Going beyond the ‘grand mean’: Advancing disease management science and evidence

Going beyond the ‘grand mean’

Advancing disease management science and evidence

Arianne Elissen

The research presented in this thesis was conducted at the School for Public Health and Primary Care (CAPHRI), Department of Health Services Research, Maastricht University. CAPHRI participates in the Netherlands School of Primary Care Research (CaRe), acknowledged by the Royal Dutch Academy of Science (KNAW). CAPHRI was classified as 'excellent' by the external evaluation committee of leading international experts that reviewed CAPHRI in December 2010.

The studies related to the European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project were funded under the European Commission's Seventh Framework Programme (FP7) for research (grant no. 223277).

Cover design: Datawyse

Layout and printing: Datawyse | Universitaire Pers Maastricht
ISBN 978 94 6159 222 4

Cover illustration: Mosaic art in Parc Guëll, Barcelona, created by the Catalan architect Antoni Gaudí. Mosaic is the art of creating images with an assemblage of small pieces of colored glass, stone, or other materials.

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PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,
op gezag van de Rector Magnificus, Prof. dr. L.L.G. Soete,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen,
op donderdag 25 april 2013 om 16.00 uur

door

Arianne Mathilda Josephus Elissen

UNIVERSITAIRE PERS MAASTRICHT

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Voor Pap en Mam, met alle liefs

Contents

Chapter 1
General introduction

"In the history of mankind few, if any, pandemics will have led to as much suffering and premature deaths as is emerging from the global epidemic of chronic disease."
Professor Sir John Bell, 2008

Parts of the general introduction have been published as:

- Elissen AMJ, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. DISMEVAL: Europees onderzoek naar 'best practices' op het gebied van disease management evaluatie. *Tijdschrift voor Gezondheidswetenschappen,* 2011;89(3):180-84.
- Elissen AMJ, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. Naar zorg op maat voor type 2 diabetes. *Tijdschrift voor Gezondheidswetenschappen*, 2013 (in press).

INTRODUCTION

Although few things in life can be predicted with certainty, there is little doubt that chronic conditions will form the top priority of 21st century health care. Medical-technological advances, greater longevity, and increasing unhealthy lifestyles have led to unprecedented numbers of people living with one or more long-standing health problem(s).[1] In the European Union (EU), 20 to 40 percent of persons aged 15 years or older has a self-reported chronic condition[2]; in the United States (US), estimates are that one in every two adults is chronically ill.[3]

In coming years, with the baby-boom generation on the verge of retirement, these numbers will unavoidably grow further.[4] Although there will be a particularly large increase in the share of the population living with co-existing chronic disorders, a phenomenon most common among the elderly, the prevalence of chronic conditions is accelerating across virtually all age groups.[5] The implications for individuals, health systems, and society as a whole are considerable. Besides causing significant morbidity and mortality[6], chronic conditions increasingly strain the human and financial capital available to health care, and thereby threaten fundamental health system principles, such as universality, solidarity, and sustainability.

This dissertation is about advancing the science and, with that, the evidence supporting decisions on how best to care for the growing population of chronically ill. Although multiple strategies for different conditions are studied, underlying research focuses on disease management interventions for type 2 diabetes mellitus. This first chapter introduces the burden and challenges of chronic conditions, explains the nature of type 2 diabetes mellitus, and discusses some of the key deficiencies in traditional care for long-standing health problems. Subsequently, the main strategies guiding international redesign efforts are discussed and the Dutch context for chronic care innovation is introduced. The chapter further explores the methodological challenges of disease management evaluation and outlines the main research project underlying this dissertation. Finally, the aims and structure of the dissertation are specified.

CHRONIC CONDITIONS

The World Health Organisation (WHO) defines chronic conditions as 'conditions of long duration and generally slow progression'.[7] Most are caused by accumulated exposure during one's lifetime to a small number of known and preventable risk factors, including tobacco use, physical inactivity, and poor nutrition.[8] The occurrence of chronic disease naturally rises with age; thus, it is not uncommon for a person reaching pensionable age to have two or three long-

standing health problems. In the Netherlands, estimates are that around two-thirds of persons aged 65 years and above suffer from multimorbidity; among those 85 years and older, this proportion is even higher.[9]

Today, the most common somatic chronic conditions are diabetes, cardiovascular diseases, chronic respiratory conditions, and cancers.[10] Besides being a leading cause of morbidity throughout the world, these conditions in particular were responsible for 36 out of 57 million global deaths in 2008, a number that is expected to increase by an additional 15 percent before the year 2020.[6] Depression is the most prevalent mental chronic condition: it is currently ranked the fourth leading cause of disability worldwide and expected to become second only to heart disease in terms of disease burden within the near future.[11,12]

Not surprisingly, chronically ill patients are large-scale consumers of health care services. Østbye et al.[13] calculated that guideline-adherent management of no more than 10 common chronic conditions requires more time than general practice has available for all patient care. Across the US and Europe, including in the Netherlands, chronic conditions already account for approximately three-quarters of available health care budgets.[14] Managing multimorbidity is especially expensive: about 96 percent of the American Medicare budget is currently allocated to older patients with co-occurring conditions.[15] In the Netherlands, estimates are that before the end of this decade, 40 percent of health care consumption will be due to people with chronic multimorbidity.[16]

TYPE 2 DIABETES MELLITUS

Type 2 diabetes mellitus, formerly known as non-insulin dependent diabetes, is a chronic metabolic disorder that develops when the human body does not respond properly to insulin, a hormone made by the pancreas.[17] Insulin is necessary to help glucose, which is a form of sugar that is drawn from food, to enter the body's cells, where it is converted into energy. Insulin resistance leads to excessive glucose levels building up in a person's blood stream, which over time may damage the nerves and small blood vessels. This predisposes diabetes patients to a number of serious complications, including cardiovascular disease, which is the leading cause of death among people with diabetes, but also kidney failure, diabetic retinopathy, and lower limb amputations, amongst others.[18]

Type 2 diabetes mellitus is the most common form of diabetes, accounting for approximately 90 percent of cases, whereas the remaining 10 percent is attributable to type 1 diabetes mellitus and gestational diabetes.[19] Notwithstanding the complex, multifactorial nature of the disease – which is caused by interactions between various genetic, environmental, and behavioural factors – its single most important predictor is excessive body weight.[20] It is therefore not surprising that over the past thirty years, parallel to rising rates of over-

weight and obesity, the global prevalence of diabetes more than doubled to an estimated 366 million people in 2011.[17] The metabolic condition is becoming especially more common among young adults and adolescents, where it was traditionally associated with higher age. Estimates are that by the year 2030, there will be 552 million diabetes patients worldwide, representing almost 10 percent of the world's adult population aged between 20 and 79 years.[17] In the Netherlands, type 2 diabetes mellitus is already the most important physical chronic condition, with approximately 1 million known cases and an associated 2.5 billion euros in direct medical costs.[21]

Lifestyle interventions, such as increased exercise and dietary modification, constitute the cornerstone of treatment for type 2 diabetes mellitus, combined, where necessary, with medications such as metformin and/or insulin.[22] With the correct management, many people with diabetes are able to prevent or at least delay the onset of complications. However, in many countries with different health care systems, usual care for type 2 diabetes mellitus – and for chronic conditions more in general – is suboptimal both in terms of the quality of services offered and the achievement of treatment goals.[23] Given the human and economic burden associated with diabetes, it is perhaps not surprising that globally, efforts to improve the management of chronic conditions typically start in the area of diabetes care.[24]

WHY TRADITIONAL CARE DOES NOT SUFFICE

Historically, health care systems were developed to fit the needs of patients experiencing acute, episodic conditions, such as infectious and perinatal diseases.[25] Although the impact of these conditions has become relatively limited over the past century, the reigning health care paradigm has only more recently begun to evolve and remains to be driven, for a considerable part, by urgent demands.[8] The growing prevalence of chronic conditions seriously challenges the effectiveness and efficiency of the acute care model.[26] Problems have become evident at all levels of the health system and range from a failure to empower and collaborate with patients to fragmentation of services, limited follow-up, insufficient evidence-based practice, inadequate information systems, and poor integration with community resources.[25,27] To illustrate, research from the US has shown that diabetes patients receive less than half of recommended care services.[28] Self-reported patient figures from the Netherlands suggest that in 2008, approximately 60 percent of diabetes patients received four basic recommended screening tests, whereas no more than 35 percent was given a written care plan to manage their care at home.[29] As a result, while health care expenditures are escalating, the effectiveness of chronic care delivery is far from optimal, improvements in population health are not accomplished, and patients are largely dissatisfied with their care.

INNOVATIVE CHRONIC CARE STRATEGIES

The health care needs of chronically ill patients are remarkably alike, regardless of their ailment. According to Nolte and McKee[4], they require 'a complex response over an extended time period that involves coordinated inputs from a wide range of professionals and access to essential medicines and monitoring systems, all of which need to be optimally embedded within a system that promotes patient empowerment'. Working from Donabedian's[30] premise that every system is perfectly designed to achieve exactly the results it gets, Wagner et al.[25] propose that meeting these needs will require nothing less than a transformation of health care, from an essentially reactive system that responds to acute episodes of illness to a proactive system focused on maintaining health and preventing or at least postponing disease.

Over the past two decades, various innovative care concepts have been developed to increase the quality of chronic care delivery, improve health outcomes, and, ultimately, reduce costs. This study focuses on the concept of disease management, which is commonly defined as 'a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant'.[31] Disease management interventions were originally initiated in the 1990s by third parties in the US health system, mostly from the pharmaceutical industry, which viewed these programmes as an opportunity to extend their activities beyond drug development to health care management.[32] The primary aim of the early programmes was to reduce the costs of chronic care delivery, by identifying patients more quickly, providing educational services, and standardising care using evidence-based guidelines and protocols.[33] Although American pharmaceutical companies were soon forced by law to significantly reduce their involvement in disease management[34], programmes in the US are still offered primarily by independent, commercial organisations.[35] Much to the contrary, in Europe and elsewhere, where the American disease management interventions quickly caught attention and initially received wide support[36], these structured care strategies are offered as an integral part of existing health care delivery systems.

In recent years, disease management interventions have increasingly come under pressure, mainly for neglecting the growing problem of multimorbidity and offering few possibilities for prevention of chronic conditions.[33,37] To overcome these limitations, several countries – amongst which the Netherlands – are slowly moving towards more comprehensive and integrated systems of chronic care delivery, often based on the Chronic Care Model (CCM).[25] Rather than adding on disease-specific interventions to existing health care structures, the CCM constitutes an evidence-based framework for health system redesign, which identifies the essential elements that encourage high-quality chronic care provision (see Figure 1). These are the community, the health system, self-

management support, delivery system design, clinical information systems, and decision support.[25]

To date, in most countries the implementation of the CCM has progressed as far as that contemporary disease management interventions combine two or more of the framework's six components to improve the quality of care for specific chronic conditions in defined patient groups. More comprehensive population health approaches, which address the full spectrum of CCM elements and target people with more than one chronic condition, are rare. The specific nature and scope of disease management interventions offered to chronically ill patients depends strongly on the health care systems in which the concept is applied.[38]

CHRONIC CARE INNOVATION IN THE DUTCH CONTEXT

In the Netherlands, share care arrangements formed a precursor for more wide-ranging disease management strategies for specific chronic conditions, which were initially introduced around the millennium by professional groups on a regional level.[26,39] The first initiatives focused primarily on type 2 diabetes mellitus, which has long been a priority disease in the chronic care policies of the Dutch Ministry of Health, Welfare and Sports. Despite considerable variation – especially during the early years – in the nature and organisation of initiatives, disease management in the Dutch context can broadly be defined as 'the programmatic and systematic approach of specific diseases and health problems by using management instruments that aim at the advancement of quality and efficacy'.[34]

Due to lack of a structured framework and fragmentary funding, the uptake of disease management initially remained limited in the Netherlands.[40] In 2003, the Netherlands Diabetes Federation, an umbrella organisation of diabetes care providers, scientists, and patients, published the first evidence-based, national care standard for a chronic condition. This standard for type 2 diabetes care, intended for diagnosed patients without serious complications, was updated in 2007 and describes the essential components of high-quality, generic diabetes management.[41] In 2005, the Diabetes Care Programme Task Force developed an action plan to further improve the care for type 2 diabetes mellitus, which, in 2007, led to the first experiments with a bundled payment scheme for integrated diabetes management on the basis of the care standard for this condition. Within the pilot programme, which was set up by the Netherlands Organisation for Health Research and Development (ZonMw) and evaluated by the National Institute for Public Health and the Environment (RIVM), ten so-called 'care groups' were offered financial incentives to start working with bundled payments covering the complete package of standard outpatient care for generic type 2 diabetes mellitus.[42-44] Care groups gather providers from

multiple disciplines, but are typically managed by general practitioners (GPs); they are situated in primary care and freely negotiate with health insurers on the price for generic diabetes care bundles.

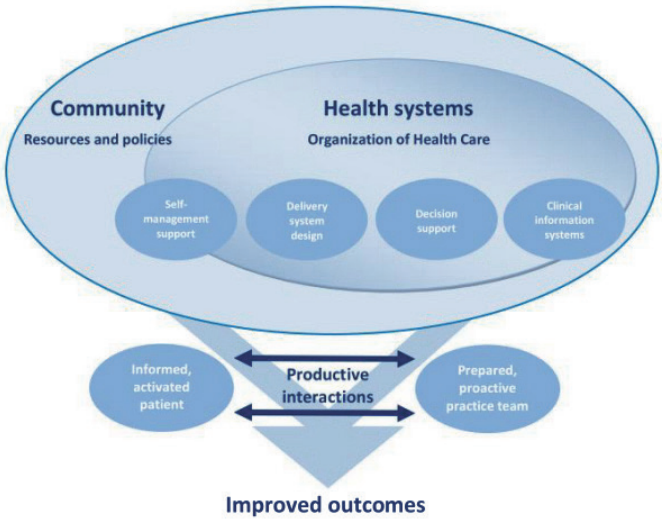

Figure 1: The Chronic Care Model [25]

The experiments in diabetes care laid the foundation for a broad innovative approach to disease management in the Netherlands. In 2010, the bundled payment system, based on recognised care standards, was formally implemented on a nationwide scale for type 2 diabetes care, COPD care, and vascular risk management. Despite considerable debate and uncertainty about the impact of the new care financing and delivery strategy, care groups rapidly achieved national coverage in the Netherlands. Today, almost 100 groups covering approximately 80 percent of Dutch GPs have a bundled payment contract with a health insurer for the delivery of type 2 diabetes disease management.[45] The Dutch government appointed a committee to evaluate the initial experiences with the bundled payment system and recommend whether or not the system should be maintained, changed, or expanded after the voluntary transition stage, which ends in 2012.[46] Based on a secondary analysis of the (preliminary) results of studies conducted by Dutch research institutes, governmental agencies, health insurers, health professionals, and patient associations, the committee concluded that the current system is a work in progress and 'might turn out to be a useful step in the direction of risk-adjusted integrated capitation payment for multidisciplinary provider groups offering primary and specialist care for a defined group of patients'.[47]

MEASURING DISEASE MANAGEMENT PERFORMANCE

Besides the US and the Netherlands, disease management approaches have been implemented on a relatively large scale in countries like Australia, England, Sweden, and Germany, which now has some of the largest programmes in the world, covering almost five million patients in 2008.[48,49] Yet the evidence on the ability of these approaches to actually resolve the problems in chronic care remains uncertain.[50] Most of what we know about the effectiveness of disease management comes from pilot studies undertaken in academic settings, which usually target high-risk patients.[51] Comparatively much less insight exists into the impact of the population-wide approaches that have been implemented in actual health care settings.

An important reason for the uncertain evidence-base is the methodological complexity of conducting disease management evaluations in routine practice. Obvious practical limitations, such as lack of a suitable number of control subjects unexposed to the intervention, hamper the use of the randomised controlled trial (RCT), which is generally considered the gold standard of medical research.[52] However, for practice-based disease management evaluations, the RCT design is not only unpractical; it arguably also lacks desirability.[53] Disease management strategies are highly complex interventions, which are implemented in different care settings, comprise multiple, interrelated components, and target whole populations of chronically ill patients, who differ in terms of disease severity, socio-demographic features, and health behaviour, amongst others. Rather than taking into account this vast amount of heterogeneity, RCTs tend to correct for variation so as to minimise the potential for confounding.[26] This leads to the situation where findings might be scientifically robust but at the same time uninformative for everyday clinical practice, where heterogeneity cannot be so easily ignored.

Observational research designs are more operationally feasible for performance assessment in real clinical practice and, as such, widely used for routine evaluations of disease management effects.[54] However, these designs commonly have methodological flaws that limit the validity and reliability of findings.[55] Moreover, they tend to produce so-called ‘grand means’ across large populations of patients, which provide little guidance regarding what works best for whom. More rigorous and detailed observational research methods are an important precondition for evidence-based decision-making on how best to respond to the complex health care needs of different groups of chronically ill patients within the context of their health care settings.

CHRONIC CARE RESEARCH AT MAASTRICHT UNIVERSITY

This dissertation is part of a long-standing tradition of research into innovative care for chronic conditions at Maastricht University Medical Centre (MUMC+), in particular within the CAPHRI School for Public Health and Primary Care, the Department of Health Services Research, and the Division Patient & Care. Over the past ten to twenty years, extensive studies have been – and are being – conducted into concepts such as, for example, joint care consultations[56], shared care initiatives[57], integrated care programmes and policies[58-63], regional disease management programmes for type 2 diabetes mellitus, asthma, and chronic obstructive pulmonary disease[26], new models of chronic care funding[64,65], theories guiding integrated service delivery[66,67], multidisciplinary cooperation between health care providers[68,69], task substitution from physicians to nurses[70], and self-management support interventions[71] such as web-based patient education tools[72,73], telemonitoring[74], and motivational interviewing techniques.[75,76] Researchers from the MUMC+ are furthermore actively involved in national policymaking in the area of chronic care, as illustrated by their participation in, amongst others, the platform for development of the care standard for vascular risk management, the Netherlands Diabetes Federation's Commission on Care Standards and Guidelines, the National Committee for Evaluation of Bundled Payment, and the Dutch Health Care Inspectorate's Visible Care Programme.

ADVANCING DISEASE MANAGEMENT EVALUATION: DISMEVAL

The majority of work described in this dissertation was conducted as part of the European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project, which was funded by the European Commission's Seventh Framework Programme (FP7) for research.[77,78] DISMEVAL was initiated in 2009 in response to the need to better understand the effects of large, practice-based chronic disease management approaches using evaluation methods that are both scientifically robust and practical for routine settings. Gathering researchers from six European countries, that is, Austria, Denmark, France, Germany, the Netherlands, and Spain, DISMEVAL aimed to improve current methods for disease management evaluation so as to support selection of effective and efficient interventions to address the increasing burden of chronic disease.

The project comprised a programme of work divided in three phases. The first phase sought to review the approaches to managing chronic conditions developed and/or implemented in different countries in Europe, as well as to provide an overview of the types of evaluation approaches being used in Europe

to estimate the impact of structured approaches to disease management on the quality and outcomes of chronic care. During the second phase, data from existing disease management approaches in the six countries participating in DISMEVAL were utilised in order to test and validate the different evaluation options reviewed in Phase 1. Finally, the third phase sought to summarise findings and present best practices and lessons learned concerning the methods for disease management evaluation.[77,78]

The Dutch country study included in Phase 2 of DISMEVAL tested and validated potentially valuable evaluation methods on routine patient data from the population-wide disease management approach for type 2 diabetes implemented in the Netherlands. Researchers from the National Institute for Public Health and the Environment (RIVM) evaluated the Dutch disease management experiments between the years 2009 and 2012[44], and cooperated as an external partner in the Dutch DISMEVAL research team.

AIM AND OUTLINE OF THE DISSERTATION

The aim of the research described in this dissertation is to advance the science underlying disease management evaluation and, in so doing, to strengthen existing evidence on the impact of population-wide disease management approaches implemented in actual health care settings in the Netherlands and abroad. Because robust evaluation requires in-depth knowledge of the intervention under study, the next three chapters of the thesis provide a detailed exploration of disease management approaches for chronic conditions implemented both nationally and internationally. *Chapter 2* describes the recent redesign of type 2 diabetes care in the Netherlands that forms the basis for the evaluation research conducted in the Dutch case study of DISMEVAL. The level of patient-centeredness of this health system reform is assessed by comparing quality improvement goals to gaps in health care quality perceived by chronically ill patients in the Netherlands. *Chapter 3* presents an overview of international chronic care management strategies for type 2 diabetes, based on a systematic review of the literature. This review is part of a series analysing the effectiveness of chronic care management for different long-standing health problems – besides diabetes, these include COPD[79], heart failure[80], and depression[81] – which was conducted by a consortium of researchers from five Dutch research institutes (i.e. Erasmus University, the National Institute for Public Health and the Environment (RIVM), Twente University, the Trimbos Institute, and Maastricht University). The included disease management interventions are analysed descriptively as well as meta-analysed to assess pooled effect estimates on care process and outcome measures. *Chapter 4* examines the role of the regulatory, funding, and organisational context in the development and implementation of approaches to chronic care, focusing specifically on policies to achieve better

coordination within and across care sectors. For this purpose, examples are used from Austria, Germany, and the Netherlands.

The remaining chapters of the dissertation, that is, chapters 5 through 9, focus on improving the methodology underlying disease management evaluations in clinical practice and providing a detailed assessment of the impact of disease management approaches on the quality and outcomes of care for (different groups of) chronically ill patients. *Chapter 5* presents the main findings from the Dutch country study embedded in the DISMEVAL project, which analyses changes over time in the clinical parameters of a total of 105,056 patients receiving disease management for type 2 diabetes, taking into account heterogeneity in the care provided and patients covered. Based on an international review, *Chapter 6* explores whether and how self-management support – a vital yet difficult to implement component of high-quality disease management – is integrated into chronic care approaches in 13 European countries. *Chapter 7* investigates the suitability of using routine performance data for assessing the 'real-world' effects of population-wide disease management approaches implemented in actual health care settings. In *Chapter 8*, multilevel regression methods are introduced as useful techniques for the analysis of patient data in practice-based disease management evaluation. By allowing investigations of the consistency of findings, these methods can identify differences in outcomes as a function of features of the intervention and/or patient population. Finally, in *Chapter 9*, the main findings presented in the dissertation are discussed and recommendations are formulated regarding future developments in disease management design and evaluation.

REFERENCES

1. Nolte E, Knai C, McKee M. *Managing chronic conditions. Experience in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008.
2. TNS Opinion & Social. *Health in the European Union. Special Eurobarometer 272e.* Brussels: European Commission; 2007.
3. Wu SY, Green A (2000). *Projection of chronic illness prevalence and cost inflation.* Santa Monica, CA: RAND Health.
4. Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective.* New York, NY: Open University Press; 2008.
5. Schäfer I, Von Leitner E, Schön G, Koller D, Hansen H, Kolonko T, Kaduszkiewicz H, Wegscheider K, Glaeske G, Van den Bussche H. Multimorbidity patterns in the elderly: a new approach of disease clustering identifies complex interrelations between chronic conditions. *Plos One*, 2010;5(12):e15941.
6. Alwan A (ed). *Global status report on noncommunicable diseases 2010.* Geneva: World Health Organization; 2010.
7. World Health Organization. *Health topics. Chronic diseases.* Retrieved, 26 September 2012, from: http://www.who.int/topics/chronic_diseases/en/

8. World Health Organization. *Innovative care for chronic conditions: building blocks for action.* Geneva: World Health Organization; 2002.
9. Health Council of the Netherlands. *Health care for the elderly with multimorbidity.* The Hague: Health Council of the Netherlands; 2008.
10. World Health Organization. *Noncommunicable diseases country profiles 2011.* Geneva: World Health Organization; 2011.
11. Murray CJ, Lopez AD. Evidence-based health policy-lessons from the Global Burden of Disease Study. *Science*, 1996;274(5288):740-43.
12. Murray CJL, Lopez AD (eds). *The global burden of disease: a comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020.* Cambridge, MA: Harvard University Press; 1996.
13. Østbye T, Yarnall KSH, Krause KM, Pollak KI, Gradison M, Lloyd Michener J. Is there time for management of patients with chronic diseases in primary care? *Annals of Family Medicine,* 2005;3(3):209-214.
14. National Center for Chronic Disease Prevention and Health Promotion. *The power of prevention. Chronic disease. The public health challenge of the 21st century.* Atlanta, GA: Centers for Disease Control and Prevention; 2009.
15. Boyd CM, Boult C, Shadmi E, Leff B, Brager R, Dunbar L, Wolff JL, Wegener S. Guided care for multimorbid older adults. *The Gerontologist*, 2007;47(5):697-704.
16. De Bakker DH, Polder JJ, Sluijs EM, Treurniet HF, Hoeymans N, Hingstman L, Poos MJJC, Gijsen R, Griffioen DJ, Van der Velden LFJ. *Op één lijn. Toekomstverkenningen Eerstelijnszorg 2020*. Bilthoven: RIVM/Nivel; 2005.
17. International Diabetes Federation. *IDF Diabetes Atlas, 5th edn*. Brussels: International Diabetes Federation; 2011.
18. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 2006;29(Suppl. 1):s43-48.
19. World Health Organization. *Diabetes Fact Sheet*. Retrieved, 17 September 2012, from: http://www.who.int/mediacentre/factsheets/fs312/en/
20. Chen L, Magliano DJ, Zimmet PZ. The worldwide epidemiology of type 2 diabetes mellitus – present and future perspectives. *Nature Reviews Endocrinology*, 2012;8:228-36.
21. Idenburg PJ, Van Schaik M, De Weerdt I. *Diagnose diabetes 2025. Over de toekomst van de Nederlandse diabeteszorg*. Schiedam: Scriptum; 2012.
22. Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, Zinman B. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*, 2009;32(1):193-203.
23. Shah BR, Hux JE, Laupacis A, Zinman B, Zwarenstein M. Deficiencies in the quality of diabetes care. Comparing specialist with generalist care misses the point. *Journal of General Internal Medicine*, 2007;22(2):275-79.
24. Nolte E, Knai C, Hofmarcher M, Conklin A, Erler A, Elissen A, Flamm M, Fullerton B, Sönnichsen A, Vrijhoef H. Overcoming fragmentation in health care: chronic care in Austria, Germany and the Netherlands. *Health Economics, Policy and Law*, 2010;7:125-46.
25. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs*, 2001;20(6):64-78.
26. Steuten LMG. *Evaluation of disease management programmes for chronically ill. Dissertation.* Maastricht: Maastricht University; 2006.
27. Institute of Medicine. *Crossing the quality chasm. A new health system for the 21st century.* Washington, DC: National Academy Press; 2001.
28. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The quality of health care delivered to adults in the United States. *New England Journal of Medicine*, 2003;348:2635-45.
29. Schoen C, Osborn R, How SKH, Doty MM, Peugh J. In chronic condition: experiences of patients with complex health care needs, in eight countries, 2008. *Health Affairs,* 2009;28(1):w1-w16.

30. Donabedian A. *An introduction to quality assurance in health care.* Oxford: Oxford University Press; 2003.
31. Care Continuum Alliance. *Care Continuum Alliance (CCA) definition of disease management.* Retrieved, 10 September 2012, from: http://www.carecontinuumalliance.org/dm_definition.asp
32. Bodenheimer T. Disease management in the American market. *British Medical Journal,* 2000;320:563-66.
33. Busse R, Blümel M, Scheller-Kreinsen D, Zentner A. *Tackling chronic disease in Europe: strategies, interventions and challenges. Observatory Studies Series Nº 20.* Copenhagen: World Health Organization; 2010.
34. Schrijvers G, Spreeuwenberg C, Van der Laag H, Rutten G, Nabarro G, Schene A, Van der Linden B, Acampo M. *Disease management in the Dutch context*. Utrecht: Igitur; 2006.
35. Schrijvers G. Disease management programs in the USA and Europe are comparable (yet?) different. *International Journal of Integrated Care,* 2006;6:e13.
36. Goodwin N. Fatal attraction? The rise of disease management programmes in Europe. *International Journal of Integrated Care*, 2007;7:e34.
37. Greβ S, Baan CA, Calnan M, Dedeu T, Groenewegen P, Howson H, Maroy L, Nolte E, Redaèlli M, Saarelma O, Schmacke N, Schumacher K, Van Lente EJ, Vrijhoef B. Co-ordination and management of chronic conditions in Europe: the role of primary care. Position paper of the European Forum for Primary Care. *Quality in Primary Care*, 2009;17(1):75-86.
38. Coleman K, Mattke S, Perrault PJ, Wagner EH. Untangling practice redesign from disease management: how do we best care for the chronically ill? *Annual Review of Public Health*, 2009;30:385-408.
39. Mur-Veeman I, Eijkelberg I, Spreeuwenberg C. How to manage the implementation of shared care: a discussion of the role of power, culture and structure in the development of shared care arrangements. *Journal of Management in Medicine,* 2001;15(2):142-55.
40. Vrijhoef HJM, Spreeuwenberg C, Eijkelberg IMJG, Wolffenbuttel BHR, Van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *British Medical Journal*, 2001;323:983-85.
41. Netherlands Diabetes Federation. *NDF Care Standard. Transparency and quality of diabetes care for people with type 2 diabetes.* Amersfoort: Netherlands Diabetes Federation; 2007.
42. Struijs JN, Van Til JT, Baan CA. *Experimenting with a bundled payment system for diabetes care in the Netherlands: the first tangible effects.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
43. Struijs JN, Baan C. Integrating care through bundled payments: lessons from the Netherlands. *New England Journal of Medicine,* 2011;364:11-12.
44. Struijs JN, De Jong-Van Til JT, Lemmens LC, Drewes HW, De Bruin SR, Baan CA. *Bundled payments of diabetes care: effects on care delivery process and quality of care at three-year follow-up.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2012.
45. Van Til JT, De Wildt J, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
46. De Bakker DH, Struijs JN, Baan CB, Raams J, De Wildt J, Vrijhoef HJM, Schut FT. Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. *Health Affairs,* 2012;31(2):426-33.
47. De Bakker D, Raams J, Schut E, Vrijhoef H, De Wildt J. *Integrale bekostiging van zorg: werk in uitvoering. Eindrapport van de Evaluatiecommissie Integrale Bekostiging.* Den Haag: Netherlands Organization for Health Research and Development (ZonMw); 2012.
48. Berthold HK, Bestehorn KP, Jannowitz C, Krone W, Gouni-Berthold I. Disease management programs in type 2 diabetes: quality of care. *American Journal of Managed Care*, 2011;17(6):393-403.

49. Van Lente EJ, Willenborg P, Egger B. Auswirkungen der Disease Management Programme auf die Versorgung chronisch kranker Patienten in Deutschland: eine Zwischenbilanz. *Gesundheits- und Sozialpolitik*, 2008;62(3):10-18.
50. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care*, 2007;13(12):670-76.
51. Mattke S, Bergamo S, Balakrishnan A, Martino S, Vakkur N. *Measuring and reporting the performance of disease management programs.* Santa Monica, CA: RAND Corporation; 2006.
52. Linden A, Adams JL, Roberts N. Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design. *Journal of Evaluation in Clinical Practice,* 2006;12(2):124-131.
53. English M, Schellenberg J, Todd J. Assessing health system interventions: key points when considering the value of randomization. *Bulletin of the World Health Organization*, 2011;89:907-12.
54. Conklin A, Nolte E. *Disease management evaluation. A comprehensive review of current state of the art.* Cambridge: RAND Europe; 2010.
55. Linden A, Roberts N. A users guide to the disease management literature: recommendations for reporting and assessing program outcomes. *American Journal of Managed Care*, 2005;11(2):81-90.
56. Schulpen G. *The joint consultation of general practitioners and rheumatologists. Dissertation.* Maastricht: Maastricht University; 2003.
57. Eijkelberg IMJG. *Key factors of change processes in shared care. Viewpoints of managers, care providers and patients. Dissertation*. Maastricht: Maastricht University; 2006.
58. Hendriks JML, De Wit R, Vrijhoef HJM, Tieleman RG, Crijns HJGM. An integrated chronic care program for patients with atrial fibrillation. *International Journal of Nursing Studies*, 2010;47(10):1310-16.
59. Hendriks JML, Nieuwlaat R, Vrijhoef HJM, De Wit R, Crijns HJGM, Tieleman RG. Improving guideline adherence in the treatment of atrial fibrillation by implementing an integrated chronic care program. *Netherlands Heart Journal*, 2010;18(10):471-77.
60. Kodner DL, Spreeuwenberg C. Integrated care: meaning, logic, applications, and implications. A discussion paper. *International Journal of Integrated Care*, 2002;2:e12.
61. Van der Linden BA, Spreeuwenberg C, Schrijvers AJP. Integration of care in the Netherlands: the development of transmural care since 1994. *Health Policy*, 2001;55(2):111-120.
62. Kümpers SNS, Mur-Veeman IM, Hardy B, Van Raak AJA, Maarse JAM. Integrating dementia care in England and The Netherlands: four comparative local case studies. *Health & Place*, 2006;12(4):404-420.
63. Paulus ATG, Van Raak AJA, Maarse JAM. Is integrated nursing home care cheaper than traditional care? A cost comparison. *International Journal of Nursing Studies*, 2008;45(12):1764-1777.
64. Duimel-Peeters I, Van Raak AJA, Bindels JAPM, Vrijhoef HJM. Het DBC-protocol voor diabetesketenzorg in de praktijk. Naleving door zorgverleners in de regio Maastricht en Heuvelland. *EADV Magazine*, 2009;24(3):16-21.
65. Ruwaard D. *De weg van nazorg naar voorzorg. Buiten de gebaande paden. Inaugurele rede.* Maastricht: Océ Business Services; 2012
66. De Rijk AE, Van Raak AJA, Van der Made JH. A new theoretical model for cooperation in public health settings: the RDIC model. *Qualitative Health Research*, 2007;17(8):1103-1116.
67. Beusmans G, Crebolder HFJM, Van Ree J. Zorg voor chronisch zieken: praktijkverpleegkundigen breed inzetten. *Medisch Contact*, 2001;7:259-62.
68. Van Raak AJA, Paulus ATG, Mur-Veeman IM. Why do health and social care providers co-operate? *Health Policy*, 2005;74(1):13-23.
69. Elissen AMJ, Van Raak AJA, Paulus ATG. Can we make sense of multidisciplinary co-operation in primary care by considering routines and rules? *Health & Social Care in the Community*, 2011;19(1):33-42.

70. Vrijhoef HJM. *Is it justifiable to treat chronic patients by nurse specialists? Dissertation*. Maastricht: Maastricht University; 2002.
71. Heinrich E, Schaper NC, De Vries NK. Self-management interventions for type 2 diabetes: a systematic review. *European Diabetes Nursing*, 2010;7:71-76
72. Heinrich E, Schaper NC, De Vries NK. Development of the web-based type 2 diabetes education programme: DIEP. *European Diabetes Nursing*, 2009;6:51-56.
73. Heinrich E, De Nooijer JM, Schaper NC, Schoonus-Spit MH, Janssen MA, De Vries NK. Evaluation of the web-based Diabetes Interactive Education Programme (DIEP) for patients with type 2 diabetes. *Patient Education and Counseling*, 2012;86(2):172-178.
74. Boyne JJJ, Vrijhoef HJM, De Wit R, Gorgels APM. Telemonitoring in patients with heart failure, the TEHAF study: study protocol of an ongoing prospective randomised trial. *International Journal of Nursing Studies*, 2011;48:94-99.
75. Heinrich E, Candel MJ, Schaper NC, De Vries NK. Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care. *Diabetes Research and Clinical Practice*, 2010;90(3):270-278.
76. Van Eijk-Hustings Y, Daemen L, Schaper NC, Vrijhoef HJM. Implementation of motivational interviewing in a diabetes care management initiative in the Netherlands. *Patient Education and Counseling*, 2011;84(1):10-15.
77. Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European healthcare systems.* Cambridge: RAND Europe; 2012.
78. Nolte E, Conklin A, Adams JL, Brunn M, Cadier B, Chevreul K, Durand-Zaleski I, Elissen A, Erler A, Flamm M, Frølich A, Fullerton B, Jacobsen R, Knai C, Krohn R, Pöhlmann B, Saz Parkinson Z, Sarria Santamera A, Sönnichsen A, Vrijhoef H. *Evaluating chronic disease management. Recommendations for funders and users.* Cambridge: RAND Europe; 2012.
79. Lemmens KMM, Lemmens LC, Boom JHC, Drewes HW, Meeuwissen JAC, Steuten LMG, Vrijhoef HJM, Baan CA. Chronic care management for patients with COPD: A critical review of available evidence. *Journal of Evaluation in Clinical Practice,* 2012 [epub ahead of print].
80. Drewes HW, Steuten LMG, Lemmens LC, Baan CA, Boshuizen H, Elissen AMJ, Lemmens KMM, Meeuwissen JAC, Vrijhoef HJM. The effectiveness of chronic care management for heart failure: a systematic review and meta-regression analysis to explain the heterogeneity in outcomes. *Health Services Research,* 2012 [epub ahead of print].
81. Meeuwissen JAC, Lemmens LC, Drewes HW, Lemmens KMM, Steuten LMG, Elissen AMJ, Vrijhoef HJM, Baan CA. Meta-analysis and meta-regression analyses explaining heterogeneity in outcomes of chronic care management for depression: implications for person-centered mental healthcare. *International Journal of Person Centered Medicine,* 2012;2(4):716-758.

PART I

EXPLORING DISEASE MANAGEMENT

Chapter 2

Assessing the patient-centeredness of chronic care redesign in the Netherlands

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Submitted for publication

ABSTRACT

Objective: The aim of this article is to assess to what extent recent chronic care reform in the Netherlands can be considered patient-centered, that is, in line with gaps in quality of service provision experienced by chronically ill patients.
Methods: We gathered literature from various national and international sources to gain insight into Dutch chronic care reform since 2008. To compare reform goals with patients' experiences of poor quality, we used the Dutch outcomes of the 2008 Commonwealth Fund International Health Policy survey of chronically ill adults (N=1,000). Four researchers independently linked policies with patient experiences, after which a meeting was held to achieve consensus.
Results: In 2009, the Netherlands formally introduced a bundled payment system for chronic care, under which health insurers and multidisciplinary care groups – guided by disease-specific care standards – negotiate the price for a complete package of outpatient services for a specific condition. In line with patients' experiences of poor quality, the reform focuses on improving coordination and chronic care management rather than access and safety. Protocol adherence and coordination of care appear to improve as a result of the bundled payment system, though considerable boundaries remain between sectors. To date, self-management support and clinical information systems remain underdeveloped.
Conclusions: Although from a patient perspective, the Dutch reform of long-term care targets the right areas for quality improvement, the daily practice of service provision is still far from patient-centered. Further improvements are necessary to meet the complex care needs of the chronically ill.

INTRODUCTION

Now that chronic conditions are the most common diseases in western society, active participation of patients in their treatment – often referred to as 'self-management' – has become both crucial and inevitable. Crucial because the outcomes of chronic care are highly contingent on patients' motivation and ability to self-care, i.e. to adequately deal with the often substantial medical, behavioural, and emotional consequences of long-term illness.[1,2] Inevitable because only patients themselves, as 'owners of their disease', can be responsible for their day-to-day care over the full course of illness.[3]

Our traditional, acutely-oriented health systems are ill-equipped to support patients in their efforts to adequately manage chronic disease. Care provision is often impersonal, fragmented across providers and settings, episodic, reactive, and insufficiently evidence-based, resulting in poor disease control and generally dissatisfied patients.[4,5] Dealing with the problems in chronic care has been characterised by some as the greatest challenge facing 21st century health care.[6] Although there is general consensus that 'doing more of the same' is not an option, the question how best to transform health systems to better meet patients' complex care needs remains subject of great debate. International diversity makes a universal solution unlikely, as what works in one setting might not be feasible in another. Nonetheless, countries can learn from experiences abroad, as illustrated by the use of originally American health service innovations, such as disease management and the well-known Chronic Care Model (CCM), to guide health system reconfigurations in countries like Australia, Canada, Germany and the United Kingdom.[6,7]

As the central actors in high-quality chronic care management[1], patients' experiences with service delivery might be the most important indicators of the type and extent of improvement that is necessary in a given health system. In 2008, the Commonwealth Fund (CWF) conducted an International Health Policy Survey of chronically ill patients' experiences with four aspects of their care: access; coordination and transitions; safety; and chronic care management.[5] Among the eight participating countries, the Netherlands often ranked first or second for positive experiences, especially with regard to (timely) access to recommended care and medications, and safety of service provision. Coordination of care, in particular during transitions from and to hospitals, was evaluated somewhat less positive than in most other countries.[5]

Since the CWF survey of 2008, Dutch government has introduced a comprehensive reform package to (further) improve the quality of chronic care delivery. In this article, we describe the reform of long-term care provision in the Netherlands and, more importantly, we use the Dutch CWF survey results to assess the level of patient-centeredness of this system redesign, by analysing the extent to which improvement goals correspond with gaps in quality experienced by patients. In order to contextualise Dutch chronic care management, a concise

overview is given of key features of the Dutch health system relevant to caring for the chronically ill. First, however, the study methods are explained.

METHODS

To gain insight into chronic care reform in the Netherlands since 2008, we used data gathered as part of the European DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project; the data collection template that was used is described in detail elsewhere.[8] The DISMEVAL data, drawn primarily from Parliamentary documents and policy notes, were complemented by a qualitative review of the published and grey literature concerning recent Dutch long-term care redesign. To assess to what extent the reform of chronic care in the Netherlands targets the right areas for improvement, i.e. those areas where patients experience gaps in quality, we used the Dutch outcomes of the 2008 Commonwealth Fund (CWF) International Health Policy Survey of chronically ill adults in Australia, Canada, France, Germany, the Netherlands, New Zealand, the United Kingdom, and the United States. In the Netherlands, this survey targeted a sample of 1,000 chronically ill adults, suffering from at least one of seven conditions: hypertension, heart disease (including heart attack), diabetes, arthritis, lung problems (asthma, emphysema, and chronic lung obstruction), cancer or depression.[5]

To allow for a structured, systematic comparison between the goals of Dutch chronic care reform on the one hand and gaps in service quality experienced by patients on the other, we summarised the questionnaire items included in the CWF survey (i.e. solely those items that specifically concerned health care experiences) into the rows of a table. For each link that could be made between a redesign goal on the one hand and an aspect of patients' health care experience (i.e. survey item) on the other, a '+' sign was filled into this table. Where no link could be found, a '-' sign was filled in. To prevent bias due to subjectivity, the linking exercise was first completed independently by each author, after which a meeting was held to discuss individual results and achieve consensus where necessary. Table 1 provides an overview of the links agreed upon during this meeting.

RESULTS

An introduction to health care in the Netherlands

Similar to some other European countries, the Netherlands has a long tradition of non-governmental health care provision, which originated in private and

often charitable, voluntary organisations.[9] The majority of Dutch hospitals and care institutions is still privately-owned; the regulation of the health system is predominantly a task of government, which has relatively weak hierarchical power.[10,11]

Since the Second World War, health care financing in the Netherlands has been characterised by a dividing line between statutory sickness fund insurance, which covered about 63% of the population, and private health insurance, covering the remaining 37%.[12] In 2006, after many years of political debate, this dual arrangement was replaced by a compulsory social health insurance (SHI) scheme with competing private insurance funds.[13] All Dutch citizens contribute to the SHI scheme, which covers 'essential curative care', by paying flat-rate premiums to the insurer of their choice as well as an income-dependent employer contribution.[9]

With regard to service delivery, a unique attribute of the Dutch health system is the pivotal role of the general practitioner (GP), who is positioned at the center of a strong primary care sector. GPs form the first point-of-contact for care-seeking individuals, are specialised in common, minor and chronic disease, and are available to their patients at close proximity both during and outside of office hours.[14] As gatekeepers to secondary care, GPs prevent unnecessary use of more expensive specialist services.[9]

Dutch chronic care redesign

Persons suffering from one or more chronic conditions require coordinated services from a wide range of health care providers over an extended period of time, embedded in a system that is organised around the patient.[13] Yet in most countries, financial, legal, cultural, and positional barriers hamper the coordination of inputs that is necessary to optimise chronically ill patients' health and prevent or at least postpone the coming about of serious complications.[15] In the Netherlands, the existence of fragmentation within and between care sectors has long been a major source of concern. In the early 1990s, shared care initiatives were developed by collaboratives of primary and secondary care professionals to reduce the boundaries between sectors in specific areas of service provision.[11] Although some local initiatives evolved into more comprehensive disease management programmes for conditions such as diabetes and stroke[16,17], uptake of disease management initially remained limited, mainly due to lack of a structured framework and fragmentary funding.[18] These two barriers to improving coordination of care were addressed simultaneously with the introduction of the so-called 'bundled payment system' for integrated chronic care based on recognised, disease-specific care standards, which started out as a small-scale, experimental pilot in type 2 diabetes care in 2007.[19,20] In 2008, the Dutch Minister of Health, Welfare and Sports presented the concept of bundled payments to Dutch Parliament in two let-

ters[21,22]; in September 2009, nationwide implementation of the reformed payment system was formally approved for type 2 diabetes care, chronic obstructive pulmonary disease (COPD) care, and vascular risk management.[23]

Under the bundled payment system, which is currently voluntary, health insurers pay a single fee to a regional care group – a legal entity in primary care, most commonly owned by GPs, that delivers care itself and/or subcontracts (other) care providers – to cover the complete package of outpatient services for a specific chronic disease.[23] Care bundle price is freely negotiated between care group and insurer; the fees for subcontractors are negotiated between care group and relevant professionals, such as physical therapists, dieticians, laboratories, and/or specialists. Since 2007, the number of care groups with a bundled payment contract for the provision of generic type 2 diabetes care has grown exponentially to more than 100 groups gathering about 80% of Dutch GPs in March 2010. A survey among 55 of these groups showed that contracts for COPD care and vascular risk management are coming about more slowly: in 2010, no more than 13% of groups had a bundled payment contract for managing one or both of these conditions.[24]

The services to be covered by bundled payment contracts are codified by disease-specific care standards developed on the national level by patient and provider organisations.[25-27] These standards are based on existing guidelines for GPs and include general modules (such as information, education and self-management support, smoking cessation, physical activity, and nutrition and diet) as well as disease-specific modules.[28] In the case of, for example, type 2 diabetes care, the latter comprise a defined frequency of GP visits, regular foot and eye examinations, and laboratory testing.[25] All services included in care bundles are covered by the basic SHI package that is mandatory for Dutch citizens.[23]

Comparing redesign goals to patient experience

Table 1 shows the rankings of the Dutch health care system on the items of the 2008 Commonwealth Fund (CWF) International Health Policy Survey of chronically ill adults.[5] In addition, the table links the chronic care reform policies introduced in the Netherlands since 2008 with the outcomes of the CWF survey, thereby showing the extent to which the right improvement areas are targeted, i.e. those areas where chronically ill patients experience poor quality. The links between chronic care reform and patients' experiences will be discussed per survey topic.

Access to care

Table 1 shows that compared to patients elsewhere, Dutch chronically ill persons are most positive about the accessibility of their care system. Comprehensive health insurance benefits guarantee that people do not experience cost as a

major deterrent to seeking (at least essential) medical help.[5] Timely access is facilitated by the existence of a well-developed primary care system, in which GPs are the central care providers.[9,14] In line with patients' positive appraisal of their access to care, Table 1 shows that the recent reform of Dutch chronic care does not target any direct improvements in this area.

Care coordination and transitions

The outcomes of the 2008 CWF survey show that Dutch chronically ill patients experience insufficient coordination of care across different providers and settings. They report problems with medical records and test coordination, unnecessary duplication of tests, a lack of insight into their medical histories, and insufficient control during transitions from ambulatory to inpatient care and vice versa.[5] Conform the poor CWF survey scores, improving coordination of care is an important goal of the recent Dutch chronic care redesign.[21,22] That being said, we found surprisingly few links between this redesign and the coordination-related survey items, most likely because while the latter focus predominantly on continuity of care during transitions between sectors, Dutch long-term care reform is concentrated in primary care.[29] By allowing free negotiations on the price of care bundles while at the same time demanding transparency regarding performance on various processes and outcomes, the system intends to motivate primary care providers to engage in (interdisciplinary) cooperation and provide coordinated, high-quality care to chronically ill patients according to evidence-based care standards.[23]

Table 1: Links between patient experiences and goals of chronic care reform in the Netherlands

SURVEY TOPICS	ITEM	DUTCH RANKING *TOP 2*	DUTCH RANKING *BOTTOM 2*	CARE REFORM
ACCESS TO CARE	**6A** Was there ever a time when you did not fill a prescription for medicine or skipped doses because of the cost in the past two years?	*		-
	6B Was there ever a time when you had a medical problem but did not visit a doctor because of the cost in the past two years?	*		-
	6C Was there ever a time when you skipped or did not get a medical test, treatment or follow-up that was recommended by a doctor because of the cost in the past two years?	*		-
	7 Last time when you needed medical care in the evening, on a weekend or on a holiday, how easy or difficult was it to get care without going to the hospital emergency department?	*		-
	8 Last time you were sick or needed medical attention, how quickly could you get an appointment to see a doctor (excluding visits to the emergency room [ER])?	*		-
	11 Is there one doctor you usually go to for your medical care?	*		-
	12 If no regular doctor or not sure or decline: is there one doctor's group, health center, or clinic you usually go to for most of your medical care? (excluding the hospital ER)	*		-
	13 How long have you been seeing this doctor/going to this place for your medical care?	*		-
	21 After learning you needed to see a specialist or consultant, how many days, weeks or months did you have to wait for an appointment?	*		-
	40 How many times have you personally used a hospital ER in the past 2 years?	*		-
	41 The last time you went to the hospital ER, was it for a condition that you thought could have been treated by your regular doctor if he or she had been available?	*		-
CARE COORDINATION AND TRANSITIONS	**17A** In the past two years, when getting care for a medical problem, was there ever a time when test results, medical records, or reasons for referrals were not available at the time of your scheduled doctor's appointment?	*		+
	17B In the past two years, when getting care for a medical problem, was there ever a time when doctors ordered a medical test that you felt was unnecessary because the test had already been done?	*		+

SURVEY TOPICS	ITEM	DUTCH RANKING *TOP 2*	DUTCH RANKING *BOTTOM 2*	CARE REFORM
	22 When you saw the specialist or consultant, did he or she have information about your medical history?			-
	36A When you left the hospital did you receive clear instructions about symptoms to watch for and when to seek further care?			-
	36B When you left the hospital, did the hospital make arrangements for you to have follow-up visits with a doctor or other health care professional?	*		-
	36C When you left the hospital, did you know who to contact if you had a question about your condition or treatment?			+
	36D When you left the hospital, did the hospital staff provide you with a written plan for your care after discharge?			-
	38 Did someone discuss with you what to do about other medications you were using before you were hospitalised?		*	+
	39 After you were discharged, were you readmitted to a hospital or did you have to go to a hospital ER as a result of complications that occurred during your recovery?		*	-
SAFETY	**25** In the past 2 years, how often have ANY of your doctors or your pharmacists "Reviewed and discussed all the different medications you are using, including medicines prescribed by other doctors?"		*	+
	26 In the past 2 years, were you ever told by a pharmacist that the prescription you were about to fill might be harmful because of other medications you were taking?	*		+
	29 Have you ever been given the wrong medication or wrong dose by a doctor, nurse, hospital, or pharmacist when filling a prescription at a pharmacy or while hospitalised in the past 2 years?	*		+
	30 Have you believed a medical mistake was made in your treatment or care in the past 2 years? (by medical mistake we mean a mistake made by a doctor, nurse, hospital, or other health care provider)	*		-
	32A In the past 2 years, have you been given incorrect results for a diagnostic or lab test, this could include getting someone else's test results?	*		-
	32B In the past 2 years, have you experienced delays in being notified about abnormal test	*		-

SURVEY TOPICS	ITEM	DUTCH RANKING *TOP 2*	DUTCH RANKING *BOTTOM 2*	CARE REFORM
	results?			
	33 Did the most recent mistake, medication error, or diagnostic test error occur while you were hospitalised?			-
CHRONIC CARE MANAGEMENT	**15B** When you need care or treatment, how often does your regular doctor tell you about treatment options and involve you in decisions about the best treatment for you?	*		+
	15C When you need care or treatment, how often does your regular doctor encourage you to ask questions?		*	+
	15D When you need care or treatment, how often does your regular doctor give you clear instructions about symptoms to watch for and when to seek further care or treatment?			+
	44 Have you had your cholesterol checked in the past year?		*	+
	45 Has your haemoglobin 'A1c', a blood test to check sugar control, been checked in the past year?	*		+
	46 Have you had your feet examined by a health professional for sores or irritations in the past year?			+
	47 Have you had an eye examination for your diabetes in the past year?	*		+
	48A Has any health care professional you see for your condition(s) given you a written plan or instructions to help you manage your own care at home?			+
	48B Has any health care professional you see for your condition(s) discussed with you your main goals or priorities in caring for your condition(s)?		*	+
	48C Has any health care professional you see for your condition(s) contacted you after a visit to see how things were going?		*	+
	50 Is there a nurse or nurse practitioner who is regularly involved in the management of your condition(s)?			+

NOTE: ER indicates emergency room; *=top/bottom ranking of the Netherlands on survey item of 2008 Commonwealth Fund (CWF) International Health Policy Survey; +=link between patient experience (i.e. CWF survey item) and goal of Dutch chronic care reform; –=no link between patient experience (i.e. CWF survey item) and goal of Dutch chronic care reform

Safety

When compared to the other countries included in the 2008 CWF survey, the Netherlands scores well on issues related to safety in health care. Relatively few patients indicate having experienced mistakes in their treatment during the two-year period prior to completing the survey. The results concerning safety of medication use appear contradictory: while the management by care providers is experienced as particularly poor, Dutch patients are least likely to experience medication errors.[5] In concurrence with patients' perception of this aspect of their care, medication control is the only safety-related issue targeted by the recent reform of chronic care in the Netherlands. By including pharmacists into the group of providers with whom care groups are stimulated to reach structural working agreements, the goal is to prevent physicians, especially those separated by different health care settings, from unknowingly prescribing potentially harmful combinations of medications to patients.[25]

Chronic care management

According to the CWF survey, chronically ill patients in the Netherlands are relatively dissatisfied with the management of their disease, especially with the extent to which they are involved in treatment decisions and the follow-up of their condition over time.[5] Table 1 shows that the goals of Dutch chronic care reform can be linked to all issues relating to chronic care management, thus reflecting the poor experiences of patients. These issues broadly concern three topics: (1) active participation/self-management of patients; (2) expanded roles for nurses; and (3) evidence-based service provision.[5] As to the first, self-management support forms an important building block of the Dutch care standards for chronic conditions, which emphasise that patients must be educated and empowered to be able to take on a central role in their treatment.[25-27] Moreover, an individual care plan stipulating agreed upon treatment goals and activities should be developed by each patient and his/her practice team.[28] Task redistribution from doctors to nurses is stimulated by the functional description of service delivery in the care standards, which stipulate what services must be offered rather than by whom or where.[20] To stimulate evidence-based care delivery, bundled payment contracts oblige care groups to provide health insurers with annual performance data on a range of standard-related indicators for chronic care processes and outcomes.[23]

DISCUSSION

Since the first experiments with bundled payments for generic diabetes care in 2007, chronic care in the Netherlands has undergone a comprehensive reform that fundamentally changed the way services are provided to patients suffering

from type 2 diabetes, COPD, and/or vascular risks. Our study shows that the goals of this reform can be considered patient-centered, i.e. in line with gaps in quality experienced by 1,000 Dutch chronically ill patients participating in the 2008 Commonwealth Fund (CWF) International Health Policy survey.[5]

Access to care and safety of service provision are experienced positively by patients and, in line with this appraisal, are not areas where direct improvements are sought after in the Netherlands. With regard to access, it is important to note that several historical characteristics of Dutch health care – most notably the universal coverage of essential care costs and the existence of a strong primary care sector – minimise the boundaries experienced by patients in gaining care and are widely considered as crucial prerequisites for improving chronically ill persons' health outcomes.[30,31] The main safety-related goal of the chronic care reform is to improve medication control, for which purpose cooperation with pharmacists is stimulated by the care standards for specific conditions. However, a survey among 55 diabetes care groups in 2010 showed that in practice, few groups (19%) have actually made structural working agreements with pharmacists.[24]

Most links with recent Dutch chronic care reform policies were found in those sections of the CWF survey where patients reported experiencing multiple gaps in quality, that is, 'care coordination and transitions' and 'chronic care management'.[5] Overcoming fragmentation is perhaps the most important aim of implementing bundled payments for chronic care in the Netherlands.[20] However, contrary to most of the coordination-related items in the CWF survey, the Dutch bundled payment system focuses mainly on bridging barriers between providers working within primary care and not on reducing fragmentation between sectors. The first-year results of experimenting with bundled payments for type 2 diabetes care showed that the coordination of services for patients with this condition improved.[19,20] Because of the strong focus of reform policies on generic, outpatient care, however, there is no population management and – perhaps even more importantly – considerable (financial) barriers remain between primary and secondary care. These barriers put patients, especially those with complex conditions who require regular inputs from both generalists and specialists, at risk of unnecessary errors and adverse advents during their transitions between ambulatory and inpatient care.[5,17]

Another potential shortcoming of the redesigned chronic care system in the Netherlands with regard to coordination of care is that service delivery follows a disease management-like, single condition approach. In recent years, disease management has come under increasing international pressure for neglecting multimorbidity, a phenomenon most common among the elderly.[28,32,33] It remains to be seen whether the Dutch care bundles for individual conditions can meet the complex needs of patients suffering from multiple conditions and not exacerbate the already existing fragmentation in service provision for this growing population.[13] Future efforts to improve coordination of care for the

chronically ill in the Netherlands should focus, amongst others, on advancing clinical information systems, which providers participating in the diabetes care experiment reported to be flawed and inadequate.[19,20] Information technology can be used to enhance communication between physicians and patients, and to enable continuous monitoring of patients' health status from a distance. Systematic reviews of international evidence have shown that telemonitoring can positively affect clinical outcomes for chronically ill patients.[34-36]

With regard to chronic care management, the Dutch reform policies target improvements in self-management support, the role of nurses, and the extent of evidence-based care provision. As to the latter two, and especially providers' adherence to evidence-based treatment protocols, the first-year evaluation of the diabetes care pilot demonstrated positive results. Across care groups, the proportion of patients with registered measurements of glycated haemoglobin, blood pressure, kidney function, low-density lipoprotein, and body mass index was above 85%. With regard to patient outcomes, the evaluation did not (yet) demonstrate considerable changes on any of these clinical measures after one year follow-up.[19] Nurses traditionally play an important role in Dutch chronic care[16,37] and are now represented in the vast majority of care groups: of 55 diabetes groups surveyed in 2010, 98% employed general practice nurses and 76% either employed or structurally collaborated with specialised diabetes nurses.[24] Studies in the Netherlands and elsewhere have shown that nurse-led care can have promising effects on patients' self-management and, ultimately, on their health outcomes.[16,37-39] However, despite the involvement of nurses and the emphasis on the central role of patients in the Dutch care standard for diabetes, self-management support remains underdeveloped and is generally not purchased by health insurers.[19,20] A recent survey among more than 630 Dutch patients receiving vascular risk management showed that less than 40% is involved in treatment decisions and that only about 6% has an individual care plan.[40,41] Given the impact of patients' self-management on their health outcomes[38], it is important that in coming years, broad dissemination of local 'best practices' in self-management support is stimulated through clear and proactive policymaking. Moreover, health care professionals must be offered the knowledge, skills, resources, and incentives to empower patients to take on an active role in their treatment. To date, patient self-management support is not part of the medical curriculum in the Netherlands, financial incentives appear to motivate standardised rather than personalised chronic care provision[42], and valuable technology – such as telemonitoring devices and interactive patient education websites – is still in its infancy.

Limitations

Our study has several limitations. Most importantly, the fact that our findings are based on literature research makes them prone to search bias. We at-

tempted to minimise this by using a structural data collection template and gathering data from multiple sources. Moreover, even though Table 1 was filled out after a consensus meeting between four independent researchers, the links identified between Dutch chronic care reform and patients' scores on the items of the CWF survey are to some extent subjective. Hence, it is important to note here that our findings, based on the linking exercise, corroborate the conclusions drawn in a recent report of the Dutch Court of Audit, which investigates whether central government policy is implemented as intended. According to the Court, the assumption that coordinated care will arise automatically following the introduction of bundled payments is too optimistic.[43]

CONCLUSIONS

Although from a patient perspective, the Dutch reform of long-term care targets the right areas for improvement, i.e. those areas where patients perceive gaps in quality, the daily practice of service provision is still far from patient-centered. The available evidence on the effects of bundled payments for diabetes care indicates that while improvements have occurred in coordination of care and protocol adherence, much work remains to be done in the Netherlands. In coming years, further advances are necessary with regard to self-management support and clinical information systems; also, attention must be given to the coordination of care across settings and, for the growing population of multimorbid older patients, across conditions. As the reform plays out, it will be essential to monitor the effects of bundling care services on a wide variety of indicators, including not only clinical outcomes but also more patient-centered measures – such as quality of life, patient satisfaction, and self-efficacy – and to compare these with experiences elsewhere, so as to stimulate evidence-based chronic care redesign.

REFERENCES

1. Holman H, Lorig K. Patients as partners in managing chronic disease. *British Medical Journal*, 2000;320(7234):526-27.
2. Koch T, Jenkin P, Kralik D. Chronic illness self-management: locating the "self". *Journal for Advanced Nursing,* 2004;48:484-92.
3. Lorig KR, Holman HR. Self-management education: history, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine*, 2003;26(1):1-7.
4. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs,* 2001;20(6):64-78.
5. Schoen C, Osborn R, How SKH, Doty MM, Peugh J. In chronic condition: experiences of patients with complex health care needs, in eight countries, 2008. *Health Affairs,* 2009;28(1):w1-w16.
6. Nolte E, Knai C, McKee M (eds). *Managing chronic conditions. Experience in eight countries.* Brussels: European Observatory on Health Systems and Policies; 2008.

7. Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective. European Observatory on Health Systems and Policies Series.* New York: Open University Press; 2008.
8. Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European healthcare systems.* Cambridge: RAND Europe; 2012.
9. Schäfer W, Kroneman M, Boerma WGW, Van den Berg M, Westert G, Deville W, Van Ginneken R. The Netherlands: health system review. *Health Systems in Transition*, 2010;12(1):1-229.
10. Van Kemenade YW (ed). *Healthcare in Europe 2007: the finance and reimbursement systems of 11 European countries.* Maarssen: Elsevier; 2007.
11. Mur-Veeman I, Eijkelberg I, Spreeuwenberg C. How to manage the implementation of shared care: a discussion of the role of power, culture and structure in the development of shared care arrangements. *Journal of Management in Medicine*, 2001;15(2):142-55.
12. Maarse H, Bartholomée Y. A public-private analysis of the new Dutch health insurance system. *The European Journal of Health Economics,* 2007;8(1):77-82.
13. Nolte E, Knai C, Hofmarcher M, Conklin A, Erler A, Elissen A, Flamm M, Fullerton B, Sönnichsen A, Vrijhoef HJM. Overcoming fragmentation in health care: chronic care in Austria, Germany and the Netherlands. *Health Economics, Policy and Law*, 2012;7:125-146.
14. Saltman RB, Rico A, Boerma W (eds). *Primary care in the driver's seat? Organizational reform in European primary care.* Brussels: European Observatory on Health Systems and Policies; 2006.
15. Hofmarcher MM, Oxley H, Rusticelli E. *Improved health system performance through better care coordination.* Paris: OECD; 2007.
16. Vrijhoef HJM. *Is it justifiable to treat chronic patients by nurse specialists? Evaluation of effects on quality of care. Dissertation.* Maastricht: Maastricht University; 2002.
17. Exel van NJA, Koopmanschap MA, Scholte op Reimer W, Niessen LW, Huijsman R. Cost-effectiveness of integrated stroke services. *QJM,* 2005;98(6):415-25.
18. Vrijhoef HJM, Spreeuwenberg C, Eijkelberg IMJG, Wolffenbuttel BHR, Van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *British Medical Journal,* 2001;323:983-985.
19. Struijs JN, Van Til JT, Baan CA. *Experimenting with a bundled payment system for diabetes care in the Netherlands: the first tangible effects.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2009.
20. Struijs JN, Baan C. Integrating care through bundled payments: lessons from the Netherlands. *New England Journal of Medicine*, 2011;364:11-12.
21. Ministry of Health, Welfare and Sports. *A programmatic approach to chronic illness care.* Letter to Parliament, 13 June 2008.
22. Ministry of Health, Welfare and Sports. *Creating patient-centered care by implementing performance based financing.* Letter to Parliament, 22 December 2008.
23. De Bakker DH, Struijs JN, Baan CB, Raams J, De Wildt JE, Vrijhoef HJM, Schut FT. Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. *Health Affairs,* 2012;31(2):426-33.
24. Van Til JT, De Wildt J, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren*. Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
25. Netherlands Diabetes Federation. *NDF Care Standard. Transparency and quality of diabetes care for people with type 2 diabetes.* Amersfoort: Netherlands Diabetes Federation; 2007.
26. Platform Vitale Vaten. *Zorgstandaard Vasculair Risicomanagement Deel I (voor zorgverleners).* Den Haag: Platform Vitale Vaten; 2009.
27. Long Alliantie Nederland. *Zorgstandaard COPD*. Amersfoort: Long Alliantie Nederland; 2010.
28. Tsiachristas A, Hipple-Walters B, Lemmens KMM, Nieboer AP, Rutten-Van Mölken MPMH. Towards integrated care for chronic conditions: Dutch policy developments to overcome the (financial) barriers. *Health Policy,* 2011;101:122-132.
29. Ketelaars CAJ. Integrated care requires integrated supervision. *International Journal of Integrated Care*, 2011;11:1-6.

30. Ham C. The ten characteristics of the high-performing chronic care system. *Health Economics, Policy and Law,* 2010;5:71-90.
31. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *Journal of the American Medical Association*, 2002;288(14):1775-9.
32. Busse R, Blümel M, Scheller-Kreinsen D, Zentner A. *Tackling chronic disease in Europe. Strategies, interventions and challenges.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2010.
33. Boult C, Reider L, Frey K, Leff B, Boyd CM, Wolff JL, Wegener S, Marsteller J, Karm L, Scharfstein D. Early effects of "Guided Care" on the quality of health care for multimorbid older persons: a cluster-randomized controlled trial. *Journal of Gerontology,* 2008;63(3):321-327.
34. Bowles KH, Baugh AC. Applying research evidence to optimize telehomecare. *Journal of Cardiovascular Nursing*, 2007;22(1):5-15.
35. Clark RA, Inglis SC, McAlister FA, Cleland JGF, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *British Medical Journal*, 2007;334:942-49.
36. Seto E. Cost comparison between telemonitoring and usual care of heart failure: a systematic review. *Telemedicine Journal and E-Health*, 2008;14(7):679-86.
37. Arts EE, Landewe-Cleuren SA, Schaper NC, Vrijhoef HJ. The cost-effectiveness of substituting physicians with diabetes nurse specialists: a randomized controlled trial with 2-year follow-up. *Journal of Advanced Nursing*, 2011 [epub ahead of print].
38. Rijken M, Jones M, Heijmans M, Dixon A. *Supporting self-management*. In: Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective.* New York: Open University Press; 2008:116-142.
39. Singh D. *Which staff improve care for people with long-term conditions? A rapid review of the literature.* Birmingham: University of Birmingham and NHS Modernisation Agency; 2005.
40. Van Boheemen CAM, Van Geffen ECG, Philbert D, Bouvy ML, Bos M, Van Dijk L. *Vasculair risicomanagement vanuit patiëntenperspectief: volgens de zorgstandaard? Nulmeting patiënten.* Utrecht: Nivel; 2010.
41. Vervloet M, Brabers A, Bos M, Van Dijk L. *Vasculair risicomanagement in de huisartspraktijk: volgens de zorgstandaard? Nulmeting eerste lijn.* Utrecht: Nivel; 2010.
42. Elissen AMJ, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. *Evaluation of disease management in the Netherlands.* In: Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European healthcare systems.* Cambridge: RAND Europe; 2012:99-112.
43. Dutch Court of Audit. *Afstemming van de zorg rond chronische aandoeningen. Terugblik 2010.* The Hague: Dutch Court of Audit; 2010.

Chapter 3

Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes

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Journal of Evaluation in Clinical Practice, 2012; epub ahead of print

ABSTRACT

Objective: To support decision-making on how best to redesign diabetes care by investigating three potential sources of heterogeneity in effectiveness across trials of diabetes care management.
Methods: Medline, CINAHL, and PsycInfo were searched for systematic reviews and empirical studies focusing on: (1) diabetes mellitus; (2) adult patients; and (3) interventions consisting of at least two components of the Chronic Care Model (CCM). Systematic reviews were analysed descriptively; empirical studies were meta-analysed. Pooled effect measures were estimated using a meta-regression model that incorporated study quality, length of follow-up, and number of intervention components as potential predictors of heterogeneity in effects.
Results: Overall, reviews (N=15) of diabetes care programmes report modest improvements in glycaemic control. Empirical studies (N=61) show wide-ranging results on glycated haemoglobin (HbA1c), systolic blood pressure, and guideline adherence. Differences between studies in methodological quality cannot explain this heterogeneity in effects. Variety in length of follow-up can explain (part of) the variability, yet not across all outcomes. Diversity in the number of included intervention components can explain 8 to 12% of the heterogeneity in effects on HbA1c and systolic blood pressure.
Conclusions: The outcomes of chronic care management for diabetes are generally positive, yet differ considerably across trials. The most promising results are attained in studies with limited follow-up (<1 year) and by programmes including more than two CCM components. These factors can, however, explain only part of the heterogeneity in effectiveness between studies. Other potential sources of heterogeneity should be investigated to ensure implementation of evidence-based improvements in diabetes care.

INTRODUCTION

Traditional models of care, developed to react to acute episodes of illness, are not sufficiently equipped to deal with complex chronic diseases, such as diabetes mellitus.[1,2] Widespread quality deficiencies exist, including fragmentation, insufficient adherence to evidence-based practice guidelines, and limited follow-up of patients over time.[3-7] As a result, the outcomes of diabetes care – in terms of effectiveness, disease control, and patient satisfaction – are often inadequate. In response to these problems, new strategies of providing diabetes care are being introduced in many countries around the world. These strategies are as diverse as the health care systems in which they are implemented and include such concepts as case management, integrated care, and care coordination.[8-10] Perhaps best known internationally are disease management and the Chronic Care Model (CCM), both of which were introduced first in the United States (US). The CCM was adopted by the World Health Organisation (WHO) as an evidence-based guide for improvement in the four basic elements necessary for the provision of high-quality chronic care: self-management support, delivery system design, clinical information systems, and decision support.[11,12]

Despite the inherent logic and appeal of chronic care management – i.e. better care today will result in better health and less expensive care in the future – coming to strong conclusions regarding effectiveness has proven difficult.[13-16] The existing evidence base is limited and flawed by a high level of statistical heterogeneity, that is, variance in measured effects.[17-23] Variation in nomenclature contributes considerably to this heterogeneity in outcomes across studies, as do differences in methodology.[24,25] It is, however, especially the inherently multicomponent nature of chronic care management that presents evaluators and, in particular, systematic reviewers with challenges. Previous research has shown that differences between studies in the number and combination of included intervention components complicate the pooling of data that is so crucial to evidence-based medicine.[26]

In recent years, some authors have cautioned against the impulse to widely implement innovative but unproven care strategies, which might waste resources and could even have adverse effects on patients' health.[14,16,27] To prevent this, it is crucial that we revisit the current body of literature and elucidate the existing heterogeneity in effectiveness. The present review addresses this issue by synthesising the international literature on diabetes care management and, subsequently, assessing the extent to which differences in outcomes between studies of diabetes care management can be explained by differences in either of three factors: (1) methodological study quality; (2) length of follow-up; and (3) number of included intervention components according to the CCM. Study quality is investigated because this has been criticised in diabetes research[25] and including good and poor quality trials in a systematic review may increase heterogeneity of estimated effects across trials.[28, 29] Length of

follow-up is important in investigating complex multicomponent interventions, such as chronic care management, because the required behavioural, organisational and cultural changes need time to come about.[13] Hence, studies with a short follow-up period may either over- or underestimate effects.[30] The number of components included in an intervention is investigated as a potential cause of heterogeneity in results because the CCM assumes that more comprehensive programmes attain more promising effects.[11,12] Meta-analysis and meta-regression will be used to determine the pooled effects of diabetes care management programmes on different outcomes as well as to investigate the three potential sources of heterogeneity described above. Aim of the review is to support the understanding of and decision-making about how best to redesign diabetes care.

METHODS

Literature search

We combined Medical Subject Headings (*patient care team; patient care planning; primary nursing care; case management; critical pathways; primary health care; continuity of patient care; guidelines; practice guideline; disease management; comprehensive health care;* and *ambulatory care)* and text words *(disease state management; disease management; integrated care; coordinated care;* and *shared care*) related to chronic care management with the MeSH term *diabetes mellitus* to search the databases Medline, CINAHL and PsycInfo for English-language systematic reviews published between 1995 and 2011. The references from each of the included reviews were hand-searched for potentially relevant empirical studies.

Study inclusion and data extraction

We included any systematic review or empirical study that focused on: (1) diabetes mellitus as the main condition of interest; (2) adult patients as the main receivers of the interventions; and (3) interventions consisting of at least 2 components of the CCM.[11-13] Case reports and expert opinions were excluded, as were studies that did not report on any relevant outcome measure. Three members of the research team (AE, LS, LL) independently screened citations and abstracted included reviews and studies using separate structured data entry forms. Disagreements were resolved by consensus.

Assessing sources of heterogeneity

Based on the existing literature, we a priori identified three potential sources of heterogeneity in effects: methodological quality[25,28,29], length of follow-up[13,30], and number of included intervention components.[11,12] We used the validated HTA-DM instrument to classify studies as demonstrating either low (<50 points), moderate (50 to 69 points), or high quality (70 to 100 points).[31] The use of quality scales in systematic reviews has been criticised, particularly as a means to exclude or assign weights to trials[28,29], yet we applied a tailor-made, validated instrument and used this solely to categorise studies according to their quality. Length of follow-up was measured in months. For the purpose of meta-analysis, this variable was dichotomised (<1 year, ≥1 year); in the meta-regression, length of follow-up was included as a continuous variable (number of months). To group diabetes care programmes according to the four basic elements of the CCM, we followed the coding method of Zwar et al.[32], using the most recent description of the model's components by Wagner et al.[12]

Statistical analyses

Data collected from the reviews were analysed descriptively; data from empirical studies were in addition meta-analysed with the Review Manager (version 5.0.2; The Cochrane Collaboration). An a priori decision was made to meta-analyse the two most frequently measured clinical outcome indicators (glycated haemoglobin [HbA1c] and systolic blood pressure [SBP]) and the single most reported indicator of process (guideline adherence). To account for baseline differences between groups in clinical outcomes, the mean changes from baseline to follow-up were compared. Variances of changes were rarely reported, in which case they were assumed to be equal to one half of the sum of the variances of the baseline and follow-up measures.[33] Missing standard deviations were calculated by using reported 95% confidence intervals (CIs) or p-values[34] or, if such estimations were impossible, requested from the authors. In case of no response, the studies were excluded from the meta-analysis.

Given the heterogeneity between studies' results, we used the random-effects meta-analysis model of DerSimonian and Laird[35] to calculate pooled mean differences and 95% CIs in HbA1c and SBP. This model was also used to determine the pooled relative ratios (RR) and 95% CIs for guideline adherence. The I^2 statistic was calculated to quantify the heterogeneity between studies on the basis of the chi-squared (χ^2) test and its degrees of freedom.[34] A univariable meta-regression model (PROC MIXED, SAS Version 9.2, SAS Institute Inc, Cary, North Carolina) was fitted to estimate the extent to which covariates on the study level can explain the differences between studies in measured effects.[36,37] For this purpose, the effects of the empirical studies were weighted

by the inverse variance weight formulas. Relative ratios were logarithm transformed.[38] All covariates – i.e. study quality, length of follow-up, and number of intervention components – were entered into the regression model as continuous variables. The level of heterogeneity explained was expressed as the percentage change in τ^2 (between-study variance) following separate inclusion of the covariates.

RESULTS

Fifteen systematic reviews[17-23,26,33,39-44] (eight of which included a meta-analysis) and 61 empirical studies[45-105] met all inclusion criteria (Figure 1). The number of studies included in the reviews varied from 5 to 58, with a median of 20. The set of empirical studies included 41 randomised controlled trials (RCTs), 6 controlled clinical trials (CCTs), and 4 before-after (BA) studies. The remaining 10 trials were observational studies.

Findings from systematic reviews

The reviews (Appendix 1) synthesise evidence on a wide variety of strategies for diabetes care, ranging from disease management and case management to telemonitoring, specialist nurse interventions, and shared care. Common aspect of the programmes is their strong focus on improving glycaemic control to prevent diabetes-related complications, such as hypoglycaemia. The outcomes reported in the reviews vary, but some frequently measured variables are HbA1c (N=13), blood pressure (N=9), and quality of life (N=5). Overall, the reviews draw positive conclusions about effectiveness, although improvements in glycaemic control are often modest.

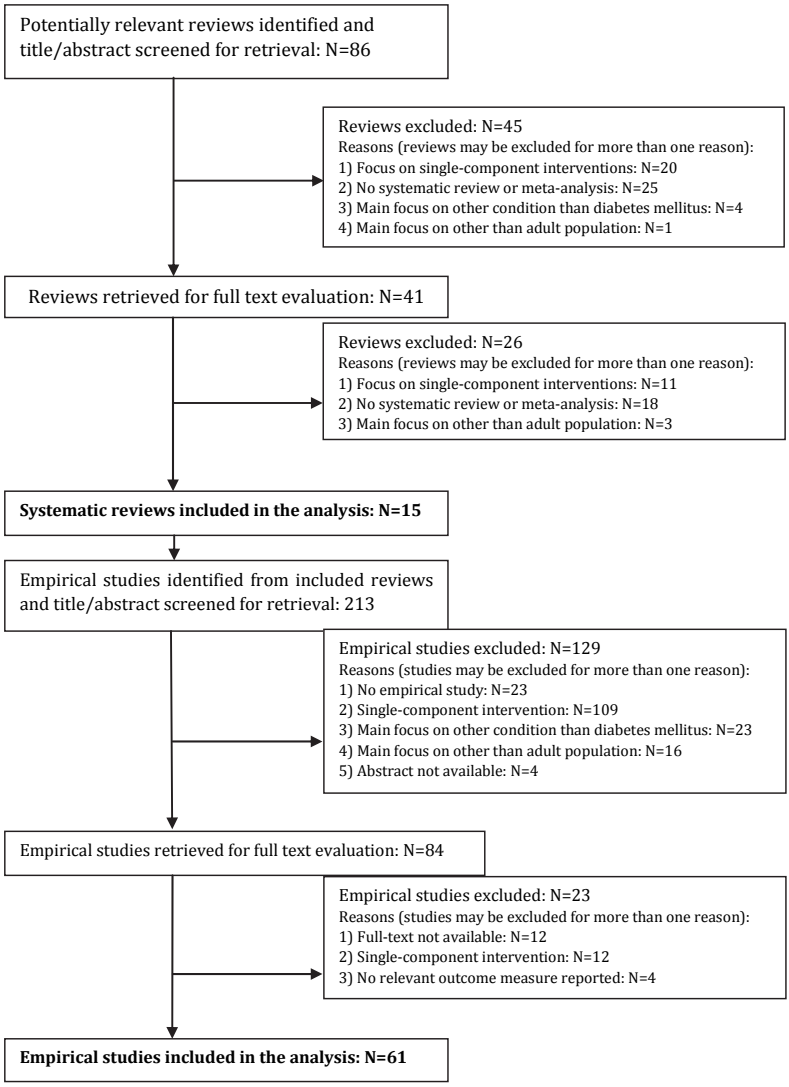

Figure 1: Study inclusion/exclusion flowchart

Findings from empirical studies

Of the 61 empirical studies (Appendix 2), 39% scored high on methodological quality, 56% scored moderate, and 5% scored poor. Length of follow-up varied from 3 to 48 months, with a median of 12 months. Forty-two studies (69%) reported a follow-up of 12 months or more. Twenty-one studies evaluated chronic care management programmes with two CCM components, 19 evaluated programmes with three components, and 21 evaluated programmes with four components. The most frequently included components of the CCM were

delivery system design (DSD; N=52) and self-management support (SMS; N=49), followed by clinical information systems (CIS; N=47) and decision support (DS; N=35). The 21 programmes consisting of two CCM components favoured a combination of SMS and DSD (43%), whereas the 19 three component interventions most commonly combined SMS, DSD, and CIS (53%).

Although the operationalisation of CCM components differed between studies, some general trends can be identified. SMS most frequently took the form of patient education and regular follow-up by diabetes nurse educators. DSD often consisted of the introduction of multidisciplinary care teams or the involvement of pharmacists, case managers, and/or nurse specialists in the care for diabetes patients. CIS were mainly telemonitoring systems but also computerised patient databases, shared patient records, and reminder systems. DS was offered through the implementation of diabetes guidelines as well as medication algorithms. Most interventions aimed to improve glycaemic control by supporting self-management, reducing fragmentation, and/or providing evidence-based care. In general, control groups continued to receive usual care from their primary care physicians, although some were also given access to educational materials (Appendix 2). The two clinical outcomes measured most frequently were HbA1c (N=60) and SBP (N=34), whereas guideline adherence was measured most regularly as a process indicator (N=19). These three variables were meta-analysed (Table 1).

Glycated haemoglobin (HbA1c)

All but one study[79] assessed HbA1c levels (N=60), although some[62,69,82,103] reported the fractions of patients accomplishing a certain level of glycated haemoglobin at study end (e.g. <53 mmol/mol [7.0%]) rather than the actual values. These studies were excluded from the meta-analysis, as were those for which missing data could not be estimated nor retrieved.[50,59,63,64,78,89,99,104]

Overall, the pooled effect estimate (N=48) demonstrates that chronic care management for diabetes results in a statistically significant reduction in HbA1c of 5 mmol/mol [0.5%], compared to (mostly) usual care (95% CI: -7 to -3.5 mmol/mol [-0.6 to -0.3%]). Subgroup analyses (Table 1) reveal that, apart from low quality studies (N=1), all subgroups of studies show a significant positive effect on HbA1c. The most notable improvements are attained by three component programmes, studies with a follow-up of less than 12 months, and moderate quality studies. The overall as well as the subgroup analyses show strong heterogeneity (I^2 ranging from 71 to 87%). Meta-regression demonstrates no significant effect of study quality, length of follow-up, or number of intervention components on the reduction in HbA1c (Table 1), although correcting for the latter covariate does result in an 8% reduction in statistical heterogeneity.

Table 1: Results of the meta-analysis and meta-regression

	No. of Studies	No. of Participants	Mean difference (95% CI; I^2)	Explained heterogeneity (p)
HbA1c (mmol/mol [%])	**48**	**11,457**	**-5 [-0.5] (-7, -3.5 [-0.6, -0.3]; 80%)**	
Study quality				*1% (p=0.68)*
Low quality	1	56	-2 [-0.2] (-9, 4 [-0.8, 0.4]; NA)	
Moderate quality	26	5,174	-6 [-0.6] (-9, -3.5 [-0.8, -0.3]; 82%)	
High quality	21	6,227	-4 [-0.4] (-6, -2 [-0.6, -0,2]; 77%)	
Length of follow-up				*0.5% (p=0.66)*
<1 year	19	2,097	-7 [-0.6] (-9, -4 [-0.9, -0.3]; 71%)	
≥1 year	29	9,360	-4 [-0.4] (-6, -2 [-0.6, -0.2]; 83%)	
Number of components				*8% (p=0.22)*
2	19	4,697	-4 [-0.3] (-6, -1 [-0.55, -0.1]; 71%)	
3	13	1,667	-8 [-0.7] (-13, -3 [-1.2, -0.3]; 87%)	
4	16	5,093	-4.5 [-0.4] (-7, -2 [-0.6, -0.2]; 75%)	
	No. of Studies	**No. of Participants**	**Mean difference (95% CI; I^2)**	**Explained heterogeneity (p)**
SBP (mmHg)	**25**	**7,719**	**-2.8 (-4.7, -0.9; 68%)**	
Study quality				*1.5% (p=0.68)*
Low quality	0	0	Not estimable	
Moderate quality	11	3,099	-2.7 (-5.0, -0.4; 54%)	
High quality	14	4,620	-3.0 (-5.9, -0.1; 76%)	
Length of follow-up				*5% (p=0.42)*
<1 year	5	593	-3.4 (-7.0, -0.25; 18%)	
≥1 year	20	7,126	-2.7 (-4.8, -0.6; 72%)	
Number of components				*12% (p=0.20)*
2	9	2,860	-0.6 (-4.6, 3.4; 83%)	
3	5	809	-3.3 (-6.1, -0.5; 3%)	
4	11	4,050	-4.4 (-6.8, -2.0; 57%)	
	No. of Studies	**No. of Participants**	**Relative ratio (95% CI; I^2)**	**Explained heterogeneity (p)**
Yearly eye examination	**10**	**6,232**	**1.88 (1.46, 2.42; 95%)**	
Study quality				*11% (p=0.2758)*
Low quality	1	1,644	1.58 (1.44, 1.74; NA)	
Moderate quality	5	3,387	3.04 (1.67, 5.55;97%)	
High quality	4	1,201	1.20 (1.05, 1.37; 52%)	
Length of follow-up				*21% (p=0.1185)*
<1 year	0	0	Not estimable	
≥1 year	10	6,232	1.88 (1.46, 2.42; 95%)	
Number of components				*7% (p=0.3727)*
2	0	0	Not estimable	
3	7	4,989	2.13 (1.56, 2.91; 96%)	
4	3	1,243	1.45 (0.87, 2.43; 94%)	

	No. of Studies	No. of participants	Relative ratio (95% CI; I^2)	Explained heterogeneity (p)
Yearly foot examination	**10**	**6,818**	**2.11 (1.55, 2.86; 98%)**	
Study quality				*1% (p=0.7341)*
Low quality	1	1,644	7.91 (5.98, 10.46; NA)	
Moderate quality	5	3,387	1.94 (1.30, 2.91; 97%)	
High quality	4	1,787	1.64 (1.14, 2.35; 95%)	
Length of follow-up				*49% (p=0.0032)*
<1 year	0	0	Not estimable	
≥1 year	10	6,818	2.11 (1.55, 2.86; 98%)	
Number of components				*1% (p=0.7360)*
2	1	769	1.27 (1.09, 1.48; NA)	
3	6	4,806	2.80 (1.72, 4.55; 98%)	
4	3	1,243	1.55 (0.97, 2.49; 94%)	

NOTE: CI indicates confidence interval; I^2, statistical heterogeneity; NA, not applicable; HbA1c, glycated haemoglobin; SBP, systolic blood pressure

Systolic blood pressure (SBP)

More than half (N=34) of the studies included in this review assessed SBP.[45,48,53-56,58,60,61,64,65,67-70,72,73,75-77,79,84-86,88-90,93,95-98,100,102] Excluded from the meta-analysis were studies reporting the fractions of patients achieving a certain level of SBP rather than the actual values at follow-up and studies for which variances of changes could not be estimated nor retrieved.[48,64,65,68,69,89,90,96,102]

The meta-analysis (N=25) demonstrates a statistically significant overall reduction in SBP of 2.8 mmHg (95% CI: -4.7 to -0.95 mmHg) in the intervention groups as compared to the control groups. Subgroup analyses show that two-component interventions and studies with a follow-up of less than one year are not associated with a significant reduction in SBP. Moderate heterogeneity exists between studies in terms of measured effects (I^2=68%). Meta-regression demonstrates no significant effect of study quality, length of follow-up, or number of intervention components on the reduction in SBP (Table 1), although correcting for the latter covariate does result in a 12% reduction in statistical heterogeneity.

Guideline adherence

About one third of the included studies (N=19) uses providers' adherence to evidence-based guidelines as an indicator of process and compares the extent to which intervention and control patients received recommended medical procedures over specific periods of time (usually 12 months).[47,52-55,60,62,64,67,69,79,80,86,89-91,100,103,104] As the content of the diabetes guidelines used in the chronic care management programmes differs considerably, the two most uniformly and frequently measured recommendations were meta-

analysed (Table 1). These concern the yearly provision of one eye examination (N=10) and one foot examination (N=10).

The meta-analysis for eye examinations[60,62,69,80,86,89,90,100,103,104] provides a pooled RR of 1.88 (95% CI: 1.46 to 2.42), indicating a significantly greater probability of yearly eye screenings in the intervention groups. The likelihood for patients to receive a yearly foot exam is 111% higher in the intervention groups (N=10; RR=2.11; 95% CI: 1.55 to 2.86).[54,60,62,69,80,86,89,90,103,104] Subgroup analyses, which were possible for number of components and study quality, demonstrate that only three-component programmes attain statistically significant improvements in the rates of yearly eye and foot examinations. Meta-regression does not, however, show significance for either of these covariates, which implies that they cannot explain the heterogeneity between studies (I^2 ranging from 52 to 98%). Variation in length of follow-up, included in the meta-regression as a continuous variable (i.e. number of months), explains 49% of the heterogeneity in effects on foot screening (p=0.003), yet cannot explain variability with regard to effects on eye examinations (p=0.12).

DISCUSSION

In line with previously conducted systematic reviews in this field, our meta-analysis suggests that chronic care management programmes have positive effects on the processes and outcomes of diabetes care. However, the empirical studies underlying our analysis differ considerably in both the directions and sizes of measured effects. Diversity in study quality does not appear to explain this statistical heterogeneity, although few of the trials included in our analysis were categorised as having low quality (which might be a consequence of our strategy of searching for empirical studies via systematic reviews). Variety in length of follow-up explains 49% of the variability across trials in effects on providers' adherence to foot screening guidelines (p=0.003). In terms of effects on clinical outcomes, the overall positive impact of chronic care management appears to diminish with increased length of follow-up, although the differences between subgroups are not statistically significant. Given that the positive effects of education on patients' self-management behaviour – and, thus, their glycaemic control – are difficult to maintain over time[106-108], short studies might overestimate effectiveness.

Variety in the number of intervention components elucidates 8 to 12% of the diversity between studies with regard to measured changes in HbA1c and SBP. Three- and four-component interventions attain stronger, though not significantly stronger, effect estimates than do two-component strategies. This finding is conform the presumption of the CCM that changes must be made in multiple areas in order to considerably improve the quality and outcomes of

chronic care.[11,12] Relatively few trials evaluated diabetes care programmes that integrated all CCM components, even despite the relatively long existence of and strong scientific support for this framework.[11-13] This might very well limit the effects of chronic care management on patient outcomes.

As far as we are aware, this study is the first meta-analysis of chronic care management for diabetes that attempts to explain statistical heterogeneity by assessing differences in methodological quality, length of follow-up, and number of intervention components according to the CCM. Shojania et al.[26] conducted a meta-analysis of diabetes care strategies with adjustment for effects of study size and mean baseline HbA1c values: these factors reduced statistical heterogeneity by approximately 50%. More recently, Pimouguet et al.[44] assessed the effect of various patient characteristics and disease management features on changes in HbA1c concentration. The authors found that disease management programmes are more effective for patients with poor glycaemic control (baseline HbA1c >8.0%). Moreover, treatment adjustment (i.e. the ability of disease managers to start or modify medical treatment) and patient education were identified as effective features of disease management. In line with our results, Pimouguet et al.[44] also found that shorter studies report more promising effects on glycaemic control than do longer studies, although this difference did not achieve statistical significance.

Other reviews have also attempted to answer the question 'what is most effective' in diabetes care[16,17,21], but their results are divergent and questionable, as there is a lack of clear terminology in the area of chronic care management. Hence, fundamentally different interventions share the same moniker, which may obscure important information concerning their working mechanisms, especially when they differ in effectiveness.[24] The potential causes of heterogeneity included in our analyses were selected on the basis of the available evidence. Nonetheless, the variation in effect sizes across trials is likely to be caused by other study-level factors, such as differences in study design, target population, and implementation context. The degree of integration of intervention components might also be an important cause of statistical heterogeneity, as the CCM assumes that programmes in which elements are strongly interrelated result in better outcomes than programmes in which elements are more loosely coupled.[11,12]

Our study used an extensive search strategy following the internationally accepted definition of chronic care management[109] and was conducted on the basis of combined expertise from five research institutes. Nevertheless, some limitations should be noted. First, it can be questioned whether the HTA-DM instrument[31] – the only relevant and tested instrument for assessing the quality of studies evaluating chronic care management – allows for proper scoring of items that bias the effect of interventions for diabetes, as it focuses primarily on the quality of reporting. Further validation of a quality instrument for studies evaluating complex interventions, such as chronic care programmes, is needed.

Second, the care received by intervention as well as control patients is often poorly described, which makes comparisons between studies difficult and complicates the mapping of intervention components to the CCM. In addition, many studies exhibit a paucity of descriptive detail – standard deviations and p-values are rarely reported – which necessitates either the use of estimates or exclusion from the analyses. Finally, the outcomes of our review are restricted to the effect measures used most frequently in the existing evidence on diabetes care management, whereas others, such as patients' health-related quality of life, self-efficacy, and satisfaction with care, might be equally or even more important.[110-113]

More research is needed to understand and support decision-making on how best to redesign the care for patients suffering from diabetes. Coming to strong and consistent conclusions about the impact of chronic care management necessitates a clear framework of the mechanisms underlying various strategies and their expected effects. The latter should be measured with adequate length of follow-up and linked logically with an intervention's aims and components as well as the underlying theory driving the anticipated behaviour change in both patients and care providers. Moreover, evaluation efforts must be based on proper understanding of the characteristics of disease management programmes (i.e. scope, content, dose, context) and the populations that specific interventions target (i.e. disease type, severity, case-mix).[114] Elucidating heterogeneity in this manner allows for more in-depth and disentangled insights into the effects of chronic care management and aids in answering the vital question of 'what works best for whom' in diabetes care.

REFERENCES

1. Bodenheimer T, Grumbach K. *Improving primary care: strategies and tools for a better practice.* New York, NY: McGraw-Hill; 2007.
2. Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century*. Washington, DC: National Academy Press; 2001.
3. Stange KC. The problem of fragmentation and the need for integrative solutions. *Annals of Family Medicine,* 2009;7(2):100-103.
4. Shah BR, Hux JE, Laupacis A, Zinman B, Zwarenstein M. Deficiencies in the quality of diabetes care. Comparing specialist with generalist care misses the point. *Journal of General Internal Medicine,* 2007;22(2):275-79.
5. Kenny SJ, Smith PJ, Goldschmid MG, Newman JM, Herman WH. Survey of physician practice behaviours related to diabetes mellitus in the US: physician adherence to consensus recommendations. *Diabetes Care*, 1993;16:1507-10.
6. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. Part one. *Journal of the American Medical Association*, 2002;288(14):1775-9.
7. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. Part two. *Journal of the American Medical Association*, 2002;288(15):1909-14.

8. Greβ S, Baan CA, Calnan M, Dedeu T, Groenewegen P, Howson H, Maroy L, Nolte E, Redaèlli M, Saarelma O, Schmacke N, Schumacher K, Van Lente EJ, Vrijhoef HJM. Co-ordination and management of chronic conditions in Europe: the role of primary care. Position paper of the European Forum for Primary Care. *Quality in Primary Care*, 2009;17:75-86.
9. Nolte E, Knai C, McKee M. *Managing chronic conditions. Experience in eight countries.* Brussels: European Observatory on Health Systems and Policies; 2008.
10. Hofmarcher MM, Oxley H, Rusticelli E. *Improved health system performance through better care coordination. OECD Health Working Paper*. Paris: Organization for Economic Cooperation and Development (OECD); 2007.
11. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Effective Clinical Practice*, 1998;1(1):2-4.
12. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs*, 2001;20(6):64-78.
13. Coleman K, Austin BT, Brach C, Wagner E. Evidence on the chronic care model in the new millennium. *Health Affairs*, 2009;28(1):75-85.
14. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care*, 2007;13(12):670-76.
15. Congressional Budget Office. *An analysis of the literature on disease management programmes.* Washington, DC: United States Congress; 2004.
16. Scott I. What are the most effective strategies for improving quality and safety of health care? Review. *Internal Medicine Journal*, 2009;39:389-400.
17. DeCoster VA, Cummings SM. Helping adults with diabetes: a review of evidence-based interventions. *Health & Social Work*, 2005;30(3):259-64.
18. Glazier RH, Bajcar J, Kennie NR, Willson K. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care*, 2006;29(7):1675-88.
19. Loveman E, Royle P, Waugh N. Specialist nurses in diabetes mellitus. *Cochrane Database of Systematic Reviews*, 2003;2:cd003286.
20. Norris SL, Chowdhury FM, Van Le K, Horsley T, Brownstein JN, Zhang X, Jack L, Satterfield DW. Effectiveness of community health workers in the care of persons with diabetes. *Diabetic Medicine*, 2006;23(5):544-56.
21. Renders CM, Valk GD, Griffin SJ, Wagner EH, Van Eijk JT, Assendelft WJ. Interventions to improve the management of diabetes in primary care, outpatient and community settings: a systematic review. *Diabetes Care*, 2001;24(10):1821-33.
22. Whittemore R. Culturally competent interventions for Hispanic adults with type 2 diabetes: a systematic review. *Journal of Transcultural Nursing*, 2007;18(2):157-66.
23. Wubben DP, Vivian EM. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: a systematic review. *Pharmacotherapy*, 2008;28(4):421-36.
24. Coleman K, Mattke S, Perrault PJ, Wagner EH. Untangling practice redesign from disease management: how do we best care for the chronically ill? *Annual Review of Public Health,* 2009;30:385-408.
25. Montori VM, Grace Wang Y, Alonso-Coello P, Bhagra S. Systematic evaluation of the quality of randomized controlled trials in diabetes. *Diabetes Care*, 2006;29(8):1833-38.
26. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK. Effects of quality improvement strategies for type 2 diabetes: a meta-regression analysis. *Journal of the American Medical Association*, 2006;296(4):427-40.
27. Auerbach AD, Landefeld CS, Shojania KG. The tension between needing to improve care and knowing how to do it. *New England Journal of Medicine*, 2007;357:608-13.
28. Jüni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. *Journal of the American Medical Association*, 1999;282(11):1054-60.
29. Jüni P, Altman DG, Egger M. Assessing the quality of controlled clinical trials. Systematic reviews in health care. *British Medical Journal*, 2001;323:42-46.
30. Linden A, Adler-Milstein J. Medicare disease management in policy context. *Health Care Financial Review*, 2008;29(3):1-11.

31. Steuten LMG, Vrijhoef HJM, Van Merode GG, Severens JL, Spreeuwenberg C. The Health Technology Assessment-Disease Management instrument reliably measured methodologic quality of health technology assessments of disease management. *Journal of Clinical Epidemiology*, 2004;57:881-888.
32. Zwar N, Harris M, Griffiths R, Roland M, Dennis S, Powell Davies G, Hasan I. *A systematic review of chronic disease management.* Sydney: University of New South Wales, Research Centre for Primary Health Care and Equity, School for Public Health and Community Medicine; 2006.
33. Knight K, Badamgarav E, Henning JM, Hasselblad V, Gano AD, Ofman JJ, Weingarten SR. A systematic review of diabetes disease management programmes. *American Journal of Managed Care*, 2005;11(4):242-50.
34. Higgins JPT, Green S (eds). *Cochrane handbook for systematic reviews of interventions. Version 5.0.2.* Chichester, West Sussex: John Wiley & Sons; 2009.
35. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Controlled Clinical Trials*, 1986;7:177-188.
36. Thompson SG, Higgins JP. How should meta-regression analyses be undertaken and interpreted? *Statistics in Medicine*, 2002;21(11):1559-73.
37. Van Houwelingen HC, Arends LR, Stijnen T. Advanced methods in meta-analysis: multivariate approach and meta-regression. *Statistics in Medicine*, 2002;21(4):589-624.
38. Lipsey MW, Wilson DB. *Practical meta-analysis. Applied social research methods series, vol. 49.* Thousand Oaks, CA: Sage; 2001.
39. Centers for Disease Control and Prevention (CDC). *Strategies for reducing morbidity and mortality from diabetes through health-care system interventions and diabetes self-management education in community settings. A report on recommendations of the Task Force on Community Preventive Services.* Atlanta, GA: CDC; 2001.
40. Griffin S, Kinmonth AL. Diabetes care: the effectiveness of systems for routine surveillance for people with diabetes. *Cochrane Database of Systematic Reviews*, 2000;2:cd000541.
41. Norris SL, Nichols PJ, Caspersen CJ, Glasgow RE, Engelgau MM, Jack L, Isham G, Snyder SR, Carande-Kulis VG, Garfield S, Briss P, McCulloch D. The effectiveness of disease and case management for people with diabetes. A systematic review. *American Journal of Preventive Medicine*, 2002;22(4):15-38.
42. Smith SM, Allwright S, O'Dowd T. Effectiveness of shared care across the interface between primary and specialty care in chronic disease management. *Cochrane Database of Systematic Reviews,* 2007;3:cd004910.
43. Verhoeven F, Van Gemert-Pijnen L, Dijkstra K, Nijland N, Seydel E, Steehouder M. The contribution of teleconsultation and videoconferencing to diabetes care: a systematic review. *Journal of Medical Internet Research*, 2007;9(5):e37.
44. Pimouguet C, Le Goff M, Thiébaut R, Dartigues JF, Helmer C. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Canadian Medical Association Journal*, 2011;183(2):E115-E127.
45. Aubert RE, Herman WH, Waters J, Moore W, Sutton D, Peterson BL, Bailey CM, Koplan JP. Nurse case management to improve glycemic control in diabetic patients in a Health Maintenance Organization. A randomized, controlled trial. *Annals of Internal Medicine*, 1998;129(8):605-612.
46. Bellazzi R, Arcelloni M, Bensa G, Blankenfeld H, Brugués E, Carson E, Cobelli C, Cramp D, D'Annunzio G, De Cata P, De Leiva A, Deutsch T, Fratino P, Gazzaruso C, Garcia A, Gergely T, Gómez E, Harvey F, Ferrari P, Hernando E, Boulos MK, Larizza C, Ludekke H, Maran A, Nucci G, Pennati C, Ramat S, Roudsari A, Rigla M, Stefanelli M. Design, methods, and evaluation directions of a multi-access service for the management of diabetes mellitus patients. *Diabetes Technology & Therapeutics*, 2003;5(4):621-629.
47. Choe HM, Mitrovich S, Dubay D, Hayward RA, Krein SL, Vijan S. Proactive case management of high-risk patients with type 2 diabetes mellitus by a clinical pharmacist: a randomized controlled trial. *American Journal of Managed Care*, 2005;11(4):253-260.

48. Chumbler NR, Neugaard B, Ryan P, Qin H, Joo Y. An observational study of veterans with diabetes receiving weekly or daily home telehealth monitoring. *Journal of Telemedicine & Telecare*, 2005;11(3):150-156.
49. Clifford RM, Batty KT, Davis TME, Davis W, Stein G, Stewart G, Plumridge RJ. A randomised controlled trial of a pharmaceutical care programme in high-risk diabetic patients in an outpatient clinic. *International Journal of Pharmacy Practice*, 2002;10:85-89.
50. Cook CB, Ziemer DC, El-Kebbi IM, Gallina DL, Dunbar VG, Ernst KL, Phillips LS. Diabetes in urban African-Americans. XVI. Overcoming clinical inertia improves glycemic control in patients with type 2 diabetes. *Diabetes Care*, 1999;22(9):1494-1500.
51. Dale J, Caramlau I, Sturt J, Friede T, Walker R. Telephone peer-delivered intervention for diabetes motivation and support: the telecare exploratory RCT. *Patient Education and Counseling*, 2009;75:91-98.
52. Davidson MB. Effect of nurse-directed diabetes care in a minority population. *Diabetes Care*, 2003;26:2281-2287.
53. De Sonnaville JJJ, Bouma M, Colly LP, Devillé W, Wijkel D, Heine RJ. Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study. *Diabetologia*, 1997;40:1334-1340.
54. Dijkstra RF, Braspenning JCC, Huijsmans Z, Akkermans RP, Van Ballegooie E, Ten Have P, Casparie T, Grol RP. Introduction of diabetes passports involving both patients and professionals to improve hospital outpatient diabetes care. *Diabetes Research and Clinical Practice*, 2005;68:126-134.
55. Domurat ES. Diabetes managed care and clinical outcomes: The Harbor City, California Kaiser Permanente Diabetes Care System. *American Journal of Managed Care*, 1999;5(10):1299-1307.
56. Doucette WR, Witry MJ, Farris KB, McDonough RP. Community pharmacist-provided extended diabetes care. *Annals of Pharmacotherapy*; 2009;43:882-89.
57. Farmer AJ, Gibson OJ, Dudley C, Bryden K, Hayton PM, Tarassenko L, Neil A. A randomized controlled trial of the effect of real-time telemedicine support on glycemic control in young adults with type 1 diabetes (ISRCTN 46889446). *Diabetes Care*, 2005;28:2697-2702.
58. Fornos JA, Andrés NF, Andrés JC, Guerra MM, Egea B. A pharmacotherapy follow-up program in patients with type-2 diabetes in community pharmacies in Spain. *Pharmacy World & Science*, 2006;28:65-72.
59. Friedman NM, Gleeson JM, Kent MJ, Foris M, Rodriguez DJ, Cypress M. Management of diabetes mellitus in the Lovelace Health Systems' Episodes of Care Program. *Effective Clinical Practice*, 1998;1(1):5-11.
60. Gabbay RA, Lendel I, Saleem TM, Shaeffer G, Adelman AM, Mauger DT, Collins M, Polomano RC. Nurse case management improves blood pressure, emotional distress and diabetes complication screening. *Diabetes Research and Clinical Practice*, 2006;71:28-35.
61. Gary TL, Bone LR, Hill MN, Levine DM, McGuire M, Saudek C, Brancati FL. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Preventive Medicine*, 2003;37:23-32.
62. Goldfracht M, Porath A. Nationwide program for improving the care of diabetic patients in Israeli primary care centers. *Diabetes Care*, 2000;23(4):495-499.
63. Gong C, Hasson NK, Lum BL. Impact of a diabetes disease management clinic on the total glycosylated hemoglobin of patients with type 2 diabetes mellitus. *Journal of Managed Care Pharmacy*, 1999;5(6):511-515.
64. Grant RW, Cagliero E, Sullivan CM, Dubey AK, Estey GA, Weil EM, Gesmundo J, Nathan DM, Singer DE, Chueh HC, Meigs JB. A controlled trial of population management. Diabetes mellitus: putting evidence into practice (DM-PEP). *Diabetes Care*, 2004;27(10):2299-2305.
65. The California Medi-Cal Type 2 Diabetes Study Group. Closing the gap: effect of diabetes case management on glycemic control among low-income ethnic minority populations. The California Medi-Cal Type 2 Diabetes Study. *Diabetes Care*, 2004;27(1):95-103.

66. Henault RG, Eugenio KR, Kelliher AF, Alexis G, Conlin PR. Transmitting clinical recommendations for diabetes care via e-mail. *American Journal of Health-System Pharmacy*, 2002;59:2166-2169.
67. Hetlevik I, Holmen J, Krüger O, Kristensen P, Iversen H, Furuseth K. Implementing clinical guidelines in the treatment of diabetes mellitus in general practice. Evaluation of effort, process, and patient outcome related to implementation of a computer-based decision support system. *International Journal of Technology Assessment in Health Care*, 2000;16(1):210-227.
68. Hirsch IB, Goldberg HI, Ellsworth A, Evans TC, Herter CD, Ramsey SD, Mullen M, Neighbor WE, Cheadle AD. A multifaceted intervention in support of diabetes treatment guidelines: a cont trial. *Diabetes Research and Clinical Practice*, 2002;58:27-36.
69. Ilag LL, Martin CL, Tabaei BP, Isaman DJ, Burke R, Greene DA, Herman WH. Improving diabetes processes of care in managed care. *Diabetes Care*, 2003;26(10):2722-2727.
70. Kelly C, Rodgers PT. Implementation and evaluation of a pharmacist-managed diabetes service. *Journal of Managed Care Pharmacy*, 2000;6(6):488-93.
71. Kim H, Oh J. Adherence to diabetes control recommendations: impact of nurse telephone calls. *Journal of Advanced Nursing*, 2003;44(3):256-261.
72. Kim MT, Han HR, Song HJ, Lee JE, Kim J, Ryu JP, Kim KB. A community-based, culturally tailored behavioral intervention for Korean Americans with type 2 diabetes. *The Diabetes Educator*, 2009:35(6):986-94.
73. Ko GTC, Li JKY, Kan ECY, Lo MK. Effects of a structured health education programme by a diabetic education nurse on cardiovascular risk factors in Chinese type 2 diabetic patients: a 1-year prospective randomized study. *Diabetic Medicine*, 2004;21:1274-79.
74. Ko SH, Song KH, Kim SR, Lee JM, Kim JS, Shin JH, Cho YK, Park YM, Jeong JH, Yoon KH, Cha BY, Son HY, Ahn YB. Long-term effects of a structured intensive diabetes education programme (SIDEP) in patients with type 2 diabetes mellitus – a 4-year follow-up study. *Diabetic Medicine*, 2007;24:55-62.
75. Krass I, Taylor SJ, McInman AD, Armour CL. The pharmacist's role in continuity of care in type 2 diabetes: an evaluation of a model. *Journal of Pharmacy Technology*, 2006;22:3-8.
76. Krass I, Armour CL, Mitchell B, Brillant M, Dienaar R, Hughes J, Lau P, Peterson G, Stewart K, Taylor S, Wilkinson J. The Pharmacy Diabetes Care Program: assessment of a community pharmacy diabetes service model in Australia. *Diabetic Medicine*, 2007;24:677-683.
77. Krein SL, Klamerus ML, Vijan S, Lee JL, Fitzgerald JT, Pawlow A, Reeves P, Hayward RA. Case management for patients with poorly controlled diabetes: a randomized trial. *The American Journal of Medicine*, 2004;116:732-739.
78. Legorreta AP, Peters AL, Ossorio RC, Lopez RJ, Jatulis D, Davidson MB. Effect of a comprehensive nurse-managed diabetes program: an HMO prospective study. *American Journal of Managed Care*, 1996;2(8):1024-1030.
79. Leung WYS, So W, Tong PCY, Chan NN, Chan JC. Effects of structured care by a pharmacist-diabetes specialist team in patients with type 2 diabetic nephropathy. *The American Journal of Medicine*, 2005;118(12):1414.e21-1414.e27.
80. Litaker D, Mion LC, Planavsky L, Kippes C, Mehta N, Frolkis J. Physician - nurse practitioner teams in chronic disease management: the impact on costs, clinical effectiveness, and patients' perception of care. *Journal of Interprofessional Care*, 2003;17(3):223-237.
81. Maislos M, Weisman D. Multidisciplinary approach to patients with poorly controlled type 2 diabetes mellitus: a prospective, randomized study. *Acta Diabetologica*, 2004;41:44-48.
82. Majumdar SR, Guirguis LM, Toth EL, Lewanczuk RZ, Lee TK, Johnson JA. Controlled trial of a multifaceted intervention for improving quality of care for rural patients with type 2 diabetes. *Diabetes Care*, 2003;26(11):3061-3066.
83. McKay HG, Glasgow RE, Feil EG, Boles SM, Barrera M. Internet-based diabetes self-management and support: initial outcomes from the diabetes network project. *Rehabilitation Psychology*, 2002;47(1):31-48.

84. McMahon GT, Gomes HE, Hickson-Hohne S, Hu TM, Levine BA, Conlin PR. Web-based care management in patients with poorly controlled diabetes. *Diabetes Care*, 2005;28(7):1624-1629.
85. Ménard J, Payette H, Baillargeon J, Maheux P, Lepage S, Tessier D, Ardilouze JL. Efficacy of intensive multitherapy for patients with type 2 diabetes mellitus: a randomized controlled trial. *Canadian Medical Association Journal*, 2005;173(12):Online1-10.
86. O'Connor PJ, Desai J, Solberg LI, Reger LA, Crain AL, Asche SE, Pearson TL, Clark CK, Rush WA, Cherney LM, Sperl-Hillen JM, Bishop DB. Randomized trial of quality improvement intervention to improve diabetes care in primary care settings. *Diabetes Care*, 2005;28(8):1890-1897.
87. Odegard PS, Goo A, Hummel J, Williams KL, Gray SL. Caring for poorly controlled diabetes mellitus: a randomized pharmacist intervention. *Annals of Pharmacotherapy*, 2005;39:433-440.
88. O'Hare JP, Raymond NT, Mughal S, Dodd L, Hanif W, Ahmad Y, Mishra K, Jones A, Kumar S, Szczepura A, Hillhouse EW, Barnett AH. Evaluation of delivery of enhanced diabetes care to patients of South Asian ethnicity: the United Kingdom Asian Diabetes Study (UKADS). *Diabetic Medicine*, 2004;21:1357-1365.
89. Peters AL, Davidson MB. Application of a diabetes managed care program. The feasibility of using nurses and a computer system to provide effective care. *Diabetes Care*, 1998;21(7):1037-1043.
90. Philis-Tsimikas A, Walker C, Rivard L, Talavera G, Reimann JO, Salmon M, Araujo R. Improvement in diabetes care of underinsured patients enrolled in Project Dulce. A community-based, culturally appropriate, nurse case management and peer education diabetes care model. *Diabetes Care*, 2004;27(1):110-115.
91. Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs Health Care System. *Diabetes Care*, 2001;24(2):202-208.
92. Polonsky WH, Earles J, Smith S, Pease DJ, Macmillan M, Christensen R, Taylor T, Dickert J, Jackson RA. Integrating medical management with diabetes self-management training. A randomized control trial of the Diabetes Outpatient Intensive Treatment program. *Diabetes Care*, 2003;26(11):3048-3053.
93. Rothman RL, Malone R, Bryant B, Shintani AK, Crigler B, Dewalt DA, Dittus RS, Weinberger M, Pignone MP. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *The American Journal of Medicine*, 2005;118(3):76-284.
94. Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S, Watson R, Swain BE, Selby JV, Javorski WC. Diabetes management in a Health Maintenance Organization. Efficacy of care management using cluster visits. *Diabetes Care*, 1999;22(12):2011-2017.
95. Samuel-Hodge CD, Keyserling TC, Park S, Johnston LF, Gizlice Z, Bangdiwala SI. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. *The Diabetes Educator*, 2009;35(3):439-54.
96. Scott DM, Boyd ST, Stephan M, Augustine SC, Reardon TP. Outcomes of pharmacist-managed diabetes care services in a community health center. *American Journal of Health-System Pharmacy*, 2006;63:2116-22.
97. Shea S, Weinstock RS, Starren J, Teresi J, Palmas W, Field L, Morin P, Goland R, Izquierdo RE, Wolff LT, Ashraf M, Hilliman C, Silver S, Meyer S, Holmes D, Petkova E, Capps L, Lantigua RA. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus. *Journal of the American Medical Informatics Association*, 2006;13(1):40-51.
98. Shibayama T, Kobayashi K, Takano A, Kadowaki T, Kazuma K. Effectiveness of lifestyle counseling by certified expert nurse of Japan for non-insulin treated diabetic outpatients: a 1-year randomized controlled trial. *Diabetes Research and Clinical Practice*, 2007;76:265-68.

99. Sidorov J, Gabbay R, Harris R, Shull RD, Girolami S, Tomcavage J, Starkey R, Hughes R. Disease management for diabetes mellitus: impact on hemoglobin A1c. *American Journal of Managed Care*, 2000;6(11):1217-1226.
100. Smith S, Bury G, O'Leary M, Shannon W, Tynan A, Staines A, Thompson C. The North Dublin randomized controlled trial of structured diabetes shared care. *Family Practice*, 2004;21(1):39-45.
101. Summers-Holtrop J, Hickner J, Dosh S, Noel M, Ettenhofer TL. "Sticking to it - diabetes mellitus": a pilot study of an innovative behavior change program for women with type 2 diabetes. *American Journal of Health Education*, 2002;33(3):161-166.
102. Taylor KI, Oberle KM, Crutcher RA, Norton PG. Promoting health in type 2 diabetes: nurse-physician collaboration in primary care. *Biological Research for Nursing*; 2005;6(3):207-215.
103. Ubink-Veltmaat LJ, Bilo HJG, Groenier KH, Rischen RO, Meyboom-De Jong B. Shared care with task delegation to nurses for type 2 diabetes: prospective observational study. *Netherlands Journal of Medicine*, 2005;63(3):103-110.
104. Wagner EH, Grothaus LC, Sandhu N, Galvin MS, McGregor M, Artz K, Coleman EA. Chronic care clinics for diabetes in primary care. A system-wide randomized trial. *Diabetes Care,* 2001;25(4):695-700.
105. Weinberger M, Kirkman MS, Samsa GP, Shortliffe EA, Landsman PB, Cowper PA, Simel DL, Feussner JR. A nurse-coordinated intervention for primary care patients with non-insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life. *Journal of General Internal Medicine*, 1995;10:59-66.
106. Goudswaard AN, Stolk RP, Zuithoff NPA, De Valk HW, Rutten GE. Long-term effects of self-management education for patients with Type 2 diabetes taking maximal oral hypoglycaemic therapy: a randomized trial in primary care. *Diabetic Medicine*, 2004;21:491-96.
107. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycaemic control. *Diabetes Care*, 2002;25(7):1159-71.
108. Wheeler ML, Wyle-Rosett J, Pichert JW. Diabetes education research. *Diabetes Care*, 2001;24:421-422.
109. Singh D. *How can chronic disease management programmes operate across care settings and providers?* Copenhagen: World Health Organization Regional Office for Europe and European Observatory on Health Systems and Policies; 2008.
110. Linden A, Adams J, Roberts N. *Evaluation methods in disease management: determining programme effectiveness. Position Paper for the Disease Management Association of America (DMAA).* Washington, DC: Disease Management Association of America; 2003.
111. Anderson RM, Funnell MM. Patient empowerment: reflections on the challenge of fostering the adoption of a new paradigm. *Patient Education and Counseling*, 2005;57:153-57.
112. Anderson RM, Funnell MM. Patient empowerment: myths and misconceptions. *Patient Education and Counseling,* 2010;79(3):277-82.
113. Ludlow AP, Gein L. Relationships among self-care, self-efficacy and HbA1c levels in individuals with non-insulin dependent diabetes mellitus. *Canadian Journal of Diabetes Care*, 1995;19:10-15.
114. Conklin A, Nolte E. *Disease management evaluation. A comprehensive review of current state of the art.* Cambridge: RAND Europe; 2011.

Appendix 1: Overview of systematic reviews

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
Centers for Disease Control and Prevention (CDC), 2001	Meta-analysis; N=25 (5 RCTs, 6 CCTs, 11 before-and-after studies, 3 other).	An organised, proactive, multicomponent approach to health care delivery that involves all members of a population with a specific disease entity such as diabetes. Care is focused on and integrated across: (1) the entire spectrum of the disease and its complications; (2) the prevention of co-morbid conditions; and (3) the relevant aspects of the delivery system.	To be included studies had to be: primary investigations; published in English; conducted in established market economies; provide information on one or more outcomes of interest; and meet minimum quality standards. All types of comparative study designs (i.e. RCTs, before-and-after studies, times series, and cohort studies) were included.	The task force strongly recommends disease and case management to improve system-level (e.g. provider monitoring) and patient (e.g. glycaemic control) outcomes.
De Coster et al., 2005	Descriptive review; N=27 (1 CCT, 17 before-and-after studies, 9 other).	Well-established social worker roles, including advocates, case managers, community organisers, educators, etc.	Studies were included when they: addressed a psychosocial component of diabetes (e.g. behavioural change, emotional adjustment, stress); detailed a strategy appropriate for clinical social work; and provided empirical evaluative support.	Clinical social workers have the potential to meet several needs of adults with type 2 diabetes, by improving physiological measures, lowering HbA1c, improving various psychological indicators, self-management and self-care knowledge.
Glazier et al., 2006	Descriptive review; N=17 (10 RCTs, 2 prospective controlled trials; 5 comparative studies).	Patient, provider and health system interventions to improve diabetes care among socially disadvantaged populations. Social disadvantage was conceptualised as related to patient, provider, and health system factors that can affect self-management and provider management and ultimately manifest as clinical outcomes.	Included were studies that: targeted interventions toward socially disadvantaged adults with type 1 or 2 diabetes; were conducted in industrialised countries; and measured self-management, provider management, or clinical outcomes. Studies had to be RCTs, CCTs, or before- after studies with a contemporaneous control group. Studies were excluded if they focused on specific age-groups such as youth, targeted only gestational diabetes, included only hospital proc-	Interventions for socially disadvantaged populations can be effective and have the potential to reduce health disparities in diabetes care and outcomes. Short-term group-based didactic teaching aimed at improving diabetes knowledge may be of limited value for disadvantaged populations. To be successful, interventions appear to require organisational inputs and resources that go well beyond

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
			ess-of-care measures, or did not clearly specify the socially disadvantaged group being studied.	traditional diabetes education programmes.
Griffin & Kinmonth, 1998	Meta-analysis; N=5 (all RCTs).	The involvement of general practitioners and primary health care teams in a system of routine review and surveillance for complications in people with diabetes.	Included were RCTs, in any language, in which people with diabetes (insulin dependent and non-insulin dependent) were prospectively, randomly allocated to a system of review and surveillance for complications by generalists/general practitioners in primary care. The following interventions were included: hospital outpatient coordinated follow-up; primary care coordinated follow-up; follow-up coordinated between hospital and primary care; follow-up in primary care with prompting for health professionals and people with diabetes; any system of coordinated recall and review involving generalists/general practitioners. Outcomes should include mortality, metabolic control, cardiovascular risk factors, quality of life, functional status, satisfaction, hospital admissions, costs, completeness of screening, and/or development of complications.	Unstructured care in the community is associated with poorer follow-up, greater mortality and worse glycaemic control than hospital care. Computerised central recall, with prompting for patients and their family doctors, can achieve standards of care as good as or better than hospital outpatient care, at least in the short term. The evidence supports provision of regular prompted recall and review of people with diabetes by willing general practitioners and demonstrates that this can be achieved, if a suitable organisation is in place.

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
Knight et al., 2005	Meta-analysis; N=24 (19 RCTs, 5 non-randomised controlled studies).	Programmes that used a systematic approach to care and included more than 1 intervention component were considered as using disease management. A systematic approach to care was defined as inclusion of any of the following components: guidelines, protocols, algorithms, care plans, or systematic patient or provider education programmes.	Acceptable designs included RCTs and controlled before-and-after studies (studies with a parallel non-randomised comparison group, with baseline and follow-up assessments of both groups). From the pool of accepted disease management assessments, those aimed at the management of diabetes mellitus were selected. Titles were rejected if they did not deal with adult patients or were reviews, case reports, editorials, letters, or meeting abstracts; abstracts were rejected if they did not report any objective measurements of disease management, referred to clinical trials comparing single pharmacological agents or diagnostic procedures, or did not use a systematic approach to care; studies were excluded if they lacked sufficient information to measure the effect of an intervention on at least 1 outcome of interest and its variance.	Diabetes disease management programmes can improve glycaemic control to a modest extent and can increase screening for retinopathy and foot complications.
Loveman et al., 2009	Descriptive review; N=6 (5 RCTs, 1 CCT)	Two diabetes specialist nurse/nurse case management interventions in diabetes care: (1) specialist nurse intervention in addition to routine care; (2) pediatric specialist nurse intervention in the management of children with diabetes.	Studies were included if they: were RCTs or CCTs with a minimum trial duration of 6 months; included patients with type 1 or 2 diabetes mellitus; compared specialist nurse interventions with no specialist nurse interventions, or pediatric nurse interventions to standard specialist nurse interventions, in which it was required that the intervention was evaluating the nurse alone (i.e. not a team approach), where education was individually based, and where nurses had re-	The presence of a diabetes specialist nurse/nurse case manager may improve patients' diabetic control over short time periods, but from currently available trials the effects over longer periods of time are not evident. There were no significant differences overall in hypoglycaemic episodes, hyperglycaemic incidents, or hospital admissions. Quality of life was not shown to be affected by input

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
			sponsibility for adjusting treatment regimens; assessed one or more of the defined outcome measures.	from a diabetes specialist nurse/nurse case manager.
Norris et al., 2002	Meta-analysis; N=27 (5 RCTs, 6 CCTs, 13 pre-post, 3 cohort studies with comparison group).	Disease management was defined as an organised, proactive, multicomponent approach to health care delivery that involves all members of a population with a specific disease entity such as diabetes.	To be included in the review, studies had to: be primary investigations of interventions selected for evaluation; be conducted in Established Market Economies; provide information on one or more outcomes of interest preselected by the team; and meet minimum quality standards. All types of comparative study designs were included, including studies with concurrent or before-and-after comparison groups.	Evidence supports the effectiveness of disease management on glycaemic control; on screening for diabetic retinopathy, foot lesions and peripheral neuropathy, and proteinuria; and on the monitoring of lipid concentrations.
Norris et al., 2006	Descriptive review; N=18 (8 RCTs, 6 before-and-after studies, 3 studies with non-randomised allocation of treatment and comparison groups, 1 study with post-intervention measures only).	Diabetes programmes including community health workers (CHWs) as team members in a variety of roles. CHWs are defined as 'community members who work almost exclusively in community settings and who serve as connectors between health care consumers and providers to promote health among groups that have traditionally lacked access to adequate health care'.	Studies included reported the evaluation of an intervention involving CHWs delivered to adults with diabetes. CHWs were either the sole focus of the intervention under study or one component of a multi-component intervention or team. Participants had to be ≥18 years old and have diabetes (type 1, 2 or gestational). Studies reporting at least one outcome among the participants were included. There were no restrictions on study design. The follow-up interval was of any duration. Excluded were: studies examining only outcomes among the CHWs (e.g. reports of CHW training interventions); studies involving peer-led patient support groups; studies involving family members as providers of care.	Diabetes programmes include CHWs as team members in a variety of roles. There are some preliminary data demonstrating improvements in participant knowledge and behaviour. Much additional research, however, is needed to understand the incremental benefit of CHWs in multicomponent interventions and to identify appropriate settings and optimal roles for CHWs in the care of persons with diabetes.

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
Pimouguet et al., 2011	Meta-analysis and meta-regression; N=41 (all RCTs)	Disease management was defined as ongoing and proactive follow-up of patients that includes at least two of the following five components: patient education (dietary and exercise counselling, self-monitoring, and knowledge of disease and medication); coaching (the disease manager encourages the patient to overcome psychological or social barriers that impede autonomy or improvement in medication compliance); treatment adjustment (the disease manager is able to start or modify treatment with or without prior approval from the primary care physician); monitoring (the disease manager gets medical data from the patient); and care coordination (the disease manager reminds the patient about upcoming appointments or important aspects of self-care and informs the primary care physician about complications, treatment adjustment or therapeutic recommendations).	Only RCTs were included. The search was limited to English language publications. Inclusion was restricted to studies that reported HbA1c. In addition to the operational definition of disease management, the following inclusion criteria were defined: the study had to involve adults with type 1 or 2 diabetes; it had to report both pre- and postintervention HbA1c levels; and postintervention HbA1c levels had to be assessed after at least 12 weeks of follow-up. Excluded were trials in which the intervention did not involve direct contact between the disease manager and the patient or was unclear, unspecified or exclusively based on contact by Internet or mail.	Disease management programmes had a clinically moderate but significant impact on HbA1c levels among adults with diabetes. Effective components of programmes were a high frequency of patient contact and the ability for disease managers to adjust treatment with or without prior physician approval.
Renders et al., 2000	Descriptive review; N=41 (27 RCTs, 12 controlled before-and-after studies, 2 interrupted time	Different interventions, targeted at health care professionals or the structure in which health care professionals deliver their care, aimed at improving the care for patients with diabetes in	Included types of studies: RCTs, CCTs, controlled before-and-after studies, interrupted time series. Included types of participants: health care professionals, taking care of non-hospitalised patients with type 1 or 2 diabe-	Multifaceted professional interventions can enhance the performance of health professionals in managing patients with diabetes. Organisational interventions that improve regular

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
	series).	primary care, outpatient and community settings.	tes mellitus in a primary care, outpatient, or community setting. Types of interventions: strategies to improve the care for patients with diabetes, including organisational, professional, and financial interventions. Types of outcome measures: objectively measured health professional performance or patient outcomes in a clinical setting and self-reported measures with known validity and reliability. Studies that only evaluated patient-oriented interventions were excluded.	prompted recall and review of patients (central computerised tracking systems or nurses who regularly contact the patient) can also improve diabetes management. The addition of patient-oriented interventions can lead to improved patient health outcomes. Nurses can play an important role in patient-oriented interventions, through patient education or facilitating adherence to treatment.
Shojania et al., 2006	Meta-analysis and meta-regression; N=66 (50 RCTs, 3 quasi-randomised trials; 13 controlled pre-post studies)	11 categories of Quality Improvement (QI) strategies: audit and feedback; case management; team changes; electronic patient registry; clinical education; clinician reminders; facilitated relay of clinical information to clinicians; patient education; promotion of self-management; patient reminder systems; continuous quality improvement.	Studies were included if they: were RCTs, quasi-randomised trials, or controlled before-after studies; involved adult outpatients with type 2 diabetes; investigated an intervention that met the definition for at least 1 of 11 specific types of QI strategies. The analysis was restricted to studies reporting mean pre- and post-intervention HbA1c values for each study group.	Most QI strategies produced small to modest improvements in glycaemic control. Team changes and case management showed more robust improvements, especially for interventions in which case managers could adjust medications without awaiting physician approval.
Smith et al., 2009	Meta-analysis; N=3 (all RCTs)	Shared care health service interventions designed to improve the management of chronic disease across the primary-specialty care interface.	Studies were included if they: were RCTs, CCTs, controlled before-and-after studies, or interrupted time series analyses; described any type of structured intervention that involved continuing collaborative clinical care between primary and specialist care physicians in the management of patients with pre-specified chronic disease; reported any objective measure of patient health outcome, patient behaviour including meas-	There is no evidence to support the widespread introduction of shared care services at present.

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
			ures of medication adherence and utilisation of health services, provider behaviour, efficiency and costs, and acceptability of the service to patients and providers, if this was reported using validated measures in a study that also reported patient outcomes or provider behaviour. The following interventions were excluded: structured disease management in either primary or specialty care that did not routinely involve pre-specified care from the other provider for the majority of participating patients; specialist outreach clinics or specialist liaison services in primary care settings that were defined as planned and regular visits by specialist physicians from a usual practice location, with no ongoing structured joint management programmes for participating patients; professional educational interventions or research initiatives where there was no specified, structured clinical care delivered to patients; interventions directed at communities of people based on location or age of participants in which there was no specified, chronic disease management component.	
Verhoeven et al., 2007	Meta-analysis; N=6 (all RCTs)	Two forms of ICT-based care for diabetes: teleconsultation (a kind of telemonitoring including patient-caregiver communication via email, phone, automated messaging systems, other	Included were empirical studies evaluating teleconsultation and/or videoconferencing developed for type 1, type 2, and/or gestational diabetes. No restrictions were imposed on the quality of study design. Included were	The selected studies suggest that both teleconsultation and videoconferencing are practical, cost-effective, and reliable ways of delivering a worthwhile health care service to diabetics.

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
		equipment without face-to-face contact, or the Internet) and videoconferencing (real-time face-to-face contact, image and voice, via videoconferencing equipment to connect caregivers and one or more patients simultaneously, usually for instruction).	studies that covered clinical outcomes plus one or more other outcomes (behavioural, care coordination, etc.). Excluded were studies dealing with broader target groups than diabetics, studies not aimed at patient-caregiver interaction but solely reporting technical aspects of the equipment used, and those that strived for clinical improvements only.	However, the diversity in study design and reported findings makes a strong conclusion premature. Improvements were mostly not statistically significant.
Whittemore et al., 2007	Descriptive review; N=11 (7 RCTs, 4 pre-post studies)	Culturally competent interventions developed for Hispanic adults with type 2 diabetes. The majority of interventions were specialised diabetes education programmes, provided over a period of time in the community setting. With the exception of two interventions that provided a specialised diabetes education programme by trained community health workers, all interventions included a nurse and/or certified diabetes educator. Most of the interventions were interdisciplinary.	Studies were included if they: were empirical reports of a culturally competent intervention to promote self-management in Hispanic adults with type 2 diabetes; were sampled primarily or completely of Hispanic culture; measured outcome variables of clinical variables, behavioural variables, or knowledge. Excluded were studies conducted in foreign countries in which the predominant language is not English.	Culturally competent interventions to support self-management have the potential to improve outcomes in Hispanic adults with type 2 diabetes. However, improvements were modest and attrition was moderate to high in many studies. Addressing linguistic and cultural barriers to care are important beginnings to improving health outcomes for Hispanic adults with type 2 diabetes.
Wubben et al., 2008	Descriptive review; N=21 (9 RCTs, 1 CCT, and 11 either prospective or retrospective cohort designs).	Diabetes quality improvement strategies delivered by pharmacists in outpatient settings.	Studies were included if they: were RCTs, CCTs or cohort studies with a control group; measured outcomes before and after intervention implementation; provided complete data; investigated quality improvement strategies implemented by pharmacists in outpatient settings; and measured either long-term complications of diabetes or short-	Pharmacist interventions for diabetes result in an overall improvement in HbA1c across a diverse group of settings and study designs.

Author, year of publication	Analysis type, no. of studies included	Concept/definition of chronic care programmes	Inclusion/exclusion criteria	Authors' conclusions
			term surrogate outcomes. Excluded were interventions directed at the patient alone, such as patient education, promotion of self-management techniques, or patient reminders as well as interventions that tested technological interventions alone such as electronic registries or drug recall systems.	

NOTE: RCT indicates randomised controlled trial; CCT, clinical controlled trial; HbA1c, glycated haemoglobin; CHW, community health worker; QI, quality improvement; ICT, information and communication technologies

Appendix 2: Overview of empirical studies

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Aubert et al., 1998	N=138 (IG=71, CG=67); age (median): IG=53 (IQR 47-61), CG= 54 (IQR 46-60); % male: IG=37%, CG=43%; setting: primary care clinics in a group model HMO; country: US.	The nurse case manager followed written algorithms under direction of a family physician and an endocrinologist. Changes in therapy were communicated to primary care physicians. All patients received ongoing care through their primary care physicians.	SMS, DSD, DS	12 months	75
Bellazzi et al., 2003	N=129 (IG=67 [54 adults+13 children]; CG=62 [50 adults+12 children]); age: IG(adult)=38.9(±13.36); IG(child)= 14.6(±3.73); CG(adult)=49.7(±9.65); CG(child)=14.1(±3.29); % male: IG=64.2%, CG=not reported; setting: secondary care/community care; country: Germany, Italy and Spain.	M2DM: a multi-access telemedicine system based on the integration of Web access, telephone access through interactive voice response systems, and the use of palmtops and smart modems for data downloading.	SMS, CIS, DS	6 months (mid-term assessment)	50
Choe et al., 2005	N=80 (IG=41; CG=39); age: IG=52.2(±11.2), CG=51.0(±9.0); % male: IG=48.8%, CG=46.1%; setting: secondary care (university-affiliated ambulatory care clinic); country: US.	Pharmacist-based case management intervention in a general internal medicine clinic setting.	SMS, DSD, CIS, DS	First HbA1c level measured after 12-month intervention was used as primary outcome measure. Patients were allowed to obtain this measurement up to 24 months after enrollment	85
Chumbler et al., 2005	N=800 (IG=400, CG=400); age: IG=68.2, CG=61.5; % male: not reported; setting: Veterans Affairs; country: US.	Patient-centered care coordination/home-telehealth (CC/HT) programme, as an adjunct to treatment for veterans with diabetes.	SMS, DSD, CIS, DS	12 months before and after enrollment in the CC/HT programme	60

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Clifford et al., 2002	N=73 (IG=48, CG=25); age: IG=60(±12), CG=61(±12); % male: IG=58%, CG=48%; setting: secondary care (hospital diabetes care outpatient clinic); country: Australia.	Pharmaceutical care programme, carried out by an experienced clinical pharmacist in cooperation with diabetes physicians and other members of the diabetes health care team.	DSD, DS	6 months	65
Cook et al., 1999	N=698 (patients served as their own control); age: mean(SEM)=57.3(0.4); % male: 34%; severity: not reported; setting: Grady Diabetes Unit, which provides care primarily to urban African-American patients with type 2 diabetes; country: US.	Structured diabetes management programme.	SMS, DSD, CIS, DS	12 months	55
Dale et al., 2009	N=141 (IG=44, CG=97); age: not reported; % male: IG=52.4%, CG=64.0%; setting: primary care; country: UK.	Telecare support provided by diabetes specialist nurses.	SMS, CIS	6 months	70
Davidson, 2003	N=713 (IG(A)=252, CG(B)=252, CG(C)=209); age: IG(A)=52.0(26-79), CG(B)=52.6(27-79), CG(C)=53.8(19-84); % male: IG(A)=24%, CG(B)=28%, CG(C)=34%; setting: primary care; country: US.	Diabetes Managed Care Programme (DMCP): diabetes care directed by nurses following detailed protocols and algorithms and supervised by a diabetologist.	DSD, DS	7-12 months	60
De Sonnaville et al., 1997	N=418 (IG=350, CG=68); age: IG=65.3(±11.9), CG=64.6(±10.3); % male: IG=41.1%, CG=58.8%; setting: primary care; country: The Netherlands.	Structured NIDDM care in general practice with a diabetes service (in which the GP is supported by a laboratory with facilities to visit patients at home, a computerised patient register and recall system, a wide-angle retinal camera, and the possibility to consult with a dietician, a diabetes nurse educator, and a podiatrist. A diabetologist, who supervises the diabetes service, can be contacted by telephone 24h a day).	SMS, DSD, CIS, DS	24 months for IG, 18 months for CG	65

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Dijkstra et al., 2005	N=769 (IG=351, CG=418); age: IG=58(±15), CG=58(±16); % male: IG=45%, CG=50%; setting: secondary care; country: The Netherlands.	Comprehensive strategy involving both patients and professionals, with the introduction of a diabetes passport as a key component.	SMS, CIS	12 months	75
Domurat, 1999	N=8610 (IG=2617, CG=5993); age: not reported; % male: not reported; setting: HMO; country: US.	Computer-supported team care.	DSD, CIS	12 months	70
Doucette et al., 2009	N=78 (IG=36, CG=42); age: IG=58.7(±13.3), CG=61.2(±10.9); % male: IG=38.2%, CG=46.3%; setting: community pharmacy practice sites; country: US.	Community pharmacist-provided extended diabetes care service.	SMS, DSD	12 months	65
Farmer et al., 2005	N=93 (IG=47, CG=46); age: IG=24.5(±4.2), CG=23.2(±4.2); % male: IG= 59.6%, CG=58.7%; setting: researchers invited patients who were registered either with the Pediatric Transition Clinic or the Young Adult Diabetes Clinic in Oxford to participate; country: UK.	A mobile phone-based telemedicine system using real-time data transfer with intensive feedback of results; a phone-based diary of insulin dose, physical activity, and food intake; and nurse-initiated support.	SMS, CIS	9 months	75
Fornos et al., 2006	N=112 (IG=56, CG=56); age: IG=62.4(±10.5), CG=64.9(±10.9); % male: IG=41.4%, CG=42.9%; setting: primary care (pharmacies); country: Spain.	Pharmacotherapy Follow-up (PFU) programme for type 2 diabetic patients. PFU is a pharmaceutical care activity that requires the involvement of the pharmacist in the outcomes of pharmacotherapy, in cooperation with the health care team and the patient.	SMS, DSD, CIS, DS	13 months	70
Friedman et al., 1998	N: 1994=954, 1995=744, 1996=1457; age: between 31 and 64 years; % male: not reported; setting: primary care; country: US.	Lovelace Episodes of Care Programme, intended to address the complex needs of patients with type 2 diabetes mellitus by using specific physician-provider and patient interventions.	SMS, DSD, CIS, DS	24 months	40

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Gabbay et al., 2006	N=332 (IG=150, CG=182); age: IG=65(±12), CG=64(±20); % male: IG=57%, CG=52%; setting: primary care; country: US.	Nurse case management, consisting of coordination of care, patient education and counselling, and close monitoring of health outcomes.	SMS, DSD, CIS, DS	6 and 12 months	65
Gary et al., 2003	N=70 (IG=36, CG=34); age: IG=60(±7), CG=57(±8); % male: IG=22%, CG=26%; setting: primary care; country: US.	Combined nurse case management (NCM)/ community health worker (CHW) intervention.	SMS, DSD	24 months	85
Goldfracht & Porath, 2000	N=876; age: 67,5% of patients were age 60 years or older; % male: 48%; setting: HMO, primary care; country: Israel.	Administrative and quality assurance interventions.	DSD, CIS, DS	24 months	60
Gong et al., 1999	N=81 (IG=47, CG=34); age (median): IG=68, CG=66; % male: not reported; setting: outpatient clinic of university-affiliated teaching hospital; country: US.	Care provided by a Diabetes Disease Management Clinic (DDMC) for type 2 diabetes patients who were initiated on self-monitoring of blood glucose (SMBG). Care in the DDMC is provided by pharmacists (among which a certified diabetes educator), pharmacy practice residents, doctor of pharmacy students, and a nurse practitioner.	SMS, DSD, CIS, DS	24 months	65
Grant et al., 2004	N=3079 (IG=898; CG=2181); age: IG=65.1(±12.9), CG=65.4(±12.8); % male: IG=47.7%, CG=55.6%; setting: four outpatient primary care medical clinics within an academic medical centre; country: US.	Population-level strategies to organise and deliver diabetes care.	DSD, CIS	20 months	55
Henault et al., 2002	N=56 (IG=21, CG=35); age: average age of all eligible patients was 66 years (range 41-87 years); % male: IG=100%, CG=100%; setting: Veterans Affairs Medical Center; country: US.	A programme of transmitting clinical recommendations for altering diabetes care via email.	CIS, DS	6.3(±2.4) months	45

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Hetlevik et al., 2000	N=776 (IG=368, CG=408); age: IG=66.3(±14.1), CG=68.2(13.1); % male: IG=46%, CG=42%; setting: primary care; country: Norway.	Implementation of clinical guidelines for diabetes mellitus in general practice with a specific computer-based clinical decision support system (CDSS) as part of the intervention.	CIS, DS	18 months and 21 months	60
Hirsch et al., 2002	N=109 (IG=44, CG=65); age: IG=60, CG=57; % male: IG=36%, CG=49%; setting: academic family practice clinic; country: US.	A multifaceted intervention including pharmacist case management, nurse and nutritionist counselling, provider didactics and computerised compliance feedback in support of staged diabetes management (SDM).	DSD, CIS, DS	14 months	65
Ilag et al., 2003	N=154 (IG=83, CG=71); age: IG=59(±14), CG=59(±12); % male: IG=43%, CG=51%; setting: university-affiliated primary care internal medicine practices affiliated with a managed care organisation (MCO); country: US.	The Annual Diabetes Assessment Programme (ADAP) was designed as a population-based programme of evaluation and feedback to support diabetes clinical practice guidelines.	SMS, CIS, DS	24 months	75
Kelly & Rodgers, 2000	N=48 (IG=32, CG=16); age: IG=47.7(±13.2), CG=50.2(±8.9); % male: IG=40.6%, CG=56.3%; setting: managed care affiliated physicians group; country: US.	A pharmacist-managed diabetes service, in which patients received dosage adjustments, diabetes self-management training, and periodic assessment of treatment goals by pharmacists.	SMS, DSD, CIS	7 months for HbA1c values and blood pressures; 9 months for lipids	70
Kim & Oh, 2003	N=36 (IG=20, CG=16); age: IG=59.7(±7.3), CG=60.9(±5.8); % male: IG=35%, CG=25%; setting: endocrinology outpatient department of tertiary care hospital (university-affiliated medical centre); country: South Korea.	Nurse telephone intervention.	SMS, DSD, CIS	3 months (12 weeks)	60
Kim et al., 2009	N=79 (IG=40, CG=39); age: IG=56.2(±8.4), CG=56.6(±7.6); % male: IG=62.5%, CG=48.7%; setting: community care; country: US.	SHIP-DM: a structured, culturally-based behavioural intervention programme that focuses on empowering patients with greater knowledge,	SMS, DSD, CIS	18 and 30 weeks	60

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
		self-efficacy, and self-help skills concerning diabetes. The SHIP-DM consisted of 3 concurrent intervention components: 2-hour weekly education sessions for 6 weeks, home glucose monitoring with teletransmission, and monthly telephone counselling by a bilingual nurse for 24 weeks.			
Ko et al., 2004	N=178 (IG=90, CG=88); age: IG=55.0(±9.0), CG=56.0(±10.2); % male: IG=48.9%, CG=38.6%; setting: primary care; country: Hong Kong.	A structured health education programme by a diabetic education nurse.	SMS, DSD	12 months	55
Ko et al., 2007	N=437 (IG=219, CG=218); age: IG=53.3(±9.3), CG=54.1(±7.4); % male: IG=42%, CG=45,9%; setting: hospital care; country: South Korea.	SIDEP: inpatient, structured intensive diabetes education programme. The programme was designed for group education (5-10 patients). The education team was composed of a diabetologist, certified diabetes educator (nurse or dietician), ophthalmologist, rehabilitation therapist, pharmacist, psychologist, family medicine doctor and rehabilitation medicine doctor.	SMS, DSD	48 months	75
Krass et al., 2006	N=118 (IG=39, CG=79); age: IG=64.1(±9.1), CG=64.2(±10.5); % male: IG=72%, CG=58%; setting: primary care (community pharmacies) and secondary care (specialised diabetes clinic pharmacies); country: Australia.	Continuity of care model for type 2 diabetes, which comprises an initial consultation with a pharmacist in the clinic, written communication to the patient's community pharmacist and GP, and ongoing monitoring of the patient by the community pharmacist on the basis of a defined protocol.	SMS, DSD, CIS, DS	6 months	65
Krass et al., 2007	N=299 (IG=157, CG=142); age: 62(±11); % male: 51%; setting: primary care (pharmacies); country: Australia.	The Pharmacy Diabetes Care Programme: a community pharmacy diabetes service model.	SMS, DSD, CIS, DS	6 months	65

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Krein et al., 2004	N=209 (IG=106, CG=103); age: IG=61(±10), CG=61(±11); % male: IG=98%, CG=95%; setting: Department of Veterans Affairs Medical Centers; country: US.	A collaborative case management intervention for patients with poorly controlled type 2 diabetes.	SMS, DSD, CIS, DS	Mean follow-up of 19(±2) months	85
Legorreta et al., 1996	N=390 (IG-A=117, CG-A=88; IG-B=123, CG-B=62); age: IG-A=60.8(±10.5), CG-A=59.6(±10.9), IG-B=57.5(±14.0), CG-B=68.6(±9.1); % male: IG-A=47%, CG-A=52%, IG-B=52%, CG-B=50%; setting: site A was a typical participating medical group (PMG), site B was an independent physician organisation (IPA), both provided health care to HMO members; country: US.	A diabetes management programme using nurses who follow specially developed protocols, linked to a computer system designed to improve compliance.	DSD, CIS, DS	The endpoint value was the last reported value after a patient had participated in the programme, or had been identified in the control site, for at least 12 months but for no longer than 28 months.	50
Leung et al., 2005	N=160 (IG=80, CG=80); age: IG=64.5(±9.7), CG=65.8(±7.8); % male: IG=62.5%, CG=55%; setting: secondary care (university-based public hospital); country: China.	A disease management programme for patients with type 2 diabetic nephropathy, executed by a team of diabetes specialists and a pharmacist, prescribing: (1) regular follow-up; (2) regular laboratory monitoring; (3) attainment of treatment targets; and (4) treatment adherence and the role of the pharmacist.	SMS, DSD, CIS, DS	24 months	80
Litaker et al., 2003	N=157 (IG=79, CG=78); age: IG=60.5(±8.5), CG=60.6(±9.6); % male: IG=41%, CG=42%; setting: tertiary care teaching hospital; country: US.	Chronic disease management programme involving a nurse practitioner – physician team.	SMS, DSD, CIS, DS	12 months	75
Maislos & Weisman, 2004	N=63 (IG=41, CG=22); age: IG=58(±14), CG=63(±9); % male: IG=50%, CG=35%; setting: primary care (HMO); country: Israel.	The Western Negev Mobile Diabetes Care Programme applies a multidisciplinary method to the treatment of patients with diabetes. The team is composed of a physician specialised in diabetes, a dietician, and a diabetes nurse educator.	SMS, DSD, CIS, DS	6 months	60

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Majumdar et al., 2003	N=393 (IG=210, CG=183); age: IG=63.9(±12.7), CG=62.0(±12.4); % male: IG=48.7%, CG=37.6%; setting: multidisciplinary diabetes outreach service (primary care); country: Canada.	Multidisciplinary diabetes outreach service for improving the quality of care for rural patients with type 2 diabetes, consisting of six monthly visits by a traveling team of specialist physicians, nurses, dieticians, and a pharmacist.	DSD, DS	6 months	65
McKay et al., 2002	N=80 (IG=40, CG=40); age: IG=62.1(±9.5), CG=60.8(±9.1); % male: IG=45.0%, CG=47.5%; setting: home-based care; country: US.	The Diabetes Network (D-Net), an internet-based diabetes self-management and peer support intervention.	SMS, CIS	3 months	60
McMahon et al., 2005	N=104 (IG=52, CG=52); age: IG=64(±7), CG=63(±7); % male: IG=99%, CG=100%; setting: Veterans Affairs hospital-based and community-based clinics; country: US.	Web-based care management.	SMS, DSD, CIS, DS	12 months	65
Medi-Cal Type 2 Diabetes Study, 2004	N=317 (IG=171, CG=146); age: IG=57.0(±0.9), CG=56.9(±1.0); % male: IG=27.4%, CG=29.1%; setting: three clinical sites (one community-based programme within a county-wide managed care plan for Medi-Cal recipients, two university-based centers); country: US.	Intensive diabetes case management for disparate populations.	SMS, DSD, CIS, DS	Mean duration of follow-up was 25.3 months	75
Ménard et al., 2005	N=72 (IG=36, CG=36); age: IG=53.7(±7.5), CG=55.9(±8.6); % male: IG=75%, CG=61.1%; setting: community/hospital care; country: Canada.	An intensive multi-therapy programme provided by a multidisciplinary team.	SMS, DSD	12 and 18 months	80
O'Connor et al., 2005	N=754 (IG=428, CG=326); age: IG=57.6, CG=58.0; % male: IG=53.7%, CG=54.9%; setting: primary care; country: US.	The IDEAL (Improving Care for Diabetes Through Empowerment, Active Collaboration, and Leadership) model: a quality improvement (QI) intervention.	SMS, DSD, CIS, DS	The project had three sequential phases over a 42-month period of time.	65

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Odegard et al., 2005	N=77 (IG=43, CG=34); age: IG=51.6(±11.6), CG=51.9(±10.4); % male: IG=52%, CG=62%; setting: primary care (University of Washington Medicine Clinics); country: US.	A pharmacist intervention composed of development of a diabetes care plan, regular pharmacist-patient communication on diabetes care progress, and pharmacist-provider communication on the subject's diabetes progress.	SMS, DSD, CIS	Patients received a pharmacist intervention (IG) or usual care (CG) for 6 months followed by a 6-month usual-care observation period for both groups	70
O'Hare et al., 2004	N=361 (IG=180, CG=181); age: mean age at baseline 58.9(±11.7); % male: IG=53%, CG=49%; setting: primary care; country: UK.	Enhanced care for diabetes, tailored to the needs of the South Asian community with type 2 diabetes, using Asian link workers and extra community diabetes specialist nurse sessions.	SMS, DSD, DS	12 months	65
Peters et al., 1998	N=164 (IG=97, CG=67); age: mean(SEM) IG=53.6(1.4), CG=58.6(1.3); % male: IG=47.4%, CG=50.8%; setting: Cedars Sinai Medical Center (secondary care), country: US.	Comprehensive Diabetes Care Service (CDCS) in which nurses provide diabetes care based on protocols and by using a computer system for clinical information.	DSD, CIS, DS	On average 24 months	55
Philis-Tsimikas et al., 2004	N=229 (IG=153, CG=76); age: IG=51(±12.9), CG=50(±12.0); % male: IG=31%, CG=33%; setting: community care; country: US.	Project Dulce, a culturally sensitive, nurse case management and peer education/empowerment approach to improving diabetes care and health status among underserved racial and ethnic populations.	SMS, DSD, CIS	12 months	65
Piette et al., 2001	N=272 (IG=132, CG=140); age: IG=60(±10), CG=61(±10); % male: IG=95%, CG=99%; setting: community care (patients were recruited from three general medicine clinics and one diabetes specialty clinic within a university-affiliated VA health care system); country: US.	Automated telephone disease management with telephone nurse follow-up.	SMS, DSD, CIS, DS	12 months	85

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Polonsky et al., 2003	N=167 (IG=89, CG=78); age: IG=48.8(±15.2), CG=53.4(±15.9); % male: IG=56.2%, CG=51.3%; setting: diabetes center at a general hospital; country: US.	The Diabetes Outpatient Intensive Treatment (DOIT) programme, a multiday group education and skills training experience combined with daily medical management, followed by case management over 6 months.	SMS, DSD	6 months	55
Rothman et al., 2005	N=217 (IG=112, CG=105); age: IG=54(±13), CG=57(±11); % male: IG=43.8%, CG=43.8%; setting: secondary care (academic general medicine practice); country: US.	Pharmacist-led, primary care-based, disease management programme, including intensive educational sessions, evidence-based algorithms, and proactive management of clinical parameters.	SMS, DSD, CIS, DS	12 months	80
Sadur et al., 1999	N=185 (IG=97, CG=88); age: IG=55.7(±9.1), CG=56.4(±9.1); % male: IG=58.8%, CG=55.7%; setting: primary care (HMO); country: US.	A multidisciplinary, nurse-led team providing comprehensive medical care for diabetic patients in a cluster visit setting.	SMS, DSD, CIS	6 months	65
Samuel-Hodge et al., 2009	N=201 (IG=117, CG=84); age: IG=57.0(±0.9), CG=61.3(±1.3); % male: IG=36%, CG=37%; setting: community care; country: US.	A church-based diabetes self-management programme for African Americans with type 2 diabetes.	SMS, DSD	8 and 12 months	80
Scott et al., 2006	N=131 (IG=64, CG=67); age (IG vs. CG): (1) <20: 1.3% vs. 1.4%; (2) 20-29: 3.9% vs. 0%; (3) 30-39: 10.5% vs. 9.6%; (4) 40-49: 34.2% vs. 34.2%; (5) 50-59: 30.3% vs. 34.2%; (6) 60-69: 19.7% vs. 20.6%; % male: IG=42.1%, CG=35.6%; setting: Siouxland Community Health Center; country: US.	Pharmacist-managed diabetes care services in a community health center.	SMS, DSD, CIS	3, 6 and 9 months	65
Shea et al., 2006	N=1665 (IG=844, CG=821); age: mean age was approximately 71 years (median=70) in both groups; % male: IG=36.5%, CG=37.9%; setting: primary and secondary care; country: US.	Telemedicine case management for older, ethnically diverse, medically underserved patients with diabetes mellitus.	SMS, DSD, CIS, DS	12 months	80

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Shibayama et al., 2007	N=134 (IG=67, CG=67); age: IG=61(±8), CG=62(±7); % male: IG=65.2%, CG=65.2%; setting: hospital; country: Japan.	Lifestyle counselling by a certified expert nurse of Japan for non-insulin-treated diabetic outpatients.	SMS, DSD	12 months	70
Sidorov et al., 2000	N=5332 (no control group); age: 60.6 (range 9 to 95); % male: 51%; setting: HMO, Penn State Geisinger Health Plan in Northeastern and Central Pennsylvania, primary care; country: US.	HMO-sponsored disease management programme with Steering Committee, clinical guidelines, primary care site-based diabetes education, coverage of glucose meters and strips, simplified outcomes reporting and support of clinical leadership.	SMS, DSD, CIS, DS	3 and 12 months	55
Smith et al., 2004	N=183 (IG=96, CG=87); age: IG=64.7(±12.3), CG=65.6(±10.8); % male: IG=54%, CG=57%; setting: primary care (general practice); country: Ireland.	A diabetes shared care model, comprised of education of participating practitioners, the introduction of a community-based diabetes nurse specialist, local agreement on clinical protocols, and structured communication across the primary-secondary care interface.	DSD, CIS, DS	18 months	75
Summers-Holtrop et al., 2002	N=132 (IG=67, CG=65); age: IG=58, CG=65, % male: IG=0%, CG=0%; setting: community care; country: US.	An innovative educational programme for women with type 2 diabetes facilitated by trained lay health advisors from the local university extension service.	SMS, DSD	6 months	60
Taylor et al., 2005	N=39 (IG=20, CG=19); age: IG=58, CG=67; % male: IG=65%, CG=68.4%; setting: primary care; country: Canada.	A nurse-physician collaborative approach to care of patients with type 2 diabetes.	SMS, DSD, CIS	3 months	60
Ubink-Veltmaat et al., 2005	N=1277 (IG=963, CG=314); age: IG=68.7, CG=70.3; % male: IG=42%, CG=40%; setting: primary care; country: The Netherlands.	The shared care intervention involved extensive task delegation from GPs to hospital-liaised nurse specialists in diabetes and included a diabetes register, structured recall, facilitated generalist-specialist communication, audit and feedback, patient-specific reminders, and emphasised patient education.	SMS, DSD, CIS	36 months	45

Study	Population (mean age, % male, severity, setting)	Intervention	Components (SMS, DSD, CIS, DS)	Follow-up (months)	Study quality
Wagner et al., 2001	N=707 (IG=278, CG=429); age: IG=61.2, CG=60.4; % male: IG=56%, CG=50.8%; setting: primary care; country: US.	Primary care group visits (chronic care clinics). Each chronic care clinic consisted of an assessment; individual visits with the primary care physician, nurse, and clinical pharmacist; and a group educational/peer support session.	SMS, DSD, CIS	24 months	80
Weinberger et al., 1995	N=275 (IG=188, CG=63); age: IG=63.9(±8.6), CG=63.2(±8.3); % male: IG=98.5%, CG=100.0%; setting: primary care (General Medical Clinic of the Durham Department of Veterans Affairs Medical Center); country: US.	A nurse-coordinated intervention delivered to patients with NIDDM between office visits to primary care physicians.	SMS, CIS	12 months	65

NOTE: SMS indicates self-management support; DSD, delivery system design; CIS, clinical information systems; DS, decision support; BP, blood pressure; HMO, health maintenance organisation; HbA1c, glycated haemoglobin; MI, myocardial infarction; IG, intervention group; CG, control group; IQR, interquartile range; IDF, International Diabetes Federation; ADA, American Diabetes Assocation; US, United States; VA, Veteran Affairs; ED, emergency department; SEM, standard error mean; GP, general practitioner; UK, United Kingdom; NIDDM, non-insulin dependent diabetes mellitus; MCO, managed care organisation; LDL, low-density lipoprotein; CVD, cardiovascular disease; PMG, participating medical group; IPA, independent physician organisation; QI, quality improvement; BMI, body mass index; GMC, general medical clinic

Chapter 4

Overcoming fragmentation in health care: chronic care in Austria, Germany and the Netherlands

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Health Economics, Policy and Law, 2012;7:125-146.

ABSTRACT

The growing recognition of care fragmentation is causing many countries to explore new approaches to health care delivery that can bridge the boundaries between professions, providers and institutions, and so better support the rising number of people with chronic health problems. This study examines the role of the regulatory, funding and organisational context for the development and implementation of approaches to chronic care, using examples from Austria, Germany, and the Netherlands. We find that the three countries have implemented a range of policies and approaches to achieve better coordination within and across the primary and secondary care interface and so better meet the needs of patients with chronic conditions. This has involved changes to the regulatory framework to support more coordinated approaches to care (Austria, Germany), coupled with financial incentives (Austria, Germany), or changes in payment systems (the Netherlands). What is common to the three countries is the comparative 'novelty' of policies and approaches aimed at fostering coordinated care; however, the evidence of their impact remains unclear.

INTRODUCTION

The rising number of people with chronic conditions presents challenges for all health systems. In the European Union, in 2006, between 20% to over 40% of the population aged 15 years and over reported a long-standing health problem and one-fourth currently receives medical long-term treatment.[1] The complex nature of many chronic health problems requires a delivery system that involves coordinated inputs from a wide range of health professionals over an extended period of time and that places patients at the centre as co-producers of care to optimise health outcomes.[2,3] Yet, service delivery has developed in ways that have tended to fragment care, both within and between sectors, through, for example, structural and financial barriers dividing providers at the primary/secondary care and at the health care and social care interface.[4]

The growing recognition of this fragmentation is causing many countries to explore new approaches to health care delivery that can bridge the boundaries between professions, providers and institutions and so provide appropriate support to patients with long-standing health problems. Key elements suggested to address fragmentation include improved collection and sharing of information, moving care into the community, and aligning payment schemes to incentivise care coordination and enhance integration of provision of services.[5] However, countries vary in their attempts to do so and approaches that are being implemented reflect the characteristics of individual health systems as they relate to the relationships between, and responsibilities of, different stakeholders in the regulation, funding, and delivery of health care.[6]

This study discusses some of the key approaches to overcoming fragmentation in health care, with a particular focus on the role of the regulatory, funding and organisational context for the development and implementation of approaches to chronic care. We illustrate these approaches with examples from Austria, Germany and the Netherlands.

Our analysis is based on a review of the published and grey literature, complemented by data collected within the DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project, using a common data collection template which is described in detail elsewhere.[7]

In order to contextualise chronic care development in each country, we provide a concise overview of selected features of the countries' health systems. We describe the key regulatory and policy measures making possible current chronic care strategies, highlighting some of the main approaches to overcoming fragmentation in chronic care and reviewing the documented evidence of their impact.

Background on chronic care in Austria, Germany and the Netherlands

The implementation of chronic care policies in Austria, Germany and the Netherlands has to be understood in the overall context of health care governance and organisation. The three health care systems are principally based on the Bismarckian model of statutory health insurance (SHI), characterised by a universal, mandatory insurance scheme with responsibility for the health care system shared by government (central and state governments in Austria and Germany) and corporatist actors. More recently, the three systems have followed different paths, in particular with regard to the introduction of market elements into the system. In brief, in 1993, Germany introduced free choice of SHI[8], whereas the Netherlands moved to a mandatory, regulated private insurance system with competing private insurance funds in 2006.[9] In Austria, competition among health insurers, although discussed, has so far not been pursued.[10] In terms of the provision of health care, the Netherlands is unique among SHI systems in western Europe in that general practitioners (GPs) act as gatekeepers to specialist care, a characteristic feature maintained after the 2006 reform.[9] In contrast, Austria and Germany principally allow for free choice of office-based generalist and specialist care providers outside hospital.[8,10] Table 1 provides an overview of selected characteristics of health care governance and provision in each country.

THE EVOLUTION OF CHRONIC CARE POLICIES

Care fragmentation, particularly at the boundary between primary and secondary care, has been a main concern in all three countries, and it has prompted a series of various regulatory measures and activities (Table 2). However, the pace, breadth, and depth with which relevant initiatives and policies have been implemented have varied.

Thus, in Germany, provisions to support more integrated models of care were introduced as early as 1993, subsequently strengthened by the 2000 SHI Reform Act and the 2004 SHI Modernisation Act, which removed certain legal and financial obstacles towards better integration.[8] In parallel, in 2002, the government introduced structured care programmes for those with chronic disease, frequently referred to as 'disease management programmes' (DMPs), in an explicit effort to provide insurers and providers with incentives to encourage evidence-based chronic care.[11] Defined as 'the coordinated treatment and care of patients during the entire duration of a (chronic) disease across boundaries between providers and on the basis of scientific and up-to-date evidence'[12], DMPs became the predominant approach to chronic illness care in Germany. Subsequent reforms introduced additional measures to strengthen coordination within the ambulatory care sector, most notably the 2004 intro-

duction of GP-centered care and of medical care centers or policlinics.[13], and provisions to enable the use of non-medical staff in chronic illness care from 2008.[14]

The Netherlands, in the 1990s, saw the introduction of the concept of shared care, based on the principle of cooperation and coordination between generalist and specialist caregivers with shared overall responsibility.[16] Although spreading rapidly throughout the 1990s, lack of sufficient funding challenged their viability and sustainability. From the 2000s, disease management approaches received growing interest[17], but uptake remained limited[18], mainly because of lack of a structured framework.[19] More recently, the 2006 health insurance reform, which granted insurers extended powers to negotiate with provider organisations, facilitated the development of new forms of service delivery and payment for more integrated care. This involved the initially diabetes-focused establishment of GP-formed 'care groups', who contract with health insurers on the basis of a 'bundled payment' for a defined package of diabetes care.[20] This was strengthened by the 2008 'Programmatic approach to chronic illness care' and proposals to generally fund chronic care through bundled payment schemes, accompanied by regulatory measures to strengthen the role of nurses in the care of the chronically ill (Table 2).[9]

Table 1: Selected features of health care systems in Austria, Germany and the Netherlands [8-10, 13, 15]

	Austria	Germany	The Netherlands
Health expenditure (2008)			
% GDP	10.5	10.5	9.9
Per capita expenditure (US$ PPP)	3,970	3,737	4,063
Main sources of financing (2008)	SHI: 44.1% Taxation: 32.8% OOP: 15.1% VHI: 4.5%	SHI: 67.9% Taxation: 8.8% OOP: 13.0% VHI: 9.5%	SHI: 70.2% Taxation: 5.1% OOP: 5.7% VHI: 5.6%
Governance of the public health system			
Principle responsibilities	Shared by central government, 9 state governments, and corporatist actors; responsibility for hospital sector mainly with the federal states	Shared by central government, 16 state governments, and corporatist actors; responsibility for hospital sector mainly with the federal states	Shared by federal and local authorities and corporatist actors
Main supervisory/regulatory body independent of government (year established)	Federal Health Agency (Bundesgesundheitsagentur) (2005); separate legal entity responsible for developing the framework for planning health service provision in	Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) (2004); decision-making body in SHI system, sets legal	Dutch Health Care Authority (Nederlandse Zorgautoriteit, NZa) (2006); responsible for monitoring and administering the markets for

	all sectors, management of the interface between sectors, development of performance-orientated reimbursement systems in all health care sectors	framework for health care provision, issues binding directives, develops recommendations for DMPs, develops quality assurance measures for ambulatory, hospital, and integrated care	health care provision, health insurance, and the purchasing of health care; oversees the lawful implementation of the Health Insurance Act and Exceptional Medical Expenses Act
Principles of health care provision outside hospital			
Provision of primary/generalist and specialist care outside hospital	Office-based primary and specialist care physicians; outpatient clinics	Office-based primary and specialist care physicians	General practitioners in group practices
Choice of provider in primary/ambulatory care	Yes	Yes	Yes; registration with GP required
GP gatekeeping	No	Voluntary ('GP contracts')	Yes; access to specialist care upon referral only
Payment of physicians in primary/ambulatory care	Blended system of fee-for-service with capitated element for basic services; determined by payment schemes based on public services or private law and supplemented by bonuses defined by the state	Combination of capitation and fee-for service based on centrally negotiated "uniform value scale" (EBM) by the Federal Association of SHI physicians and the National Association of SHI Funds	Combination of capitation and fee-for-service; maximum remuneration fees for GPs negotiated between National Association of GPs, Health Insurers Netherlands and Ministry of Health, Welfare and Sport
Payment of hospitals	Performance-oriented hospital financing system (LKF) (1997)	German diagnosis-related groups (G-DRG) (phased in from 2003)	Diagnosis and treatment combinations (DBCs) (2005)

NOTE: PPP indicates purchasing power parity; SHI, statutory health insurance; OOP, out-of-pocket payment; VHI, voluntary health insurance; DBCs, Diagnosis and treatment combinations; DMPs, disease management programmes; EBM, Einheitlicher Bewertungsmassstab; GPs, general practitioners; LKF, Leistungsorientierte Krankenanstalten-finanzierung; G-DRG, German diagnosis-related groups.

Table 2: Overview of the regulatory framework for chronic care policies and approaches implemented during the 2000s in Austria, Germany and the Netherlands

Country	Title of reform/regulation	Stated aim(s) of reform/regulation
Austria	2005 Health Reform Act	Established state health funds (*Landesgesundheitsfonds*) (2006); created financial pool at state level (*Reform pool*) as a means to promote coordination of and cooperation between ambulatory and hospital care; established Federal Health Agency; introduced e-card and made provisions for planning and accordance of electronic patient record (ELGA) by introducing the Health Data Transmission Law (*Gesundheitstelematikgesetz)*
	2008 Agreement according to Federal Constitution Article 15a on the Organisation and Financing of the Health Care System 2008-2013	Commits to continue and develop further measures implemented with the 2005 reform, including (among others) the integrated planning of health services across sectors; the implementation of needs- and patient-centered pilot projects in ambulatory care, and the strengthening and further development of the reform pool to support chronic care approaches
	2010 Act to Strenghten Ambulatory Care	Introduced right for physicians to establish group practices ('ambulatory care centres') as limited liability company
Germany	2000 SHI Reform Act	Introduced provisions for the development of integrated care structures between the ambulatory care and hospital sector; required SHI funds to set aside a defined amount per member for primary prevention or health promotion activities
	2001 Risk Structure Compensation Reform Act	Introduced, from 2002, structured care programmes for those with chronic disease (disease management programmes) into the German health care system
	2004 SHI Modernisation Act	Established Federal Joint Committee; strengthened integrated care and GP-centered care (through GP contracts); introduced medical care centres which provide care across several health care specialities within the ambulatory care sector
	2007 Act to Strengthen Competition within SHI	Made health insurance mandatory for all and introduced the morbidity-adjusted risk compensation scheme with effect from 2009
	2008 Long-term Care Reform Act	Enabled delegation of selected medical tasks to non-medical staff in the framework of pilot projects
	2008 Act on the Advancement of Organisational Structures within SHI	Further strengthened provisions for GP-centered care
Netherlands	2006 Health Insurance Act	Established single mandatory insurance system; introduced possibility of selective contracting with collectives to target care delivery to those with chronic conditions
	2007 Social Support Act	Introduced provisions to enable chronically ill

	and/or disabled people to live independently and participate in society
2009 Act for Allowances for Chronically Ill and Handicapped Persons	Introduced entitlement for chronically ill and disabled persons to receive a fixed allowance to compensate for excessive health care expenses
2009, Amendment of the 1993 Individual Health Care Professions Act	Facilitated use of nurses in the care of chronically ill and elderly people, enabling clinical nurse specialists with set qualifications to autonomously perform common and minor medical procedures

NOTE: SHI indicates statutory health insurance; GP, general practitioner.

In Austria, activities to strengthen more integrated provision of care have been a more recent phenomenon, with the 2005 health reform contributing to the development of related approaches.[10] It established, in 2006, the State Health Funds in each of Austria's nine federal states and created a financial pool at state level (Reform pool), which combines funds from SHI and regional governments to finance projects that coordinate health care delivery across sectors, in particular between ambulatory and hospital care. These 'reform pool projects' have formed the basis for the majority of current approaches to chronic care in Austria, most frequently disease management programmes. Other efforts have aimed, since 2007, to establish ambulatory care centres to enhance integration of service delivery, particularly for those with chronic illness.[21] This was part of a wider policy development including the conclusion of agreements between the medical profession and health insurance funds to establish group practices, and the 2008–2013 government programme that made improving patient access to ambulatory care services a priority as part of an overall move to increase the effectiveness and efficiency of integrated health care services in the Austrian health care system.[22]

APPROACHES TO CHRONIC CARE

The regulatory and policy measures facilitated the implementation of chronic care approaches. This section describes in more detail the key features of approaches pursued in each of the countries, focusing on commonalities and differences between countries. As indicated above, the overarching care model tends to be a form of disease management, whose main characteristics as they relate to funding mechanisms, distribution and uptake, alongside principles of provider and patient participation and the coordination process are summarised in Tables 3 and 4.

A focus on single chronic conditions

Most approaches pursued in all three countries tend to be disease-specific, with type 2 diabetes most typically targeted. The focus on diabetes is perhaps not surprising, given the disease and cost burden associated with this condition worldwide.[23] However, a focus on diabetes was also prompted by existing examples of care models that could be drawn upon. For example, in the Netherlands, the development of diabetes care groups was greatly informed by a care model developed in Maastricht, the Maastricht Transmural Diabetes Organisation, which originates from the 1990s.[19] In Austria, the diabetes DMP was modelled, in part, on the disease management programme for type 2 diabetes developed in Germany. Other diseases targeted include cardiovascular disease, chronic respiratory disease, and breast cancer (Germany).

However, the focus on single diseases has been identified as a concern, given the often multiple health problems among people with chronic conditions. In an attempt to address this, regulation in Germany has mandated the development of additional disease management modules for obesity and chronic heart failure to supplement existing DMPs.[11] In the Netherlands, a framework to address overweight and obesity within the care group approach is being developed.[24] Approaches addressing a wider spectrum of needs, including those arising from multiple conditions, frequently centering on populations aged 65 years and above (here referred to as 'generalist' approaches) have also been introduced but have as yet remained geographically localised and/or restricted to pilot programmes.

Table 3: Key features of the principal approach to chronic care management in Austria, Germany and the Netherlands

Approach	Aim/general description	Target population	Year implemented	Funding	Use of financial incentives	Distribution and uptake
Austria						
Diabetes disease management programme (DMP) (*Therapie Aktiv*)	To improve the quality of life and extend life for people with chronic disease, to place the patient at the center of care, and to make efficient use of health care resources and also reduce hospitalisations	Type 2 diabetes	2006	Regional SHI fund and federal state contribute about 50% each; programme development funded by regional SHI funds	DMP physicians: patient sign-up and quarterly fee for treatment and documentation	Implemented in 5 of 9 states; 2 states operate separate programmes, one of which is to be integrated into Therapie Aktiv. About 17,000 patients are enrolled in the DMP across Austria (~4.3 percent of all people with diabetes type 2)
Germany						
Disease management programmes (DMPs)	Organisational approach to medical care that involves the coordinated treatment and care of patients with chronic disease across boundaries between individual providers on the basis of scientific and up-to-date evidence	Type 1 and 2 diabetes, coronary disease (+chronic heart failure), breast cancer, asthma/COPD (obesity module in preparation)	2003	Funded from usual sources (statutory health insurance (SHI))	DMP physicians: additional payment for documentation, education Patients: may be exempted from practice fee	DMPs are offered by SHI funds, with around 2,000 DMPs for each condition (2010); number of participating physicians varies, around 65% of GPs act as DMP physician for diabetes type 2. By the end 2010, a total of 5.75 million individuals were enrolled in one or more DMPs, from 127,700 in breast cancer DMP to ~3.4 million in diabetes type 2 DMP (around two-thirds of diagnosed diabetics in the SHI system)

Netherlands					
Bundled payment contract ('care group')	To facilitate multidisciplinary cooperation through the elimination of existing financial barriers between providers and sectors based on nationally defined care standards that encompass early detection, treatment and rehabilitation	Type 2 diabetes, vascular risk, COPD (heart failure under development)	2007 (diabetes)	Funded from usual sources (mandatory insurance) on the basis of a bundled payment contract	Physicians: bundled payment for defined package of care Insurer: to negotiate low price for care bundle	There were 97 care groups in March 2010 with bundled payment contracts with health insurers, mostly for diabetes care. Relatively few groups provide VRM: of 55 groups surveyed in 2010, two had a bundled payment contract in place for VRM, while 17 were preparing to contract

NOTE: DMP indicates disease management programme; COPD, chronic obstructive pulmonary disease; SHI, statutory health insurance; VRM, vascular risk management.

Table 4: Features of the principal approach to chronic care in Austria, Germany and the Netherlands: participation, principles of care coordination, patient self-management support, use of information systems

Name	Participation: provider	Participation: Patients	Care coordination	Self-management support	Use of information systems
Austria					
'Therapie Aktiv' disease management programme	Principally offered by regional SHI fund based on contracts between regional SHI fund and providers. Participation is voluntary for providers who have to attend mandatory provider training to be accredited as DMP physician; annual advanced training sessions and quality circles	Participation is voluntary. Patients chose physician who participates in the DMP and acts as coordinating physician (usually GP). Eligibility for participation is determined based on presence of diabetes	DMP physician oversees referral between levels of care according to care pathways developed by the Austrian Society of Diabetes (ÖDG) and ensures regular follow-up	Patient education through group instruction courses provided by DMP physician or diabetes advisors/specialists. Patient involvement in determining therapeutic goals and timelines, with agreed targets signed jointly	Standardised documentation of clinical and diagnostic measures and treatment; nationwide monitoring is planned but regular feedback reports to participating physicians have yet to be implemented
Germany					
Disease management programmes	Principally offered by SHI funds based on collective contracts between funds and providers at regional level. Participation is voluntary for providers who have to meet defined training standards and may have to attend further training and/or quality circles on a regular basis	Participation is voluntary for patients. Patients chose physician who participates in the DMP and acts as coordinating physician (usually family physician/GP). Eligibility for participation is determined based on presence of chronic condition	Patient management comprises coordination of three care levels (coordinating physician, specialised outpatient care, and inpatient care) according to conditions for referral set out in regulation. DMP physician ensures regular patient follow-up	Obligatory patient education programme (approved by Federal Insurance Office) provided by DMP physician or local training centre. Patient involvement in determining therapeutic goals and timelines. Telephone-based support by some SHI funds	Standardised electronic documentation of treatment, patient's condition and test results, medication regime, and agreed treatment goals; centralised data analysis to produce quality reports and provider feedback on performance and for benchmarking

Name	Participation: provider	Participation: Patients	Care coordination	Self-management support	Use of information systems
Netherlands					
Bundled payment contract ('care group') (example: Maastricht diabetes care group)	Offered by care group who contracts with health insurers providing a package of care defined by national standards. Care group contracts with and/or employs providers (GPs, specialists, allied staff); Maastricht diabetes care group brings together nearly all GPs in the region	Patients join programme through GP they are registered with	Patients are stratified according to disease severity into four regular modules plus two modules for (complex) problems. GP acts as central coordinator supported by nurses responsible for care management. GP oversees referral to secondary care according to defined criteria and ensures follow-up	Regular check-ups include education on self-management by practice nurses/specialised diabetes nurses, depending on the level of need; level of need defines frequency and duration of consultations to be conducted for educational purposes	Disease-specific electronic patient record ('MediX') contains check-up and referrals data within care programme, allows for information sharing and automatisation of care protocols, can be linked to laboratory data and functional measurements

NOTE: DMP indicates disease management programme; SHI, statutory health insurance; GP, general practitioner.

Disease management as a means to strengthen coordination

The overarching approach to strengthen care coordination is through some form of disease management although the content and scope of related approaches differs considerably between the three countries. Thus, the care groups in the Netherlands have been conceived as a multidisciplinary team approach with a physician ('director') overseeing the overall coordination between the various participating care providers, whereas patient management is, to great extent, delegated to nurses (Table 4). In contrast, in Germany and Austria, disease management has remained very much within the traditional structure of care provided by doctors within the ambulatory care sector, although following a strict protocol overseeing the patient management between levels of care, and in which non-medical staff (typically confined to practice assistants) play, if anything, a small role. Indeed, the use of non-medical staff such as specialised nurses or practice assistants in Austria and Germany is a fairly recent phenomenon. Examples include GP contracts in Germany[14] or home care for patients with chronic heart failure in Salzburg, Austria.[25] In Germany, services provided by non-medical staff may include monitoring; the assessment of mental, physical, or psychological problems; and coordination with other service providers. However, by law, all services must be assigned and performed under the supervision of the GP.[26]

Incentivising the implementation of care coordination

Several approaches use financial incentives, usually targeted at physicians although funders have also benefitted from additional (time limited) resources earmarked for care coordination and integration initiatives. For example, in Germany, to make disease management programmes an attractive option for the SHI funds, their introduction was linked to the risk structure compensation scheme (RSA). This provided SHI funds with a substantial financial incentive to offer DMPs as part of their portfolio of services and to motivate their members to take part in these programmes. This strategy had considerable success: by October 2009, SHI funds offered over 13,300 DMPs and a total of 5.5 million patients had signed up to at least one DMP.[27] However, since 2009, following a reform of the RSA scheme with the introduction of a morbidity-adjusted RSA, the financial incentive for SHI funds has been reduced markedly, and numbers of patients signing up for DMPs have been stagnating since.[14] Whether this stagnation reflects a saturation effect or is a consequence of the reduced financial incentive is as yet unclear.

At the same time, SHI funds were also given the possibility to designate financial resources, of a total of 1% of their income, for selective contracting with single providers or networks of providers.[8] The nature and scope of integrated care contracts has varied, with many focusing on the interface between

acute hospital and rehabilitative care. By the end of 2008, approximately 6400 integrated care contracts had been concluded, covering 6% of all SHI insured. However, by the end of 2008, when the financial incentive was concluded, less than half of these contracts had incorporated elements of intersectoral care.[28]

In the Netherlands, the bundled payment scheme is based on the principle of a care group, a legal entity that brings together providers (mostly GPs) in primary care. As the principal contractor, the care group enters into a contract with a health insurer to provide a package of care for a given condition according to a nationally developed care standard ('bundled payment contract'). The price for the package of care is negotiated between the provider care group and the insurance fund on the basis of the performance of the care group. Conceived as an 'experiment' in 2007, with 10 diabetes care groups receiving start-up funding for a period of 16 months and accompanying evaluation[20], the government subsequently decided to roll-out this strategy nationally for the delivery of care for patients with diabetes, chronic obstructive pulmonary disease (COPD), or vascular risk.[29] However, although diabetes care contracts have achieved national coverage, the negotiation of bundled payments for COPD care and vascular risk management has remained a challenge.[30]

In Austria, as noted earlier, the reform pool made it possible to explicitly fund projects in integrated care, including disease management programmes described above, as well as a wide range of other approaches, such as various forms of case management including managed discharge[31] or integrated care for stroke patients.[5] However, implementation of reform pool activities has been uneven across states and related projects have been slow to take off partly because of a lack of financial incentives for physicians to participate in such projects. There has been limited federal oversight of the reform pool funds and projects, leading to duplication of efforts and a lack of scale-efficiency in some regions. The highest number of projects was funded in 2007 (23), at a cost of €11 million, but project activity fell subsequently. Of all funds available, only 16% had been put to use, but this varied greatly by region with over 30% used in Styria and only 1.5% in Tyrol.[32]

Encouraging uptake of programmes by patients and providers

In all three countries, participation in the coordinated care approaches is voluntary for physicians and patients, and they are funded within the statutory system, thus making them principally available to all eligible patients. However, coverage is varied, in the case of diabetes care programmes ranging from some 4.3% of the population with type 2 diabetes in Austria[33] up to ~60% in Germany.[34,35] In the Netherlands, approximately two-thirds of an estimated 750,000 people with diabetes are covered by a bundled payment contract.[30]

The comparatively low uptake in Austria partly reflects variation in availability of relevant programmes across the different states, which, in turn, re-

flects variation in the participation rates of primary care physicians in such programmes [36], ranging from an estimated 16% in Lower Austria and Vienna to 36% in Salzburg (authors' estimates based on Habl and Bachner[37]). Low participation may reflect physicians' resistance to the (perceived or real) additional administrative burden imposed by DMPs.

The administrative burden caused by documentation requirements was initially also a concern for physicians in Germany, following the introduction of DMPs[11]; processes have since been simplified. In Germany, ~65% of GPs participate in the diabetes DMP, which may be explained by financial incentives offered to participating physicians. In the Netherlands, participation rates of GPs in structured care programmes are likely to be higher, with relevant incentives inherent in the structure of the bundled payment contract, offering considerable means to negotiate prices. Participation is estimated at 77% of all GPs[30] and is likely to increase further with government plans to move all care for diabetes (and other chronic conditions) to bundled payment contracts.

What has the impact been?

The preceding sections have demonstrated how all three countries reviewed here have implemented a range of policies and approaches to achieve better coordination within and across the primary and secondary care interface and so better meet the needs of patients with chronic conditions. This has involved changes to the regulatory framework to support more coordinated approaches to care (Austria, Germany), coupled with financial incentives (Austria, Germany) or changes in payment systems (the Netherlands). What is common to the three countries, as indeed in most other OECD countries[5], is the comparative 'novelty' of policies and approaches aimed at fostering coordinated care, and the evidence of their impact remains unclear.

In Germany, evidence from the statutory evaluation of diabetes DMPs points to improved quality of care for participating patients.[34,35] The few existing controlled studies provide limited evidence of improved outcomes, such as quality of life[38] and mortality[39,40] as well as reduced costs.[40] However, the extent to which improved survival can indeed be attributed to the diabetes DMP remains uncertain[34,35,39], with other studies failing to provide evidence of improved medical outcomes.[41] In addition to methodological challenges, a major question remains as to whether disease-specific approaches, such as the German DMPs, are suited to meet the needs of the typical patient in primary care who frequently has multiple health problems with complex needs.[14] More general approaches, such as integrated care contracts or policlinics, might potentially be better equipped to respond to more complex patient needs, yet evidence of their effect within the German health care system remains poorly understood because of lack of systematic evaluation.

In Austria, the phasing-in of DMPs was accompanied by evaluation in almost all federal states. For example, the diabetes DMP Therapie Aktiv, implemented in Salzburg, was evaluated using a cluster-randomised controlled trial. The evidence was mixed, however, with non-significant improvements in metabolic control, the main clinical outcome, although other measures (weight and cholesterol) improved significantly.[42] Improved process measures were also observed for the diabetes DMPs implemented in Lower Austria, for example, demonstrating a reduction in hospital utilisation among those enrolled in a DMP pointing to the potential for cost savings although the overall evidence for DMPs to actually do so has remained inconclusive.[43]

In the Netherlands, findings from the evaluation of the first year of the 10 'experimental' diabetes care groups found wide variation in number and type of participants, the content of the packages of care covered, and price (between €258 and €474 per patient per year).[20] Thus, contracts differed in the extent to which they offer additional services beyond the core package of care, such as smoking cessation guidance and/or foot care. Importantly, as the precise content of care is not clearly defined, there is a risk of 'double-billing' of selected care components, although the extent to which this is happening in practice is unknown. Evidence of impact on outcomes has remained inconclusive thus far. An expectation that diabetes care groups will, through improving the quality of (diabetes) care, lead to cost reductions could not be verified at 12-month follow-up; indeed, although costs might be saved due to reduced hospitalisations, they may at the same time increase because of 'intensification' of care for diabetic patients[20], an observation that was also made for selected DMPs in Austria.[43]

DISCUSSION

In this paper, we have traced the evolution of chronic care in Austria, Germany, and the Netherlands, all of which are principally financed from SHI. We find that countries have implemented a range of policies and approaches to overcome fragmentation in the health care system to achieve better coordination within and across the primary and secondary care interface and so better meet the needs of those with chronic conditions. A predominant model of care in the form of structured disease management has emerged in all three countries, although the evolution of these models has differed. Thus, in Germany, disease management was introduced in a top-down process, using a regulatory framework to ensure nationwide implementation.[11] The Dutch model, although implemented nationwide upon government initiative, evolved from an experiment with a limited set of providers and informed by earlier experience of a delivery model developed in the 1990s.[19] In Austria, disease management programmes were made possible within the framework of a new financial instru-

ment at the level of federal states, with states introducing such approaches broadly modelled on German DMPs. However, programmes have been slow to take off because projects require additional funds, and therefore disincentivising project approval.[5]

Recent reforms in Austria have attempted to shift supply from inpatient to outpatient settings and improve patient access to ambulatory care services. However, these reforms have been restricted to physicians and are yet to take off in practice. Overall, this highlights the challenges experienced in Austria to arriving at an overarching strategic approach in a system that involves multiple actors in the negotiation of ambulatory care, including 21 SHI funds, the Federation of Austrian Social Security Institutions, the Austrian Medical Association, and associations of other health professions.[10] One area where the central government has taken a clear position is in efforts to promote a more integrated approach to planning, which is now being pursued towards coordinated supply across health care sectors.

In Germany, in contrast, while also involving multiple actors, negotiations relating to the ambulatory care sector are centralised at the national level[8], which may have facilitated the development of a national framework. However, it should be noted that the introduction of DMPs was strongly supported by SHI funds such as the general regional funds, which, because of their member profile, were disadvantaged by the RSA and their national association took a leading role in the promotion of the programmes. The government was also very supportive of swift implementation of DMPs and it took provisions to do so despite resistance from many stakeholders.

At the same time, although the creation of a strict national regulatory framework has been viewed as beneficial in ensuring that programmes meet appropriate standards, there have been concerns that this may limit the way in which this approach is able to address local need.[11] The Dutch approach of 'incremental' implementation[44], starting out with a select set of pilots experimenting with bundled payment and that are being evaluated for subsequent roll-out may be regarded as an approach that combines centrally defined requirements and local autonomy, although it should be noted that national roll-out was advocated by the government before evaluation findings were available. Ham[45] has highlighted how competing pressures on organisations, that arise from policies initiated by health care reformers on one hand and established ways of delivery on the other, are likely to result in a gap between policy intent and actual implementation.[45] A critical role has to be played by professionals, who exert a large degree of control in health care organisations such as primary care practices and hospitals. Failure to engage them in the reform process is likely to hamper sustainable change. Indeed, as work on 'chains of care' in Sweden has demonstrated, approaches that engaged professionals, or were indeed initiated by professionals themselves, succeeded in developing improved inter-organisational and interprofessional coordinated structures, whereas those

initiated top-down by councils did not.[46] However, a supportive policy environment was also found to be critical for success.

Fundamentally, it is, however, important to highlight that DMPs in Germany and Austria did not fundamentally alter (or indeed challenge) existing structures in the health care system. Services continue to be provided within the existing delivery structure, comprising family physicians, specialists in private practice, and hospitals. The integration of non-medical health professionals into the care system, which has led to considerable improvements in chronic care elsewhere, has only recently been pursued, although remaining limited to certain settings. In Germany, although wider use of nurses was considered and supported by the German nurses association as a means to strengthen the role of nurse practitioners, other stakeholders, in particular family physicians and their associations, were concerned about introducing another layer of care as well as losing control over the provision of medical care. It is interesting to note, in this context, that the role of nurses in the Dutch care groups, although prominent, has been reduced somewhat compared to the model that informed their development.[19] Here, the specialist diabetes nurse acted as liaison between the hospital and primary care for all patients and indeed acted as consultant to the GP, who was responsible for the management of diabetes patients with low intensity needs. In 2007, the model was transformed into the diabetes care group by the Regional General Practitioners Organisation in the Maastricht region. Thus, professional resistance to change remains a challenge in all systems.

Finally, one of the greatest challenges for the systems reviewed here remains the development of a system-wide model of care for patients with chronic disease. As noted earlier, disease-specific approaches such as disease management programmes are ill-suited to meet the needs of the typical patient in primary care, who frequently has multiple health problems with complex needs.[2,3] The Dutch care groups, although disease-focused, are envisaged as multidisciplinary care teams and, through stratification of patients according to severity and required care intensity, may go some way to meeting the requirements of those with multiple health problems. However, more generalist approaches such as the integrated care contracts implemented in Germany are potentially better equipped to respond to more complex patient needs, yet the evidence as to their effect within the German health care system remains poorly understood. There is a need for more systematic evaluation of new models of care as a means to inform the development of efficient and effective interventions to address the growing burden of chronic conditions in Europe and elsewhere.

ACKNOWLEDGEMENTS

This work was supported, in part, by the DISMEVAL project funded under the European Commission FP7 programme (Grant no. 223277). The authors further gratefully acknowledge the research assistance provided by Leslie Tarver.

REFERENCES

1. TNS Opinion and Social. *Health in the European Union. Special Eurobarometer 272e.* Brussels: European Commission; 2007.
2. Nolte E, McKee M (eds). *Caring for people with chronic conditions: a health system perspective*. Maidenhead: Open University Press; 2008.
3. Nolte E, McKee M. *Making it happen*. Nolte E, McKee M (eds). *Caring for people with chronic conditions: a health system perspective.* Maidenhead: Open University Press; 2008:222-244.
4. Glasby J, Dickinson H, Peck E. Guest editorial: partnership working in health and social care. *Health and Social Care in the Community*, 2006;14:373-374.
5. Hofmarcher MM, Oxley H, Rusticelli E. *Improved health system performance through better care coordination*. Paris: OECD; 2007.
6. Nolte E, Knai C, McKee M. *Managing chronic conditions: experience in eight countries*. Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008.
7. RAND Europe and London School of Hygiene & Tropical Medicine. *Chronic disease management. An overview of 13 countries. Unpublished report.* Cambridge: RAND Europe; 2011.
8. Busse R, Riesberg A. *Health care systems in transition: Germany*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies; 2004.
9. Schäfer W, Kroneman M, Boerma WGW, Van den Berg M, Westert G, Deville W, Van Ginneken R. The Netherlands: health system review. *Health Systems in Transition*, 2010;12(1):1-229.
10. Hofmarcher M, Rack H. Austria: health system review. *Health Systems in Transition*, 2006;8(3):1–247.
11. Siering U. *Germany*. In: Nolte E, Knai C, McKee M (eds). *Managing chronic conditions: experience in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008:75-96.
12. Bundesversicherungsamt (2011). *Zulassung der Disease Management Programme (DMP) durch das Bundesversicherungsamt (BVA).* Accessible at: http://www.bundesversicherungsamt.de/-cln_108/nn_1046154/DE/DMP/dmp__inhalt.html
13. Ettelt S, Nolte E, Mays N, Thomson S, McKee M, and the International Healthcare Comparisons Network. *Health care outside hospital. Accessing generalist and specialist care in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2006.
14. Fullerton B, Nolte E, Erler A. Qualität der Versorgung chronisch Kranker in Deutschland. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen,* 2011 [in press].
15. OECD. *OECD Health Data*. Paris: OECD; 2010.
16. Linden B. *The birth of integration. Explorative studies on the development and implementation of integrated care in the Netherlands. Dissertation*. Utrecht: University of Utrecht; 2000.
17. Vrijhoef HJM, Spreeuwenberg C, Eijkelberg IMJG, Wolffenbuttel BHR, Van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *British Medical Journal*, 2001;323:983-985.
18. Steuten LMG, Vrijhoef HJM, Spreeuwenberg C, Van Merode GG. Participation of general practitioners in disease management: experiences from the Netherlands. *International Journal of Integrated Care*, 2002;2:1-5.

19. Klein-Lankhorst E, Spreeuwenberg C. *The Netherlands*. In: Knai C, Nolte E, McKee M (eds). *Managing chronic conditions: experience in eight countries.* Copenhagen: European Observatory on Health Systems and Policies; 2008.
20. Struijs JN, Van Til JT, Baan CA. *Experimenting with a bundled payment system for diabetes care in the Netherlands: the first tangible effects.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
21. Eichwalder S, Hofmarcher M. *Failure to improve care outside hospitals*. Health Policy Monitor; 2008. Accessible at: http://www.hpm.org/survey/at/a11/2
22. Hofmarcher M, Hawel B. *Ambulatory care reforms fail to face the facts?* Health Policy Monitor; 2010. Accessible at: http://hpm.org/survey/at/a15/1
23. Pomerleau J, Knai C, Nolte E. *The burden of chronic disease in Europe*. In: Nolte E, McKee M (eds). *Caring for people with chronic conditions: a health system perspective*. Maidenhead: Open University Press; 2008:15-42.
24. Partnership Overweight Netherlands. *Tackling the problem of overweight and obesity: the Dutch approach*. Partnership Overweight Netherlands; 2009. Accessible at: http://www.partnerschapovergewicht.nl/site_files/uploads/RVWS020%20Affiche%20KCO-CO-PON.pdf
25. Arbeitskreis Vorsorgemedizin Salzburg (2010). *Kardiomobil: Heimbetreuung für Herzinsuffizienz-PatientInnen*. Accesible at: http://www.avos.at/konzept/kardio.htm
26. Bewertungsausschuss nach § 87 Abs. 1 Satz 1 SGB V (2009). *Durchführungsempfehlung des Bewertungsausschusses nach § 87 Abs. 1 Satz 1 SGB V in seiner 176.* Sitzung am 17. März 2009 zur Finanzierung der Kostenpauschalen im Zusammenhang mit der Einführung delegierbarer Leistungen in das vertraglich vereinbarte Kapitel 40 des Einheitlichen Bewertungsmaßstabes (EBM) zum 1 April 2009. Accessible at: http://www.kbv.de/8157.html
27. Bundesversicherungsamt (2007). *Zulassung der Disease Management Programme (DMP) durch das Bundesversicherungsamt (BVA).* Accessible at: http://www.bva.de/
28. Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen. *Koordination und Integration – Gesundheitsversorgung in einer Gesellschaft des längeren Lebens.* Bonn: Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen; 2009.
29. Vrijhoef HJM. Chronische zorg in Nederland anno 2010: leidt verandering tot verbetering? *Forum*, 2010;2:59-62.
30. Van Til JT, De Wildt JE, Struijs JN. *De organisatie van zorggroepen anno 2010. Huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
31. Czypionka T, Kraus M, Röhrling G, Straka H. *Case management in Austria and Europe.* Vienna: The Institute for Advanced Studies; 2008.
32. Czypionka T, Röhrling G. Analyse der Reformpool-Aktivitzät in Österreich: Wie viel Reform ist im Reformpool? *Health System Watch*, 2009;II:1-16.
33. Österreichische Diabetes Gesellschaft (2010). *Presseinformation der ÖGD. Erfolgreiche 1. Zwischenbilanz für Diabetes Programm, Therapie Aktiv.* Accessible at: http://www.oedg.org/pdf/PA_10_04_DMP.pdf
34. Schäfer I, Küver C, Gedrose B, Hoffmann F, Russ-Thiel B, Brose HP, Van den Bussche H, Kaduszkiewicz H. The disease management program for type 2 diabetes in Germany enhances process quality of diabetes care: a follow-up survey of patient's experiences. *BMC Health Services Research*, 2010;10:55.
35. Schäfer I, Küver C, Gedrose B, Von Leitner E, Treszl A, Wegscheider K, Van den Bussche H, Kaduszkiewicz H. Selection effects may account for better outcomes of the German Disease Management Program for type 2 diabetes. *BMC Health Services Research*, 2010;10:351.
36. Therapie Aktiv Diabetes im Griff (2011). *Umsetzungsstand in Österreich*. Accessible at: http://diabetes.therapie-Aktiv.at/portal27/portal/diabetesportal/channel_content/cmsWindow?action52&p_menuid566241&p_tabid52
37. Habl C, Bachner F. *Health care in Austria.* Vienna: Österreichisches Bundesinstitut für Gesundheitswesen; 2010.

38. Ose D, Wensing M, Szecsenyi S, Joos S, Hermann K, Miksch A. Impact of primary care-based disease management on the health-related quality of life in patients with type 2 diabetes and comorbidity. *Diabetes Care*, 2009;32:1594.
39. Miksch A, Laux G, Ose D, Joos S, Campbell S, Riens B, Szecsenyi J. Is there a survival benefit within a German primary care-based disease management program? *American Journal of Managed Care*, 2010;16:49-54.
40. Stock S, Drabik A, Büscher G, Graf C, Ullrich W, Gerber A, Lauterbach KW, Lüngen M. German diabetes management programs improve quality of care and curb costs. *Health Affairs*, 2010;29:2197-2205.
41. Linder R, Ahrens S, Köppel D, Heilmann T, Verheyen F. The benefit and efficiency of the disease management program for type 2 diabetes. *Deutsches Ärzteblatt International*, 2011;108:155-162.
42. Sönnichsen AC, Winkler H, Flamm M, Panisch S, Kowatsch P, Klima G, Fürthauer B, Weitgasser R. The effectiveness of the Austrian disease management programme for type 2 diabetes: a cluster-randomised controlled trial. *BMC Family Practice*, 2010;11:86.
43. Ruh C, Winter S, Zeiler E, Robausch M. Evaluation des Reformpool-Projektes Disease-Management-Programm Diabetes mellitus Typ 2: Therapie Aktiv in der Region Waldviertel. *Soziale Sicherheit*, 2009;May:267-277.
44. Helderman JK, Schut FT, Van der Grinten TED, Van de Ven WPMM. Market-oriented health care reforms and policy learning in the Netherlands. *Journal of Health Politics, Policy and Law*, 2005;30:189-209.
45. Ham C. Improving the performance of health services: the role of clinical leadership. *The Lancet*, 2003;361:1978-80.
46. Ahgren B, Axelsson R. Determinants of integrated health care development: chains of care in Sweden. *International Journal of Health Planning and Management*, 2007;22:145-157.

PART II

ADVANCING DISEASE MANAGEMENT SCIENCE AND EVIDENCE

Chapter 5

Toward tailored disease management for type 2 diabetes

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American Journal of Managed Care, 2012;18(10):619-30.

ABSTRACT

Objective: To assess the differentiated effects of population-based disease management programmes (DMPs) for type 2 diabetes on intermediate clinical outcomes in the Netherlands.
Methods: Data covering a period from 20 to 24 months between January 2008 and December 2010 were collected from 18 Dutch care groups (primary care provider networks that have bundled payment contracts for delivery of diabetes DMPs). Meta-analysis and meta-regression methods were used to conduct differentiated analyses of these programmes' effects over time on 4 clinical indicators: glycated haemoglobin, low-density lipoprotein, systolic blood pressure, and body mass index. Heterogeneous average results were stratified according to various patient and process characteristics to investigate whether differences in these features could explain variation in outcomes.
Results: Between 56% and 71% of patients (N=105,056) had valid first- and second-year measurements of the study outcomes. Although average changes in these measures over time were small, stratified analyses demonstrated that clinically relevant improvements were achieved in patients with poor first-year health values. Interactions with age, disease duration, comorbidity, and smoking status were not consistent across outcomes; nonetheless, heterogeneity in results decreased considerably when simultaneously correcting for known patient characteristics. Positive effects tended to diminish with longer length of follow-up, while greater measurement frequency was associated with improved results, especially in patients with poor health.
Conclusions: Our data suggest that tailored disease management, in which not only evidence-based guidelines but also patient characteristics directly determine care processes, including self-management support, has great potential to improve the cost-effectiveness of current chronic care delivery.

INTRODUCTION

Rising costs, an aging population, and the recognition of severe deficiencies in traditional care have motivated the development of innovative models for chronic illness management. Examples include shared care, case management, and stepped care, but perhaps most well known internationally are disease management and the Chronic Care Model.[1-3] Differences aside, these concepts have in common their basic assumption that better treatment today will result in better health and less expensive care in the future. Specific quality improvement efforts tend to focus on: (1) reducing fragmentation between providers and settings; (2) stimulating evidence-based practice; (3) promoting active and planned follow-up; and (4) supporting patients' self-management.[4-7]

Developed in the United States, disease management programmes (DMPs) have quickly spread to other countries such as Canada, the United Kingdom, and Germany, which now has some of the largest DMPs in the world.[8,9] In the primary care-oriented Dutch health system, chronic disease management initiatives developed from the 1990s onward. Initially, uptake of these initiatives remained limited, mainly due to lack of a structured framework and fragmentary funding.[10,11] The 2006 health insurance reform granted health insurers extended power to negotiate with care providers and, in so doing, facilitated the development of a more integrated funding method, the so-called 'bundled payment system'.[12-14] Under this system, insurers pay care groups, which are provider networks based in primary care, a single fee for the full range of outpatient services for a specific chronic condition.[15] Bundled payments are seen as a way to stimulate primary care providers, predominantly general practitioners (GPs), to engage in multidisciplinary cooperation and deliver integrated, evidence-based disease management in an ambulatory setting, therefore limiting the need for specialist care.[16,17]

Although the evidence base for their impact on the quality and outcomes of care is limited, integrally financed DMPs for type 2 diabetes quickly achieved national coverage in the Netherlands. In March 2010, more than 100 groups representing approximately 80% of GPs had a bundled payment contract for diabetes care.[17,18] In the same year, the payment system was expanded to cover the management of chronic obstructive pulmonary disease (COPD) and vascular risks. Hence, the support for disease management in the Netherlands appears to be a matter more of faith than fact, as is the case in other countries as well. International studies and reviews of DMPs demonstrate highly heterogeneous results and so far have failed to answer the basic question of what works best for whom, not least because of variation in both methodology and nomenclature.[3,19-22] It is, however, especially the multicomponent and population-based nature of disease management that makes it difficult to draw unambiguous conclusions concerning effectiveness. Analysing complex DMPs necessitates a clear framework that links expected outcomes to the characteristics of both

the programme and its target population, and measures effects over an adequate period of time.[23]

As part of the DISMEVAL (Developing and Validating Disease Management Evaluation Methods for European Health Care Systems) project, this study's objective was to assess the effects of the Dutch diabetes DMPs on a range of intermediate clinical outcomes. To investigate heterogeneity in results across different care processes and patients, we designed the study as a population-based, multilevel meta-analysis and meta-regression. Given that experimental comparisons were not possible, because of the nationwide roll-out of the DMPs and the unsuitability of using historical controls[9], these methods allow for the most in-depth assessment of effectiveness. Such differentiated insight, which goes beyond the 'grand means' that currently inform many health system redesigns, can support professionals and policymakers in their efforts to better meet the complex care needs of the growing and inherently diverse population of chronically ill patients.

METHODS

Study design and participants

The bundled payment system for generic diabetes disease management in the Netherlands obliges care groups to provide insurers with a specific number of performance indicators for both processes and outcomes on an annual basis.[24] We retrospectively gathered individual patient data on these indicators from a convenience sample of 18 groups, which were set up between 2006 and 2009 and represent nearly all regions of the Netherlands. Nine groups were part of an experimental pilot concerning bundled payments evaluated by the National Institute for Public Health and the Environment (RIVM)[15]; to include 9 other, non-experimental groups, 14 care groups were approached (response rate 64.3%).

Across the included groups, 106,623 patients had at least 1 registered visit during the research period, which – depending on the availability of data – was either 20 or 24 months between January 2008 and December 2010. We excluded type 1 diabetes patients (N=1567) because they are treated primarily by specialists. Since patient data were drawn from groups' clinical information systems, plausibility was verified through range checks. Outliers were removed based on cut-off points determined by Dutch diabetes experts (Appendix 1). Missing values were not imputed.

Because patient data were not available for the period before introduction of the bundled payment system, we assessed the effects of the diabetes DMPs by comparing the last measurement of each clinical outcome during the first year of the research period (or the first 8 months for the 2 groups with a 20-month

research period) with the last measurement of that outcome in the second year. Per outcome-specific analysis, we excluded patients who: (1) lacked registrations of the first- or second-year measurement, or both; (2) missed registrations of 1 or more of the patient and/or process characteristics used for stratification; and/or (3) had an observation period between first- and second-year outcome measurement of fewer than 3 months. The maximum length of follow-up per patient was 23 months. The study flow chart is shown in Figure 1.

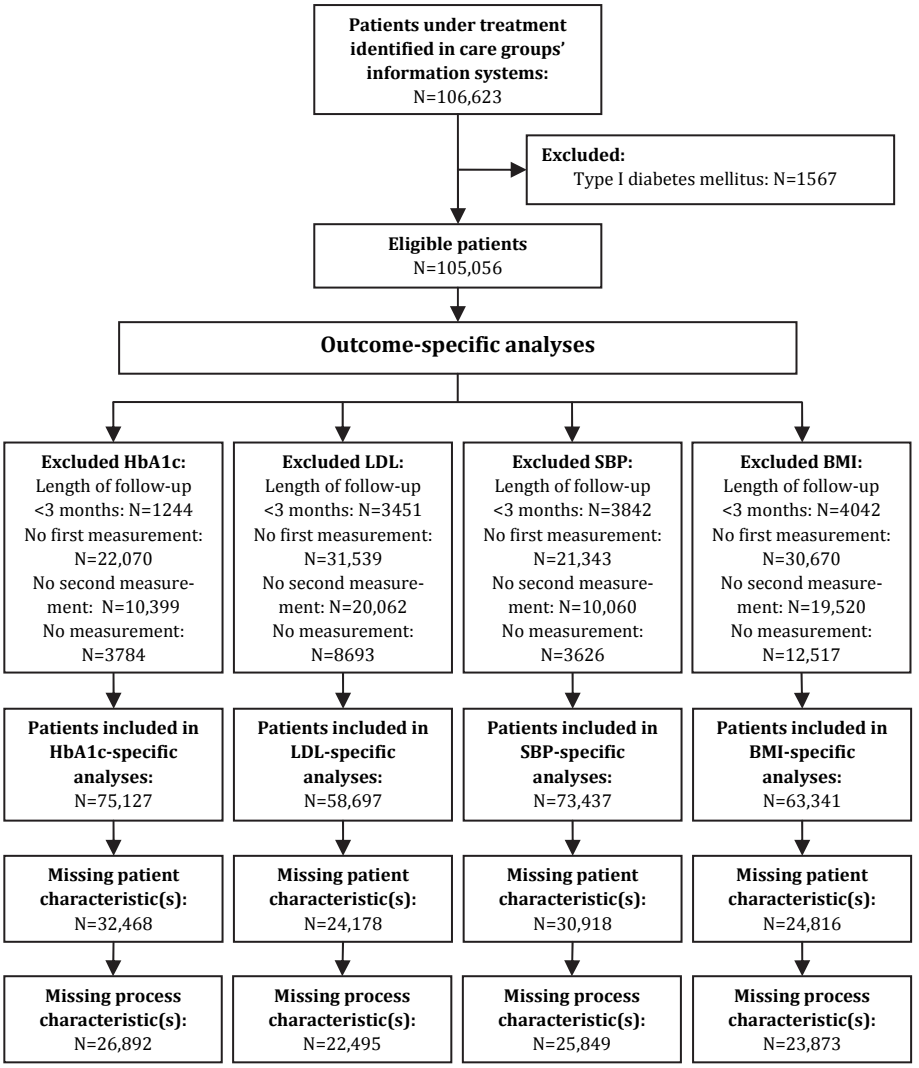

Figure 1: Study flowchart
NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

Diabetes disease management programmes in the Netherlands

In 2007, 10 Dutch care groups started experimenting with a bundled payment system that allows the different components of care for generic type 2 diabetes to be purchased, delivered, and billed as a single product or service. Care groups are legal entities in primary care, which consist of multiple care providers, are most commonly owned by GPs, and form the principal contracting partners for health insurers involved in bundled payment contracts.[17] Groups either deliver the various components of a diabetes DMP themselves or subcontract other providers, including GPs, physical therapists, dieticians, laboratories, and/or specialists, to do so. The price of a specific programme (i.e. care bundle) as well as the fees for individual subcontractors are freely negotiable between care groups on the one hand and health insurers or care professionals on the other. Patients are automatically enrolled by their GP.[15,16]

The services to be covered in the diabetes DMPs are codified by a national care standard for generic diabetes care.[25] This standard is based on existing evidence-based guidelines for GPs and includes general modules (e.g. information, education and self-management support, smoking cessation, physical activity, nutrition and diet) as well as disease-specific modules.[24] The latter comprise a defined frequency of GP visits, regular foot and eye examinations, and laboratory testing. To stimulate task redistribution from GPs to practice nurses, who traditionally play an important role in Dutch chronic care, the standard describes care in terms of functions rather than providers, defining what services must be delivered rather than by whom or where.[16,25] For more information on the contents of the Dutch diabetes DMPs, the diabetes care standard can be accessed online: http://www.diabetesfederatie.nl/zorg/zorg-standaard.html.

Definition of variables and data validation

We defined intermediate clinical outcomes as mean changes in glycated haemoglobin (HbA1c), low-density lipoprotein (LDL), systolic blood pressure (SBP), and body mass index (BMI) between the first- and second-year measurements. In addition, we assessed and compared the proportions of patients within 3 target range groups for glycaemic control (HbA1c≤53 mmol/mol; HbA1c=54-74 mmol/mol; HbA1c≥75 mmol/mol) at these 2 measurement points.[25]

Care processes were described in terms of measurement frequency and range, and duration of care. We codified measurement frequency as the number of registrations of each clinical outcome during follow-up; to describe measurement range, we assessed the number of different outcomes registered, which across care groups could be a maximum of 8 (i.e. HbA1c, total cholesterol, LDL and high-density lipoprotein, triglycerides, SBP and diastolic blood pressure,

BMI). Duration of care was defined as the number of months between the first- and second-year measurements of each clinical outcome.

To describe patients, we used age in years, disease duration in years, health status, comorbidity, and smoking status. Health status was determined by the first-year values of each clinical outcome. Comorbidity was defined as the presence of 1 or more of the 4 most frequently registered co-occurring conditions across the included care groups (i.e. angina pectoris, myocardial infarction, stroke, transient ischemic attack). We dichotomised smoking status as previous smoker or non-smoker versus current smoker.

Data analysis

We used a 2-step approach to population-based, multilevel meta-analysis, in which we clustered the individual patient data by care group.[26,27] During the first step, we conducted paired-sampled t-tests (2-sided; α=0.05) using SPSS version 18 (IBM Corporation, Armonk, New York) to calculate the group-specific mean differences in clinical values and associated standard deviations. In the second step, these were synthesised with Review Manager (RevMan version 5.1.1; The Cochrane Collaboration) into pooled mean differences and 95% confidence intervals, for which – owing to significant heterogeneity in results – we used the random-effects meta-analysis model of DerSimonian and Laird.[28] Using this model, we weighted the aggregate effects by the inverse of their variances while assuming random treatment effects across care groups.[29] To quantify heterogeneity, we calculated the I^2 statistic – which can range from 0% to 100% – on the basis of the χ^2 test.[30] For outcomes showing moderate (I^2>50%) to high (I^2>75%) heterogeneity, subgroup analyses were conducted to examine the consistency of results across diabetes care processes and patients.[26] For this purpose, most continuous variables were categorised into 2 or 3 groups on the basis of either scientific literature (age[31,32], disease duration[33]) or median values (measurement frequency, length of follow-up). We dichotomised measurement range as 8 outcomes (the maximum number of clinical indicators that could be registered) versus fewer than 8 outcomes; first-year health status was categorised according to the target range values for clinical outcomes included in the diabetes care standard.[25]

We used multilevel meta-regression analysis of individual patient data, stratified by care group, to further assess the influence of potential effect modifiers as well as to investigate potential interactions between care processes and patient characteristics.[34,35] To conduct the meta-regressions, we used the PROC MIXED command in the SAS 9.2 software (SAS Institute Inc, Cary, North Carolina), which uses a random-effects iterative method to provide a maximum likelihood estimate of the regression parameters. The meta-regression models were multivariable, though process and patient characteristics were included separately; continuous covariates were included as such. For each clinical out-

come, we calculated the intraclass correlation coefficient to assess the percentage of total heterogeneity in effects occurring between care groups. The larger the intraclass correlation coefficient, the greater the proportion of variance that can be attributed to differences between rather than within groups.[36] We examined collinearity with the variance inflation factor: a variance inflation factor value of greater than 10 is generally taken as an indication of serious multicollinearity.[37] Explained heterogeneity was expressed as the percentage change in between-group variance (τ^2) and within-group variance (σ^2).

RESULTS

Diabetes care processes and patients

With regard to care processes, patients' SBP was assessed most frequently (median=4) during the period between the first- and second-year measurements, followed by BMI (median=3) and HbA1c (median=2). LDL was measured least often (median=1). Across care groups, the average share of patients with the maximum outcome measurement range varied from 44.4% to 86.7%, with a mean of 62.3%. Median length of follow-up varied from 10 to 12 months between groups.

Table 1 shows the patients' main characteristics and first-year clinical values. Age ranged from 15 to 105 years with a mean of 65.7 (±11.9) years. Diabetes duration varied from 0 to 76 years with a mean of 4.8 (±5.6) years. Approximately 16% of patients had a known comorbidity; 18.4% were registered as current smokers. Depending on the clinical outcome of interest, roughly 56% to 71% of patients (N=105,056) had both a first- and second-year measurement. For most outcomes, the mean first-year values for patients were within normal range. Mean first-year BMI (29.7±5.2 kg/m^2), however, signified severe overweight to borderline obesity.

Table 1: Characteristics of the research population

Characteristic	Patients for whom characteristic was known, % (n) (N =105,056)	Estimate, Mean ± SD
First-year age	99.9 (105,013)	65.7 ± 11.9
First-year diabetes duration	71.9 (75,498)	4.8 ± 5.6
First-year health status		
HbA1c (mmol/mol; target <53)	71.5 (75,127)	50.2 ± 9.8
LDL cholesterol (mmol/l; target <2.5)	55.9 (58,697)	2.6 ± 0.9
SBP (mmHg; target <140)	69.9 (73,437)	140.4 ± 18.0
BMI (kg/m^2; target <25)	60.3 (63,341)	29.7 ± 5.2
Comorbidity†	94.5 (99,278)	
None	84.2 (75,357)	
One or more	15.8 (14,165)	
Smoking status	74.6 (78,384)	
No or Ex-smoker	81.6 (63,943)	
Current smoker	18.4 (14,441)	

NOTE: †Included were four major comorbidity associated with diabetes mellitus: angina pectoris, myocardial infarction, stroke, and transient ischemic attack; HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

Clinical outcomes

Table 2 shows the overall results of the random-effects meta-analysis across 18 care groups, presented per clinical outcome. Mean HbA1c increased by 0.17 mmol/mol (95% confidence interval [CI]: -0.60 to 0.93) between the first- and second-year measurements. LDL was reduced significantly by a mean of 0.09 mmol/l (95% CI: -0.13 to -0.05); SBP decreased significantly by an average of 0.95 mmHg (95% CI -1.25, -0.64). There was a small average decrease in BMI of 0.04 kg/m^2 (95% CI: -0.10 to 0.02). Except for BMI, the effects of the diabetes DMPs on all intermediate outcomes were moderately to highly heterogeneous, with I^2 values ranging from 57% for SBP to 98% for HbA1c.

Table 2: Results of the overall random-effects meta-analysis per clinical outcome

Intermediate outcome	Care groups, n	Patients, n	Mean difference [95%CI]	Heterogeneity, I^2
HbA1c (mmol/mol)	18	75,127	0.17 [-0.60, 0.93]	98%*
LDL (mmol/l)	18	58,697	-0.09 [-0.13, -0.05]*	93%*
SBP (mmHg)	18	73,437	-0.95 [-1.25, -0.64]*	57%*
BMI (kg/m^2)	18	63,341	-0.04 [-0.10, 0.02]	0%

NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index; *Statistically significant ($p<0.05$); I^2 quantifies the total level of heterogeneity in effects

Figure 2 shows the proportions of patients within 3 target range groups for glycaemic control at the first- and second-year measurements. Glycaemic control improved in the vast majority of patients, especially in the group with highly uncontrolled diabetes (HbA1c≥75 mmol/mol). Diabetes was brought under control in roughly 68% of these patients; in 19%, the values improved to 53 mmol/mol or lower. Of the patients with first-year HbA1c concentrations between 53 and 75 mmol/mol, approximately 36% improved their glycaemic control, 60% remained within the same range, and 4% deteriorated. Of those within target range at the first measurement (HbA1c≤53 mmol/mol), 83% maintained their HbA1c control, whereas HbA1c control deteriorated up to levels of <75 mmol/mol in 16.5%. Roughly 0.5% saw their HbA1c increase to ≥75 mmol/mol. In terms of mean age and disease duration, the patients within target range at the first-year measurement were most comparable to the overall patient population. Those in the subgroups with initial HbA1c values above 53 mmol/mol and 75 mmol/mol were significantly younger but had a longer-than-average disease duration.

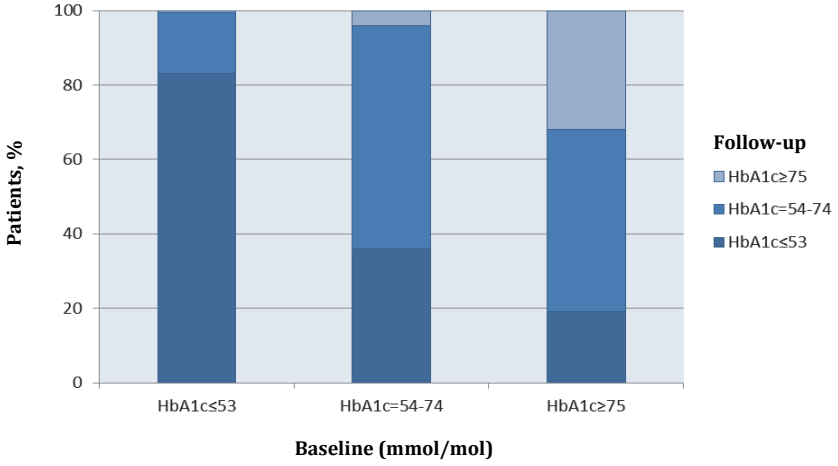

Figure 2: Glycaemic control from first- to second-year measurement according to target values [25]
NOTE: HbA1c indicates glycated haemoglobin

Investigating heterogeneity

With regard to heterogeneity, the intraclass correlation coefficients identified in the meta-regression – ranging from 0.1% to 4.3% across outcomes – suggest that the vast majority of variance in effects on HbA1c, LDL, and SBP occurs within rather than between care groups. Subgroup meta-analysis and meta-regression were conducted to investigate to what extent this heterogeneity can be explained by variation in care processes and patient characteristics. Evidence

for multicollinearity (variance inflation factor >10) among the different covariates on these levels was not identified (Tables 3-6).

Variation in care processes

Table 3 shows that subgroup meta-analyses identified 1 significant difference in effects based on a process characteristic: patients with a length of follow-up of 1 year or less achieved greater reductions in SBP than patients followed for more than 1 year. The meta-regressions demonstrated relationships between length of follow-up and all clinical outcomes, indicating that as the duration of care increases, the positive effects of the DMPs are difficult to maintain. A higher measurement frequency was associated with progressively greater reductions in all included outcomes, although statistical significance was not achieved for HbA1c. The results for measurement range (<8 outcomes vs. 8 outcomes) were inconsistent. Despite the identified interactions, simultaneously correcting for the 3 known process features resulted in no more than minor changes in the existing heterogeneity in effects within groups.

Table 3: Effect of process characteristics on changes in HbA1c, LDL, and SBP levels between first- and second-year measurements

	Groups, n	Patients, n	Mean difference [95% CI; I^2]	RC	Change in τ^2, %	Change in σ^2, %	VIF
HbA1c, mmol/mol	**18**	**75,127**	**0.17 [-0.60, 0.93; 98*]**	**26**		**-0.1**	
Measurement frequency	14			-			1.04
≤Median		27,322	0.09 [-0.85, 1.03]				
>Median		20,913	-0.06 [-1.47, 1.36]				
Measurement range	18			-*			1.05
<8 outcomes		15,641	0.13 [-1.08, 1.34]				
8 outcomes		51,820	0.05 [-0.66, 0.75]				
Length of follow-up	18			+*			1.05
≤1 year		57,069	0.02 [-0.77, 0.81]				
>1 year		18,058	0.53 [-0.22, 1.27]				
LDL, mmol/l	**18**	**58,697**	**-0.09* [-0.13, -0.05; 93*]**	**-36.9**		**0.7**	
Measurement frequency	14			-*			1.02
≤Median		25,420	-0.08* [-0.12, -0.05]				
>Median		10,782	-0.20* [-0.26, -0.15]				
Measurement range	18			-			1.00
<8 outcomes		6500	-0.10* [-0.15, -0.05]				
8 outcomes		45,301	-0.10* [-0.14, -0.06]				
Length of follow-up	18			+*			1.02
≤1 year		43,901	-0.09* [-0.13, -0.05]				
>1 year		14,796	-0.11* [-0.15, -0.06]				
SBP, mmHg	**18**	**73,437**	**-0.95* [-1.25, -0.64; 57*]**	**15.6**		**5.2**	
Measurement frequency	14			-*			1.08
≤Median		21,764	-0.99* [-1.57, -0.41]				
>Median		25,824	-1.01* [-1.38, -0.64]				
Measurement range	18			+*			1.06
<8 outcomes		14,397	-1.60* [-2.02, -1.17]				
8 outcomes		50,392	-0.79* [-1.15, -0.43]				
Length of follow-up	18			+*			1.07
≤1 year		55,686	-1.27* [-1.60, -0.95]				
>1 year		17,751	-0.04 [-0.52, 0.44]				

NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; CI, confidence interval; RC, regression coefficient; VIF, variance inflation factor; *Statistically significant (p<0.05); +=positive; -=negative

Variation in patient characteristics

The findings from the analyses stratified by patient characteristics are displayed in Tables 4 to 6. Both the subgroup meta-analyses and the meta-regressions demonstrated an association between progressively greater health improvements and initially poorer clinical values. Across the 18 care groups, patients

with a first-year HbA1c of ≥75 mmol/mol achieved a mean reduction in this clinical measure of 16.8 mmol/mol, whereas those starting within the target range (≤53 mmol/mol) experienced a slight deterioration (1.79 mmol/mol). For LDL and SBP, similar interactions were found. The results of the remaining analyses (i.e. for age, disease duration, comorbidity, and smoking status) were less conclusive and inconsistent across clinical outcomes. Nevertheless, simultaneously including all patient characteristics into a meta-regression model allowed for substantial reductions in within-group variance in results.

Table 4: Effect of patient characteristics on changes in HbA1c levels between first- and second-year measurements

	Groups, n	**Patients, n**	**Mean difference [95% CI; I^2]**	**RC**	**Change in τ^2, %**	**Change in σ^2, %**	**VIF**
HbA1c (mmol/mol)	**18**	**75,127**	**0.17 [-0.60, 0.93; 98*]**		**-12.5**	**-23.5**	
Age	18			-*			1.12
≤59 years		20,538	0.21 [-0.56, 0.98]				
60-69 years		24,204	0.23 [-0.55, 1.02]				
≥70 years		30,382	0.03 [-0.78, 0.83]				
Disease duration	14			+*			1.09
≤2 years		21,261	-0.12 [-1.12, 0.88]				
3-5 years		13,342	0.11 [-0.76, 0.98]				
≥5 years		20,474	-0.07 [-1.08, 0.95]				
First-year HbA1c	18			-*			1.05
≤53		51,545	1.79* [1.17, 2.41]				
54-74		21,637	-2.62* [-3.46, -1.78]				
≥75		1945	-16.82* [-18.67, -14.96]				
Comorbidity	16			+*			1.03
No		53,065	0.04 [-0.63, 0.71]				
Yes		10,183	-0.06 [-0.76, 0.65]				
Smoking	17			+*			1.04
No/previously		46,277	0.23 [-0.28, 0.73]				
Yes		10,375	0.20 [-0.85, 1.25]				

NOTE: HbA1c indicates glycated haemoglobin; CI, confidence interval; RC, regression coefficient; VIF, variance inflation factor; *Statistically significant ($p<0.05$); +=positive; -=negative

Table 5: Effect of patient characteristics on changes in LDL levels between first- and second-year measurements

	Groups, n	Patients, n	Mean difference [95% CI; I^2]	RC	Change in τ^2, %	Change in σ^2, %	VIF
LDL (mmol/l)	**18**	**58,697**	**-0.09* [-0.13, -0.05; 93*]**		**-33.9**	**-21.7**	
Age	18			+*			1.11
≤59 years		15,857	-0.12* [-0.16, -0.07]				
60-69 years		19,364	-0.09* [-0.13, -0.05]				
≥70 years		23,474	-0.08* [-0.12, -0.03]				
Disease duration	14			-			1.05
≤2 years		16,756	-0.14* [-0.19, -0.08]				
3-5 years		10,607	-0.08* [-0.12, -0.03]				
≥5 years		15,857	-0.06* [-0.10, -0.01]				
First-year LDL	18			-*			1.02
<2.5		29,311	0.15* [0.12, 0.18]				
2.5-3.5		19,984	-0.17* [-0.20, -0.14]				
>3.5		9402	-0.72* [-0.77, -0.67]				
Comorbidity	16			-*			1.04
No		39,721	-0.10* [-0.14, -0.06]				
Yes		7994	-0.08* [-0.15, -0.01]				
Smoking	17			-			1.03
No/previously		38,294	-0.09* [-0.13, -0.04]				
Yes		7762	-0.11* [-0.15, -0.06]				

NOTE: LDL indicates low-density lipoprotein; CI, confidence interval; RC, regression coefficient; VIF, variance inflation factor; *Statistically significant ($p<0.05$); +=positive; -=negative

Table 6: Effect of patient characteristics on changes in SBP between first- and second-year measurements

	Groups, n	Patients, n	Mean difference [95% CI; I^2]	RC	Change in τ^2, %	Change in σ^2, %	VIF
SBP (mmHg)	**18**	**73,437**	**-0.95* [-1.25, -0.64; 57*]**		**74.8**	**-29.9**	
Age	18			+*			1.15
≤59 years		20,139	-0.57* [-0.92, -0.23]				
60-69 years		23,689	-1.00* [-1.38, -0.62]				
≥70 years		29,605	-1.34* [-1.72, -0.96]				
Disease duration	14			+			1.04
≤2 years		21,673	-1.04* [-1.47, -0.62]				
3-5 years		13,117	-0.55* [-0.97, -0.13]				
≥5 years		19,645	-1.22* [-1.61, -0.84]				
First-year SBP	18			-*			1.04
≤140		42,784	4.59* [4.21, 4.97]				
>140		30,653	-8.91* [-9.67, -8.16]				
Comorbidity	16			-*			1.04
No		50,780	-0.93* [-1.29, -0.58]				
Yes		9788	-1.25* [-1.75, -0.75]				
Smoking	17			-			1.04
No/previously		46,908	-0.90* [-1.24, -0.56]				
Yes		10,504	-1.07* [-1.54, -0.59]				

NOTE: SBP indicates systolic blood pressure; CI, confidence interval; RC, regression coefficient; VIF, variance inflation factor; *Statistically significant ($p<0.05$); +=positive; -=negative

Combining variation in processes and patients

Meta-regression identified 1 significant interaction between care processes and patients that was consistent across all included outcomes (Table 7). This interaction indicates that the poorer a patient's initial values were, the more beneficial frequent measurement of that particular clinical outcome was in terms of achieving improvements.

Table 7: Interactions between measurement frequency and first-year clinical values, and effects of the diabetes DMPs on HbA1c, LDL and SBP

	Groups, n	Patients, n	Coefficient	Change in τ^2, %	Change in σ^2, %
HbA1c, mmol/mol	**14**	**48,235**		**-11.2**	**-19.2**
Intercept			13.2497*		
Measurement frequency			1.5295*		
First-year HbA1c			-0.2743*		
Measurement frequency X First-year HbA1c			-0.02614*		
LDL, mmol/l	**14**	**36,202**		**-62.2**	**-21.2**
Intercept			0.6997*		
Measurement frequency			0.1095*		
First-year LDL			-0.3024*		
Measurement frequency X First-year LDL			-0.05091*		
SBP, mmHg	**14**	**47,588**		**69.8**	**-23.0**
Intercept			63.5490*		
Measurement frequency			1.8236*		
First-year SBP			-0.4683*		
Measurement frequency X First-year SBP			-0.01115*		

NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; *Statistically significant ($p<0.05$)

DISCUSSION

As far as we are aware, this study is one of the largest to date (N=105,056) that analysed the effects of population-based disease management on the intermediate outcomes of diabetes care. In terms of the Chronic Care Model[1,4], the DMPs for diabetes in the Netherlands can be considered a 'light' form of practice redesign, focusing primarily on improvements in 2 areas: decision support and the delivery system design. During the 12-month evaluation of the bundled payment system, Dutch providers indeed reported improved evidence-based practice and coordination of care based on the guiding principles of the diabetes care standard.[15-17] Thus far, self-management support is not part of most contracts and, as such, is less of a target point for improvement efforts. While contracts do include record-keeping obligations and the diabetes care standard emphasises the importance of adequate data exchange, clinical information systems also remain underdeveloped.[15]

Based solely on the undifferentiated mean changes in clinical values shown by our meta-analysis – which differ from a simple paired t-test to the extent that

they are pooled and weighted per care group – one would conclude that the Dutch DMPs have little impact on the health of patients suffering from type 2 diabetes. However, one of the strengths of multilevel meta-analysis and meta-regression of individual patient data is that these methods allow for the investigation of subgroups of patients for whom certain care processes might be more or less effective. Most notably, the stratified results suggest that the DMPs are considerably more beneficial for patients with poorly controlled diabetes than for those within the target range of important clinical indicators. A recent meta-analysis of the international literature conducted by Pimouguet et al.[21] supports this finding, which – given that the vast majority of patients included in our research had good first-year values for HbA1c, LDL, and SBP – provides a plausible explanation for the small average effects of the diabetes DMPs. Contrary to what is often assumed, the patients benefiting most from disease management in our study were not those recently diagnosed with diabetes, but rather patients with a longer-than-average disease duration. Stratified analyses for HbA1c showed that in patients with controlled diabetes (HbA1c≤53 mmol/mol), whose clinical values leave limited room for further improvement, the DMPs implemented in the Netherlands successfully maintained HbA1c levels within target range, thereby preventing the severe complications associated with deteriorating glycaemic control.[32,38] Although the interactions between the effects of the DMPs and patient characteristics other than first-year health status were far less conclusive, the existing heterogeneity in results was reduced considerably after simultaneously correcting for patient features. Characteristics not included in our study (e.g. level of education, socioeconomic status) may be equally important and informative, given their influence on people's health care behaviours.[39]

The rising prevalence of long-term conditions strains the human and financial capital of current health care systems in many countries and urges cost-effective solutions.[40,41] Our study was based on the assumption that evaluations of DMPs should take into account the heterogeneous nature of care processes and patients (something that randomised controlled trials have thus far failed to do[9,19,21]) because this information can help health care professionals and policymakers to achieve such solutions. In its current form, the Dutch bundled payment system appears to motivate care providers to deliver highly standardised diabetes care based on performance indicators monitored by health insurers.[15] Among other things, these indicators prescribe a defined intensity of service delivery and target values for clinical measures. Our findings support a move toward a more tailored approach to disease management, in which the characteristics of patients directly determine care processes. Frequent monitoring was shown to be especially useful for improving clinical values in patients with poorly controlled diabetes. For those in relatively good health, perhaps as a result of having previously been monitored intensively, a less physician-guided form of care that emphasises self-management might be

equally effective – and probably less costly – for maintaining glycaemic control. Multiple studies have shown that self-management support programmes can improve patients' health behaviours and clinical and social outcomes, and reduce medical costs.[42,43] Further research is necessary to assess whether intensive, physician-guided disease management might indeed be redundant for relatively healthy subgroups of diabetes patients and could be replaced by adequate self-management support.

Tailoring care provision for diabetes requires improvements in the clinical information systems used to register data in the daily practice of health care, as valid and reliable information concerning the patient under treatment must guide decisions on care content and dose. Despite record-keeping obligations, missing values were ubiquitous in the data sets gathered from our care groups. Tailored disease management further necessitates broad implementation of effective strategies for self-management support (which should reach beyond the boundaries of the health care system) to provide patients with the knowledge, skills, resources, and confidence to care for their illness(es).[1,44,45] Most importantly, however, the financial incentives embedded in funding systems should motivate providers to deliver high-quality care rather than to achieve overly standardised levels of service delivery, as appears to be the case with the Dutch bundled payment system. Health care professionals cannot be expected to work in a patient-centered – or for that matter, efficient – manner if they are reimbursed on the basis of performance indicators stipulating, for instance, that patients should be seen at least 4 times per year, regardless of their care needs or self-management skills.

Future evaluations of disease management should utilise longitudinal data in order to improve insights into the long-term impact on patients' health. In line with previous research[21,46], our findings suggest that studies conducted over shorter periods of time might overestimate effects, as length of follow-up is negatively related to health outcomes. Coming to strong conclusions regarding how we can best treat patients who have 1 or more chronic diseases requires more population-based research. Randomised controlled trials, generally perceived as the gold standard for evaluating health care interventions, not only are difficult to apply to analyses of complex DMPs but also produce results that are difficult to generalise to the larger and inherently more heterogeneous populations of chronically ill patients.[47] Future studies should take into account the variation in both patients and interventions, and focus on gaining differentiated insights into the modes of care provision that are most effective for treating specific subgroups of chronically ill patients such as those suffering from severe multimorbidity.

Most of the limitations of this study relate to the choice to collect data in a retrospective fashion. Of the 18 included care groups, no more than 2 were able to provide data on all of the requested process and patient characteristics, and intermediate outcomes. As a result, few analyses of the interactions between

these variables could be conducted on the basis of data from all groups. Within care groups, we had to exclude considerable numbers of patients lacking valid registrations of included characteristics or outcomes. Nonetheless, our population did not differ from other diabetes populations studied in the Netherlands in terms of average age or disease duration, or from the overall Dutch population with respect to percentage of smokers.[15,48,49] The prevalence of co-occurring conditions was considerably lower in our research group than in the total cohort of Dutch diabetes patients[50], which likely signifies registration problems. Gathering data retrospectively also limited our choice of effect measures to the included set of intermediate clinical outcomes; more patient-centered indicators (e.g. health-related quality of life, self-efficacy, patient satisfaction) were not available. Furthermore, we were not able to stratify patients based on information about their GP (practice) or their use of services offered by other professionals, even though variation on the provider level likely causes heterogeneity in effects. Finally, the recent implementation of the diabetes DMPs in the Netherlands did not allow for analyses of time series, nor were we able to assess changes in the processes of diabetes care as a consequence of the implementation of these programmes.

Strengths of our study include the large sample size, the setting in daily health care practice, an adequate length of follow-up, and the analytic methods used for evaluation, which allowed us to determine the differential effects of disease management for diabetes across different care processes and patients.

ACKNOWLEDGMENTS

This study was conducted with support from the DISMEVAL consortium (in particular Dr. Ellen Nolte and Dr. John Adams) and based in part on care group data collected by Dr. Caroline Baan and Dr. Jeroen Struijs of the Dutch National Institute for Public Health and the Environment (RIVM). Data were also made available by nine Dutch care groups not involved with the RIVM evaluation: Coöperatie Zorgcirkels Woerden, Groninger Huisartsen Coöperatie, Huisartsenzorg Drenthe Medische Eerstelijns Ketenzorg, Regionale Huisartsenzorg Maastricht/Heuvelland, Eerstelijns Centrum Tiel, Zorggroep Zwolle, Diabetes Zorgsysteem West-Friesland, Cohesie Cure & Care, Huisartsenketenzorg Arnhem. For the Groninger Huisartsen Coöperatie, data were obtained from the Groningen Initiative to Analyse Type 2 Diabetes Treatment (GIANTT) database, which contains anonymised information retrieved from electronic medical records of general practitioners and is maintained by the University Medical Center Groningen.[51]

REFERENCES

1. Wagner E. Chronic disease management: what will it take to improve care for chronic illness? *Effective Clinical Practice*, 1998;1(1):2-4.
2. Bodenheimer T, Grumbach K. *Improving primary care: strategies and tools for a better practice*. New York, NY: McGraw-Hill; 2007.
3. Coleman K, Mattke S, Perrault PJ, Wagner EH. Untangling practice redesign from disease management: how do we best care for the chronically ill? *Annual Review of Public Health*, 2009;30:385-408.
4. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs*, 2001;20(6):64-78.
5. Bourbeau J, van der Palen J. Promoting effective self-management programmes to improve COPD. *European Respiratory Journal*, 2009;33(3):461-463.
6. Stange KC. The problem of fragmentation and the need for integrative solutions. *Annals of Family Medicine*, 2009;7(2):100-103.
7. Greβ S, Baan CA, Calnan M, Dedeu T, Groenewegen P, Howson H, Maroy L, Nolte E, Redaèlli M, Saarelma O, Schmacke N, Schumacher K, Van Lente EJ, Vrijhoef B. Co-ordination and management of chronic conditions in Europe: the role of primary care. Position paper of the European Forum for Primary Care. *Quality in Primary Care*, 2009;17(1):75-86.
8. Nolte E, Knai C, McKee M (eds). *Managing chronic conditions. Experience in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008.
9. Berthold HK, Bestehorn KP, Jannowitz C, Krone W, Gouni-Berthold I. Disease management programs in type 2 diabetes: quality of care. *American Journal of Managed Care*, 2011;17(6):393-403.
10. Vrijhoef HJ, Spreeuwenberg C, Eijkelberg IM, Wolffenbuttel BH, Van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *British Medical Journal*, 2001;323(7319):983-985.
11. Klein Lankhorst E, Spreeuwenberg C. *The Netherlands.* In: Nolte E, Knai C, McKee M (eds). *Managing chronic conditions. Experience in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008:97-114.
12. Knottnerus JA, ten Velden GHM. Dutch doctors and their patients: effects of health care reform in the Netherlands. *New England Journal of Medicine*, 2007;357(24):2424-26.
13. Seddon N. Is the future Dutch? *Lancet,* 2008;372(9633):103-104.
14. Westert GP, Burgers JS, Verkleij H. The Netherlands: regulated competition behind the dykes? *British Medical Journal*, 2009;339:839-842.
15. Struijs JN, Van Til JT, Baan CA. *Experimenting with a bundled payment system for diabetes care in the Netherlands: the first tangible effects*. Bilthoven: National Institute for Public Health and the Environment (RIVM); 2009.
16. Struijs JN, Baan CA. Integrating care through bundled payments: lessons from the Netherlands. *New England Journal of Medicine*, 2011;364(11):990-991.
17. De Bakker DH, Struijs JN, Baan CB, Raams J, De Wildt J, Vrijhoef HJM, Schut FT. Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. *Health Affairs*, 2012;31(2):426-433.
18. Van Til JT, De Wildt J, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
19. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK. Effects of quality improvement strategies for type 2 diabetes: a meta-regression analysis. *Journal of the American Medical Association,* 2006;296(4):427-40.
20. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care*, 2007;13(12):670-676.

21. Pimouguet C, Le Goff M, Thiébaut R, Dartigues JF, Helmer C. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Canadian Medical Association Journal*, 2011;183(2):E115-E127.
22. Montori VM, Grace Wang Y, Alonso-Coello P, Bhagra S. Systematic evaluation of the quality of randomized controlled trials in diabetes. *Diabetes Care,* 2006;29(8):1833-1838.
23. Conklin A, Nolte E. *Disease management evaluation: a comprehensive review of current state of the art*. Cambridge: RAND Europe; 2010.
24. Tsiachristas A, Hipple-Walters B, Lemmens KM, Nieboer AP, Rutten-Van Mölken MP. Towards integrated care for chronic conditions: Dutch policy developments to overcome the (financial) barriers. *Health Policy,* 2011;101(2):122-132.
25. Netherlands Diabetes Federation. *NDF care standard: transparency and quality of diabetes care for people with type 2 diabetes*. Amersfoort: Netherlands Diabetes Federation; 2007.
26. Riley RD, Lambert PC, Abo-Zaid G. Meta-analysis of individual participant data: rationale, conduct, and reporting. *British Medical Journal*, 2010;340:c221.
27. Stewart LA, Tierney JF, Clarke M. *Reviews of individual patient data*. In: Higgins JPT, Green S (eds). *Cochrane handbook for systematic reviews of interventions*. Version 5.1.0 (updated March 2011). The Cochrane Collaboration; 2011.
28. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Controlled Clinical Trials*, 1986;7(3):177-188.
29. Lipsey MW, Wilson DB. *Practical meta-analysis. Applied social research methods series. Vol 49.* Thousand Oaks, CA: Sage; 2001.
30. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *British Medical Journal*, 2003;327(7414):557-560.
31. Martin BC, Warram JH, Krolewski AS, Bergman RN, Soeldner JS, Kahn CR. Role of glucose and insulin resistance in development of type 2 diabetes mellitus. *Lancet,* 1992;340(8825):925-929.
32. Almdal T, Scharling H, Jensen JS, Vestergaard H. The independent effect of type 2 diabetes mellitus on ischemic heart disease, stroke, and death. *Archives of Internal Medicine*, 2004;164(13):1422-1426.
33. Tesfaye S, Stevens LK, Stephenson JM, Fuller JH, Plater M, Ionescu-Tirgoviste C, Number A, Pozza G, Ward JD. Prevalence of diabetic peripheral neuropathy and its relation to glycaemic control and potential risk factors: the EURODIAB IDDM Complications Study. *Diabetologia*, 1996;39(11):1377-1384.
34. Thompson SG, Higgins JP. How should meta-regression analyses be undertaken and interpreted? *Statistics in Medicine*, 2002;21(11):1559-1573.
35. Thompson SG, Higgins JP. Treating individuals 4: can meta-analysis help target interventions at individuals most likely to benefit? *Lancet,* 2005;365(9456):341-346.
36. Berthold MR, Lenz HJ, Bradley E, Kruse R, Borgelt C (eds). *Advances in intelligent data analysis V. 5th International Symposium on Intelligent Data Analysis IDA 2003, Berlin, Germany, August 2003. Proceedings.* Berlin: Springer-Verlag; 2003.
37. Kennedy P. *A guide to econometrics*. Cambridge, MA: MIT Press; 1992.
38. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *British Medical Journal*, 2000;321(7258): 405-412.
39. Pincus T, Esther R, DeWalt DA, Callahan LF. Social conditions and self-management are more powerful determinants of health than access to care. *Annals of Internal Medicine*, 1998;129(5):406-411.
40. Østbye T, Yarnall KS, Krause KM, Pollak KI, Gradison M, Michener JL. Is there time for management of patients with chronic diseases in primary care? *Annals of Family Medicine*, 2005;3(3):209-214.
41. Borger C, Smith S, Truffer C, Keehan S, Sisko A, Poisal J, Clemens MK. Health spending projections through 2015: changes on the horizon. *Health Affairs*, 2006;25(2):w61-w73.

42. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. *Effective Clinical Practice*, 2001;4(6):256-262.
43. Kennedy A, Reeves D, Bower P, Lee V, Middleton E, Richardson G, Gardner C, Gately C, Rogers A. The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial. *Journal of Epidemiology and Community Health*, 2007;61(3):254-261.
44. Ham C. The ten characteristics of the high-performing chronic care system. *Health Economics, Policy and Law*, 2010;5(pt 1):71-90.
45. Barr VJ, Robinson S, Marin-Link B, Underhill L, Dotts A, Ravensdale D, Salivaras S. The expanded Chronic Care Model: an integration of concepts and strategies from population health promotion and the Chronic Care Model. *Hospital Quarterly*, 2003;7(1):73-82.
46. Linden A, Adler-Milstein J. Medicare disease management in policy context. *Health Care Financial Review,* 2008;29(3):1-11.
47. Linden A, Adams JL, Roberts N. Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design. *Journal of Evaluation in Clinical Practice,* 2006;12(2):124-131.
48. Limperg K. *Rookprevalentie 2004-2008. Continu onderzoek rookgewoonten*. Amsterdam: TNS NIPO; 2009.
49. Lutgers HL, Gerrits EG, Sluiter WJ, Ubink-Veltmaat LJ, Landman GWD, Links TP, Gans ROB, Smit AJ, Bilo HJG. Life expectancy in a large cohort of type 2 diabetes patients treated in primary care (ZODIAC-10). *PLoS One*, 2009;4(8):e6817.
50. Van Leest LATM, Koek HL, Van Trijp MJCA, Baan CA, Jacobs MAM, Bots ML, Verschuren WMM. *Diabetes mellitus*. In: Van Leest LATM, Koek HL, Van Trijp MJCA, Van Dis SJ, Peters RJG, Bots ML, Verschuren WMM (eds). *Hart- en vaatziekten in Nederland 2005, cijfers over risicofactoren, ziekte, behandeling en sterfte*. Den Haag: Nederlandse Hartstichting; 2005:33-59.
51. Voorham J, Denig P. Computerized extraction of information on the quality of diabetes care from free text in electronic medical patient records of general practitioners. *Journal of the American Medical Informatics Association*, 2007;14(3):349-354.

Appendix 1: Cut-off points for data cleaning

Indicator	Lower	Upper	Excluded, n	Excluded, %
Glycated haemoglobin (HbA1c, mmol/mol)	18	108	913	0.5
Low-density lipoprotein (LDL, mmol/l)	1	7.3	2110	1.3
Systolic blood pressure (SBP, mmHg)	70	250	25	0.01
Body Mass Index (BMI, kg/m^2)	16	70	123	0.08

Chapter 6

Is Europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches

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Submitted for publication

ABSTRACT

Background: Self-management support is a key component of effective chronic care management, yet in practice appears to be the least implemented and most challenging. This study explores whether and how self-management support is integrated into chronic care approaches in 13 European countries. In addition, it investigates the level of and barriers to implementation of support strategies in health care practice.

Methods: We conducted a review among the 13 participating countries, based on a common data template informed by the Chronic Care Model. Key informants presented a sample of representative chronic care approaches and related self-management support strategies. The cross-country review was complemented by a Dutch case study of health professionals' views on the implementation of self-management support in practice.

Results: Self-management support for chronically ill patients remains relatively underdeveloped in Europe. Similarities between countries exist mostly in involved providers (nurses) and settings (primary care). Differences prevail in mode and format of support, and materials used. Support activities focus primarily on patients' medical and behavioural management, and less on emotional management. According to Dutch providers, self-management support is not (yet) an integral part of daily practice; implementation is hampered by barriers related to, among others, funding, information technology, and medical culture.

Conclusions: Although collaborative care for chronic conditions is becoming more important in European health systems, adequate self-management support for patients with chronic disease is far from accomplished in most countries. There is a need for better understanding of how we can encourage both patients and health care providers to engage in productive interactions in daily chronic care practice, which can improve health and social outcomes.

INTRODUCTION

The rising incidence and prevalence of chronic conditions – especially cardiovascular disease, cancer, chronic respiratory illness, and diabetes – pose a threat to the long-term sustainability of health care delivery systems worldwide.[1,2] In many countries, the direct medical costs of managing chronic disease, and in particular multimorbidity, already take up a disproportionate share of the national health care budget.[3-5] Conversely, the quality of services provided to patients has remained largely suboptimal, with consequences for disease control and patient experience.[6,7]

In response, a wide range of innovative care concepts has been developed and implemented in many OECD countries.[8,9] One influential framework to conceptualise chronic care has been the Chronic Care Model (CCM).[10,11] Conceived as an 'evidence-based guide to comprehensive health care system redesign'[12], it proposes six components to be core to providing high-quality, patient-centered chronic care: community resources and policies; the health care system; self-management support; delivery system design; clinical information systems; and decision support.[10]

While the CCM recognises the importance of interrelated change in multiple areas of care to better meet the needs of the chronically ill, self-management support has been identified as a key component of the framework.[13] Chronic illness confronts patients with a spectrum of needs that requires them to alter their behaviour and engage in activities that promote physical and psychological well-being, which often have a more direct impact on disease control than the actions of health professionals.[14,15] Evidence across multiple conditions suggests that effective self-management support can improve persons' self-efficacy, i.e. their belief in their own ability to accomplish specific goals[16], and health-related behaviours, which, in turn, may impact their health and/or functional status.[17-21] Yet, in practice, approaches to self-management support appear to be the least implemented and most challenging area of chronic care management.[22] This is in part because self-management support will have to be targeted to meet individual needs, with consequent demands on providers' time and resources in practice. Moreover, to help patients improve their self-efficacy requires communication skills and psychological counselling techniques which have not traditionally been part of most medical professionals' training.[23,24]

In this study, we review whether and how self-management support is integrated with existing approaches to chronic care management in 13 European countries, and the extent to which these approaches provide patients with the knowledge, skills, and confidence to effectively manage their condition. Nested within this review, we examine one country, the Netherlands, in more detail, assessing the level of and barriers to implementation of self-management support in current health care practice from the perspective of care professionals.

Defining self-management support

Self-care and self-management are two distinct concepts that are often used interchangeably.[25] While self-care has been defined by the World Health Organisation (WHO) as 'the activities that individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health'[26], self-management tends to refer to the active participation of patients in their treatment.[27] According to Corbin and Strauss[28], self-management concentrates on three distinct sets of activities: (1) medical management, which refers to tasks such as taking medication and adhering to dietary advice; (2) behavioural management, that is, learning new meaningful roles in the context of a specific condition; and (3) emotional management, which refers to dealing with the feelings of frustration, fright, and despair that are often experienced by chronically ill individuals. Self-management support is generally understood to target all three sets of tasks set out by the Corbin and Strauss framework. The CCM proposes that 'by using a collaborative approach, providers and patients work together to identify problems, set priorities, establish goals, create treatment plans and solve issues along the way'.[29] To facilitate patients to play such an active role in their care, patient education is usually a key part of self-management support.[30] Standardised interventions to support patients' self-management furthermore may combine services available within health care (e.g. dietary advice, collaborative care planning) with services in the broader community (e.g. exercise programmes, peer support).[10,31]

METHODS

Data template

This paper builds on work carried out within the DISMEVAL (Developing and Validating Disease Management Evaluation Methods for European Health Care Systems) project, a European collaborative project that aimed to identify 'best practices' in the area of disease management evaluation.[32] As part of DISMEVAL, a common template was developed for the collection of qualitative data on approaches to chronic care management in Europe. Template development was based on a structured questionnaire used in a previous study and informed, to great extent, by the CCM.[8] Thus, the template sought to gather information on: (1) the health system and policy context; and (2) the type and format of approaches to managing chronic disease, examining the nature and scope of the components identified by the CCM as crucial to effective chronic care management. The template was paper-based, written in English, and used simple checkboxes as well as open-ended questions. Where appropriate and relevant,

sections included a glossary of definitions of terms and guidance for completion by means of examples and checklists. A shortened copy of the data collection template can be found elsewhere.[32] This paper reports the findings across countries pertaining to the CCM-component self-management support.

Key informants

Data collection using the finalised template was undertaken by key informants in 13 countries, which were selected to capture the range of approaches to funding and governing health care, different levels of economic development, and geographical spread across Europe. We thus included: Austria, Denmark, England, Estonia, France, Germany, Hungary, Italy, Latvia, Lithuania, the Netherlands, Spain and Switzerland. Of these 13 countries, seven were represented by DISMEVAL project partners (Austria, Denmark, England, France, Germany, the Netherlands, and Spain) who were invited to complete the template. DISMEVAL project partners included two to four expert health service researchers per country. For countries not represented in DISMEVAL, key informants were identified from an established network of country experts in eight European countries (the International Healthcare Comparisons Network).[33] Informants thus identified had to demonstrate expertise in the area of chronic disease and/or an understanding of the health policy and system context of the country in question as shown by relevant publications in the academic literature and/or roles in relevant government advisory bodies. One to four researchers and/or policymakers per country, who fulfilled these criteria, were selected as key informants for Estonia, Hungary, Italy, Latvia, Lithuania, and Switzerland (see Acknowledgments).

Data collection

In completing the template, informants were asked to adopt an evidence-based, comprehensive approach, by making use of the best data available and cooperating with organisations involved in the management of chronic disease. Where appropriate and necessary, additional information was gathered through interviews with key stakeholders and reviews of work in progress, such as pilot projects and committee reports. As it was beyond the scope of DISMEVAL to provide a complete inventory of all chronic care management approaches being implemented in the included countries, key informants were asked to present a sample of approaches considered representative of a given health system in terms of the type and setting of delivery model, providers involved, key strategies employed, and population covered. For each approach, respondents described whether and how self-management support activities were implemented according to the CCM-related Assessment of Chronic Illness Care (ACIC) survey[34]; that is, patient education, collaborative care planning, provision of

self-management tools, and structured follow-up. Principal data collection was carried out from June 2009 to December 2009, with sequential follow-up review untill July 2011 to complete missing data and clarify information.

Case study

Template completion in the 13 countries was complemented by a case study of the Dutch DISMEVAL partner, which aimed to assess health professionals' perspectives of the level of and barriers to implementation of self-management support activities in daily practice. Interviews were undertaken with a purposeful sample of 27 providers involved in disease management for type 2 diabetes in the Netherlands, using an ACIC-informed semi-structured interview guide.[32] Respondents represented an equal number of professionals from three different health care disciplines (i.e. managers, general practitioners (GPs), and nurses) and were selected from diverse care settings in terms of geographical location and practice size. The interviews were conducted mostly face-to-face, with five undertaken by telephone, by one member of the Dutch research team (AE) between February and June 2011. All interviews were audio recorded and transcribed.

Data analysis

We used a general inductive approach to data analysis, in which emerging themes related to self-management support were identified through examination of the completed data template containing evidence from 13 countries. The data were analysed in detail by the lead author (AE) to identify key themes, which were discussed with and agreed by all coauthors. In total, three categories of themes were distinguished: (1) support mode and content ('what'); (2) support format and materials ('how'); and (3) support providers and locations ('who and where'). Data were then organised into a purposely built matrix comprising the three emerged categories of themes, which facilitated systematic cross-country comparison of self-management support approaches in the 13 countries. For consistency, the same matrix was used to process and analyse the transcripts of the Dutch interviews concerning the implementation of self-management support in practice.

RESULTS

An overview of self-management support in 13 countries

Table 1 provides an overview of approaches to chronic disease management or their equivalent in the 13 countries reviewed here. Keeping in mind that the

overview is based on a sample of approaches considered representative of a given country context, the findings suggest that many countries have implemented a range of frequently small-scale chronic care management programmes at the local or regional level. In some cases, these have been conceptualised as pilot studies for subsequent roll-out to larger areas, while there are also examples of approaches that aim to target the entire population, in particular where these have been embedded within the existing primary care system. The majority of chronic care approaches in Europe as reviewed here involves some form of patient self-management support (see Table 1), although there are considerable differences in terms of: (1) mode and content ('what'); (2) format and materials ('how'); and (3) providers and locations ('who and where').

Support mode and content

Most chronic care approaches reviewed here involve education for self-management, frequently in the form of group-based exercises and/or one-to-one activities. For example, within the Austrian disease management programme 'Therapie Aktiv', nine hours of patient education including self-management training are offered in four modules with a group size of three to 12 patients. The German disease management programmes, which were introduced between 2003 and 2006 for six conditions (breast cancer, type 1 and 2 diabetes, coronary heart disease, asthma and chronic obstructive pulmonary disease), offer self-management support activities for each disease. Here too, self-management training is usually undertaken in groups, although individual support is an option.

With regard to content, the education offered within the reviewed support approaches tends to focus on three broad topics: (1) information about the disease; (2) information about healthy behaviour (e.g. physical training sessions, nutritional consultation sessions, and smoking cessation programmes); and (3) practical instructions concerning, for instance, blood glucose monitoring, foot examination, or insulin injection.

Respondents from 10 countries – except Latvia, Lithuania and Spain – reported that patients are involved in setting care goals and developing individual treatment plans (i.e. collaborative care planning). Patients' needs, activities, problems and accomplishments are regularly assessed by means of structured follow-up in all countries except for Latvia, where self-management support appears relatively most underdeveloped. Within the German disease management programmes, individual treatment goals (concerning, for example, blood pressure, weight and exercise) are discussed between patients and their doctors during regular three to six-monthly follow-up consultations. French patients enrolled in provider networks have a 'personal care plan', which is set up jointly with their physician and contains treatment goals as well as concrete care measures.

Table 1: Overview of approaches to chronic disease management or their equivalent in 13 European countries

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Austria						
Ambulatory aftercare of stroke patients, Salzburg	1989	To facilitate access to specialised ambulatory care for stroke patients and enable timely rehabilitation and reduce costs through early discharge	Stroke	Team of therapists (neurorehabilitation team) (Working group for Preventive Medicine, Salzburg, AVOS)	Service principally accessible to all stroke patients across Land Salzburg; lack of therapists in remote areas reduces access	Access to team of occupational therapists, speech therapists and physiotherapists in one-to-one and group settings; social activities; information through events
Care coordination/ Interface management, Styria	2002/03 (pilot)	To improve the continuity of care following discharge from hospital using a care coordinator	Patients in hospital	Care coordinator at the regional SHI fund	Introduced as pilot project in one locality, the approach was gradually extended across Styria; Graz model to be transferred into usual care	Involvement of patients and their carers in discharge planning and subsequent care arrangements including information and practical assistance such as arrangement of devices and services
KardioMobil Home care for patients with chronic heart failure	2004 (pilot)	To support patients with chronic heart failure to enhance disease/self-management, reduce hospital admissions and complications, improve quality of life	Chronic heart failure	Trained nurse (AVOS)	Programme comprises five trained nurses operating across Land Salzburg	Education about the disease, instruction in self-monitoring, and in handling emergency situations by trained nurse; follow-up assessment of patient self-management competences and needs
Integrated stroke care, Upper Austria	2005	To improve care for patients with stroke both in relation to acute care and at the interface to rehabilitation	Stroke	General practitioner, Regional SHI fund	Implemented across Upper Austria and involving all hospitals that provide acute stroke care, medical emergency services and 3 rehabilitation centres	Information (stroke awareness campaigns, brochures distributed in GP practices and hospitals, dedicated website, targeted lectures)

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
'Therapie Aktiv' diabetes disease management programme	2006	To improve the quality of life and prolong life for people with chronic disease, to place patients at the centre of care, reduce hospitalisations	Type 2 diabetes	DMP physician (general practitioner /family physician)	Implemented in 6 of 9 states; 1 state operates separate programmes, one of which is to be integrated into 'Therapie Aktiv'	Education through group instruction; involvement in goal setting and timelines, with agreed targets signed jointly; regular follow-up
Denmark						
SIKS project – Integrated effort for people living with chronic disease	2005	To support people with chronic conditions through coordinated rehabilitation	Type 2 diabetes, asthma/COPD, chronic heart failure, IHD, balance problems	Multidisciplinary team at health care centre / hospital (determined by severity of condition)	Initially implemented in Østerbro health care centre and Bispebjerg hospital in Copenhagen for period of three years, subsequent transfer into usual care; elements of the programme taken up by Copenhagen City and hospitals	Education and regular documentation of self-management needs and activities; involvement in developing individualised treatment plans and goal setting; access to physical exercise intervention; information
Regional disease management programmes	Ongoing	An interdisciplinary, intersectoral and coordinated effort using evidence-based recommendations and coordination of and communication between all parties	Type 2 diabetes, COPD (in preparation: CVD, dementia, musculoskeletal disorder)	DMP General practitioner	Early stage; DMPs for COPD and type 2 diabetes implemented in Capital Region (end 2010); DMPs for other conditions and/or in other regions are planned or being developed	Structured (disease-specific and general) education; information; involvement in developing care treatment plan and goal setting including agreeing timeline and methods for evaluation of goals; regular assessment and follow-up of problems and needs
Integrated clinical pathways	2008 (cancer) 2010 (heart disease)	To ensure fast and optimal treatment and management of patients with heart disease/cancer	Heart disease, cancer	Care ('pathway') coordinator (specialist nurse)	As a national programme, integrated clinical pathways will be implemented across Denmark	Not specified

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
England						
Expert Patients programme (EEP)	2001 (pilot)	To develop the confidence and motivation of patients to use their own skills and knowledge to take effective control over life with a chronic illness	Generalist and disease-specific	Patient/service user	2006 government policy set to increase EEP places to >100,000 by 2012; EEP also available as online classes so in theory accessible to everyone with internet access	Education of patients by lay instructors aimed at strengthening competencies and skills to cope with chronic illness including development of care plans
Case management/ community matron	2004	To enable intensive, home-based case management for older people at risk of hospitalisation and other high-intensity service users	Older people at risk of hospitalisation	Specialist nurse	2004 policy foresaw implementation of case management and appointment of 3,000 community matrons by all PCTs in 2007; there are now between 620 and 1,350 community matrons	Education provided by specialist nurse; involvement in development of care plan and goals; regular assessment and documentation of needs and activities
Partnerships for older people project (POPP)	2005–2010	To provide person-centred and integrated services for older people, encourage investment in care approaches that promote health, wellbeing and independence, to prevent/delay need for higher intensity or institutional care	Older people (>65 years)	Varied: multidisciplinary team (health and social care); social or 'hybrid' worker; volunteer organisation	POPP ran a total of 146 projects involving 522 organisations including the police and housing associations; 85% of projects secured funding beyond the pilot phase into usual care	Varied: involvement of older people in project development, operation and evaluation; peer support, including EEP; staff and volunteers acting as 'navigators' to helping older people through the system; follow-up; expert carer programme

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Integrated care pilot programme	2009–2011	To improve the quality of care and outcomes for patients, to enhance partnerships on care provision and to make more efficient use of scarce resources	Generalist and disease-specific (e.g. diabetes, COPD, dementia)	Varied: GP-led care, multidisciplinary team working, nurse-led case management, skilled key worker-led care coordination	The pilot programme involves 16 primary care trusts	Varied: patient education and provision of self-management tools by senior nurses; training in self-management of medicines
Estonia						
Quality management in primary health care	2003 (completion of GP system)	Chronic disease management as a concept not established but indirectly embedded in the overall structure and organisation of the health care system	Type 2 diabetes, cardiovascular disease (chronic heart failure, IHD)	General practitioner	Quality management framework for diabetes and chronic CVD implemented across Estonia and covering all GP practices	Education provided by GP/family nurse; involvement in development of care plan; regular assessment and follow-up; additional support by home care nurse or social worker where necessary
Chronic disease management at the primary/secondary care interface	Various	Chronic disease management as a concept not established but indirectly embedded in the overall structure and organisation of the health care system	Multiple sclerosis, Parkinson's disease, schizophrenia, COPD	Specialist (centre); comorbidities managed by GP in coordination with specialist	Implemented across Estonia as part of usual care	Education (specialist); involvement in development of care plan; regular assessment and follow-up; mentoring/peer-support through patient associations (e.g. Multiple sclerosis, Parkinson's disease); support at home by nurse or social worker where necessary

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
France						
Health action by teams of self-employed health professionals (ASALEE)	2004–2007	To improve health care quality by delegating selected tasks to nurses	Diabetes, CVD	Trained nurse	ASALEE is a non-profit organisation which, as of 2007, brought together 41 GPs and 8 nurses in 18 GP practices	Education on disease provided by trained nurse
Sophia diabetes care programme	2008	To improve the coordination, efficiency and quality of diabetic care	Type 1 and 2 diabetes	General practitioner, in collaboration with nurse	Experimental phase targeted patients of 6,000 GPs (6.4% of all GPs) in 10 departments; expanded in 2010 to reach 17,500 GPs in 19 departments; aim to roll-out across France by 2013	Advice and information on self-management of disease and health behaviour; facilitating communication with health professionals; access to dedicated programme website
Health networks						
Diabetes networks: REVESDIAB	2001	To improve the quality of care for people with diabetes type 2	Type 2 diabetes	Pathway coordinator: general practitioner or nurse	REVESDIAB is based in 3 departments in the Paris region, involving, in 2007-2008 around 500 health professionals in Essonne department; overall, in 2007, there were 72 diabetes networks, involving 14,000 health professionals	Information and education (e.g. diet); coaching by nurses; involvement in developing treatment plan towards a 'formal' agreement between patient and network; regular assessment and follow-up including patient 'log-book' completed with doctor consulted
Coordination of professional care for the Elderly (COPA)	2006	To better integrate service provision between health and social care; to reduce inappropriate health care use, including ER and hospital utilisation; to	Frail elderly (>65 years)	Specialist nurse as case manager	The network is established in one district of Paris only and in 2007 involved 79 out of 200 primary care physicians practising in the area	Involvement in developing treatment plan and goal setting

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
		prevent long-term nursing home institutionalisation				
Measures in the 2003–2007 Cancer Plan						
Protocol for disease communication and promotion of shared decision-making (Dispositif d'annonce)	2004	To improve the organisation of processes and competencies in discussing a cancer diagnosis, and promoting shared decision-making between professionals, patients and their carers	Cancer	Specialist	As part of the national cancer plan principally rolled out across the country within the timeframe of the 2003-2007 Cancer Plan; by 2006, only half of the funds set aside by regions had been used for this purpose and accessible to all newly diagnosed cancer patients	Access to dedicated time informing about the illness and support; involvement in decision-making; access to psychological and social support; regular assessment of patient needs; follow-up
Multi-disciplinary team meeting (RCP)	2004	To promote the systematic use of multidisciplinary teams in the development of cancer care plans so as to improve the quality of cancer diagnosis, treatment and support	Cancer	'Médecin référent' (frequently surgeon)	As part of the national cancer plan principally rolled out across the country within timeframe of 2003-2007 Cancer Plan and accessible to all newly diagnosed cancer patients	As implemented within Dispositif d'annonce
Regional cancer networks	2004	To coordinate all relevant actors and levels of care in the management of cancer, and to guarantee the quality and equity of care across all regions	Cancer	As in RCP	As part of the national cancer plan rolled out across the country within the timeframe of the 2003-2007 Cancer Plan and accessible to all cancer patients	As implemented within Dispositif d'annonce

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Local cancer or local multi-pathology networks	2004	To facilitate the local management and monitoring of cancer patients through better integration of GPs into networks of cancer care	Cancer	General practitioner	As part of the national cancer plan principally rolled out across the country within the timeframe of the 2003-2007 Cancer Plan and accessible to all cancer patients	As implemented within Dispositif d'annonce
Germany						
Disease management programmes	2003	Organisational approach to medical care that involves the coordinated treatment and care of patients with chronic disease across providers on the basis of scientific and up-to-date evidence	Type 1 and 2 diabetes; IHD (+heart failure), breast cancer, asthma/ COPD	DMP physician	DMPs are offered by SHI funds across Germany; in 2010 there were ~2,000 DMPs for each condition; number of participating physicians varies, ~65% GPs act as DMP physician for type 2 diabetes (57% on IHD)	Education programme in group sessions; involvement in agreeing treatment goals; regular follow-up, with patient reminders for missed sessions; some SHI funds also offer telephone services to further support their members participating in DMPs
GP contracts	2004	To improve the coordination of care and strengthen the role of primary care in the German health system	Generalist (some contracts target over 65s)	General practitioner/ family physician	By the end of 2007, 55 GP contracts had been concluded with GP participation varying among regions	Annual checkups; advice on preventive measures and information; assessment of cardiovascular risk factors ('*arriba*') supports shared decision-making on treatment options

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Medical care centres (MVZ): Polikum Berlin	2004	To provide comprehensive, coordinated and interdisciplinary care	Generalist	Multidisciplinary team	There are ~1,500 MVZ (2010), with a total of 7,500 physicians (>80% as salaried employees [65,000 physicians work in solo practice; 19,500 in group practices]); Polikum employs 45-50 physicians	Education programmes (e.g. weight reduction, stress management, smoking cessation) and practical instruction (e.g. self-monitoring of insulin therapy)
Integrated care: Healthy Kinzigtal	2005	To establish more efficient and organised health care for the residents of the Kinzigtal area	Generalist	Care coordinator (physician / psychotherapist)	By the end of 2008, ~6,400 integrated care contracts had been concluded. However, content and scope varies widely; Healthy Kinzigtal involves 70 providers (2010)	Regular checkups and risk assessments; involvement in development of individual treatment/ prevention plans and goal setting; representation through patient advisory board and a patient ombudsman
Community nurses: Care assistant in family practice (VerAH)	2005	To support GP services in under-served areas	Generalist (typically targeting over 65s)	Practice assistant	Incorporated in selected GP models, see above	Access to trained case managers
Hungary						
Care coordination pilot (CCP)	1998/99–2008	To incentivise providers to take responsibility for the spectrum of services (primary to tertiary care) for an enrolled population in a defined area	Generalist	Care organisation (CCO): (groups of) general practitioners, policlinic or hospital	The CCP gradually expanded from 9 care coordinators in 1999 to 16 care coordinators in 2005 when 1,500 GP practices participated; established in the region of Veresegyház, the CCP was terminated in 2008	Education by specialised nurses; involvement in developing treatment plan and goal setting; access to self-management tools; regular assessment of problems and accomplishments

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Asthma disease management programme	2004	To enhance the quality of asthma care	Asthma	Specialist (asthma) nurse	The programme has evolved into a formal national network of asthma nurses, with around 850 trained asthma nurses across Hungary (2010); the number of pulmonary dispensaries is around 160 (2007)	Patient education on asthma; access to self-monitoring tools; involvement in treatment plan, goal-setting, decisionmaking; regular assessment of problems and accomplishments
Treatment (and financing) protocols	2005 (cancer)	To control costs of treatment such as those for expensive drugs in the case of cancer care	Asthma/ COPD, CVD (heart failure, IHD, stroke), cancer	Varies by disease (e.g. general practitioner for hypertension; specialist for cancer)	As part of the main system, coverage, in principle, is 100%. In practice, the adherence to treatment protocols is rarely audited	Information material on cancer, hypertension and other CVD; self-management support by patient associations and by health care staff pre-discharge for hospitalised patients
Gluco.net	2009	To provide a decision-support tool to guide patients in the monitoring and analysis of their blood sugar levels	Type 1 and 2 diabetes	Internet-based self-management support tool	In principle, available to every patient with diabetes through the internet	Access to web-based software that permits automatic upload of self-monitoring data and feedback
Multifunctional community centres	Ongoing	To improve efficiency in the health care system through better quality of care at lower costs	Generalist	Community centre	Programme implementation is ongoing; it is anticipated that 50–60 centres/ projects will be established	Patient education may be provided
Diabetes care management programme	Various	To improve the care of patients with type 2 diabetes through a range of measures, with nurse-led care at its core	Type 2 diabetes	Diabetes specialist (physician, nurse)	Extent to which programme has been implemented by specialist diabetes outpatient units is not well understood; in 2008, there were 176 specialist diabetes	Education provided by a diabetes nurse; access to self-monitoring devices (glucometer); regular follow-up to routinely assess problems and accomplish-

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
					units, including 41 in Budapest	ments, both in person and by telephone
Italy						
Leonardo Pilot Project, Puglia	2004–2007	To improve the quality and effectiveness of health care for those with chronic conditions and to facilitate systematic integration into the existing organisational framework set by local health agencies	Type 1 and 2 diabetes, chronic heart failure, high cardiovascular risk	Specialist nurse	Total of 85 GPs in Puglia region (~2.5% of GPs practising in the region), working with some 30 care managers	Education based on the 'eight priorities' approach defined by Lorig; systematic assessment of patient needs (in person/ by telephone) and follow-up
Integration, Management and Assistance for diabetes (IGEA)	2006	National strategy to support the implementation of disease management for type 2 diabetes at regional level	Type 2 diabetes	Multidisciplinary team/nurse (case management)	Implementation at regional level has been a gradual process; 35% of GP practices in Piedmont participate (2009); as a government sponsored programme involvement of all GPs anticipated	Structured diabetes education by trained staff (specialists, nurses, GPs); involvement in developing care plan; access to self-management tools; routine assessments of problems and accomplishments
Project Raffaello, Marche and Abruzzi	2007	To assess the effectiveness of an innovative model of patient care for the prevention of cardiovascular disease on the basis of disease and care management in general practice	Types 1 and 2 diabetes, cardiovascular risk	Specialist nurse	The research project involves 16 clusters of GPs participating in the experimental arm of the study	Participation in devising care plan and decision-making; access to coaching and follow-up activities by telephone, doctor's office or patient's home; access to information material on disease, services availability and lifestyle

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
From On-Demand to Proactive Primary Care, Tuscany	2009	A three-year strategy towards the development of a new organisational approach to health care that emphasises proactive patient care	Hypertension, diabetes, chronic heart failure, COPD, stroke	Multiprofessional teams ('module') (general practitioner lead, community health doctor, specialist nurse)	Two stage-implementation: initial phase in 2010 involves establishment of ~50 modules with addition of modules ongoing; project expected to go into fully operational stage in 2011	Education and counselling; instruction in self-monitoring activities; involvement in developing and consent to care plan; regular assessments of problems and needs; support by social workers where needed
Latvia						
General primary health care system	1996/98 (PHC reform)	Not applicable	Generalist	General practitioner	Chronic disease management embedded within primary care involving all GPs	Not specified
Lithuania						
Clinical guidelines	From 2002	To control medication costs; to improve collaboration between primary and secondary care	Diabetes, CVD, breast cancer, chronic renal failure, multiple sclerosis, depression; high-intensity users	General practitioner or specialist (depending on condition)	Clinical guidelines should in principle be implemented across health services in Lithuania; precise data are not available	Routine assessment of clinical indicators
Improving intersectoral collaboration	From 2004	To improve collaboration between health and social care	Generalist and disease-specific (diabetes, CVD, cancer, chronic renal	Nurse	Principally implemented in all 60 municipalities of Lithuania	Routine assessment of problems and accomplishments; access to psychosocial rehabilitation services in some cases (mental health)

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
			failure, multiple sclerosis, depression, HIV/AIDS)			
Netherlands						
Stroke Service Delft	1997 (pilot)	Evolved from pilot project for improving stroke care initiated in 1997 and funded by the Netherlands Institute for Health Research and Development (ZonMw)	Stroke	Shared care nurse	Following the experiences of pilots the government actively promoted further implementation through 'breakthrough projects' and benchmarking of stroke services; as a result, by 2003, each region had developed at least one stroke service (a total of 69 in 2003)	Education adapted to the wishes and needs of the individual patient and his/her carers (verbal or written; communicated in group meetings alternating with individual sessions or through media such as internet or DVD)
Matador disease management programme Maastricht-Heuvelland	2000-2006	Builds on a pilot scheme established in 1996, which used specialised diabetes nurses to reduce the number of patients seen by medical specialists in outpatient care	Type 2 diabetes	Core team of general practitioners, specialist diabetes nurse and endocrinologist	In 2006, a total of 63 of 90 GPs (70%) in the Maastricht region participated in the Matador programme	Access to 'Diabetes Interactive Education Programme' (DIEP), comprising lifestyle intervention training component for providers to engage patients in the development of treatment plan and goals; DIEP website; systematic patient follow-up
Primary care bundle for type 2 diabetes Maastricht-Heuvelland	2007	The primary care bundle for diabetes type 2 describes the whole continuum of care for diabetes	Type 2 diabetes	General practitioner	All regional GPs are members of care group Maastricht-Heuvelland and as such participate in the	Regular checkups that include education on self-management by practice nurses/specialised diabetes

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
		patients and is financed on the basis of the bundled payment system			diabetes care programme (just under 90 GPs by the end of 2009); there were 97 care groups in March 2010 with bundled payment contract with a health insurer, mostly for diabetes care	nurses, depending on the level of need
National care standard for vascular risk management	2010	Describes the minimum requirements for appropriate, patient-centered care along the care continuum from prevention and early detection to treatment and rehabilitation	Vascular risk	Central care giver (determined by programme)	There are relatively few care groups for the provision of vascular risk management; of 55 care groups surveyed in early 2010, two had a bundled payment contract in place for vascular risk management, 17 prepared to contract	Involvement in shared decision-making, development of care plan and goal setting; acquire self-management competencies through 'task-oriented communication'; motivational interviewing; and/or 'emotional-oriented communication'
Spain						
Case management, Andalucía	2002	To improve the quality of life of persons with chronic conditions, reduce the burden placed on carers, provide improved access to social care and rehabilitation services and reduce emergency admissions	Mental health disorders, chronic disease, the over 65s	Nurse case manager	Over a period of four to five years, more than 300 case managers, linked to primary care teams, were deployed to care for seven million residents in Andalucía	Individualised and integral assessment; case managers offer support workshops for the main carers of people included in the programme to provide information on patient care and self-care in the home; all case managers have mobile phones to be reachable to their patients

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Expert Patients Programme, Catalonia	2006	To promote patient self-management; improve quality of life, knowledge, behaviour and lifestyle; involve patients in their care and increase satisfaction	Heart failure, anti-coagulant therapy, and COPD	Patient/service user and primary care team	By 2010, 31 groups of EPP had been developed by 18 primary care teams of the Catalan Health Institute with total of 287 participants (24 as expert patients)	Education of patients by lay instructors aimed at strengthening competencies and skills to cope with chronic illness including development of care plans
Switzerland						
Physician network Delta, Geneva	1992	Physician networks form part of the service structure in ambulatory care; Delta was conceived as an HMO and in 2004 transformed into a physician network	Generalist; DMPs for diabetes, heart failure and asthma under develop-ment	Primary care physicians/ General practitioners	In 2010, the Delta network comprised 160 primary care physicians (10-20% generalists, internists, GPs); in Vaud canton, the network includes 20 physicians	Regular information (two information letters per year), detailing provisions for access to health promotion and disease prevention consultations and activities; website
Diabaide diabetes care network	2004	Developed based on an inventory of the needs of diabetic patients in the region of Nyon-Morges, Canton de Vaud and the creation of a working group of health care stakeholders involved in diabetes care	Type 1 and 2 diabetes	Endocrinologist-diabetologist	Jointly run by the Association Réseau de Soins de la Côte (one of the five care networks operating in the canton of Vaud) and two regional hospitals	Information material; customised face-to-face self-management education and follow-up; regular assessment of problems and needs; involvement in goal setting and developing a treatment plan

Name	Year implemented	Aim/general Description	Target group	Principal coordinator	Distribution	Self-management support
Breast cancer clinical pathway, Lausanne University Hospital and Lausanne University	2008–2009	To improve the quality and efficiency of health care	Breast cancer	Hospital (oncology)	Currently offered by Lausanne University Hospital only but there are plans for it to be extended to other regional hospitals in the canton of Vaud	Written information; regular reassessment of the patient's situation; shared decision-making; support by trained nurses and social workers; possible access to peer support groups

NOTE: Data presented reflect the systems and features in place in the countries concerned as in July 2011. SHI indicates statutory health insurance; DMP, disease management programme; COPD, chronic obstructive pulmonary disease; IHD, ischaemic heart disease; CVD, cardiovascular disease; PCT, primary care team; ER, emergency room; PHC, primary health care; HMO, health maintenance organisation

Support format and materials

Respondents from all but two countries (Latvia and Lithuania) reported the use of support materials to help patients manage their chronic disease. In some programmes, the format of support is limited to written information, such as brochures detailing provisions for access to health promotion and disease prevention services. An example is the Delta Physician Network programme in Geneva, Switzerland. German statutory health insurance (SHI) funds provide disease management patients with information leaflets about their condition in situations where they develop complications, do not comply with treatment and referral guidelines, fail to reach their treatment goals (e.g. target blood pressure), or miss appointments for follow-up and patient training. In most of the reviewed chronic care programmes, such as the Danish SIKS project and the Italian Raffaello project, written information materials complement oral patient education, which offers patients an opportunity to ask questions and discuss problems with health professionals. In Austria, education is also provided through awareness campaigns and targeted lectures for stroke patients within 'Integrated-stroke-care-Upper-Austria' and similar projects in other states.

Respondents from four countries reported that local projects offer patients access to interactive websites, such as 'Gluco.net' in Hungary, 'DIEP.info' in the Netherlands, and comparable initiatives in France and Switzerland. In Andalucía, Spain, a school for patients was developed in 2008 to instruct individuals on the management of their chronic illness. In addition, the region has a 24-hour health service telephone line which patients can contact in case of doubts or questions. Telephone-based support is also provided in projects in Germany, Hungary, and Italy, as well as in the French disease management programme for diabetes (the Sophia project) to provide patients with personalised information on how to manage their disease.

Respondents from three countries reported the use of peer support in specific chronic care programmes. In Switzerland, peer support is part of a regional breast cancer clinical pathway introduced between 2008 and 2009, which is hospital-based and targets adults with breast cancer. In Estonia, peer support is offered through patient associations. Some of the Partnerships for Older People Projects (POPP) in England also offer peer support, for example in the form of broader health and well-being advice from other older people.

Support providers and locations

In all reviewed countries, self-management support is offered by health professionals including physicians and/or, more often, trained nurses. The latter is the case in Austria, Denmark, England, Estonia, France, Germany, Hungary, Italy, the Netherlands, and Switzerland. In England, the 2004 NHS Improvement Plan introduced the concept of the 'community matron', a specialised senior nursing role undertaking intensive home-based case management for elderly people at risk of hospitalisation and other high-intensity care users.

In Denmark, self-management training is provided either in outpatient clinics associated with the hospital, i.e. for patients with severe chronic disease, or in the municipalities for non-complex patients. In Estonia, support can be provided at home by a nurse or social worker. For some conditions, community services, such as the Estonian Parkinson's Association, may be involved in supporting patients by providing information materials, organising lectures, and offering practical training and mentoring. Within the Italian Leonardo project, a care manager, usually a specialist nurse, guides patients in raising their level of self-awareness. Although few of the reviewed approaches to self-management support in the 13 countries use lay expertise, one well-known example is the English Expert Patient Programme, a six-week lay-led educational course for chronically ill patients.

Case study: Dutch health professionals' perspective on the implementation of self-management support in daily practice

Textbox 1 summarises the Dutch approach to structured disease management for chronic conditions and, in particular, the self-management support activities included in that approach.

Textbox 1: Chronic care management and self-management support in the Netherlands

In January 2010, after several years of experiments, a bundled payment system for integrated chronic care provision on the basis of evidence-based care standards for type 2 diabetes care[35], COPD care[36], and vascular risk management[37] was implemented in the Netherlands. Under this system, health insurers pay a single fee to one or more of the approximately 100 regional care groups that are currently in place. Care groups are legal entities in primary care, mostly owned by GPs, which deliver care and/or subcontract (other) providers to deliver services. The insurers' bundled payment contracts cover a complete package of outpatient chronic care services for a specific condition, which is informed by national care standards.[38-40]

Supporting self-management is a key element of the Dutch care standards for integrated chronic care delivery. This is illustrated by the description of the role of patients in managing their disease in the standard for type 2 diabetes care[35]:

"Following diagnosis of type 2 diabetes by the GP, medical history, lifestyle and physical fitness are mapped. Subsequently, an individual risk profile, treatment goals, and a treatment plan are drafted based on guidelines. The treatment plan is discussed with the patient and general target values are translated into individual goals, with the patient's contribution playing a central role. In order to allow the patient to contribute to treatment, an educational course is com-

pleted. The individual treatment plan contains targets for weight, glucose regulation, blood pressure, lipids and kidney function. Moreover, agreements are made regarding lifestyle changes, cardiovascular risk profile, feet, eyes, and kidney function. Check-ups occur at least three-monthly, paying specific attention to complaints, problems, lifestyle changes, weight, glucose regulation, blood pressure and other conditions (un)related to diabetes."

Support mode and content

Our interviews indicate that the Dutch approach to self-management support for chronically ill patients is individual- rather than group-based, and focuses on educating patients about their condition as well as about healthy behaviours and self-monitoring skills. According to respondents, patient education is still very much traditional in the Netherlands, with health professionals deciding what information and skills to teach, rather than allowing patients to identify their problems and providing them with techniques to make decisions and take appropriate actions:

"We ask patients about their lifestyle. We give them advice about their lifestyle. And if that is not enough, we can refer them to a dietician or physical therapist" (Nurse).

Although collaborative care planning is emphasised in the Dutch care standard for type 2 diabetes, none of the interviewed professionals report actually working with individual treatment plans. Insufficient information technology (IT) and counteracting financial arrangements are mentioned as barriers towards more individual care management:

"We're still very much in the development phase, searching for ways to support patients' self-management. It's not an integral part of the care process yet, nor has it been implemented in protocols or IT" (GP).

"The current financing system focuses on measurable results and, in so doing, hampers self-management. GPs tell patients: 'you have to visit four times a year, whether you need it or not'. That completely opposes any form of self-management" (Manager).

The latter comment illustrates the reports of the vast majority of professionals that there is structured follow-up of patients, which is motivated by reimbursement of care professionals on the basis of performance indicators stipulating, among others, that patients should be seen in general practice at least four times per year. Some respondents believe such 'far-reaching' standardisation of care provision opposes self-management, while others indicate that regular monitoring of diabetes patients is key to achieving good health outcomes.

Support format and materials

Most respondents note that while supporting self-management is an important goal of their care programmes, the operationalisation of this care component remains underdeveloped. Nationwide approaches do not (yet) exist and regional interventions are often not standardised in care groups' diabetes care protocols, meaning that efforts can differ between practices and providers. The lack of proactive policymaking on self-management support is mentioned by some respondents as a barrier to broad dissemination of local 'best practices':

"As far as self-management support goes, we're still very much searching for ways to operationalise; we realise that it is important, but we still have a long way to go" (Manager).

Some groups report using motivational interviewing or web-based education programmes, such as DIEP.info, to help patients in their efforts towards self-management. In most groups, however, support efforts appeared to be limited:

"There is attention for patients' self-care during consultations, but self-management support has not yet been institutionalised" (Manager).

In the broader community, cognitive-behavioural interventions are widely available for smoking cessation and physical exercise, amongst others, yet such programmes are rarely part of regional diabetes care packages, which are covered entirely by the basic social health insurance (SHI) package that is mandatory for Dutch citizens. Hence, additional payments might be necessary in order to gain access to such services.

Support providers and locations

The interviews with Dutch health professionals suggest that in practice, nurses are most involved in supporting patients' efforts to self-manage their disease "*simply because they have more time to do so*" (GP). General practice nurses usually see patients at least three times per year; during these quarterly check-ups – as well as during the annual, more elaborate visit with the GP – patients' self-management needs and activities are assessed and education concerning diabetes self-monitoring is provided. When deemed necessary, patients may be referred to dieticians, physical therapists, other primary care-based health providers, and/or community services that can support them in improving their health-related behaviours.

DISCUSSION

In this paper, we reviewed self-management support approaches for patients with chronic conditions in 13 European countries. We find that, in general, self-management support remains relatively underdeveloped in Europe, although

some countries appear further than others in implementing the key support components distinguished by the CCM, i.e. patient education, collaborative care planning, provision of self-management tools, and structured follow-up. This difference might be explained, in part, by facilitative factors in countries' health system context, such as the financing context which might incentivise self-management support efforts, and/or in what can broadly be viewed as medical culture, including length of consultation[41], nature of doctor-patient communication[42], or interdisciplinary teamwork [43]. At the same time, although there are differences in the 'what, how, who and where' of support activities across countries, there are considerable similarities as well. Important commonalities were: (1) the role of nurses as main support givers, which research has shown to lead to better outcomes for the chronically ill[44-46]; and (2) the setting of support activities in primary care, which is widely regarded as most suitable to serve as 'medical home' for chronically ill patients.[47] Moreover, respondents from most countries reported on the presence of collaborative care planning and structured follow-up of patients' self-management over time, as suggested by the CCM, although it is often unclear how (well) these activities are implemented in practice. Findings from recent international surveys of patients' experiences with chronic care suggest that there are still substantial shortfalls in the actual level of patient engagement in terms of patient-provider communication, shared decision-making, and follow-up and support between visits.[7,48]

The self-management support approaches reviewed here differ primarily in terms of mode, format, and materials. Across and within countries, patients are offered a wide variety of educational resources and services, ranging from written materials only to different combinations of individual and/or group-based education sessions, interactive websites, telephone services, and/or peer support. According to a systematic review by Barlow et al.[49], diversity in self-management interventions is advisable because 'no approach will meet the needs of all participants at all points in time'. With regard to content, support efforts in the 13 countries tend to focus primarily on the first two sets of activities distinguished in the Corbin and Strauss framework[28], namely medical and behavioural management, but less so on helping patients deal with the emotional consequences of chronic illness. Active involvement of patient associations in chronic care provision, which is the case in some countries, might be an important step towards better support for patients' emotional management. The six-month evaluation of the Expert Patient Programme in England showed that lay-led education efforts can result in improvements in patients' partnerships with doctors, their self-efficacy, self-reported energy levels, health-related quality of life, and psychological wellbeing.[50] In Austria, the added benefit of peer support in the Therapy Aktiv programme is currently being evaluated.[51]

Our interviews with health professionals in the Netherlands suggest that, despite the emphasis on the role of patients in recent chronic care policymaking, the actual degree of self-management support in practice remains limited, an

observation also reported for other countries.[7,8,48] Care providers seem to recognise that engaging patients as partners in their care is key to achieving better health outcomes, yet experience difficulties in operationalising this phenomenon in their daily working routines. Based on the barriers to patient participation perceived by our respondents, improvements seem necessary in existing IT arrangements and financial incentives to support the use of individual treatment plans. Moreover, it will be important to create a tighter connection between the field of health promotion and the health care system, for instance by including smoking cessation interventions as part of disease management programmes.[31] Broad implementation of self-management support, and of a collaborative approach to chronic care more generally, will require a paradigm shift among health professionals, who have traditionally been trained to take control of and responsibility for patients' acute health problems.[52] Studies in the area of shared decision-making suggest that adoption of the so-called 'empowerment paradigm' – which acknowledges that chronically ill patients provide most of their care themselves – will require time and effort, and a supportive health system context in terms of medical education, care processes, quality measurement, and provider reimbursement.[53] There is a need for further research into barriers and facilitators to implementation to strengthen the dissemination and, with that, the impact of effective self-management support approaches for chronically ill patients within the financial and time-related constraints of daily health care practice.

An important strength of this study is the relatively large number of countries reviewed, which allowed us to provide a broad overview of approaches to self-management support in Europe. Adding an in-depth analysis of support activities in the Netherlands offered more insight into the actual level of and barriers to implementation of self-management support in daily health care practice. A limitation of our study is that, despite the use of a data template and the operationalisation of self-management support, country-specific descriptions of support approaches differed in their level of detail and thus some approaches might be relatively underrepresented in this paper. The most important weakness of the research, however, is that we were unable to include the patient perspective, as it was not possible to survey a sufficiently large sample of patients in each country within the time frame of our study. It is likely that patients' perceptions of the (degree of) self-management support they receive will differ from those of researchers, policymakers/advisors, and health professionals. Existing work has highlighted how, from a patient's perspective, support for self-management for those with chronic disease in Europe and elsewhere remains underdeveloped, with a 2011 survey of people with chronic conditions in 11 countries finding 20 to 60 percent to report that health professionals do not help them make treatment plans they can carry out in daily life.[54] Moreover, 25 to 50 percent felt that their doctor did not spend sufficient time with them or explained things in a way that patients would find easy to under-

stand.[54] Combined with our own findings, these findings further stress the importance of future research in the area of self-management support.

CONCLUSION

The findings from our 13-country study of self-management support approaches suggest that while Europe might increasingly be talking the talk of patient participation in chronic care, it appears to be far from walking the walk. Support activities are relatively underdeveloped and remain quite traditional, that is, focused on medical and behavioural skills, with limited attention for the emotional consequences of illness. Reported barriers to implementation of self-management support include insufficient IT and counteractive financial incentives, but also a lack of (proactive policy to stimulate) adoption of the 'empowerment paradigm' in health care practice. There is a need for better understanding of how we can encourage both patients and health professionals to engage in productive interactions in daily chronic care practice, which can improve health and social outcomes. Involving patients as 'experts' and 'peer supporters' might be an important step towards improving emotional support in chronic care. Future research should investigate to what extent barriers related to health system context and/or medical culture are hampering the implementation of effective self-management support theories in practice.

ACKNOWLEDGMENTS

This study was conducted with support from the DISMEVAL consortium. It draws on additional information from DISMEVAL partners and key informants who contributed information on approaches to chronic disease management in selected countries: Fadila Farsi, Hélène Labrosse (DISMEVAL partner, Centre Anticancereux Leon Berard: cancer networks France), Taavi Lai (Estonia, Latvia, Lithuania); Péter Gaál and Márton Csere (Hungary); Walter Ricciardi, Antonio G. De Belvis, Maria Lucia Specchia, TD Luca Valerio (Italy); Liubove Murauskiene, Marija Veniute (Lithuania); and Isabelle Peytremann-Bridevaux, Bernard Burnand and Ignazio Cassis (Switzerland); and was undertaken in cooperation with nine Dutch primary care groups: Regionale Huisartsenzorg Maastricht/Heuvelland, Diabetes Zorgsysteem West-Friesland, Groninger Huisartsen Coöperatie, Huisartsenzorg Drenthe Medische Eerstelijns Ketenzorg, Eerstelijns Centrum Tiel, Coöperatie Zorgcirkels Woerden, Zorggroep Zwolle, Huisartsenketenzorg Arnhem, Cohesie Cure & Care. The DISMEVAL-project was funded under the European Commission's Seventh Framework Programme (FP7) (grant no. 223277).

REFERENCES

1. Beaglehole R, Bonita R, Horton R, Adams C, Alleyne G, Asaria P, Baugh V, Bekedam H, Billo N, Casswell S, Cecchini M, Colagiuri R, Colagiuri S, Collins T, Ebrahim S, Engelgau M, Galea G, Gaziano T, Geneau R, Haines A, Hospedales J, Jha P, Keeling A, Leeder S, Lincoln P, McKee M, Mackay J, Magnusson R, Moodie R, Mwatsama M, Nishtar S, Norrving B, Patterson D, Piot P, Ralston J, Rani M, Srinath Reddy K, Sassi F, Sheron N, Stuckler D, Suh I, Torode J, Varghese C, Watt J. Priority actions for the non-communicable disease crisis. *Lancet,* 2011;377:1438-47.
2. The World Bank. *The growing danger of non-communicable diseases: acting now to reverse course. Conference edition. September 2011.* Washington, DC: The World Bank; 2011.
3. Hoffman C, Rice D, Sung H. Persons with chronic conditions. Their prevalence and costs. *Journal of the American Medical Association,* 1996;276:1473-9.
4. Boyd CM, Boult C, Shadmi E, Leff B, Brager R, Dunbar L, Wolff JL, Wegener S. Guided care for multimorbid older adults. *Gerontologist,* 2007;47:697-704.
5. Østbye T, Yarnall KSH, Krause KM, Pollak KI, Gradison M, Lloyd Michener J. Is there time for management of patients with chronic diseases in primary care? *Annals of Family Medicine,* 2005;3:209-14.
6. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. Part one. *Journal of the American Medical Association,* 2002;288:1775-9.
7. Schoen C, Osborn R, How SKH, Doty MM, Peugh J. In chronic condition: experiences of patients with complex health care needs, in eight countries, 2008. *Health Affairs,* 2009;28:w1-16.
8. Nolte E, Knai C, McKee M (eds). *Managing chronic conditions. Experience in eight countries.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008.
9. Hofmarcher MM, Oxley H, Rusticelli E. *Improved health system performance through better care coordination. OECD Health Working Paper Nº 30.* Paris: Organisation for Economic Co-operation and Development (OECD); 2007.
10. Wagner E. Chronic disease management: what will it take to improve care for chronic illness? *Effective Clinical Practice,* 1998;1:2-4.
11. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs,* 2001;20:64-78.
12. Epping-Jordan JE, Pruitt SD, Bengoa R, Wagner EH. Improving the quality of health care for chronic conditions. *Quality and Safety in Health Care,* 2004;13:299-305.
13. Renders CM, Valk GD, Griffin SJ, Wagner EH, Van Eijk JT, Assendelft WJJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. A systematic review. *Diabetes Care,* 2001;24:1821-33.
14. Jarvis J, Skinner TC, Carey ME, Davies MJ. How can structured self-management patient education improve outcomes in people with type 2 diabetes? *Diabetes Obesity and Metabolism,* 2009;12:12-19.
15. Anderson RM, Funnell MM. Patient empowerment: myths and misconceptions. *Patient Education and Counseling,* 2010;79:277-82.
16. Coleman MT, Newton KS. Supporting self-management in patients with chronic illness. *American Family Physician,* 2005;72:1503-10.
17. Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations. *Cochrane Database of Systematic Reviews,* 2001;4:CD003267.
18. Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care,* 2001;24:561-87.
19. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care,* 2002;25:1159-71.

20. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *Journal of the American Medical Association,* 2002;288:2469-75.
21. Heinrich E, Schaper NC, De Vries NK. Self-management interventions for type 2 diabetes: a systematic review. *European Diabetes Nursing,* 2010;7:71-76.
22. Glasgow RE, Davis CL, Funnell MM, Beck A. Implementing practical interventions to support chronic illness self-management. *Joint Commission Journal on Quality and Safety,* 2003;29:563-74.
23. Skochelak SE. A decade of reports calling for change in medical education: what do they say? *Academic Medicine,* 2010;85:S26-33.
24. Towle A, Godolphin W. The neglect of chronic disease self-management in medical education: involving patients as educators. *Academic Medicine,* 2011;86:1350.
25. Rijken M, Jones M, Heijmans M, Dixon A. *Supporting self-management.* In: Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective.* New York, NY: Open University Press; 2008:116-142.
26. World Health Organization (WHO). *Health education in self-care: possibilities and limitations. Report of a scientific consultation.* Geneva: WHO; 1983.
27. Koch T, Jenkin P, Kralik D. Chronic illness self-management: locating the "self". *Journal of Advanced Nursing,* 2004;48:484-92.
28. Corbin J, Strauss A. *Unending work and care: managing chronic illness at home.* San Francisco, CA: Jossey-Bass; 1988.
29. Von Korff M, Gruman J, Schaefer J, Curry S, Wagner EH. Collaborative management of chronic illness. *Annals of Internal Medicine,* 1997;127:1097-1102.
30. Rijken M, Bekkema N, Boeckxstaens P, Schellevis FG, De Maeseneer JM, Groenewegen PP. Chronic disease management programmes: an adequate response to patients' needs? *Health Expectations*, 2012 [epub ahead of print].
31. Barr VJ, Robinson S, Marin-Link B, Underhill L, Dotts A, Ravensdale D, Salivaras S. The Expanded Chronic Care Model: an integration of concepts and strategies from population health promotion and the Chronic Care Model. *Hospital Quarterly,* 2003;7:73-82.
32. Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European health care systems.* Cambridge: RAND Europe; 2012.
33. Nolte E, Ettelt S, Thomson S, Mays N. Learning from other countries: an on-call facility for health care policy. *Journal of Health Services Research and Policy,* 2008;13(Suppl. 2):58-64.
34. Bonomi AE, Wagner EH, Glasgow RE, VonKorff M. Assessment of Chronic Illness Care (ACIC): a practical tool to measure quality improvement. *Health Services Research,* 2002;37:791-820.
35. Netherlands Diabetes Federation. *NDF care standard. Transparency and quality of diabetes care for people with type 2 diabetes.* Amersfoort: Netherlands Diabetes Federation; 2007.
36. Long Alliantie Nederland. *Zorgstandaard COPD*. Amersfoort: Long Alliantie Nederland; 2010.
37. Platform Vitale Vaten. *Zorgstandaard vasculair risicomanagement deel 1 (voor zorgverleners).* Den Haag: Platform Vitale Vaten; 2009.
38. Van Til JT, De Wildt J, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
39. Struijs JN, Baan C. Integrating care through bundled payments – lessons from the Netherlands. *New England Journal of Medicine,* 2011;364:11-12.
40. De Bakker DH, Struijs JN, Baan CB, Raams J, De Wildt JE, Vrijhoef JH, Schut FT. Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. *Health Affairs,* 2012;31:426-33.
41. Peyrot M, Rubin RR, Lauritzen T, Skovlund SE, Snoek FJ, Matthews DR, Landgraf R. Patient and provider perceptions of care for diabetes: result of the cross-national DAWN Study. *Diabetologia,* 2006;49:279-88.
42. Bensing JM, Roter DL, Hulsman RL. Communication patterns of primary care physicians in the United States and the Netherlands. *Journal of General Internal Medicine,* 2003;18:335-42.

43. Zwarenstein M, Goldman J, Reeves S. Interprofessional collaboration: effects of practice-based interventions on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews,* 2009;3:CD000072.
44. Strömberg A, Martensson J, Fridlund B, Levin LA, Karlsson JE, Dahlström U. Nurse-led heart failure clinics improve survival and self-care behaviour in patients with heart failure. *European Heart Journal,* 2003;24:1014-23.
45. Singh D. *Which staff improve care for people with long-term conditions? A rapid review of the literature.* Birmingham: University of Birmingham and NHS Modernisation Agency; 2005.
46. Vrijhoef HJM, Spreeuwenberg C, Eijkelberg IMJG, Wolffenbuttel BHR, Van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *British Medical Journal,* 2001;323:983-5.
47. Ham C. The ten characteristics of the high-performing chronic care system. *Health Economics, Policy and Law,* 2010;5:71-90.
48. Osborn R, Squires D. International perspectives on patient engagement. Results from the 2011 Commonwealth Fund Survey. *Journal of Ambulatory Care Management,* 2012;35:118-28.
49. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. *Patient Education and Counseling,* 2002;48:177-87.
50. Kennedy A, Reeves D, Bower P, Lee V, Middleton E, Richardson G, Gardner C, Gately C, Rogers A. The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial. *Journal of Epidemiology and Community Health,* 2007;61:254-61.
51. Sönnichsen A. *Self-efficacy and peer support enhance the effectiveness of disease management in diabetes type 2 (SPEED).* Registered with Current Controlled Trials Ltd.: ISRCTN10291077
52. Anderson RM, Funnell MM. Patient empowerment: reflections on the challenge of fostering the adoption of a new paradigm. *Patient Education and Counseling,* 2005;57:153-7.
53. Légaré F, Ratté S, Gravel K, Graham I. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Education and Counseling,* 2008;73:526-35.
54. Schoen C, Osborn R, Squires D, Doty M, Pierson R, Applebaum S. New 2011 survey of patients with complex care needs in eleven countries finds that care is often poorly coordinated. *Health Affairs,* 2011 [epub ahead of print].

Chapter 7

Using routine health care performance data to assess the impact of chronic disease management

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Submitted for publication

ABSTRACT

Objective: To illustrate how routine health care data can be used to conduct rigorous evaluations of disease management impact.
Design: The study builds on the European DISMEVAL project, which tested and validated advanced evaluation methods, such as difference-in-differences analysis and regression discontinuity analysis, on data from existing disease management approaches in six countries.
Setting: Austria, Denmark, France, Germany, the Netherlands, and Spain.
Participants: Health care providers and/or statutory insurance funds providing routine data from their disease management interventions, mostly retrospectively.
Interventions: This study did not make an intervention but evaluated the impact of existing disease management interventions implemented in European care settings.
Main outcome measures: Outcome measures were largely dependent on available routine data, but could concern health care structures, processes, and outcomes.
Results: Data covering 10 to 36 months were gathered concerning more than 154,000 patients with three conditions. Data on intermediate health outcomes were most commonly available, followed by process measures. The analyses demonstrated significant positive effects of disease management on process quality (Austria, Germany), yet no more than clinically moderate improvements in intermediate health outcomes (Austria, France, Netherlands, Spain) or pace of disease progression (Denmark) in intervention patients, where possible compared to a matched control group.
Conclusions: Routine health care data provide a useful resource for rigorous, 'real-world' disease management evaluation. Besides offering large numbers and enabling long-term follow-up, they allow for retrospective creation of control groups and provide baseline data. A disadvantage is that routine measures can be too narrow to adequately reflect quality of care.

INTRODUCTION

Over the past two decades, many countries have implemented disease management approaches to improve the quality of care for persons with chronic conditions, enhance health outcomes, and, ultimately, mitigate costs.[1-3] Notwithstanding variation in the nature and scope of approaches, disease management can broadly be defined as 'a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant'.[4] In this context, interventions and communications typically involve actions to enhance patient monitoring and education, increase the coordination of care, and/or stimulate service standardisation.[5,6]

While intuitively appealing, the available evidence on the ability of disease management to achieve its intended goals remains uncertain.[7] Much of what we know about the impact of approaches on the quality and outcomes of care comes from small-scale pilot studies that are frequently conducted in academic settings, the results of which are difficult to generalise.[8] Once programmes are rolled out, there is typically little incentive for researchers to continue tracking their impact with less rigorous observational study designs, which are operationally feasible for use in routine practice.[9] Conversely, approaches used to benchmark disease management performance in routine care settings tend to be limited methodologically, so reducing the scientific credibility and relative usefulness of findings of intervention effect.[10]

Given that disease management is essentially a population-based care strategy, developing study methods that are both scientifically robust and feasible for evaluation in daily practice will be pivotal to improve available evidence on effectiveness and enable continuous quality improvement. The European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project sought to support this process by testing and validating potentially valuable evaluation methods on data from existing approaches to disease management in six countries: Austria, Denmark, France, Germany, the Netherlands, and Spain.[11] Building on that work, the aim of this study is to illustrate how routine data available in health care practice can be used to conduct rigorous evaluations of the impact of disease management approaches on the quality and outcomes of care for chronically ill patients.

METHODS

The testing and validation of disease management evaluation methods carried out within DISMEVAL comprised studies conducted in six countries. A key requirement for country cases to be included in the project was the availability of

routine data from existing, population-based approaches to chronic disease management. In order to capture a wide range of approaches, we applied a broad definition of 'disease management', considering those that included at least one of the following elements: (a) a collaborative model of care among providers such as physicians, hospitals, laboratories, and pharmacies; (b) patient education; and (c) monitoring/collection of patient outcomes data for the early detection of potential complications.[12] Approaches studied were: disease management programmes for type 2 diabetes in Austria and Germany, type 2 diabetes care groups in the Netherlands, provider networks for diabetes and for cancer in France, an interdisciplinary and -sectoral rehabilitation programme for people with chronic obstructive pulmonary disease (COPD) in Denmark, and a nurse-led intervention targeting a working-age population at risk of cardiovascular disease in Spain. All interventions were implemented in a non-experimental setting; the only exception was the diabetes disease management programme in Salzburg, Austria, which was implemented as a pragmatic cluster-randomised controlled trial. An overview of the principle disease management approaches analysed is presented in Table 1.

We defined routine data as 'existing, observational health care performance data originally collected for purposes other than scientific research'.[13] Table 2 illustrates that such data were gathered retrospectively from different sources depending on the evaluation methods being tested. These included providers (Austria, Denmark, France, the Netherlands) and statutory (health) insurance funds (Austria, France, Germany, Spain). Two country studies combined available, routine performance data with newly collected research data as part of the intervention design (Austria, Denmark). Based on Donabedian's framework for quality assessment in health care, relevant performance measures could concern health care structures, processes, and outcomes.[14] Within the 'outcome' domain, we distinguished: (1) intermediate clinical outcomes related to disease control, e.g. glycated haemoglobin (HbA1c) in diabetes patients; (2) definite clinical outcomes, e.g. mortality and functional status; (3) patient experience, e.g. patient satisfaction and quality of life; (4) health care utilisation, e.g. hospital admission rates; and (5) financial outcomes, e.g. direct health care costs of the intervention.[8]

As interventions and the settings in which they were implemented varied, so did the approaches to testing and validating evaluation methods, which were informed, in part, by a review of evaluation methods conducted within DISMEVAL.[15] In Table 1, the methodological aims of the six country-specific disease management evaluations are summarised.

Table 1: Intervention under study and evaluation aim(s) per DISMEVAL country study

Approach	Target condition	Main care components	Evaluation aims
Austria			
Disease management programme 'Therapy Aktiv'	Type 2 diabetes	• Patient management through coordinating physician following care pathways developed by the Austrian Society of Diabetes • Patient education through group instruction; involvement in goals setting and timelines, with agreed targets signed jointly; regular follow-up • Standardised documentation of clinical and diagnostic measures and treatment *In 2011, about 17,000 patients were enrolled in DMPs across Austria (~4.3 percent of all people with type 2 diabetes)*	• To quantify differences in effect sizes of structured care within a diabetes disease management programme using a cluster-randomised design
Denmark			
Integrated Rehabilitation Programme for Chronic Conditions (SIKS) project	COPD	• Multidisciplinary team supports the delivery of rehabilitation; regular patient follow-up; regular inter-organisational meetings • Patient education and regular documentation of self-management needs and activities; involvement in developing individualised treatment plans and goal setting; access to physical exercise intervention • Monitoring of practice team performance; systematic collection of clinical and other data *During 2005–2007 about 80,000 patients were covered by the SIKS project*	• To test different approaches to identifying treatment-control matches in non-experimental settings and quantify the likely impact on the effect estimates of an interdisciplinary and -sectoral intervention for patients with COPD.
France			
Diabetes provider networks	Diabetes	• Multidisciplinary health care team; development of individualised care plan by core team; discussion forum and quality circles; regular follow-up • Patient involvement in developing treatment plan towards a 'formal' agreement between patient and network • Shared information system involving a database collecting routine clinical indicators and used for evaluation and quality control	• To test for selection bias for participating in a structured care programme for diabetes

Approach	Target condition	Main care components	Evaluation aims
		In 2007, around 50,000 people with diabetes were enrolled in diabetes networks (~2.5 percent of people with diabetes in France)	
Germany			
Disease management programme for diabetes	Type 2 diabetes	• Coordination of three care levels by GP on the basis of evidence-based guidelines developed by the German Institute for Evidence-based Medicine and Institute for Quality and Efficiency in Health Care • Patient education in group sessions; involvement in agreeing on treatment goals; regular follow-up , with patient reminders for missed sessions • Standardised electronic documentation of treatment, patient's condition and test results, medication regime, and agreed treatment goals; central data analysis to produce quality reports and provider feedback on performance and for benchmarking *By the end of 2010, ~3.4 million individuals were enrolled in a type 2 diabetes DMP (70–85 percent of diagnosed diabetics in the statutory health insurance system)*	• To compare different methods to adjust for confounding in a non-experimental setting using routine data to assess intervention impact of a diabetes disease management programme • To test for selection bias for participating in a structured care programme for diabetes
Netherlands			
Bundled payment contracts for diabetes care ('diabetes care group')	Type 2 diabetes	• Stratification of patients according to disease severity; GP oversees referral to secondary care and ensures follow-up according to nationally defined standards for diabetes care and multidisciplinary care protocol • Patient education on self-management by practice nurses/specialised diabetes nurses, depending on the level of need • Disease-specific electronic patient record with check-up and referrals data within care programme which allows for information sharing and automatisation of care protocols *In 2011, an estimated 750,000 people with diabetes were covered by a bundled payment contract*	• To employ advanced methods of disease management evaluation in non-experimental settings to better understand the differential effects of structured care components on subpopulations of patients

Approach	Target condition	Main care components	Evaluation aims
Spain			
Nurse-led intervention for the prevention of cardiovascular disease	Cardiovascular risk	• Structured telephone interview after 1, 4 and 8 months from initial medical check-up conducted by a trained nurse to assess knowledge about cardiovascular risk; adherence to recommendations (e.g. quitting smoking); awareness of clinical symptoms *The programme is provided by a mutual fund (Ibermutuamur); between May 2004 and May 2007 just under 1 million medical checkups were carried out, of which around 630,000 were first medical checkups; of these 5,200 persons were identified to be at moderate to high risk to develop cardiovascular disease and offered the intervention*	• To employ advanced methods of disease management evaluation in non-experimental settings to better understand the differential effects of structured care components on subpopulations of patients

NOTE: COPD indicates chronic obstructive pulmonary disease; GP, general practitioner; DMP, disease management programme

Table 2: Data source(s) per country study

Country study	Routine data	Newly collected data
Austria	Health insurance funds	Providers (General practitioners)
Denmark	Danish national registers	Hospital
France	Providers (diabetes provider networks) Statutory health insurance (control)	
Germany	Statutory health insurance fund	
Netherlands	Providers (Care groups)	
Spain	Mutual Fund for Workers' Injuries and Occupational Diseases	

RESULTS

Table 3 shows the main characteristics of the evaluations conducted in the six country studies. Evaluations analysed data from between 118 to 105,056 patients, with length of follow-up ranging from 10 to 36 months. Analytical tools for creating comparison groups included different approaches to matching, such as propensity score matching (Denmark, Germany, Spain), difference-in-differences analysis (Denmark), regression discontinuity analysis (Spain), and calibration (France). The Dutch case study employed meta-analysis and meta-regression techniques to assess the impacts of (components of) the intervention on different patient groups.

We present the results of our study by first illustrating the performance measures that were possible to collect from routine data in each country. We then describe the effects of the disease management approaches that were possible to measure given the routine data.

Table 3: DISMEVAL evaluations in six countries

	Research population (IG/CG)	Length of follow-up	Principal approach	Analytic tools
Austria	649/840	Mean: 401±47 days	Cluster-randomised controlled trial	Randomised controlled comparison using intention-to-treat analysis
Denmark	Functioning and quality: 118/0	2 years	Before-after, no comparison	Mixed-model linear regression
	Utilisation: 118/118	2 years	Before-after, with comparison	Propensity score matching Difference-in-differences analysis
France	241/2,415	1 year	Before-after, with comparison	Calibration

	Research population (IG/CG)	Length of follow-up	Principal approach	Analytic tools
Germany	6,663/37,342	3 years	Before-after, with comparison	Comparison of propensity score matching, propensity score weighting, and direct covariate matching
Netherlands	105,056/0	Mean: 11-12 months	Before-after, no comparison	Meta-analysis Meta-regression
Spain	1,128/627	10-14 months	Before-after, with comparison	Propensity score matching Regression discontinuity analysis

NOTE: IG/CG indicates intervention group/control group

Available performance measures in routine data

An overview of the performance measures assessed in the six DISMEVAL country studies is presented in Table 4. Data concerning measures of structure were not routinely reported for any of the approaches evaluated here. We found that process measures were more commonly available and could be analysed in three country studies, including measures of adherence to guidelines concerning regular foot-, eye- and HbA1c-measurement (Austria and Germany), prescription rates (Germany), the frequency and range of clinical measurements, and length of follow-up (Netherlands), and participation in patient education (Austria).

All country studies assessed intermediate clinical outcome measures; the only exception was the evaluation of the German diabetes disease management programme. Intermediate measures most commonly included body mass index (BMI), blood pressure, cholesterol, and HbA1c levels. Definite clinical outcome measures included the prevalence of micro- and macrovascular complications and mortality (Germany), and physical functioning (Denmark). Measures of patient experience were only available to the Danish country study, which evaluated general and disease-specific quality of life. Data on health care utilisation or costs were not routinely available in most country studies except for Denmark (COPD-specific utilisation) and Germany (non-specific utilisation and cost).

Table 4: Performance measures used in six country-specific disease management evaluations

Domain	**Performance measures**				
Process					
Austria	Regular HbA1c measurement	Annual eye examination	Annual foot examination	Patient education	
Germany	Regular HbA1c measurement	Annual eye examination	Guideline-adherent medication		
Netherlands	Frequency of clinical measurements	Range of clinical measurements	Length of follow-up		
Outcome	*Intermediate clinical*	*Definite clinical*	*Patient experience*	*Utilisation*	*Costs*
Austria	HbA1c Cholesterol Creatinine Blood pressure BMI				
Denmark[1]	Blood pressure Weight Waist circumference BMI	Physical functioning	Quality of life, disease specific and general	GP visits Specialist visits Hospital contacts Bed days Outpatient visits ER visits Medication	
France	HbA1c BMI Renal function				
Germany[2]		Microvascular complications Macrovascular complications Mortality		Ambulatory care Hospital days	Inpatient Prescription
Netherlands	HbA1c Cholesterol Blood pressure BMI				
Spain	Cholesterol Blood pressure BMI Cardiovascular risk				

NOTE: [1]Danish utilisation measures are COPD-specific; [2]German utilisation and cost measures are all-cause; HbA1c indicates glycated haemoglobin; BMI, body mass index

Disease management impact

Table 5 shows the impact of the disease management approaches evaluated in the six country studies on included performance measures.

Effects on process measures

The Austrian study demonstrated significantly greater improvements in all measures of process quality in the intervention group compared to the control group after one year. Similarly, the German country study found evidence for participation in the disease management programme for diabetes to improve process measures. The evaluation of the Dutch diabetes care groups, using a before-after design, found that more frequent measurement of clinical values appeared to be accompanied by greater health improvements, especially in patients with poor glycaemic control, while a longer length of follow-up was associated with less positive effects. Table 5 illustrates these findings specifically with regard to effects on HbA1c levels; similar results were found on all other included outcome measures.

Effects on outcome measures

Intermediate clinical outcomes

The Austrian country study found statistically significant, modest reductions in intervention patients' HbA1c levels (-0.13%; p=0.026) and BMI (-0.27 kg/m^2; p=0.004) compared to control patients. The evaluation of the Danish rehabilitation programme for COPD found significant reductions in the intervention group's diastolic blood pressure (-2.3 mmHg; p<0.05) and BMI (-0.2 kg/m^2; p<0.05). However, these findings were observed for an uncontrolled design only as available data did not allow for a controlled analysis of intermediate clinical outcome measures. The evaluation of the French diabetes provider networks identified significant improvements in the intervention groups' HbA1c concentrations (-0.23%; p=0.002) and BMI (-0.29 kg/m^2; p=0.019) after one year of disease management compared to a national reference, while renal function deteriorated significantly (-4.87 ml/min; p<0.001). The uncontrolled Dutch country study found modest average improvements in intervention patients' cholesterol values, blood pressure, and BMI, while HbA1c levels somewhat increased after a median one year follow-up. Subgroup analyses suggested for the Dutch intervention to be considerably more beneficial for patients with poorly controlled diabetes, as illustrated by the significantly greater than average improvements in these patients' HbA1c levels displayed in Table 5. This finding was consistent across all outcome measures. The evaluation of a nurse-led intervention for the prevention of cardiovascular risk in a working age population in Spain found greater improvements in all intermediate outcomes except for HDL cholesterol, among those with a moderate to high cardiovascular risk who received the intervention compared to those with an equally moderate to high cardiovascular risk but who were not available to receive the intervention.

Table 5: Effects of disease management approaches on performance measures analysed in six countries

Country	Quality domain	Measure	Scale	Effect size
Austria	**Processes**	Regular HbA1c measurement	% of patients	IG= 44.1, CG= 36.0*
		Annual eye examination	% of patients	IG= 71.0, CG= 51.2**
		Annual foot examination	% of patients	IG= 73.8, CG= 45.1**
		Patient education	% of patients	IG= 49.5, CG= 20.1**
	Intermediate clinical	HbA1c (%)		CG-IG= -0.13 [-0.24; -0.02]*
		Cholesterol (mmol/l)		CG-IG= -0.05 [-0.16; 0.05]
		LDL (mmol/l)		CG-IG= 0.05 [-0.04; 0.14]
		HDL (mmol/l)		CG-IG= 0.01 [-0.01; 0.04]
		Triglycerides (mmol/l)		CG-IG= -0.06 [-0.21; 0.09]
		Creatinine (µmol/l)		CG-IG= 1.77 [-0.88; 4.42]
		Systolic blood pressure (mmHg)		CG-IG= -1.80 [-3.65; 0.05]
		Diastolic blood pressure (mmHg)		CG-IG= -0.55 [-1.62; 0.51]
		BMI (kg/m^2)		CG-IG= -0.27 [-0.45; -0.08]*
Denmark	**Intermediate clinical**	Systolic blood pressure (mmHg)		IG= -0.5 [1.99]
		Diastolic blood pressure (mmHg)		IG= -2.3 [1.01]*
		Weight (kg)		IG= -0.4 [0.23]
		Waist circumference (cm)		IG= -0.3 [0.31]
		BMI (kg/m^2)		IG= -0.2 [0.09]*
	Definite clinical	Physical functioning	SFT st (times per 30 s)	IG= 2.3 [0.22]**
			SFT 2.45 (s)	IG= -0.5 [0.14]**
			SWT (s)	IG= 146.4 [25.82]**
			Borg (0-10)	IG= -0.5 [0.18]*
			MRC (1-5)	IG= -0.4 [0.08]**

Country	Quality domain	Measure	Scale	Effect size
		Disease-specific functioning	FEV1 (dL)	IG= 1.5 [1.51]
			FEV1 % of expected	IG= 1.1 [0.78]
			FEV1/FVC	IG= 0.1 [1.09]
	Patient experience	Quality of life	SF 36 physical	IG= 4.3 [1.32]*
			SF 36 mental	IG= 7.0 [1.80]**
			CCQ total (6-0)	IG= -2.1 [0.91]*
			Avlund (0-12)	IG= 0.9 [0.17]**
	Utilisation	GP visits	Number	CG-IG= 0.93 [0.83; 1.06]
		Specialist visits	Number	CG-IG= 0.99 [0.68; 1.43]
		Hospital contacts	Number	CG-IG= 0.66 [0.37; 1.19]
		Bed days	Number	CG-IG= 0.73 [0.34; 1.58]
		Outpatient visits	Number	CG-IG= 0.59 [0.28; 1.23]
		ER visits	Number	CG-IG= 0.43 [0.18; 1.01]
		Medication	Number	CG-IG= 1.32 [1.02; 1.74]*
France	**Intermediate clinical**	HbA1c (%)		CG-IG= -0.23 [1.08]*
		BMI (kg/m^2)		CG-IG= -0.29 [1.86]*
		Renal function (ml/min)	Glomerular Filtration Rate	CG-IG= -4.87 [17.95]*
Germany	**Processes**	Regular HbA1c measurement	% of patients	IG= 54, CG= 41
		Annual eye examination	% of patients	IG= 56, CG= 36
		Guideline-adherent medication	% of patients	IG= 64, CG= 63
	Definite clinical	Microvascular complications		
		Dialysis	*Incidence rate*[1]	*IG= 4.3, CG= 4.5*
		Lower limb amputations	*Incidence rate*	*IG= 2.6, CG= 2.8*
		Macrovascular complications		
		Myocardial infarction	*Incidence rate*	*IG= 16.4, CG= 15.4*

Country	Quality domain	Measure	Scale	Effect size
		Stroke	*Incidence rate*	*IG= 6.6, CG= 7.9*
		Mortality	Mortality rate[1]	IG= 13.0, CG= 20.4*
	Utilisation	Ambulatory care consultations	Number/year	IG= 32, CG= 26
		Hospital days	% of patients with >0 days	IG= 27, CG= 26
	Costs	Inpatient	Change in costs (%)	IG= 30, CG= 32
		Prescription	Change in costs (%)	IG= 44, CG= 19
Netherlands	**Processes**	Measurement frequency		
		≤Median (N=3)	*Change in HbA1c*	*SG= 0.09 [-0.85;1.03]*
		>Median (N=3)	*Change in HbA1c*	*SG= -0.06 [-1.47;1.36]*
		Measurement range		Insignificant interaction
		Length of follow-up		
		≤Median (1 year)	*Change in HbA1c*	*SG= 0.02 [-0.77;0.81]*
		>Median (1 year)	*Change in HbA1c*	*SG= 0.53 [-0.22;1.27]*
	Intermediate clinical	HbA1c (mmol/mol)		IG = 0.17 [-0.60;0.93]
		First-year HbA1c ≤53		*SG= 1.79 [1.17;2.41]***
		First-year HbA1c 54-74		*SG= -2.62 [-3.46;-1.78]***
		First-year HbA1c ≥75		*SG= -16.82 [-18.67;-14.96]***
		Total cholesterol (mmol/l)		IG = -0.10 [-0.14;-0.06]**
		LDL (mmol/l)		IG = -0.09 [-0.13;-0.05]**
		HDL (mmol/l)		IG = 0.02 [0;0.03]*
		Triglycerides (mmol/l)		IG = -0.05 [-0.07;-0.03]**
		Systolic blood pressure (mmHg)		IG = -0.95 [-1.25;-0.64]**
		Diastolic blood pressure (mmHg)		IG = -0.80 [-0.93;-0.67]**
		BMI (kg/m^2)		IG = -0.04 [-0.10;0.02]

Country	Quality domain	Measure	Scale	Effect size
Spain	**Intermediate clinical**	Total cholesterol (mg/dl)		IG= -13.74, CG= -12.08
		LDL (mg/dl)		IG= -16.12, CG= -14.68
		HDL (mg/dl)		IG= 5.84, CG= 6.25
		Systolic blood pressure (mmHg)		IG= -5.61, CG= -2.96*
		Diastolic blood pressure (mmHg)		IG= -2.40, CG= -1.01*
		BMI (kg/m^2)		IG= -1.82; CG= -1.09**
		Cardiovascular risk	SCORE	IG= -0.0055, CG= -0.0012*

NOTE: *p<0.05; **p<0.001; [1]Incidents/1000 person years (after propensity score weighting); HbA1c indicates glycated haemoglobin; IG, intervention group; CG, control group; CG-IG, mean difference calculated as control group score minus intervention group score; LDL, low-density lipoprotein; HDL, high-density lipoprotein; BMI, body mass index; GP, general practitioner; ER, emergency room; SG, subgroup of intervention patients

Definite clinical outcomes

The German country study was unable to demonstrate a statistically significant difference in the risk for micro- and macrovascular complications between intervention and control groups after three years. The analyses did find a significant reduction in mortality in the intervention group, especially during the first year after enrolment in the programme. Using an uncontrolled design, the Danish evaluation found statistically significant improvements in intervention patients' physical functioning.

Patient experience, care utilisation and costs

In terms of effects on patient experience, the Danish country study identified significant improvements in the quality of life of patients participating in the rehabilitation intervention for COPD. With regard to utilisation, it found the intervention to decrease the pace of COPD progression, as measured by a non-significant increase in COPD-specific hospital contacts, bed days, outpatient visits, and emergency room visits in the intervention group, while these indicators significantly increased in the entire sample. The German evaluation found evidence that intensified care – as indicated by improvements in process measures – was accompanied by higher utilisation and costs. Thus, participants in the disease management programme showed an increase in the number of outpatient visits and prescription costs, although hospital days and inpatient costs did not differ from the control group.

DISCUSSION

Experimental study designs, particularly randomised controlled trials, are generally considered to provide the most scientific rigour for determining the effects of an intervention.[10,15] In such designs, individuals are randomly assigned to either the intervention group or a control group, giving each person an equal chance to be chosen for the intervention so that any observed difference in outcome is not affected by systematic differences in factors, known and unknown, between those who receive a given intervention and those who do not.[16,17] However, use of an experimental design may not be possible and/or desirable for population-based disease management interventions, which are implemented in operational settings, target large and inherently heterogeneous patient populations, and do not usually have a control group available.[18,19] In such cases, observational study designs are more suitable and can be sufficiently robust if certain data problems are taken into account.[10,20]

This paper demonstrates how routine health care performance data can provide a useful resource in the design of rigorous non-experimental studies. Such data, which are typically inexpensive to collect from the perspective of

researchers, provide a potentially rich source of longitudinal information on a large number of patients with different health problems across diverse health care settings.[21,22] Thus, within DISMEVAL, we were able to include mostly routine data describing a period of 10 to 36 months from more than 154,000 patients receiving disease management or usual care for three different conditions in six European countries. Perhaps even more important, routine data can be used to retrospectively create matched control groups and provide baseline data, which is essential for any evaluation that aims to assess whether or not the intervention under study did indeed have an effect on the intervention group that would not have occurred otherwise.[15]

However, despite the practical and methodological advantages of using a routine dataset in situations where randomisation is not possible, it may be inadequate for the purpose of evaluation as it is typically used for administrative purposes only and may not record measures of interest.[21,22] Our analyses show that this was the case for the majority of routine data used in DISMEVAL. Within the datasets made available by health care providers and insurance funds, there was an emphasis on intermediate clinical outcomes, such as blood pressure and cholesterol, while data on process measures, definite clinical outcomes, patient experience, health care utilisation, or costs were accessible in two or three cases only. This reflects to certain degree the context within which related programmes and approaches were being implemented, with intermediate measures used to monitor progress towards treatment goals.[23] There is, however, also a general tendency to focus on intermediate health outcomes in disease management evaluations, in part because of their ease of measurement with standard tests and procedures in place, even though the relevance for long-term health outcomes sometimes remains unclear.[15,24]

Despite the use of rigorous analytic methods, ranging from propensity score matching and calibration to regression discontinuity analysis and meta-regression, the results of our six country case studies must be interpreted with caution, keeping the methodological limitations of observational research in mind.[9,10,15] Further research into the 'real-world' impact of disease management on a broad range of process and outcome measures is crucial to support health care professionals in working towards more patient-centered, effective and efficient chronic care delivery, which were stipulated as important health system objectives in the Institute of Medicine's seminal *Crossing the Quality Chasm* report.[25] Our study suggests that this may necessitate additional data collection efforts in practice, with consequent resource implications.[13] Also, there is a need to allow for sufficient length of observation in disease management evaluations, consistent with what is known about the time course of a disease, to enable valid conclusions to be drawn about health effects. Intermediate clinical outcome measures are heavily influenced by an individual's health behaviour, improvements in which are often difficult to maintain over time. Adequate length of follow-up is also necessary for measurement of 'hard' clinical

outcomes, such as morbidity and mortality. This is illustrated by the German country study as well as by an unrelated Danish trial[26], both of which could not demonstrate effects on the prevalence of various types of diabetes-related complications within a time frame of three and six years respectively. The German evaluation did observe a significantly higher risk of death among control patients compared to intervention patients. However, this mortality difference between groups fell considerably after the first year of enrolment in the disease management programme; hence, it was more likely a result of selection bias than an effect attributable to the intervention.[11,20]

Limitations

This study has several limitations. Most notably, data collection was influenced by the availability and validity of data for research purposes as well as by methodological choices. Thus, the performance measures assessed in DISMEVAL do not fully describe the spectrum of metrics that may be potentially useful for disease management evaluation in the individual countries. Rather, each set of measures included in a specific country study represents what could be measured in a scientifically sound fashion on the basis of routine performance data. Furthermore, the diversity of disease management approaches studied in DISMEVAL limits the potential for cross-country comparisons of effectiveness. Finally, while concerted efforts were made to obtain detailed and valid datasets to allow, where possible, for the retrospective creation of suitable treatment-control matches adjusted for confounding variables, unobserved confounders may still have resulted in misleading intervention effects.

CONCLUSIONS

Routine health care performance data provide a valuable resource for 'real-world' disease management evaluations using advanced observational study designs. They contain the large numbers and opportunities for long-term follow-up required to investigate health effects; moreover, they allow for retrospective creation of control groups and provide baseline data, both of which are necessary to detect a true treatment effect. A disadvantage of using routine data is that the measures systematically assessed in health care can be too narrow to adequately reflect the quality of care provided. These data tend to emphasise intermediate clinical outcomes and, to a somewhat lesser extent, process measures. Additional data collection and evaluation efforts over sufficient observation periods may be necessary to gain insight into the impact of disease management strategies on definite clinical outcomes, measures of patient experience, health care utilisation, and costs.

REFERENCES

1. Nolte E, Knai C, McKee M. *Managing Chronic Conditions. Experience in Eight Countries.* Brussels: European Observatory on Health Systems and Policies; 2008.
2. Coleman K, Mattke S, Perrault PJ, Wagner EH. Untangling practice redesign from disease management: how do we best care for the chronically ill? *Annual Review of Public Health,* 2009;30:385-408.
3. Ouwens M, Wollersheim H, Hermens R, Hulscher M, Grol R. Integrated care programmes for chronically ill patients: a review of systematic reviews. *International Journal for Quality in Health Care,* 2005;17:141–46.
4. Care Continuum Alliance. *Care Continuum Alliance (CCA) definition of disease management.* Retrieved, 25 July 2012, from: http://www.carecontinuumalliance.org/dm_definition.asp
5. Epstein R, Sherwoord L. From outcomes research to disease management: a guide for the perplexed. *Annals of Internal Medicine,* 1996;124:832-37.
6. Steuten LMG, Vrijhoef HJM, Landewé-Cleuren S, Schaper N, Van Merode GG, Spreeuwenberg C. A disease management programme for patients with diabetes mellitus is associated with improved quality of care within existing budgets. *Diabetic Medicine,* 2007;24:1112-20.
7. Berthold HK, Bestehorn KP, Jannowitz C, Krone W, Gouni-Berthold I. Disease management programs in type 2 diabetes: quality of care. *American Journal of Managed Care,* 2011;17:393-403.
8. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care,* 2007;13:670-676.
9. Mattke S, Bergamo S, Balakrishnan A, Martino S, Vakkur NV. *Measuring and reporting the performance of disease management programs.* Santa Monica, CA: RAND Corporation; 2006.
10. Linden A, Adams J, Roberts N. *Evaluation methods in disease management: determining program effectiveness.* Position paper commissioned by the Disease Management Association of America (DMAA); 2003.
11. Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European health care systems*. Cambridge: RAND Europe; 2012
12. Krumholz H, Currie P, Riegel B, Phillips CO, Petersen ED, Smith R, Yancy CW, Faxon DP. A taxonomy for disease management: a scientific statement from the American Heart Association Disease Management Taxonomy writing group. *Circulation,* 2006;114:1432-45.
13. Powell AE, Davies HTO, Thomson RG. Using routine comparative data to assess the quality of health care: understanding and avoiding common pitfalls. *Quality and Safety in Health Care,* 2003;12:122-28.
14. Donabedian A. *An introduction to quality assurance in health care.* New York, NY: Oxford University Press; 2003.
15. Conklin A, Nolte E. *Disease management evaluation. A comprehensive review of current state of the art.* Cambridge: RAND Europe; 2010.
16. Sibbald B, Roland M. Understanding controlled trials. Why are randomised controlled trials important? *British Medical Journal,* 1998;316:201.
17. Linden A, Roberts N. A user's guide to the disease management literature: recommendations for reporting and assessing program outcomes. *American Journal of Managed Care,* 2006;11:113–20.
18. Norman G. Disease management outcomes: are we asking the right questions yet? *Population Health Management,* 2008;11:183–87.
19. Berwick D. The science of improvement. *Journal of the American Medical Association,* 2008;299:1182–84.
20. Nolte E, Conklin A, Adams JL, Brunn M, Cadier B, Chevreul K, Durand-Zaleski I, Elissen A, Erler A, Flamm M, Frølich A, Fullerton B, Jacobsen R, Knai C, Krohn R, Pöhlmann B, Saz Parkinson Z, Sarria Santamera A, Sönnichsen A, Vrijhoef H. *Evaluating chronic disease management. Recommendations for funders and users.* Cambridge: RAND Europe; 2012.

21. Smith PC, Mossialos E, Papanicolas I, Leatherman S. *Performance measurement for health system improvement. Experiences, challenges and prospects.* Cambridge: Cambridge University Press; 2009.
22. Nolte E. *International benchmarking of healthcare quality. A review of the literature*. Cambridge: Rand Europe; 2010.
23. Fullerton B, Nolte E, Erler A. Qualität der Versorgung chronisch Kranker in Deutschland. *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundhwesen,* 2011;105:554-562.
24. Bailie R, Robinson G, Kondalsamy-Chennakesavan S, Halpin S, Wang Z. Investigating the sustainability of outcomes in a chronic disease treatment programme. *Social Science and Medicine,* 2006;63:1661–70.
25. Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century.* Washington, DC: The National Academies Press; 2001.
26. Olivarius NF, Beck-Nielsen H, Andreasen AH, Hørder M, Pedersen PA. Randomised controlled trial of structured personal care of type 2 diabetes mellitus. *British Medical Journal,* 2001;323:970-975.

Chapter 8

Advancing current approaches to disease management evaluation: capitalising on heterogeneity to understand what works and for whom

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Accepted for publication in BMC Medical Research Methodology

ABSTRACT

Background: Evaluating large-scale disease management interventions implemented in actual health care settings is a complex undertaking for which universally accepted methods do not exist. Fundamental issues, such as a lack of control patients and limited generalisability, hamper the use of the 'gold-standard' randomised controlled trial, while methodological shortcomings restrict the value of observational designs. Advancing methods for disease management evaluation in practice is pivotal to learn more about the impact of population-wide approaches. Methods must account for the presence of heterogeneity in effects, which necessitates a more granular assessment of outcomes.
Methods: This paper introduces multilevel regression methods as valuable techniques to evaluate 'real-world' disease management approaches in a manner that produces meaningful findings for everyday practice. In a worked example, these methods are applied to retrospectively gathered routine health care data covering a cohort of 105,056 diabetes patients who receive disease management for type 2 diabetes mellitus in the Netherlands. Multivariable, multilevel regression models are fitted to identify trends in clinical outcomes and correct for differences in characteristics of patients (age, disease duration, baseline health, comorbidity, smoking status) and the intervention (measurement frequency and range, length of follow-up).
Results: After a median one year follow-up, the Dutch disease management approach was associated with small average improvements in systolic blood pressure, low-density lipoprotein, and body mass index, while a slight deterioration occurred in glycated haemoglobin. Differential findings suggest that patients with poorly controlled diabetes tend to benefit most from disease management in terms of improved clinical measures. Additionally, a greater measurement frequency was associated with better outcomes, while longer length of follow-up was accompanied by less positive results.
Conclusions: Despite concerted efforts to adjust for potential sources of confounding and bias, there ultimately are limits to the validity and reliability of findings from uncontrolled research based on routine intervention data. While our findings are supported by previous randomised research in other settings, the trends in outcome measures presented here may have alternative explanations. Further practice-based research, perhaps using historical data to retrospectively construct a control group, is necessary to confirm results and learn more about the impact of population-wide disease management.

INTRODUCTION

Disease management is commonly defined as a 'system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant'.[1] Originally developed in the US, disease management interventions have been introduced in many countries to address widespread deficiencies in the care for chronically ill patients, including fragmentation, insufficient evidence-based practice, and limited self-management support.[2] However, especially outside of the US, available evidence about the impact of disease management remains uncertain and tends to be based on mostly small studies, which frequently target high-risk patients and are performed in academic settings.[3] Although some large-scale, realistic evaluations have already been conducted[4], there remains a need for better insight into the effects of comprehensive, population-based approaches, such as have been implemented in, for example, Germany and the Netherlands.[5]

An important reason for this limited evidence base is the lack of universally accepted methods for 'real-world' disease management evaluation that are both scientifically sound and operationally feasible.[6,7] According to Linden et al.[8], three fundamental limitations preclude use of the 'gold-standard' randomised controlled trial (RCT). First, from a practical perspective, population-wide implementation of approaches can make it difficult to find a suitable number of control subjects. Second, withholding treatment that is assumed to be effective from control patients poses an ethical dilemma. Third and most important, however, the strict in- and exclusion criteria limit generalisability of findings across patients and contexts. Observational research designs are more suitable for practice-based disease management evaluation, yet commonly have methodological flaws that limit the validity and reliability of findings.[9]

Advancing existing methods for disease management evaluation in routine situations where randomisation is not possible will be pivotal in drawing valid conclusions about the impact of this care concept on the quality and outcomes of chronic care provision. Evaluation methods must account for the presence of heterogeneity in effects of disease management, produced by differences in interventions and targeted patients.[10-13] This variation necessitates calculation of more detailed effect estimates than the commonly assessed 'grand means' across large populations of patients, if they are to be informative for day-to-day clinical practice.

The aim of this paper is to introduce multilevel regression methods as useful techniques for the analysis of patient data in practice-based disease management evaluation. These methods enable researchers to identify differences in outcomes as a function of features of the intervention and/or patient population, and, in so doing, support efforts to create effective and efficient disease management strategies. The article starts with a brief, non-technical description of the proposed analytic approach. Subsequently, a worked example is given of

its application in the evaluation of a population-wide disease management intervention for type 2 diabetes mellitus implemented in the Netherlands. This evaluation, which was part of the European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project[5,14], was designed as an uncontrolled cohort study using routine patient data gathered retrospectively from clinical practice.

MULTILEVEL REGRESSION METHODS: WHAT AND WHY?

In health services research, especially studies conducted in practice settings, data commonly have a hierarchical nature, with variable measures – such as cholesterol measurements – clustered within different levels of the hierarchy.[15] For example, in a practice-based study examining factors that influence the use of shared decision-making in general practice, patients would be clustered within physicians, who in turn might be nested within group practices. Traditional statistical methods, such as linear regression analysis, tend to ignore the multilevel structure of routine health care data and do not account for the possibility of similarities among individuals clustered within higher-level units.[16] Yet in reality, subjects within clusters are often more alike than randomly chosen individuals with regard to important characteristics, such as sociodemographic features. Hence, assuming that observations within clusters are uncorrelated is unrealistic and can result in false conclusions about associations between particular variables.[16,17]

Multilevel regression methods enable researchers to explicitly include the hierarchical nature of practice data into their analyses.[15] Similar in essence to simple regressions, multilevel regression entails predicting an outcome variable according to the values of one or more explanatory variables, which may be measured at different levels in the hierarchy.[18] The latter are usually called covariates, i.e. characteristics that might influence the size of a particular intervention's effects. Person-level covariates can enter the model in two different ways. First, they may appear as ordinary covariates at level one of the hierarchy. Second, they may appear in interaction terms with intervention characteristiccs. These interaction terms capture the idea of 'effect modification' by allowing the person-level variables to modify the intervention effect.

Applying multilevel regression methods is of particular relevance when patient outcomes are regarded as heterogeneous, as is typically the case with disease management. In a simple two-level model, total heterogeneity in effects can be divided into two variance components: within-groups and between-groups.[16] Multilevel regression techniques make it possible to capitalise on this variation in three ways, the outcomes of which can support further improvements in the quality and outcomes of disease management.[19] First, it enables identification of subgroups of patients for whom treatment is associated

with the most positive effects. Second, it permits investigation of characteristics of an intervention, either active (treatment features) or passive (setting features), that are associated with favourable outcomes.[18,20] Third, it allows for multiple factors measured at different levels in the hierarchy to be examined together, the results of which may facilitate stratified medicine. In the remainder of this paper, we will show how multilevel regression methods were applied in our evaluation of the Dutch approach to disease management for type 2 diabetes.

WORKED EXAMPLE: DUTCH DISEASE MANAGEMENT EVALUATION

In 2007, the Netherlands Organisation for Health Research and Development (ZonMw) started a governmentally subsidised pilot called the 'Integrated Diabetes Care research programme' to overcome existing barriers to coordination of care for type 2 diabetes patients. As part of the pilot, ten so-called 'care groups' – i.e. provider networks in primary care, gathering mostly general practitioners (GPs) and affiliated personnel – were offered financial incentives to start experimenting with a bundled payment system that allows the different components of outpatient care for type 2 diabetes to be purchased, delivered, and billed as a single product (i.e. a disease management intervention).[21,22] Care groups are responsible for all patients covered by their diabetes care programme; they deliver services themselves and/or subcontract services from other providers, such as physical therapists, dieticians, laboratories, and, to a limited extent, specialists.[23] A national evidence-based care standard for type 2 diabetes care guides negotiations between care groups and health insurers on the content and price of diabetes care programmes.[24]

One of the main goals of implementing the bundled payment system was to stimulate the transfer of non-complex chronic care from the hospital setting to general practice, which traditionally is a strong sector in the Netherlands and is widely regarded as most suitable to serve as ´medical home´ for chronically ill patients.[25] Nearly all Dutch citizens are registered with a GP, who constitutes the first point of contact for care-seeking individuals and acts as gatekeeper for secondary care.[23] Although some regional bundled payment contracts include a limited amount of specialist care, these services are generally reserved for patients with complex and unstable long-standing health problems, such as type 1 diabetes patients and/or multimorbid patients.

Despite uncertainty about the effectiveness of the new financing and delivery system, care groups with bundled payment contracts for type 2 diabetes disease management interventions rapidly achieved national coverage in the Netherlands.[26] For evaluators, this broad dispersion, combined with the unsuitability of using historical controls – evidence suggests that the quality of diabetes care improves over time as a secular trend[27] – limits the use of ex-

perimental comparisons. Thus, to analyse the impact of the Dutch approach to disease management for type 2 diabetes, we conducted an uncontrolled, practice-based cohort study using multilevel regression methods. Although these methods preclude the establishment of cause-effect relationships, they enabled us to identify trends in outcome measures that might suggest that components of the intervention under consideration have an effect for (subgroups of) type 2 diabetes patients.[28] Our study was conducted in five steps: (1) participant selection; (2) data collection and validation; (3) variable definition; (4) data analysis; (5) outcome interpretation.

Participant selection

We selected a convenience sample of 18 care groups, which were set up between the years 2006 and 2009. Nine groups were part of the pilot of the bundled payment system, for which they were selected ensuring diversity in geographical location and size.[21] We used the same criteria to include nine additional, non-experimental groups, i.e. regional initiatives that have a bundled payment contract for diabetes disease management interventions with a health insurer but do not receive (financial) support from the pilot. The 18 care groups represent all but one region of the Netherlands, employ between 7 and 230 GPs per group, and cover patient populations ranging from 348 to 18,531 persons. From each group, we selected all type 2 diabetes patients with at least one registered visit to general practice during the research period (N=106,623), which – depending on the availability of data – was either 20 or 24 months between January, 2008 and December, 2010. We excluded type 1 diabetes patients (N=1567), because they are treated primarily by specialists.

Data collection and validation

The bundled payment system for chronic care in the Netherlands requires care groups to register a specific number of performance indicators for care processes and clinical outcomes on an annual basis. We retrospectively gathered patient data on a selection of those indicators from the clinical information systems of our 18 care groups. Data plausibility was verified through range checks; we removed outliers in clinical values based on cut-off points determined by Dutch diabetes experts (see Table 1). Missing values were not imputed.

Table 1: Cut-off points for data cleaning

Indicator	Lower	Upper	Excluded, n	Excluded, %
Glycated haemoglobin (HbA1c, mmol/mol)	18	108	913	0.5
Low-density lipoprotein (LDL, mmol/l)	1	7.3	2110	1.3
Systolic blood pressure (SBP, mmHg)	70	250	25	0.01
Body Mass Index (BMI, kg/m^2)	16	70	123	0.08

Because patient data were not available for the period before introduction of the bundled payment system, we used the last measurement of each clinical outcome registered per patient during the first year of the research period (or first eight months, for the two groups with a 20-month research period) as baseline. Thus, the baseline data used in this study represent data at the introduction of the disease management intervention (i.e. bundled payment system). Given that patients were enrolled at different time points during the first year, using the last measurement registered in that period as baseline was preferred over the first measurement to minimise heterogeneity in follow-up duration between patients. This is a conservative decision because for some cases a portion of the programme effects will be incorporated in the baseline measurements.

To identify trends in outcome measures, we calculated changes in clinical parameters from baseline to follow-up, which was operationalised as the last measurement of each clinical outcome per patient registered during the second year of the research period. Large correlations between observations within person make the choice of modeling change scores rather than separate cross-sections compelling for maximising statistical power. Modeling change scores also controls for unmeasured but fixed person-level covariates. Before conducting each outcome-specific analysis, we excluded patients who: (1) lacked valid registrations of baseline or follow-up measurement, or both; (2) missed registrations of one or more of the characteristics used as covariates in the multilevel regression analyses; and/or (3) had an observation period between baseline and follow-up of less than three months. The maximum length of follow-up per patient was 23 months. The study flowchart is shown in Figure 1.

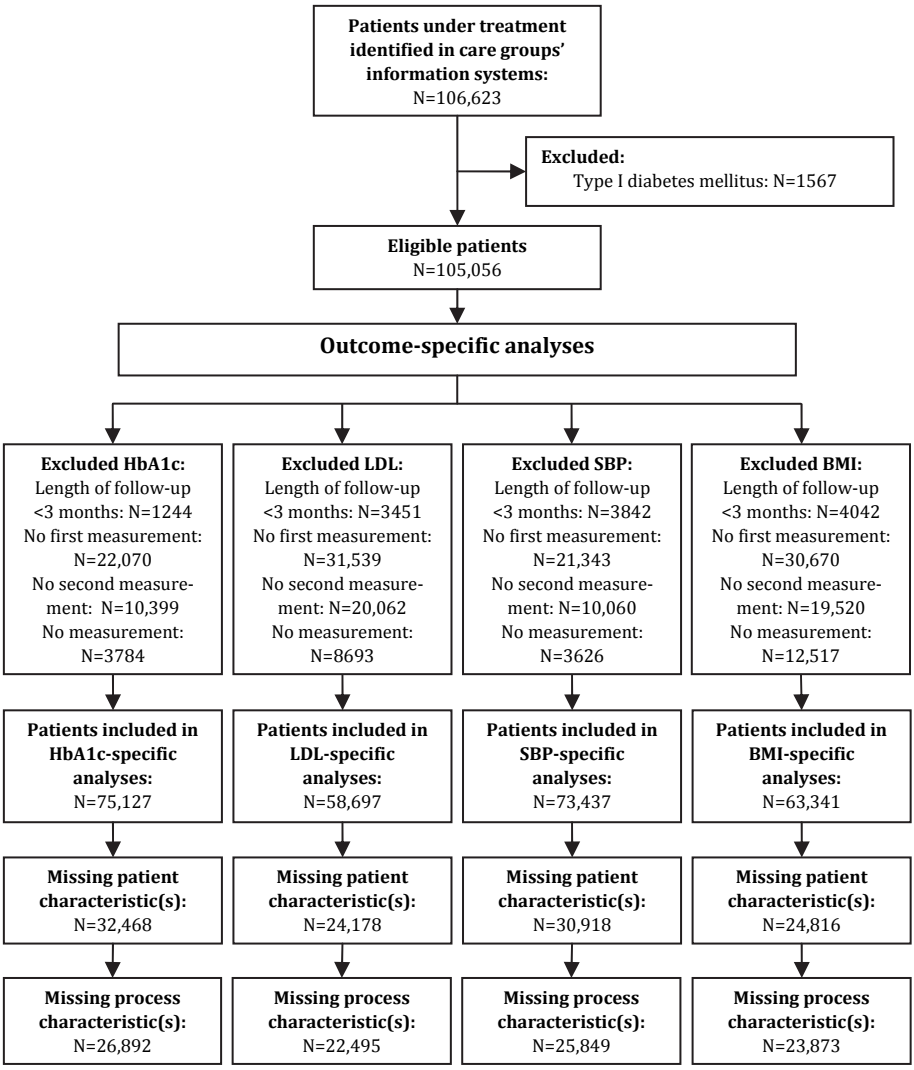

Figure 1: Study flowchart
NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

Variable definition

To enable investigation of heterogeneity in effects on clinical outcomes, we defined relevant variables relating to patient characteristics and active features of the intervention. Figure 2 shows a graphical conceptualisation of the included variables and the number of care groups able to provide data on those variables.

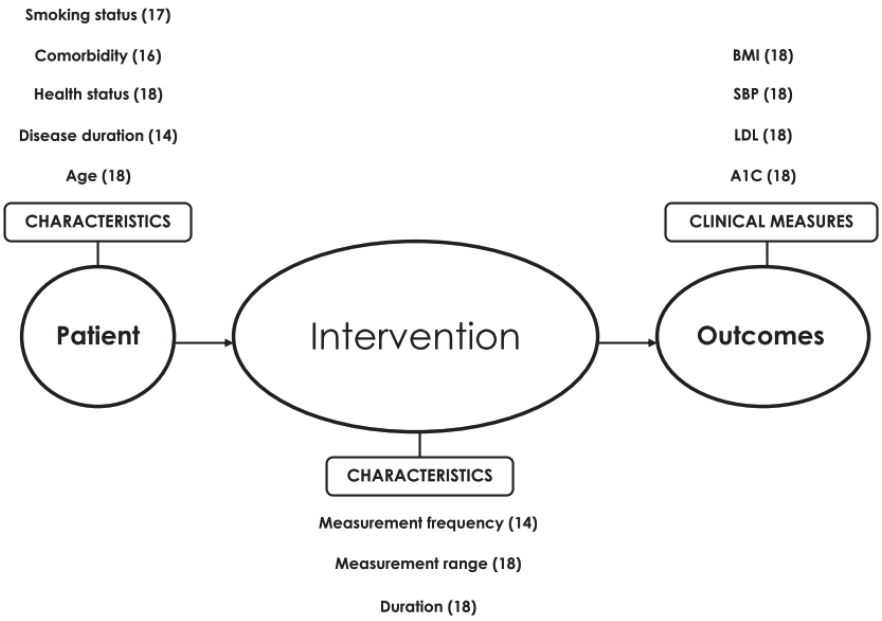

Figure 2: Conceptual overview of variables (and number of registering care groups)
NOTE: A1C indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

With regard to intervention features, we coded measurement frequency as the number of registrations of each clinical outcome during follow-up. To describe measurement range, we assessed the amount of different outcomes registered per patient over baseline, which could be a maximum of eight (i.e. glycated haemoglobin, total cholesterol, low- and high-density lipoprotein, triglycerides, systolic and diastolic blood pressure, and body mass index). Duration of care was defined as an individual patient's length of follow-up in months.

To describe patients, we used these characteristics: age (in years), disease duration (in years), health status, comorbidity, and smoking status. Health status was determined by the baseline values of each clinical outcome. Comorbidity was defined as the presence, registered since diagnosis of type 2 diabetes (that is, either before or during the research period), of one or more of the four most frequently registered co-occuring conditions across the included care groups, i.e. angina pectoris, myocardial infarction, stroke, and/or transient ischemic attack. We dichotomised smoking status as previous or non-smoker versus current smoker. Finally, we defined clinical outcomes as changes over baseline in glycated haemoglobin (HbA1c), low-density lipoprotein (LDL), systolic blood pressure (SBP), and body mass index (BMI).

Data analysis

We conducted univariate analyses to describe intervention and patient characteristics, which were reported either as means and associated standard deviations (age, disease duration, health status), median values (measurement frequency, length of follow-up), or percentages (comorbidity, smoking, measurement range). Using paired sample t-tests (two-sided, α=0.05), we calculated the care group-specific and overall mean differences in clinical outcomes between baseline and follow-up, and 95% confidence intervals. To quantify the heterogeneity in clinical results among our 18 care groups, we calculated the I^2 statistic on the basis of the chi-square (χ^2) test. I^2 describes the percentage of total variation in effects across groups that is due to heterogeneity rather than chance. The principal advantage of I^2 – which lies between 0 and 100% with larger values showing increasing heterogeneity – is that it can be calculated and compared across groups irrespective of differences in size and type of outcome data.[29]

For outcomes showing moderate (I^2>50%) to high (I^2>75%) heterogeneity, multivariable, two-level hierarchical regression models – with patients at level one and care groups at level two – were used to analyse the influence of selected covariates on changes in clinical outcomes between baseline and follow-up. Two separate models were fit to test all covariates related to patient and intervention characteristics, respectively. In a third series of models, we investigated every possible interaction between patient characteristics and intervention features. The models used were similar to the kind that might be fit in a multicenter study, i.e. mixed models incorporating a random care group effect (PROC MIXED command in the SAS 9.2 Software, SAS Institute Inc, Cary, North Carolina), which was considered most suitable given the possibility of 'residual heterogeneity'.[30] Where possible, covariates were analysed both as continuous and as categorical variables, with categories based on scientific literature (age[31], disease duration[32]), on median values (measurement frequency, length of follow-up), or, in the case of baseline health status, on the target values for clinical parameters incorporated in the Dutch care standard for type 2 diabetes.[24] Measurement range was categorised as eight registered outcomes versus less than eight registered outcomes.

For each outcome, we calculated the intraclass correlation coefficient (ICC) which describes the proportion of total heterogeneity in effects attributable to between-group variance rather than within-group variance.[33] We examined collinearity with the variance inflation factor (VIF): a VIF value greater than 10 is generally taken as an indication of serious multicollinearity.[34] The regression coefficients obtained from our multilevel analyses describe how a specific effect estimate changes following a unit increase in a covariate; whether there is actually a relationship between both is expressed in the statistical significance. We expressed 'explained heterogeneity' as the percentage change in between-

group variance (τ^2) and within-group variance (σ^2) after correcting for selected covariates.

Interpretation of results

Univariate analyses

Included in our analyses were 105,056 patients, about half of whom (50.6%) were female. The average age of the research population was 65.7 (±11.9) years and average disease duration 4.8 (±5.6) years. Further details are shown in Table 2. With regard to care processes, patients' SBP was assessed most frequently during follow-up (median=4), followed by BMI (median=3), and HbA1c (median=2). LDL was measured least often (median=1). Across groups, the average share of patients with the maximum measurement range varied from 44.4 to 86.7%, with a mean of 62.3%. Median length of follow-up was 12 months.

Table 2: Baseline characteristics of the research population

Characteristic	Patients for whom characteristic was known, % (n) (N =105,056)	Estimate, Mean ± SD
Age	99.9 (105,013)	65.7 ± 11.9
Diabetes duration	71.9 (75,498)	4.8 ± 5.6
Health status		
HbA1c (mmol/mol; target <53)	71.5 (75,127)	50.2 ± 9.8
LDL (mmol/l; target <2.5)	55.9 (58,697)	2.6 ± 0.9
SBP (mmHg; target <140)	69.9 (73,437)	140.4 ± 18.0
BMI (kg/m^2; target <25)	60.3 (63,341)	29.7 ± 5.2
Comorbidity†	94.5 (99,278)	
None	84.2 (75,357)	
One or more	15.8 (14,165)	
Smoking status	74.6 (78,384)	
No or Ex-smoker	81.6 (63,943)	
Current smoker	18.4 (14,441)	

NOTE: †Included were four major comorbidity associated with diabetes mellitus: angina pectoris, myocardial infarction, stroke, and transient ischemic attack; HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

Table 3 presents the mean changes over baseline in clinical outcomes across the total of 18 care groups. Overall, we found a small, non-significant increase in HbA1c levels between baseline and follow-up, while small but significant reductions in mean levels were observed for LDL and SBP. Except for BMI, all outcomes showed moderate to high statistical heterogeneity, from 57% for SBP to 98% for HbA1c, suggesting that the effects of the diabetes disease management

interventions on these outcomes varied across care groups. To elucidate this heterogeneity and identify trends in the measured results, multilevel regression analyses were conducted.

Table 3: Mean changes over baseline per clinical outcome

Intermediate outcome	Care groups, n	Patients, n	Mean change [95%CI]	Heterogeneity, I^2
HbA1c (mmol/mol)	18	75,127	0.17 [-0.60, 0.93]	98%*
LDL (mmol/l)	18	58,697	-0.09 [-0.13, -0.05]*	93%*
SBP (mmHg)	18	73,437	-0.95 [-1.25, -0.64]*	57%*
BMI (kg/m^2)	18	63,341	-0.04 [-0.10, 0.02]	0%

NOTE: HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index; *Statistically significant ($p<0.05$); I^2 quantifies the total level of heterogeneity in effects

Multilevel regression analyses

The results of the multilevel regression analyses are summarised in Table 4, which shows the changes in between- and within-group heterogeneity in effects on HbA1c, LDL and SBP after correcting for included covariates, with the direction of covariate influence indicated (positive or negative). We observed that the vast majority of variance in the effects of disease management on clinical outcomes occurred within care groups rather than between groups, with ICCs ranging from 0.1 to 4.3% across outcomes. Simultaneously correcting for known patient characteristics resulted in the most considerable reductions in within-group variance in effects. We found no evidence of multicollinearity in any of the regression models.

Table 4: Directions of regression coefficients and associated changes in between-group (τ^2) and within-group (σ^2) variance in effects

Intermediate outcome	HbA1c	LDL	SBP	BMI
Intervention characteristics				
Measurement frequency (N=14)	-	-*	-*	-
Measurement range (N=18)	-*	-	+*	+
Length of follow-up (N=18)	+*	+*	+*	+
Change in τ^2	26.0%	-37.0%	15.6%	15.6%
Change in σ^2	-0.1%	0.7%	5.2%	1.8%
Patient characteristics				
Age (N=18)	-*	+*	+*	-*
Disease duration (N=14)	+*	-	+	+*
Health status (N=18)	-*	-*	-*	-*
Comorbidity (N=16)	+*	-*	-*	+
Smoking status (N=17)	+*	-	-	-*
Change in τ^2	-12.5%	-33.9%	74.8%	22.3%
Change in σ^2	-23.5%	-21.7%	-29.9%	3.4%

NOTE: +=positive regression coefficient; -=negative regression coefficient; *statistically significant ($p<0.05$); HbA1c indicates glycated haemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure; BMI, body mass index

The multilevel regression model incorporating intervention characteristics showed that two covariates significantly influenced the effects of disease management in a consistent manner across clinical outcomes. Whereas a greater measurement frequency of clinical outcomes was associated with better results on those outcomes, longer length of follow-up was accompanied by diminishing positive effects on HbA1c, LDL and SBP. The results for measurement range were inconsistent across clinical outcomes.

The model for patient characteristics found significant and consistent associations between health status (i.e. baseline clinical values) and intervention effects, suggesting that the impact of disease management becomes progressively better as patients' initial health values are poorer. Figure 3 demonstrates how across the 18 care groups, diabetes patients with a baseline HbA1c of ≥75 mmol/mol achieved a mean reduction in this clinical outcome of 16.8 mmol/mol (95% CI: -18.7, -15.0), whereas those starting within the target range for HbA1c (≤53 mmol/mol) experienced a slight deterioration in glycaemic control (1.79 mmol/mol [95% CI: 1.2, 2.4]). The HbA1c levels of those with baseline values between 54 and 74 mmol/mol reduced by an average of 2.6 mmol/mol (95% CI: -3.5, -1.8). For LDL and SBP, similar trends were found. Those with poor baseline values tended to show the greatest improvements. The findings for age, disease duration, comorbidity and smoking status were less conclusive and inconsistent across clinical outcomes.

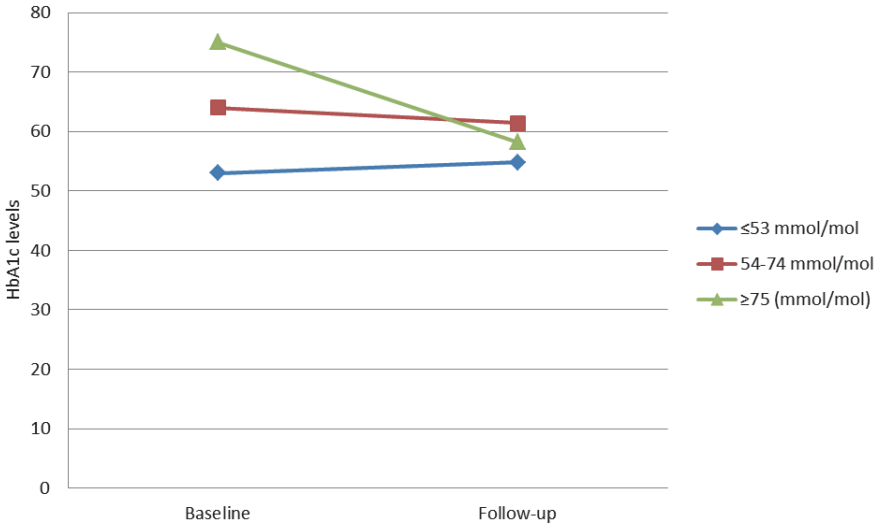

Figure 3: Glycaemic control (mmol/mol) from baseline to follow-up according to the target values of the Dutch care standard for type 2 diabetes mellitus
NOTE: HbA1c indicates glycated haemoglobin

The multilevel regression models incorporating covariates related to both patients and the intervention found one significant interaction that was consistent across all included outcomes. Thus, for patients with poorer initial values of a particular clinical outcome, more frequent assessment of that outcome was associated with progressively greater health improvements than was the case for patients with healthier baseline levels.

DISCUSSION

Evaluating the effects of population-wide disease management interventions implemented in actual health care settings is a complex undertaking.[35] The Dutch example described in this paper illustrates how practical issues, such as a lack of suitable control patients, can limit the use of experimental comparisons to establish whether a given intervention yields a 'true' effect. Indeed, attributing observed changes in outcome measures to the disease management approach under consideration is one of the key challenges in practice-based evaluation.[5,14] In cases like ours, where rigorous performance assessment is complicated because data collection is tied to the intervention and real baseline data is lacking, a frequently used solution is to report data from a first observation period as baseline and to use changes from this baseline as estimates of effects.[6] Such an observational approach is susceptible to various sources of confounding and bias, which threaten the internal validity of study results and

cannot always be observed and/or measured so as to enable statistical adjustment. In evaluating complex health service innovations such as disease management, however, even randomisation is unlikely to successfully control for the large number of factors and interactions on different levels that might influence outcomes.[36]

Although results must be interpreted with caution, given the methodological limitations of uncontrolled research, the value of our proposed methods lies in the opportunity to analyse routine data from clinical practice in a manner that produces meaningful results for further development of disease management strategies. Rather than providing a single effect estimate across many patients, which offers little guidance on what works and for whom, multilevel regression models allow researchers to capitalise on existing heterogeneity in effects by conducting a more granular assessment of the impact of an intervention's features on the health outcomes of different patient groups. Our univariate analysis results demonstrate that a simple, unclustered comparison of Dutch disease management patients' baseline and follow-up clinical measures would have led to the conclusion that the effects of the intervention are small at best. Yet our multilevel regression findings reveal that for patients with poor baseline clinical values, disease management was associated with significant and clinically relevant health improvements after a median follow-up of 12 months. Although this might suggest regression to the mean, which is a common phenomenon in disease management research, this is to some extent refuted by the small percentage of patients (17% for HbA1c) in the healthiest disease categories whose clinical values moved towards to the mean, despite the degenerative nature of diabetes. A 2008 large-scale, practice-based disease management evaluation conducted in Germany[4] as well as a recent meta-analysis of 41 RCTs[10] also found that disease management is most beneficial for poorly controlled diabetes patients, which – given that the vast majority of our patients had healthy baseline values of most clinical parameters – provides a plausible explanation for the small average effects of the Dutch disease management strategy for type 2 diabetes on health outcomes.

With regard to the effectiveness of different intervention features, the findings from our covariate analyses suggest that particularly for patients with poor disease control, intensive monitoring of clinical values might be an important intervention feature that is associated with better health outcomes. Other studies of disease management for diabetes have shown a similar association between more intensive interventions and better glycaemic control.[10,37] The well-known population management model used by Kaiser Permanente divides patients with chronic conditions into three distinct groups based on their degree of health care need: (1) supported self-management, for patients with a relatively low level of need for health care (65-80%); (2) disease management, for patients at increased risk because their condition is unstable (15-30%); and (3) case management, for highly complex patients requiring active management

by specialists (5%), such as type 1 diabetes patients in the Netherlands.[38,39] Further research is necessary to assess whether intensive disease management might indeed be redundant for the relatively healthy subgroup of diabetes patients and could be substituted by adequate self-management support programmes that integrate primary care and community services.[40] Future studies might also investigate the impact of passive intervention characteristics (i.e. setting features) on changes in patients' health outcomes. While a separate, unreported analysis of four passive intervention characteristics in this research – that is, experimental status of the care groups (pilot vs. non-pilot), care group size, diabetes care bundle price, and level of collaboration with specialists – demonstrated no significance for the effects of disease management on any of the studied outcomes, other factors could be of more relevance.[5]

Also in line with previous research, we found that longer length of follow-up was accompanied by less positive effects on clinical outcomes.[10,11] Although this seems counterintuitive, given that increased measurement frequency was accompanied by better results, there is no strict dose-response relationship in the Dutch disease management approach, which means that patients with a longer observation period were not necessarily seen more often than patients followed over a shorter time frame. A plausible explanation for the identified association between length of follow-up and clinical outcomes could be that the positive effects of education on patients' self-management behaviour – and, consequently, their glycaemic control – are difficult to maintain over time, which means that effects measured after a short duration of care might be overestimated.[41,42]

Limitations

Although our findings are confirmed by previous randomised research, there ultimately are limits in the level of confidence we can have in our results given the lack of an untreated comparison group and true baseline data. The trends in outcome measures presented here may have alternative explanations that cannot be explored within the available data. A cautious approach would therefore be to treat these results as exploratory and look for further opportunities to confirm them in other settings, perhaps using historical benchmarking data derived from a comparable population (matched within strata) and corrected for secular trends. In particular the counter-intuitive association between length of follow-up and clinical outcomes might be explained by some unmeasured confounders, such as patients' socioeconomic status or educational level, both of which are known to greatly influence individuals' health behaviour.[43] Alternatively, the lack of pre-intervention data may have introduced post-treatment bias, which leads to underestimation of intervention effects and could also to some extent explain results not lasting over time. Future research would benefit from analysing multiple repeated measurements over time, the opportunity for

which was limited in this study due to the relatively recent implementation of the studied disease management strategy in the Netherlands.

Bias might also have been introduced by missing values, which were numerous in the routine data provided by our 18 care groups and necessitated exclusion of 28 to 44% of patients across the four outcome-specific analyses. Nonetheless, our findings cover a relatively large population (approximately 14% of known diabetes patients in the Netherlands in 2011[44]), which did not differ from other diabetes populations studied in the Netherlands in terms of average age and disease duration, nor was the percentage of smokers different from that in the overall Dutch population.[21,45,46] The prevalence of co-occurring conditions, however, was considerably lower in our research group as compared to the total population of Dutch diabetes patients.[47] This observation might signify registration problems but could also indicate that patients with comorbidity are more likely to be treated by specialists than by primary care providers in the Netherlands.

ACKNOWLEDGMENTS

This study was conducted with support from the DISMEVAL consortium and based in part on care group-data collected by Dr. Caroline Baan and Dr. Jeroen Struijs of the Dutch National Institute for Public Health and the Environment (RIVM). Data were also made available by nine Dutch care groups not involved with the RIVM evaluation: Coöperatie Zorgcirkels Woerden, Huisartsenzorg Drenthe Medische Eerstelijns Ketenzorg, Regionale Huisartsenzorg Maastricht/Heuvelland, Eerstelijns Centrum Tiel, Zorggroep Zwolle, Diabetes Zorgsysteem West-Friesland, Cohesie Cure & Care, Huisartsenketenzorg Arnhem, and Groninger Huisartsen Coöperatie. For the latter group, data were obtained from the Groningen Initiative to Analyse Type 2 Diabetes Treatment (GIANTT) database, which contains anonymised information retrieved from electronic medical records of general practitioners and is maintained by the University Medical Center Groningen.[48] The DISMEVAL-project was funded under the European Commission's Seventh Framework Programme (FP7) (grant no. 223277).

REFERENCES

1. Care Continuum Alliance. *Care Continuum Alliance (CCA) definition of disease management*. Retrieved, 26 August 2012, from: [http://www.carecontinuumalliance.org/dm_definition.asp]
2. Nolte E, Knai C, McKee M (eds). *Managing chronic conditions. Experience in eight countries*. Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies; 2008.

3. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care*, 2007;13(12):670-676.
4. Rothe U, Müller G, Schwarz PEH, Seifert M, Kunath H, Koch R, Bergmann S, Julius U, Bornstein SR, Hanefeld M, Schulze J. Evaluation of a diabetes management system based on practice guidelines, integrated care, and continuous quality management in a Federal State of Germany. A population-based approach to health care research. *Diabetes Care,* 2008;31(5):863-868.
5. Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European health care systems*. Cambridge: RAND Europe; 2012.
6. Mattke S, Bergamo S, Balakrishnan A, Martino S, Vakkur N. *Measuring and reporting the performance of disease management programs.* Santa Monica, CA: RAND Corporation; 2006.
7. Linden A, Roberts N. A users' guide to the disease management literature: recommendations for reporting and assessing program outcomes. *American Journal of Managed Care*, 2005;11(2):81-90.
8. Linden A, Adams JL, Roberts N. Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design. *Journal of Evaluation in Clinical Practice*, 2006;12(2):124-131.
9. Conklin A, Nolte E. *Disease management evaluation. A comprehensive review of current state of the art.* Cambridge: RAND Europe; 2010.
10. Pimouguet C, Le Goff M, Thiébaut R, Dartigues JF, Helmer C. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Canadian Medical Association Journal*, 2011;183(2):E115-127.
11. Elissen AMJ, Steuten LMG, Lemmens LC, Drewes HW, Lemmens KMM, Meeuwissen JAC, Baan CA, Vrijhoef HJM. Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes. *Journal of Evaluation in Clinical Practice*, 2012 [epub ahead of print].
12. Lemmens KMM, Lemmens LC, Boom JHC, Drewes HW, Meeuwissen JAC, Steuten LMG, Vrijhoef HJM, Baan CA. Chronic care management for patients with COPD: a critical review of available evidence. *Journal of Evaluation in Clinical Practice*, 2012 [epub ahead of print].
13. Drewes HW, Steuten LMG, Lemmens LC, Baan CA, Boshuizen H, Elissen AMJ, Lemmens KMM, Meeuwissen JAC, Vrijhoef HJM. The effectiveness of chronic care management for heart failure: a systematic review and meta-regression analysis to explain the heterogeneity in outcomes. *Health Services Research*, 2012 [epub ahead of print].
14. Nolte E, Conklin A, Adams JL, Brunn M, Cadier B, Chevreul K, Durand-Zaleski I, Elissen A, Erler A, Flamm M, Frølich A, Fullerton B, Jacobsen R, Knai C, Krohn R, Pöhlmann B, Saz Parkinson Z, Sarria Santamera A, Sönnichsen A, Vrijhoef H. *Evaluating chronic disease management. Recommendations for funders and users.* Cambridge: RAND Europe; 2012.
15. Austin PC, Goel V, Van Walraven C. An introduction to multilevel regression models. *Canadian Journal of Public Health,* 2001;92(2):150-54.
16. Dickinson LM, Basu A. Multilevel modeling and practice-based research. *Annals of Family Medicine*, 2005;3(Suppl. 1):S52-60.
17. Maas CJM, Hox JJ. Robustness issues in multilevel regression analysis. *Statistica Neerlandica*, 2004;58(2):127-37.
18. Hox JJ. *Multilevel analysis: techniques and applications*. New York, NY: Routledge; 2010.
19. Linden A, Adams JL. Determining if disease management saves money: an introduction to meta-analysis. *Journal of Evaluation in Clinical Practice*, 2007;13:400-407.
20. Stuck A, Siu A, Wieland G, Adams JL, Rubenstein L. Comprehensive geriatric assessment: a meta-analysis of controlled trials. *Lancet*, 1993;342(8878):1032-36.
21. Struijs JN, De Jong-Van Til JT, Lemmens LC, Drewes HW, De Bruin SR, Baan CA. *Bundled payments of diabetes care: effects on care delivery process and quality of care at three-year follow-up*. Bilthoven: National Institute for Public Health and the Environment (RIVM); 2012.
22. Struijs JN, Baan C. Integrating care through bundled payments – lessons from the Netherlands. *New England Journal of Medicine*, 2011;364:11-12.

23. De Bakker DH, Struijs JN, Baan CB, Raams J, De Wildt J, Vrijhoef HJM, Schut FT. Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. *Health Affairs*, 2012;31(2):426-33.
24. Netherlands Diabetes Federation. *NDF care standard. Transparency and quality of diabetes care for people with type 2 diabetes.* Amersfoort: Netherlands Diabetes Federation (NDF); 2007.
25. Ham C. The ten characteristics of the high-performing chronic care system. *Health Economics, Policy and Law,* 2010;5:71-90.
26. Van Til JT, De Wildt J, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren*. Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
27. Berthold HK, Bestehorn KP, Jannowitz C, Krone W, Gouni-Berthold I. Disease management programs in type 2 diabetes: quality of care. *American Journal of Managed Care*, 2011;17(6):393-403.
28. Victora CG, Habicht J, Bryce J. Evidence-based public health: moving beyond randomized trials. *Public Health Matters*, 2004;94(3):400-05.
29. Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *British Medical Journal*, 2003;327:557-60.
30. Muthén B, Asparouhov T. Multilevel regression mixture analysis. *Journal of the Royal Statistical Society*, 2009;172:639-57.
31. Martin BC, Warram JH, Krolewski AS, Bergman RN, Soeldner JS, Kahn CR. Role of glucose and insulin resistance in development of type 2 diabetes mellitus. *Lancet,* 1992;340(8825):925-929
32. Tesfaye S, Stevens LK, Stephenson JM, Fuller JH, Plater M, Ionescu-Tirgoviste C, Nuber A, Pozza G, Ward JD. Prevalence of diabetic peripheral neuropathy and its relation to glycaemic control and potential risk factors: the EURODIAB IDDM Complications Study. *Diabetologia,* 1996;39(11):1377-1384.
33. Berthold MR, Lenz HJ, Bradley E, Kruse R, Borgelt C (eds). *Proceedings of the 5th International Symposium on Intelligent Data Analysis: 28-30 August 2003; Berlin.* Berlin Heidelberg: Springer-Verlag; 2003.
34. Kennedy P. *A guide to econometrics*. Cambridge, MA: MIT Press; 1992.
35. Linden A, Adams J, Roberts N. *Evaluation methods in disease management: determining program effectiveness.* Position paper commissioned by the Disease Management Association of America (DMAA); 2003.
36. English M, Schellenberg J, Todd J. Assessing health system interventions: key points when considering the value of randomization. *Bulletin of the World Health Organization*, 2011;89:907-12.
37. Gary TL, Batts-Turner M, Yeh HC. The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial. *Archives of Internal Medicine*, 2009;169:1788-94.
38. Bodenheimer T, Wagner E, Grumbach, K. Improving primary care for patients with chronic illness. *Journal of the American Medical Association*, 2002;288:1775–9.
39. Nolte E, McKee M. *Integration and chronic care: a review*. In: Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective.* New York, NY: Open University Press; 2008.
40. Barr VJ, Robinson S, Marin-Link B, Underhill L, Dotts A, Ravensdale D, Salivaras S. The Expanded Chronic Care Model: an integration of concepts and strategies from population health promotion and the Chronic Care Model. *Hospital Quarterly*, 2003;7(1):73-82.
41. Singh D. *How can chronic disease management programmes operate across care settings and providers?* Copenhagen: World Health Organization Regional Office for Europe and European Observatory on Health Systems and Policies; 2008.

42. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycaemic control. *Diabetes Care*, 2002;25(7):1159-71.
43. Pincus T, Esther R, DeWalt DA, Callahan LF. Social conditions and self-management are more powerful determinants of health than access to care. *Annals of Internal Medicine*, 1998;129(5):406-411.
44. Diabetes Fonds. *Actuele cijfers over diabetes. Factsheet.* Oktober 2011. Accessible at: http://www.diabetesfonds.nl/sites/default/files/Cijfers%20over%20diabetes%20oktober%202011.pdf
45. Limperg K. *Rookprevalentie 2004-2008. Continu onderzoek rookgewoonten*. Amsterdam: TNS NIPO; 2009.
46. Lutgers HL, Gerrits EG, Sluiter WJ, Ubink-Veltmaat LJ, Landman GWD, Links TP, Gans ROB, Smit AJ, Bilo HJG. Life expectancy in a large cohort of type 2 diabetes patients treated in primary care (ZODIAC-10). *Plos One*, 2009;4(8):e6817.
47. Van Leest LATM, Koek HL, Van Trijp MJCA, Baan CA, Jacobs MAM, Bots ML, Verschuren WMM. Diabetes mellitus. In: Van Leest LATM, Koek HL, Van Trijp MJCA, Van Dis SJ, Peters RJG, Bots ML, Verschuren WMM. *Hart- en vaatziekten in Nederland 2005, cijfers over risicofactoren, ziekte, behandeling en sterfte.* Den Haag: Nederlandse Hart Stichting; 2005:33-59.
48. Voorham J, Denig P. Computerized extraction of information on the quality of diabetes from free text in electronic medical patient records of general practitioners. *Journal of the American Medical Informatics Association*, 2007;14(3):349-354.

Chapter 9
General discussion

INTRODUCTION

The aim of the research presented in this dissertation was to advance the science underlying disease management evaluation and, in so doing, to strengthen existing evidence on the impact of complex, population-wide disease management approaches implemented in actual health care settings in the Netherlands and abroad. This final chapter summarises the main findings from the individual studies, explores several methodological considerations for conducting 'real-world' disease management evaluation, and discusses the strengths and limitations of the applied study methods. Subsequently, the policy context in which findings should be viewed is explored. The chapter ends with recommendations for disease management policy, practice, and research.

GENERAL CONCLUSIONS

To ensure that the evaluations conducted in this research were based on adequate knowledge of the intervention under study, the first part of the dissertation (Chapters 2 through 4) provided an exploration of the concept disease management and reviewed existing evidence concerning its impact on the quality and outcomes of chronic care. In the second part (Chapters 5 through 8), we conducted realistic evaluations – using a mixture of quantitative and qualitative research methods – of the level of implementation and effects of (specific components) of disease management approaches in actual health care settings in Europe, with a particular focus on the Netherlands.

Exploring the concept and impact of disease management

Disease management constitutes an important and widespread innovation in the care for chronically ill patients, which has been conceptualised in vastly different ways over the past twenty years.[1] Early definitions range from 'discrete programmes directed at reducing costs and improving outcomes for patients with particular conditions'[2] to 'an approach to patient care that coordinates medical resources for patients across the entire delivery system'.[3] More recently, the Care Continuum Alliance (CCA), formerly known as the Disease Management Association of America (DMAA), defined disease management as 'a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant'.[4] This new conceptualisation explicitly adopts a broader view on chronic care, thus illustrating international efforts to move towards a more population-based approach to managing long-standing health problems, often based on the Chronic Care Model (CCM).[5] Where traditional disease management interventions

focus on improving the provision of care for specific conditions in distinct populations[6], the CCM targets comprehensive, interrelated changes in the behaviour of patients and providers (micro-level), the organisation of the care process (meso-level), and the design of the health system in which these elements come together (macro-level), which is viewed as part of a broader community.[5,7]

In line with the new, more comprehensive definition of disease management, the systematic review of the international literature presented in this dissertation focused explicitly on interventions comprising at least two of the four meso-level components of the CCM, which are self-management support, delivery system design, clinical information systems, and decision support.[5] The findings illustrated that disease management has been investigated extensively over the past years: we were able to include 15 systematic reviews and 61 empirical studies published between 1995 and 2011 concerning multicomponent interventions for adult patients with type 2 diabetes. Interventions concerned mostly small-scale pilot programmes, which differed considerably in terms of both the combination and operationalisation of care components, although strategies integrating all CCM elements were generally found to be the least common. This suggests that the CCM, which is inherently a disruptive health system innovation, is being implemented into health care practice in an incremental manner, which limits its potential for success in improving the quality and outcomes of chronic care.

Variation in the scope and content of chronic care programmes was also visible when comparing nationwide approaches implemented in Austria, Germany, and the Netherlands, which thus far tend to be fully disease-specific, although some pilot programmes are being conducted locally that address a wider spectrum of both disease-specific and generic health needs. While the main goal of introducing disease management in these three countries was to strengthen the coordination of care services, the strategies used to achieve this varied significantly, reflecting differences in the regulation, funding, and organisation of national health systems. For example, while in the Netherlands the introduction of disease management triggered considerable organisational reform in primary care, traditional structures were maintained in Austria and Germany. Differences between countries were also found with regard to the involvement of non-medical staff in disease management, approaches to incentivise implementation, and the level of participation by patients and providers.

By analysing the Dutch approach to disease management from the patient's perspective, we found that while this care strategy targets the 'right' areas for improvement – that is, those areas were Dutch persons with long-standing health problems report experiencing gaps in quality – further effort is needed to support the implementation of essential reform elements in practice. Notwithstanding differences between regions, thus far improving the coordination and evidence-based standardisation of care for non-complex cases of chronic disease appears to have been the main priority in the Netherlands; more work is

needed to develop adequate clinical information systems, increase patient participation, and reduce fragmentation in the care continuum for complex and multimorbid chronically ill patients. The latter two objectives are arguably more difficult to realise than what has been accomplished so far, as they require a fundamental culture shift in health care from a supply- to a demand-driven environment.[8]

With regard to disease management impact, prior evaluations of the approaches implemented in Austria, Germany, and the Netherlands show mixed (preliminary) results. Findings point towards improved quality of care, mainly in terms of coordination and evidence-based practice, yet fail to provide conclusive evidence of improved health outcomes and/or reduced costs.[9-11] Our systematic review demonstrated generally positive results of international disease management strategies for type 2 diabetes mellitus on care processes and clinical outcomes, yet identified considerable heterogeneity in effects across empirical trials, which was partially explained by differences in the number of care components that constitute a given disease management intervention. Conform the presumption of the CCM that changes are needed in multiple areas in order to considerably improve the quality of chronic care[12], comprehensive interventions – which were found to be least common internationally – attained the strongest effect estimates. Variation in length of follow-up also to some extent explained heterogeneity in effects on care processes and intermediate health outcomes: compared to studies of longer duration, trials with limited follow-up (<1 year) reported more promising, though perhaps overestimated, results. This pleads for evaluations focusing on a broader range of performance measures, including both short-term outcomes (e.g. patient-reported health measures, quality of life) and long-term outcomes (e.g. prevalence of micro- and macrovascular complications, mortality), which should be measured across sufficiently long observation periods in order to distinguish the sustained effects of disease management from mere temporal influences.[13]

Advancing disease management science and evidence

This research illustrated how routine health care data can be used to conduct rigorous and meaningful evaluations of the 'real-world' impact of disease management approaches implemented in actual health care settings in Europe. Across six country studies, which were conducted in Austria, Denmark, France, Germany, the Netherlands and Spain, a wide range of sophisticated quasi-experimental and observational analytic methods were tested and validated on available data from existing disease management approaches. By explicitly taking into account relevant data problems and potential sources of bias and confounding in disease management research, these methods produced sufficiently valid findings to support further quality efforts in chronic care practice, although results must be interpreted with caution in light of these limitations.

Specific evaluation methods were selected based on the nature and content of the disease management interventions under study. Thus, to assess the impact of the Dutch approach to disease management for type 2 diabetes mellitus – which can be characterised as a heterogeneous, multicomponent, population-wide intervention – we used multilevel regression methods to identify trends in health outcomes as a function of features of the approach and/or patient population. Most notably, findings suggested that: (1) patients with poorly controlled type 2 diabetes mellitus benefit most from disease management in terms of improved clinical outcomes; (2) a greater measurement frequency of clinical outcomes is associated with better results, particularly for patients with poor disease control; and (3) longer length of follow-up is accompanied by less positive effects. Although there are limits to the level of confidence that we can have in these findings, given the lack of an untreated comparison group and true baseline data, the identified trends in health outcomes were supported by (meta-analyses of) previous randomised research.[14-16] Moreover, a growing consensus that certain subpopulations of chronically ill patients offer greater opportunities for improving care quality and outcomes, including costs, can be recognised in the increased interest in prospective patient identification methods for chronic care management programmes.[17]

Based on a qualitative review of approaches in 13 countries, we found that self-management support – which is arguably the central but also most difficult to implement component of high-quality chronic care management – remains relatively underdeveloped in Europe, which supports our review-based observation that the implementation of the CCM in practice is incremental and far from complete. Self-management support activities were found to focus mainly on proper medication use and health-related behaviours, with limited attention to patients' emotional management. Across Europe, support services are offered mainly in primary care by nurses; differences prevail in the mode and format of support, and materials used. Our interviews with Dutch care providers suggested that barriers related to, amongst others, funding, information technology and medical culture hamper the integration of self-management support in daily chronic care practice.

METHODOLOGICAL CONSIDERATIONS

This section will address the most important methodological considerations for practice-based disease management evaluation, based on experience of work undertaken in this dissertation. Additionally, the strengths and weaknesses of the methods used are discussed, and potential sources of bias in the research findings are explored.

Selecting a study design for disease management evaluation

Given the need to improve quality of care and the limited resources available for health care provision, rigorous evaluations and sound evidence are crucial prerequisites for adequate decision-making on how to best care for the growing group of chronically ill patients.[18] Here, from a methodological viewpoint, it is important to distinguish between efficacy and effectiveness: whereas the former concept refers to the impact of an intervention under ideal circumstances, the latter denotes results under normal conditions in practice settings.[19] In the case of complex, population-wide health service interventions, such as disease management, which comprise multiple, interrelated care components, demonstrating effectiveness is inherently difficult. Design choice is influenced by inevitable trade-offs between scientific rigour and practical feasibility, and these determine the extent to which causal inferences can be derived about the impact of a given intervention on relevant performance measures.[20]

Our research has demonstrated how in practice situations where randomisation is not possible and/or desirable, due to the complex nature and widespread implementation of a given disease management strategy, quasi-experimental and observational study designs can be used to produce robust findings about intervention impact in daily health care practice. The most suitable approach in such a situation is to utilise a pre-post design with a control group matched for known differences.[21] The DISMEVAL country studies in, for example, Denmark, Germany and France showed that matched control groups can be constructed retrospectively on the basis of routine health care data using advanced analytic techniques, such as propensity score matching or calibration.

In cases such as the Netherlands, where sufficient numbers of control patients are no longer available and data collection is tied to the intervention, an uncontrolled pre-post design is the most robust research design possible for realistic evaluation.[20] While using such a design did not allow us to draw causal inferences, it provided opportunities to identify trends in the health outcomes of patients who receive disease management in the natural environment of health care. Notwithstanding the obvious methodological limitations of uncontrolled research, we argue that practice-based studies must constitute a crucial part of disease management evaluation; randomised controlled research is rightly regarded as the 'gold standard' in clinical decision-making but is never sufficient in itself when the aim is to assess the effectiveness of interventions with long, complex causal pathways that in reality can be affected by numerous characteristics of care processes, patients, and settings.[22] In such cases, randomised controlled trials (RCTs) can only determine efficacy and should be combined with realistic evaluations to produce meaningful findings concerning the effectiveness of disease management in actual health care settings.

Multilevel regression methods

Using both quantitative and qualitative study methods, we found that disease management is associated with vast amounts of heterogeneity, a conclusion that has also been drawn in previous studies and that has hampered synthesis of effect estimates in meta-analyses.[23] Interventions differ in terms of the combination and nature of care components offered, patients vary in demographics, disease severity, and socioeconomic status, amongst others, and care is provided in unlike contexts influenced by diverse regulations, funding mechanisms, and organisational cultures. Given this heterogeneity, evaluations focused on assessing 'grand mean' effects of disease management across large populations of patients produce unacceptably artificial results, which offer little guidance for day-to-day clinical practice where individual patients are treated.

To allow for a more granular assessment of the impact of the Dutch approach to disease management, we used multilevel regression methods, which enabled us to investigate trends in patients' health outcomes as a function of features of the intervention and/or target population. Using multivariable, two-level hierarchical regression models – with patients at level one and care groups at level two – we analysed the associations between health outcomes and a considerable number of covariates. Contrary to our a priori assumptions, variance in the effects of disease management on the care group level was virtually non-existent, while our interviews with health professionals suggested that some groups are considerably further than others in facilitating high-quality care provision through implementation of, for example, clinical information systems and adequate decision support. That no more than minor variation was identified in results between care groups might be due to the relatively limited sample size on this aggregate level (N=18). An alternative explanation could be that the effects of health system change on care processes and, ultimately, on outcomes require time to come about and our study was, in this sense, preliminary. It has been suggested that three to five years are needed for a given intervention to be fully implemented and for any individual level effect to become evident.[24,25]

On the patient level, vast amounts of heterogeneity were identified in the effects of the Dutch approach to type 2 diabetes management on health outcomes. Variation in intervention features, such as the frequency of clinical outcome measurements, could elucidate some of the existing variance in effects, yet the most explanatory covariates were those related to patients. Previous studies have confirmed this finding, which we believe stresses the need to tailor disease management provision to the needs and characteristics of relevant subgroups of patients.[14,23] Besides the level of diabetes control, which we found to be significantly associated with clinical outcomes, other relevant patient features might be socioeconomic status and education level, given their influence on people's self-management behaviour, which in turn is a powerful determinant of their health.[26]

Routine data and performance measures

The choice to retrospectively gather routine health care data for a 'real-world' evaluation of the Dutch disease management approach has several methodological consequences. Besides the obvious advantages – which include the opportunity to collect large numbers, assess relatively long-term effects within a narrow time frame, capture information on daily practice of health care provision and registration, and minimise the financial costs of data collection[27,28] – an important limitation is that the performance measures available to us inherently constituted an 'opportunity sample', the composition of which was determined mainly by the data sources used. The 18 Dutch care groups included in this research were able to provide data concerning intermediate clinical outcomes and, to a lesser extent, care processes. Patient-centered performance measures, such as quality of life, patient satisfaction, and patient-reported health outcomes, were not systematically assessed in most care groups nor did current data collection efforts – which are guided predominantly by regulations set by external agents, such as health care insurers and governmental agencies – support efforts towards population management based on patients' degree of health care need.[29] In general, what appeared to be lacking in routine chronic care practice in the Netherlands is a systems approach to service delivery and assessment, based firmly on continuous efforts to learn about and improve the influence of health care structures on the provision of recommended care processes, which subsequently affect the health, functional and social status of different patient groups, and, ultimately, the costs of care provision.

Besides offering a narrow view on quality of care, retrospectively collected routine data from clinical practice are innately less valid and reliable than data gathered prospectively and explicitly for research.[27] This is particularly true in the context of Dutch chronic care, where clinical information systems are used for multiple purposes, amongst which internal and external performance monitoring and provider reimbursement by health insurers. We subjected available data to systematic scrutiny to assess the magnitude and implications of missing and invalid values for the analysis and interpretation of findings. A lack of completeness was the major issue in the Dutch datasets; invalid outlier values were comparatively less prevalent. Across our 18 care groups, no more than two were able to provide data concerning the full spectrum of evaluated indicators. Within the data that could be provided, a considerable number of patients lacked (valid) registrations of one or more of the included variables. Alongside shortcomings in the quality of supporting information technology, an important reason for the observed lack of completeness of data available for our evaluation might be the relative inexperience of care groups in operating shared clinical information systems.

The fact that only a small set of analyses could be conducted on the basis of data from all groups and all patients likely introduced bias. While it is difficult to

assess the size of this bias, the research population did not differ systematically from other diabetes populations studied in the Netherlands on important variables, such as average age and disease duration, nor was the percentage of smokers different from that in the overall Dutch population.[11,30,31] However, the prevalence of four important co-occurring conditions associated with diabetes – that is, angina pectoris, stroke, myocardial infarction, and transient ischemic attack – was lower in our patient sample than would have been expected based on the characteristics of the total population of Dutch diabetes patients.[32] This might be attributable to registration problems but could also reflect the generic nature of the Dutch primary care-based disease management approach, in which complicated cases are managed primarily by medical specialists.

Length of observation

Another important consideration in evaluating disease management approaches relates to the timeframe for observation, which should be aligned with the goals of performance assessment.[21] Our systematic review illustrated that there is a tendency for studies of individual disease management strategies to be conducted over a period of 12 months or less. If the goal of evaluation is to determine the level of implementation of recommended care processes, then such a relatively short time frame might be sufficient.[1] However, if an evaluation aims to assess the impact of a specific approach on, for example, patients' health outcomes, then there is a strong need to allow for longer length of follow-up (>12 months). This is important for at least two reasons. First, when measuring the impact of disease management on intermediate health outcomes – which is the primary goal of most evaluations – then a sufficient length of follow-up is needed to distinguish temporal influences from sustainable effects.[24,33] Our research demonstrated that short term evaluations (<12 months) might overestimate effects on measures related to disease control, perhaps because the improvements in individuals' health behaviour that are necessary for adequate control are difficult to maintain over time.[34,35]

Second, sufficient length of follow-up is necessary to assess whether improvements in intermediate health outcomes, such as glycated haemoglobin (HbA1c) and systolic blood pressure (SBP), actually result in achievement of the long-term oriented goals of disease management, which include improving functional status, preventing complications, and, ultimately, reducing direct health care costs. Such 'hard' outcomes require time to come about, as illustrated by the German country study in DISMEVAL as well as by an unrelated Danish trial[36], both of which could not demonstrate effects on the prevalence of various types of diabetes-related complications within a time frame of three and six years respectively. The ten-year post-trial data from the landmark United Kingdom Prospective Diabetes Study (UKPDS) did establish that intensive glucose

therapy results in persistent risk reductions for microvascular disease, myocardial infarction, and all-cause mortality.[37] As chronic disease progression can involve the development of such serious long-term complications, it is critical to demonstrate whether disease management initiatives have lasting effects, which can only be evidenced by a longer period of evaluation.[38] A study duration of more than 12 months will also be important for assessing economic impact, since disease management may actually increase costs in the short term for some chronic diseases as a result of the investment required to implement such an intervention in the first place.[25] This will be especially true for evaluations in the area of diabetes, which has been a priority illness throughout the world when it comes to quality improvement efforts in health care.[39]

Mixed methods

Given that the implementation of disease management approaches is essentially a process of social change, which appears far from complete in most countries, simply measuring changes over time in relevant outcome measures cannot generate sufficient understanding to support decision-making in this area. Pawson and Tilley[40], the developers of realistic evaluation, and more recently Berwick[41], have argued that the outcomes of complex interventions are dependent not only on the introduction of appropriate mechanisms but also on whether existing contextual factors are fitting. A similar premise can be recognised in Donabedian's work on quality assurance in health care, who proposes that outcomes are produced by processes, which in turn are determined by structures.[42] Hence, there is a need for evaluations to move beyond the question of whether a specific disease management strategy 'works' towards establishing the conditions under which specific care processes are effective for particular populations of patients in different health care contexts.

Realistic evaluation requires the use of a mixed-methods approach – that is, a mixture of quantitative and qualitative study techniques – to allow numerical data concerning the processes and outcomes of disease management to be combined with qualitative information on contexts.[43] This dissertation combined quantitative data analyses with the use of diverse qualitative methods, specifically a document study (Chapter 2), an expert data template (Chapters 4 and 6), and semi-structured interviews (Chapter 6), to be able to assess not only the effects of different care processes on the clinical outcomes of (subgroups of) chronically ill patients but combine this with knowledge concerning the context and level of implementation of the Dutch approach to disease management for type 2 diabetes. Based on the additional insights gained from using a mixed-methods research design, we will be able to, at the end of this chapter, formulate detailed recommendations for policy and practice concerning which further efforts are needed to create the health care structure and process requirements necessary to adequately manage chronically conditions.

To limit the potential for bias in the qualitative research findings, purposive samples of respondents were selected both for the expert data template concerning chronic care management approaches in Europe and for the interviews with health care professionals in the Netherlands. Furthermore, the data template was completed according to an evidence-based comprehensive approach, with inputs based on available scientific and grey literature including government reports, policy statements, theses and dissertations, and research reports. The questionnaire for and analysis of the interviews with Dutch health care professionals involved in disease management for type 2 diabetes was also structured according to a validated instrument – that is, the CCM-related Assessing Chronic Illness Care (ACIC) survey[44] – so as to minimise the potential for subjective findings.

Validity and reliability of findings

According to Linden and Adams[45], selection bias and regression to the mean are the major sources of bias that can cloud the interpretation of disease management outcomes when using uncontrolled, pre-post evaluation techniques. Selection bias ensues when a sample does not accurately reflect the population from which it was drawn, which can lead to distorted research findings.[45] In the evaluation of the Dutch approach to disease management, selection bias occurred on the care group level, given that one of the main, pragmatic inclusion criteria for participation in the research was the availability of a digitalised dataset describing the processes and outcomes of diabetes care over a period of at least 20 months between January 2008 and December 2010. Hence, the care groups evaluated here represent what may be viewed as a convenience sample of 'early adopters' of disease management in the Netherlands.[46] A potential consequence could be that our qualitative findings concerning the level of implementation of disease management in the Dutch context, which suggest that patient-centered care is far from achieved, might to some extent even be exaggerative of the actual situation in the Netherlands. Although selection bias on the care group level may also have affected the quantitative findings concerning disease management effects, it is important to note that the patient sample drawn from the 18 groups, which represents approximately 10 percent of the total number of known type 2 diabetes patients in the Netherlands in 2012, did not differ significantly from other/larger populations on the majority of patient characteristics measured.[11,30,31] Moreover, the multilevel regression analysis identified nearly nil variation in patient outcomes existing on the care group level, despite there being differences between included groups in terms of the level of implementation of recommended care elements.

Regression to the mean is comparatively more likely to have influenced our quantitative research findings, especially given the lack of 'true' baseline data concerning the period prior to disease management implementation. Regression

to the mean is a statistical phenomenon that can lead researchers to mistakenly interpret change in specific measures over time as an effect of disease management, while it is actually natural variation.[45] Linden and Adams[13] have demonstrated that, without the effect of a disease management intervention, patients with high health care utilisation in the baseline year tend to use fewer services in the following year, and vice versa. Regression to the mean is a ubiquitous phenomenon in uncontrolled pre-post data and, as such, should always be considered as a possible cause of observed changes in outcome measures.[47] Our finding that poorly controlled diabetes patients achieved the strongest improvements in clinical outcomes after a median 12 months of (intensive) disease management might to some extent be a result of regression to the mean, although this is at least partially refuted by the small percentage of patients (17 percent for HbA1c) in the healthiest disease categories whose clinical values moved towards the mean, even despite the degenerative nature of type 2 diabetes.

Despite concerted efforts to create detailed and valid datasets, the use of advanced research methods, and adjustment for a relatively wide range of potential confounders, there ultimately are limits to the level of reliability one can attach to the findings from uncontrolled pre-post research. Hence, it is important to stress that our results are supported by those of previously conducted (randomised) controlled trials. A recently conducted meta-analysis of 41 RCTs of disease management interventions for type 2 diabetes confirms our identified trend in health outcomes suggesting that intensive management is most beneficial for patients with poor diabetes control.[14] The counterintuitive association found between length of follow-up and clinical outcomes has also be demonstrated in previous systematic reviews of the disease management literature, including the review presented in Chapter 3 of this dissertation.[14,16]

EXAMINING THE CONTEXT FOR RESEARCH IMPLICATIONS

With health care expenditures rising to unprecedented levels, achieving more effective and efficient care provision for the growing population of chronically ill is high on the policy agenda in the Netherlands. Over the past five years, an impressive body of grey literature has been published on developments in chronic care management by Dutch research institutes, governmental agencies, health insurers, professional groups, expert committees, and patient associations.[48] Without any pretence of being exhaustive, we believe it is important to summarise some of the key points in the ongoing debate on how best to redesign the care for chronic conditions in the Netherlands, as these constitute the background against which the implications of this dissertation for future directions in Dutch chronic care policy and practice should be viewed.

Scans of the current health care landscape in the Netherlands, which were conducted by the National Institute for Public Health and the Environment (RIVM) in 2010 and 2011, show that the implementation of bundled payments for generic disease management has triggered important improvements in the organisation of Dutch chronic care.[49,50] Within a relatively short time frame, a nationwide network of ambulatory care groups has been realised which have bundled payment contracts with health insurers for the provision of integrated care for type 2 diabetes and, to a lesser extent, COPD and vascular risks. Notwithstanding the importance of this development, there are inherent limitations and drawbacks to the current chronic care strategy in the Netherlands. Services are still provided in a predominantly disease-specific and supply-driven manner rather than on the basis of patient needs, as illustrated by the Health Care Inspectorate's (IGZ) observation that current type 2 diabetes management does not (yet) meet the level of patient-centeredness described in the care standard.[51] Moreover, regional differences aside, integration is generally limited to the non-complex services offered in primary care, which does not only complicate the coordination of care across sectors for the growing group of complex, multimorbid elderly patients but also fails to recognise the opportunities that cooperation with the broader community offers for health promotion and prevention, and self-management support.[52,53]

While conform international evidence[29], the primary care sector is rightfully considered the lead actor in Dutch chronic care, the general trend that can be recognised in contemporary policy recommendations is that service integration must reach beyond its boundaries to account for health needs that are better met in either the community or the secondary care sector. Thus, the Council for Public Health and Care (RVZ; [54]) and, more recently the NYFER Forum for Economic Research[52], proposed that the reigning health care paradigm in the Netherlands must shift from 'illness and treatment' towards 'health and behaviour', which requires: (1) a central role for patients in their social environment rather than for diseases; (2) a focus on health and quality of life, and the improvement thereof; (3) adequate coordination between care consumers, providers, and organisations; and (4) integration of prevention and health care provision. Similarly, the Committee on the Evaluation of Bundled Payment, which was assigned by the Dutch Ministry of Health, Welfare and Sports to monitor the implementation and effects of the bundled payment system, concluded that the current, disease-oriented payment method should be considered a 'work in progress' that needs to be developed further into a system that facilitates population health management based on individuals' degree of need.[53] This supposition was shared by the Advisory Group Integrated Care of the Dutch Society for General Practitioners (LHV). An exploration by the Dutch Health Care Authority (NZa; [55]) of the possible effects of different funding mechanisms for integrated care demonstrated the feasibility of population-based chronic care funding, which will be piloted in several regions in the Netherlands in 2013.

RECOMMENDATIONS

This final paragraph explores the implications of the dissertation for future directions in chronic care policy making, practice, and research. In so doing, the Expanded Chronic Care Model (ECCM; [56]) is used as a framework to structure recommendations. This model, which is depicted in Figure 1, expands the scope and depth of the community resources and policy-linkage components of the original CCM so as to incorporate aspects related to health promotion and prevention.[56]

Recommendations for policy and practice

Most notably, our research findings concerning the ´real-world' impact of the Dutch approach to structured disease management for type 2 diabetes suggest that improving the quality and outcomes of chronic care for the entire population of patients in the Netherlands will require a move from disease-oriented, standardised service delivery to more patient-centered, tailored care provision, including self-management support. By demonstrating that the current programmatic care strategy is beneficial mainly for a subgroup of non-complicated diabetes patients with poor disease control, the research provides quantitative data supporting recent policy recommendations to implement a more comprehensive population health management model, that takes into account the heterogeneous nature of the chronically ill and their, often multicomplex, health care demands.

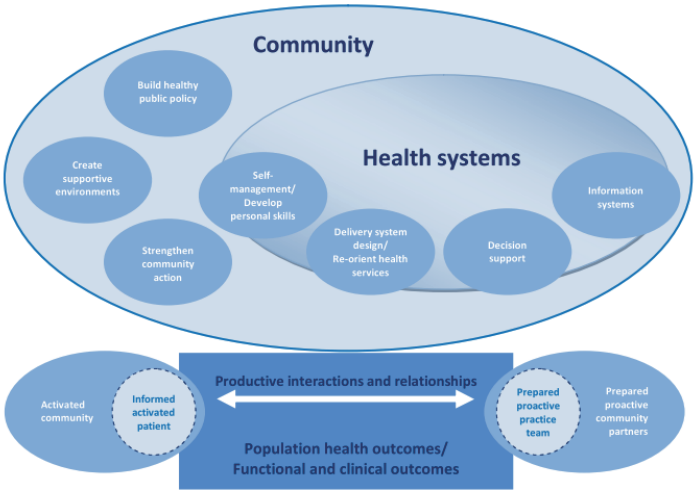

Figure 1: The Expanded Chronic Care Model [56]

Internationally as well, the importance of more tailored chronic care provision has been emphasised by systematic literature research and has spurred efforts to distinguish patient groups based on their degree of health care need. The well-known Kaiser Permanente population health management model, which is based on the CCM, divides chronically ill into: (1) patients with a relatively low level of need for health care (65-80%); (2) patients at increased risk because their condition is unstable (15-30%); and (3) highly complex patients (5%).[57,58] In line with the recommendations for targeted care strategies that follow from the Kaiser Permanente risk stratification pyramid, the latter category of patients, that is, those with complex forms of chronic disease[57], are actively managed by specialists in the Dutch health system. However, no distinction is made in the Netherlands between the first two categories of patients, who – based on the national care standard for type 2 diabetes management – currently receive an equal and highly standardised intensity of service provision in the primary care sector, regardless of their actual level of need. Based on this dissertation, we recommend that the existing, standard-driven Dutch disease management approach should be refocused from targeting the entire population of non-complex cases of type 2 diabetes towards actively pursuing only those patients at risk for deterioration. That is, those belonging in the second category of health needs defined by Kaiser Permanente, for whom the effectiveness of structured disease management was demonstrated in this practice-based evaluation as well as by previous randomised research.[14]

For patients with a relatively low level of health care need, our findings suggest that intensive disease management might be redundant. The benefit that these patients have from receiving programmatic, provider-driven care is limited to maintaining disease control, which studies have demonstrated could be achieved in an equally effective and probably considerably more efficient manner by adequate self-management support programmes that integrate primary care and community services.[59,60] If our research population is indeed an adequate reflection of the total Dutch (diabetes) population – which it appears to be in terms of average age, disease duration, clinical values, and smoking status – then restructuring health service provision according to patients' degree of need has the potential to significantly relieve the increasing pressure that chronic conditions place on the human and economic resources available to Dutch health care, since the vast majority of type 2 diabetes patients in the Netherlands will fall into the self-management support category.

However, considerable improvements will be necessary in the level of self-management support currently offered to chronically ill patients in the Netherlands – and across Europe more in general – in order to provide them with the information, (technological) tools, and confidence needed to adequately manage their health. Notwithstanding promising local initiatives to support chronically ill patients' self-management, for example by means of web-based education programmes[61] and motivational interviewing techniques[62], chronic care

provision generally remains largely supply-driven and based on paternalistic viewpoints concerning what is best for patients, rather than on productive interactions with actively involved patients aimed at creating solutions that fit their personal needs and circumstances. Explicit policymaking in the area of self-management support seems to be necessary to ensure not only that successful bottom-up innovations in this area are disseminated nationwide, but also to stimulate a more basic culture shift in health care from the supply-driven 'illness and treatment'-paradigm, as formulated by the Dutch Council for Public Health and Care (RVZ; [54]), towards a patient-centered 'health and behaviour'-model. While this research focused on self-management support offered following the diagnosis of chronic disease, the aim of which is to avoid or at least postpone further deterioration, it is important to emphasise that more attention to population-wide prevention, which is a vital element of the Kaiser Permanente pyramid[57], will be crucial to curb the growing epidemic of lifestyle-related, long-standing health problems in the Netherlands. Recent developments in this area – such as the introduction of the so-called 'prevention consultation', which aims to detect patients at risk for developing cardiometabolic disorders early and discuss their lifestyle behaviours[63] – should be viewed as promising, in the sense that they illustrate an increasing appreciation of the social determinants of health. However, the true challenge for the Dutch health system lies in acknowledging the modest role it plays in determining the health status of the population and recognising the potential for reducing chronic disease prevalence that can be achieved by active cooperation with community-based health services.[56]

Developing a chronic care management approach in which patients truly play a central role, with service delivery based on their degree of health care need, will require a supportive health system environment, for which we can formulate several recommendations based on this dissertation. First, the existing bundled payment system, which integrates almost exclusively the services for specific chronic conditions that can be delivered in primary care, will need to be reconfigured so as to stimulate cooperation and coordination across the entire spectrum of care and support available to the chronically ill. This will be especially important to increase the quality and safety of care for the growing group of multimorbid elderly patients, who are at risk for adverse events due to existing fragmentation of care across different conditions as well as between primary and secondary care settings.[64] However, by, for example, incentivising collaboration between ambulatory care groups and community-based health services, such as tobacco use prevention and smoking cessation programmes, population-based chronic care funding could also be a vital means to achieving more adequate self-management support for those with a low level of health care need.[56] Second, current performance indicators, which are stipulated mainly by health insurers and prescribe, amongst others, the number of check-ups that should be conducted per patient per year, are at odds with a system of

health care delivery that centralises patients in their social environment. Notwithstanding the significance of standardising care according to evidence-based guidelines, there must be room for deviations from protocol there where either characteristics of patients or their social context necessitate tailored, effective solutions.

Third, the ubiquitous nature of missing values in the datasets provided by care groups participating in this research implies that improvements are necessary in data registration. While lacking and invalid data can be attributed in part to deficiencies in existing clinical information systems, which need to be developed further in order to meet the information needs of health care professionals, there also appears to be a general inexperience in and perhaps even adversity towards comprehensive data registration in health care, which is often considered an administrative burden rather than a vital aspect of high-quality chronic care provision. A combination of stronger reinforcement policies and bottom-up efforts by health professionals to develop a meaningful set of quality and outcome indicators for chronic care evaluation is needed to stimulate more adequate data registration, which facilitates not only population health management based on accurate patient information, but is also a vital prerequisite for multidisciplinary cooperation across the considerable number of different health care disciplines and settings involved in patient-centered chronic care management.[27] Here, an important starting point might be to increase the level of attention payed to health care quality assurance and improvement models, including the value of data management, in the education of medical professionals.

In conclusion, the findings from this dissertation imply that creating a balance between standardisation and individualisation in chronic care provision, including self-management support, is a complicated yet crucial next step in the process of improving the quality and outcomes of care for people with long-standing health problems. What is needed is a systems approach to comprehensive chronic care redesign, which, based on available evidence concerning 'what works best for whom and under which circumstances', actively seeks to create the structures that facilitate high-quality, patient-centered health management for the entire population of chronically ill. This must be combined with increased attention for health promotion and prevention of chronic conditions, so as to enable not only improvements in population health and functional status, but also reduce or at least control the rising level of health care expenditures associated with chronic disease.

Recommendations for future research

Based on this dissertation, several recommendations can also be formulated for future research in the area of chronic care management. While we acknowledge that the RCT is the most robust approach to clinical evaluation, gaining insight

into the effects of complex, multicomponent care strategies, such as disease management, in their natural environment will require moving beyond the current undue reliance on randomisation.[19,66] What is needed is a comprehensive approach to realistic, practice-based evaluation that aims to bridge the gap between the scientific rigour of experimental designs and the operational feasibility of observational research, and that is based on adequate knowledge of the (interrelated) components that constitute a given intervention, the contextual factors influencing success, and the characteristics of the population targeted. Such an approach necessitates the use of mixed-methods research, in which quantitative data concerning patients, treatments, and outcomes are combined with qualitative information on contexts.[40,41]

Where possible, practice-based evaluations of disease management effectiveness should be conducted in a controlled fashion, using advanced matching techniques such as propensity score matching or calibration[1], so as to minimise the influence of potential confounding factors on studied outcomes. While such an approach cannot control for the possible impact of unobserved external factors on measured effects, it has been proposed that even randomisation is unlikely to successfully control for the large number of factors and interactions on different levels that might influence the outcomes of complex health service innovations, such as disease management.[22] Hence, it will be important for any evaluation, regardless of study design, to understand and explore in detail the nature and sources of potential bias in disease management effects, as well as to conduct sensitivity analysis as a means to assess the level of 'hidden bias' caused by unobserved differences in the populations under study.[1] When evaluation data are retrieved retrospectively from routine practice, systematic cleaning and validation of performance measures constitutes a crucial first step towards producing robust findings concerning the impact of disease management in the actual context of health care.

This research introduced multilevel regression methods as useful techniques for meaningful analysis of patient data in practice-based disease management evaluation. Most studies of chronic care strategies, whether RCTs or observational studies, focus on measuring a single treatment effect across many patients, which offers little guidance for the day-to-day practice of chronic care provision, where heterogeneity is highly prevalent and an important determinant of treatment success. Multilevel regression techniques allow researchers to capitalise on existing variation in chronic care: by enabling differences in outcomes to be identified as a function of features of the intervention and/or patient population, these methods can provide detailed support to those involved in creating effective and efficient disease management strategies. In future practice-based research, the characteristics to be investigated as potentially relevant for the impact of disease management should go beyond those included in our study. Particularly, we recommend that more research is conducted into the influence of sociodemographic patient features, such as level of education and

socioeconomic status, on the potential for success of different approaches to disease management, so as to inform efforts to tailor the intensity of care delivery to patients' self-management capabilities.

The spectrum of outcomes used in disease management evaluation should be broadened as well, from focusing primarily on intermediate health outcomes related to disease control towards a comprehensive sample of performance measures that match the system-level goals of this care strategy. This implies that variables should be analysed related to care structures and quality (e.g. the degree of recommended care), patient-centeredness (e.g. quality of life, patient satisfaction), health and functional status (e.g. disease control, morbidity, mortality), and health care utilisation and costs. In assessing the effects of disease management on such an inclusive array of performance measures, this research demonstrated that adequate length of observation is crucial. Achieving better quality and outcomes of chronic care, including costs, is a complex process that implies interrelated changes on multiple levels of the health system and broader community, in the culture of health service delivery, and the level of participation and self-care behaviour of patients. Evaluations must acknowledge this complexity by allowing sufficient time for intended effects to come about. While it is not known what period is 'optimal' to ensure measurement of sustainable effects[18], our findings suggest that studies with a length of follow-up of less than 12 months likely yield overestimated findings.

To conclude, there is as much need for diversification in the evaluation of disease management as there is in the application of the care concept itself, in order to produce a robust and meaningful body of evidence supporting effective improvements in the structures, processes, and outcomes of care for the chronically ill. Rigorous randomised controlled studies are useful to determine the efficacy of specific approaches, but must be complemented by robust practice-based evaluations demonstrating effectiveness in actual health care settings. Although the usefulness of specific methods will depend largely on the context of evaluation, ultimately what is needed is a clear framework underlying each disease management evaluation that draws on an understanding of the mechanisms producing intervention effects, allows for sufficient time for sustainable effects to become apparent, and – perhaps most importantly – acknowledges that producing 'grand means' across large populations of patients is incompatible with the goals of patient-centered chronic care management. In this sense, stimulating differentiated performance measurement in chronic care research might very well be the first step towards implementation of effective population management in daily health care practice.

REFERENCES

1. Nolte E, Conklin A, Adams JL, Brunn M, Cadier B, Chevreul K, Durand-Zaleski I, Elissen A, Erler A, Flamm M, Frølich A, Fullerton B, Jacobsen R, Knai C, Krohn R, Pöhlmann B, Saz Parkinson Z, Sarria Santamera A, Sönnichsen A, Vrijhoef H. *Evaluating chronic disease management. Recommendations for funders and users.* Cambridge: RAND Europe; 2012.
2. Rothman A, Wagner E. Chronic illness management: what is the role of primary care? *Annals of Internal Medicine*, 2003;138:256-61.
3. Ellrodt G, Cook D, Lee J, Cho M, Hunt D, Weingarten S. Evidence-based disease management. *Journal of the American Medical Association*, 1997;278:1687-92.
4. Care Continuum Alliance. *Care Continuum Alliance (CCA) definition of disease management.* Retrieved, 25 July 2012, from: http://www.carecontinuumalliance.org/dm_definition.asp
5. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Effective clinical practice*, 1998;1(1):2-4.
6. Geyman J. Disease management: panacea, another false hope, or something in between? *Annals of Family Medicine*, 2007;5:257-60.
7. Coleman K, Mattke S, Perrault PJ, Wagner EH. Untangling practice redesign from disease management: how to we best care for the chronically ill? *Annual Review of Public Health*, 2009;30:385-408.
8. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs*, 2001;20(6):64-78.
9. Sönnichsen AC, Winkler H, Flamm M, Panisch S, Kowatsch P, Klima G, Fürthauer B, Weitgasser R. The effectiveness of the Austrian disease management programme for type 2 diabetes: a clustered randomized trial. *BMC Family Practice*, 2010;11:86.
10. Berthold HK, Bestehorn KP, Jannowitz C, Krone W, Gouni-Berthold I. Disease management programs in type 2 diabetes: quality of care. *American Journal of Managed Care*, 2011;17(6):393-403.
11. Struijs JN, De Jong-Van Til JT, Lemmens LC, Drewes HW, De Bruin SR, Baan CA. *Bundled payments of diabetes care: effects on care delivery process and quality of care at three-year follow-up.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2012.
12. Renders CM, Valk GD, Griffin SJ, Wagner EH, Van Eijk JT, Assendelft WJJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. A systematic review. *Diabetes Care*, 2001;24:1821-33.
13. Linden A, Adams J, Roberts N. Evaluating disease management program effectiveness: an introduction to time-series analysis. *Disease Management*, 2003;6:243-55.
14. Pimouguet C, Le Goff M, Thiébaut R, Dartigues JF, Helmer C. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Canadian Medical Association Journal*, 2011;183(2):E115-27.
15. Gary TL, Batts-Turner M, Yeh HC. The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial. *Archives of Internal Medicine*, 2009;169:1788-94.
16. Elissen AMJ, Steuten LMG, Lemmens LC, Drewes HW, Lemmens KMM, Meeuwissen JAC, Baan CA, Vrijhoef HJM. Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes. *Journal of Evaluation in Clinical Practice*, 2012 [epub ahead of print].
17. Freund T, Mahler C, Erler A, Gensichen J, Ose D, Szecsenyi J, Peters-Klimm F. Identification of patients likely to benefit from care management programmes. *American Journal of Managed Care*, 2011;17(5):345-52.
18. Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? *American Journal of Managed Care*, 2007;13:670–76.
19. Victora CG, Habicht J, Bryce J. Evidence-based public health: moving beyond randomized trials. *Public Health Matters*, 2004;94(3):400-405.

20. Mattke S, Bergamo S, Balakrishnan A, Martino S, Vakkur N. *Measuring and reporting the performance of disease management programs.* Santa Monica, CA: RAND Corporation; 2006.
21. Conklin A, Nolte E. *Disease management evaluation. A comprehensive review of the current state of the art.* Cambridge: RAND Europe; 2010.
22. English M, Schellenberg J, Todd J. Assessing health system interventions: key points when considering the value of randomization. *Bulletin of the World Health Organization*, 2011;89:907-12
23. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK. Effects of quality improvement strategies for type 2 diabetes: a meta-regression analysis. *Journal of the American Medical Association*, 2006;296(4):427-40.
24. Linden A, Adams J, Roberts N. *Evaluation methods in disease management: determining program effectiveness.* Retrieved, 30 September 2012, from: http://www.lindenconsulting.org/Papers/White%20Paper%20-%20Final.pdf
25. Serxner S, Baker K, Gold D. Guidelines for analysis of economic return from health management programs. *American Journal of Health Promotion,* 2006;20(Suppl):1-17.
26. Pincus T, Esther R, DeWalt DA, Callahan LF. Social conditions and self-management are more powerful determinants of health than access to care. *Annals of Internal Medicine*, 1998:129(5):406-11.
27. Smith PC, Mossialos E, Papanicolas I, Leatherman S. *Performance measurement for health system improvement. Experiences, challenges and prospects.* Cambridge: Cambridge University Press; 2009.
28. Nolte E. *International benchmarking of healthcare quality. A review of the literature*. Cambridge: Rand Europe; 2010.
29. Bodenheimer T, Wagner E, Grumbach K. Improving primary care for patients with chronic illness. *Journal of the American Medical Association*, 2002;288:1775-79.
30. Limperg K. *Rookprevalentie 2004-2008. Continu onderzoek rookgewoonten*. Amsterdam: TNS NIPO; 2009
31. Lutgers HL, Gerrits EG, Sluiter WJ, Ubink-Veltmaat LJ, Landman GWD, Links TP, Gans ROB, Smit AJ, Bilo HJG. Life expectancy in a large cohort of type 2 diabetes patients treated in primary care (ZODIAC-10). *Plos One,* 2009;4(8):e6817.
32. Van Leest LATM, Koek HL, Van Trijp MJCA, Baan CA, Jacobs MAM, Bots ML, Verschuren WMM. *Diabetes mellitus*. In: Van Leest LATM, Koek HL, Van Trijp MJCA, Van Dis SJ, Peters RJG, Bots ML, Verschuren WMM. *Hart- en vaatziekten in Nederland 2005, cijfers over risicofactoren, ziekte, behandeling en sterfte*. Den Haag: Nederlandse Hart Stichting; 2005:33-59.
33. Bailie RS, Robinson G, Kondalsamy-Chennakesavan SN, Halpin S, Wang Z. Investigating the sustainability of outcomes in a chronic disease treatment programme. *Social Science & Medicine*, 2006;63:1661-70.
34. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycaemic control. *Diabetes Care*, 2002;25(7):1159-71.
35. Wheeler ML, Wyle-Rosett J, Pichert JW. Diabetes education research. *Diabetes Care*, 2001;24:421-422.
36. Olivarius NF, Beck-Nielsen H, Andreasen AH, Hørder M, Pedersen PA. Randomised controlled trial of structured personal care of type 2 diabetes mellitus. *British Medical Journal*, 2001;323:970-75.
37. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAWN. 10-year follow-up of intensive glucose control in type 2 diabetes. *New England Journal of Medicine*, 2008;359:1577-89.
38. Loveman E, Cave C, Green C, Royle P, Dunn N, Waugh N. The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation. *Health Technology Assessment*, 2003;7(22):1-190.
39. Nolte E, Knai C, Hofmarcher M, Conklin A, Erler A, Elissen A, Flamm M, Fullerton B, Sönnichsen A, Vrijhoef H. Overcoming fragmentation in health care: chronic care in Austria, Germany and the Netherlands. *Health Economics, Policy and Law*, 2010;7:125-46.

40. Pawson R, Tilley N. *Realistic evaluation*. London: Sage Publications; 1997.
41. Berwick DM. The science of improvement. *Journal of the American Medical Association*, 2008;299(10):1182-84.
42. Donabedian A. *An introduction to quality assurance in health care*. Oxford: Oxford University Press; 2003.
43. Cretin S, Shortell SM, Keeler EB. An evaluation of collaborative interventions to improve chronic illness care: framework and study design. *Evaluation Review*, 2004;28(1):28–51.
44. Bonomi AE, Wagner EH, Glasgow RE, VonKorff M. Assessment of Chronic Illness Care (ACIC): a practical tool to measure quality improvement. *Health Services Research*, 2002;37:791-820
45. Linden A, Adams JL, Roberts N. Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design. *Journal of Evaluation in Clinical Practice*, 2006;12(2):124-131.
46. Rogers E. *The diffusion of innovations*. New York, NY: The Free Press; 2003.
47. Barnett AG, Van der Pols JC, Dobson A. Regression to the mean: what it is and how to deal with it. *International Journal of Epidemiology*, 2005;34(1):215-20.
48. Lemmens LC, De Jong-Van Til JT, Baan CA, Struijs JN. *Onderzoek op het gebied van integrale bekostiging. Een inventarisatie in opdracht van de Evaluatiecommissie Integrale Bekostiging*. Bilthoven: National Institute for Public Health and the Environment (RIVM); 2012.
49. Til van JT, Wildt de JE, Struijs JN. *De organisatie van zorggroepen anno 2010: huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2010.
50. De Jong-Van Til JT, Lemmens LC, Baan CA, Struijs JN. *De organisatie van zorggroepen anno 2011. Huidige stand van zaken en de ontwikkelingen in de afgelopen jaren.* Bilthoven: National Institute for Public Health and the Environment (RIVM); 2012.
51. Inspectie voor de Gezondheidszorg (IGZ). *Implementatie zorgstandaard diabetes na vier jaar onvoldoende gevorderd. Meer bestuurskracht nodig van zorggroepen*. Den Haag: Inspectie voor de Gezondheidszorg; 2012.
52. Berenschot L, Van der Geest L. *Integrale zorg in de buurt*. Utrecht: NYFER; 2012.
53. De Bakker D, Raams J, Schut E, Vrijhoef H, De Wildt J. *Integrale bekostiging van zorg: werk in uitvoering. Eindrapport van de Evaluatiecommissie Integrale Bekostiging.* Den Haag: Netherlands Organisation for Health Research and Development (ZonMw); 2012.
54. Raad voor de Volksgezondheid en Zorg. *Zorg voor je gezondheid! Gedrag en gezondheid: de nieuwe ordening.* Den Haag: Raad voor de Volksgezondheid en Zorg (RVZ); 2010.
55. Nederlandse Zorgautoriteit. *Advies bekostiging huisartsenzorg en geïntegreerde zorg. Verkenning van vier opties.* Utrecht: Nederlandse Zorgautoriteit (NZa); 2012.
56. Barr VJ, Robinson S, Marin-Link B, Underhill L, Dotts A, Ravensdale D, Salivaras S. The Expanded Chronic Care Model: an integration of concepts and strategies from population health promotion and the Chronic Care Model. *Hospital Quarterly*, 2003;7(1):73-82.
57. Singh D, Ham C. *Improving care for people with long-term conditions. A review of UK and international frameworks*. Birmingham: University of Birmingham and NHS Institute for Innovation and Improvement; 2006.
58. Nolte E, McKee M. *Integration and chronic care: a review*. In: Nolte E, McKee M (eds). *Caring for people with chronic conditions. A health system perspective*. New York, NY: Open University Press; 2008
59. Lorig KR, Holman HR. Self-management education: history, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine*, 2003;26(1):1-7.
60. Kennedy A, Reeves D, Bower P, Lee V, Middleton E, Richardson G, Gardner C, Gately C, Rogers A. The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial. *Journal of Epidemiology and Community Health*, 2007;61(3):254-261.
61. Heinrich E, De Nooijer JM, Schaper NC, Schoonus-Spit MH, Janssen MA, De Vries NK. Evaluation of the web-based Diabetes Interactive Education Programme (DIEP) for patients with type 2 diabetes. *Patient Education and Counseling*, 2012;86(2):172-178.

62. Heinrich E, Candel MJ, Schaper NC, De Vries NK. Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care. *Diabetes Research and Clinical Practice*, 2010;90(3):270-278.
63. Noordman J, Verhaak P, Van Dulmen S. Discussing patient's lifestyle choices in the consulting room: analysis of GP-patient consultations between 1975 and 2008. *BMC Family Practice*, 2010;11:87.
64. Schoen C, Osborn R, How SKH, Doty MM, Peugh J. In chronic condition: experiences of patients with complex health care needs, in eight countries, 2008. *Health Affairs*, 2009;28(1):w1-w16.
65. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and evaluating complex interventions: new guidance.* London: Medical Research Council; 2008.
66. Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *International Journal of Epidemiology*, 1999;28:10-18.

Chapter 10

Summary
Samenvatting
List of acronyms and abbreviations
Dankwoord
Curriculum vitae
Publication list

SUMMARY

The purpose of this dissertation was to advance current methods for evaluation of the 'real-world' effects of complex disease management approaches implemented in actual health care settings on the quality and outcomes of care for people with chronic conditions. In so doing, the research aimed to improve the evidence underlying disease management and support policymakers and professionals in their efforts to successfully redesign the care for long-standing health problems. Because robust evaluation requires adequate knowledge of the nature, scope, and context of the intervention under study, Chapters 2 through 4 provided a detailed exploration of disease management approaches for chronic conditions implemented in the Netherlands and internationally. In the remaining chapters, that is, Chapters 5 through 8, diverse realistic evaluation methods were applied to a combination of qualitative and quantitative data gathered from existing disease management approaches in various European health care systems.

Chapter 2 analysed the current Dutch approach to disease management, which started with experiments in the area of type 2 diabetes care in 2007 and is based on a bundled payment system covering the full range of care standard-driven services for non-complex cases of specific chronic diseases. By comparing the goals of Dutch chronic care reform with the gaps in quality perceived by chronically ill patients – as indicated by the scores attained by the Netherlands on the 2008 Commonwealth Fund International Health Policy survey of sicker adults – we assessed the level of patient-centeredness of the disease management approach implemented in the Netherlands. Findings demonstrated that while important improvements have been attained in Dutch chronic care, especially with regard to the level of evidence-based care provision and coordination in primary care, further steps are necessary to meet the complex care needs of patients with long-standing health problems. Specifically, more effort is needed to develop adequate clinical information systems, increase patient participation, and reduce fragmentation in the care continuum for complex and multimorbid chronically ill patients.

Chapter 3 reviewed the international literature on disease management interventions for type 2 diabetes published between 1995 and 2011. In line with the Care Continuum Alliance's new, broader definition of disease management, the review included interventions comprising at least two of the four meso-level components of the Chronic Care Model, which are self-management support, delivery system design, clinical information systems, and decision support. Considerable variation was identified in terms of the combination and operationalisation of these four care components in the reviewed disease management

interventions, although programmes targeting improvements in all four elements were found to be least common internationally. The measured effects of interventions on the processes and outcomes of type 2 diabetes care were generally positive, yet considerable heterogeneity in effects existed between trials. This variance in outcomes was partially explained by differences in the number of care components that constitute a given disease management intervention, with comprehensive programmes attaining the strongest effect estimates. Variation in length of follow-up also to some extent explained heterogeneity in effects: trials with limited follow-up (<1 year) reported more promising, though possibly overestimated, effects on care processes and clinical outcomes than studies of longer duration.

Chapter 4 traced the evolution of chronic care management in Austria, Germany and the Netherlands, all of which are health systems principally financed from statutory health insurance. Although in response to the problem of fragmentation in chronic care delivery, a predominant model of care in the form of structured disease management has emerged in all three countries, specific reform efforts vary, reflecting differences in the regulation, funding, and organisation of national health systems. Amongst others, differences exist in the extent of organisational reform introduced in primary care, the level of involvement of non-medical staff in disease management, the approaches used to incentivise implementation, and the extent of participation by patients and providers. Existing evidence on the impact of the approaches to disease management implemented in Austria, Germany and the Netherlands remains uncertain: (preliminary) evaluation results have pointed towards improved quality of care, mainly in terms of coordination and standardisation, yet fail to provide conclusive proof of improved health outcomes and/or reduced costs.

Chapter 5 aimed to assess the differentiated effects of the population-wide disease management approach for type 2 diabetes implemented in the Netherlands on four intermediate clinical outcomes, that is, glycated haemoglobin, low-density lipoprotein, systolic blood pressure, and body mass index. For this purpose, patient data (N=105,056) covering a period from 20 to 24 months between January, 2008 and December, 2010 were collected from 18 Dutch care groups, which are provider networks based in primary care with a bundled payment contract for the delivery of type 2 diabetes management. Using multilevel regression methods – that is, meta-analysis and meta-regression – we found that while average changes over time in the included outcomes were small, clinically relevant improvements were achieved in patients with poor initial health values. Greater measurement frequency of clinical outcomes was also associated with more promising improvements in these outcomes, especially in patients with poor diabetes control. A longer length of follow-up was accompanied by diminishing positive effects. Based on these findings, we con-

cluded that tailored disease management, in which not only evidence-based guidelines but also patient characteristics and health care needs determine care processes, including self-management support, has great potential to improve the cost-effectiveness of current chronic care delivery in the Netherlands.

In **Chapter 6**, we explored whether and how self-management support – which is arguably the central component of effective chronic care – is integrated into existing chronic care management approaches in 13 European countries. Moreover, this chapter investigated the level of and barriers to implementation of support strategies in actual health care practice. Based on the findings from a structured expert review among the participating countries, we concluded that self-management support for chronically ill patients remains relatively underdeveloped in Europe. Similarities between countries exist mostly in involved providers (nurses) and settings (primary care). Differences prevail in the mode and format of support, and materials used. Support activities focus primarily on patients' medical and behavioural management, and less on emotional management. According to the results of a series of 27 interviews with Dutch health care providers involved in disease management for type 2 diabetes, it was concluded that self-management support is not (yet) an integral part of daily practice in the Netherlands and that implementation is hampered by barriers related to, amongst others, funding, information technology, and medical culture. Improving the health and social outcomes of the chronically ill will require a better understanding of how we can encourage both patients and health care providers to engage in productive interactions in everyday chronic care practice.

Building on country studies in Austria, Denmark, France, Germany, the Netherlands, and Spain, **Chapter 7** illustrated how routine health care data can be used to conduct rigorous and meaningful evaluations of disease management impact in the actual context of health systems. As part of the European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project, research teams in each of these countries tested and validated advanced evaluation methods, such as difference-in-differences analysis, regression discontinuity analysis, and multilevel modeling, on data from existing disease management strategies, which were retrieved mostly retrospectively from health care providers and/or statutory insurance funds. Using routine data offered large numbers (~154,000 patients with three conditions), enabled long-term follow-up (10 to 36 months), allowed for retrospective creation of control groups, and provided baseline data. A disadvantage was that routine measures can be too narrow to adequately reflect quality of care, as they tend to focus mainly on intermediate health outcomes, and, to a lesser extent, care processes. By explicitly taking into account relevant data problems and potential sources of bias and confounding in practice-based disease management research, the applied methods produced sufficiently valid

findings to support further quality efforts in chronic care, although results must be interpreted with caution in light of these limitations. Most notably, findings pointed towards significant positive effects of disease management on process quality (Austria, Germany), yet no more than clinically moderate improvements in intermediate health outcomes (Austria, France, Netherlands, Spain) or pace of disease progression (Denmark) in intervention patients, where possible compared to a matched control group.

Chapter 8 introduced multilevel regression methods as valuable techniques to evaluate 'real-world' disease management approaches in a manner that produces robust and meaningful findings for everyday practice. In a worked example, these methods were applied to retrospectively gathered routine health care data covering 105,056 diabetes patients who received disease management for type 2 diabetes mellitus in the Netherlands. Multivariable, multilevel regression models were fit to identify trends in the clinical outcomes of patients as a function of components of the intervention offered (measurement frequency and range, length of follow-up) and/or characteristics of the target population (age, disease duration, baseline health, comorbidity, smoking status). Use of multilevel regression techniques enabled concerted efforts to adjust for potential sources of confounding and bias in practice-based research and produced quantitative evidence supporting current efforts to tailor chronic care provision to patients' characteristics and degree of health care need. Although the identified trends in disease management outcomes were confirmed by previous randomised research, there ultimately are limits to the validity and reliability of findings from uncontrolled research based on routine intervention data. Further practice-based research is necessary to confirm results and learn more about the impact of population-wide disease management strategies on the quality and outcomes of chronic care.

SAMENVATTING

Dit proefschrift had tot doel het verbeteren van de huidige methoden voor evaluatie van de effecten van complexe disease management strategieën, geïmplementeerd in de dagelijkse zorgpraktijk, op de kwaliteit en uitkomsten van zorg voor mensen met chronische aandoeningen. Daarmee tracht het onderzoek het bestaande bewijs voor disease management uit te bouwen alsook beleidsmakers en zorgverleners te ondersteunen bij hun inspanningen om de zorg voor langdurige gezondheidsproblemen succesvol te hervormen. Omdat adequaat inzicht in de aard, omvang en context van een interventie een noodzakelijke voorwaarde is voor robuuste evaluatie, exploreerden Hoofdstukken 2 tot en met 4 op gedetailleerde wijze een selectie van disease management strategieën voor chronische aandoeningen, die worden toegepast in Nederland alsook in het buitenland. In de resterende hoofdstukken, te weten Hoofdstukken 5 tot en met 8, werden diverse realistische evaluatiemethoden toegepast op een combinatie van kwalitatieve en kwantitatieve data met betrekking tot bestaande disease management aanpakken in verschillende Europese zorgsystemen.

Hoofdstuk 2 analyseerde de huidige Nederlandse disease management aanpak voor chronische aandoeningen. De eerste experimenten met deze zorgbenadering startten in 2007 en richtten zich specifiek op verbetering van de kwaliteit van zorg voor diabetespatiënten in de eerste lijn, door middel van invoering van integrale financiering van gestandaardiseerde, non-complexe diabeteszorg op basis van keten-DBCs. Om de mate van patiëntgerichtheid van de Nederlandse disease management aanpak te bepalen, werden de doelen van deze zorghervorming vergeleken met de tekortkomingen in kwaliteit van zorg zoals waargenomen door chronisch zieke patiënten in Nederland. Daartoe werden de scores gebruikt van Nederlandse patiënten op de Commonwealth Fund International Health Policy survey uit 2008. De bevindingen toonden aan dat hoewel belangrijke verbeteringen zijn bereikt in de Nederlandse chronische zorg, met name in de standaardisatie en coördinatie van diensten binnen de eerste lijn, verdere stappen noodzakelijk zijn om tegemoet te kunnen komen aan de complexe zorgbehoeften van patiënten met langdurige gezondheidsproblemen. Verdere inspanningen zijn vooral nodig om ontwikkeling van adequate klinische informatiesystemen te stimuleren, om participatie van patiënten in hun zorg te bevorderen en om fragmentatie te reduceren binnen het continuüm van zorg voor patiënten met gecompliceerde en meervoudige aandoeningen.

In **Hoofdstuk 3** werden de resultaten gepresenteerd van een review van de internationale literatuur betreffende disease management interventies voor type 2 diabetes, gepubliceerd tussen 1995 en 2011. Conform de nieuwe, uitgebreidere definitie van disease management door de Care Continuum Alliance,

includeerde de review interventies bestaande uit minimaal twee van de vier componenten van het Chronic Care Model op mesoniveau, te weten zelfmanagement ondersteuning, zorgorganisatie, klinische informatiesystemen en beslis-kundige ondersteuning. Hoewel de combinatie en operationalisering van deze componenten binnen de gereviewde disease management interventies aanzienlijk verschilden, waren programma's die verbetering nastreefden in alle vier de zorgelementen het minst vaak voorkomend. De gemeten effecten van de interventies op de processen en uitkomsten van type 2 diabeteszorg waren over het algemeen positief, maar verschilden sterk qua richting en omvang tussen studies. Variatie in het aantal zorgcomponenten per studie kon deze heterogeniteit in resultaten deels verklaren, waarbij bredere programma's, bestaande uit drie of vier componenten, de meest positieve effecten behaalden op klinische uitkomsten. Verschillen in observatieduur waren ook deels verklarend voor de heterogeniteit in disease management effecten: in kortere studies (<1 jaar) werden positievere, doch wellicht overschatte, resultaten gemeten dan in langere studies.

Hoofdstuk 4 beschreef de ontwikkeling van chronische zorg in Oostenrijk, Duitsland en Nederland, drie zorgsystemen die hoofdzakelijk worden gefinancierd vanuit ziektekostenverzekeringen. Bestaande fragmentatie in de zorg voor chronische aandoeningen heeft in alle drie deze landen geleid tot de introductie van gestructureerde disease management modellen. Desalniettemin zijn er verschillen te herkennen in de specifieke hervormingsstrategieën per land, welke kunnen worden teruggeleid naar verschillen in de regulering, financiering en organisatie van nationale zorgsystemen. Diversiteit bestaat onder meer in de mate van hervorming van de organisatie van zorg, de betrokkenheid van niet-medische staf bij chronische zorgverlening, de prikkels om implementatie van disease management te bevorderen en de participatie van patiënten en zorgverleners. Het bewijs omtrent de impact van de disease management benaderingen in Oostenrijk, Duitsland en Nederland blijft onzeker: (voorlopige) evaluatieresultaten wijzen op verbeterde kwaliteit van zorg, met name inzake coördinatie en standaardisatie, maar zijn er tot op heden niet in geslaagd overtuigend blijk te geven van verbeterde gezondheidsuitkomsten en/of verminderde kosten.

Hoofdstuk 5 presenteerde de resultaten van een gedifferentieerde analyse van de effecten van de populatiebrede disease management aanpak voor type 2 diabetes in Nederland op vier klinische uitkomstmaten, te weten geglyceerde hemoglobine, LDL cholesterol, systolische bloeddruk en body mass index. Hiertoe werden patiëntdata (N=105,056) verzameld over een periode van 20 tot 24 maanden tussen januari 2008 en december 2010 van 18 Nederlandse zorggroepen met een keten-DBC voor type 2 diabetes management. Analyses van deze data met behulp van multilevel regressie methoden – waaronder diverse meta-analyses en meta-regressies – toonden aan dat, hoewel de gemiddelde verande-

ringen over tijd in de geïncludeerde uitkomsten bescheiden waren, er klinisch relevante verbeteringen werden bereikt in patiënten met ongezonde beginwaarden. Frequentere meting van klinische uitkomstparameters werd bovendien geassocieerd met sterkere effecten op die parameters, vooral voor patiënten met onvoldoende diabetescontrole. De analyses toonden verder aan dat wanneer het aantal maanden in zorg toenam, de effecten op klinische uitkomsten minder positief werden. De conclusie op basis van deze bevindingen was dat zorg op maat, waarbij niet alleen zorgstandaarden en richtlijnen maar ook de kenmerken en zorgbehoeften van patiënten bepalend zijn voor de processen van zorg, een veelbelovende strategie is om de kosteneffectiviteit van de huidige chronische zorgaanpak in Nederland te verbeteren.

Hoofdstuk 6 trachtte in kaart te brengen in hoeverre en op welke wijze zelfmanagement ondersteuning, de wellicht meest belangrijke component van effectieve chronische zorg, is geïntegreerd in bestaande chronische zorgstrategieën in 13 Europese landen. Daarnaast onderzocht dit hoofdstuk de mate van en barrières voor implementatie van ondersteuningsstrategieën in de dagelijkse zorgpraktijk. Op basis van de resultaten van een gestructureerde expert review in de participerende landen concludeerden we dat zelfmanagement ondersteuning voor chronisch zieke patiënten in Europa relatief onderontwikkeld blijft. Gelijkenissen tussen landen hebben met name betrekking op de bij zelfmanagement ondersteuning betrokken hulpverleners (verpleegkundigen) en sectoren (eerste lijn). Verschillen zijn veelvoorkomend in toegepaste methoden en systemen, alsook in gebruikte materialen. Ondersteuningsactiviteiten zijn primair gericht op het medische en gedragsgerelateerde zelfmanagement van patiënten; er is minder aandacht voor emotioneel management. De resultaten van een serie van 27 interviews met Nederlandse zorgverleners, die zijn betrokken bij disease management voor type 2 diabetes, lieten zien dat zelfmanagement ondersteuning (nog) geen integraal onderdeel is van de dagelijkse chronische zorgpraktijk, alsook dat implementatie wordt belemmerd door barrières in onder andere de financiering van zorg, informatie technologie en medische cultuur. Om de gezondheid en sociale status van chronisch zieken te verbeteren is het noodzakelijk beter inzicht te krijgen in de wijze waarop we zowel patiënten als zorgverleners kunnen stimuleren om op productieve wijze met elkaar te interacteren in de dagelijkse chronische zorgpraktijk.

Op basis van landenstudies in Oostenrijk, Denemarken, Frankrijk, Duitsland, Nederland en Spanje illustreerde **Hoofdstuk 7** hoe routinematige data – die standaard worden verzameld in de zorgsector – gebruikt kunnen worden om de impact van disease management op rigoureuze en betekenisvolle wijze te evalueren binnen de context van zorgsystemen. Als onderdeel van het Europese DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project hebben onderzoeksteams in elk van

deze landen geavanceerde evaluatiemethoden – waaronder 'difference-in-differences analysis', 'regression discontinuity analysis' en 'multilevel modeling' – getest en gevalideerd op basis van data van bestaande disease management strategieën. Data werden voornamelijk retrospectief verzameld van zorgverleners en zorgverzekeraars. Het gebruik van routinematige data leverde grote aantallen (~154,000 patiënten met drie aandoeningen), maakte lange termijn follow-up mogelijk (10 tot 36 maanden), bood de optie om retrospectief controlegroepen te creëren, en leverde baseline gegevens. Een nadeel was dat de parameters, die standaard in de zorgsector worden gemeten, te beperkt kunnen zijn om op adequate wijze kwaliteit weer te geven, aangezien de focus vooral ligt op middellange gezondheidsuitkomsten en, in mindere mate, op zorgprocessen. Door relevante dataproblemen en potentiële bronnen van bias en confounding in praktijkonderzoek expliciet in overweging te nemen, produceerden de toegepaste methoden voldoende valide resultaten om verdere inspanningen op het gebied van kwaliteitsverbetering in de chronische zorg te ondersteunen. Desalniettemin moeten resultaten met voorzichtigheid geïnterpreteerd worden in het licht van de beperkingen van ongerandomiseerd onderzoek. De belangrijkste resultaten toonden significante positieve effecten van disease management op de kwaliteit van zorgprocessen (Oostenrijk, Duitsland), maar niet meer dan klinisch bescheiden verbeteringen in middellange gezondheidsuitkomsten (Oostenrijk, Frankrijk, Nederland, Spanje) of ziekteprogressie (Denemarken) in interventiepatiënten, waar mogelijk vergeleken met een gematchte controlegroep.

Hoofdstuk 8 introduceerde multilevel regressie methoden als waardevolle technieken voor de evaluatie van disease management binnen de natuurlijke context van het zorgsysteem, op een manier die resulteert in robuuste en betekenisvolle bevindingen voor de dagelijkse praktijk. In een uitgewerkt voorbeeld werden deze methoden toegepast op retrospectief verzamelde routinematige data van 105,056 diabetes patiënten, die disease management voor type 2 diabetes mellitus ontvangen in Nederland. Multivariabele, multilevel regressie modellen werden toegepast om trends in de klinische uitkomsten van patiënten te identificeren als een gevolg van verschillen in aspecten van de interventie (meetfrequentie, meetvariatie, observatieduur) en/of kenmerken van de behandelde populatie (leeftijd, ziekteduur, baseline gezondheid, comorbiditeit, rookstatus). Het gebruik van multilevel regressie technieken maakte het mogelijk om resultaten te corrigeren voor potentiële bronnen van confounding en bias in praktijkonderzoek; bovendien produceerden deze methoden kwantitatief bewijs ter ondersteuning van huidige inspanningen om maatwerk te leveren binnen de chronische zorg op basis van de zorgbehoeften van patienten. Hoewel de geïdentificeerde trends in disease management uitkomsten bevestigd worden door eerder gerandomiseerd onderzoek, zijn er grenzen aan de validiteit en betrouwbaarheid van de bevindingen van ongecontroleerd onderzoek op basis van routinematige interventiedata. Meer praktijkgericht onderzoek is nodig om

de resultaten te bevestigen en meer te leren over de impact van populatiebrede disease management strategieën op de kwaliteit en uitkomsten van chronische zorg.

LIST OF ACRONYMS AND ABBREVIATIONS

ACIC	Assesing Chronic Illness Care
BMI	Body mass index
CCA	Care Continuum Alliance
CCM	Chronic Care Model
CCT	Controlled clinical trial
CI	Confidence interval
CIS	Clinical information systems
COPD	Chronic obstructive pulmonary disease
CWF	Commonwealth Fund
DISMEVAL	Developing and Validating Disease Management Evaluation Methods for European Health Care Systems
DMAA	Disease Management Association of America
DMP	Disease management programme
DS	Decision support
DSD	Delivery system design
ECCM	Expanded Chronic Care Model
EU	European Union
FP7	Seventh Framework Programme for research
GP	General practitioner
HbA1c	Glycated haemoglobin
HDL	High-density lipoprotein
IGZ	Inspectie voor de Gezondheidszorg
ICC	Intraclass correlation
IT	Information technology
LHV	Landelijke Huisartsen Vereniging
LDL	Low-density lipoprotein
MUMC+	Maastricht Universitair Medisch Centrum
NZa	Nederlandse Zorgautoriteit
POPP	Partnerships for Older People Projects
RCT	Randomised controlled trial
RIVM	Rijksinstituut voor Volksgezondheid en Milieu
RR	Relative ratio
RSA	Risk structure compensation scheme
RVZ	Raad voor de Volksgezondheid en Zorg
SBP	Systolic blood pressure
SHI	Social health insurance
SMS	Self-management support
UKPDS	United Kingdom Prospective Diabetes Study
US	United States
VIF	Variance inflation factor
WHO	World Health Organisation
ZonMw	Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie

DANKWOORD

Eindelijk is het dan zover, mijn proefschrift is af. Maar promoveren doe je zeker niet alleen en dus is het hoog tijd om de mensen te bedanken, die me in de afgelopen jaren hebben geholpen bij het bereiken van deze mijlpaal. Een aantal wil ik graag in het bijzonder noemen.

Allereerst wil ik mijn promotoren, prof. dr. Bert Vrijhoef en prof. dr. Cor Spreeuwenberg, en mijn copromotor, dr. Inge Duimel-Peeters, bedanken. Ik had me geen beter begeleidingsteam kunnen wensen. Vanaf het begin hebben jullie me de vrijheid, het vertrouwen en de support gegeven om dit onderzoek tot een goed einde te brengen. Jullie aanstekelijke enthousiasme en expertise als het gaat om de zorg voor chronisch zieken was daarbij van onschatbare waarde voor me. Bert, in de afgelopen vier jaar hebben we over allerlei afstanden samengewerkt. Maar of je nou op een andere verdieping, in een andere stad of op een ander continent zat, ik kon altijd bij je terecht met welke vraag dan ook. Wat was het fijn om me onder jouw vleugels te kunnen ontwikkelen als onderzoeker. Bedankt voor het delen van je kennis, voor je motiverende houding, je persoonlijke betrokkenheid en voor de vele deuren die je in de afgelopen jaren voor me hebt geopend. Ik ben blij dat ook de afstand tussen Maastricht en Singapore weer goed te overbruggen blijkt en hoop dat we nog lang kunnen samenwerken! Cor, niet lang na mijn start als promovenda ging jij met pensioen, maar daar is je betrokkenheid bij mijn onderzoek zeker niet minder om geworden. Ik geloof niet dat er ooit een paper van mij veel langer dan een dag op je bureau heeft gelegen. Bedankt voor je deskundigheid, je interesse in mijn werk en je positief kritische feedback, waar ik enorm veel van heb geleerd. Inge, wat ben ik blij dat jij mijn copromotor was! We hebben een ontzettend leuke band opgebouwd en onze overleggen zijn doorgaans dan ook even gezellig als dat ze informatief zijn. Ik heb veel van je mogen leren op onderzoeksgebied en ook voor de meer praktische zaken die bij een promotietraject komen kijken, kon ik altijd bij je terecht. Ontzettend bedankt voor je betrokkenheid bij mijn werk en voor je inzet om daar een vervolg aan te geven, ik zie onze toekomst vol vertrouwen tegemoet!

De leden van de beoordelingscommissie, prof. dr. Dirk Ruwaard, prof. dr. Niek Klazinga, prof. dr. Ab Klink, prof. dr. Job Metsemakers en prof. dr. Nicolaas Schaper, wil ik hartelijk bedanken voor hun inspanningen om mijn proefschrift te beoordelen.

Dit proefschrift was niet tot stand gekomen zonder de medewerking van negen zorggroepen uit heel het land, die data hebben aangeleverd over hun diabeteszorg en bereid waren om ons interviews te laten afnemen met managers, huisartsen en praktijkondersteuners. Bedankt voor het inzicht dat jullie ons daar-

mee hebben geboden in de processen en uitkomsten van zorg voor mensen met type 2 diabetes in Nederland. Dr. Caroline Baan en dr. Jeroen Struijs van het RIVM wil ik eveneens graag hartelijk bedanken voor hun betrokkenheid bij het DISMEVAL project. Jullie bereidheid om zowel jullie datasets als jullie kennis over het evalueren van integrale diabeteszorg te delen, heb ik zeer gewaardeerd.

I would also like to thank all the European researchers participating in the DISMEVAL project for their contributions to the Dutch country study and for acting as coauthors on several of the papers included in this thesis. Working with you has been an inspiring journey and I am grateful for the stimulating discussions we had during our biannual meetings, for all of your hard efforts in writing up our results, and for the enthusiasm you have given me to continue doing research in this area. I would especially like to thank dr. Ellen Nolte for sharing her enormous expertise in chronic care management and for, together with Annalijn Conklin, Cécile Knai and Saba Hinrichs, doing such an incredible job in coordinating the colossal project that was DISMEVAL. You are amazing and it was (and still is) a privilige to work with you! I am furthermore especially grateful to dr. John Adams and dr. Ariel Linden for the statistical advice and support offered during DISMEVAL and for coauthoring our paper on the methodological aspects of disease management evaluation.

De onderzoekers uit het TERM consortium – dr. Caroline Baan, dr. Hanneke Drewes, dr. Karin Lemmens, dr. Lidwien Lemmens, drs. Jolanda Meeuwissen, dr. Lotte Steuten en prof. dr. Bert Vrijhoef – wil ik graag bedanken voor de prettige samenwerking bij het schrijven van een serie systematische reviews over de effectiviteit van ketenzorg voor diverse chronische aandoeningen. Het was een interessant en ambitieus project, dat mooie resultaten heeft opgeleverd!

Joyce Janssen, zonder jouw hulp zou ik waarschijnlijk nu nog datafiles aan het opschonen zijn... Het verwerken van de grote hoeveelheid data in dit onderzoek was een gigantische klus en het is dankzij jouw kennis en inzet dat we die tijdig hebben geklaard. Ontzettend bedankt! Charlotte Depondt ben ik erkentelijk voor het snel en zorgvuldig uitwerken van de interviews binnen het DISMEVAL project.

Dr. Marieke Spreeuwenberg, hartelijk bedankt voor je ondersteuning bij de data-analyse voor DISMEVAL. Je hebt het talent om statistiek begrijpelijk en zelfs leuk te maken voor de bijna-leken onder ons en hebt me op de (be)valreep goed op weg geholpen met de talloze analyses die ik wilde draaien. Bedankt ook voor je persoonlijke betrokkenheid bij de afronding van mijn proefschrift en voor de leuke samenwerking binnen de projecten waar we nu druk mee zijn.

Sinds de afronding van mijn proefschrift ben ik als postdoc werkzaam binnen het programma Duurzame Zorg dat wordt uitgevoerd door de vakgroep Health Services Research. Prof. dr. Dirk Ruwaard, hartelijk bedankt voor de mogelijkheid die je me hebt geboden om binnen dit programma verder te werken aan mijn onderzoekslijn. Ik stel je betrokkenheid bij mijn huidige werkzaamheden zeer op prijs en kijk uit naar onze verdere samenwerking.

Alle collega's bij de vakgroep Health Services Research en speciaal de onderzoekers binnen het programma Redesigning Health Care wil ik graag bedanken voor de fijne samenwerking. Arno, Aggie en Hans, het is voor een groot deel aan jullie te danken dat ik ooit ben begonnen aan een promotieonderzoek. Bedankt voor het vertrouwen om me na mijn master aan te stellen als junior onderzoeker en voor jullie niet aflatende betrokkenheid bij mijn carrière in de wetenschap. De dames van het secretariaat, in het bijzonder Brigitte, Suus en Rietje, wil ik hartelijk bedanken voor alle hulp en ondersteuning, zeker in de afgelopen maanden. Het is altijd fijn om bij jullie binnen te lopen!

Ik heb in de afgelopen jaren verschillende kamergenoten gehad, waarvan ik er een aantal speciaal wil bedanken. Ties, tijdens mijn eerste jaren als promovenda heb ik veel van je geleerd en genoten van ons eindeloze gebabbel. Ik hoop dat het je goed gaat in de VS. Sharon, wat was het een gezellig jaar met jou op een kamer. Ik vond het jammer dat je vertrok, maar ben blij dat je in Eindhoven je plekje hebt gevonden. Lieve Janneke, Reina en Cindy, wat is het een geweldig feest om sinds februari vorig jaar met jullie een kamer te delen! Ik heb me vanaf de eerste dag welkom gevoeld en inmiddels lijkt het alsof ik al jaren op kamer 0.044 vertoef. Bedankt voor alle gezelligheid en hilariteit onder werktijd (dit proefschrift lijkt me het ultieme bewijs dat in luidruchtige omgevingen een enorme arbeidsproductiviteit kan worden bereikt), voor de geweldige etentjes in Budel, Bilzen en Herderen (zo kom je nog eens ergens…) en voor jullie hulp bij al het 'geregel' dat komt kijken bij een promotie. Wat voel ik me rijk met Reina als paranimf aan mijn zijde en Janneke en Cindy als 'co-paranimfen' op de eerste rij tijdens de grote dag; jullie zijn geweldig!

Dankzij mijn lieve vriendengroep heb ik in de afgelopen jaren ook de nodige afleiding gehad van mijn onderzoek. Kim, Rian, Stefanie, Naomi, Chantal, Roel, Erik, Bart, Xavier, Dominique en Maarten, wat een gezellige boel is het toch altijd met jullie! Bedankt voor alle leuke feestjes (inclusief onnozele dansjes), de weekendjes weg, de chaotische etentjes, de lange avonden kletsen en alle andere dingen die we samen doen. Lieve Kim, al sinds onze kleutertijd delen wij alle leuke en minder leuke dingen in het leven. Je kent me als geen ander en staat altijd voor me klaar. Het is onmogelijk je in een paar zinnen te bedanken, maar weet dat onze vriendschap me dierbaar is en dat ik blij en dankbaar ben dat je ook deze mijlpaal weer met me meebeleeft.

Lieve pap en mam, met heel veel liefde draag ik dit proefschrift aan jullie op. Zonder jullie onvoorwaardelijke steun en vertrouwen, en de mogelijkheden die jullie me hebben gegeven, was ik hier nooit gekomen. Pap, jij staat altijd voor me klaar met een helpende hand, een goed advies of een brede schouder om even tegenaan te leunen. Weten dat jij er altijd bent, geeft me vleugels. Mam, jij hebt me van kleins af aan geleerd om hard te werken, om niet op te geven en bovenal om te geloven in mezelf. Je bent mijn grote voorbeeld en mijn meest trotse supporter. Wat ben ik dankbaar dat ik altijd bij jullie terecht kan en dat jullie er zijn om dit bijzondere moment samen met mij mee te maken. Daniëlle, een liever zusje dan jij kan niemand zich wensen. Ik ben dan misschien de oudste van ons twee, maar van jouw enthousiasme en doorzettingsvermogen leer ik elke dag weer. Terwijl ik onderzoek doe naar de zorg, sta jij er dagelijks met beide benen midden in en de manier waarop je dat doet is een inspiratie voor me. Ik twijfel er niet aan dat je al je dromen zult verwezenlijken. Je betekent de wereld voor me en ik ben ongelofelijk blij en trots dat je naast me staat als paranimf op deze belangrijke dag.

Huub, Marga, René en Loes, wat is het fijn om een tweede thuis te hebben bij jullie in Herkenrade, waar het altijd gezellig is. Bedankt voor alle manieren waarop jullie Rick en mij helpen en voor jullie interesse in mijn af en toe veel te lange verhalen over dit proefschrift. Na vandaag worden ze vast en zeker steeds korter!

Lieve Rick, de laatste zinnen van dit dankwoord heb ik bewaard voor jou. In al je bescheidenheid wil je nog wel eens onderschatten hoe belangrijk jouw steun voor me is. Misschien helpt het dat ik het nu op papier kan zetten. Je zorgzaamheid, je relativeringsvermogen en je grenzeloos vertrouwen in mijn kunnen zijn de afgelopen jaren onmisbaar voor me geweest bij het schrijven van dit proefschrift. En ondertussen ben je ook nog afgestudeerd, heb je een baan gevonden en hebben we samen ons eerste huis gekocht. Ik ben ongelofelijk dankbaar en trots dat ik jou in mijn leven heb en kan niet wachten om te zien wat de toekomst ons nog allemaal zal brengen. Je bent mijn maatje, mijn rots, mijn grote liefde en mijn thuis. Lieve schat, ik hou van je.

CURRICULUM VITAE

Arianne Elissen was born in Heerlen, the Netherlands, on August 10, 1984. She attended secondary school (VWO) at the Jeanne d'Arc College in Maastricht. In September 2003, she enrolled at Maastricht University to study Health Sciences at the Faculty of Health, Medicine and Life Sciences. During the bachelor period, she combined the specialisations Policy & Management and Health Care Studies with an elective minor in Health Law at Maastricht University's Faculty of Law.

In August 2007, Arianne received a master's degree in Health Policy, Economics and Management after finishing her thesis concerning the influence of routines and rules on multidisciplinary cooperation in primary care. In September of that same year, she was offered a junior researcher position within the former department of Health Organisation, Policy and Economics at Maastricht University, where she was involved, amongst others, in the evaluation of an outreach care intervention for homeless persons in Eindhoven. Early 2009, she started working as a PhD student on the European collaborative DISMEVAL ('Developing and Validating Disease Management Evaluation Methods for European Health Care Systems') project, under supervision of prof. dr. Bert Vrijhoef, prof. dr. Cor Spreeuwenberg and dr. Inge Duimel-Peeters. During this period, as a member of the department of Health Services Research, she also performed various educational roles within the bachelor and master programmes in Health Sciences offered at Maastricht's Faculty of Health, Medicine and Life Sciences.

Since December 2012, Arianne works as a postdoctoral research fellow based in the Redesigning Health Care research programme at the CAPHRI School for Public Health and Primary Care. Her research activities are aimed at optimising the organisation, funding, and evaluation of integrated care for people with chronic conditions. She is currently also vice-coordinator of the course on Innovation and Quality Management of Health Services offered within the master programme Health Policy, Innovation and Management.

PUBLICATION LIST

International journals

- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM, Saz-Parkinson Z, Sarria-Santamera A. Advancing existing approaches to evaluation: experiences from the Netherlands and Spain (abstract). *European Journal of Public Health,* 2010;20(Suppl 1):13.
- **Elissen AMJ**, Van Raak AJA, Paulus ATG. Can we make sense of multidisciplinary cooperation in primary care by considering routines and rules? *Health & Social Care in the Community,* 2011;19(1):33-42.
- Nolte E, Knai C, Hofmarcher M, Conklin A, Erler A, **Elissen AMJ**, Flamm M, Fullerton B, Sönnichsen A, Vrijhoef HJM. Overcoming fragmentation in health care: chronic care in Austria, Germany and the Netherlands. *Health Economics, Policy and Law*, 2012;7(1):125-46.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Spreeuwenberg M, Vrijhoef HJM. Toward tailored disease management for type 2 diabetes. *American Journal of Managed Care*, 2012;18(10):619-30.
- **Elissen AMJ**, Steuten LMG, Lemmens LC, Drewes HW, Lemmens KMM, Meeuwissen JAC, Baan CA, Vrijhoef HJM. Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes. *Journal of Evaluation in Clinical Practice*, 2012 (epub ahead of print).
- Drewes HW, Steuten LMG, Lemmens LC, Baan CA, Boshuizen HC, **Elissen AMJ**, Lemmens KMM, Meeuwissen JAC, Vrijhoef HJM. The effectiveness of chronic care management for heart failure: meta-regression analyses to explain the heterogeneity in outcomes. *Health Services Research*, 2012 (epub ahead of print).
- Meeuwissen JAC, Lemmens LC, Drewes HW, Lemmens KMM, Steuten LMG, **Elissen AMJ**, Vrijhoef HJM, Baan CA. Meta-analysis and meta-regression analyses explaining heterogeneity in outcomes of chronic care management for depression: implications for person-centered mental healthcare. *International Journal of Person-Centered Medicine*, 2012;2(4):716-58.
- **Elissen AMJ**, Van Raak AJA, Derckx EWCC, Vrijhoef HJM. Improving homeless persons' utilisation of primary care: lessons to be learned from an outreach programme in the Netherlands. *International Journal of Social Welfare,* 2013;22:80-89
- Knai C, Nolte E, Brunn M, **Elissen AMJ**, Conklin A, Pedersen JS, Brereton L, Erler A, Frølich A, Flamm M, Fullerton B, Jacobsen R, Krohn R, Saz-Parkinson Z, Vrijhoef HJM, Chevreul K, Durand-Zaleski I, Farsi F, Santamera AS, Soennichsen A. Reported barriers to evaluation in chronic care: experiences in six European countries. *Health Policy*, 2013 (in press).

- **Elissen AMJ**, Adams JL, Spreeuwenberg M, Duimel-Peeters IGP, Spreeuwenberg C, Linden A, Vrijhoef HJM. Advancing current approaches to disease management evaluation: capitalising on heterogeneity to understand what works and for whom. *BMC Medical Research Methodology*, 2013 (in press).

National journals

- **Elissen AMJ**, Van Raak AJA, Derckx EWCC, Vrijhoef HJM. Dokter voor vagebonden. Laagdrempelige straatdokterspraktijk haalt daklozen wél binnen. *Medisch Contact,* 2009;64(19):842-845.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. DISMEVAL: Europees onderzoek naar 'best practices' op het gebied van disease management evaluatie. *Tijdschrift voor Gezondheidswetenschappen,* 2011;89(3):173-177.
- **Elissen AMJ**, Steuten LMG, Lemmens LC, Drewes HW, Lemmens KMM, Meeuwissen JAC, Baan CA, Vrijhoef HJM. Effectiviteit van diabetes ketenzorg: een meta-analyse. *Nederlands Tijdschrift voor Geneeskunde,* 2012;156(48):2027-32.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. Naar zorg op maat voor type 2 diabetes. *Tijdschrift voor Gezondheidswetenschappen*, 2013 (in press).

Reports

- **Elissen AMJ**, Van Raak AJA, Derckx EWCC, Vrijhoef HJM. *De Nurse Practitioner als ´Street Nurse': Een onderzoek naar de haalbaarheid en de kosten van het Eindhovense Straatdokterproject.* Maastricht: Maastricht University, 2008.
- Dierick-van Daele A, Ramcharan A, **Elissen AMJ**, Duimel-Peeters I, Vrijhoef, B. *Pilotproject Internet Raadplegen Donorregister.* Maastricht: Maastricht UMC+, 2009.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. *Op weg naar betere prestaties: de chronische zorg in beweging.* In: Vrijhoef HJM, Fiolet JFBM (eds). *Het Chronic Care Model in de praktijk. 10 jaar Transmurale Zorg.* Maastricht: Maastricht UMC+, 2011.
- Van Dijk CE, **Elissen AMJ**, Swinkels ICS, Korevaar JC. *Disease management: diabetes mellitus.* In: Van Dijk CE, Swinkels ICS, Lugt MGH, Korevaar JC. *Integrale bekostiging. Evaluatie van verwachte effecten op kwaliteit, toegankelijkheid en betaalbaarheid.* Utrecht: NIVEL, 2011:29-34.

- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Vrijhoef HJM. *Evaluation of disease management in the Netherlands.* In: Nolte E, Hinrichs S (eds). *DISMEVAL. Developing and validating disease management evaluation methods for European health care systems.* Cambridge: RAND Europe, 2012:99-112.
- Nolte E, Conklin A, Adams J, Brunn M, Cadier B, Chevreul K, Durand-Zaleski I, **Elissen AMJ**, Erler A, Flamm M, Frølich A, Fullerton B, Jacobsen R, Knai C, Krohn R, Pöhlmann B, Saz-Parkinson Z, Sarria-Santamera A, Sönnichsen A, Vrijhoef H*. Evaluating chronic disease management. Recommendations for funders and users.* Cambridge: RAND Europe, 2012.

Conferences

- **Elissen AMJ**. *Chronic illness care in the Netherlands: from policy to patient satisfaction (poster presentation).* Working Conference Health Services Research in Europe, the Hague, the Netherlands, 8-9 April 2010.
- **Elissen AMJ**, Vrijhoef HJM. *DISMEVAL: Developing and Validating Disease Management Evaluation Methods for European Health Care Systems (oral presentation)*. NCEBP/Care Symposium 2010 'Chronic Disease: Balancing on the tightrope of health', Arnhem, the Netherlands, 4 June 2010.
- **Elissen AMJ**, Saz-Parkinson Z. *Advancing existing approaches to evaluation: experiences from the Netherlands and Spain (workshop)*. 3rd EUPHA conference, Amsterdam, the Netherlands, 10-13 November 2010.
- **Elissen AMJ**. *Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes (poster presentation)*. Annual CAPHRI Research Meeting, Maastricht, the Netherlands, 19 May 2011.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Spreeuwenberg M, Vrijhoef HJM. *Advancing existing approaches to disease management evaluation: experiences from the Netherlands (poster presentation).* Annual Research Meeting, Academy Health, Orlando, Florida, 24-26 June 2012.
- **Elissen AMJ**, Huizing A. *DISMEVAL: Europees gefinancierd onderzoek over evaluatie van disease management (workshop).* Congres Chronische Zorg, Utrecht, 29 juni 2012.
- **Elissen AMJ**, Duimel-Peeters IGP, Spreeuwenberg C, Spreeuwenberg M, Vrijhoef HJM. *Advancing existing approaches to disease management evaluation: experiences from the Netherlands (poster presentation).* ISQUA's 29th International Conference, Geneva, Switzerland, 21-24 October 2012.