies - such as the *High Risk Patient Programme* in the UK - give an indication of what may be possible when hospitals take a more proactive role in integrated care, such as a significant drop in avoidable hospital and emergency readmissions, a decline in preventable bed usage, a drop in bed usage among people with ambulatory care-sensitive conditions, and a reduction in length of hospital stay [32].

Invest in Health Information Technology

Within the rapidly shifting healthcare landscape from acute to chronic illness care and the broad spectrum of healthcare services and professionals needed for chronic patients, integrated care is a bedrock principle. Health information technology has the capacity to assist in improving communication and information sharing throughout the healthcare system; that is beyond the boundaries of a single healthcare setting, institution, or profession. The latter is essential in improving care transitions for the chronically ill [33]. A primary benefit of using health information technology in delivering healthcare is just the ability to ensure that real-time access to all necessary information is available at all stages in the healthcare process so transition of care is smooth and safe [34]. Health information technology can be defined as '*the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of healthcare information, data, and knowledge for communication and decision making*' and has three functionalities: digital storage of data, communication, and decision support [35].

Today, the range of possible health information applications is enormous and changes constantly, making it very dynamic. Health information technology encompasses electronic health records, e-prescriptions, computerised provider order entry systems (i.e., any system in which clinicians directly place orders electronically, directly transmitted to the recipient), picture archiving and communication systems, and videoconferencing for doctor appointments. Especially the use of electronic health records has greatly expanded in recent years [36]. Many have high hopes for health information technology. Lluch once stated that: '*the advantages of health information technologies over paper records are readily discernible to techno-enthusiasts: i.e., digital environment allow reliable and efficient storage, gathering and exchange of data, thus improving performance and quality of care, especially for patients with multiple chronic conditions*' [37].

Since 2000, it has often been claimed by policymakers that health information technology may address many quality and safety concerns in today's healthcare [38]. Nevertheless, there still remains a large gap between the theoretical and empirical benefits [39-41].

Electronic prescribing is able to reduce the number of medication errors by half in acute settings and electronic health records are associated with lower mortality rates in hospitals [42,43]. In addition, health information systems have the potential to reduce delayed, missed, or incorrect diagnoses [44]. Moreover, several reviews show positive results of health information technology such as declines in hospital admissions, length of hospital stays, emergency department visits, and mortality rates [45-48]. However, the rapid uptake of these technologies may have unintended consequences. New types of error may result from computerised provider order entry, alarm fatigue arising from proliferation of well-intended safety alerts, and problems with poor interoperability of different health record systems [49]. Health information technology has the potential to improve patient safety, but only if technology-specific risks can be minimised. Technology-related errors occur when health information applications are unavailable for use, malfunctions during use, are used incorrectly, or when they interact with another system, resulting in data being lost or incorrectly entered, displayed, or transmitted. These errors significantly increase organisational inefficiencies and the risk for patient harm [50].

Health information technology is not a stand-alone solution. As explained earlier, the care system in which these technologies will be implemented is likely to be characterised by care fragmentation. Worldwide, large budgets are being invested and the number of reviews and meta-analyses on health information technology has increased considerably in recent years. Indeed, health information technology which supports integrated care may create optimal conditions to improve patient safety. However, this reasoning only applies when well-implemented and state-of-the-art health information applications are used.

Give Patients a More Active Role in their Care

The role patients can play in promoting safety and reducing adverse events is an international policy priority. In its *Technical Series on Safer Primary Care*, the World Health Organization emphasises the engagement of patients and families [51] and the Institute of Medicine identified patient-centredness as an essential component for delivering high-quality care [38]. Patients have an essential role as co-producers of care as they are the only consistent factor throughout the care continuum.

Feedback from patients gives insight into their needs and preferences which can be collected through surveys (e.g., *Patient Measure of Safety Tool* or *Patient Incident Reporting Tool*), interviews, or focus groups. Moreover, plenty of evidence indicates that patients are willing and able to participate in incident prevention strategies [9].

Tapping into such a rich information source could contribute in improving patient safety in primary care [52]. However, research is lacking as systematic reviews concluded that there is limited and poor quality evidence that patient engagement may benefit patient safety [53-55]. Furthermore, resources may be better used if they align with the patients' needs, which is critical for the future sustainability of healthcare systems across the world. Patients provide key information on care processes since quality of care from the patients' perspectives involves other dimensions such as access to and continuity of care. An 11-countries multinational consumer survey study found that an increase in respondents' perceptions of care coordination decreased the odds of self-reporting medication errors and laboratory errors, suggesting the importance of guaranteeing integrated care [56].

Primary care services are increasingly at the heart of integrated people-centred care. Person-centred integrated care can help to realise the *Triple Aim* goals; that is improving population health, increasing quality of care, and lowering healthcare-related costs. The challenge is to maintain this holistic and person-oriented character. To enable, healthcare services must be open and receptive to engaging with patients. However, reviews identified several factors that potentially affect patient engagement in safety, namely the patient himself (e.g., demographic characteristics or health literacy), health conditions (e.g., illness severity), healthcare professionals (e.g., knowledge and attitude), and the healthcare settings (e.g., primary or secondary care) [57]. Additionally, healthcare professionals' barriers to include patients' perspectives are the lack of support for patient-centred care and the low value attached to patient involvement [58].

Although there is no clear evidence on the most effective intervention to engage patients in a safer primary care [59], research suggests three broad categories: educating patients and healthcare professionals [60], obtaining retrospective feedback from patients (e.g., through surveys or formal event-reporting systems for patients) [61], and engaging patients for improvements in systems or services (e.g., patient advisory committees) [62]. Additionally, there are a number of tools available to encourage patients to play an active role in preventing errors and system failures. For example, the US Joint Commission developed an approach known as *Speak Up* (Speak up if you have any questions or concerns, Pay attention to the care delivered, Educate yourself, Ask a trusted family member to be your advocate, Know what medicines you are taking, Understand more about the organisation, and Participate in all decisions), which is a useful framework for engaging patients in their safety [15].

Structurally Integrate Patient Safety in Healthcare Education

Patient safety education remains largely absent from education in many healthcare settings. For instance, a survey of 125 medical schools in the USA found that only 10% had patient safety content in elective or required courses [63]. Possibly the most important approach to improve patient safety - which is highly important, but poorly implemented - is integrating patient safety in the education and ongoing professional development of healthcare professionals from all disciplines.

Healthcare professionals do their best to provide safe care, but they need the right skills and resources to identify risks and reduce potential harm due to gaps in knowledge and skills [51]. In a survey of primary care professionals and researchers, education and training was considered as one of the most important strategies to improve patient safety in primary care [64]. There are three main types of education to support a safer primary care; that is [1] pre-service education for trainee healthcare professionals in technical skills, preventive care, diagnostics, and therapeutic care, [2] in-service education for practising healthcare professionals to maintain competencies and knowledge on the latest guidelines or evidence-based initiatives, and [3] patient education and awareness raising [51].

The *Multi-Professional Patient Safety Curriculum Guide* of the World Health Organization suggests that 11 topics about patient safety should be included in all healthcare education [65]:

1. What is patient safety;
2. Why applying human factors is important for patient safety;
3. Understanding systems and the effect of complexity of care;
4. Being an effective team player;
5. Learning from errors to prevent harm;
6. Understanding and managing clinical risks;
7. Using quality improvement methods to improve care;
8. Engaging patients and caregivers;
9. Infection prevention and control;
10. Patient safety and invasive procedures;
11. Improving medication safety.

As the World Health Organization stated: '*ensuring that the core characteristics of primary care are included in the education process of all healthcare professionals will help to build a healthcare culture where safety and quality are valued because they are central to the patient well-being*' [51].

RECOMMENDATIONS AND SUGGESTIONS FOR FUTURE RESEARCH

First, patient safety in primary care remains a significantly under-researched issue that does not receive the priority and funding that it warrants. This slower uptake may relate to the perception that primary care is a relatively low-risk environment where the frequency of adverse events is lower and where technology is much less used compared to hospital-based care. However, patient factors (e.g., increasingly complex co-morbidities and polypharmacy) and practice factors (e.g., workload) have resulted in an increased potential for medical incidents in primary care. Consequently, more research on the commonest forms of patient harm and their underlying causes in primary care is urgently needed.

First, a clear and detailed clarification of core concepts relating to safety in primary care is required. In literature, many definitions of *patient safety*, *harm*, and *preventability* are used, possibly hampering comparison between studies and the development of improvement strategies. Consequently, the research field urgently needs a unique international terminology and classification system. In addition, prospective mixed-methods approaches are promoted to identify the underlying causes of patient safety incidents in primary care by triangulating evidence from different sources; that is healthcare professionals' feedback, medical records, and patient-reported information. Indeed, it is only by understanding how patient safety incidents occur that learning can be derived.

Second, major gaps in the understanding of patient safety in primary care is largely due to the lack of appropriate measurement methods. Current tools almost exclusively focus on healthcare professionals' reporting. Nevertheless, a large body of evidence points out towards patients as a reliable source of information to detect problems in healthcare [66]. Capturing patients' experiences of safety incidents is however challenging. To date, no single validated tool currently measures patients' experiences of safety incidents in primary care. A recent systematic review of patient-reported safety measures showed that such tools mainly focus on a few relevant dimensions - such as medication - rather than providing a comprehensive assessment of safe care [67]. Moreover, the physical, financial, and psychological harm to patients resulting from safety incidents are sparse [68]. Recently, the *Patient Reported and Outcomes of Safety in Primary Care* (PREOS-PC) was developed in a multistage process, supported by an international expert panel, systematic review of instruments, meta-synthesis of qualitative studies, four patient focus groups, 18 cognitive interviews, and a pilot study [69]. The trial version of the PREOS-PC survey covered five domains; that is 'practice activation', 'patient activation', 'experiences of patient safety events', 'harm', and 'general perceptions of patient safety'. The questionnaire was posted to 6.736 patients in 45 practices across the UK and showed potential for use in primary care. Moreover, the triangulation of in-depth interviews, focus group discussions, and surveys with free-text options offer patients the opportunity to report medical events. Finally, the approach of engaging patients also makes part of an open culture in which communication is important and patients can be more assertive [70].

Third, a triangulation of quantitative and qualitative techniques is recommended to fully assess patient safety culture in primary care. Perceptions can be measured by using quantitative questionnaires, individual behaviour can be assessed by observation, and more underlying aspects of safety culture can be examined by qualitative methods such as in-depth interviews. Additionally, research indicated that educational workshops are valuable additions to questionnaires as risk awareness arise and patient safety is more discussed in an open atmosphere [71].

Furthermore, future research should examine the extent to which patient safety perceptions are related to specific patient outcomes on the one hand and focus on enriching scientific evidence on the effectiveness of strategies aimed at improving patient safety culture on the other hand. For primary care, it is not clear what the effect of possible interventions is on patient safety culture [71,72].

CONCLUSIONS

Twenty-five years ago, the field of patient safety barely existed. Undoubtedly, there have been considerable efforts made in the last decade to improve the safety of healthcare delivery. Research regarding the epidemiology of patient safety incidents and harm, the causes and contributory factors, and the potential solutions are mostly hospital-based. Nevertheless, care provided in community-based primary care will become increasingly important to cope with the rise in chronic conditions, but has not been addressed in a systematic manner. We can foresee that healthcare systems around the globe will change dramatically in the way they are organised and the way care is delivered towards more integrated healthcare services along a transmural pathway. For the future, we need a healthcare paradigm shift from fragmented, provider-centred, hospital-centralised care with a focus on threatening sickness towards integrated, patient-centred, and community care with a focus on preventing sickness [6].

Within the wider healthcare system, future progress will require a broader vision of patient safety. As we now consider patient safety in primary and community care settings, we have to look at the whole patient journey and thus expanding the perimeter of safety.

Probably the greater danger to patients comes from the cumulative impact of minor problems along the care continuum. As Vincent and Amalberti stated: '*patient safety becomes the management of risk over time as the patient and family move through the healthcare system*' [6].

To conclude, we formulated concrete implications for practice and health policy:

1. Promote incident reporting in primary care;
2. Stimulate a nonpunitive approach to incident reporting;
3. Reduce complexity and move towards more integrated care;
4. Invest in health information technology;
5. Give patients an active role in their care;
6. Integrate patient safety in the education of healthcare professionals.

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Nederlandstalige samenvatting

Door de vergrijzing, langere levensduur van de bevolking en de evolutie van medische technologieën (zowel inzake diagnostiek en behandeling) neemt ook het aantal chronische patiënten toe. De zorgnoden van patiënten met chronische aandoeningen zijn vaak divers en evoluerend in tijd. Hierdoor beslaat chronische zorg verscheidene gezondheidszorgdomeinen, met als gevolg dat het aantal zorgprofessionals (vanuit diverse disciplines), die betrokken zijn in de zorg van de patient, toeneemt. Coördinatie en goede afstemming van zorgnoden vormt een belangrijke uitdaging in de praktijk en in het bijzonder tijdens de transfer tussen en binnen zorgorganisaties.

FRAGMENTATIE VAN ZORG

Vanuit het patiëntenperspectief zijn er echter nog heel wat breuklijnen in de veelal gefragmenteerde zorgprocessen. Communicatie en informatiedeling vormen dan heel vaak de zwakke schakel. Een gebrek aan coördinatie en continuïteit kan echter leiden tot suboptimale zorg en zo ook de veiligheid van patiënten in gevaar brengen; en dit in termen van medicatiefouten en ziekenhuisopnames. Investeren in de ontwikkeling van nieuwe zorgconcepten en -modellen in goede afstemming met patiënten en zorgprofessionals en die bovendien optimaal gebruik maken van nieuwe technologische mogelijkheden, is meer dan ooit noodzakelijk. Maar zorgzaamheid in de aanpak is aangewezen, want dergelijke nieuwe zorgconcepten en -modellen kunnen ook patiëntveiligheidsrisico's introduceren of bestaande risico's versterken. Patiëntveiligheid vereist dan ook expliciete aandacht, zowel in het ziekenhuis en in de eerstelijn alsook doorheen het transmuraal zorgtraject.

PATIËNTVEILIGHEID IN DE EERSTELIJNSGEZONDHEIDSZORG

De opmars van patiëntveiligheid ontwikkelde zich in eerste instantie in ziekenhuizen, maar inmiddels zijn ook andere sectoren in de gezondheidszorg hier volop mee bezig. Ook in de eerstelijnsgezondheidszorg zijn een aantal dossieronderzoeken uitgevoerd naar de incidentie van zorggerelateerde schade en de mogelijke vermijdbaarheid. Het aantal incidenten in de eerstelijn wordt geraamd op twee tot drie per 100 consultaties, waarvan 4% kan leiden tot schade voor de patiënt. Wanneer we deze cijfers extrapoleren naar België, zouden er dagelijks 25 incidenten met schade (*adverse events*) voorvallen in de huisartsenpraktijken alleen. Het grootste deel van deze incidenten wordt veroorzaakt door gebrekkige communicatie tussen zorgverleners onderling en/of met de patiënt, maar ook factoren gerelateerd aan administratie, medicatie en diagnostiek spelen een belangrijke rol.

PATIËNTVEILIGHEIDSCULTUUR: VAN EEN ONTKENNENDE NAAR EEN AANSPREEKCULTUUR

Zorgprofessionals en leidinggevenden spelen uiteraard ook een belangrijke rol in het waarborgen van veilige zorg. Ze werken immers niet solitair, maar in een dynamisch systeem waarin iedereen een rol heeft in het realiseren van verantwoorde en veilige zorg. Het nakomen van afspraken, goed onderling samenwerken rond de patiënt, efficiënte communicatie, adequate informatieoverdracht en goede coördinatie van zorg zijn essentiële voorwaarden om vermijdbare schade voor de patiënt te voorkomen. Deze elementen hebben vooral te maken met attitude en gedrag van zorgprofessionals rond patiëntveiligheid. Het onderwerp van veiligheidscultuur heeft de afgelopen 15 jaar sterk aan belang gewonnen in de gezondheidszorg. Een belangrijke stap richting veilige zorg is dan ook het ontwikkelen van een open en constructieve veiligheidscultuur, zeg maar de perceptie en attitude van zorgverleners omtrent patiëntveiligheid.

Veiligheidscultuur is een concept dat vooral bekend is in de luchtvaartsector, maar het begrip wint ook binnen de gezondheidszorgsector aan belang. Een positieve veiligheidscultuur wordt gekenmerkt door openheid en transparantie, waarbij zorgverleners worden gestimuleerd om incidenten te melden en waaruit lessen getrokken worden om ze in de toekomst te vermijden. Het verbeteren van de aanspreekcultuur is nog steeds een grote uitdaging. Uiteindelijk willen we streven naar een intrinsieke verbetercultuur.

AANBEVELINGEN

Iedereen moet uitdragen dat patiëntveiligheid een belangrijk thema is. Zorg zal nooit 100% veilig zijn, maar door samen en vanuit ieder zijn eigen discipline kunnen we de risico's zo laag mogelijk houden. Hieronder formuleren we nog enkele concrete aanbevelingen:

1. Promoot incidentenrapportering in de eerstelijn;
2. Stimuleer een open, constructieve, lerende en niet-bestraffende cultuur;
3. Reduceer complexiteit en streef naar meer geïntegreerde zorg;
4. Investeer in goed uitgebouwde *eHealth*-initiatieven, waaronder een gedeeld elektronische patiëntendossier;
5. Stimuleer zoveel als mogelijk de proactieve rol van patiënten;
6. Integreer patiëntveiligheid in de opleiding van alle zorgprofessionals.

***Zie ook**: Desmedt, M., Vandijck, D. & Hellings, J. Patiëntveiligheid in een goed onderling afgestemde (eerstelijns)zorg. In: Van Hootegem, G. & Dessers, E. (reds); Onbezorgd – leven en werken in een geïntegreerd gezondheidssysteem. 2017: 135-156. Acco: Leuven.*

Additional Paper

Integrating and Safeguarding Care: The Potential Role of Health Information Technology

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SUMMARY

The increasing burden of chronic diseases is one of the greatest challenges healthcare systems globally are facing. Across the world, compelling demands can be found for a fundamental shift in the organisation of health and social care to meet the needs of chronic patients. Integrated care has gathered momentum to overcome fragmentation of care in order to create care systems which are demand-driven, client-centred and cost-conscious. Health information technology - often referred to as eHealth - is usually considered to be an essential building brick of integrated care. Moreover, health information technology is said to hold potential for improving patient safety in chronic care settings. The current perspective paper explores the role of health information technology in integrating and safeguarding care. We argue that health information technology - which supports integrated care - may create optimal conditions to improve patient safety, but only when well-implemented, state-of-the-art technologies are used.

INTRODUCTION

Rapidly aging populations and the related rise in chronic care needs represent major challenges for healthcare systems worldwide. As a consequence, several countries are experimenting with new models of care delivery. Integrated care is seen as an important new approach allowing healthcare systems to cope with the aforementioned challenges and which is aimed at more coordination and continuity of care [1]. Health information technology (HIT) - often referred to as *eHealth* - is usually considered to be an essential building brick of integrated care as it allows healthcare professionals to better manage and coordinate patient care through the secure use and sharing of health-related information. By making health information electronically available when and where it is needed, HIT may also improve patient safety in chronic care settings. After all, the rising number of chronic patients shifts the balance of care delivery from secondary to primary healthcare [2]. Poor care transitions at the interface between secondary and primary care may introduce new patient safety risks such as adverse drug events or hospital readmissions [3].

The current perspective paper explores the role of health information technology in integrating and safeguarding care. The article consists of six parts. The first part sets the context of the rising chronic care needs. In the second part, the prospect of integrated care to meet these rising needs is discussed. The third part of the paper discusses the potential role of health information technology in integrating and safeguarding chronic care delivery. This potential role is illustrated by discussing HIT initiatives in Belgium in part four. Based on the previous parts, some implications for practice are formulated in part five and the paper ends in part six with some concluding remarks.

RISING CHRONIC CARE NEEDS

In recent decades, tremendous progress has been made in healthcare. The improvement in life-threatening conditions resulted in large falls in death rates for many communicable diseases that includes HIV/AIDS, heart attacks and strokes. The progress in healthcare is worthy of praise, but the future sustainability of healthcare systems is nevertheless jeopardized.

Due to an aging population, globalisation and unhealthy lifestyles, the increasing burden of chronic diseases is one of the greatest challenges healthcare systems around the globe are facing. Although *overall* life expectancy of the world population rose with 10.1 years between 1980 and 2015, *healthy* life expectancy only gained 6.1 years during the same period, resulting in more years of life with illness and disability. The burden of ill health has shifted from communicable, maternal, neonatal, and nutritional disorders (including HIV/AIDS, malaria and lower respiratory infections) to disabling non-communicable diseases such as cancer, ischaemic heart diseases and osteoarthritis [4].

Chronic care is often complex, both clinically and on the organisational level. It is the sum of different care needs, usually answered by different health and social care professionals and organisations. Chronic care has been developed in ways that have tended to fragment care delivery - within and between healthcare settings - and which is largely built around the long-standing acute and episodic model of care. Yet, chronic patients are in high need of a broad range of professionals and skills from different healthcare settings and practices which are offered as integrated and coordinated services, embedded within a system that promotes patient empowerment. Moreover, a lack of integration and coordination may endanger patient safety in terms of potentially preventable hospitalisation or adverse drug events [5,6]. Hence, fragmentation of care poses a major challenge for chronic care delivery.

INTEGRATED CARE

Across the world, compelling demands can be found for a fundamental shift in the organisation of health and social care to meet the needs of chronic care patients. For instance, the World Health Organization (WHO) calls for a fundamental shift in the way healthcare services are delivered to '*integrated people-centred health services that puts the needs of people and communities at the centre of health systems and empowers people to take charge of their own health*' [7]. The Lucian Leape Institute - established by the US National Patient Safety Foundation - identified five concepts as fundamental to endeavor meaningful improvements in care delivery: transparency, patient engagement, restoration of joy and meaning in work, medical education reform, and finally *care integration* [8].

Integrated care has gathered momentum to overcome fragmentation of care in order to create healthcare systems which are demand-driven, client-centred and cost-conscious. Integrated care is defined by the WHO as '*the management and delivery of health services such that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation and palliative care services, through the different levels and sites of care within the health system, and according to their needs throughout the life course*' [7]. Integrated care is driven by the so-called Triple Aim approach; that is a simultaneous focus on cost-savings, better patient care experiences and improved health outcomes [9]. Numerous studies have revealed that integrated care indeed has the potential to improve quality of patient care, reduce fragmentation of care and control costs [10,11]. Consequently, care integration is needed to provide chronic care patients with high-quality and efficient care across time and across various healthcare settings involved.

To date, the implementation of integrated care is a challenge for many in daily practice. There is no one-size-fits-all model for successful integrated care, nor is there a firm empirical foundation for specific strategies. Several guidelines and redesign models are available, but few consist of a whole-systems approach [12-15]. In recent years, integrated care literature moved away from disease-specific care integration towards population-based care integration.

Policymakers, care organisations, patients, and other stakeholders reconfigure care systems on the basis of medical-demographic prognoses for the population within a particular geographic area. Yet, many questions remain regarding the practical organisation of whole-system integrated care and inherently the role of health information technology. One can learn not only from guidelines, but also from ongoing experiences to improve healthcare delivery. There has been an increase in initiatives to encourage professional partnerships such as *Integrated Care Strategies* in Australia [16], *New Care Models and Integrated Care Pioneers* in England [17] and *Population Health Management Pilots* in the Netherlands [18].

HEALTH INFORMATION TECHNOLOGY

As mentioned before, healthcare systems are at risk due to the increasing burden of chronic diseases, spiraling costs, inconsistent quality of care, and poorly coordinated care processes. In response, policy makers are constantly searching for suitable strategies, one of which consists of investing in health information technology. Health information technology (HIT) can be defined as '*the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of healthcare information, data, and knowledge for communication and decision making*' and has three functionalities: digital storage of data, communication and decision support [19]. Today, the range of possible health information technologies is enormous and changes constantly, making HIT very dynamic. HIT encompasses electronic health records, e-prescriptions, computerised provider order entry systems (i.e., any system in which clinicians directly place orders electronically, directly transmitted to the recipient), picture archiving and communication systems, and videoconferencing for doctor appointments. Especially the use of electronic health records has greatly expanded in recent years [20].

There are many barriers to the adoption and implementation of HIT such as the lack of connectivity between healthcare professionals from different settings, the lack of shared goals related to care transitions, misaligned incentives, the challenge of health literacy in engaging patients and their family caregivers, and issues of trusts [21]. Nevertheless, many have high hopes for health information technology.

Lluch once stated that: '*the advantages of health information technologies over paper records are readily discernible to techno-enthusiasts: i.e., digital environment allow reliable and efficient storage, gathering and exchange of data, thus improving performance and quality of care, especially for patients with multiple chronic conditions'* [21]. The following two parts of the present paper will explore this potential role of health information technology, first for integrated care and then for patient safety.

HIT and Integrated Care

Within the rapidly shifting healthcare landscape from acute to chronic illness and the broad spectrum of healthcare services and professionals needed for chronic patients, integrated care is a bedrock principle. After all, care episodes of chronic patients often indicate the involvement of multiple healthcare settings and professionals, with little or no communication between them. Health information technologies have the capacity to assist in improving communication and information sharing throughout the healthcare system; that is beyond the boundaries of a single healthcare setting, institution or professional. The latter is essential in improving care transitions for the chronically ill. A *primary* benefit of using HIT in delivering healthcare is just the ability to ensure that real-time access to all necessary information is available at all stages in the healthcare process so transition of care is smooth and safe [22]. A *second* benefit of HIT is the facilitation of medication reconciliation. Schnipper *et al*. demonstrated a reduction in unintentional medication discrepancies using IT in conjunction with a medication reconciliation process redesign compared to no IT support [23]. In addition, several reviews show positive results of health information technologies in integrated care such as declines in hospital admissions, length of hospital stays, emergency department visits, and mortality rates [24-27].

A case study across eight different European countries (Denmark, Estonia, Germany, France, Italy, the Netherlands, Spain, and the UK) found that health information technologies were strongly in line with developments towards integrated care delivery [28]. Moreover, HIT enabled the sharing of relevant health-related information between healthcare professionals which is crucial in closing the gaps between fragmented areas in health and social care.

By making information sharing possible along the care continuum, HIT becomes an enabler of integrated care models [29]. According to Bauer *et al.*, effective HIT is vital for the delivery of effective integrated care. Health information technologies support patient-centred, evidence-based, measurement-based, and accountable care.

Moreover, HIT potentially improves health literacy, explains and offers treatments to patients and incorporates them into electronic health records, monitors outcomes systematically and adjusts treatments, tracks a defined population of patients, allows providers to target care towards patients who are in the greatest need, and finally aggregates data on clinical processes and patient outcomes to support quality improvements [30]. On the opposite, several studies show negative consequences of HIT. Steventon *et al*. found that telecare did not lead to significant reductions in service use compared to regular care in the UK [31]. Chaudry *et al*. concluded that telemonitoring did not improve outcomes such as hospitalisation and mortality for patients with heart failure [32].

HIT and Patient Safety

Since 2000, it has often been claimed by policymakers that health information technology may address many quality and safety concerns in today's healthcare [33]. Nevertheless, there still remains a large gap between the theoretical and empirical benefits of HIT applications [34-36]. Electronic prescribing is able to reduce the number of medication errors by half in acute settings and electronic health records are associated with lower mortality rates in hospitals [37,38]. In addition, HIT systems have the potential to reduce delayed, missed or incorrect diagnoses [39]. However, the rapid uptake of health information technologies may result in unintended consequences. New types of error may result from computerized provider order entry, alarm fatigue arising from proliferation of well-intended safety alerts and problems with poor interoperability of different health record systems [40]. HIT has the potential to improve patient safety, but only if technology-specific risks can be minimized. Technology-related errors occur when health information technologies are unavailable for use, malfunctions during use, are used incorrectly, or when they interact with another system which may result in data being lost or incorrectly entered, displayed or transmitted. These errors significantly increase organisational inefficiencies and the risk of patient harm [41].

In conclusion, the effect of health information technology in integrated care has not been shown unequivocally and a number of questions still remain regarding the impact on patient safety in healthcare delivery. As explained earlier, the care system in which health information technologies are implemented is likely to be characterised by care fragmentation for which integrated care is being advanced as a possible solution, hopefully leading to improved health outcomes and patient safety. In conclusion, HIT is not a stand-alone solution. There are other important preconditions for organising care integration, such as legislation (e.g., responsibilities of healthcare professionals), financial incentives (e.g., pay for coordination) and developing competence (e.g., healthcare professionals become skilled in multidisciplinary working).

THE BELGIAN CASE

The federal state of Belgium encompasses three Regions (Flanders, Wallonia and Brussels) and three Communities (the Flemish, French and German-speaking Community). Since 1980, parts of the responsibilities for health policy have gradually moved from the federal government to these sub-national authorities. In Belgium, over one quarter of the population (27.2%) reports to have a chronic disease, mainly back pain (17.7%), allergies (13.0%), joint diseases (12.7%), hypertension (12.7%), neck pain (9.4%), headaches (8.1%), and respiratory disorders (7.9%). Unfortunately, these chronically ill patients often suffer from multimorbidity as well: 50 to 70% of individuals over the age of 70 have at least two chronic conditions [42]. Moreover, the increasing prevalence of chronic patients places a high financial burden on the healthcare system. In 2015, Belgium devoted 10.4% of the gross domestic product (GDP) to healthcare which is higher than the OECD average of 9% [43].

Belgium carries out considerable actions to reform the health technological landscape. In 2012, it launched the project *eGezondheid* (in English *eHealth*) that includes several actions to facilitate health information technology by 2019 [44].

These actions include the development or improvement of a summarized electronic health record, electronic patient records in hospitals, medication schedules, electronic prescribing, Resident Assessment Instrument (BEL-RAI), legal frameworks and financial incentives, personal health records, eHealth education, national taxonomy, and a governance structure. Recently, the federal government invested €3.50 million in 24 pilot projects. The aim of the funding is to test the use of applications and mobile devices in practice.

Furthermore, numerous HIT applications have already been developed and implemented, both on the federal and on the regional level [45]. At the federal level, eHealth Platform, Hubs & Metahubs, eHealth Box, eHealth Consent, Recip-e, and MyCareNet were launched. The *eHealth Platform* - founded in 2008 - is a federal public service which provides an electronic platform devoted to data exchange between all stakeholders in healthcare, including professionals, facilities and patients. The ultimate goal of the platform is to improve the quality and continuity of care, simplify administration and contribute to healthcare policy. It is a federal health network that respects medical confidentiality and guarantees information security and privacy protection. The eHealth Platform is not a central data storage, but it implies a controlled access to decentralized databases and uses encrypted personal data. Furthermore, a *hub* is a central system in which hospitals can collect patient information. *Metahubs* connect these individual hubs. The *eHealth Box* is an electronic mailbox for all actors in healthcare. Patients are not able to send messages to healthcare professionals, but can receive all relevant documents. Through *eHealth Consent*, patients are able to give their informed consent for the electronic exchange of their health-related information. The application *Recip-e* provides electronic prescribing and *MyCareNet* facilitates digital communication with healthcare insurance. In addition to these federal initiatives, each of the three regions in Belgium also developed a digital platform to facilitate communication and information exchange between healthcare actors: *Vitalink* (Flemish region), *Inter-Med* (Walloon region) and *BruSafe* (Brussel-Capital region).

Despite these considerable efforts, critical comments are formulated regarding the rather slow transformation of the eHealth project (suggesting that 2030 would be a more realistic time limit for the reform rather than 2019), the limited role of patients in eHealth applications, the absence of explicit procedures for sanctions in case of unauthorized access, the number of healthcare professionals in minority, and the absence of patients' representatives in the eHealth Board [45,46]. Furthermore, one could argue that HIT initiatives are generally not firmly embedded in broader efforts to realise effectively integrated care.

The initiatives listed above not only show potential overlap, but to a certain extent also seem to take the current highly fragmented care delivery system as a given. There is a plethora of HIT initiatives in Belgium that lack coordination in terms of their design and operation. A policy framework is therefore essential, especially in the context of more hospital collaborations in Belgium where different electronic health records are still being used. This also occurs in other healthcare systems around the globe as HIT initiatives are often developed through the succession of uncoordinated projects that are not harmonized with the public health system [47].

IMPLICATIONS FOR PRACTICE

Recent healthcare policies encourage the adoption of health information technology as it may improve processes of care and patient outcomes. Indeed, evidence - such as the Chronic Care Model of Wagner [48] - emphasize the use of HIT as a wider strategy to overcome inconsistent quality and fragmentation of care. A comprehensive and integrated care delivery approach is required in which health information technology operates as a building brick and where special attention is given to the quality and safety of care as well as to the quality of working life of healthcare professionals. Health information technology can facilitate better coordination between healthcare professionals and the patient, resulting in more integrated care and thus less fragmentation. Following, improved access to care is an important benefit of HIT, especially for countries with chronic shortages of healthcare professionals which tackle the challenge of providing patient care to people over a broad geographical area [47]. HIT should be implemented in a way that supports integrated care by giving care teams more autonomy and stimulating self-management of the patient.

Furthermore, HIT-supported integrated care models may create optimal conditions to improve patient safety by integrating safety-related competences and responsibilities in the healthcare team. However, this reasoning only applies when well-implemented, state-of-the-art health information technologies are used. For example, healthcare professionals have not fully embraced HIT due to barriers such as the structure of the healthcare organisational system (with often strong hierarchical traditions, lack of cooperation and teamwork in care delivery, cultural barriers, and autonomy issues), tasks definitions (i.e., still largely traditional, task-focused and provider-centred care), people policies (including lack of training, IT literacy, time, support, trust, and legal frameworks), incentives (e.g., lack of adequate funding), and information and decision processes (including workload concerns) [21]. In addition, patients mention as barriers the lack of additional benefits, the conviction that only regular care is efficient, technological difficulties, and the high degree of dependency of ICT [49]. With these barriers in mind, it is of great importance to refine high-functioning and interoperable HIT initiatives. Moreover, empowering healthcare professionals and patients with the knowledge and skills to use health information technologies and sharing examples of best practices may increase the use of HIT.

A second example are the security risks that may also curb the dissemination of health information technology. The level of trust patients and professionals have in these technologies can significantly be reduced due to technical software failures, professionals having unauthorized access to electronic health records of all patients, hackers invading the IT-system, vulnerable authentication, and database matching [1]. Initiatives to improve the protection of health-related information are needed. Several guidelines and new frameworks - for example the SAFER guidelines and the Health IT Safety (HITS) framework - can provide conceptual foundation for HIT-related patient safety measurement, monitoring and improvement [33,50]. In particular the WHO National eHealth Strategy Toolkit is a practical guide that provides governments and stakeholders with a solid foundation and method for developing and implementing a national eHealth strategy in three stages; that is developing a national eHealth vision that responds to health and development goals, defining a roadmap that reflects country priorities and the eHealth context and establishing a plan to monitor implementation and to manage associated risks [51].

CONCLUSIONS

Managing the increasing prevalence of chronic care needs is one of the most important challenges healthcare systems are facing. Health information technology is often considered efficacious for integrating and safeguarding care. Worldwide, large budgets are being invested and the number of reviews and meta-analyses on HIT has increased considerably in recent years. Indeed, health information technology which supports integrated care may create optimal conditions to improve patient safety. However, this reasoning only applies when well-implemented and state-of-the-art health information technologies are used.

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Questionnaires Used

PATIENTS' PERSPECTIVES (PART II)

Persoonlijke kenmerken

1. Geslacht: ☐ Man ☐ Vrouw
2. Leeftijd: .... jaar
3. Postcode: ....
4. Burgerlijke staat : ☐ Gehuwd of samenwonend

   ☐ Alleenstaand (nooit gehuwd, weduwe(naar) of gescheiden)
5. Hoogste diploma?

   ☐ Lager onderwijs

   ☐ Secundair onderwijs

   ☐ Hoger niet-universitair onderwijs

   ☐ Universitair onderwijs
6. Welke chronische aandoening heeft u? (Meerdere selecties mogelijk)

   ☐ Lage rugprobleem

   ☐ Nekprobleem

   ☐ Hoog cholesterolgehalte

   ☐ Hoge bloeddruk

   ☐ Allergie

   ☐ Artrose

   ☐ Artritis

   ☐ Diabetes

   ☐ Ernstige hoofdpijn

   ☐ Astma

   ☐ Chronisch longlijden

   ☐ Multiple sclerosis

   ☐ Kanker

   ☐ Andere (welke?) ....
7. Heeft u nog andere aandoeningen?

   ☐ Ja (welke?) ....

   ☐ Neen

Zorgomkadering

Hoeveel keer kwam u de **afgelopen 6 maanden gemiddeld** in contact met volgende zorgverleners? (Indien niet van toepassing, is het antwoord "0").

8. **Aantal** bezoeken aan of door uw **huisarts**: .... keer **per maand**
9. **Aantal** bezoeken aan een **specialist**: .... keer **per maand**
    i. Welk specialisme (bv. neuroloog, longarts, …)? ....
10. **Aantal** bezoeken **per week** bij:
    i. Kinesitherapeut: .... keer per week
    ii. Ergotherapeut: .... keer per week
    iii. Logopedist: .... keer per week
    iv. Diëtist: .... keer per week
    v. Podoloog: .... keer per week
    vi. Andere (welke?): ....: .... keer per week
11. **Aantal** bezoeken door de **thuisverpleegkundige**: .... keer **per week**
    i. Welke zorgen krijgt u dan toegediend? (Meerdere selecties mogelijk)

    ☐ Toiletzorg/hygiënische zorgen/wassen en kleden

    ☐ In en uit bed helpen, hulp bij verplaatsingen en transfers

    ☐ Wondzorg/verbanden aan- of uitdoen

    ☐ Klaarzetten en/of toedienen medicatie

    ☐ Inspuitingen

    ☐ Zorg rond stoma's, blaassondes

    ☐ Andere (welke?): ....
12. Aantal uren **gezinshulp per week**: .... **uren**
13. Aantal uren **mantelzorg** van familie (inclusief partner, kinderen en ouders), buren en kennissen krijgt u gemiddeld **per week**: .... **uren**
14. **Duur** van de **(thuis)zorg en ondersteuning**:

    ☐ Minder dan 6 maanden ☐ 6 maanden tot 1 jaar ☐ Meer dan 1 jaar
15. Gaat u regelmatig naar een **dagcentrum**? ☐ Ja .... keer **per week** ☐ Neen

Gezondheidstoestand

Vink onder elke titel het **ENE** vakje aan dat het best uw gezondheid **vandáág** beschrijft.

(Slechts één selectie mogelijk)

Mobiliteit

☐ Ik heb geen problemen met rondwandelen

☐ Ik heb een beetje problemen met rondwandelen

☐ Ik heb matige problemen met rondwandelen

☐ Ik heb ernstige problemen met rondwandelen

☐ Ik ben bedlegerig

Zelfzorg

☐ Ik heb geen problemen met mijzelf te wassen of aan te kleden

☐ Ik heb een beetje problemen met mijzelf te wassen of aan te kleden

☐ Ik heb matige problemen met mijzelf te wassen of aan te kleden

☐ Ik heb ernstige problemen met mijzelf te wassen of aan te kleden

☐ Ik ben niet in staat mijzelf te wassen of aan te kleden

Dagelijkse activiteiten

(Bijvoorbeeld: werk, studie, huishouden, gezins- of vrijetijdsactiviteiten)

☐ Ik heb geen problemen met mijn dagelijkse activiteiten

☐ Ik heb een beetje problemen met mijn dagelijkse activiteiten

☐ Ik heb matige problemen met mijn dagelijkse activiteiten

☐ Ik heb ernstige problemen met mijn dagelijkse activiteiten

☐ Ik ben niet in staat mijn dagelijkse activiteiten uit te voeren

Pijn/klachten

☐ Ik heb geen pijn of andere klachten

☐ Ik heb een beetje pijn of andere klachten

☐ Ik heb matige pijn of andere klachten

☐ Ik heb ernstige pijn of andere klachten

☐ Ik heb zeer ernstige pijn of andere klachten

Angst/depressie

☐ Ik ben niet angstig of depressief

☐ Ik ben een beetje angstig of depressief

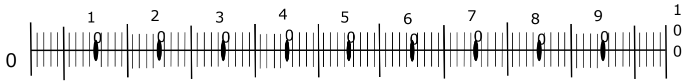
☐ Ik ben matig angstig of depressief

☐ Ik ben erg angstig of depressief

☐ Ik ben extreem angstig of depressief

We willen graag weten hoe goed of hoe slecht uw gezondheid **vandáág** is.

Duid hieronder het punt op de meetschaal aan dat volgens u aangeeft hoe uw gezondheidstoestand vandáág is. **100** staat voor de **beste** gezondheid die u zich kunt voorstellen. **0** staat voor de **slechtste** gezondheid die u zich kunt voorstellen.



SLECHTST VOORSTELBARE GEZONDHEIDSTOESTAND

BEST VOORSTELBARE GEZONDHEIDSTOESTAND

Zorgafstemming

Wij willen graag meer weten over de **zorg en ondersteuning** die u krijgt van uw zorgteam.

Met "zorgteam" verwijzen we naar alle zorgverleners (huisarts, verpleegkundige, specialist, verzorgende, kinesist, diëtist, …) die aan u hulp of ondersteuning bieden.

Geef aan in welke mate volgende stellingen voor u van toepassing zijn.

(Slechts één selectie mogelijk)

Toen ik zorg of ondersteuning ontving, gedurende de afgelopen 6 maanden:					
(Kruis het hokje van uw keuze aan)	Bijna nooit	Over het algemeen niet	Soms	Meestal	Bijna altijd
1. Werd er naar mijn eigen ideeën en verwachtingen gevraagd bij het maken van een behandelplan (een plan voor mijn zorg en begeleiding)	☐1	☐2	☐3	☐4	☐5
2. Werden mij keuzes in de behandeling voorgelegd waar ik over kon nadenken	☐1	☐2	☐3	☐4	☐5
3. Werd mij gevraagd of ik ooit problemen heb gehad met mijn medicijnen of met de (bij)werkingen ervan	☐1	☐2	☐3	☐4	☐5
4. Werd mij (schriftelijke) informatie gegeven met adviezen om mijn gezondheid te verbeteren	☐1	☐2	☐3	☐4	☐5
5. Was ik tevreden over de organisatie van de zorg die ik kreeg	☐1	☐2	☐3	☐4	☐5
6. Werd mij uitgelegd hoe mijn eigen handelen of gedrag mijn gezondheid beïnvloedt	☐1	☐2	☐3	☐4	☐5
7. Werd mij gevraagd om te vertellen wat ik zelf wil bereiken met de zorg voor mijn aandoening	☐1	☐2	☐3	☐4	☐5
8. Werd ik geholpen om specifieke doelen op te stellen om mijn eetgedrag en bewegingspatroon te verbeteren	☐1	☐2	☐3	☐4	☐5
9. Werd mij een kopie van mijn behandelplan gegeven	☐1	☐2	☐3	☐4	☐5
10. Werd ik aangemoedigd om naar een cursus of (groep)bijeenkomst te gaan die mij zou kunnen helpen om beter om te kunnen gaan met mijn aandoening	☐1	☐2	☐3	☐4	☐5
11. Werden mij direct of in een onderzoek vragen gesteld over mijn leefstijl (roken, bewegen, eten, …)	☐1	☐2	☐3	☐4	☐5

Integratie en veiligheid chronische zorg vanuit het perspectief van de patiënt (M)

Toen ik zorg ontving, gedurende de afgelopen 6 maanden:					
(Kruis het hokje van uw keuze aan)	Bijna nooit	Over het algemeen niet	Soms	Meestal	Bijna altijd
12. Was ik zeker dat mijn zorgteam rekening hield met wat ik belangrijk vond toen zij mij behandelingen adviseerden	☐1	☐2	☐3	☐4	☐5
13. Werd ik geholpen een behandelplan te maken dat ik in mijn dagelijkse leven kon toepassen	☐1	☐2	☐3	☐4	☐5
14. Werd ik geholpen om vooruit te plannen, zodat ik - zelfs als ik me ziek of niet lekker voel - met mijn aandoening om kan gaan	☐1	☐2	☐3	☐4	☐5
15. Werd mij gevraagd hoe mijn aandoening mijn leven beïnvloedt	☐1	☐2	☐3	☐4	☐5
16. Werd na een bezoek aan (of van) de huisarts, medisch specialist of verpleegkundige contact met mij opgenomen om nog eens te vragen hoe het met mij ging	☐1	☐2	☐3	☐4	☐5
17. Werd ik aangemoedigd om deel te nemen aan activiteiten bij mij in de buurt die mij zouden kunnen helpen	☐1	☐2	☐3	☐4	☐5
18. Werd ik doorverwezen naar andere zorgverleners (bijvoorbeeld een diëtist, een kinesist of een maatschappelijk werker)	☐1	☐2	☐3	☐4	☐5
19. Werd mij verteld waarom mijn bezoeken aan andere zorgverleners belangrijk zijn in mijn behandeling	☐1	☐2	☐3	☐4	☐5
20. Werd mij gevraagd hoe mijn bezoeken aan andere zorgverleners verliepen	☐1	☐2	☐3	☐4	☐5
21. Voelt u zich veilig verzorgd thuis (met andere woorden: in goede handen)?	☐1	☐2	☐3	☐4	☐5
22. Voelt u zich voldoende ondersteund en omkaderd om veilig thuis te kunnen blijven wonen?	☐1	☐2	☐3	☐4	☐5
23. Ik ervaar dat er een goede communicatie is tussen mijn artsen, verpleegkundigen en/of andere zorgverleners	☐1	☐2	☐3	☐4	☐5

Integratie en veiligheid chronische zorg vanuit het perspectief van de patiënt (M)

Veiligheidsgevoel

16. Bent u de **afgelopen 6 maanden** gevallen? ☐ Ja ☐ Neen

    i. Indien ja: Hoeveel keer bent u de afgelopen 6 maanden gevallen? …………………… keer

17. Hoeveel keer bent u de **afgelopen 6 maanden** opgenomen in het ziekenhuis? ……….. keer

    i. Wat was de reden?

    ……

    ……

    ……

    ……

18. Heeft u zelf ooit een incident of fout meegemaakt door een zorgverlener **BUITEN** het ziekenhuis (dus in uw zorg thuis, bij de huisarts, …)?

    ☐ Ja ☐ Nee

    i. Indien ja: Over welk soort incident ging het? (<u>Meerdere selecties mogelijk</u>)

    ☐ Medicatiefout

    ☐ Verkeerde diagnose

    ☐ Verkeerde behandeling

    ☐ Andere (<u>welke</u>?):

    ……

    ii. Heeft u het gevoel dat dit kwam door een minder goede communicatie tussen de verschillende zorgverleners?

    ☐ Ja ☐ Neen

    Gebeurde dit incident de **afgelopen 6 maanden**?

    ☐ Ja ☐ Neen

Heeft u andere opmerkingen naar aanleiding van deze vragenlijst?

……

……

……

Bedankt voor het invullen van deze vragenlijst!

Integratie en veiligheid chronische zorg vanuit het perspectief van de patiënt (M)

A. Het Wit-Gele Kruis X

1. Geef aan in welke mate u het eens of oneens bent met de volgende stellingen over uw werkomgeving (WGK X). Geef uw antwoord door per stelling slechts <u>één</u> <u>antwoord</u> aan te kruisen.

	Helemaal niet akkoord	Niet akkoord	Neutraal	Akkoord	Helemaal akkoord	Niet van toepassing
1.1 Medewerkers in mijn werkomgeving steunen elkaar	□	□	□	□	□	□
1.2 We hebben genoeg medewerkers om de werklast aan te kunnen	□	□	□	□	□	□
1.3 Wanneer er veel werk snel verricht moet worden, werken we als een team samen om het werk af te krijgen	□	□	□	□	□	□
1.4 In mijn werkomgeving behandelen medewerkers elkaar met respect	□	□	□	□	□	□
1.5 Dat ernstige fouten hier niet (vaker) gebeuren, berust eigenlijk op toeval	□	□	□	□	□	□
1.6 We zijn actief bezig met het verbeteren van de patiëntveiligheid	□	□	□	□	□	□
1.7 We gebruiken meer uitzendkrachten en/of invalkrachten dan goed is voor de patiëntenzorg	□	□	□	□	□	□
1.8 Medewerkers hebben het gevoel dat hun fouten tegen hen gebruikt worden	□	□	□	□	□	□

1.9 Fouten hebben hier tot positieve veranderingen geleid	□	□	□	□	□	□
1.10 In mijn werkomgeving maken we langere werktijden dan goed is voor de patiëntenzorg	□	□	□	□	□	□
1.11 Als iemand in mijn werkomgeving het heel druk heeft, helpen anderen mee	□	□	□	□	□	□
1.12 Wanneer een incident wordt gemeld, voelt het alsof de aandacht naar de melder gaat en niet naar het probleem	□	□	□	□	□	□
1.13 We werken altijd onder erg hoge druk: we proberen te veel te snel te doen	□	□	□	□	□	□
1.14 Medewerkers vrezen dat de fouten die zij maken in hun personeelsdossier worden bijgehouden	□	□	□	□	□	□
1.15 We hebben problemen met de patiëntveiligheid in mijn werkomgeving	□	□	□	□	□	□
1.16 Onze procedures en werkwijzen zijn adequaat om vergissingen te voorkomen	□	□	□	□	□	□

B. De dagelijkse leidinggevende

1. Heeft u een leidinggevende?

Ja	☐ **BEANTWOORD ONDERSTAANDE VRAGEN**
Neen	☐ **GA DOOR NAAR HET VOLGENDE HOOFDSTUK**

2. Geef aan in welke mate u het eens of oneens bent met de volgende stellingen over uw directe leidinggevende. Geef uw antwoord door per stelling slechts <u>één antwoord</u> aan te kruisen.

	Helemaal niet akkoord	Niet akkoord	Neutraal	Akkoord	Helemaal akkoord
2.1 De leidinggevende geeft een compliment als hij/zij ziet dat werkzaamheden volgens de vastgelegde patiëntveiligheid procedures worden verricht	☐	☐	☐	☐	☐
2.2 De leidinggevende neemt suggesties van medewerkers met betrekking tot patiëntveiligheid serieus in overweging	☐	☐	☐	☐	☐
2.3 Telkens wanneer de druk toeneemt, wil de leidinggevende dat we harder werken, zelfs als dit ertoe leidt dat we stappen in de procedures overslaan	☐	☐	☐	☐	☐
2.4 De leidinggevende ziet problemen die zich keer op keer voordoen over het hoofd	☐	☐	☐	☐	☐
2.5 De leidinggevende zorgt voor een werkklimaat waarin patiëntveiligheid gestimuleerd wordt	☐	☐	☐	☐	☐
2.6 Uit de activiteiten die de leidinggevende verricht, blijkt dat patiëntveiligheid hoge prioriteit heeft	☐	☐	☐	☐	☐
2.7 De leidinggevende lijkt alleen geïnteresseerd in patiëntveiligheid als zich een incident met schadelijk gevolg heeft voorgedaan	☐	☐	☐	☐	☐

C. Communicatie

1. Hoe vaak komen de volgende gevallen in uw werkomgeving voor? Geef uw antwoord door per stelling slechts <u>één antwoord</u> aan te kruisen.	Nooit	Zelden	Soms	Meestal	Altijd
1.1 We worden geïnformeerd over veranderingen die zijn ingevoerd op basis van gemelde incidenten	☐	☐	☐	☐	☐
1.2 Medewerkers voelen zich vrij om te spreken als zij iets zien dat mogelijk een negatief effect heeft op de patiëntenzorg	☐	☐	☐	☐	☐
1.3 We worden geïnformeerd over vergissingen die in mijn werkomgeving voorkomen	☐	☐	☐	☐	☐
1.4 Medewerkers voelen zich vrij om beslissingen of acties van collega's met meer bevoegdheden ter discussie te stellen	☐	☐	☐	☐	☐
1.5 In mijn werkomgeving bespreken we mogelijkheden om te voorkomen dat vergissingen zich herhalen	☐	☐	☐	☐	☐
1.6 Zorgverleners bespreken voorgekomen fouten/incidenten onderling	☐	☐	☐	☐	☐
1.7 Zorgverleners bespreken voorgekomen fouten/incidenten samen met de andere disciplines	☐	☐	☐	☐	☐
1.8 Over een eigen melding wordt persoonlijk feedback gegeven	☐	☐	☐	☐	☐

UHASSELT
KNOWLEDGE IN ACTION

D. Bespreken en melden van incidenten

1. Worden incidenten/vergissingen op een of andere manier (informeel of formeel) besproken in uw werkomgeving?

Ja	☐
Neen	☐

2. Als u in uw werkomgeving een incident meemaakt, hoe vaak meldt u ze dan op een of andere manier? Geef uw antwoord door per stelling slechts één antwoord aan te kruisen.

	Nooit	Zelden	Soms	Meestal	Altijd
2.1 Als een vergissing wordt gemaakt, maar wordt ontdekt en gecorrigeerd voordat deze de patiënt heeft bereikt, hoe vaak meldt u dit?	☐	☐	☐	☐	☐
2.2 Als een vergissing wordt gemaakt, die niet tot schade aan de patiënt kan leiden, hoe vaak meldt u dit?	☐	☐	☐	☐	☐
2.3 Als een vergissing wordt gemaakt, die de patiënt had kunnen schaden, maar niet geschaad heeft, hoe vaak meldt u dit?	☐	☐	☐	☐	☐

3. Worden gemelde incidenten structureel besproken tijdens een (werk)overleg? Met structureel wordt bedoeld dat het een vast agendapunt van het (werk)overleg is.

Ja	☐
Neen	☐

4. Heeft u een meldprocedure voor incidenten in uw werkomgeving?

Ja	☐ **BEANTWOORD ONDERSTAANDE VRAAG**
Neen	☐ **GA DOOR NAAR HET VOLGENDE HOOFDSTUK**

5. **Uitgaande van de laatste 12 maanden, hoe vaak heeft u een meldingsformulier voor incidenten ingevuld en ingediend? Geef <u>één antwoord</u>.**

……………………………………………………………………………………………………… meldingsformulieren

E. Waardering voor patiëntveiligheid

1. **Geef uw werkomgeving een beoordeling voor patiëntveiligheid. Geef <u>één antwoord</u>.**

Slecht	□
Matig	□
Acceptabel	□
Goed	□
Uitstekend	□

F. Samenwerking

1. **Geef aan in welke mate u het eens of oneens bent met de volgende stellingen. Geef uw antwoord door per stelling slechts <u>één antwoord</u> aan te kruisen.**

	Helemaal niet akkoord	Niet akkoord	Neutraal	Akkoord	Helemaal akkoord	Niet van toepassing
1.1 Problemen ontstaan vaak bij de uitwisseling van informatie tussen disciplines	□	□	□	□	□	□
1.2 Het feit dat patiënten bij verschillende zorgverleners terecht kunnen, zorgt voor problemen	□	□	□	□	□	□

1.3 De verschillende disciplines waar wij mee samenwerken, stemmen onderling niet goed af	□	□	□	□	□	□
1.4 In mijn werkomgeving is er een goede overdracht tussen de zorgverleners onderling	□	□	□	□	□	□
1.5 In mijn werkomgeving is er een goede overdracht tussen de ondersteunende medewerkers onderling	□	□	□	□	□	□
1.6 Er vallen zaken "tussen wal en schip" als patiënten van de ene naar de andere discipline worden gestuurd	□	□	□	□	□	□
1.7 Belangrijke informatie over patiënten gaat vaak verloren doordat patiënten verschillende zorgverleners zien	□	□	□	□	□	□

G. Achtergrondinformatie

1. Wat is uw primaire werkomgeving binnen het Wit-Gele Kruis X? Geef slechts <u>één antwoord</u> door de afdeling aan te duiden waar de hoofdopdracht wordt uitgevoerd.

X	☐
XX	☐
XXX	☐
XXXX	☐
XXXXX	☐

2. Welke functie oefent u uit binnen het Wit-Gele Kruis X? Geef slechts <u>één antwoord</u>.

Directie	☐
Leidinggevende	☐
Verpleegkundige	☐
Zorgkundige	☐
Vroedvrouw	☐
Polyvalent verzorgende	☐
Diëtiste	☐
Gespecialiseerde voetverzorgende	☐
Stafmedewerker	☐
Administratief medewerker	☐
Logistiek assistent	☐
Interieurverzorgster	☐
Andere, specificeer:	………………………………………………………………………

3. Hoeveel werkervaring heeft u in uw huidige functie?

……………………………………………………………………………………… aantal jaren

4. Hoelang werkt u reeds bij het Wit-Gele Kruis X?
…………………………………………………………………………………………………… aantal jaren

5. Hoeveel uren per week werkt u doorgaans bij het Wit-Gele Kruis X?	
Minder dan 20 uren	□
20 uren	□
24 uren	□
28.5 uren	□
32 uren	□
38 uren	□

6. Wanneer werkt u het vaakst bij het Wit-Gele Kruis X? Geef slechts <u>één antwoord</u>.	
Voormiddag	□
Volle dagen	□
's-avonds	□
's nachts	□

7. Heeft u doorgaans directe interactie of contact met patiënten?	
Ja	□
Neen	□

8. Wat is uw geslacht?	
Man	□
Vrouw	□

9. Wat is uw leeftijd?
………………………………………………………………………

UHASSELT
KNOWLEDGE IN ACTION

H. Commentaar
Voel u vrij om hier om het even welke opmerkingen te schrijven in verband met de zorg en de veiligheid bij de patiënt binnen uw werkomgeving.

Hartelijk dank voor het invullen van deze vragenlijst!

Curriculum Vitae

PERSONALIA

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EDUCATION

PhD in Biomedical Sciences

Hasselt University, 2015 – current

Postgraduate Certificate in Patient Safety

Hasselt University, 2017 – 2018, summa cum laude

Master of Science in Health Care Management and Policy

Ghent University, 2013 – 2015, magna cum laude

Bachelor of Speech Therapy and Audiology: option Audiology

Arteveldehogeschool Gent, 2010 – 2013, cum laude

Grammar School

Course Latin and Modern Languages

Atheneum Wispelberg Gent, 2003 - 2009

Postacademic Degrees in Statistics and Methodology

- Research Design (FLAMES), 2017
- Basic Parametric Statistics (FLAMES), 2017
- Basic Non-Parametric Statistics (FLAMES), 2017
- Basic Regression Analysis (FLAMES), 2017
- Categorical Data Analysis (FLAMES), 2017
- Survival Analysis (FLAMES), 2017
- Introduction to R (FLAMES), 2016

PROFESSIONAL EXPERIENCE

December 2015 – December 2017

Research fellow, Hasselt University

Faculty of Medicine and Life Sciences

Department of Patient Safety, Health Economics & Healthcare Innovation

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EXPERT OPINION

External reviewer for the following journals:

- Value in Health
- Journal of Advanced Nursing
- Acta Clinica Belgica
- Safety in Health Editorial Office
- International Journal of Diabetes and Clinical Research

CO-PROMOTOR OF MASTER THESES

Bernard, C. **Kosten en levenskwaliteit bij patiënten met multiple sclerosis**. Master of Science in Health Care Management and Policy (Ghent University). Year 2015 – 2017

Beuckelaere, P. **Veiligheidscultuurmeting in woonzorgcentra**. Master of Science in Health Care Management and Policy (Ghent University). Year 2015 – 2017

Vandooren, M. & Vanhooren, S. **Kosten en levenskwaliteit van patiënten bij zelfstandige ergotherapeuten**. Master of Science in Health Care Management and Policy (Ghent University). Year 2015 – 2017

Vanderper, C. **De combinatie tussen mantelzorg en betaald werk.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

Van Aerde, K. **Geïntegreerde zorg in de geestelijke gezondheidszorg.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

De Nil, R. **Geïntegreerde zorg voor MS-patiënten.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

Bussens, J. **Overdracht tussen eerstelijn- en tweedelijnsgezondheidszorg.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

Pede, T. **De perceptie van studenten omtrent patiëntveiligheid in de opleiding verpleegkunde.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

Abbeloos, Y. & Danneels, E. **Medicatiefouten in ziekenhuizen.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

Ackaert, L. **De relatie tussen teamwork in een operatiekwartier en het correct gebruik van de *surgical safety checklist*.** Master of Science in Health Care Management and Policy (Ghent University). Year 2016 – 2018

PUBLICATIONS

Publications in international, peer-reviewed journals

Desmedt, M., Vertriest, S., Hellings, J., Bergs, J., Dessers, E., Vankrunkelsven, P., Vrijhoef, H., Annemans, L., Verhaeghe, N., Petrovic, M. & Vandijck, D. Economic Impact of Integrated Care Models for Patients with Chronic Diseases: A Systematic Review. *Value in Health*. 2016; 19(6): 892-902.

Desmedt, M., Pless, S., Dessers, E. & Vandijck, D. Integrating and Safeguarding Care: The Potential Role of Health Information Technologies. *International Journal of Care Coordination*. 2017; 20(3): 112-118.

Desmedt, M., Bergs, J., Vlayen, A., Willaert, B., Hellings, J., Claes, N., Schrooten, W. & Vandijck, D. The SCOPE-PC Survey for Assessing Patient Safety Culture in Primary Care: A Psychometric Evaluation. *Acta Clinica Belgica*. 2017; Published Online First on July 9th.

Cool, L., Missiaen, J., Debruyne, P., Geldhof, K., Lefebvre, T., **Desmedt, M.**, Foulon, V., Pottel, H., Vandijck, D., Van Eygen, K. Oncological Home-Hospitalization: Prospective Randomized Trial to Evaluate its Implications for Patient and Society. *Annals of Oncology*. 2017; 28: Issue supl 5.

Desmedt, M., Hellings, J. & Vandijck, D. Quality and Safety of Chronic Illness Care Through Patients' Eyes (CORTEXS). *International Journal of Integrated Care.* 2017; 17(5): 12.

Dessers, E., Vrijhoef, H., Boermans, S., **Desmedt, M.**, Pless, S., Van den Oord, S., Verhaeghe, N. & Van Hootegem, G. Organizing Integration of Care – Results from Project CORTEXS. *International Journal of Integrated Care*. 2017; 17(5): 502

Desmedt, M., Petrovic, M., Bergs, J., Vrijhoef, H., Hellings, J., Vermeir, P., Cool, L., Dessers, E. & Vandijck, D. Seen Through the Patients' Eyes: Safety of Chronic Illness Care. *International Journal for Quality in Healthcare*. 2017; 29(7): 916-921.

Desmedt, M., Bergs, J., Vertriest, S., Vlayen, A., Schrooten, W., Hellings, J. & Vandijck, D. Systematic Psychometric Review of Self-Reported Instruments to Assess Patient Safety Culture in Primary Care. *Journal of Advanced Nursing*. 2017; Published Online First on October 25th.

Desmedt, M., Vertriest, S., Petrovic, M., Bergs, J., Vrijhoef, H., Dessers, E., Hellings, J. & Vandijck, D. Seen Through the Patients' Eyes: Quality of Chronic Illness Care. *Family Practice*. 2017; Published Online First on December 9th.

Bergs, J., Lambrechts, F., **Desmedt, M.**, Hellings, J., Schrooten, W., Vlayen, A. & Vandijck, D. Seen Through the Patients' Eyes: Surgical Safety and Checklists. *International Journal for Quality in Healthcare*. 2018; Published Online First on January 18th.

Desmedt, M., Bergs, J., Willaert, B., Schrooten, W., Vlayen, A., Hellings, J., Claes, N. & Vandijck, D. Exploring and Evaluating Patient Safety Culture in a Community-Based Primary Care Settings. *Journal of Patient Safety*. 2018; Published Online First on February 5th.

Desmedt, M., Petrovic, M., Beuckelaere, P. & Vandijck, D. Assessing Resident Safety Culture in Six Nursing Homes in Belgium. *Journal of Patient Safety*. ACCEPTED.

Bergs, J., Lambrechts, F., Marneffe, W., Vandijck, D., **Desmedt, M.**, Vlayen, A., Schrooten, W. & Hellings, J. What Nurses and Doctors Really Think About Checklists: A Mixed Methods Study of Clinicians' Perceptions and Attitudes Towards Surgical Safety Checklists in the Operating Theatre. *Journal of Patient Safety*. IN REVIEW.

Cool, L., Vandijck, D., Debruyne, P., **Desmedt, M**., Lefebvre, T., Lycke, M., De Jonghe, P., Pottel, H., Foulon, V. & Van Eygen, K. Organization, Quality and Cost of Oncological Home-Hospitalization: A Systematic Review. *Critical Reviews in Oncology/Hematology*. IN REVIEW.

Publications in national, peer-reviewed journals

Desmedt, M., Bergs, J., Hellings, J., Vertriest, S., Dessers, E., Vankrunkelsven, P., Petrovic, M. & Vandijck, D. Patiëntveiligheid in de eerstelijnsgezondheidszorg: een stand van zaken en aanbevelingen. *Tijdschrift voor Geneeskunde*. 2017; 73(4): 202-211.

Desmedt, M., Bergs, J., Hellings, J., Vertriest, S., Petrovic, M. & Vandijck, D. De economische waarde van mantelzorg en de financiële impact ervan op de ziekteverzekering. *Tijdschrift voor Geneeskunde*. 2017; 73(23): 1473-1480.

Books/Book chapters

Desmedt, M., Vandijck, D. & Hellings, J. Patiëntveiligheid in een goed onderling afgestemde (eerstelijns)zorg. In: Van Hootegem, G. & Dessers, E. (reds); *Onbezorgd – leven en werken in een geïntegreerd gezondheidssysteem*. 2017: 135-156. Acco: Leuven.

Abstracts

Desmedt, M., Bergs, J., Hellings, J., Petrovic, M. & Vandijck, D. Informal Care: A Literature Review and Simulation Model of the Economic Value and Financial Impact on Healthcare Insurance. *International Scientific Nursing and Midwifery Congress* (2017). Poster Presentation.

Desmedt, M., Hellings, J. & Vandijck, D. Patients' Assessment of Chronic Illness Care. *International Scientific Nursing and Midwifery Congress* (2017). Poster Presentation.

Cool, L., Missiaen, J., Vandeghinste, D., Degraeve, S., **Desmedt, M.**, Lefebvre, T., Pottel, H., Foulon, V., Vandijck, D. & Van Eygen, K. Oncological Home-Hospitalisation in Belgium - Concept for optimizing ambulant cancer care. *The Belgian Society of Medical Oncology Annual Meeting* (2017). Poster Presentation.

Desmedt, M., Bergs, J., Claes, N., Hellings, J. & Vandijck, D. Patient Safety Culture Assessment in Primary Care. *International Forum on Quality and Safety in Healthcare* (2017). Poster Presentation.

Desmedt, M., Hellings, J. & Vandijck, D. Quality and Safety of Chronic Illness Care Through Patients' Eyes (CORTEXS). *International Conference on Integrated Care: Building a Platform for Integrated Care* (2017). Oral Presentation.

Desmedt, M., Willaert, B., Hellings, J. & Vandijck, D. Patient Safety Culture Assessment in Primary Care. *Knowledge for Growth* (2017). Poster Presentation.

Cool, L., Missiaen, J., Debruyne, P., Geldhof, K., Lefebvre, T., **Desmedt, M.**, Foulon, V., Pottel, H., Vandijck, D. & Van Eygen, K. Oncological Home-Hospitalisation in Belgium - Prospective randomized controlled trial to evaluate its implications for patient and society. *The European Society of Medical Oncology Annual Meeting* (2017). Poster Presentation.

SCIENTIFIC LECTURES

Desmedt, M. & Vandijck, D. Patiëntveiligheid in de eerstelijnsgezondheidszorg. *CORTEXS-lunch seminary*. Brussels (Belgium), September 14th, 2016 (Dutch).

Desmedt, M., Hellings, J. & Vandijck, D. Quality and Safety of Chronic Illness Care Through Patients' Eyes (CORTEXS). *International Conference on Integrated Care: Building a Platform for Integrated Care*. Dublin (Ireland), May 8th, 2017 (English).

Desmedt, M., Hellings, J. & Vandijck, D. Patiëntveiligheid vanuit het transmuraal perspectief. *Executive Course Postgraduaat Patient Safety*. Hasselt (Belgium), June 9th, 2017 (Dutch).

Desmedt, M. Patiëntveiligheid en veiligheidscultuurmetingen in de eerstelijn. *FOD Volksgezondheid*. Brussels (Belgium), November 21st 2017 (Dutch).

Desmedt, M. & Vandijck, D. Patiëntveiligheid in een goed onderling afgestemde (eerstelijns)gezondheidszorg. *CORTEXS Slotconferentie*. Mechelen (Belgium), December 1ste 2017 (Dutch).
