DISMEVAL

Developing and validating disease management evaluation methods for European healthcare systems

Final report

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TR-1226-EC

February 2012

Prepared by the Project Coordinator for the European Commission on behalf of the DISMEVAL Consortium

RAND EUROPE

Preface

This report is the fifth formal deliverable (D5) to the European Commission of the DISMEVAL project (grant agreement 223277). DISMEVAL is a European collaborative project with the overarching aim to contribute to developing new research methods and to generating the evidence base to inform decisionmaking in the field of chronic disease management evaluation.

We here report on the overall findings of the work carried out within the DISMEVAL project, documenting background, methods, results and discussion for each of the work packages WP2 to WP10. The project has identified and tested a wide range of methods that can be employed in situations where experimental approaches are not possible, emphasising that rigorous evaluation is still possible even where baseline or predefined control groups are not available and how advanced designs can help better understanding how different (combinations of) care components and processes might be effective for managing chronic disease in patients with different characteristics. Future evaluation work drawing on such approaches can provide insight into what works for whom in the area of disease management, a question that randomised trials have thus far been unable to answer.

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Summary

The DISMEVAL project was funded under the European Commission's Seventh Framework Programme (grant agreement 223277). DISMEVAL's three-year programme of work was developed around a set of key objectives, which include **(1) to review current approaches** to chronic care management and their evaluations, as implemented by EU Member States at national and regional level, **(2) to explore the policy context** for chronic disease management in European countries, **(3) to develop and validate disease management evaluation methods** using data from existing programmes and approaches through employing a range of evaluation designs and assessing the sensitivity of findings to selected methods, and **(4) to formulate recommendations** for scientifically sound yet operationally feasible evaluation approaches for chronic disease management that are relevant to planned and ongoing policies at the EU and wider European level as well as internationally. This final report presents the overall findings of the work carried out within the project. The learning from these various work streams led to the formulation of recommendations for chronic disease management evaluation methods. We report these recommendations in the form of a separate guidebook, which will be published alongside this final report.

Chronic disease management in Europe

We reviewed the policy context for, and approaches to, chronic disease management in 13 European countries. We found that fragmentation between ambulatory/primary care and hospital/secondary care, and between the health and social care sector remains a key concern in most healthcare systems. Countries have sought to create a regulatory and policy framework to respond to chronic disease during recent years. These generally aim to promote approaches that better integrate care and improve coordination between sectors and levels of care but countries differ with regard to their vision towards controlling and managing chronic disease.

Approaches to chronic disease management vary in scope and nature across Europe

While our review did not attempt to present a comprehensive inventory of all approaches being implemented in a given country, some of the key observations were that:

- the majority of countries tend to focus on care models for populations with defined conditions, most frequently diabetes type 2, and involve some form of GP-led care coordination.
- nurse-led approaches are becoming more common although there are differences in the degree to which nurses can operate independently.

- patient access is typically granted in line with access to usual care although many approaches are being implemented in selected geographical regions so potentially limiting access to defined population groups.
- the majority provide some form of patient self-management support, although the level and scope of support offered varies.
- the overall the use of clinical information systems for chronic disease management tends to be the least developed strategy in most approaches.

Existing approaches to evaluating chronic disease management in Europe are diverse

Most chronic disease management initiatives reviewed here had undergone some form of evaluation or had evaluation plans in place. However, the nature and scope of evaluations varied, with differences in objectives, design, the performance metrics used, the length of observation and approaches to data collection. We identified a range of challenges posed to the more systematic use of evaluation of complex healthcare interventions such as disease management in European health systems, such as a perceived lack of an evaluation culture in some settings, alongside lack of financial and human resources to conduct systematic evaluation. We note that evaluation of approaches to disease management reviewed would likely benefit analytically from increased use of sophisticated statistical techniques, but also conceptually from drawing more explicitly on one of the many possible theories of behaviour change to better link the choice of performance measures to the goals of the intervention (and of the evaluation). There may also be scope to more systematically draw in mixed-methods approaches to help place observed quantitative findings into the context within which the intervention under evaluation is embedded. More information is needed about the characteristics of the intervention and its intended populations, requiring greater specification of the wider context so as to improve comparisons and potential transferability across settings and countries in Europe.

There remain considerable challenges towards the development of a policy framework for providing a strategic response to chronic disease

Interviews with key informants in a sample of countries highlighted a series of continued challenges to arrive at a more comprehensive or strategic response to chronic disease. These included a continued focus of chronic care on complications management, with some movement towards more systematic disease management, and an overall lack of coordination between levels; failure to integrate risk minimisation and disease prevention with other components along the care spectrum; misalignment of financial incentives that tend to reward 'cure' over prevention; and a disjoint between intent, at national level, to enhance coordination and integration, and ability at regional or local level to translate these ambitions into practice. While perhaps not specific to chronic care as such, these observations emphasise the need for the development of a coherent response to chronic disease that takes account of the various tiers in the system and along the care continuum, with involvement of professionals forming a crucial component for achieving sustainable change.

Testing and validation of methods and metrics for the evaluation of chronic disease management

The testing and validation of disease management evaluation methods comprised studies carried out in six countries and using data from existing interventions. These were: disease

management programmes for diabetes type 2 in Austria and Germany, 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 and for diabetes 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 study.

As interventions and the setting in which they were implemented varied, so did their approaches to testing and validation approaches to evaluation. Thus, country studies aimed to:

- quantify differences in effect sizes of structured care within a diabetes disease management programme using randomised and non-randomised controlled and non-experimental designs (Austria)
- test different approaches to identify treatment-control matches in non-experimental settings and quantify the likely impact on the effect estimate of an interdisciplinary and sectoral intervention for patients with chronic obstructive pulmonary disease or diabetes (Denmark)
- compare different methods to adjust for confounding in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme (Germany)
- test for selection bias for participating in a structure care programme for diabetes (Germany, France)
- employ advanced methods of disease management evaluation in non-experimental settings to better understand differential effects of structured care components on sub-populations (Netherlands, Spain).

Secondary goals of each analysis further included evaluating the effects of the intervention under study on patient outcomes more generally (all countries), alongside better understanding of the usefulness of current approaches to evaluation in the context of intervention practice (France, Netherlands) and to derive recommendations for further development of interventions and evaluation practice.

Evaluating the diabetes disease management programme in Austria using an uncontrolled design overestimates treatment effect

In Austria, the evaluation of the effect of the diabetes disease management programme 'Therapie Aktiv', using a randomised controlled design, found a reduction in HbA1c levels of 0.13 percent after one year. This effect was not statistically significant while measures of process quality such as regular eye and foot examination and patient education improved significantly. In contrast, using an uncontrolled before-after design, treatment effect was estimated at a significant reduction in HbA1c levels of 0.41 percent in the intervention group. Extrapolating these findings to clinically relevant endpoints such as number needed to treat to avoid one case of myocardial infarction or one diabetes complication over a period of ten years, the uncontrolled before-after design overestimated treatment effect by a factor of three. These findings support the general notion that use of a randomised controlled design should be considered as the main means for evaluating treatment effect

of a structured care intervention. Cluster randomisation as applied in the case of Austria can be seen to provide a pragmatic approach to DMP evaluation where a randomised controlled design is not feasible.

Different approaches used to identify treatment-control matches in a non-experimental intersectoral intervention for patients with chronic obstructive pulmonary disease in Denmark provide different estimates of treatment effect

In Denmark, the evaluation of the effect of an interdisciplinary and intersectoral rehabilitation programme for patients with chronic obstructive pulmonary disease (COPD) used three different methods: (i) pre-post analysis to assess changes in the intervention group over time; (ii) intervention-control analysis in the post-period to assess actual differences between intervention and control patients at the point of the evaluation; and (iii) difference-in-difference analysis to assess the impact of the intervention in a particular context and time. The analysis found effect sizes to vary with the method of constructing control groups for the intervention-control and the difference-in-difference analysis. For example, propensity score matched sampling lowered the magnitude of the predicted intervention effect for COPD-specific hospital bed days when compared with controls created by random sampling. Likewise, control groups not matched by disease severity overestimated the effects of pulmonary rehabilitation on COPD-specific hospital contacts and bed days.

The study considered the method of control group construction and matching using propensity scoring and the use of difference-in-difference analyses to assess intervention effect to be optimal for evaluating the impact of interventions in a non-experimental setting. As for the impact of the overall programme, the case study provided evidence that the intervention might have decreased the pace of disease progression in the intervention group, which was reflected in a non-significant increase in COPD hospital contacts, bed days, ambulatory visits and emergency room visits in the intervention group, while these indicators significantly increased in the entire sample.

Different methods to adjust for baseline differences in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme in Germany result in similar effect measures

In Germany, the evaluation of intervention effect of a diabetes disease management programme (DMP) in a non-experimental setting applied different approaches to adjust for baseline differences between DMP and the control group created from routine data. The main finding was that all matching and/or weighting methods used resulted in similar effect measures for the outcome variables analysed. There was a slight preference for propensity score weighting derived from a general boosted regression model, which provided the best fit in terms of lowest mean standardised differences and lowest maximum difference. However, applicability of available statistical methods and tools to perform a sound evaluation of programme effects is conditional on the availability of real baseline data prior to enrolment in the intervention, so enabling adjustment of differences between intervention and control group. Therefore, effort should be made to ensure a thorough collection of detailed and valid data to maximise the usefulness of routine data for evaluation.

As for the impact of the overall programme, the case study confirmed the findings of other studies that participation in the diabetes DMP improved process parameters in diabetes care especially those related to the monitoring of the disease. However, intensified care in the programme was accompanied by higher overall costs, primarily because of higher prescription costs. In order to draw valid conclusions about DMP effects on clinical endpoints such as mortality or micro- and macro-vascular complications, a longer study period consistent with what is known about the time course of the disease should be chosen.

Patient selection for participating in a structured care programme for diabetes in Germany and France leads to misestimation of findings of the effect of the intervention

The evaluation of the diabetes disease management programme in Germany also observed a significant reduction of mortality in the intervention group. This effect was largest in the first year following enrolment in the programme, but then decreased. Such an observation is counterintuitive since an effect attributable to a given intervention would be expected to increase rather than decline. It is therefore more likely that GPs systematically excluded patients from joining the programme who were more likely to die in the near future. Adjusting for baseline variables reduced this effect compared with the unadjusted analysis. Future analyses should include further adjustment for variables suited to predict short-term mortality risk. Furthermore, a longer observation period would be required to assess whether the mortality difference diminishes over the years.

Evidence of patient selection into the intervention was also observed in the case study for France, which examined patient characteristics of those enrolled with a diabetes provider network. These patients were found to be of younger age, whose diabetes was diagnosed more recently but who showed evidence of worse glycaemic control than patients in the reference population. By comparing a standard uncontrolled pre-post evaluation design with a pre-post design after calibration with the reference population at baseline, the analysis further showed that the uncontrolled evaluation design overestimated the intervention effect on a number of clinical outcomes, including improvements in HbA1c levels and body mass index while underestimating deterioration in renal function in diabetic patients.

Advanced methods of disease management evaluation in non-experimental settings help understand the differential effects of care components on sub-populations and so inform further development of structured care approaches

Given that most randomised controlled trials are conducted in academic settings and provide limited insight into the impact of disease management in the everyday practice of health care, in the Netherlands, the evaluation of integrally financed, regional disease management programmes for diabetes used different approaches to better understand the effects of the programmes. It found that applying methods that permit for sub-group analyses provide important new insights into differential component effects. Thus, while the overall analysis of intervention effects found only modest impacts of the care programmes on the health status of patients with diabetes type 2, sub-group analyses revealed disease management to be considerably more effective for patients with poor baseline clinical values. As the vast majority of patients included in the analyses had good baseline values of most clinical endpoints, this differentiation provided a plausible

explanation for the modest overall effects of the intervention. This suggests that further development of the intervention should move towards a more tailored approach to diabetes care, in which the characteristics of patients directly determine the processes of diabetes care, including self-management support. However, such a move will require improvements in the current systems for data registration to provide valid and reliable information on patients' health status to determine care intensity. Similarly, in assessing the effect of a nurse-led intervention targeting a working-age population at risk of cardiovascular disease in Spain, the use of advanced methodological approaches that permit for sub-group analysis in a non-experimental setting provided important new insights into the effects of the intervention.

Continued challenges and lessons learned

The DISMEVAL project set out to enhance our understanding of the use of various approaches to the evaluation of disease management in Europe. It further aimed to identify examples of best practice and lessons learned and to provide evidence-based recommendations to policymakers, programme operators and researchers on evaluation approaches that may be most useful in a given context.

The Austrian case study in DISMEVAL has illustrated how it can be feasible to employ a randomised design in routine settings where the context allows for such a design to be applied. However, use of an experimental design may not be possible (or desirable) for population-wide disease management interventions, which are frequently implemented in an operational setting and do not usually have a control group available, such as those implemented in Germany and the Netherlands. Here, observational study designs are more suitable, keeping their methodological limitations in mind. Given that disease management is essentially a population-based care strategy, advancing observational study designs is therefore crucial to inform on how to best target sub-groups of chronically ill patients in the daily healthcare practice.

The DISMEVAL project has identified and tested a wide range of methods that can be employed in situations where randomisation is not possible, emphasising that rigorous evaluation is still possible even where baseline or predefined control groups are not available and how advanced designs can help better understanding how different (combinations of) care components and processes might be effective for managing chronic disease in patients with different characteristics. Future evaluation work drawing on such approaches can provide insight into what works for whom in the area of disease management, a question that randomised trials have thus far been unable to answer. Project work further highlighted, through the introduction of statistical controls for selection or statistical matching, how findings were substantially different from simple comparisons of patients receiving a given disease management intervention and those who do not. Thus, the DISMEVAL project has shown how the use of randomisation or other methods of control is necessary to accurately assess the impact of such interventions. It also identified a range of methods that can be employed successfully to implement such controls.

The findings from these different work streams led to the development of a set of recommendations for the evaluation of chronic disease management. This has been published as a separate report alongside this final report.

DISMEVAL Consortium

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Acknowledgements

This project is funded under the European Commission's Seventh Framework Programme (FP7) (grant no. 223277). The DISMEVAL Consortium is indebted to John Adams for his methodological advice and guidance on work packages 5-10. We are also very grateful to Jack Needleman and Martin Roland for their very insightful comments and suggestions on earlier drafts of this report.

We would also like to thank the following key informants who contributed survey information on the policy context for, and approaches to, chronic disease management in selected countries: Taavi Lai (Estonia, Latvia, Lithuania); 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).

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CHAPTER 1 Introduction

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1.1 Context

The rising burden of chronic disease presents challenges for all health systems.[1] In the European Union, in 2006, between 20 and over 40 percent of the population aged 15 years and over reported a long-standing health problem and one in four currently receives long-term medical treatment.[2] Other studies find the prevalence of common chronic disorders to be around 50 percent among adults aged 18 and older in seven high-income countries, including Germany, the Netherlands and the UK.[3] Assessing the precise level, distribution and nature of the chronic disease burden in Europe remains a challenge;[4] yet, it is clear that chronic diseases are an important cause of premature mortality and disability, greatly impacting on the years of life lived in good health. In high-income countries, depressive disorder, ischaemic heart disease and cerebrovascular disease, dementia, chronic obstructive pulmonary disease (COPD) and diabetes are among the ten leading contributors to the burden of disease,[5] with diabetes projected to rise further in importance during the next two decades, especially against the background of increasing levels of overweight and obesity.[6]

Chronic diseases pose a sizeable burden for national economies, with some studies estimating the associated costs at up to seven percent of a country's gross domestic product.[7] Societal costs arise partly as a result of direct healthcare costs, including from healthcare utilisation, medication and potentially costly interventions, but these can also be caused by other factors, such as a decrease in work productivity.[8] These challenges add to the complexity facing health systems, which require effective measures to prevent disease through reducing the major chronic disease risk factors and addressing influences that drive exposure,[9] while also providing services to meet the requirements caused by chronic health problems, ensuring that people with established illnesses can participate in society.

Structured disease management has been proposed as a means to improve the quality and reduce the cost of healthcare, and to improve health outcomes for people with chronic conditions. However, the evidence on the ability of such approaches to achieve this remains inconclusive, and what we know is mainly based on small studies of high-risk patients, often undertaken in academic settings.[10] Much less is known about large-scale programmes or small-scale interventions that are rolled out from the site of the original

developer to other locations. This is, in part, because of a lack of widely accepted methods to attribute change to a given intervention that are scientifically sound while operationally feasible. Pilot interventions are frequently implemented and evaluated as randomised controlled trials but where they are is rolled out there is typically little incentive to continue tracking the impact of any given intervention with less rigorous observational research designs. Conversely, evaluation approaches that are used in routine practice tend to be methodologically flawed, so limiting the validity and usefulness of observed programme effect. Overall, there is a need to better understand and learn more about the effects of large, population-based programmes using widely accepted evaluation methods that are scientifically sound and are also practicable in routine settings. Such evaluation methods should form a precondition for the selection of efficient and effective interventions to address the growing burden of chronic disease.

1.2 The DISMEVAL project

DISMEVAL (Developing and validating DISease Management EVALuation methods for European healthcare systems), a European collaborative project, aimed to contribute to developing new research methods and to generate the evidence base to inform decisionmaking in the field of chronic disease management evaluation. The DISMEVAL project sought (i) to enhance our understanding of the use of various approaches to the evaluation of disease management in Europe and to identify examples of best practice and lessons learned; (ii) to provide evidence-based recommendations to policymakers, programme operators and researchers on which evaluation approach is most useful in a given context; (iii) to promote and support the networking and coordination of research and innovation activities relating to scientific knowledge and policy development in this area, building on existing work carried out in Member States and at the wider European level; and (iv) to analyse scientific knowledge and developments as well as actions and policies within EU Member States, develop tools to assist policy analysis, and work in close collaboration with the Commission services, networks and experts in this area, and with stakeholder groups and various agencies to provide scientific input to support ongoing and planned actions and policies in the European Union.

The DISMEVAL project spanned multiple scientific domains by bringing together ten partners in seven European countries, representing a variety of disciplines including evaluation science, chronic care, disease management design and operations, epidemiology, economics, and health policy (see DISMEVAL Consortium, p. xxiii). Partner countries were selected to represent the variety of chronic disease management interventions that can be found across the EU, stretching from large-scale, population-based programmes to smaller, provider-centric interventions.

Within this broad context, DISMEVAL's three-year programme of work was developed around a set of key objectives:

(1) To review current approaches to chronic care implemented by EU Member States at national and regional level and to examine whether and how these interventions are being evaluated.

(2) To enhance our understanding of the impact of macro-level health system features on chronic care interventions through exploring the policy context for chronic disease management in European countries.

(3) To develop and validate methods for evaluating disease management programmes using data from existing programmes and approaches by employing a range of evaluation designs and assessing the sensitivity of findings to selected methods.

(4) To formulate recommendations for scientifically sound yet operationally feasible evaluation approaches for chronic disease management that are relevant to planned and ongoing policies at the EU and wider European level as well as internationally.

This was to be achieved through a programme of work that can be differentiated into three phases: (1) review of current approaches to the implementation and evaluation of chronic disease management; (2) testing and validation of methods and metrics for the evaluation of chronic disease management; and (3) development and recommendations for methods and metrics for the evaluation of chronic disease management. Here we briefly outline each of the three phases and the work packages carried out therein.

Phase 1: Review of current approaches to the implementation and evaluation of chronic disease management in Europe

Phase 1 comprised work packages two to four. Work package 2 (WP2) 'Approaches to chronic disease management' sought to review approaches to managing chronic conditions that have been developed and/or implemented in different countries in Europe, and to assess whether and how countries evaluate approaches to chronic disease management, so feeding into work package 3 (WP3) 'Assessment of disease management evaluation approaches in Europe'. Thus, based on data collected in WP2, WP3 aimed to provide an overview of the types of evaluation approaches that are being used in Europe to assess the impact of structured approaches to disease management on the cost and quality of chronic illness care. Both work packages informed WP4 'Assessing the policy context for chronic disease management in Europe', which aimed to assess the overall policy framework for chronic disease management in selected European countries.

Phase 2: Testing and validation of methods and metrics for the evaluation of chronic disease management

Phase 2 of the project included work packages 5–10. The main aim of this phase was to utilise data from existing chronic disease management programmes, or their equivalent, in partner countries, to test and validate different evaluation options reviewed in Phase 1 of the project. The countries included were Austria (WP5), Denmark (WP6), Germany (WP7), France (WP8), the Netherlands (WP9), and Spain (WP10).

Phase 3: Development and recommendations for methods and metrics for the evaluation of chronic disease management

Phase 3 comprised work package 11, which sought to summarise the findings and to present best practice and lessons learned from work undertaken in WPs 5–10. It further aimed to present validated recommendations on performance indicators and evaluation methods for disease management programmes or their equivalent. The final output of this work package is a report on evaluation of chronic disease management that outlines choices, options and trade-offs to policymakers, programme operators and researchers, and

with recommendations presented alongside their rationale. The report is being published alongside this final project report.[11]

Below we outline the structure of this final report. Before doing so it will be important to define how we conceptualised 'chronic disease' and '(chronic) disease management' in the context of DISMEVAL so as to provide a common ground for what is an inherently complex and diversely defined area of research.

1.3 Conceptualising chronic disease and chronic disease management

We conceptualise chronic disease by broadly following the National Library of Medicine's Medical Subject Heading Terms (MeSH) key word nomenclature developed for Medline. This defines chronic conditions as those 'which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by non-reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care.'[12] This definition includes a range of health problems such as diabetes, coronary heart disease, depression, chronic obstructive pulmonary disease, progressive multiple sclerosis, chronic heart and renal failure as well as HIV/AIDS. We also consider cancer as in some settings approaches to chronic disease management may also target certain cancer sites (for example breast cancer disease management programmes in Germany; provider cancer networks in France).

We restrict the scope of this study to the management of people with established disease, as opposed to primary disease prevention and health promotion. We also consider measures of secondary prevention targeted at people at high risk of developing a chronic disabling disease, such as vascular risk management.

Although the DISMEVAL project focuses on approaches that can be broadly subsumed under the heading of 'disease management', it is important to acknowledge that definitions of this concept vary widely.[13,14] Indeed, there is a range of terms frequently used interchangeably with disease management such as care management, case management and multidisciplinary care, among others, although these are conceptually different. Disease management, by definition, traditionally targets patient groups with specific conditions, such as diabetes while, for example, case management is aimed more broadly at people with complex needs that arise from multiple chronic conditions, coupled with increasing frailty at old age. Boundaries are not clear-cut however, with more recent definitions of disease management explicitly adopting a broader view towards a population-based approach that addresses multiple needs.[15,16]

In line with the literature, we define disease management as comprising the following components: (a) collaborative models 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.[14] According to this definition, disease management does not normally involve general coordination of care. It also does not normally include preventive services such as flu shots. However, we acknowledge that approaches that are being implemented and tested across Europe may not fully meet this definition and we also sought to capture the range of models that use a sub-set of disease management interventions or else are conceptualised in a different way

while pursuing the same objective, that is, to improve the care for those with chronic disease. We therefore considered a wider range of approaches that we termed 'chronic disease management' or chronic care. An overview of the range of approaches considered is provided in the template for data collection and individual chapters will also provide further detail on approaches examined in the framework of DISMEVAL (see Appendix A).

1.4 Structure of this report

This report presents the findings of work carried out within the DISMEVAL project. We broadly follow the structure of the programme of work presented in Section 1.2, presenting each of the work packages WP2 to WP10 as separate chapters. Each chapter is principally organised along common research reporting headings, including background, methods, results and discussion sections although there may be variations in individual chapter structures where work packages followed a different outline. Where appropriate, individual chapters are introduced by a flow chart that outlines the main components of work undertaken and described therein. Given the breadth of the nature and scope of work undertaken, this final report focuses on the main observations and findings of work packages, and major points of discussion. Further details on methodological approaches and additional material will be published elsewhere and/or are available on request. The findings of work package 11 'Development and recommendations for methods and metrics for disease management evaluation' is available as a separate report alongside this final report.[11]

CHAPTER 2 Approaches to chronic disease management in Europe

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2.1 Introduction

This chapter provides an overview of the policy and legal context for chronic disease management in 13 European countries, outlining reform efforts and broader policy developments that have been pursued to enable healthcare services to transform into a system that is better suited to meet the needs of people with chronic health problems. It further examines the actual approaches to chronic disease management and models of care delivery that have been or are being implemented in these countries (WP2).

We begin by introducing some of the key reforms adopted in each country and summarising their relevance to chronic disease control and management. We then examine the current 'vision' for controlling and managing chronic diseases proposed by the countries under review. We further describe the key types of approaches countries are employing, the nature and scope of professionals and healthcare providers involved, the extent to which patients are actively engaged and/or supported, the use of support structures such as decisionmaking tools and guidance, approaches to financing and the use of financial incentives, and the availability or distribution of approaches and population/s covered.

2.2 Methods

Selection of countries

Many countries in Europe are in the process of implementing and/or experimenting with various approaches to chronic care, so the selection of countries to be included here was of necessity pragmatic. It was guided by three main criteria in order to capture (1) the range of approaches to funding and governing health care across Europe; (2) the range of stages in economic development; and (3) geographical spread across the EU.

On this basis, we selected 13 countries for detailed analyses: Austria, Denmark, England, Estonia, France, Germany, Hungary, Italy, Latvia, Lithuania, the Netherlands, Spain and

Switzerland (the only non-EU country). Five of these countries (Denmark, England, France, Germany and the Netherlands) were already reviewed in our previous work.[19] However, renewed inclusion was justified as all have further developed existing approaches and/or introduced new approaches that potentially provide important insights into the factors that have made these developments possible (or indeed hindered further advancement).

All of the countries reviewed here have a similar commitment to providing universal and reasonably equitable access to healthcare for their populations, but do so in different ways. Five countries (Denmark, England, Italy, Latvia, Spain) operate primarily tax-funded systems, while the health systems in Austria, Estonia, France, Germany, Hungary, Lithuania and the Netherlands are primarily funded through statutory social health insurance. Switzerland operates a mandatory private insurance system (Table 2.1).

Countries also represent different governance systems, with the systems in England, France, Hungary, Latvia and Lithuania characterised by governance structures that tend to be concentrated at the central (national) level, with decentralisation of some functions to bodies at arm's length from government, while elsewhere, administrative and political responsibility is partly or fully devolved to local or regional authorities (Denmark, Estonia, Italy, Spain) or state (Austria, Germany) or cantonal governments (Switzerland). In Austria, Germany and the Netherlands, corporate actors (for example social health insurance, providers) also play an important role.

Table 2.1 Selected features of countries reviewed

	Health expenditure (2008)		Main sources of funding for healthcare *(percent of total health expenditure in 2008)*	Governance of the public health system
	percent GDP*	US$ PPP‡		
Austria	10.1	3,836	Combination of statutory health insurance (44.9) and general taxation (31.7), OOP ¥ (15.3)	Responsibility for the health system shared by central government, nine state governments and corporatist actors; responsibility for hospital sector mainly with the states
Denmark	9.9	3,630	General taxation (84.7), OOP (13.6)	Responsibility for the health system shared by central government, regions and municipalities; regions and municipalities are largely responsible for organising healthcare
England (UK)	9.0	3,230	General taxation (82.8), OOP (10.8)	Responsibility for the health system is at central level by government and agencies at arm's length from government; local health service organisations (primary care trusts) purchase and provide healthcare
Estonia	5.9	1,226	National health insurance (66.6), taxation (12.1), OOP (6.8)	Responsibility for the health system is concentrated at the central level with some involvement of local authorities especially in the hospital sector
France	11.1	3,778	Statutory health insurance (73.8), VHI† (13.5), OOP (6.8)	Responsibility for the health system traditionally concentrated at national level with gradual decentralisation of (selected) governance functions to regional agencies
Germany	10.4	3,692	Statutory health insurance (67.8), general taxation (9.0), VHI (9.3), OOP (13.1)	Responsibility for the health system shared by central government, 16 state governments and corporatist actors; responsibility for hospital sector mainly with the states
Hungary	7.4	1,419	Statutory health insurance (58.0), general taxation (12.3), OOP (25.2)	Responsibility for the health system is at central level by government and agencies at arm's length from government
Italy	9.0	2,825	National and regional taxation (77.3), OOP (19.4)	Responsibility for the health system is shared by the central government and the 20 regions with regions having extensive autonomy
Latvia	6.5	1,112	General taxation (59.3), OOP (39.0)	Responsibility for the health system is concentrated at the central level by government and agencies at arm's length from government
Lithuania	6.2	1,178	Statutory health insurance (59.3), taxation (13.7), OOP (26.6)	Responsibility for the health system is concentrated at the central level
Netherlands	9.1	3,749	Statutory health insurance (76.5), taxation (5.5), VHI (6.1), OOP (6.3)	Responsibility for the health system shared by national and local authorities and corporatist actors
Spain	8.7	2,791	National and regional taxation (67.8), VHI (5.7), OOP (20.3)	Responsibility for organising publicly funded healthcare rests largely with the 17 regions (autonomous communities); national government sets regulatory framework and allocates funding
Switzerland	10.5	4,620	Mandatory health insurance (42.5), taxation (16.4), VHI (9.3), OOP (30.8)	Shared by the national and 26 cantonal governments with the cantons having extensive autonomy

NOTE: * gross domestic product; ‡ purchasing power parity/capita; ¥ household out-of-pocket expenditure; † voluntary health insurance

SOURCE: WHO (2010)[17];Ettelt et al. (2008)[18], authors

Survey of approaches to chronic disease management

We developed a common template for the collection of data on approaches to chronic disease management in European systems and on methods and metrics used to evaluate these approaches. The development of the template was based on a structured questionnaire used in the framework of a previous study by Nolte, Knai and McKee (2008)[19], and informed, to a great extent, by the Chronic Care Model (CCM) developed by Wagner and colleagues in the United States.[20] The CCM comprises four interacting components that are considered key to providing high-quality care for those with chronic health problems: self-management support, delivery system design, decision support, and clinical information systems. These are set within a health system context that links an appropriately organised delivery system with complementary community resources and policies. Accordingly, the template sought to gather information on (i) the health system and policy context and (ii) the type and format of approaches to managing chronic disease, examining nature and scope of the four components identified by the CCM as crucial to effective chronic disease management. The template was amended further to include a third section on the evaluation of existing approaches and a final section that explores system markers of success or failure for organisational approaches to chronic disease management. This also included an analysis of the strengths, weaknesses, opportunities and threats (SWOT) of the current system context and the critical success factors for chronic disease management in the country under review. Template development was coordinated by RAND Europe in close collaboration with the London School of Hygiene and Tropical Medicine.

The template uses simple checkboxes as well as open-ended questions. Where appropriate and relevant, sections include a glossary of definitions of terms, for example approaches to chronic disease management as described earlier, and guidance for completion including examples (such as SWOT) and checklists. A draft template was circulated among partners of the DISMEVAL project to ensure that definitions appropriately reflect different health systems contexts and the overall applicability of the instrument. A shortened copy of the template is provided in Appendix A of this report.

Data collection using the finalised template was undertaken by key informants in the countries under review. Of the 13 countries considered for review, seven were represented by DISMEVAL project partners (Austria, Denmark, England, France, Germany, the Netherlands, Spain) who were invited to complete the template. For countries not represented in DISMEVAL, key informants were identified through existing professional networks by the project leader coordinating an established network of country experts in eight European countries (the International Healthcare Comparisons Network).[21] Key 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 governmental advisory bodies.

Project partners and key informants were asked to adopt an evidence-based approach by making use of the best data available, using all relevant sources including completed/ongoing research projects, policy documents and routine statistics, surveys and census data related to chronic disease. They were further asked to compile data in consultation with organisations involved in the management of chronic disease such as

central government departments, health authorities (or their equivalent), arm's-length bodies/subordinate agencies and academic and training organisations. Where appropriate and necessary, additional information was to be gathered through interviews with key stakeholders and reviews of work in progress such as pilot projects, green/white papers, consultation documents, committee reports, parliamentary hearings, and proposals.

A number of countries are characterised by a wide range of frequently small-scale approaches at the local or regional level, in some cases conceptualised as pilot studies intended for subsequent rollout to larger geographical areas (such as Austria, Denmark, Italy and Switzerland). As it was beyond the scope of this study to provide a comprehensive inventory of all approaches being implemented in a given country, 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 the population covered.

Principal data collection was carried out from June 2009 to December 2009. Each completed template formed the basis for a country report, compiled and coordinated by RAND Europe and the London School of Hygiene and Tropical Medicine, with a follow-up to complete missing data and clarify information. Draft country reports were reviewed by the key informant leading template completion for each country to ensure accuracy and allow for the update of information where necessary and appropriate. Country reports formed the basis of the systematic cross-country comparison presented in this report; full country reports will be published in due course.[22]

Findings presented in Chapters 2 to 4 reflect the systems and features in place in the countries concerned as at July 2011.

2.3 Findings

Healthcare reform and chronic disease

In recent years, many European countries have sought to create a regulatory and policy framework to respond to chronic disease, generally aiming to promote approaches that better integrate care and improve coordination between sectors and levels of care (Table 2.2). In Germany, for example, the 2000 health reform introduced provisions for the development of integrated care structures, linking the ambulatory care and hospital sectors. In Austria, the 2005 health reform led to the creation of a financial pool at the state level (reform pool) to promote coordination of and cooperation between ambulatory and hospital care. The 2004 NHS Improvement Plan in England explicitly placed the care for those with chronic conditions at the centre of (successive) government reforms, emphasising the need to strengthen integration between providers and sectors. This objective was also central to recent efforts in Hungary and Lithuania to strengthen chronic care. Other reform efforts have aimed at supporting care coordination through the introduction and further development of nurse-led strategies in most countries reviewed here, although the degree to which relevant efforts have been implemented has varied. This ranges from nurses forming an integral part of primary care (for example in England, the Netherlands and Spain) to their deployment within defined areas of care delivery, as is the case in Austria, France and Germany. However, it is important to note that in many settings reform efforts have to be seen to be placed within a wider movement to improve

the overall quality of care, typically, although not exclusively, targeting chronic disease in particular, given their importance within the healthcare system.

At the same time, several countries have introduced more fundamental reforms which, although not necessarily introduced to specifically address chronic disease or indeed the healthcare sector, have impacted on the ability of systems to develop an integrated policy response to the rising burden of chronic illness. Most notable are reforms of national administrative structure, as in Italy and Denmark. For example, the 1992 Law 502 in Italy introduced the gradual decentralisation of administrative and financial functions, affording regions and local authorities increasing organisational and operative responsibilities. This was further strengthened and expanded by the 2001 Constitutional reform and 2009 legislation, which stipulated fiscal autonomy of regional institutions. While this has provided regions with the means to organise healthcare according to local needs, it has also meant that centrally planned policies tend to be fragmented and uncoordinated, resulting in considerable variation among (and within) regions. In Denmark, the 2007 administrative reform also changed the ways healthcare is funded and organised, with most responsibilities moving to regions as a means to increase efficiency of service delivery. At the same time municipalities were made responsible for co-financing of health services to encourage them to improve preventative services, which are organised at regional level, so as to reduce hospitalisation

Table 2.2 Overview of key reforms enabling chronic disease management in 13 countries in Europe

Country	Title of reform or regulation	Relevance to chronic disease management
Austria	1998 Health Promotion Act	Established the Healthy Austria Fund, which in 2006 became a division of the newly created Gesundheit Österreich GmbH ('Austria Health corporation')
	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
	2008 Agreement according to Federal Constitution Article 15a on the Organisation and Financing of the Healthcare system 2008–13	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-centred pilot projects in ambulatory care and the strengthening and further development of the reform pool to support chronic care approaches
	2010 Act to Strengthen Ambulatory Care	Introduced right for physicians to establish group practices ('ambulatory care centres') as limited liability company
Denmark	2007 Structural Reform	Reallocation of responsibilities in the healthcare sector between the five newly established regions and 98 municipalities
England	2000 NHS Plan	Substantial investment into the NHS; introduced national standards and targets; strengthened inspection and regulation through the reinforcing of inspection and regulation, to be supported by newly created national bodies to develop standards (National Institute for Health and Clinical Excellence) and to inspect health care facilities (Commission for Health Improvement, subsequently Care Quality Commission)
	2004 NHS	Introduced GP practice-based commissioning; placed care for those

Country	Title of reform or regulation	Relevance to chronic disease management
	Improvement Plan	with chronic conditions at the centre of (successive) government reform; committed to invest in services closer to home; required primary care trusts to implement case management by 2008
	2009 Health Act	Introduced the NHS Constitution, which set out rights and responsibilities for NHS patients and providers; implemented a personal health budget pilot scheme for the chronically ill
	2010 White Paper Equity and Excellence: Liberating the NHS	*Envisages for patients with chronic conditions to have choice in their care as part of personalised care planning, to further support self-management, and the further integration of health and social care services (bill under consideration by parliament)*
Estonia	Reorganisation of primary care (1991–2003)	Established general practitioners as first contact point and gatekeepers to specialist care; 1997 primary care reform plan set out to expand primary care to cover the whole population with family physician services by 2003; framework for family medicine distinct part of the 2001 Health Service Organisation Act
	2000 Hospital Master Plan 2015	Reform ongoing: small hospitals providing predominantly long-term care transformed into nursing homes or primary care centres for outpatient care
France	2002 Patients' Rights and Quality of Care Act	Formalised health networks with the aim to strengthen the coordination, continuity and interdisciplinarity of health care provision, with a focus on selected population groups, disorders or activities
	2004 Health Insurance Reform Act	Introduced a reform of the long-term disease ('ALD') scheme; introduced a form of gatekeeping through the preferred doctor scheme in the ambulatory care sector from 2005 and higher co-payments for patients accessing care outside a coordinated care pathway; created the National Authority for Health
	2004 Public Health Act	Proposed health targets for 2005–2009, half of which relevant to chronic condition; foresaw development of a national public health plan for people with chronic illness (2007); created the National Cancer Institute; formalised patient education and self-management
	2007 Plan for the improvement of the quality of life of chronically ill patients	Strengthened the focus on self-management of chronically ill patients and on improving the daily quality of life of people living with chronic conditions
	2009 Hospital, Patients, Health and Territories Act	Legalised transfer of tasks between professionals beyond experiments through development of contractual agreements of care protocols between professionals; clarified regulations pertaining to multidisciplinary and multiprofessional care centres; introduced the concept of patient education into the public health code
Germany	2000 SHI Act	Introduced provisions for the development of integrated care structures between the ambulatory care and hospital sector; required statutory health insurance funds to set aside a defined amount per member for primary prevention or health promotion activities
	2001 Risk Structure Compensation Reform Act	Introduction from 2002 of structured care programmes for those with chronic disease (disease management programmes)
	2004 SHI Modernisation Act	Established Federal Joint Committee; strengthened integrated care and general practitioner-centred care (through GP contracts); introduced medical care centres, which provide care across several healthcare 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	Further strengthened provisions for general practitioner-centred care

Country	Title of reform or regulation	Relevance to chronic disease management
	Organisational Structures within SHI	
Hungary	1990 Act LXV	Established statutory health insurance system
	1998 Act XCI of SHI Funds' Budget 1999	Reformed payment system; introduced Care Coordination Pilot programme; formed basis for treatment and financing protocols
	2006–2007 Cost containment reform	Reduced hospital capacity by 16,000 acute hospital beds; introduced 7,500 chronic care and rehabilitation beds
Italy	1992 Law 502	Transformed USLs into local public enterprises; begins successive process of decentralisation, with regions assigned increasing organisational and operative responsibilities
	1999 Legislative decree 299	Established regulatory framework to promote better integration of health and social care
	2001 Constitutional Law 3	Increased the degree of financial autonomy within the framework of minimum standards in welfare services
	2009 Law 42	Required central government to enact legislation, by May 2010, to guarantee the fiscal autonomy of regional institutions; introduction of accountability mechanisms and expenditure control systems
Latvia	1996 Development of primary health care	Formally endorsed general practitioner-based model of healthcare as a strategic priority
	2004 Regulations of the Cabinet of Ministers on Organisation and Financing of Health Care	Established current system of healthcare organisation and financing; outlined services and volume financed by the state; established unified payment system for all providers after extended experimentation with different payment systems during 1990s
	Programme of Development of Primary and Hospital Care Services for 2005–2010	World Bank-led reform to ensure integrated healthcare system development through optimising number and distribution of health service providers
Lithuania	1998 Introduction of primary care	Introduced family physician medical norm; development of family physician practices and a network of community mental health centres
	2007 Primary health care development concept	Expansion of the concept of primary care to include primary personal healthcare, dental healthcare and primary mental healthcare; improving collaboration of family physicians and specialists; and involving family physicians in municipal health and social care programmes
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 the Chronically Ill and Handicapped Persons	Intrdouced entitlement for the chronically ill and disabled persons to receive a fixed allowance to compensate for excessive healthcare 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
Spain	2001 Law on the financing system of the autonomous communities	Devolved health responsibilities to regional administrations; integrated health funds within Autonomous Communities' general funding system; 2009 revision increased Autonomous Communities' fiscal autonomy
	2003 SNS Cohesion and Quality Act	Developed national health strategies addressing common chronic diseases and rare diseases; introduced national strategy on patient

Country	Title of reform or regulation	Relevance to chronic disease management
		safety
	2006 SNS Common benefits package	Established process for updating common benefits package to enable response to technological advances and changing population need; further revision under discussion
Switzerland	1996 Health Insurance Law	Introduced mandatory insurance system; set out provisions for managed care and hospital financing
	2006 Federal Law on Health Promotion and Disease Prevention (ongoing)	Development by Federal Council in progress; aim to improve the conduct, coordination and evaluation, at a national level, of health promotion and disease prevention.

Tracking key developments in the policy context for chronic care in 13 countries

Many of the reforms described in the preceding section will pave the way for the development of a comprehensive policy response to chronic diseases. Ideally, such a response would adopt a population health management approach, bringing together elements of health promotion and primary prevention, early detection and treatment, alongside the management of co- and multi-morbidities and complications as well as palliation and end-of-life care in one overarching framework.[23] However, health systems vary and policies that are implemented will reflect the characteristics of individual systems as they relate to the relationships between, and responsibilities of, different stakeholders in the regulation, funding and delivery of healthcare. Therefore, and not surprisingly, countries reviewed vary with regard to their vision for controlling and managing chronic disease and the extent to which the broader healthcare reforms described in the preceding section have been translated into strategic policies.

It is beyond the scope of this report to provide a detailed and systematic account of how a given environment has influenced the policy choices addressing chronic disease that have been or are being made in the countries reviewed; we will explore some of these issues in further Chapter 4. We here summarise the key policy developments documented for the 13 countries under consideration, focusing on major initiatives that have been implemented or are being considered for implementation. A detailed description of policies adopted in the 13 countries is provided in an accompanying publication.[22]

At the risk of simplification, we can conceive policies that have been implemented to be lying on a spectrum that stretches from overarching strategies for chronic disease control to a lack of an explicit policy focus on chronic diseases altogether. While there are a few examples illustrating either end of the spectrum, including Denmark and possibly England as examples of the former, and the three Baltic states as an example of the latter, the majority of countries reviewed here can be seen to be lying somewhere in the middle of the spectrum, by having implemented a range of frequently parallel policies targeting specific elements along the care continuum. However, we make a deliberate attempt to not grade or categorise countries according to the level of comprehensiveness of chronic care policies that are being adopted. Any such attempt might be misleading in that any one policy may be judged as superior over another when, in reality, policy choices, intentionally or not, will be determined to some degree by what has happened in the past and reflect the context within which they are being made.

Thus, **Austria** has so far not developed an overarching national and integrated strategy on chronic disease. However, recent developments signal attempts to move to a more integrated approach, with various recently intoduced legal and regulatory measures aiming to strengthen cooperation between the different sectors of the health system. Of particular importance is the 'reform pool' (Table 2.2), a financial instrument to promote the coordination of and cooperation between ambulatory and hospital care;[24] the majority of current approaches to chronic care such as structured disease management programmes have evolved from reform pool projects. However, implementation of reform pool activities has been uneven across states and it remains challenging to arriving at an overarching strategic approach in a system that involves multiple actors in the negotiation in the ambulatory care sector in particular.

Conversely, **Denmark** has developed a government-endorsed national vision of chronic disease control and management in the form of the overarching 2002 Healthy throughout Life strategy.[25] Driven by consensus for a need to re-organise delivery of healthcare services, its focus is on major preventable diseases and disorders, and on improving quality of life and minimising health inequalities. The implementation of the policy hinges upon a high degree of collaboration between the leadership in the regions and municipalities as well as general practitioners. This 2007 administrative reform described earlier introduced a new role for municipalities in the healthcare sector and the government has granted about €70 million to the regions and the municipalities to support improvement in chronic care. Thus, successful implementation will depend on capacity developed at municipal level to fulfil its new role in healthcare, as well as coherent, well-evaluated programmes informed by the policy.

In **England**, the need to better address chronic diseases has been recognised since the late 1990s. Policy initiatives have involved the setting of national standards and guidelines; the increasingly systematic use of non-medical professions in chronic disease and case management; and a national pay-for-performance scheme to incentivise high-quality chronic care in particular. The NHS and Social Care Long Term Conditions Model provides the closest representation of a national vision for addressing chronic conditions in the English NHS.[26] The focus is on prevention, supporting self-management and partnership working. However, although stipulated as the basis for chronic care policies in England, the extent to which this overall vision has been or is being implemented in practice remains unclear. Newly proposed reforms by the Coalition government have raised questions about the ability of providers and the system overall to deliver integrated services within an increasingly competitive environment. At the time of writing, the government's proposals were still being considered by parliament.[27]

Similarly, in **France**, the 2007 national Public Health Plan on Quality of Life for the Chronically Ill may be viewed to go some way towards a national vision[28]; it is the first attempt at chronic disease management in France that simultaneously involves health professionals, patients and the statutory health insurance. Recurring themes in policy development include reinforcing prevention and patient education; redefining task sharing between physicians and nurses; and the development and implementation of novel delivery and remuneration concepts. Overall it remains unclear to what extent these novel approaches will find sufficient ground within the French healthcare system, given the

continued strong cultural and professional reluctance to an intermediate type of chronic disease manager and to novel methods of monitoring health and delivering care.

Germany has introduced various legal and regulatory measures to stimulate and facilitate the implementation of new models of care to better meet the needs of those with chronic conditions. Statutory health insurance funds and providers have made use of these new opportunities, with structured care or disease management programmes such as those introduced by the 2001 Risk Structure Compensation Reform Act representing the principal regulatory and policy framework for chronic care in the country.[29] However, the implementation of more efficient and effective care for those with chronic conditions continues to face considerable barriers and there is a need for better understanding of how current and future health (and social) care needs can best be addressed with a restructuring of the care and (financial) incentive system.

Conversely, in **Hungary** government policy has been dominated by efforts to reduce public spending in healthcare in response to fiscal constraints. However, there are examples of measures aimed at addressing chronic disease, building, in part, on historically established structures such as dispensaries, and nationwide, disease-specific strategies within the 2003 National Public Health Programme, focusing on primary and secondary prevention in particular.[30] However, the unfavourable fiscal climate for healthcare in Hungary has meant that very few programme plans or other approaches to chronic care were implemented in practice and a decrease in funding allocated to the national programme poses challenges for the extent to which this approach can address the prevention of chronic conditions.

In **Italy**, the decentralised structure of the health system has meant that there is considerable diversity with regard to the extent and quality of chronic disease strategies across regions. However, national strategies to address chronic diseases are receiving greater attention, through a series of national health plans, introduced since the late 1990s, aimed at health promotion and disease prevention, with an emphasis on structured approaches to chronic care formulated from 2003 onwards.[31] More recent efforts to overcome fragmentation include the implementation of a national framework for diabetes to guide initiatives at, and endorsed by, the regional and local level. Parallel developments have involved experimental initiatives to chronic disease management at local and regional level, which are expected to spread slowly across localities.

In the **Netherlands**, the control and management of chronic conditions have become a priority in healthcare policymaking, with a nation-wide push to improve the quality of care for these conditions in the form of the 2008 programmatic approach to chronic illness care.[32] However, a principal document setting out a national strategy for chronic disease overall is lacking. The main features of the programmatic approach include the use of nationally developed, evidence-based care standards and quality indicators, the promotion of multidisciplinary care teams, a focus on self-management and the promotion of performance-based financing on the basis of bundled payments. A key challenge remains the development of care models that meet the needs of those with multiple conditions.

In **Spain**, the national health system's Quality Plan 2010 focuses in part on promoting the development of new strategies and cross-sectoral actions for individuals with chronic diseases.[33] However, the success of any national policy direction on chronic care will

depend on its uptake within a highly decentralised administrative structure. The Basque government, in its 2009–13 Health Strategy, proposes a strategy on chronic care for the Basque country, building on the Chronic Care Model.[34]

Finally, the highly decentralised structure of the health system in **Switzerland** has been viewed to present a major obstacle for a nationwide public health strategy and the integrated organisation of healthcare.[35] However, general interest in chronic disease initiatives is emerging and there is a range of cantonal and/or local or regional initiatives targeting chronic diseases. Currently, managed care as set out in the Health Insurance Law represents the principal regulatory and policy framework for chronic disease management in Switzerland. A federal law on health promotion and disease prevention, aimed at improving the conduct, coordination and evaluation, at a national level, of health promotion and disease prevention is under consideration.

Countries such as Estonia, Latvia and Lithunia have yet to formulate an explict strategy to address chronic disease at either the national or the regional level. However, **Estonia** has established a strong base for the further development of chronic care and one of the stated goals of healthcare system restructuring was the need to provide chronic disease management in primary healthcare.[36] In **Lithuania**, health policy documents are increasingly addressing the issues of integrated care and coordination between health and social care. This is enabled by the further development of primary healthcare. Likewise, in **Latvia** there is consensus that future developments of a system of chronic disease care will focus on primary healthcare and homecare.

Overview of approaches to chronic disease management

This section examines in more detail the actual approaches to chronic disease management and models of care delivery that have been or are being implemented in a range of European countries. We review some 50 approaches and groups of approaches described for 13 countries in Europe, describing the key types of approaches countries are employing, together with the nature and scope of professionals and healthcare providers involved. We also examine the extent to which patients are actively engaged and/or supported, the use of support structures such as decisionmaking tools and guidance, approaches to financing and the use of financial incentives and the availability or distribution of approaches and population(s) covered. We should note that the terms 'approaches', 'care models' and 'programmes' are being used interchangeably to describe a given chronic disease intervention.

As noted earlier, it is beyond the scope of this study to provide a comprehensive inventory of all approaches being implemented in a given country; instead we focus on a 'sample' of approaches considered representative of a given health system. Against this background, and given the highly selective nature of the types of approaches described below, we have refrained from attempting to quantify observed features through counts or proportions. Instead, we provide a narrative account of key observations.

As the focus of this work has been specifically to identify and describe approaches that broadly aim to improve the care for those with chronic health problems, the stated aims of the various approaches typically have the improvement of the quality of care at their core. However, it is important to note that the majority of approaches focus on care models for populations with defined conditions, most frequently targeting diabetes type 2, followed

by asthma/COPD, cardiovascular disease, mainly chronic heart failure, ischaemic heart disease, cardiovascular risk, stroke, cancer and mental health problems (Table B.1 Appendix B).

At the same time, several countries reviewed here are also implementing approaches with a more general focus, typically centring on older people. These tend to be available in selected regions only and/or are operated as pilot studies. Examples include the Partnership for Older People Project (POPP) in England, the COPA Coordination of Professional Care for the Elderly programme in Paris/France, selected integrated care contracts in Germany and the Care Coordination Pilot (CCP) in Hungary. Several of these pilot programmes are being adapted for implementation in other regions (for example COPA programme in France) or are being supported beyond completion of the pilot phase (for example 85 percent of POPP projects in England).

Three countries, Estonia, Latvia and Lithuania, have not (yet) established chronic disease management as a distinct concept. Instead, chronic care is seen to be embedded within the primary care system, which was newly introduced in the 1990s, with the general practitioner or family physician at the core. However, within this framework, Estonia and Lithuania are implementing strategies specifically targeting (complex) chronic conditions.

Most approaches and care models were introduced in the 2000s, with some in an ongoing process of implementation and/or a pilot stage. Only few approaches described here date back to the 1990s or earlier; these include the ambulatory after-care service for stroke in the state of Salzburg, Austria (1989), the stroke service in Delft, the Netherlands (1994), and the Delta physician network in Geneva, Switzerland (1992). This confirms our earlier observation that chronic disease care has only relatively recently become the focus of health policymakers, regulators, funders and other stakeholders. It also reflects the academic discussion around approaches to, and models of care for chronic health problems that has emerged from the mid-1990s onwards, largely evolving from accumulating evidence of the effectiveness of structured disease management in the United States.[13] At the same time it is important to recognise, as indicated here, that countries have experimented with new models of care well before the current chronic care debate, usually in the context of care for the frail elderly at the interface between the cure and care sectors; related concepts are frequently referred to as share care. Indeed, the Matador model of diabetes care described for the Maastricht region in the Netherlands has evolved from a shared care approach implemented in 1996.

At the risk of simplification, most approaches and care models described for countries involve some form of care coordination, with the general practitioner or family physician typically acting as the principal coordinator (DMPs in Austria, Germany, and France). Where multidisciplinary teams act as principal coordinator, these are frequently led by a GP or other physician/s (for example SIKS project in Copenhagen, Denmark; selected integrated care pilots in England; local cancer networks in France; integrated care contracts and medical care centres in Germany and others, see Appendix B). The majority of countries are also employing, or are beginning to introduce, nurse-led approaches although there are differences in the degree to which nurses can operate independently. For example, models in place in England or in the Netherlands allow for a high degree of independence while approaches such as the Sophia diabetes care programme in France and the

KardioMobil home care for patients with chronic heart failure programme in Salzburg, Austria involves nurse-led interventions to support patient self-management in collaboration with the patient's GP. Germany has recently introduced nurse-led approaches using care assistants in family practice (VerAH), with selected medical tasks delegated to the practice nurse but legally assigned and performed under the supervision of a GP.

A small number of approaches use care coordinators with a non-medical and non-nursing background. These tend to focus on after-care, rehabilitation and general support schemes. Those involved include allied health professionals (for example, team of therapists in the ambulatory after-care of stroke patients programme in Salzburg, Austria), social or 'hybrid' (health and social care) workers (Partnerships for Older People Project, England), volunteer organisations (Partnerships for Older People Project, England) or skilled key workers (selected integrated care pilots, England). The care coordination/interface management programme in Styria, Austria, offered by the regional social health insurance fund, uses an employee of the SHI fund as the principal coordinator for discharge management; similar approaches in other parts of Austria use nurses or social workers.

Financing, distribution and uptake of approaches

The majority of approaches reviewed here are funded from **usual sources**, frequently supplemented by additional resources made available through (time limited) funds earmarked for care coordination and integration initiatives (Table B.1, Appendix B). In several cases, additional funding has provided a one-off, start-up grant to support project implementation; examples include the two major pilot programmes in England (Partnerships for Older People Projects; Integrated Care Pilots) and integrated care contracts in Germany. There are a few examples of additional funding provided by the pharmaceutical industry, including in Hungary (the asthma disease management and diabetes care management programmes) and Italy (the Leonardo and Raffaelo diabetes disease and care management projects).

Several approaches use ongoing financial incentives, usually targeted at physicians. These typically involve additional reimbursement for documentation, patient enrolment and/or regular assessment (for example DMPs in Austria and Germany; the Sophia diabetes care programme in France) and/or for quality improvement activities (for example quality management in primary healthcare in Hungary; GP contracts in UK and Germany; the Delta physician network in Switzerland). Selected approaches also involve elements of pay for performance and/or financial risk sharing of providers. Examples include the Care Coordination Pilot in Hungary; From On-Demand to Proactive Primary Care in Tuscany, Italy; the Leonardo Project in Puglia, Italy; and the bundled payment contracts in the Netherlands. The latter also provides one of the few examples of attempts to integrate funding for the full range of services for patients with a given condition.

Given that most of the approaches reviewed here are funded within the usual system, patient access is typically granted in line with access to usual care. Indeed, the majority of approaches are free of charge. Only a few approaches require co- or full payment by patients to enable access; these include ambulatory after-care for stroke patients in Salzburg (with exemption from co-payments for those on low incomes) and the Gluco.net website in Hungary, although access was made free of charge in 2010. Some approaches offer

explicit incentives for patients to participate. These typically include exemption from co-payments for usual care services they would otherwise have to pay for (for example health networks in France; DMPs and GP contracts in Germany).

Even where approaches are free at the point of use, many are implemented in selected geographical regions, potentially limiting access to defined population groups. National approaches include, for example, the Quality and Outcomes Framework in England and the disease management programmes in Germany. Several approaches have been implemented at the regional level but are being (gradually) extended towards countrywide coverage. These have frequently, although not always, evolved from pilot or experimental projects. Examples include the diabetes disease management programmes in Austria; the IGEA diabetes disease management programme in Italy and the GP-formed care groups in the Netherlands. Some approaches are fairly localised but are being considered for implementation elsewhere, such as the SIKS Integrated effort for people with chronic disease project in Copenhagen/Denmark and the previously described COPA coordination of professional care for the elderly programme in Paris/France.

Components of chronic disease management

As noted in the Introduction to this report, data collection on approaches to chronic disease management in Europe has sought to examine the extent to which these make use of the four components considered key to providing high-quality care for those with chronic health problems as identified by the Chronic Care Model (Section 2.2).[20] These are identifed as four core components that are embedded within a supportive health system context:

- self-management support
- delivery system design
- decision support
- clinical information systems.

Using this categorisation, we find that the large majority of approaches provides some form of **patient self-management support**, although the level of support offered varies considerably, from the provision of information material such as brochures (Table B.2, Appendix B) (for exampleIntegrated stroke care Upper Austria; Delta physician network, Switzerland) or an interactive website (Gluco.net in Hungary), to routine assessment of clinical indicators (for example clinical guidelines in Lithuania) to access to coaching and face-to-face or telephone follow-up (for example Raffaelo project, Italy), lifestyle intervention training (for example Matador disease management programme, Netherlands) and counselling techniques (for example National care standard for vascular risk management, Netherlands). Most approaches involve patients in the development of a care or treatment plan and goal setting, and provide regular assessment of patient needs and problems. However, the extent to which these support mechanisms are implemented in practice is often unclear.

In the majority of cases, self-management support is provided by health professionals including physicians (eg disease management programmes in Austria and Germany; chronic disease management at the primary/secondary care interface in Estonia), or, more

frequently, trained nurses (eg selected integrated care pilots in England; quality management in primary care in Estonia; the Sophia diabetes care programme and health networks in France; Care Coordination Pilot in Hungary; IGEA, Leonardo Pilot Project and Project Raffaello in Italy; GP-formed care groups and stroke services in the Netherlands; the breast cancer clinical pathway in Lausanne, Switzerland). Self-management support provided by others including lay groups appears uncommon; examples include the Expert Patients Programme and selected projects implemented within the Partnerships for Older People Project in England.

Most approaches reviewed here involve some form of **delivery system design** but as with self-management support the nature and scope of related strategies varies. Common elements include a clear definition of roles, the development of (individualised) care or treatment pathways and patient follow-up. Several approaches use case finding and/or risk stratification (for example Care coordination/Interface management Styria/Austria; Partnership for Older People Project and Integrated Care Pilot projects, England; COPA Coordination of Professional care for the Elderly, France; selected integrated care contracts, Germany; National care standard for vascular risk management, Netherlands). These approaches also tend to involve case management, or indeed constitute dedicated case management approaches, such as within the Partnership for Older People Project and Integrated Care Pilot projects in England; the COPA Coordination of Professional Care for the Elderly in France; and the improving intersectoral collaboration approach in Lithuania. Case management elements are also incorporated within selected GP contracts in Germany and other approaches.

These strategies commonly include **decision-support** tools such as guidelines and protocols, developed at organisational, regional, national or international level with some strategies also incorporating training in translating national or regional guidelines to the local level as, for example, within local cancer networks in France. Dedicated staff training tends to be common for those strategies that involve (the delegation of tasks to) non-medical professionals such as nurses (for example IGEA, Leonardo Pilot Project and Project Raffaello in Italy; breast cancer clinical pathway in Lausanne, Switzerland), practice assistants (for example VerAH Care assistant in family practice, Germany; GP-formed care groups, Netherlands) or allied health professionals (for example therapists in ambulatory after-care of stroke patients in Salzburg, Austria). Physicians acting as DMP coordinator in Austria, Denmark, Germany and Italy are required to undergo additional training; in other settings, this is provided within the framework of continuous medical education (for example Estonia, France, Hungary).

A number of approaches also provide training in the use of specific programmes designed to support case finding (for example Care coordination/Interface management Styria, Austria; COPA Coordination of professional care for the Elderly, France). However, overall the use of **clinical information systems** for chronic disease management tends to be the least developed strategy in most approaches. Exceptions include England and Estonia, with both employing standardised electronic medical records and electronic booking and reminder systems throughout the primary care system.

2.4 Summary

This section has reviewed the regulatory context for, and approaches to, chronic disease management in 13 European countries. It finds that most countries have sought to create a regulatory and policy framework to respond to chronic disease during recent years but they differ with regard to their vision towards controlling and managing chronic disease and the nature and scope of their response. Likewise, approaches to chronic disease management vary in scope and nature across Europe. This review did not attempt to present a comprehensive inventory of all approaches being implemented in a given country; however, in summary we find that:

- the majority tend to focus on care models for populations with defined conditions, most frequently diabetes type 2, and involve some form of GP-led care coordination
- nurse-led approaches are becoming more common although there are differences in the degree to which nurses can operate independently
- patient access is typically granted in line with access to usual care although many approaches are being implemented in selected geographical regions so potentially limiting access to defined population groups
- the majority provide some form of patient self-management support, although the level and scope of support offered varies
- overall, the use of clinical information systems for chronic disease management tends to be the least developed strategy in most approaches.

CHAPTER 3 Assessment of existing approaches to evaluate disease management in Europe

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3.1 Introduction

As highlighted in the Introduction to this report, while there is growth in the use of structured approaches to better manage the care of those with chronic illness, the existing evidence that such approaches improve care quality and patient health outcomes remains uncertain. This is in part due to a lack of widely accepted, and consistently applied, evaluation methods to measure and report programme performance in a scientifically sound fashion that is also practicable for routine operations.

This chapter presents first a summary of the current state of the art of methods and metrics used to evaluate chronic disease management, drawing on a comprehensive review of the academic and grey literature that has been published elsewhere.[37] We begin by outlining some of the key challenges and areas for improvement that emerged from the review: these were conceptual, methodological and analytical in nature. We include some strategies and techniques that have been suggested to enhance the rigour and likelihood of measuring the 'true' effects of chronic disease management.

Second, we present an overview of documented approaches to evaluation of chronic disease management initiatives or their equivalent in European countries. Specifically, we describe the evaluation aims and designs and the range of indicators of effect and data sources that have been applied. We also consider the actors involved in documented evaluations, targeted audiences and funding associated with evaluation activities.

3.2 Methods

Review of the literature

We carried out a two-stage review to identify the literature on existing methods and metrics to evaluate disease management programmes, approaches or interventions. We identified papers for possible inclusion by combining searches of electronic databases, hand searches of reference lists of included papers, contact with experts in the field and a

purposive electronic search of grey literature on key websites. Details of our search strategy, inclusion and exclusion criteria have been described elsewhere[37]; we here briefly outline our approach, which was conducted between February and September 2009, with additional literature included following peer-review of the draft review in September 2010. At the time of the search, no limits were placed on the publication date of papers included.

The first stage of the review identified 72 documents for inclusion based on a targeted search of existing reviews of methodology papers in peer-reviewed journals and grey literature; subject-specific journals; articles and references provided by leading authors in the relevant field; and common search engines and websites of organisations and companies known to offer disease management programmes. The second stage involved a systematic search that focused on three concepts: evaluation research; disease management; and indicator of effect. The search term combinations used were informed by the first stage of the review, using Medline/PubMed, Web of Science and CINAHL. We identified a total of 4,053 titles of which we extracted 332 for abstract review and duplicate removal. Further review resulted in 34 additional titles for inclusion in the review.

In total, the literature review included peer-reviewed articles (n=89), book chapters (n=6), working papers/reports (n=10) and other grey literature such as professional journals or fact sheets (n=7).

Survey of approaches to evaluation of chronic disease management in Europe

As described in Chapter 2, a common template was developed to collect information on approaches to chronic disease management in European healthcare systems that also collected data on methods and metrics used to evaluate these approaches. This covered, for example, evaluation goals, evaluation design and methods of attribution, indicators of programme effect, data sources used and use of evaluation findings to inform policy (Appendix A).

Of the 13 countries included in the survey (Chapter 2), we did not review approaches to evaluation in countries where the intervention only targeted people at-risk of chronic disease. We therefore reviewed 12 countries: Austria, Denmark, England, Estonia, France, Germany, Hungary, Italy, Latvia, Lithuania, the Netherlands and Switzerland. Details on data collection are provided in Chapter 2, section 2.2.

Data were extracted according to two dimensions: (i) the chronic disease management approach by country and (ii) evaluation categories as identified in the structured questionnaire (aim, audience, focus, budget, frequency, design, length, data source, indicators of programme effect, feedback mechanisms in place). Data on indicators of programme effect were extracted as reported, following a priori response categories: cost; utilisation; structure (registry, reminder, other); and process (referral rates, monitoring, clinical, knowledge, other) measures. Open responses to 'other' evaluation measures were clustered (for example self-management, quality of life, health status) where possible, to ensure consistency and enable comparison. Data extracted into summary tables were twice verified with country informants for accuracy and completeness.

We used content analysis to categorise the data and, as appropriate, determined numbers and frequencies of these categories. We then summarised the data using a narrative approach for identifying commonalities and differences between evaluation approaches.[38]

3.3 Findings

Review of current state of the art in disease management evaluation

There is a large body literature on the methods and performance measures used for the evaluation of disease management. The review identified a number of conceptual, methodological and analytical challenges.

Conceptually, evaluation faces the challenges of a diversity of interventions subsumed under the heading of 'disease management', which are implemented in various ways, and a range of target populations for a given intervention. It is therefore important to clarify the characteristics of a disease management intervention in terms of its scope, content, dose and wider context. Doing so would permit an understanding of the effects expected and how the intervention might produce them; it would also allow for the replication of the evaluation and the implementation of the intervention in other settings and countries. Other conceptual challenges relate to the selection of evaluation measures that often fail to link indicators of effect within a coherent framework to both the aims and elements (patient-related and provider-directed) of a disease management intervention and the evaluation's objectives.

A key methodological and analytical challenge is the establishment of the counterfactual, that is, what would have happened in the absence of the intervention. Randomised controlled trials are generally viewed as the 'gold standard' to assess the efficacy of a given intervention where individuals are randomly allocated to an intervention or a control group so providing for a controlled environment to allow for conclusions on causality to be drawn. In the context of multi-component, multi-actor disease management initiatives, this design is frequently not applicable because randomisation may not be possible (or desirable) for reasons such as cost, ethical considerations, generalisability, and practical difficulties of ensuring an experimental design. As a consequence, alternative comparison strategies need to be considered to ensure that the findings of intervention effect(s) are not explained by factors other than the intervention. Yet, as these alternative strategies move away from the conditions of a controlled experiment, the number of 'threats' to the validity of findings from possible sources of bias and confounding increase (for example attrition, case-mix, regression to the mean, seasonal and secular trends, selection, therapeutic specificity). These challenges imply the need for a comparison strategy that involves closely mirroring what would have happened without the intervention.

Our review describes the limitations of different options for study designs other than the controlled experiment. We describe analytical strategies for constructing a control group that most closely establish the counterfactual. These include predictive modelling or propensity scoring techniques that can create controls randomly matched to intervention participants; controls that can be created statistically by developing baseline trend estimates on the outcomes of interest for comparison with the intervention's effects. However, a set of limitations remains and analytical challenges must be carefully considered and may be addressed at the analysis stage. While selected statistical techniques can be applied *ex post facto* to achieve the objectives of randomised controlled trials, such as regression discontinuity analysis, it may be preferable to plan prospectively before a given intervention is implemented to obtain greater scientific returns on the evaluation effort.

Other methodological and analytical challenges for the evaluation of disease management include accounting for sufficient statistical power to detect a significant effect given the frequency of small numbers, non-normal distribution of outcomes and variation in dose, case-mix, and so on, that are common for disease management initiatives. Several of these challenges can be addressed by analytical strategies such as through extending the measurement period from 12 month to 18 months or longer, and adjusting for case-mix to calculate sample size, for example. Ultimately, what is required is a clear framework of the mechanisms of action and expected effects that draws on an understanding of the characteristics of disease management (scope, content, dose, context), those of the intervention and target populations (disease type, severity, case-mix), an adequate length of observation to measure effects (three to five years) and the logical link between performance measures and the intervention's aims, elements and underlying theory driving anticipated behaviour change among participants, both providers and patients.

Review of evaluation approaches of chronic disease management in Europe

Most of the approaches to chronic disease management described in Chapter 2 have undergone some form of evaluation or have evaluation plans in place. However, the nature and scope of evaluations vary, with differences in objectives, design, the performance metrics used, the length of observation and approaches to data collection. In Latvia and Lithuania, we were unable to identify documented evidence of evaluations of chronic disease management approaches; this is largely because dedicated approaches have only just been implemented in Lithuania, and are still under consideration in Latvia (Chapter 2). The range of approaches to the evaluation of chronic disease management were characterised by a mix of controlled and non-controlled studies measuring primarily clinical process and intermediate outcome indicators on a sub-population of patients with a single chronic disease, usually over one to three years. Appendix C summarises the main characteristics of documented evaluations for the chronic disease management approaches reviewed.

Evaluation aims and designs

The aims of chronic disease management evaluations varied widely, with many evaluations pursuing two or more aims. There were differences within and between countries in the design and use of comparison strategy for measuring true intervention effect (Table C.1 in Appendix C).

Evaluations were generally designed to assess the performance (and/or process) of a given programme or approach in relation to established targets, including quality, effectiveness (clinical and/or cost), satisfaction and adherence (to treatment by patients, or to protocols by providers). Precise and measurable information about established targets against which intervention effects might be compared, was rarely specified however (for example 40 percent participation of new breast cancer patients; the inclusion of a minimum of 150 patients per year). Programme evaluations that focused on outcomes varied widely within and between countries. We identified:

- randomised controlled studies (RCTs)
- controlled prospective and retrospective longitudinal evaluations
- controlled pre-post or post-only studies

- pre-post or post-only assessments without control but with benchmark comparisons
- cross-sectional studies with or without control
- non-controlled non-comparative pre-post or post-only assessments.

A number of programme evaluations also included qualitative methods, often to provide context for quantitative results or to combine outcomes and process evaluation. Examples include: Integrated care stroke Upper Austria; Expert Patients Programme, England; Partnerships for Older People Project, England; Integrated Care Pilot Programme, England; Quality management in primary care diabetes and CVD, Estonia; Programme for multidisciplinary meeting RCP and Dispositif d'accès aux soins de support, France; Care Coordination Pilot, Hungary; IGEA project, Italy.

Several formative evaluations aimed to assess the feasibility of a given approach (for pilot implementation and/or roll-out). An example was the Therapie Aktiv diabetes disease management programme in Austria that used a pre-post design, controlled for post-only analysis. Others used, for example, a pre-post formative evaluation such as the Leonardo Pilot Project (Italy); this latter was the only feasibility study to aim at identifying and refining evaluation techniques for future use.

Some evaluations resembled auditing to monitor implementation or report activity, in some cases also to identify areas for improvement of service, staff or quality. Where information was available, these audits varied in design, ranging from qualitative or non-controlled cross-sectional (Austria and France) to controlled longitudinal studies (Germany). In some studies, the aim of monitoring performance was combined with aims of a process or a programme evaluation (for example integrated clinical pathway for heart disease, Denmark; IGEA project, Italy).

Very few approaches were evaluated solely for economic impact. These included a return on investment study of Gesundes Kinzigtal integrated care contract in Germany and a controlled observational study of Prosper Net integrated care contract, also in Germany. However, economic effects were commonly examined, aiming to assess value for money (for example REVESDIAB and DIABAIX diabetes networks, France); cost utility (Project Raffaello, Italy); cost effectiveness (for example Expert Patients Programme, England; Diabaide diabetes care programme, Switzerland; Matador diabetes disease management programme, the Netherlands); or cost reduction (GP contracts, Germany) and savings (Care Coordination Pilot, Hungary).

Evaluation designs that employed a comparison strategy varied in the source for creating controls. These could include concurrent hospital patients (for example Stroke Service Delft, the Netherlands); patients with diabetes in the region of the intervention (Therapie Aktiv disease management programme); or general population as derived from a national household panel Partnership for Older People Project, England. References employed in benchmark comparisons included international best practice or the literature (for example SIKS project, Denmark); performance targets or timelines (for example chronic disease management programme for multiple sclerosis, Estonia; bundled payment system for diabetes, the Netherlands); other regions, sites or practices in the country (for example

IGEA project, Italy) or regional standard or mean value (for example From On-Demand to Proactive Primary Care and IGEA project, Italy).

Performance metrics, length of observation and data sources

There were substantial differences within and between countries in the indicators of effect and length of observation used to evaluate disease management approaches (Table C.2 in Appendix C). Evaluations commonly used combinations of metrics, including processes such as hospitalisation or utilisation rate, outcomes (for example satisfaction, survival, mortality, quality-adjusted life years (QALY)) or measures of cost (for example cost effectiveness or cost-benefit). Many used intermediate health outcomes such as HbA1c, cholesterol levels, body mass index and blood pressure, alongside medication.

Process measures showed the most variation. Most evaluations included one or more clinical process measures (for example referral rates, laboratory tests, prescription rates, adherence to clinical standards) and sometimes organisational process measures of regular monitoring (for example number, type and waiting times for consultations). Very few evaluations measured patient or provider knowledge; examples include Therapie Aktiv diabetes disease management programme and Coordinated care/Interface management Styria, Austria; Gesundes Kinzigtal integrated care contract, Germany.

Where identified, 'other' structural metrics were included; examples are building space measured in square metres; equipment purchased; the scope of services, access, and hotline provision; assessment procedures; the extent of IT penetration ('informatisation'); educational resources and budget (data not shown). Structural measures of effect such as registries and reminders were much less studied. Examples include the Leonardo Pilot Project, Italy (reminders) and the breast cancer clinical pathway, Lausanne/Switzerland.

Evaluation timeframes were equally variable but tended to involve either 12 or 36 months of observation. Health and/or economic impacts were most commonly measured after only 12 months' observation while others examined shorter periods (SIKS project and integrated clinical pathway for heart diseases, Denmark; Care Coordination Pilot, Hungary). There were also examples of longer-term evaluations of clinical and financial outcomes of 36 months duration such as in England, France, Germany and the Netherlands, and one 60-month evaluation to assess the sustainability of multi-functional community centres in Hungary. Some evaluations had flexible or recurring timeframes, so producing a series of data points to measure such longer-term effects without risk of bias. These include the continuous evaluations of France's health networks (every 12 months), Estonia's quality management in primary care and chronic disease management approaches (every 12 months), and Italy's IGEA project and the From On-Demand to Proactive Primary Care approach.

The majority of approaches were evaluated using new data and routine sources such as medical records, laboratory tests or provider registries. Surveys were the dominant method of collecting new data for evaluation (for example Coordinated care/Interface management Styria, Austria; Expert Patients Programme, England; health networks and multi-disciplinary team RCP, France; GP contracts, Germany; Project Raffaello, Italy; Matador diabetes disease management programme, the Netherlands). Other sources of new data for evaluations included interviews, focus groups, site visits or direct observation, intervention-specific datasets, and literature or document review.

Evaluation actors, audience and budget

Evaluations of approaches were carried out by a variety of actors. These included external evaluators (for example integrated clinical pathway for cancer and for heart diseases, Denmark), internal evaluators (for example chronic disease management approaches in Estonia) or a combination of both (for example SIKS project, regional disease management programmes, Denmark). In England, France, Germany, Italy and the Netherlands, external evaluations appeared to dominate. Conversely, most approaches documented for Austria were evaluated internally.

Evaluations were predominantly aimed at funders and providers; these included statutory health insurers such as in Austria and Germany; managers, for example health management in Denmark, medical director boards in Switzerland or the regional hospital agency in France; national government (for example ministries of health in France, Germany and the Netherlands; the national assembly in Hungary) and local government (for example Tuscany's public administration); patients or patient organisations (for example Matador diabetes disease management programme, bundled payment system for diabetes, the Netherlands); the general public (for example Care Coordination Pilot, Hungary) and the scientific community (Project Raffaello , Italy).

Data on evaluation budgets were often not available. When described, the majority of earmarked funds were reported for external evaluations; examples include the SIKS project in Denmark, health networks in France, disease management programmes in Germany, and others. Evaluations with earmarked funds tended to be *ad hoc* or routine rather than continuous in frequency, which is unsurprising given that evaluation and monitoring rarely present a standard budget line item.

Feedback mechanisms and policy influence

There appeared to be feedback mechanisms in place for evaluating approaches taken in Austria, France, Hungary, the Netherlands and Switzerland. Similar observations hold for a smaller number of approaches in Italy (IGEA project, From On-Demand to Proactive Primary Care), Estonia (diabetes and CVD quality management in primary care) and Germany (disease management programmes). However, feedback mechanisms and policy impact do not necessarily coincide. For example, the Leonardo Pilot Project and Project Raffaello in Italy, described as having no formal feedback mechanism, were reported to have influenced policy. Similar observations were made for the SIKS project in Denmark (data not shown).

Reported challenges to evaluation

The survey undertaken within the DISMEVAL project was not structured to capture the reasons for employing a given method and/or metric for a particular evaluation of disease management as documented in the preceding sections. Instead, key informants completing the survey were invited to provide a broader perspective on the role of evaluation of chronic disease management approaches as part of overall assessment of health system performance and on perceived barriers and facilitators to the implementation of appropriate policies on evaluation. The level of detail of descriptions offered varied by country and we here report on some of the key observations that seem to be emerging. This section should be read in conjunction with Chapter 4, which reports on findings from key informant interviews carried out with stakeholders from Austria, Denmark,

France, Germany, the Netherlands and Spain and which provides additional insight into the challenges to conducting robust evaluation of chronic care initiatives (Section 4.3). At the outset it should be noted that experiences presented here are not necessarily specific to the evaluation of disease management programmes but reflect on a broader culture around evaluation of healthcare interventions, in particular as they related to assessments of quality of care.

Perceived lack of evaluation culture

Survey reports identified a 'lack of a general evaluation culture' as one main barrier towards producing sound evidence on disease management approaches. For example, respondents from Denmark noted that evaluation is frequently not considered to be important, while in France provider networks reportedly perceive evaluation, which is mandatory, as a mechanism of 'control' rather than a means to produce evidence to inform improvement.

The potential need for, or benefit of, conducting evaluations may generally be largely unknown among policymakers and practitioners, as indicated by respondents from Estonia, so acting as an important barrier to implementation of evaluation of programmes. Similar low levels of awareness were reported for Latvia and Lithuania. As a consequence, capacity to perform evaluation is likely to be low and so will be provider interest in evaluation, with the latter reinforced by the prospect of potential financial penalties for producing poor results, as indicated by respondents from Lithuania.

Professional disinterest in or possible reluctance to engage in evaluation activities may also result from the associated additional burden imposed by, for example, documentation required, as reported for Germany. Furthermore, providers may question the validity of metrics used for evaluation, perceived to not necessarily represent the 'true' quality of care provided. This notion was reported by Dutch respondents, further reinforced by the German informants who noted that making available such data to, for example, health insurers may be interpreted by providers as compromising their freedom of practice. Furthermore, there may be uncertainty about the purpose of making the data available, with concerns that it could potentially be used to question provider performance.

Concern about the consequences of increased transparency was also mentioned for Hungary, referring to experience that the use of a provider activity database to construct indicators for evaluating the quality of care had, in some cases, introduced an incentive to over- (and falsely) report on performance.

Lack of financial and human resources acting as a barrier to systematic evaluation

Closely related to the general lack or under-development of an evaluation culture is the ability to draw in the necessary financial and human resources to conduct systematic evaluation. Such barriers were reported for a number of countries. For example, respondents from Austria noted that the large number of actors involved in funding and/or providing healthcare services has led to a fragmentation of roles and responsibilities, a lack of communication between different levels and discontinuity within interests and objectives on resource allocation and control. This has meant that in instances there has been strong resistance by particular policymakers towards evaluation.

For the Netherlands, respondents highlighted that health insurers as the main funders of care tend to be risk averse and, as such, may have little incentive to finance research into

healthcare innovations. This reluctance may be reinforced further by the challenges associated with conducting research into the cost-effectiveness of complex interventions in daily practice and the translation of research findings into policy measures.

Lack of financial and human resources was identified as a particular challenge by survey respondents from Hungary who noted that despite the availability of a rich data set that would allow for sound evaluation, such as the provider activity database held by the national health insurance fund (NHIFA), these were not analysed on a regular basis for that reason. Similar challenges were reported for Estonia, highlighting the lack of earmarked funding and of a comprehensive mandatory accountability system that would put place data from such evaluations into the public domain. Human resource issues and training as a challenge to conducting evaluations was also reported by the French survey respondents, who further noted that evaluation was a recent phenomenon and therefore there was a lack of experienced evaluators.

Heterogeneity of IT infrastructure

A common challenge across countries, which can restrict the types of evaluation approaches that can be adopted in practice, is the available information technology. Various points reported on this issue concerned the lack of infrastructure, difficulty of use or system variation.

Such concerns were reported by respondents from Austria and Germany, noting that providers used different documentation systems within and between sectors. Information systems operated by providers are not necessarily compatible and may necessitate adjustment to meet requirements imposed by evaluators. This will limit the possibility for evaluations to pool data since evaluators are not able to receive data in a uniform format. Similar challenges were reported for Denmark, where the diverse IT systems that are in place tend to be difficult to use for both data input and output. For the Netherlands, survey respondents also noted challenges posed by the use of different clinical information systems by various care providers (hospitals, GPs, etc.).

3.4 Summary

This chapter has reviewed documented approaches to the evaluation of chronic disease management models and programmes, or their equivalent, in a range of European countries. We find that most of the approaches to chronic disease management reviewed have undergone some form of evaluation or have evaluation plans in place. However, the nature and scope of evaluations vary, with differences in objectives, design, the performance metrics used, the length of observation and approaches to data collection. We identify a range of challenges posed to the more systematic use of evaluation of complex healthcare interventions such as disease management in European health systems. Based on the evidence presented here it may be fair to conclude that evaluations of approaches to disease management as documented here are likely to benefit analytically from increased use of sophisticated statistical techniques, but also conceptually from drawing more explicitly on one of the many possible theories of behaviour change to better link the choice of performance measures to the goals of the intervention (and of the evaluation). There may also be scope to more systematically draw in mixed-methods approaches to help place observed quantitative findings into the context within which the intervention under

evaluation is embedded. More information is needed about the characteristics of the intervention and its intended populations, requiring greater specification of the wider context so as to improve comparisons and potential transferability across settings and countries in Europe.

CHAPTER 4

Assessing the policy context for chronic disease management in Europe

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4.1 Introduction

Chapter 2 has shown how countries in Europe vary in their approaches to better address the challenge of chronic disease, illustrating how some have considerable experience in implementing innovative models of care, and in addressing the challenges related to this, while others are in the early stages of developing such approaches. Nolte and McKee (2008) identified key areas that need to be addressed in order to facilitate the transition from the 'traditional' model of care characterised by fragmentation to one that better meets the needs for chronic illness care.[39] These include arrangements for sustained financing, the creation of an appropriately trained and motivated workforce, supportive information technology, and the creation of systems that enable patients to self-manage effectively, with prevention embedded at all stages, along with the development of systematic approaches to evaluating new forms of care.

However, while forming important elements of a comprehensive response to chronic disease, on their own they are not sufficient to move health systems forward. Indeed, there is a need to better understand broader system-level requirements of an effective response, such as the enablers and barriers towards the development of a consistent and comprehensive policy environment that facilitates the implementation of approaches that are contextually appropriate; an understanding of what works in what circumstances; of the appropriate balance between top-down regulation and bottom-up approaches; of whether change will be possible within the current governance and regulatory structures; and of the impact of policies in other areas on the implementation of new approaches to care.

This chapter aims to assess some of the macro-level factors that influence, enable or hinder the successful implementation of approaches to chronic disease management in the context of the diversity of European health care systems (WP4). It further aims to explore the level of commitment by policymakers/key stakeholders towards developing a systematic

response to the rising burden of chronic disease, partly by gauging their involvement in including disease prevention and disease risk minimisation along the continuum of care. We here provide a summary of key findings of the work carried out in WP4.

Framework for analysing the policy context for chronic disease management

Health policy has been defined as comprising 'courses of action (and inaction) that affect the set of institutions, organizations, services and funding arrangements of the health system'.[40] A range of frameworks and theories have been developed to analyse policy and its many components such as agenda setting, policy development, and policy change.[41,42,43] One commonly employed model to capture these components specifically in the context of health policy is the (health) policy triangle framework developed by Walt and Gilson (1994) (Figure 4.1).[44] This influential framework was developed partly in response to the observation that health policy research tended to focus on the content of policy rather than the actors, context and processes and their relationships, which play an important role in policy development and implementation.[45]

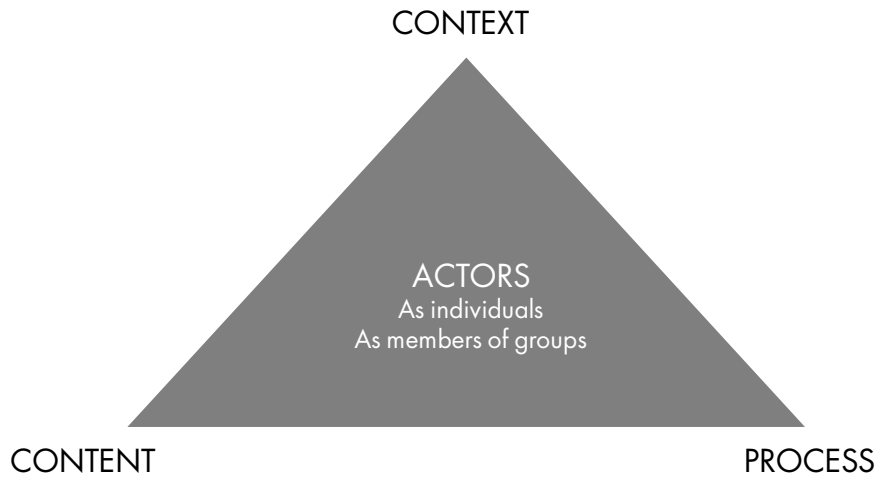

Figure 4.1 Framework for health policy analysis
SOURCE: adapted from Walt and Gilson (1994)[44]

We here use an adaptation of the Walt and Gilson (1994) triangle as the conceptual framework to guide the analysis. The model provides a structure within which the 'messy' elements of policy development in relation to chronic care can be categorised and better understood; it is used not as a methodological tool but as a means to prompt and organise possible analytical questions.[46] It considers four interlinked components: the context, the content, processes and actors. With regard to chronic care in Europe, the **context** refers to the rising burden of chronic illness and the need to develop a systematic approach towards minimising the consequences through appropriate preventive and curative/care interventions and initiatives, so creating the need to develop policy and implement a range of programmes and approaches to meet policy objectives (**content**) by involving **actors** (regulators, payers, providers, patients/public) and employing certain processes to set their

activities and allocate their resources (for example regulation, negotiation, bargaining, bottom up/top down decisionmaking and approaches).

However, these developments are seen to be set against the wider background of external or environmental factors, including political, administrative, economic and other considerations, further conceptualised by Leichter (1979)[47]:

(1) *situational factors*: transient events with direct influence on policymaking (for example regime change; EU enlargement)

(1) *structural factors*: comprise factors such as the economic base (rate of economic growth, labour force participation, types of employment, etc); political institutions (stability, capacity of administrative bodies at different levels of government, balance of power between central and regional authorities, etc) and the demographic structure (age structure, dependency ratio, household structure, etc)

(2) *environmental factors*: events/structures/values outside the political system but impacting on decisions within the system, for example EU regulations, advances in science/technology; corporate influences

(3) *cultural factors*: value commitments of groups within communities, for example trust in government and the rule of law, status of professionals, perceptions of informal networks.

This framework points to the importance of understanding the content of policies, their processes, involved actors, and the context within which policy development and decisionmaking takes place. Crucially, it helps to understand the difficulties and constraints to achieving policy objectives.

4.2 Methods

Key informant interviews

To better understand how the macro-level framework enables (or indeed hinders) the development and implementation of systematic approaches to chronic care there is a need to go beyond the documented evidence and explore the perspectives of stakeholders involved in the policy process to enable assessment of how contextual factors affect the development, implementation and sustainability of policies addressing chronic disease.

We therefore carried out semi-structured interviews with key informants involved in the decisionmaking process as it relates to various aspects of chronic disease management in a given health system context. For this analysis we focused on a subset of six countries, representing the countries of DISMEVAL partners in Austria, Denmark, France, Germany, the Netherlands and Spain.

We approached individuals in senior positions representing the decisionmaker, payer, provider and/or patient perspective. Study participants were identified through purposive and 'snowball' sampling, drawing from an established professional network of international contacts[21] and through DISMEVAL partners based in the six countries. Where necessary, we explored the websites of agencies and organisations considered relevant to chronic care,

to identify further potential interview partners, with recommendations from study participants used to identify additional participants.

Potential interviewees were invited by email, with an information sheet explaining the background to the study and further explanation where required. Upon agreement to participate, participants were provided with further information on the key topic areas to be covered in the interview (Appendix D), and a consent form. Themes covered by the interviews included: (1) the perception of participants as to the location of the country's strategic emphasis on chronic disease along the care continuum; (2) approaches to chronic disease management, which were considered as successful and why / by what criteria; (3) approaches to chronic disease management were considered less successful and why / by what criteria; (4) components considered necessary to adequately address chronic disease management in the country; and (5) perceived obstacles/barriers to development and implementing these components.

Interviews were undertaken as telephone interviews between July and October 2010, using a semi-structured interview guide. Interviews were undertaken by two members of the project team, with a third member present to take notes. All interviews were held in English, with native language explanations where necessary and appropriate. One interview was held in French, one in Spanish. Interviews lasted one hour on average. Two study participants declined to be interviewed in person but provided their answers in writing.

Data processing and analysis

Interviews were recorded and transcribed verbatim. Where necessary, interviews were translated into English.

The transcripts were analysed using textual and thematic analysis, applying the constant comparative method of coding and a systematic process to identify relevant emergent themes.[48] This process is particularly dynamic with the thematic framework evolving throughout. A preliminary list of key ideas and recurrent themes was identified from a careful reading of the interview transcripts and then recorded in a purpose-built Excel matrix. Data were then gradually organised by topic and themes coded into categories. This process was inductive and flexible[49] and facilitated description of the data and generation of explanatory patterns. The findings are reported here according to the conceptual framework described above (Figure 4.1).

The London School of Hygiene & Tropical Medicine Ethics Committee granted ethical approval for the study.

4.3 Findings

We conducted a total of 42 interviews with key informants in Austria, Denmark, France, Germany, the Netherlands and Spain representing the decision-maker, payer, provider and/or patient perspective (Table 4.1). The highest number of interviews was undertaken with key informants in the Netherlands, followed by Germany, Spain and Denmark. In contrast, for France we were only able to secure three interviews. This variation most likely reflects many individuals' unease at conducting the interview in the English language, albeit with the offer to conduct these in their native language. Of the four main sectors, the most frequently represented were decisionmakers (government or regulatory agencies) and

other (research organisation, expert panel, public health societies, etc), and the least represented were patient groups.

Table 4.1 Number of interviews by sector and country

Sector	Austria	Denmark	France	Germany	Netherlands	Spain	Total
Decision-maker	2	2	1	2	4	3	**14**
Payer	2	-	-	1	2	-	**5**
Provider	1	1	-	2	1	-	**5**
Patient	-	-	1	-	-	1	**2**
Other	-	4	1	3	4	4	**16**
Total	**5**	**7**	**3**	**8**	**11**	**8**	**42**

Primary prevention is not well integrated and fragmentation of care overall remains a challenge

Key informants were presented with an illustration of the population-based health management approach as described by Petersen and Kahne (1997)[23], as a means to identify the current strategic focus, in relation to chronic disease (Figure 4.2).

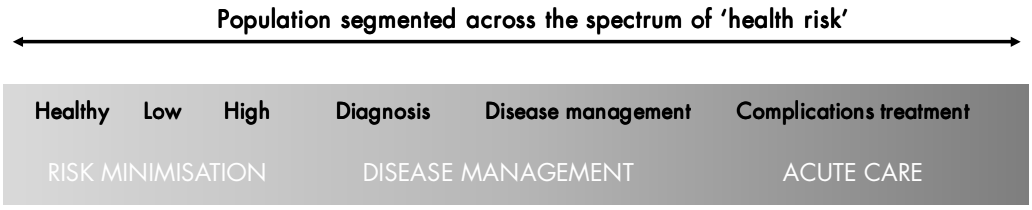

Figure 4.2 Population-based health management approach

SOURCE: Adapted from Petersen and Kahne (1997)[23]

The majority of respondents in each country noted that complications management has remained the main focus of chronic care, with some movement towards more systematic disease management, but overall a lack of coordination between levels. In contrast, risk minimisation and disease prevention, while considered important and necessary, were typically not integrated with other components along the care spectrum and indeed considered to be difficult to achieve.

Orientation to the biomedical model of health services and the current financing system reinforce limited attention to chronic care management

Respondents noted a range of reasons for this, including a continued emphasis on the (bio)medical model dominating the overall approach to healthcare organisation and delivery, as for example reported for France and Germany:

> *I think that in France the culture, the medical or health culture, is more concerned on acute care than on prevention. […] the health authority has organised a lot of information and prevention campaigns and they are communication campaigns, but communication is not prevention.* (France)

> *We are very bad in prevention of chronic diseases in Germany […] and the focus is maybe between diagnosis and disease management […] public health in Germany is underdeveloped. […] Since 1945 the medical sector [has been] strong. They gained power and influence. […] It is power to have 253 billion Euros invested in the health system, less acute care means that there are losers in this area and that is not easy to manage.* (Germany)

Importantly, it was highlighted how the current approach to financing the healthcare system can be seen as a major obstacle to strengthening disease prevention as a component of the care continuum:

> *In Austria the area of risk minimisation is still considered as less important –perhaps not in theory but certainly when it comes to finding financial means for those programmes. Approaches concerning disease management are starting to get some attention at the moment. Provisions for acute care are very good.* (Austria)

The financing structure appears to pose particular challenges for systems that are based on statutory health insurance in which the insurer may have little incentive to more proactively engage in offering preventive programmes, as noted by respondents from Germany and the Netherlands:

> *The problem with primary prevention is that sickness funds are in competition [but] primary prevention [efforts] have to be not only targeted to our own insurees but also on the insurees of other sickness funds. So we are not very motivated to make big primary prevention programmes when we know that other organisations will take benefit from it and we have to pay for it.* (Germany)

> *[I]t is a question of financing: there are very cost effective interventions which are not implemented because health insurers […] do not really see prevention as part of their remit [...]* (the Netherlands)

One respondent from Denmark also noted how disease prevention over treatment may require a cultural shift in society:

> *I would say that Denmark is between disease management and acute care. And not that much in risk minimisation. […] This is due to the political situation right now […] where everything you do is connected to whether you want to gain votes […] and if you do risk minimisation then you tell people not to smoke and do more exercise, and on that you will lose votes because nobody wants to quit their smoking; but they do if they get […] lung cancer, then they want acute care. […] you have to focus on acute care because that is what is selling votes.*

A related issue is that existing incentive structures are not suited to encourage providers towards more proactive engagement with and of patients in the management of their own condition:

> *We are still in a system which is mainly focused on the acute care. […] the current financing system pays the actions of the professions. So it pays the doctor, it pays the nurse, but it doesn't pay working together and it doesn't pay self-management of the patients. […] it starts with the treatment of complications.* (the Netherlands)

> *[T]he remuneration system has to be changed in some way, away from this fee for services and more to a capitation system, but this is not – I mean if you tell this to anyone in the sickness fund, no – so far I haven't heard anyone agree on this.* (Austria)

For a change in the incentive structure to lead to such changes as expressed in the quotes above will require a fundamental change in the overall 'medical culture' perceived as characteristic for the current approaches to providing care in some settings:

> *Office-based physicians are lone fighters [...] we have to do something for the doctors to work more – to have more control on what they're doing, and to get them to work more according to guidelines, and also to share some of the responsibilities. In Austria the practice nurses virtually don't exist. We have nurses going to people who really need nursing at home, but they're not really collaborating with the doctors.* (Austria)

This challenge is further highlighted by observations from France where a Commission on Chronic Disease within the High Level Public Health Council, created in 2004, was mandated to conduct analyses of chronic care and provide evidence-based advice to the government. However, since the creation of the commission, not one request for information was made; this lack of requests was mainly attributed to the notion that '*[i]t is not yet in our habits to consider that chronic disease is a public health problem for which we need expert advice [...] [which] is a question of medical culture.*

There are major challenges of coordinating care that must be met in implementing disease management

At the same time, the discussion is beginning to develop further in some settings, as for example reported for the Netherlands:

> *[T]he Netherlands is good at the diagnosis phase and good at complications treatment [and] the last few years is gaining more interest in disease management ... Risk minimisation or prevention, the discussion is starting, the discussion of who is in charge of risk minimisation, the people themselves or local government or the health insurer... This is the discussion that runs now.* (Netherlands)

However, even where preventive services are being offered and integrated within the delivery structure, the overall coordination of care between providers and across different levels to ensure care continuity for people with chronic conditions remains a challenge although improvements are being noted, as reported by key informants from Spain:

> *Our health care system is typically 'acute-oriented', followed by far, by risk minimisation, a service well implemented in primary health care […], some screening services. The gap [between] primary health care and specialised care acts as a key barrier for continuity of patient care along the different episodes of chronic disease. […] However, there have been remarkable experiences [in disease management] in some regions […] like the Chronic Care Plan in the Basque Country where many features of disease management have grounded their development.* (Spain)

The notion of a lack of coordination between providers at the primary/ambulatory and secondary/specialist boundary was highlighted by respondents in most countries considered here:

> *So we have ambulatory care, hospital care, we have some services, public or private, in trying to do some preventive care but they are very disconnected and fragmented [...] (*France)

In particular, respondents highlighted how this disconnect can affect patients:

> *[C]caregivers are working autonomously and have their own ways of working and it is not connected to each other. So there are happening a lot of things double and twice or things are not happening, and there is no real coordination in it. I think that a lot of patients are feeling*

> *very very lonely in the health care system, especially if they have more than one disease [...] because they have to shop around, as we call it, and they have not one contact person, for example.* (the Netherlands)

> *[...]people having more than one disease [...] very often tell you they went […] to some specialist, and the specialist is looking only at this specific disease and does not look right, does not look left, yes? Does not ask about which drugs they're taking, about which other diseases there're around. I mean, it's really a bit frightening.* (Austria)

The reasons for, and the extent of this disconnect will vary among countries, with, for example, respondents from Germany highlighting the well-documented strict separation between the ambulatory and hospital care sector[50] as one major obstacle to better coordination, as well as the lack of a registration system for patients in ambulatory care:

> *The first thing is that we don't have a system where people have to go to their GP before they go to a specialist. Everyone who wants and also anyone registered in a [disease management programme] can always decide not to go to a GP but go to a cardiologist whenever they want so if people are not happy with the care they get with their GP they always have ways to go to other doctors. It is because of that that we lose a lot of information about those patients.* (Germany)

'Loss of information' was identified as a challenge by several respondents with, for example, one respondent from Austria noting that *the information does not go as quickly or all the information does not go across the interfaces in the health system* although the introduction of an electronic health record (the e-card) from 2005 (see Table 2.2) is expected to go some way to improving this situation. Similar observations were made for the Netherlands, which is seen as an important step towards better coordination although the use of different systems among care groups presents challenges to more systematic assessment and evaluation of data at a system level:

> *[T]here's the EPD (electronic patient dossier), and what we see in these care groups in the primary care setting that the parties that work together some already have one EPD so they work together with one electronic system, patient-based, and they write in the same system [...][but] there is not one system. Everybody is doing their best and trying their own system, in fact [...]* (the Netherlands)

Administrative decentralisation was identified by respondents from Denmark and Spain as a main obstacle to achieving better coordination between sectors with, for example, respondents from Spain emphasising fragmentation of budget responsibilities to pose a particular challenge to bringing together health and social care:

> *We have a very complicated political and governmental structure […]; the national and regional governments […] have the competencies for most things you can think of. But then we have councils […] in charge of the whole social thing and they don't manage the same budget and they don't have the same bosses or interests. So there you have the big problem.* (Spain)

In Denmark, the 2007 administrative reform led to the reorganisation of regions and municipalities, giving municipalities more responsibility for health as described earlier in this report (Chapter 2). Specifically, the reform required municipalities to contribute 20 percent to healthcare funding so as to encourage them to increase preventive services and, ultimately, reduce hospitalisations. However, there was concern that the lack of a coherent framework to guide municipalities in their new tasks may impede the development of much-needed competencies in health and this was confirmed by respondents:

> *[Following the administrative reform] the municipalities should have a central place in [solving] problems of the healthcare sector. The municipalities [have the responsibility] to create new health centres [...] [designed to overcome] barriers to coordination [...] [However] municipalities do not have the competence and knowledge about health care. And there is no systematic development in this area; [...] it is dependent on learning from the regional level.* (Denmark)

Such disjoint between intent, at national level, to enhance coordination and integration, and ability at regional or local level to translate these ambitions into practice was also reported by respondents in France.

For example, the 2009 Hospital, Patients, Health and Territories Act stipulated that patient education should form a mandatory component of chronic illness care. However, this stipulation was not accompanied by adequate resources to implement relevant initiatives on the ground. As one respondent observed:

> *[F]unding for patient education has only got limited or ad hoc financing […] usually allocated for one year, and then [once the funding runs out] it is always put into question. The law now says that patient education is mandatory. However, where the financing comes from is still not clear* [...]*The nursing profession is collectively in agreement for [...] developing and implementing patient education programmes but this is based on the assumption that they have money to do it and at the moment they don't.* (France)

Furthermore, the creation, in 2010, of regional health agencies (*agences régionales de santé*, ARS) was aimed at ensuring that healthcare provision should meet the needs of the population by improving coordination between ambulatory and hospital care and health and social care services. Yet respondents highlighted that this recent decentralisation tended to result in unclear responsibilities and thus (further) fragmentation in decisionmaking and a lack of continuity of care.

Implementation of evaluation faces a range of challenges

One of the key challenge to responding to chronic disease is, with a few exceptions as described earlier (Chapter 1), the general lack of sound evidence on the effectiveness and cost-effectiveness of the range of policies and programmes. There are many innovative approaches to chronic disease management in Europe, however these are not usually well evaluated.

Key informants interviewed for DISMEVAL noted that this may, in part, be attributable to a general lack of an 'evaluation culture' and associated capacity as highlighted earlier in Chapter 3:

> *I think we absolutely have a challenge, there is no culture of evaluation. […] The culture of the organisation (of healthcare) is not very prone to evaluation. […] If you have never done it, you don't know how to do it, there it is quite difficult to start it and nobody has asked for it in the past.* (Spain)

Even where there is capacity to undertake sound evaluation, there may be an unwillingness on the part of funders, providers or other actors in the system to provide adequate support:

> *It is probable that there is a relationship between the programme and better outcome but there is no proof, no RCTs. […] There were clear political reasons. […] And this is a big political issue which was the debates between social democratic party which was in favour of chronic*

> *disease management and the connection to the RSA* [the risk structure compensation scheme] *and the conservative/liberal party who were not in favour.* (Germany)

At the same time, funders or providers might express little interest overall in wanting to know whether a given innovation does in fact lead to improvements in processes or outcomes:

> *The social health insurance funds have a long history of not being interested in what is done with the money they spend. A long history. Since only the last 10 or 15 years they have discovered that it might be interesting for them to have influence on what is done with their money.* (Germany)

However, several countries have implemented mandatory stipulations for selected care approaches to be evaluated. For example, in Austria, reform-pool projects, such as disease management programmes that have emerged from these, require evaluation but time frames may be insufficient to come to conclusions on the effectiveness of newly implemented approaches:

> *The problem is always – I mean in general with this reform pool project that times for the project itself to be evaluated is quite short. And it's usually too short to see any major changes.* (Austria)

As noted earlier, particular challenges relate to the availability and quality of data that can be used for evaluation, especially where data collection is not uniform or fragmented:

> *We have done the bundled payment introduced 3–4 years ago and on an experimental basis, for diabetes only. [...] it was very difficult for the care groups to give information from their register to us. They found it difficult to exchange the information on that: [...] a care group consists of about 100 [...] general practitioners [and other allied health professionals]. [...] They all have their own system for registering and what they are doing and what is the outcome of it. And the connection between the different systems is not ready yet. There are care groups who can provide the information but most have many difficulties.* (the Netherlands)

4.4 Summary

Interviews with key informants in Austria, Denmark, France, Germany, the Netherlands and Spain in the context of this project provided an opportunity to learn how representatives from different sectors are approaching chronic care, and their perception of the policy framework for providing a strategic response to chronic disease. Some of the reported challenges included a continued focus of chronic care on complications management, with some movement towards more systematic disease management, and an overall lack of coordination between levels; failure to integrate risk minimisation and disease prevention with other components along the care spectrum; misalignment of financial incentives that tend to reward 'aggressive' treatment of complications rather than management to maintain functioning and reduce risk of complications; and a disjoint between intent, at national level, to enhance coordination and integration, and ability at regional or local level to translate these ambitions into practice. While some of these observations are perhaps not specific to chronic care as such, they emphasise the need for the development of a coherent response to chronic disease that takes account of the various tiers in the system and along the care continuum, with the involvement of professionals, who exert a large degree of control in healthcare organisations, such as primary care

practices and hospitals. As we and others have argued elsewhere, failure to engage them in the reform process is likely to hamper sustainable change.[39,55,51]

CHAPTER 5 Evaluation of disease management in Austria

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5.1 Introduction

This chapter reports on the testing and validation of evaluation methods and metrics within the context of a diabetes disease management programme in Austria (WP5). In Austria, about 4.5 percent of the adult population has been diagnosed with diabetes[52]; in about 50 percent of diabetics, the diabetes and other cardiovascular risk factors are poorly controlled and more than 20 percent have secondary complications.[53] In response, the diabetes disease management programme (DMP) 'Therapie Aktiv' was implemented across most regions in Austria as a measure for improving diabetes care. The programme was designed by Styrian public health insurance in cooperation with the Austrian Diabetes Association. To assess the effectiveness of the programme, the implementation in 2007 of the DMP in the province of Salzburg was carried out as a cluster-randomised controlled trial (RCT).[54] This trial formed the basis of the work presented in this chapter.

The overarching goal was to quantify possible differences in demonstrated effects (effect sizes) of structured care within the diabetes disease management programme using different evaluation methods, including randomised controlled comparison, controlled non-randomised comparison, pre-post comparison within a research trial and pre-post-comparison in a pragmatic, non-research-setting. Analyses further sought to identify how different forms of bias may have exerted an influence on measured treatment effects.

[*] The authors would like thank all participating physicians of the province of Salzburg, the Medical College of Salzburg and the statutory public health insurance of the provinces of Salzburg, Styria, and Upper Austria, with particular thanks to Dr. Gert Klima, Mag. Helmut Nagy, DI Fritz Bruner, Mag Franz Kiesl, DI Birgit Otruba, Dr. Anita Offenthaler and Mag. Bernhard Kaiser, and Prim Dr Johann Ecker.

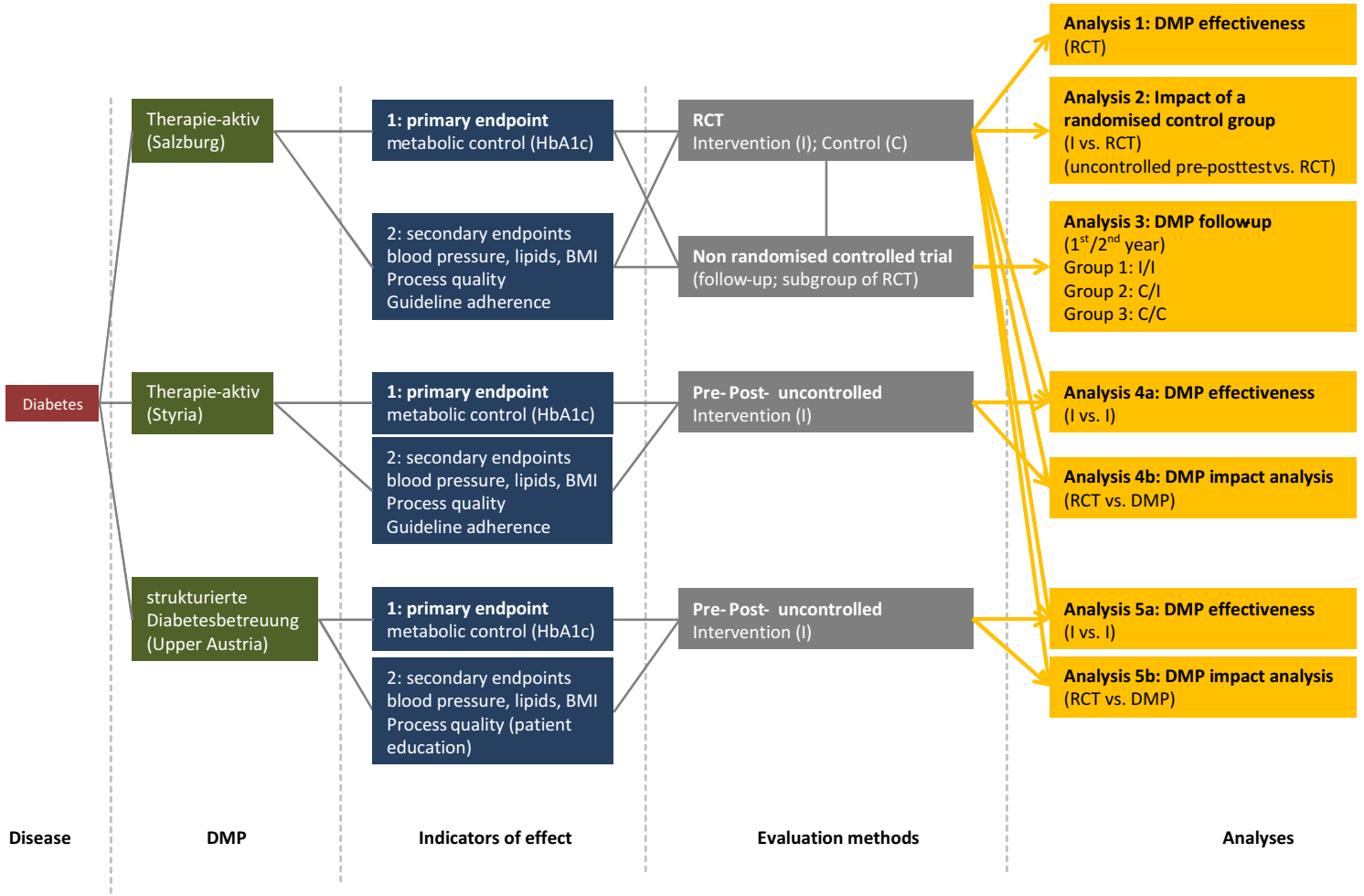

Figure 5.1 Overview of evaluation methods and metrics applied to a diabetes disease management programme in Austria

5.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in Austria

The intervention that formed the basis for testing and validating evaluation methods and metrics was the disease management programme (DPMP) 'Therapie Aktiv', which targets people with diabetes type 2. The programme has been described in detail elsewhere.[55] In brief, principal components of the programme include structured interdisciplinary care according to guidelines developed by the Austrian Diabetes Association (ÖDG)[56], systematically scheduled quarterly appointments and patient reminders; patient education through group instruction, involvement in therapeutic goal setting, with agreed targets signed jointly; and standardised documentation of physical examination, laboratory findings and diabetes complications. Participation is voluntary for physicians and patients; participating physicians have to attend mandatory training (ten hours). Prior to the implementation of the DMP, patient training modules were offered across the province of Salzburg but not used widely.

5.3 Methods

Work carried out in WP5 comprised five sets of analyses, which included: a randomised controlled comparison (analysis 1), a pre-post comparison within a research trial (analysis 2); a controlled non-randomised comparison (analysis 3) and a pre-post-comparison in a pragmatic, non-research setting (analysis 4 and 5). For ease of comparison, Table 5.1 provides a summary of the key features of each analysis undertaken. Further details on specific methods employed are available on request; those applied in the first and second set of analyses have been published elsewhere.[57,58]

Table 5.1 Summary of key components of analyses undertaken in WP5

	Analysis 1	Analysis 2	Analysis 3	Analysis 4	Analysis 5
Objective	To assess the impact of the DMP 'Therapie Aktiv' in Salzburg on metabolic control and quality of care for persons with diabetes type 2	To compare DMP-effectiveness using a randomised controlled vs before-after (no control) design	To assess the effectiveness of the DMP 'Therapie Aktiv' as open observational trial following completion of RCT over two years	To compare the effectiveness of the DMP 'Therapie Aktiv' implemented in two provinces and using two evaluation designs	To compare the effectiveness of two comparable DMPs implemented in two provinces and using two evaluation designs
Intervention	Diabetes DMP 'Therapie Aktiv'	As in Analysis 1	As in Analysis 1	As in Analysis 1	Salzburg: As in Analysis 1 Upper Austria: DMP 'Strukturierte Diabetesbetreuung'[59] *
Setting	Province of Salzburg	As in Analysis 1	As in Analysis 1	Provinces of Salzburg and of Styria	Provinces of Salzburg and of Upper Austria
Design	Pragmatic cluster-randomised controlled trial[60]	(i) Before-after without control (ii) Randomised controlled analysis (as in Analysis 1)	Before-after in three groups: 1.former DMP participants remaining in DMP 2.former controls joining DMP 3.former controls remaining controls	(i) Randomised controlled trial data (as in Analysis 1) (Salzburg) (ii) Non-experimental setting using routine data (Styria)	(iii) Randomised controlled trial data (as in Analysis 1) (Salzburg) (iv) Non-experimental setting using routine data (Upper Austria)
Participants	92 primary care physicians	As in Analysis 1	71 of initially 92 physicians remained in the study	Salzburg: as in Analysis 1 Styria: data not available	Salzburg: as in Analysis 1 Upper Austria: data not available
Control group	Persons with diabetes receiving usual care	As in Analysis 1	As in Analysis 1	Salzburg: as in Analysis 1 Styria: n/a	Salzburg: as in Analysis 1 Upper Austria: n/a
Sample size	N=1489 persons (intervention (n=649), control (n=840))	(i) Intervention only: n=649 (i) Randomised controlled analysis: n=1489	N=801 persons with 2 measurements at beginning and end of at least 600 day period Group 1: 355 Group 2: 335	N=2,564 persons with measurements for baseline Salzburg: n=600 Styria: n=1,964	N=3,530 persons with measurements for baseline (649 Salzburg: n=649; Upper Austria: n= 2,881) Per-protocol-analysis (PPA) of all patients with two measured values (difference at least

	Analysis 1	Analysis 2	Analysis 3	Analysis 4	Analysis 5
			Group 3: 111		300days) Salzburg: n= 598 (intervention) Upper Austria: n=2,680 (intervention)
Outcome measures	Primary endpoint: Change in HbA1c levels Secondary endpoints: changes in blood pressure, lipids, body mass index; frequency of HbA1c measurements, of eye and foot examinations and participation in patient education	Primary endpoint: change in HbA1c levels Risk reduction regarding clinically relevant endpoints	Primary endpoint: change in HbA1c levels Secondary endpoints: changes in blood pressure, lipids, body mass index; frequency of HbA1c measurements, of eye and foot examinations and participation in patient education	Primary endpoint: change in HbA1c levels Secondary endpoints: changes in blood pressure, lipids, body mass index; frequency of HbA1c measurements, of eye and foot examinations and participation in patient education Per-protocol-analysis (PPA) of all patients with 2 measured values	Primary endpoint: change in HbA1c levels Secondary endpoints: blood pressure, LDL, body mass index; Per-protocol-analysis (PPA) of all patients with two measured values
Observation period	12 months	12 months	24 months	12 months	12 months

NOTES: n/a – not available; * The DMPs 'Strukturierte Diabetesbetreuung' and 'Therapie Aktiv' are broadly similar but vary in relation to the physician training component, which is shorter in the former and does not require a 'refresher' which is obligatory for 'Therapie Aktiv' physicians; also, the DMP 'Strukturierte Diabetesbetreuung' requires additional documentation in the form of a 'diabetes passport' which is not required by 'Therapie Aktiv'

5.4 Findings

Assessing the impact of the DMP 'Therapie Aktiv' in Salzburg on metabolic control and quality of care for persons with diabetes type 2

Ninety-two physicians (43 intervention group, 49 control group) recruited 1,489 patients, 649 in the intervention and 840 in the control group. There were no relevant differences between the intervention and the control group.

After an average of 401days, 90.9 percent of participants in the intervention group (n=590) and 89.8 percent on the control group (n=754) had complete data on primary outcome measures. Applying an intention-to-treat (ITT) approach using the last available data carried forward method, we observed a reduction in HbA1c levels of 0.41 percent in the intervention group and of 0.28 percent in the control group. The pre-post-comparison was significant at a level of $p<0.0001$ (paired T Test) for both groups. Levels of secondary outcome measures including triglycerides, BMI, systolic and diastolic blood pressure decreased significantly in the intervention group in pre-post analysis, but not in the control group.

The ITT analysis using unadjusted between-group analysis demonstrated significant reduction of HbA1c (-0.13 percent) and BMI (-0.27 kg/m^2) ($p=0.026$ and 0.004 respectively; independent T Test). Calculating intra-cluster correlation coefficients (ICC) for both levels of clustering and using mixed models to adjust for cluster effects and baseline value we found that, after adjustment, only weight loss and cholesterol reduction were significantly greater in the intervention group than in controls ($p=0.040$ and 0.043 respectively).

Process measures including the proportion of patients receiving guideline-adherent foot-, eye-, and HbA1c-examinations showed significantly higher levels in the intervention group compared to the control group. Also, there were significantly more individuals in the intervention group (49.5 percent) who participated in patient education than in the control group (20.1 percent, $p<0.0001$; Fisher's Exact Test).

Comparing DMP-effectiveness using a randomised controlled design vs. before-after (no control) design

Using the effect sizes described for the observed change in the primary endpoint as intervention and control groups as described in the preceding section, the second set of analyses estimated the consequences using a control group on intervention effect, using the concept of 'number needed to treat'.

Specifically, we used estimates of relative risk for cardiovascular disease among persons with diabetes produced by Selvin et al. (2004), which, based on a meta-analyses, gave the relative risk as 0.9 for a decline of 0.9 percent of HbA1c levels.[61] Assuming a linear relationship, a relative risk of 0.9 was considered equal to a 10 percent relative risk reduction (RRR) per 0.9 percent decline in HbA1c levels. Applying these estimates for relative risk reduction to the two scenarios under investigation (uncontrolled before-after analysis and randomised controlled analysis), we find the relative risk reduction for cardiovascular disease to be overestimated by 229 percent in the uncontrolled before-after design (RRR 4.6 percent vs. 1.4 percent).

We further used the absolute risk for diabetes-related complications as identified by the UK Prospective Diabetes Study (1998).[62] That study found diabetic patients to have a 17.4 percent absolute risk (AR) for developing myocardial infarction within ten years.

Combining the figures in relative risk reduction with the absolute risk as described above we calculated the absolute risk reduction (ARR) for myocardial infarction (MCI) in ten years as:

ARR(DMP) = ARR(UKPDS)*RRR(DMP)/100.

This translated into an estimate for the absolute risk reduction associated with the DMP for myocardial infarction in ten years at 0.8 percent in the uncontrolled before-after analysis and 0.24 percent in the randomised controlled comparison. These estimates translated into, respectively, 125 and 417 persons with diabetes who need to be treated within the DMP to avoid one case of myocardial infarction within ten years. Using a similar approach, we calculated the number needed to treat to avoid one case of diabetes related complications as 43 for the uncontrolled before-after design and 135 persons for the randomised controlled design.

This effect was then monetised by applying reimbursement rates for physicians participating in the DMP, who receive a one-off payment for the initial examination for each patient joining the DMP plus additional payment for follow-up examinations every three months. The estimated costs for the DMP to avoid one case of myocardial infarction within ten years were found to differ by more than €300,000 between the uncontrolled and controlled designs; the difference was just under €100,000 for avoiding any diabetes-related complication within ten years (Figure 5.2).

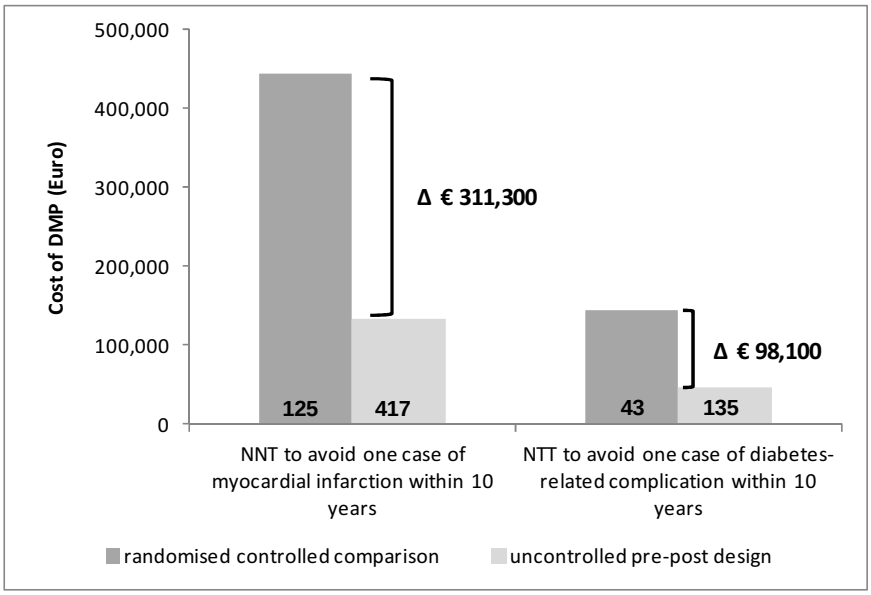

Figure 5.2 Estimated costs based on uncontrolled before-after compared with a randomised controlled comparison

NOTE: adapted from Flamm et al. (2011)[58]

Assessing the effectiveness of the DMP 'Therapie Aktiv' following completion of the trial period over two years

The number of patients with two measured values at the beginning and end of the observation period (at least 600 days between first and last value) was 801. These patients were recruited by 55 physicians. Of study participants, n=355 were former DMP participants who had remained in the DMP (Group 1), n=335 were former control patients (usual care) who enrolled into the DMP following completion of the research trial period (Group 2) and n=111 former control patients (usual care) who remained in the study as controls (Group 3). Primary and secondary outcome measures at baseline were not significantly different; however, those in Group 3 were significantly older (p=0.016, F-Test).

After an observation period of two years there was no significant difference between the three groups regarding the primary outcome measure HbA1c reduction, or secondary outcome measures. The only exception was HDL-cholesterol, with levels in Group 1 increasing significantly more in Group 1 compared with Groups 2 and 3 (p=0.001, ANOVA F Test). Patients in Group 1 were also more likely to have attended patient education and, in the first year, had a significantly higher proportion receiving regular eye- and foot examinations. The proportion of those receiving regular eye- and foot examinations increased significantly for Group 2 persons who joined the DMP after one year.

We further examined possible differences in observed DMP effectiveness in patients with concomitant participation in a randomised controlled trial and DMP (ie who had remained within the DMP intervention over the entire period of two years) (n=592), and those receiving the intervention in a sequential manner by 'acting' as controls in the RCT and subsequently entering the DMP (n=338). There were no significant differences between the two groups at baseline (independent T Test/ Welch Test). Furthermore, both group showed significant improvements in HbA1c levels, triglycerides, HDL and systolic blood pressure; the first group also had significant improvements in BMI, while for the second group we observed additional significant reductions in cholesterol and diastolic blood pressure. When comparing mean changes between the two groups, we observed a larger reduction in cholesterol (p<0.001) and LDL-cholesterol (p=0.009) levels in the second group (F Test, repeated measures GLM).

Comparing the effectiveness of the DMP 'Therapie Aktiv' implemented in two provinces and using two evaluation designs

The analysis consisted of a per-protocol-analysis including data of all patients with two measured values (with at least 300 days' difference between first and last value). In total data of 2,564 patients were included in the analysis (Salzburg DMP n=600; Styria DMP n=1,964). At baseline, the two intervention groups differed significantly on a number of measures: HbA1c (7.42 vs. 7.25 percent, p=0.009), creatinine (0.96 vs.1.02 mg/dl, p<0.001) LDL (111.52 vs. 116.47 mg/dl, p=0.006), and diastolic blood pressure (82.29 vs. 80.94 mmHg, p=0.008) (independent T Test/ Welch Test).

Before-after analysis of changes within the groups found significant improvement for HbA1c levels, triglycerides, HDL-cholesterol, systolic and diastolic blood pressure and BMI among those participating in the Salzburg DMP (dependent T Test). For participants of the Styria DMP, we observed significant improvement in all outcome parameters

(HbA1c, creatinine, triglycerides, HDL-, LDL- and total cholesterol, systolic blood pressure, diastolic blood pressure and BMI, (dependent T Test)). However, improvements as measured by mean changes were found to be significantly higher for the Salzburg DMP for HbA1c levels (0.12 percent, $p<0.001$) and BMI (0.21 kg/m^2, $p=0.012$); conversely, Styria DMP participants showed significantly greater improvements for LDL (-7.4 mg/dl, $p<0.001$) and total cholesterol (-5.66 mg/dl, $p=0.004$) (independent T Test/ Welch Test). These findings did not change after adjusting for baseline differences between the two groups (F Test). For patients participating in the Salzburg DMP we also observed a significantly higher proportion receiving regular eye examinations ($p<0.001$) and patient education ($p<0.001$) (Chi^2 Test).

We further undertook an 'impact analysis' to understand whether and to what extent the conditions within which a given intervention is being implemented (here: participation in intervention or control group in a randomised controlled trial as was the case for the Salzburg DMP and 'intervention DMP only' as was the case for the Styria DMP). Examining the primary endpoint, that is, change in HbA1c values, we found that, after adjustment for baseline differences in this measure, the three groups differed significantly after one year ($p=0.009$, F-Test). However, *post hoc* tests did not provide conclusive evidence that would permit attributing observed reductions in HbA1c levels to the RCT or the DMP.

Comparing the effectiveness of two comparable DMPs implemented in two provinces and using two evaluation designs

The analysis included data of 3,530 patients in the baseline comparison (Salzburg DMP n=649; Upper Austria DMP n=2,881). At baseline, the two intervention groups differed significantly on a number of measures: HbA1c (7.47 vs. 6.96 percent, $p<0.001$), creatinine (0.96 vs. 0.9 mg/dl, $p<0.001$) LDL (111.94 vs. 123.78 mg/dl, $p<0.001$), systolic blood pressure (140.56 vs. 144.29 mmHg, $p<0.001$) and diastolic blood pressure (82.52 vs. 83.71 mmHg, $p=0.011$) (independent T Test/ Welch Test).

Before-after analysis of changes within the groups found significant improvement for HbA1c levels, systolic and diastolic blood pressure and BMI among those participating in the Salzburg DMP. For participants of the Upper Austria DMP, we observed significant improvements for LDL, diastolic blood pressure and BMI (dependent T Test). Improvements as measured by mean changes were found to be significantly higher for the Salzburg DMP for HbA1c levels (0.37 percent, $p<0.001$) while Upper Austria DMP participants showed significantly greater improvements for LDL (-8.84 mg/dl, $p<0.001$) (independent T Test). These differences became non-significant after adjusting for baseline differences between the two groups (F Test).

Similar to Analysis 4 described in the preceding section, we undertook an impact analysis to understand whether and to what extent the conditions within which a given intervention is being implemented (here: as a randomised controlled trial as was the case for the Salzburg DMP and 'intervention only' as was the case for the Upper Austria DMP). Examining the primary endpoint, that is, change in HbA1c values, we did not find, after adjustment for baseline differences in this measure, significant differences between the two groups (F Test).

5.5 Discussion

This chapter has described the findings of analyses aimed at testing and validating methods and metrics of a large-scale diabetes disease management programme, implemented by statutory public health insurance in Austria. Analyses drew on an evaluation that was carried out as a cluster-randomised controlled trial representing a pragmatic experimental approach for the evaluation of disease management. Analyses presented here find that the Austrian DMP 'Therapie Aktiv' does not significantly improve metabolic control as measured by HbA1c after one year but leads to significant, albeit small, improvements in body mass index and cholesterol levels as well as improvement of process measures. It remains to be investigated in long-term studies, whether the small benefits seen in secondary outcome and in process measures will lead to better patient outcomes.

While the randomised design of the evaluation study as presented in Analysis 1 presents an important strength, some weaknesses must be considered. For example, participation in the study may have impacted on physician performance and patient adherence.[63] Characteristically for pragmatic trials, blinding was not possible and knowledge of being in the intervention or control group may have influenced the findings. Nonetheless, the greater improvement in the intervention group regarding body mass index and cholesterol levels, alongside observed improvement in process measures suggest that it may be worthwhile implementing DMPs and further develop the systematic disease management approach to improve chronic care, especially for patients who are motivated to participate in such programmes.

Furthermore, there are several sources of risk of bias. First, only one third of the eligible physicians practising in Salzburg province participated in the study, which might have favoured selection of more motivated physicians who are early adopters. Thus, it could be hypothesised that the effect of the DMP, in particular when assessed as physician education, might have been greater if all physicians had been included. This is because less motivated physicians might provide lower quality care and will consequently present larger potential for improvement. Alternatively, the DMP could have been even less effective in a less motivated group of physicians, as suggested by the cluster effects at the physician-level in our study. Second, as concealment of patient allocation was undertaken at physician level rather than at patient recruitment, there was potential of selection bias at patient level. Differential patient recruitment was minimised by inviting physicians to recruit consecutively and control group patients to sign up for DMP-participation following completion of the RCT. Similarity of baseline data between intervention and control groups indicated that the recruitment method chosen largely resolved this problem. Third, selection bias could still have occurred as the DMP used a volunteer-based enrolment strategy rather than an opt out model frequently used in the United States.[64] It is conceivable that patients with poorer blood glucose levels may have been less motivated and less adherent despite their greater potential for improvement. Because the trial was conceptualised as a pragmatic study, a disproportionate recruitment of 'healthy' patients is likely to reflect real life, with unmotivated patients less likely to opt for such programmes.

The trial analysed in this chapter is characterised by a high level of internal validity. It will be possible to generalise findings to DMPs implemented and executed in a similar way, that is, on a voluntary basis, while transferability is less likely to programmes characterised

by the mandatory participation of physicians and/or patients. The findings of Analysis 2 were based on extrapolated estimations and should not be interpreted as absolute numbers, but rather as a trend, illustrating the potential for misinterpretation when using evaluation designs without a control.

Not all participants who were primarily recruited for the randomised controlled trial remained in the ongoing open observational study (Analysis 3); this reduced the initial number of participants and might also have affected the power of the observational study. Determined by the optional alternative to continue the study in the intervention or control group after the first year certainly limits the scientifically valid comparability of the groups. Moreover, it has to be mentioned that a substantial number of patients left the study due to the attending physician dropping out, rather than as a result of their own motivation.

For Analyses 4 and 5 we used data collected routinely by social health insurance using DMP documentation forms alongside data collected for the randomised controlled trial. In Analysis 4 we examined the data of a diabetic population in Styria, and in Analysis 5 data from Upper Austria. We compared both sets of data with those collected for the diabetic population in the randomised controlled trial in Salzburg. It was not possible, within the context of these analyses, to verify extreme values/outliers derived from plausibility checks; we aimed to address this issue by defining exclusion criteria (see methods) for implausible values. Overall, the interpretation of the findings of Analysis 4 and 5 is challenging. Due to the significant heterogeneity at baseline, comparability of the respective two DMP populations (Salzburg and Upper Austria; Salzburg and Styria) was limited. The reasons for observed differences at baseline remain unclear. Possible explanations include: lack of ability to assess data quality of data for Upper Austria and Styria and some outliers/extreme values might easily influence the data and possibly cause differences at baseline as well as differences within enrolment strategies due to the controlled study setting in Salzburg compared with routine programme implementation in Styria and Upper Austria. Furthermore, there are small differences in the estimated prevalence of diabetes between provinces (2.5–3.5 percent) that might have influenced the population enrolled. We aimed to address this problem by examining the differences between groups adjusted for baseline, however interpretation of results remains difficult and limited. In this study, routinely collected data presented limited suitability and validity for the evaluation of disease management interventions in Austria. Based on the analyses presented in this chapter we conclude that, first, randomised controlled trials present a feasible method for the evaluation of disease management interventions in routine settings. Given the methodological strengths of this study design, the use of non-randomised or non-controlled study designs, in settings where a randomised controlled trial would have been feasible, certainly stands for a lost opportunity. It has to be pointed out, though, that use of a randomised controlled design will usually only allow for the evaluation of surrogate endpoints.

Second, cluster-randomisation presents a pragmatic experimental approach for the evaluation of disease management interventions. We evaluated the effects of a disease management programme (DMP) implemented by statutory public health insurance in a cluster-randomised controlled trial, representing a 'pragmatic' experimental approach in DMP evaluation. Randomisation was carried out at the district level of the Salzburg province and resulted in a three-level cluster design in which the surgery was nested within

the district, and patients were nested within the surgeries. Randomisation at the patient level would have led to contamination effects because a single GP could not treat certain patients according to usual care and others according to the DMP. Randomisation at the GP level would have led to contamination effects because of overlapping patient groups, especially in rural areas. The Austrian DMP 'Therapie Aktiv' as evaluated here does not significantly improve metabolic control measured by HbA1c after one year, but the programme significantly improves process measures.

Third, using an uncontrolled devaluation design for a disease management evaluation might result in overestimation of programme net-effect. Analyses presented here suggest that an uncontrolled design can lead to a more than threefold overestimation of HbA1c reduction. Furthermore, risk-reduction for clinically relevant outcomes, such as cardiovascular events, was overestimated by more than 200 percent. As disease management interventions such as the DMP tested here are resource-intensive healthcare interventions, a randomised controlled evaluation prior to roll-out of such programmes should be considered whenever possible.

Fourth, as we cannot predict the effect of structured disease management on clinical outcomes based on our observation period of only 12 months, the simultaneous implementation of a randomised controlled pilot evaluation alongside programme implementation with subsequent long-term observational studies might provide a useful approach to evaluate endpoints such as mortality or cardiovascular morbidity, while use of routine data as a sole source for assessing long-term effects may not be useful given the limitations of related data identified in the context of analyses presented in this chapter.

Fifth, we aimed to evaluate the effect on HbA1c comparing the intervention (the DMP) with a study-effect (that is, participating in an RCT). Our analyses did not yield a conclusive result, but data suggest that the study effect does not mask the possible DMP-effect. This in turn strengthens our observation that the intervention-effect of the diabetes DMP 'Therapie Aktiv' tested here on metabolic control is small. Most likely, the observed effects are at least partially due to regression to the mean, if metabolic control is assumed to form the mean.

Finally, the findings of the disease management evaluation presented here provide considerable potential to inform the advancement of related interventions and programmes. In the case of the Austrian case study, this led to the development of a newly designed cluster-randomised controlled trial to evaluate improved patient self-management support approaches involving peer support for the management of diabetes, diet and physical activity as an additional component of a standard DMP previously implemented on a nationwide level.[65]

CHAPTER 6 Evaluation of disease management in Denmark

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6.1 Introduction

This chapter reports on the testing and validation of evaluation methods and metrics on the basis the Integrated Rehabilitation Programme for Chronic Conditions (SIKS) project in Denmark (WP6). Targeting people with four chronic conditions, including chronic obstructive pulmonary disease (COPD) and diabetes type 2 (DM2), the project was implemented in the local area of the municipality of Copenhagen from April 2005 to September 2007.[66,67] Funded by the Ministry of Interior and Health, it was based on a high degree of cooperation between three organisations representing different sectors within the Danish health care system: Bispebjerg Hospital (secondary healthcare; responsibility of the regions); the municipality of Copenhagen (rehabilitation; responsibility of the municipalities); and General Practitioners (GPs). The project has previously been evaluated in terms of organisation, processes and patient outcomes using both qualitative and quantitative methods.[68,69,70]

The analyses presented in this chapter pursued two overarching aims. First, we sought to estimate the difference in intervention effect on patient functioning and quality of life using two statistical methods within a before-after design for patients with chronic obstructive pulmonary disease (COPD) and patients with diabetes type 2. Second, we sought to compare three evaluation methods for the assessment of rehabilitation effect for COPD patients on healthcare utilisation conditionally on the choice of control group.

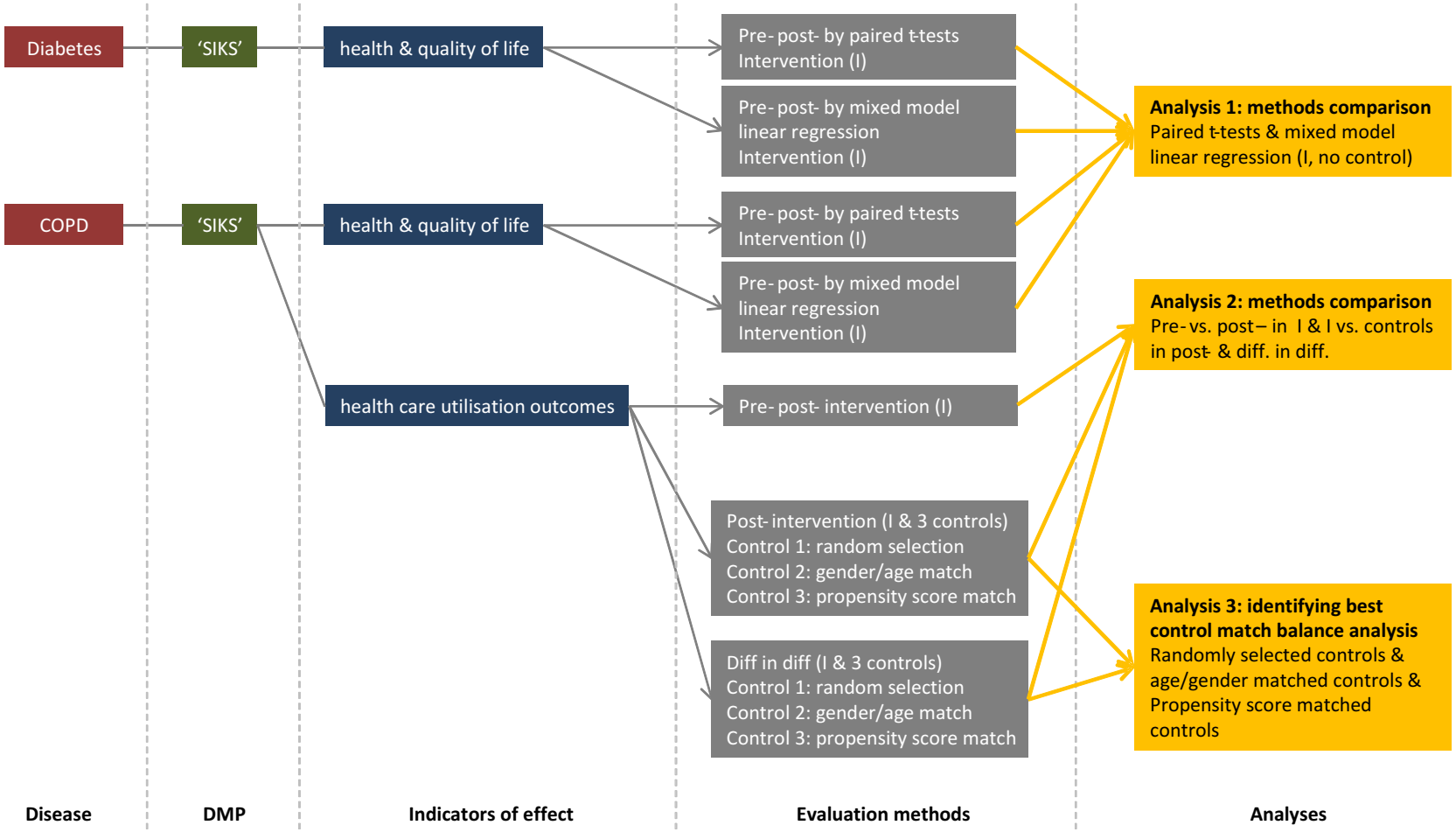

Figure 6.1 Overview of evaluation methods and metrics applied to the Integrated Rehabilitation Programme for Chronic Conditions (SIKS) project in Denmark

6.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in Denmark

The intervention was a rehabilitation programme for patients with chronic conditions. Depending on the severity of the diseases, patients were stratified to undergo the rehabilitation in the hospital or in one of the healthcare centres in the municipality. The intervention has been described in detail elsewhere.[67] In brief, key components included the use of a multidisciplinary team that support the delivery of rehabilitation and regular inter-organisational meetings; patient education and regular documentation of self-management needs and activities, alongside involvement in developing individualised treatment plans and goal setting and access to physical exercise intervention; and monitoring of practice team performance; systematic collection of clinical and other data. The intervention lasted approximately three months.

6.3 Methods

Data

Data was drawn from two principle sources. First, on entering and completing the three-month intervention, those joining (voluntarily) were assessed on a number of health indicators, including general measures (for example BMI, blood pressure), general- and disease-specific functioning (for example senior fitness tests, spirometric tests endurance shuttle walk test (End SWT), Borg's dyspnoea scale, Medical Research Council dyspnoea scale (MRC), Avlund scale, Clinical COPD questionnaire (CCQ) for COPD patients; glycated haemoglobin and lipid values for diabetes patients), and health-related quality of life. This data was used for the first set of analyses to estimate the difference in intervention effect on patient functioning and quality of life. Second, routine data on a range of socio-demographic characteristics, health service utilisation patterns and medication as well as disease duration D, extracted from Danish national registers for use in the second set of analyses that aimed to assessment of rehabilitation effect for COPD patients on healthcare utilisation.

For the latter, utilisation data were retrieved for pre- and post-intervention periods. The pre-intervention period was defined as the two years before the start of the intervention and the post-intervention period as the two years after the end date of the intervention (see Figure 6.2). Utilisation outcomes were standardised for persons entering the intervention during the pre-period (ie, the pre-period was shorted than two years) and for those leaving the intervention or dying during the post-period (ie the post-period was shorter than two years).

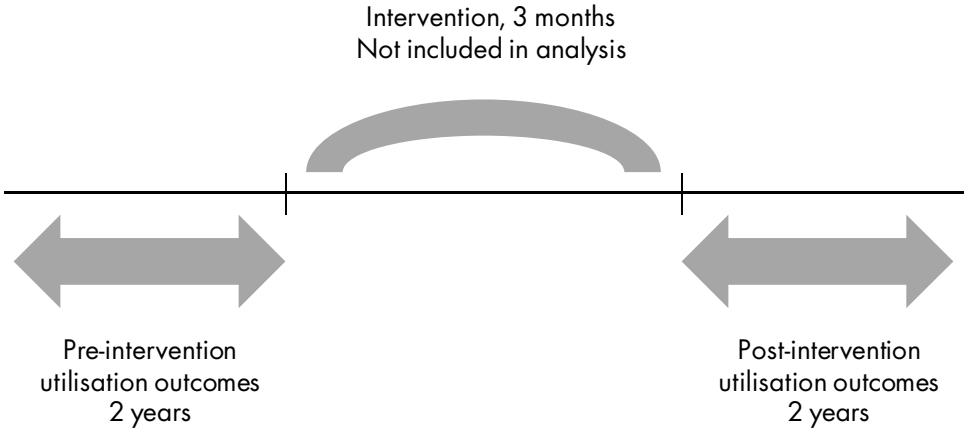

Figure 6.2 Graphical presentation of the periods which utilisation data were used in the analysis

Analytical approach

To estimate the difference in intervention effect on patient functioning and quality of life, we compared statistical methods within a before-after design: paired t-tests and linear mixed models regression for repeated measurements (fixed effects for time measurement and random effects on personnel level).[71,72]

The second set of analyses of the impacts of the programme used three designs:

a) pre-post comparison (without control) to assess changes in the intervention group over time

b) post-period comparison (with control) to assess differences between intervention and control patients after the intervention

c) difference-in-differences analysis (DID), which measures the differential change within intervention and control group.

The ***intervention group*** comprised 118 COPD patients who had participated the SIKS project[68] who had completed the rehabilitation programme, that is, had adhered to at least half of scheduled rehabilitation activities.

Control groups were created retrospectively, based on registry data from the population of individuals with COPD in the municipality of Copenhagen who had a documented hospital contact during the period 2005–2007 and who were aged over 35 years at the time of diagnosis (n=3,474), using three techniques:

(1) Random selection[73]: n=236 individuals with COPD randomly selected from the control population. For each intervention patient two controls alive at the date of the end of the rehabilitation programme were selected.

(2) Gender and age matching: n=236 individuals with COPD from the control population matched with the intervention group by gender and age on the condition that the control patient was alive at the end of the rehabilitation programme for the matched intervention patient.

(3) Propensity score matching: n=118 individuals with COPD from the control population matched with the intervention group by propensity score on the condition that the control patient were alive at the end of the rehabilitation programme for the matched intervention patient.

Propensity scores were calculated using socio-demographic characteristics, health service utilisation patterns and medication in the pre-intervention period, as well as disease duration; matching was conducted by the nearest neighbour without replacement methodology.[74]

All analyses used SPSS version 18.00; SAS version 6 was used for data cleaning, validation, propensity score model and intervention-control matching procedures.

6.4 Findings

Assessing rehabilitation effect on patients groups

Table 6.1 illustrates the findings of the assessment of the effect of the rehabilitation programme on functioning and quality of life among persons with chronic obstructive pulmonary disease, using two statistical techniques within a before-after design without control. The findings for individuals with diabetes type 2 were principally similar (data not shown) in that the analysis did not identify substantial differences in the performance of either technique (paired t-tests and mixed model linear regression for repeated measurements with random effects on person level) in relation to observed effects. The only exception was that the mixed models approach identified more associations that were statistically significant, although this was largely attributable to differences in sample sizes between the two models.

Table 6.1 Effects of the rehabilitation for COPD patients who underwent the rehabilitation in the outpatient setting

	Variables	Mean of post-pre change [SE] estimated by paired t-test (N)	Estimate of post-pre difference by mixed models linear regression [SE] for repeated measurements (N)
General health	Weight (kg)	-0.4 [0.23] (108)	-0.4 [0.23] (150)
	BMI	-0.2 [0.09]* (109)	-0.2 [0.09]* (151)
	Waist circumference (cm)	-0.3 [0.31] (110)	-0.3 [0.31] (147)
	BP systolic (mmHg)	-1.1 [2.06] (109)	-0.5 [1.99] (150)
	BP diastolic (mmHg)	-2.6 [1.04]* (109)	-2.3 [1.01]* (150)
General functioning	SFT st (times per 30 s)	2.3 [0.22]** (97)	2.3 [0.22]** (133)
	SFT 2.45 (s)	-0.6 [0.14]** (98)	-0.5 [0.14]** (131)
	SWT (s)	145.9 [25.84]** (109)	146.4 [25.82]** (145)
	Borg (0-10)	-0.5 [0.19]* (103)	-0.5 [0.18]* (143)
	MRC (1-5)	-0.4 [0.08]** (108)	-0.4 [0.08]** (148)
Disease specific functioning	FEV1 (dL)	1.5 [1.51] (57)	1.5 [1.51] (145)
	FEV1 % of expected	1.2 [0.84] (56)	1.1 [0.78] (144)
	FEV1/FVC	0.2 [1.12] (56)	0.1 [1.09] (140)
General and disease specific quality of life	SF 36 physical	3.6 [1.38]* (135)	4.3 [1.32]* (241)
	SF 36 mental	6.7 [1.66]** (168)	7.0 [1.80]** (253)
	CCQ total (6-0)	**-1.7 [0.94] (105)**	**-2.1 [0.91]* (147)**
	Avlund (0-12)	0.8 [0.18]** (72)	0.9 [0.17]** (106)

NOTE: * p<0.05, ** p<0.001; COPD – chronic obstructive pulmonary disease; SE – standard error; N – number of subjects

Assessing the impact of the rehabilitation on healthcare utilisation conditionally on the choice of control group

The findings of the intervention effect analyses conditionally on the choice of control groups, using negative binomial regression, are presented in Table 6.2. For each outcome, the top row in each column indicates the differences between intervention and control group patients in the relevant analyses (reference: control group); the middle row shows the difference between the outcomes in pre- and post-periods in the relevant analysis (reference: outcomes in the pre-intervention period); the third row shows the impact of the intervention as identified in the difference-in-differences analyses (reference: not intervention group and post-period interaction).

Table 6.2 Results of analysis of the rehabilitation effect on healthcare utilisation among COPD patients conditionally on control groups

	Pre-post[a]	Control 1[b]	Control 2[c]	Control 3[d]	DID control 1[e]	DID control 2[f]	DID control 3[g]
GP visits		0.88 [0.81-1.13]	0.89 [0.74-1.17]	0.96 [0.74-1.23]	0.99 [0.84-1.10]	0.99 [0.86-1.14]	1.03 [0.90-1.19]
	1.18** [1.08-1.30]				1.30** [1.20-1.40]	1.27** [1.18-1.36]	1.26** [1.16-1.37]
					0.91 [0.81-1.02]	0.93 [0.83-1.05]	0.93 [0.83-1.06]
Specialist visits		1.88** [1.41-2.50]	1.67** [1.27-2.20]	1.67* [1.20-2.34]	1.51* [1.14-2.00]	1.69** [1.29-2.21]	1.65* [1.21-2.25]
	0.97 [0.76-1.25]				1.01 [0.81-1.27]	0.89 [0.72-1.09]	1.00 [0.76-1.31]
					0.98 [0.70-1.37]	1.09 [0.80-1.50]	0.99 [0.68-1.43]
COPD hospital contacts		0.83 [0.58-1.18]	0.51** [0.35-0.72]	0.83 [0.55-1.25]	1.20 [0.74-1.96]	1.20 [0.78-1.84]	1.14 [0.70-1.87]
	1.02 [0.67-1.56]				1.47 [0.97-2.23]	2.29** [1.58-3.32]	1.49* [1.00-2.20]
					0.66 [0.37-1.19]	0.43* [0.24-0.75]	0.66 [0.37-1.19]
COPD bed days		0.86 [0.65-1.13]	0.77 [0.59-1.01]	1.06 [0.77-1.45]	1.77* [1.02-3.08]	1.18 [0.66-2.11]	1.50 [0.82-2.75]
	1.22 [0.64-2.23]				2.16** [1.41-3.31]	1.74* [1.16-2.62]	1.57 [0.98-2.51]
					0.50 [0.24-1.06]	0.65 [0.32-1.34]	0.73 [0.34-1.58]
COPD outpatient visits		0.73* [0.55-0.96]	0.68 [0.52-0.89]	0.59** [0.43-0.80]	1.61* [1.03-2.51]	1.00 [0.65-1.54]	0.94 [0.52-1.71]
	1.17 [0.75-1.82]				2.66** [1.54-4.57]	1.72* [1.12-2.66]	1.84* [1.01-3.33]
					0.58 [0.31-1.09]	0.70 [0.38-1.30]	0.59 [0.28-1.23]
COPD emergency room visits		0.75 [0.46-1.23]	0.52* [0.32-0.83]	0.88 [0.49-1.56]	1.35 [0.60-3.04]	1.13 [0.54-2.36]	2.16 [0.95-4.91]
	0.68 [0.34-1.34]				1.30 [0.79-2.15]	1.59* [1.04-2.43]	1.72* [1.04-2.82]
					0.57 [0.24-1.39]	0.45 [0.20-1.01]	0.43 [0.18-1.01]
COPD medicine summary DDD		1.58** [1.22-2.05]	1.30* [1.00-1.69]	1.40* [1.04-1.88]	1.43* [1.13-1.81]	1.26 [0.99-1.62]	1.10 [0.85-1.42]
	1.28** [1.10-1.49]				1.33** [1.14-1.54]	1.33** [1.14-1.54]	1.14 [0.98-1.33]
					1.10 [0.86-1.43]	1.13 [0.87-1.47]	1.32* [1.02-1.74]

NOTE: *p<0.05; **p<0.001; COPD – chronic obstructive pulmonary disease; DDD – defined daily dose; DID – Difference-in-differences; [a]pre-post – pre-post analysis in intervention group; [b]Control 1 – intervention vs. control 1 in post-intervention period; [c]Control 2 – intervention vs. control 2 in post-intervention period; [d]Control 3 - intervention vs. control 3 in post-intervention period; [e]Control 1 – randomly selected control; [f]Control 2 – gender/aged matched control; [g]Control 3 – propensity score matched control.

Overall, as shown by the estimates for the pre-post design, findings point to disease progression as evidenced by increased utilisation over time (GP visits, hospitalisations, outpatient visits, medication). However, utilisation was more frequent among controls than among the intervention group, indicating that the rehabilitation impacted on healthcare utilisation by decreasing COPD-specific hospital contacts, bed days, outpatient and emergency room visits. The magnitude of observed changes in the frequency of hospitalisation was smaller in the before-after design, while the difference-in-differences analysis found a larger effect size that was statistically significant. This points to a rehabilitation effect in the intervention group; that is, the intervention slowed disease progression.

Importantly, the magnitude of the predicted intervention effect as assessed by difference-in-differences analysis changed with the chosen control strategy. Thus, the effect size fell when moving from randomly selected to propensity score-matched controls for COPD-specific emergency room visits. The *c* statistics for the propensity model applied was equal to 0.75.

6.5 Discussion

This chapter has described the findings of analyses aimed at testing and validating methods and metrics of an integrated rehabilitation intervention targeting people with chronic disease in Copenhagen, Denmark.

Assessing the effect of the intervention in treatment groups

Analyses first assessed the effect of the intervention in treatment groups, using two statistical tests involving different approaches to covariate adjustment in a pre-post model. Analyses found intervention effect calculated by these two statistical methods not to differ significantly although the mixed models showed uncovered a larger number of statistical significant associations.[75] This finding was related, largely, to the differences in sample size used and because the two statistical methods differ with regard to statistical power.[71] This 'non-finding' is important as it highlights the need to develop a standard or criteria to guide evaluators on which approach to choose in what contexts, in particular where statistical expertise is lacking or suboptimal. Thus, on the basis of analyses undertaken here we cannot provide any definite recommendation on which method to prioritise in evaluation of intervention effect using pre-post data.

Assessing the impact of the rehabilitation on healthcare utilisation conditionally on the choice of control group

The second set of analyses assessed the impact of the rehabilitation on healthcare utilisation conditionally on the choice of control group, using three evaluation methods tested (pre-post, intervention-control, and DID). Difference-in-differences analysis (DID) measures the differential change within intervention and control group. A consistent finding of all analyses was an indication of disease progression in healthcare utilisation: with time, COPD patients visited their GPs more often, were more frequently hospitalised because of their condition, and stayed there longer. Also the number of outpatient visits increase as did COPD-specific medication. Another finding, which was also consistent, pointed to more severe disease stage in controls when compared to the intervention group as reflected in more frequent COPD-specific hospital contacts, more bed days, more frequent

outpatient and emergency room visits. Specialist visits were found to be more frequent in the intervention group, which might indicate a stronger self-care attitude in the intervention group.[76]

The key finding of the analyses was however an observed tendency that the rehabilitation decreased COPD-specific hospital contacts, bed days, outpatient visits, and emergency room visits, which corresponds to evidence reported elsewhere.[77,78] This conclusion can also be drawn from observations on the comparison of the pre-post and DID analyses. More specifically, we found that the change in hospitalisation frequency was smaller in magnitude in case of the pre-post analysis, while the DID analysis identified a larger effect size that was statistically significant. This observation can be interpreted as the rehabilitation impacting on COPD hospitalisation in that it increase at a slower pace in the intervention group (pre-post analysis); when compared to the entire intervention-control sample (DID analysis for period), findings indicate that the rehabilitation slowed disease progression.

Based on these observations we may conclude that DID analysis produces estimates of intervention effect that are in principle more plausible than those based on a single difference (either over time or between groups). Nevertheless, we found that pre-post analyses gave additional information to DID; therefore, we encourage others to undertake pre-post analyses alongside with DID.

Identifying the 'best' control

The use of propensity score matching for creating controls is aimed at making them resemble the intervention patients in all characteristics except the fact of receiving the intervention. The key difference to an experiment (for example randomised control trial) is however that even the most sophisticated matching techniques have to rely on observable characteristics only. The fundamental assumption for the validity of matching is that, when observable characteristics are balanced between the two groups, the two groups should be similar with regard to all the characteristics influencing participation in the treatment under study that might also influence the outcome. The larger the number of available pre-intervention characteristics, the greater the chances that this assumption holds true.[79] Where our understanding of factors influencing participation is imperfect or incomplete, having more characteristics to match may increase our confidence in the assumption.

In the analyses presented here, using propensity scoring was aimed at matching on disease severity, which for COPD patients, has been shown to be related to healthcare utilisation.[80] COPD disease severity is defined by Global Initiative for Chronic Obstructive Lung Disease (GOLD) standards and depends on lung function[81]; this data is however not routinely collected in the Danish national registers. Bsaed on the balance analysis, propensity scoring led to the closest match between the intervention group and the control group patients.

Another finding pointing to the importance of using matching by propensity score was the change in magnitude of the predicted intervention effect following change of control strategy in DID analyses. The change of the magnitude of the predicted differences is implicit in the change of magnitude of the estimated incidence risk ratio (IRR). When using different a control, the magnitude of the predicted intervention effect remained

approximately the same in the case of GP visits, specialist visits, COPD hospital contacts, and COPD outpatient visits. However, it became smaller in the case of COPD emergency room visits and larger in the case of COPD bed days. This means that matching by disease severity (or propensity score calculated based on healthcare utilisation pattern) is especially important in order to not over- or underestimate the effect of pulmonary rehabilitation on the two latter outcomes, respectively. Based on analyses reported here, we would recommend the method of matching by propensity score as a technique for control group construction in a non-experimental setting.

CHAPTER 7 Evaluation of disease management in Germany

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7.1 Introduction

This chapter reports on the testing and validation of evaluation methods and metrics within the context of a diabetes disease management programme in Germany (WP7). In Germany, in 2002, the government introduced population-wide structured care or disease management programmes (DMPs), in an explicit effort to provide insurers and providers with incentives to encourage evidence-based chronic care.[82] There are DMPs for: breast cancer; diabetes type 1 and type 2; coronary heart disease (CHD); asthma and chronic obstructive pulmonary disease (COPD). They are principally offered by statutory health insurance (SHI) funds; in 2011 there were 10,340 DMPs in Germany as a whole, and almost 6 million people had enrolled in at least one.[83] As the content and organisational structure of DMPs by disease is regulated at the national level, DMPs are very similar.

Evidence from the statutory evaluation of diabetes DMPs points to improved quality of care for participating patients with diabetes[84] as do existing controlled studies[85,86], with some also finding improved outcomes such as quality of life[87] and mortality[88] or reduced costs[89], while others failed to find any effect.[90] However, the extent to which improved intermediate or definite outcomes, such as survival, can indeed be attributed to the diabetes DMP remains uncertain, with questions on whether existing evaluations adequately addressed potential confounders and biases.

The analyses presented in this chapter aimed to explore this issue further, by comparing the ability of different matching methods to select a balanced control group before outcome analysis, by adjusting for different covariate distributions in the intervention and control groups. In addition, analyses sought to explore whether (i) there is a systematic difference between diabetic patients who participate in a diabetes disease management programme and those who do not; (ii) DMP participation affects clinical outcomes within a three-year follow-up period; and (iii) how lack of control group and baseline data affect the validity of the analysis.

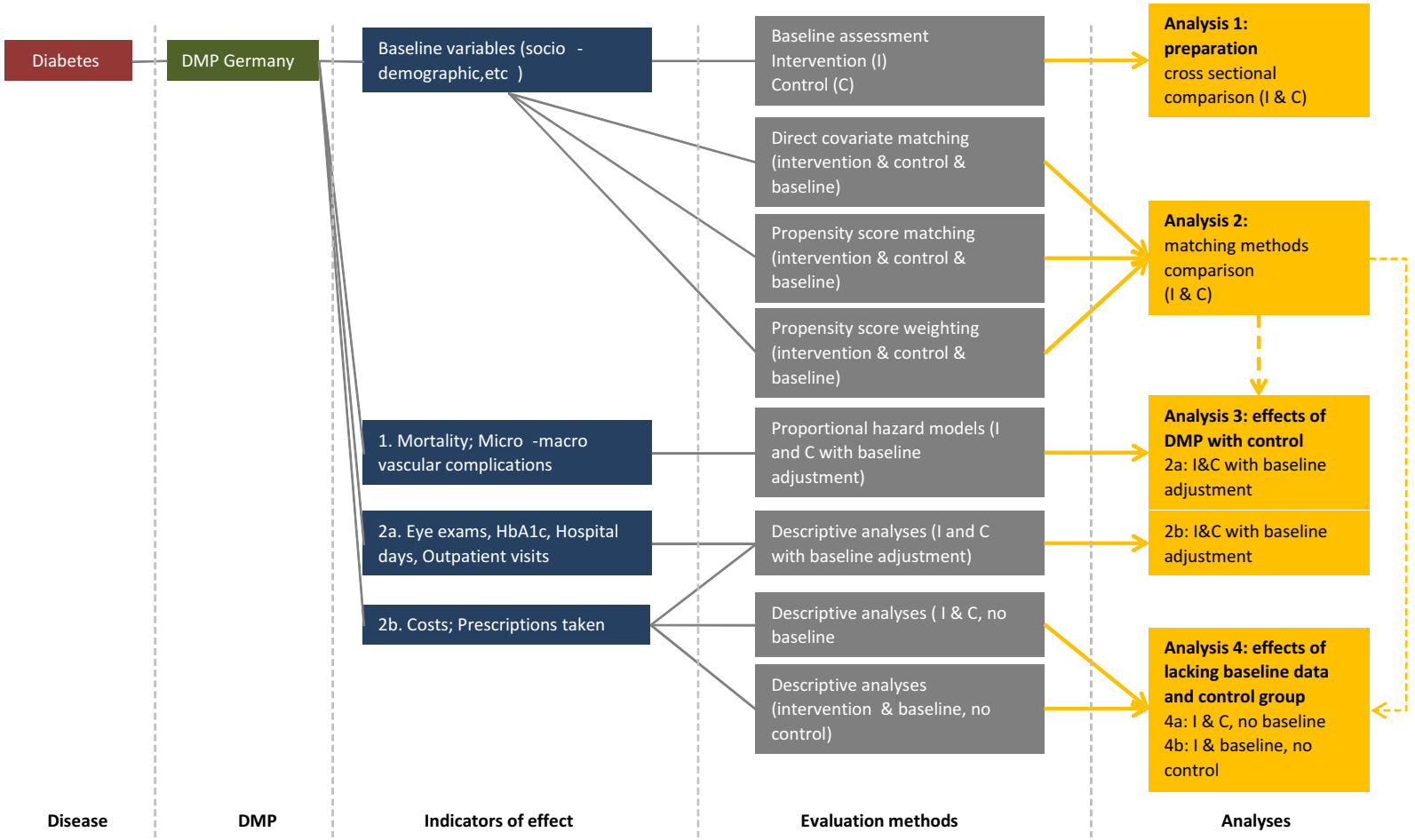

Figure 7.1 Overview of evaluation methods and metrics applied to a diabetes disease management programme in Germany

7.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in Germany

In 2011, there were about 3.6 million persons with diabetes enrolled in the diabetes type 2 DMP, equating to approximately 50 percent of persons with diabetes in Germany.[91] The DMPs diabetes type 2 is expected to lead to more structured care with general practitioners (GPs) taking a coordinating role in the treatment process. Central components of the DMP are clearly defined treatment guidelines, regular consultations including examination of feet and HbA1C checks with the GP every three to six months, documentation of routine examinations, referrals for eye examination once a year and to other specialists (for example cardiologist) as required, patient education, and provider feedback.

Individuals join the DMP voluntarily following confirmed diabetes diagnosis; they have to be willing and able to actively participate in the programme and in patient education and consent to the collection, analysis and use of data on DMP components. Enrolment is also informed by the extent to which the patient will benefit in terms of an improvement in quality of life and life span through intensive treatment within the DMP. The GP as coordinating physician decides whether the individual meets these criteria.

7.3 Methods

Data

We used routine data from a large statutory health insurance (SHI) fund (Techniker Krankenkasse) from three regions in Germany (North Rhine, Hesse, and North Wurttemberg) for 2004–2008. These contain socio-demographic information of SHI insured (for example age, gender, insurance status) and region, alongside administrative data collected from different healthcare providers (for example diagnosis, medication, procedures and costs such as for hospitalisations, prescription medicines, home healthcare, sick days).

Based on these data we generated an intervention group of SHI members who entered the DMP in 2005 and a control group comprising SHI members who did not participate in the DMP until 2008, with 2004 data used to assess baseline differences between the two groups. Interventions and controls had to be 18 years or older (2004) and have a diagnosis of diabetes type 2 as identified from ambulatory care, hospital and/or prescription data.

Primary outcome measures were mortality, microvascular and macrovascular complications during a three-year follow-up (2006–2008). Secondary outcomes included process parameters (annual eye examinations, regular HbA1C measurements, guideline-adherent medication), utilisation (hospital days, doctor's consultations) and costs (overall, inpatient, prescription and other costs).

Analytical approach

We carried out four sets of analyses. First, to investigate whether those enrolled with the DMP showed systematic differences to controls, we compared the two groups in 2004 on baseline characteristics. For categorical variables, we calculated absolute and relative frequencies; for continuous variables the mean and standard deviation unless their

distribution was skewed, in which case we categorised variables or we calculated the median and quartiles instead. Second, we analysed DMP impact on mortality, micro- and macro-vascular complications using Cox proportional hazard models. Microvascular complications as defined here were restricted to dialysis and lower limb amputations; for patients with several microvascular events, we used the first occurrence only. Macrovascular complications included stroke and myocardial infarction. The analysis of utilisation compared the number of 'all cause' ambulatory care consultations and hospital days per year. Routine data used in this study did not allow for identification of diabetes-related consultations. Similarly, to assess costs, we calculated 'all cause' inpatient and prescription costs, costs for home healthcare, therapeutic aids and appliances, and a combined variable for overall costs. We were not able to assess costs for ambulatory care use from our routine data set.

Third, we compared the performance of different methods to adjust for confounding in the primary outcome analysis: multivariate regression, direct covariate matching, propensity score matching and weighting methods with different sets of variables. Direct covariate matching used variables as described by Riens et al. (2010)[92]; we also tested a second set of matching variables that was selected by general boosted regression. Propensity score (PS) matching was varied by calculation method (logistic regression versus general boosted regression), number of matching partners (1:1 versus 1:3) and choice of variables. Propensity score weighting was performed in R 2.11.1 using the TWANG software. Performance of the different methods was assessed on the balance achieved between the intervention and control group, using standardised mean differences for each covariate.[93] The matching method with the lowest mean and maximum standardised difference for baseline adjustment was used in the secondary endpoint analysis.

Fourth, we estimated the impact of not adjusting for baseline differences between intervention and control group or foregoing a controlled design altogether on prescription costs and the proportion of intervention and controls who received statin therapy.

7.4 Findings

We included 44,005 adults with diabetes type 2 in 2004 of whom 6,663 were newly enrolled in the DMP diabetes type 2 in 2005 (intervention group). The control group was formed by 37,342 persons not participating in the DMP for the duration of the study. Intervention and control groups differed significantly on a number of characteristics. Thus, at baseline (2004) intervention group patients were more likely to be male and to reside in the region of North Rhine. Levels of co- and multimorbidity differed, with dementia, depression, cerebrovascular disease or osteoporosis more frequent among control group patients while ischaemic heart disease, hypertension or obesity tended to be more frequent among intervention group patients. The latter group also showed a higher frequency of micro- and macro-vascular complications at baseline and of exacerbations such as hypoglycaemia or ketoacidosis and received diabetes-related medication, mostly oral anti-diabetics or a combination therapy (Table 7.1). Furthermore, the quality of diabetes care received by intervention group patients tended to be higher at baseline with, for example, one third receiving regular eye examinations compared with one quarter in the control group; also those in the intervention group were significantly more likely to have received

regular HbA1C measurements. At the same time, the number of prescriptions and of doctor's consultations, as well as prescription costs, were higher in the intervention group. There were no differences in hospital admissions.

Table 7.1 Differences in diabetes-related complications at baseline in intervention (DMP) and control group patients

	DMP (n = 6,663)	Control group (n = 37,342)	p value*
Hypoglycaemia	6.7% (446)	4.5% (1693)	<0.0001
Ketoacidosis	1.0% (63)	0.6% (239)	0.005
Neuropathy	9.6% (636)	5.6% (2,099)	<0.0001
Retinopathy	22.9% (1,523)	18.0% (6,718)	<0.0001
Renal disease	5.4% (357)	4.9% (1,834)	0.123
Dialysis	0.3% (20)	0.6% (207)	0.008

NOTE: * Chi^2 test

The regression analysis for the primary endpoint mortality showed a significantly higher risk for control group patients (Figure 7.2). We found that hazard ratios for mortality using direct covariate matching methods were relatively similar to the unadjusted model. All other matching and weighting methods as well as multivariate regression adjusting for baseline variables yielded fairly similar hazard ratios. However, comparing the underlying mortality rates in both groups found that the observed effect was mostly due to a large difference between the intervention and control group in the first year after DMP enrolment; this difference decreased considerably during the further follow-up period (data not shown).

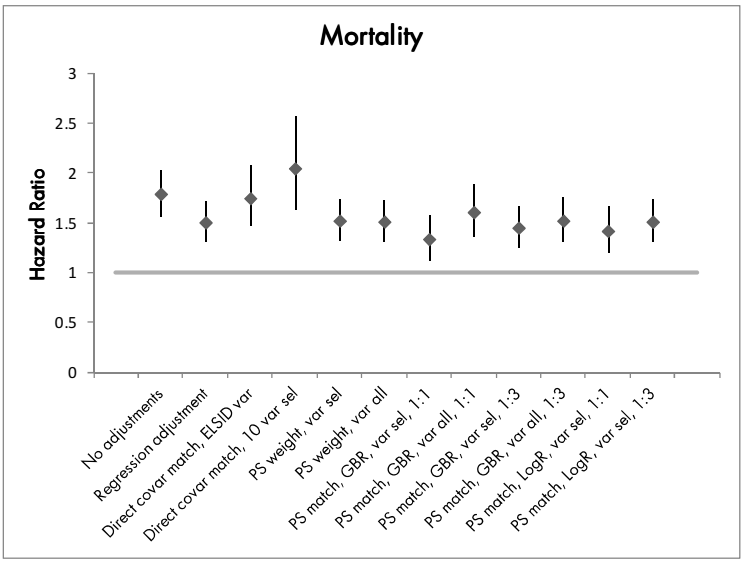

Figure 7.2 Mortality risk of control group patients compared with the intervention (DMP) group patients with and without adjustment for potential confounders by multivariate regression and different matching methods (hazard ratios with 95% confidence intervals, years 2006–2008)

There were no significant differences between intervention and control group patients regarding the risk of micro- and macrovascular diabetes complications (Figure 7.3, Figure 7.4).

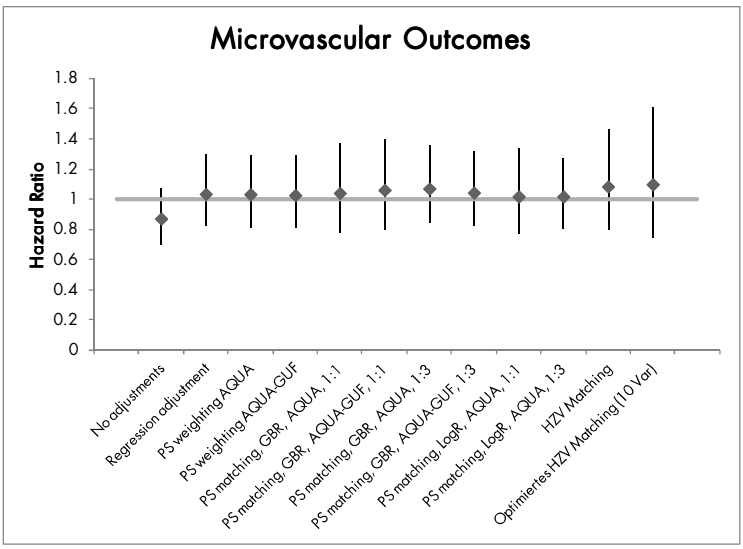

Figure 7.3 Risk of microvascular complications of control group patients compared with intervention group (DMP) patients with and without adjustment for potential confounders by multivariate regression and different matching methods (hazard ratios with 95% confidence intervals, years 2006–2008)

However, in the case of macrovascular complications, we found all multivariate regression and all matching methods to yield similar hazard ratio; the only exception was the direct covariate matching method using ten selected variables, which showed a significantly increased risk of macro-vascular complications in the control group (Figure 7.4). However, with this method, only 3,688 patients could be matched to a control so that 83 percent of the study population were excluded from the analysis.

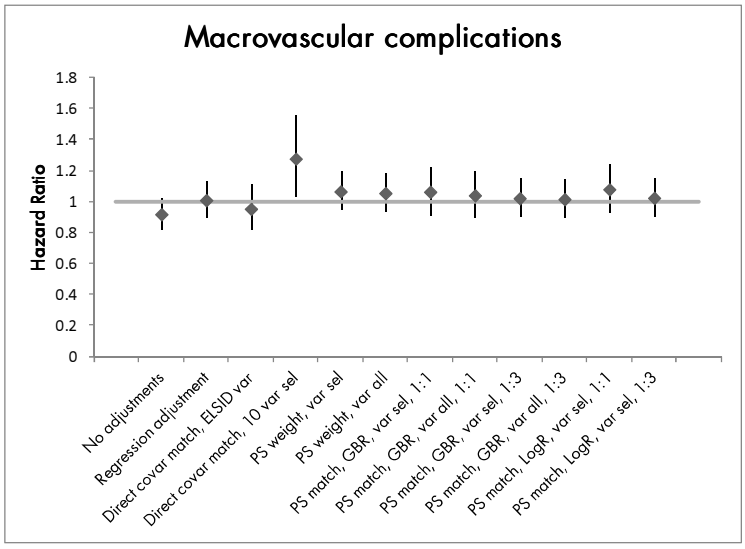

Figure 7.4 Risk of macrovascular complications of control group patients compared with intervention group (DMP) patients with and without adjustment for potential confounders by multivariate regression and different matching methods (hazard ratios with 95% confidence intervals, years 2006–2008)

All primary analyses were performed using the intention-to-treat principle. A sensitivity analysis using a per-protocol analysis (excluding patients who missed at least one DMP follow-up visit since 2005) found a slightly higher mortality risk (hazard ratio 1.68, 95 percent CI 1.40; 2.03) for control group patients. However, there were no significant effects concerning micro- and macro-vascular complications (data not shown).

The different matching methods tested reduced baseline differences in the assessed variables to varying degrees. All matching methods resulted in a reduction of the average standardised differences compared with unmatched groups (Figure 7.5).

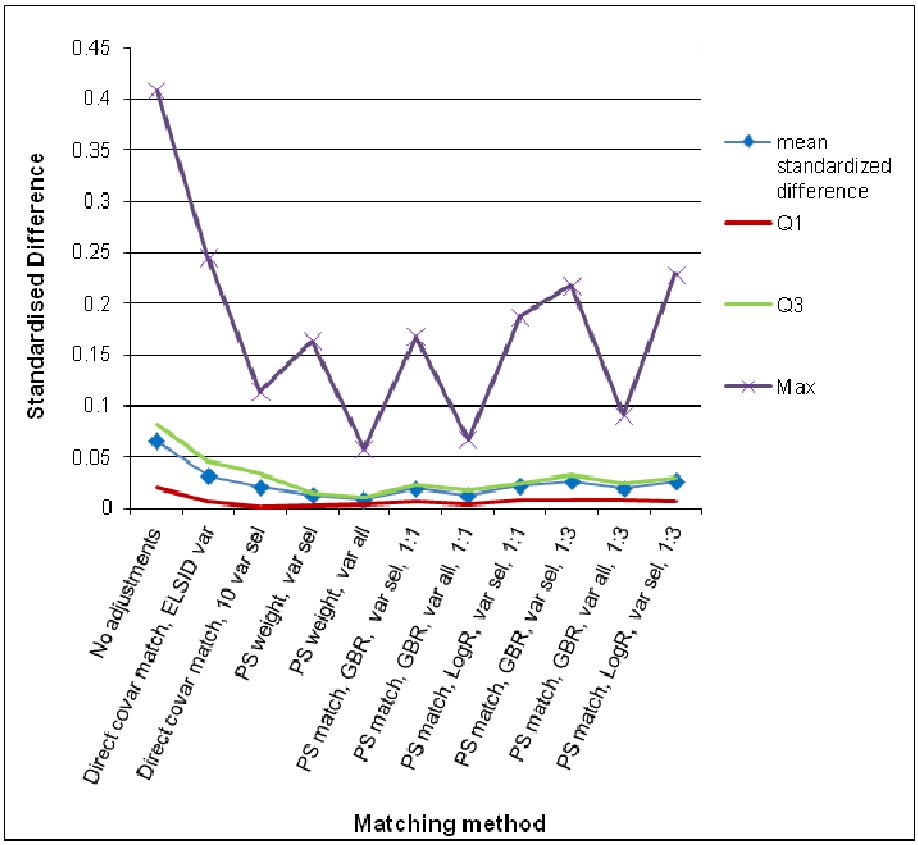

Figure 7.5 Standardised differences for matching methods used in the analysis

The 'best' match between intervention (DMP) and control group was achieved by the propensity score weighting method that included all baseline variables; this method showed the smallest average standardised difference and the smallest maximum standardised difference (Figure 7.5). According to Normand (2001)[94], standardised differences should be lower than 0.1 to be considered as best fit; this was achieved by three of the matching methods, namely multivariate regression, propensity score matching and propensity score weighting methods. In general, matching using direct covariate matching methods resulted in larger errors due to a lower number of patients for which a suitable match could be found.

We found evidence for improved process parameters in the intervention (DMP) group: a larger proportion of patients received an annual eye examination, and HbA1c was measured more regularly. However, these improvements were accompanied by higher utilisation and costs. DMP patients showed an increase in the number of ambulatory care visits, and in prescription as well as overall costs. There were no differences in inpatient days or hospital costs (data not shown). The costs of therapeutic aids and devices were also slightly higher among DMP patients (daily self-monitoring of blood glucose levels; data not shown).

We used the example of prescription costs to illustrate how the impact of DMP can be misleading if adjustment for baseline data is not performed. Thus, when comparing prescription costs without adjusting for baseline differences, we found these to be markedly

higher in the DMP than in the control group (difference of €183.39 for DMP patients in 2005). This effect might be attributable to the DMP. However, by 2004, for those who were to join the DMP in 2005, prescription costs were higher than for those not joining the intervention (difference of €108.10 for DMP patients in 2004) (Figure 7.6). When adjusting for these baseline differences, this difference between the groups becomes much smaller (difference of €70.94 for DMP patients in 2005). Here, adjustment refers to PS weighting with all variables included, that is the method that performed best in the comparison of matching methods.

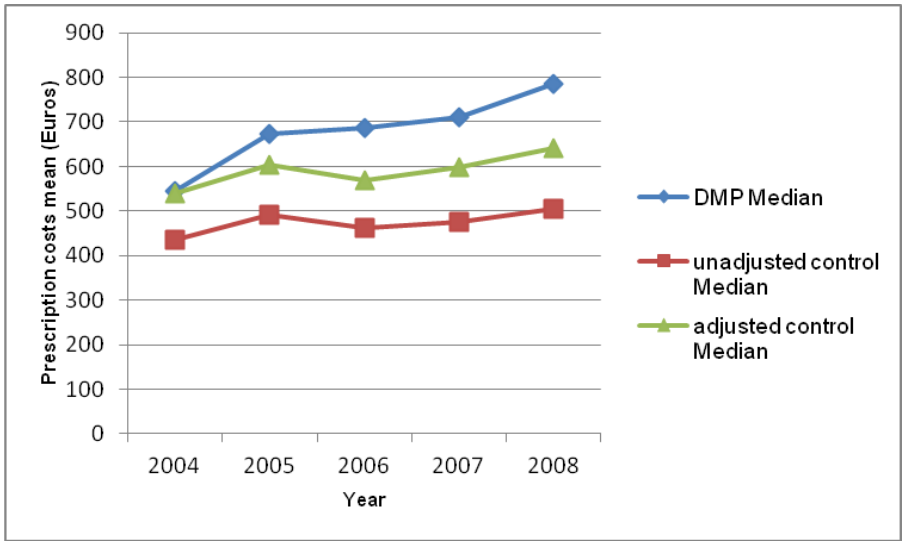

Figure 7.6 Prescription costs with and without adjustment for baseline differences between DMP and control group

Using the example of statin therapy we assessed the impact of not using a comparison group to assess intervention effect. Thus, we found that the proportion of patients receiving statins had risen steadily from 30 percent to 39 percent between 2005 and 2008 in the DMP group, which could be attributed to the DMP. However, when considering a control group of patients not participating in the DMP, the proportion of those receiving statin therapy equally rose during the same period, if at a lower level, from 21 percent to 27 percent (data not shown).

7.5 Discussion

One of the main concerns in evaluating the effectiveness of disease management intervention using observational data is the risk of selection bias. The analyses presented in this chapter found evidence for selection of participants into such an intervention, a diabetes disease management programme (DMP) in Germany. By comparing DMP and control group at baseline, we identified systematic differences that are not related to the DMP intervention. In keeping with the DMP inclusion criterion 'ability of the patient to actively participate in the programme', our data showed a tendency for those who enrolled

in the DMP to be less likely to have been diagnosed with depression, dementia, cancer and osteoporosis. This supports similar findings made by Schäfer et al. (2010).[95]

We next compared different methods to adjust for these baseline differences between DMP and the control group. Based on standardised differences of all baseline variables, we found that propensity score weighting after determining the propensity score using a general boosted regression model showed the lowest mean standardised differences and maximum difference, so providing the best fit.

However, comparing different methods to adjust for confounding is challenging for several reasons. First, standardised mean differences, although commonly used, only compare the means of the covariates. Ideally the multidimensional distributions of all variables should be matched to accurately assess balance between intervention and control group.[96,97] However, methodological challenges remain, although ongoing research might provide graphical tools allowing applied researchers to more easily compare different matching methods in the future.[98] Second, in order to produce effect estimates with low bias and variance, achieving good balance is only one aspect. Attention also needs to be given to the number of subjects to be excluded from the sample because they could not be matched. For example, while the direct covariate matching method with ten selected variables as done here achieved fairly good balance between DMP and the control group, only 17 percent of the study population could be included in the outcome analysis, which resulted in a high variance of the effect estimate. Furthermore, there is no clear guidance in the literature about the degree to which intervention and control group need to be 'balanced' to minimise biased effect estimates. As noted earlier, it has been suggested that standardised differences should be lower than 0.1 to be considered as best fit[94,99] although Imai et al. (2008) highlighted that the threshold below which effect estimates can be assumed to be unbiased remains uncertain. [100]

Using measures of covariate balance to identify the best matching/weighting method also poses challenges in that these measures are usually based on a large number of baseline variables with only some being 'true' confounders.[101] Propensity score matching/weighting methods use variables that are associated with DMP enrolment, but in order to be a true confounder this variable also needs to be associated with the outcome variable (and not on the causal path between intervention and outcome).

Importantly, however, as holds for analyses beyond those described in this chapter, one of the key challenges of evaluations using observational data is that of unobserved confounders. Any matching or weighting technique can only adjust for confounding variables that are assessed or are at least correlated with the assessed variables. Thus, in our analysis of primary endpoints we observed a significant reduction in mortality in the intervention group, regardless of the method chosen to adjust for differences in baseline variables. While this finding might represent a true effect of the intervention, that is the DMP, further exploration of data underlying the analysis showed that the largest difference in mortality between intervention and control groups was observed for 2006, the year after enrolment in the DMP. This difference became smaller subsequently. If the observed mortality decline was indeed attributable to the disease management intervention, we would expect this difference to increase over time. Therefore, a more likely explanation is that GPs systematically did not enrol into the DMP patients who they expected to die in

the near future. Adjusting for baseline variables reduced this effect compared with the unadjusted analysis, yet the routine data set we used for baseline adjustment might have missed important variables suitable to predict this short-term mortality risk.

Contrary to other studies (for example Stock et al. (2010)[89]) we were unable to demonstrate a difference in the risk for micro- and macrovascular complications between intervention and control groups. However, compared with other studies, participants analysed here were younger and only half of them required medication, pointing to earlier and less severe diabetes stages with a lower risk to develop complications within the three-year follow-up period. To enable valid conclusions to be drawn about the impact of the DMP on definite endpoints such as mortality or micro- and macrovascular complications, the analysis undertaken here points to the need for a longer observation period, consistent with what is known about the time course of the disease.

Overall, analyses presented in this chapter confirmed the findings of other studies that evaluated the impact of the DMP for diabetes type 2 on process measures, demonstrating how participation in the DMP led to intensified care while accompanied by higher overall costs.[85,86,95,102] However, in contrast to other work, our analyses did not find a reduction in hospitalisations and lower inpatient costs in the DMP group.[85,89] This might be because our analyses excluded from our baseline sample all patients who had died in 2005 in order to avoid what is commonly referred to as 'immortality bias' in survival analysis.[103,104] A sensitivity analysis including these patients showed a higher proportion of cancer-related hospital admissions in the control group.

We used data that are routinely collected by the statutory insurance funds. These data are collected for administrative purposes only and lack important clinical measures for diabetes type 2 (for example blood pressure, HbA1c levels), patient-related outcomes (for example improvement in self-management), and potential confounders such as the reason why a given person was not enrolled into the intervention, which may have important consequences for selection bias.[88] Also, the validity of coded data such as ICD-10 outpatient diagnosis may be questionable, so restricting the accurate identification of patients with diabetes type 2.[105] In addition, data completeness can pose challenges, for example where there are no standardised electronic documentation requirements for a service that is no longer reimbursed. For example, in our study, mortality data appeared incomplete for the years 2007 and 2008, probably as a consequence of the abolition of the burial allowance which, until 2004, was paid for by statutory health insurance. Since then, SHI funds have had difficulties assessing whether or when an SHI member had died. However, there is no reason to believe that reporting of deaths in the DMP group was systematically different from the control group and we therefore assumed that this specific shortcoming in the data was non-differential and should not have biased the observed findings of DMP effect on mortality as reported here.

In our study we observed that all matching/weighting methods to adjust for baseline variables resulted in fairly similar effect measures for all primary outcome variables analysed. Therefore, we would recommend that evaluations in routine settings would not need to commit too many resources to the deployment of advanced methods that require substantial statistical expertise or computational power. Instead, it may be sufficient to make use of already implemented tools, which are available for most standard statistical

software packages. Instead, explicit efforts should be made to obtain a data set as detailed and valid as possible, since, as we show here, our analysis was chiefly restricted by the lack of information available in the routine data set.

CHAPTER 8 Evaluation of disease management in France

Diabetes provider networks and other non-cancer provider networks

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8.1 Introduction

This chapter reports on the testing and validation of evaluation methods and metrics using the example of provider networks in France (WP8). In France, provider networks are considered the main approach to providing coordinated care for those with complex care needs, with an estimated 1,000-plus networks operating across the country.[106] A provider network responds to a defined health need, in a defined geographic region, for one or several specific disease(s) and/or a specific population, with diabetes networks particularly well established, alongside cancer networks. The origins of the provider networks date to the late 1980s, and the approach has been complemented and formalised by the establishment of a legal framework for funding under the statutory health insurance (SHI) system, providing a financial incentive to set up or consolidate networks.

All provider networks that have benefited from public funds must submit to an evaluation procedure, the framework of which is jointly defined by SHI and the Ministry of Health.[107] However, little is known about how this is applied in practice, with anecdotal evidence and sporadic publications pointing to wide variation of evaluation methods employed, reflecting the heterogeneity of network objectives and services provided. Furthermore, there is concern about the usefulness of provider network evaluations as patients and providers enrol voluntarily in provider networks so giving rise to the possibility of selection bias. Such selection hampers objective evaluation because it is

difficult to distinguish if the success of an intervention is due to the actual services provided or the nature of the selected patients.

The analyses presented in this chapter aimed to explore methods that can be recommended for the evaluation of provider networks in France. Specifically, analyses sought to (i) examine the impact of selection bias on the effectiveness of diabetes provider networks, thereby allowing assessment of the impact of network interventions if they were to be implemented for the entire target population; (ii) describe and analyse methods that are currently being used for the evaluation of different types of networks (diabetes, non-cancer and cancer networks) and to provide recommendations that allow a match between the type of disease management intervention and the evaluation method.

8.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in France

Analyses presented in this chapter considered different types of provider networks, namely diabetes networks for assessment of selection bias and diabetes, non-cancer and cancer networks for the analysis of existing evaluation approaches. Given the variation between provider networks, we here describe the principles of diabetes and cancer networks.

As noted above, diabetes networks are particularly well established, and include, for example, the REVESDIAB network (*Réseau de santé Val de Marne Essonne Seine et Marne pour les diabétiques de type 2*).[108] Diabetes networks are coordinated at national level by the National Association for the Coordination of Diabetes Networks (ANCRED). For 2007, ANCRED reported on 72 funded networks covering 50,000 patients and 14,000 health professionals.[109] Principal components include the use of multidisciplinary teams, the development of individualised care plans by a core team, interdisciplinary discussion fora and quality circles; the involvement of patients in developing a treatment plan towards a formal agreement between patient and network; and the use of a shared information system involving a database collecting routine clinical indicators and used for evaluation and quality control.

Networks in the field of oncology have been established in France since the 1990s and have informed the organisation and mission of current cancer networks. Regional cancer networks coordinate all relevant actors and levels of care in the management of cancer and guarantee the quality and equity of care across all regions. The network must ensure multidisciplinary management and continuity of care, from diagnosis to return-to-home care. Every patient should receive support in the network with all clinics, hospitals and cancer care centres in a given territory being either directly part of a regional network or organising a network of cancer care in their own territory. The regional network is intended to bring together existing local networks. The latter are not solely structured around cancer; indeed, these types of networks will in future be required to join the other health networks within 'local health platforms' in which the cancer will be one of the chronic diseases to manage.

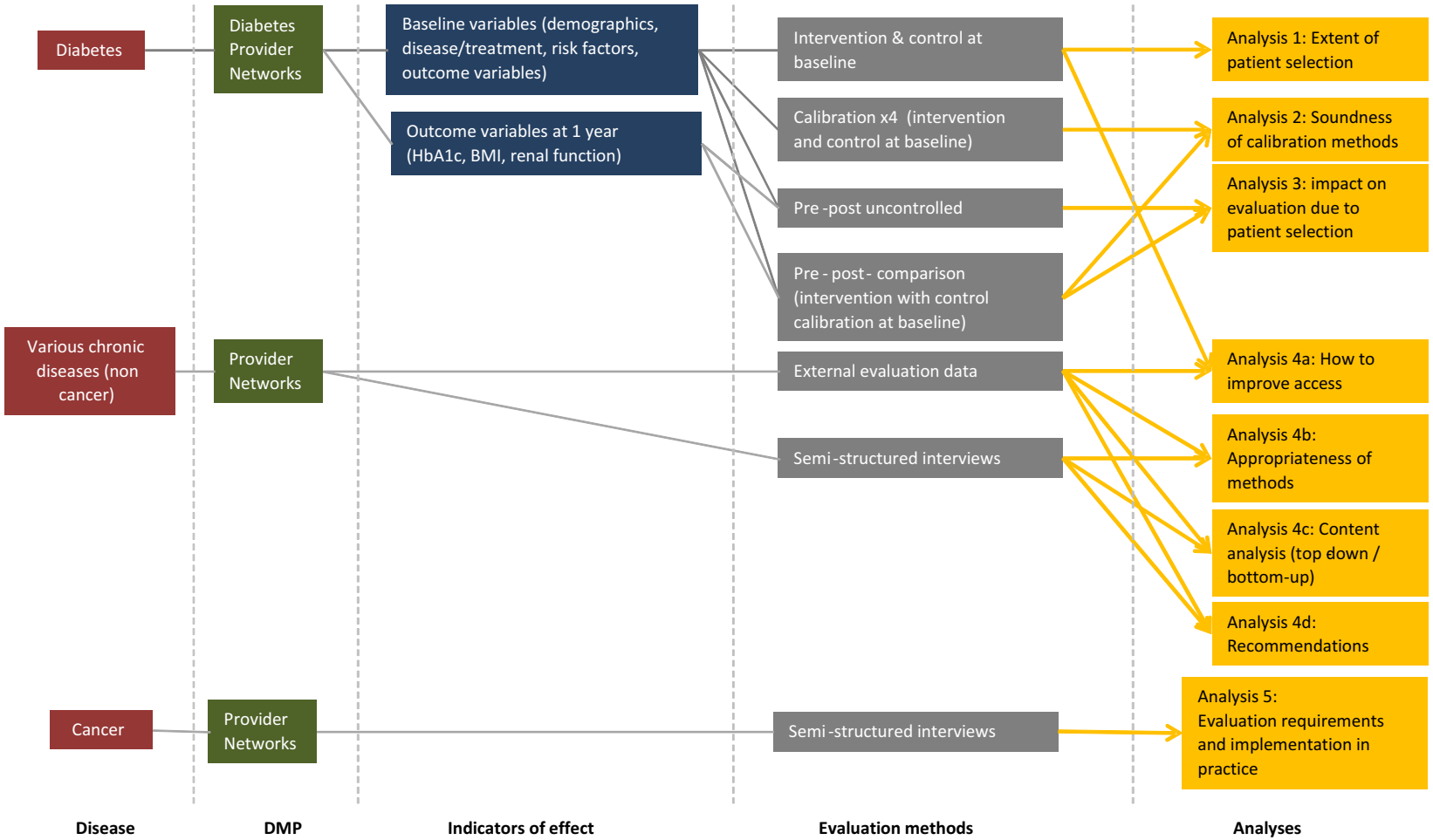

Figure 8.1 Overview of evaluation methods and metrics applied to provider networks in France

8.3 Methods

Data

Analyses that sought to examine the impact of selection bias on the effectiveness of diabetes provider networks used data obtained from (a) two diabetes provider networks, which formed the basis for creating the intervention group, and (b) the national representative sample of persons with diabetes (*Echantillon national témoin représentatif des personnes diabétiques*, ENTRED 2007–2010[110]), which formed the basis for the control group.

The reference population for the control group included all adults who claimed reimbursement for at least one oral hypoglycaemic agent or insulin in 2007 from the major French SHI insurer (covering about 80 percent of the French population). The sample was based on claims data and questionnaires of 9,781 diabetic patients. Of these, clinical data were available for 2,485 persons who formed the control group for our study. To minimise bias, in- and exclusion criteria for participants in the intervention were aligned with those for the control group. Thus, patients had to have enrolled in the provider networks in 2007 or 2008, had their initial checkup completed within one year after enrolment, and met the definition of diabetes diagnosis as applied to the ENTRED population. Furthermore, intervention group participants had to have no diagnosis of mental disease (network A) or of significant impairment of cognitive functions and severe co-morbidity (B), be able to participate in educational workshops (A) or to maintain a household (B), and to reside in the geographical region targeted by the intervention.

The primary endpoints considered in the analysis were: HbA1c levels, body mass index and renal function as measured by glomerular filtration rate (GFR).

Analytical approach

Assessing the impact of selection bias

To assess the impact of selection bias on the evaluation of diabetes provider networks, we carried out a before-after analysis, comparing the characteristics of intervention and control group at baseline and after one year of enrolment in the diabetes provider network (t1) (Figure 8.2).

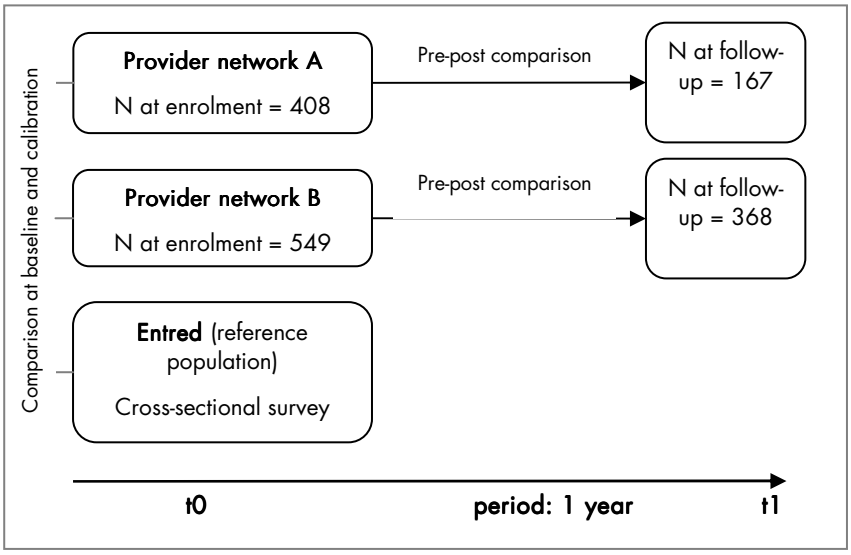

Figure 8.2 Overview of intervention and control populations used to assess the effectiveness of diabetes provider networks in France

We then applied calibration methods to adjust for differences between the intervention and control groups, using calibration weights (coefficients). We assumed that diabetes provider networks represent a random sample of the general diabetic population and that the general diabetic population was represented by the ENTRED survey, since 2.5 percent of those surveyed in ENTRED had reported to be enrolled in a diabetes provider network.

Differences in patient characteristics at baseline were rebalanced by assigning a coefficient to each patient (for example a patient with very high values for a set of variables was assigned a low weight in order to take these 'extreme' values into account). We performed a before-after analysis by (re-)weighting each patient with the weight initially determined, using, first the Horvitz-Thompson estimator that assigns each individual a sampling weight d_k equalling the individual's inverse probability of inclusion in the sample. We then calculated a new calibration weight w_k that adjusted all chosen variables (depending on the scenario, see below) of the intervention group on the reference population.[111] We used the distance function G to minimise the sum of the weight ratio w_k and d_k, applying Linear, Raking ratio, Logit and Truncated Linear functions which were compared and assessed in terms of their weight dispersion, where a low dispersion was considered favourable. In addition, we tested two scenarios, with Calibration no. 1 using demographic characteristics (age, gender), information on disease (disease duration, medication) and risk factors (smoking status, blood pressure, HDL and LDL cholesterol, triglycerides, creatinine, coverage by the statutory chronic disease coverage (ALD) Scheme (ALD), as a proxy for co-morbidity) for the calibration. Calibration no. 2 also included the outcome variables HbA1c, body mass index and renal function (GFR) at baseline in the calibration.

In order to perform the calibration, continuous variables were transformed into categorical variables. All analyses were performed using SAS version 9.2, Microsoft Excel 2007 and the 'Calmar' macro developed by INSEE (French National institute of Statistics and Economic Studies).[112] A p-value of 5 percent was considered as statistically significant.

Analysing methods that are currently being used for the evaluation of different types of networks

Analyses of existing provider network evaluation practices drew on documented, non-public external evaluations of the most recent triennial period as well as the three most recent internal activity reports (2007–2009 obtained from 12 provider networks targeting diverse conditions). We also conducted 13 semi-structured interviews with network coordinators, evaluators, stakeholders and funding entities. Specifically, analysis sought to explore (i) the extent to which a given evaluation method was linked to the provider network's objectives; (ii) whether a link could be established between the evaluation method and the services provided by the network; (iii) whether the evaluation method employed was appropriate to assess whether the provider network's objectives had been met; (iv) whether the evaluation method applied was appropriate to assess the performance of the network's service provision; (v) how, where applicable, the evaluation method used by networks conformed with the national framework for provider network evaluation; and (vi) which evaluation method/s can be recommended considering the characteristics of the chronic disease management intervention provided by a given network.

Additional analyses focused on understanding existing evaluation requirements and their application in practice for cancer provider networks. This analysis drew on 18 semi-structured interviews with regional leaders in oncology and leaders of regional cancer networks in four regions, characterised by differences in size, population and the nature of territorial health problems; these were the regions of Poitou-Charentes (n=2), of Picardie (n=2), Midi-Pyrénées (n=2) and Rhône-Alpes (n=7). In addition, we interviewed national representatives of the national cancer institute (INCa; n=1) and the national cancer council (CNC; n=1), alongside three stakeholders representing the regional health agency (*agence régionale de santé,* ARS) in Rhône-Alpes.

8.4 Findings

Assessing the impact of selection bias on the evaluation of diabetes provider networks

Patient characteristics at enrolment of those enrolled in one of two diabetes provider networks differed significantly from the control group (Table 8.1). For example, patients in the intervention group were significantly younger, had shorter disease duration, had higher HbA1c levels but lower systolic blood pressure, and were more likely to receive insulin treatment. Other differences between intervention and control differed by network however; also, there were no differences between intervention and control regarding HDL cholesterol, triglycerides and gender.

One year follow-up data were only available for a sub-sample of the intervention groups (167 out of 408 patients in provider network A and 368 out of 549 patients in provider network B) because of missing data, for example, because the follow-up examination had not been performed. Testing for within-group differences at enrolment for the sub-samples and the whole intervention group did not identify any differences within the provider networks. Further, differences between these sub-samples and the control group were similar to the differences observed between the entire intervention group and the control group.

Table 8.1 Comparison of patient characteristics in two diabetes provider networks at baseline with the control group

Variables	Control (n=2415)		Provider network A (n=408)			Provider network B (n=549)		
	Mean	SD	Mean	SD	p-value	Mean	SD	p-value
Age (years)	64.59	± 12.47	62.15	±11.52	**<.001**	59.08	± 13.49	**<.001**
Duration of diabetes (years)	11.61	± 10.03	7.77	± 8.35	**<.001**	7.92	± 8.67	**<.001**
HbA1c (%)	7.14	± 1.19	7.50	± 1.46	**<.001**	7.78	± 1.76	**<.001**
BMI (kg/m²)	29.40	± 5.70	30.09	± 5.32	**0.025**	29.63	± 6.05	0.410
SBP (mmHg)	133.41	± 11.83	131.76	±11.94	**0.011**	132.19	± 14.61	**0.038**
DBP (mmHg)	76.82	± 7.84	75.39	± 8.20	**0.001**	78.45	± 8.38	**<.001**
HDL (g/l)	0.53	± 0.18	0.55	± 0.28	0.070	0.54	± 0.33	0.280
LDL (g/l)	1.06	± 0.34	1.09	± 0.43	0.120	1.16	± 0.40	**<.001**
Triglyceride (g/l)	1.49	± 0.95	1.57	± 1.22	0.210	1.54	± 1.18	0.360
Creatinine (mg/l)	9.79	± 3.19	10.03	± 3.12	0.210	10.22	± 3.95	**0.009**
GFR (ml/min)	87.72	± 34.91	91.53	±33.91	0.060	93.18	± 38.68	**0.002**
Gender					0.650			0.600
Men		54%		55%			55%	
Women		46%		45%			45%	
Type of treatment					**<.001**			**0.001**
One oral hypoglycaemic agent (HA)		42%		18%			37%	
Two or more oral HA		36%		55%			33%	
Insulin and no, one or more oral HA		22%		27%			30%	
ALD								**<.001**
Yes		87%			NA		81%	
No		13%					19%	
Type of diabetes					**0.004**			**<.001**
Type 1		6%		9%			11%	
Type 2		94%		91%			89%	
Tobacco status					**<.001**			0.330
Smoker		14%		8%			15%	
Ex-smoker/Non-smoker		86%		92%			85%	

NOTE: BMI = Body Mass Index; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; GRF = Glomerular Filtration Rate; ALD = coverage by the chronic disease scheme; NA = not available

Calibration to adjust for differences between the intervention and control groups

Here we present the findings of the four different calibration techniques to adjust for baseline differences between intervention and control group, using different sets of variables. For each calibration, patients had to be excluded due to missing data. Comparisons between the control and the total follow-up population (without exclusions) without calibration, and between the total follow-up population and the population after

exclusions for missing data did not identify any significant differences. For provider network A, exclusion of patients led to numbers that were below the threshold of 10 percent of the control group that is recommended for the use of calibration methods. Below, we therefore present findings for provider network B only.

The calibration for demographic characteristics, disease information and risk factors (Calibration no. 1) required the exclusion of a total of 116 patients of provider network B because of missing data (n=252). Differences in the outcome variable HbA1c, which was not used for calibration, remained significant between the intervention group (provider network B) and the control group after calibration for all methods used. Body mass index and renal function did not differ significantly before calibration and the difference remained non significant after calibration for all methods used. The raking ratio and the logit method had the smallest weight distribution in terms of inter quartile range (IQR), whereas the range and the 95 percent range were relatively similar for the four methods. The linear method generated negative weights that cannot be used for the categorical variables (see Figure 8.3).

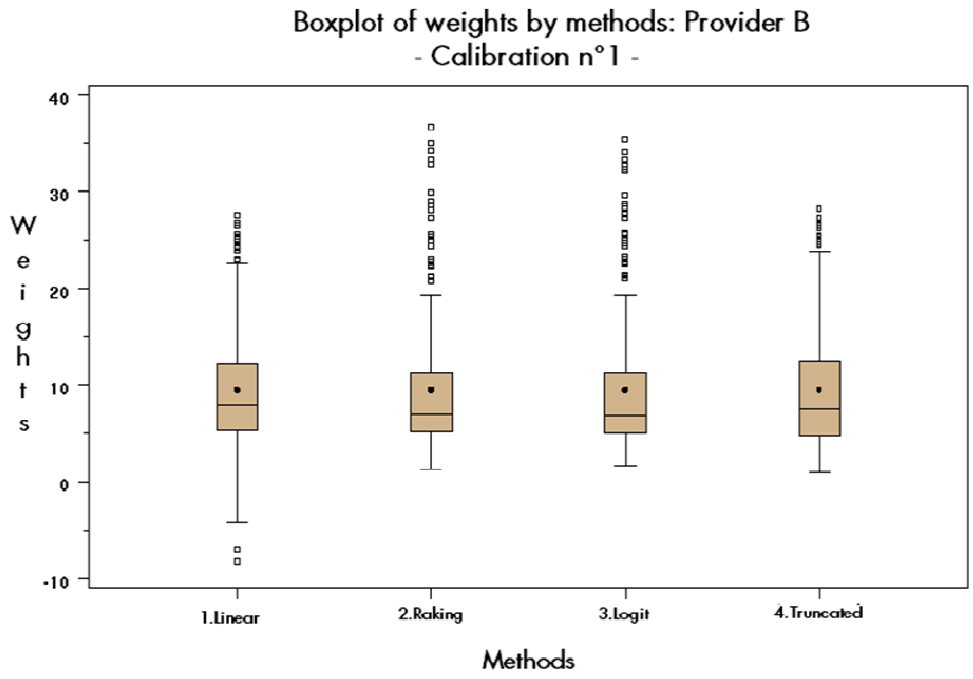

Figure 8.3 Boxplot of the weight distribution in provider network B after Calibration no. 1 for the different methods

NOTE: The whiskers are drawn to the most extreme points in the group that lie within the fences. The upper fence is defined as the third quartile (represented by the upper edge of the box) plus 1.5 times the interquartile range. The lower fence is defined as the first quartile (represented by the lower edge of the box) minus 1.5 times the interquartile range. The mean is a black point, the median a horizontal line within the box. Observations outside the fences are identified with a square dot.

The calibration for demographic characteristics, disease information, risk factors and outcome variables (Calibration no. 2) required exclusion of 127 patients from the

intervention group due to missing data (n=241). As with Calibration no. 1, the outcome variable HbA1c levels remained significant after calibration, although this finding applied to the linear method only. Body mass index and renal function did not differ significantly before calibration and the difference remained non significant after calibration for all methods used. In terms of IQR, the raking ratio and logit methods had a smaller weight distribution than the other methods, whereas the 95 percent range was relatively comparable between the methods (Figure 8.4).

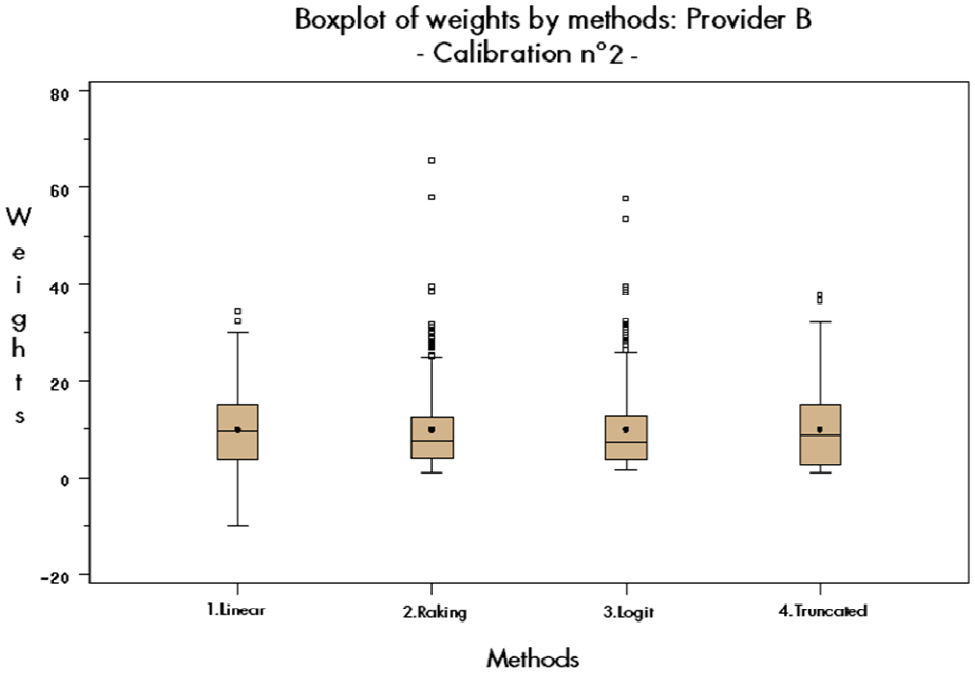

Figure 8.4 Boxplot of the weight distribution in provider network B after Calibration no. 2 for the different methods

NOTE: The whiskers are drawn to the most extreme points in the group that lie within the fences. The upper fence is defined as the third quartile (represented by the upper edge of the box) plus 1.5 times the interquartile range. The lower fence is defined as the first quartile (represented by the lower edge of the box) minus 1.5 times the interquartile range. The mean is a black point, the median a horizontal line within the box. Observations outside the fences are identified with a square dot.

In a variation of Calibrations nos. 1 and 2, we carried out a third set of analyses (no. 2b) that considered demographic characteristics, disease information and outcome variables, so increasing the size of the intervention group to n=280 patients. Like Calibration no. 2, the outcome variable HbA1c levels remained significant after calibration, but this finding applied to the linear method only. Body mass index and renal function remained non significant. Overall, the range and 95 percent range of this calibration was low for all four methods. As previously, the dispersion measured by IQR was lowest for the raking ratio and logit methods (Figure 8.5).

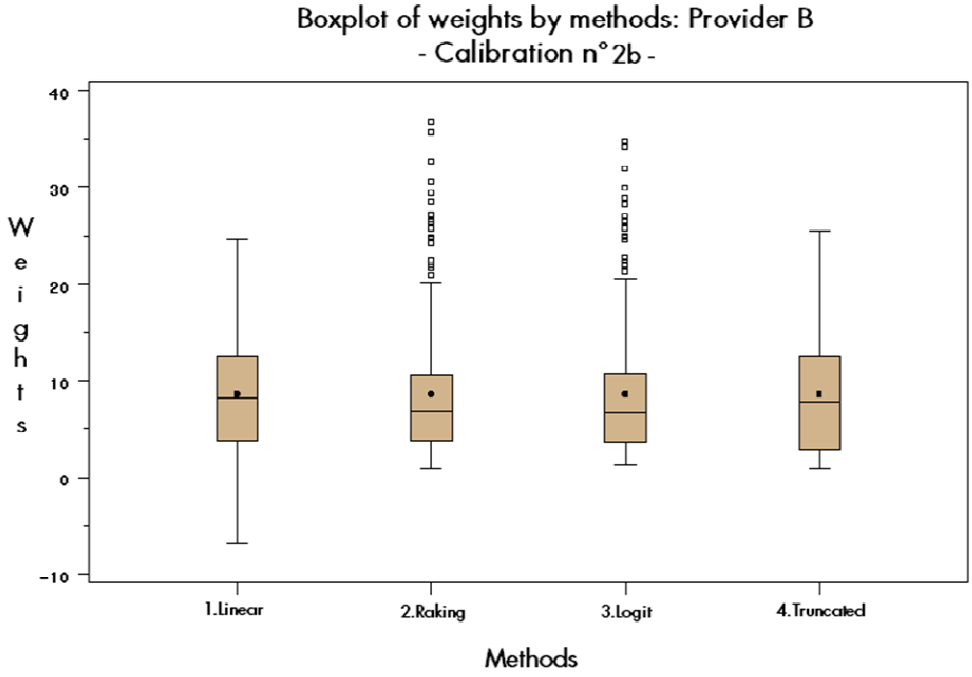

Figure 8.5 Boxplot of the weight distribution in provider network B after Calibration no. 2b for the different methods

NOTE: The whiskers are drawn to the most extreme points in the group that lie within the fences. The upper fence is defined as the third quartile (represented by the upper edge of the box) plus 1.5 times the interquartile range. The lower fence is defined as the first quartile (represented by the lower edge of the box) minus 1.5 times the interquartile range. The mean is a black point, the median a horizontal line within the box. Observations outside the fences are identified with a square dot.

Comparing intervention effect using before-after design with and without calibration

Using the calibration methods raking ratio and logit that were identified as the most appropriate calibration method in the above analyses, we here present the comparison for network B only, while data of network A is also discussed.

We find that the impact of enrolment in the diabetes provider network B in terms of reducing HbA1c levels after one year became less marked when the before-after analysis corrected for differences in the enrolled population on demographic characteristics and risks factors (Calibration no. 1) (-14.61 percent for raking ratio; -14.17 percent for logit) (Table 8.2). The observed reduction became even smaller when correction was also made on differences on disease severity (Calibration no. 2) (-50.50 percent for raking ratio, -49.67 percent for logit). There were no substantial differences for calibrations using raking ratio or logit methods. The impact of calibration on findings for HbA1c is further illustrated in (Figure 8.6).

Table 8.2 Differences in outcome variables between t0 and t1 in provider network B with and without selected calibration scenarios

Calibration	Method	Outcome	Mean	SD	p-value	Percentage variation of outcome difference
Without calibration		HBA1C	0.46	1.60	<.001	NA
		BMI	0.48	2.35	<.001	NA
		GFR	3.62	19.84	0.001	NA
No. 1: Demographic characteristics and risk factors	Raking ratio	HBA1C	0.39	1.31	<.001	-14.61%
		BMI	0.27	2.08	0.052	-44.13%
		GFR	5.25	19.06	<.001	45,08%
	Logit	HBA1C	0.39	1.31	<.001	-14.17%
		BMI	0.27	2.08	0.052	-44.13%
		GFR	5.25	19.02	<.001	45,24%
No. 2: Demographic characteristics with risk factors and outcome variables	Raking ratio	HBA1C	0.23	1.08	0.002	-50.50%
		BMI	0.29	1.86	0.019	-38.70%
		GFR	4.87	17.95	<.001	34.65%
	Logit	HBA1C	0.23	1.08	0.001	-49.67%
		BMI	0.29	1.86	0.018	-38.70%
		GFR	4.90	17.95	<.001	35.43%
No. 2b: Demographic characteristics and outcome variables	Raking ratio	HBA1C	0.20	1.01	0.002	-55.66%
		BMI	0.37	1.95	0.003	-23.31%
		GFR	4.71	17.92	<.001	30.30%
	Logit	HBA1C	0.20	1.09	0.002	-54.76%
		BMI	0.37	1.95	0.003	-23.31%
		GFR	4.72	17.89	<.001	30.60%

NOTE: BMI = Body Mass Index, unit = kg/m^2; GFR = Glomerular Filtration Rate, unit = ml/min; unit for HbA1c = %; 'percent variation' expresses the variation in the outcome difference (t0 and t1) when calibration is performed, as compared with 'without calibration'. For example, when calibration no. 2 is performed using the raking ratio method, the differences in HbA1c between t0 and t1 are 50.5% smaller when compared to the difference measured without calibration.

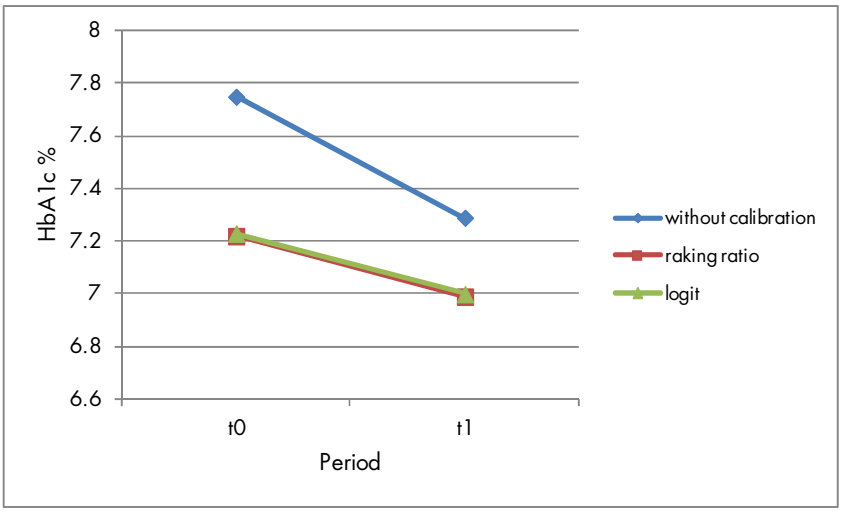

Figure 8.6 Differences in results of HbA1c levels after one year with and without use of calibration (raking ratio or logit for all variables), provider network B

Similar observations were made for body mass index, which indicated a reduction after one year. Following calibration, the observed difference became smaller and did not vary greatly when outcomes variables were used in the calibration (-44.13 percent for calibration without outcome variables and -38.70 percent when outcome variables were included for raking ratio). This can be related to the observation that the difference on this variable between intervention and control groups was not significant at the time of enrolment. Again, the choice of the calibration method had no impact on the relative difference -38.70 percent for both raking ratio and logit when all variables were used for calibration) (Table 8.2).

In case of renal function (GFR), the intervention led to a decrease over time, which means that there was deterioration. While this deterioration was more marked when calibrations were performed, it was lower when outcomes were included (+45.08 percent and +34.65 percent change in difference for raking ratio). Again, the use of the raking ratio or the logit method did not show significant difference on results (Table 8.2).

In contrast, findings for provider network A found these to be inconsistent after calibration. This observation confirmed that for this provider network the sample size (less than 10 percent of the control population) is not sufficient to obtain robust calibration results.

Analysing methods that are currently being used for the evaluation of different types of networks

Diabetes and non-cancer provider networks

A total of 12 networks have been retained in the analysis, based on the availability of a triennial external evaluation. Diseases targeted included common conditions such as diabetes and obesity but also rarer conditions such as multiple sclerosis, motor neuron disease and perineal disease. Four networks in the sample were based in the Paris metropolitan region, and the remaining eight were distributed across medium-sized cities or rural areas. Network size varied between 231 and 4,985 patients in 2009.

In order to summarise and compare the evaluation methods used, we created categories after a first qualitative analysis of external evaluation reports. Evaluation reports typically described the structure and organisation of the provider networks, listed their activities, reported on patient and provider satisfaction and in a limited number of cases performed analysis on quantitative data. They generally provided a narrative conclusion and recommendations.

There was no obvious association between the objectives and services provided by a given network and the evaluation method used. The only exceptions were two networks that had stated explicit quantitative objectives and that had performed a quantitative evaluation. Thus, a diabetes provider network had the specific objective to 'follow up on the outcomes of the care delivered' and used descriptive statistics and evolution over three years of risk factors, clinical outcomes and treatment of 447 patients with an initial assessment, 349 patients with a one-year follow-up, and 126 patients with a follow-up after two years through comparison of means. An obesity provider network had the specific objective to 'reduce weight by 5–10 percent and stabilise this weight loss' and used a pre-post test over a period of 12 months for weight, body mass index, nutrition scores, quality of life and satisfaction of patients and providers. However, the remaining two networks that also employed quantitative evaluation methods did not explicitly link these to quantitative targets in their specific objectives.

The external evaluations of the provider networks in our sample did, by and large, follow the stipulations set out by the National Authority for Health (HAS) and the Ministry of Health (MoH) 2007 document on evaluation.[113] For example, the MoH document set out that 'the presence of organisational guidelines has to be verified, as well as their application and their impact on professional practice'. The external evaluators of a diabetes provider network analysed the proportion of patients receiving the procedures recommended. In the case of a provider network targeting a less common condition, the evaluation noted that 'specific treatment guidelines are currently being set up'. At the same time, the MoH document also set out that the evaluation 'requires being comparative', either using a pre-post or a controlled design. However, only four of the 12 provider networks used a comparative design.

Cancer provider networks

Interviews with stakeholders at the various tiers of the (cancer) system that sought to understand existing evaluation requirements, and their application in practice for cancer provider networks, identified considerable heterogeneity in respondents' perspectives. We here present some of the key themes that have emerged from the analysis.

Overall, the context for evaluation was considered useful by all respondents; however, it was highlighted that evaluation would be seen as positive only if it contributed to quality improvement. This view was voiced particularly by regional leaders in oncology who noted that the benefits of evaluations that have accompanied the development and implementation of cancer plans was to organise and formalise a multidisciplinary approach to cancer care, noting that *multidisciplinarity in oncological decisionmaking already existed before cancer plans.* In particular, evaluations were seen to have informed improvement overall:

> *After evaluating the cancer plan the improvement is evident… I speak as radiotherapist. We have upgraded most of the technical facilities and we have secured most of all technical facilities in France. We have removed which was not viable, and target little equipment and it is therefore more secure and modernised. It has given more quality.*
>
> *In fact, it is perhaps the most authoritative assessment, I do not know if this is the most important as we can say that everything we did for 10 years under the two plans its improved cancer not only the quality of care I am convinced now. But also the results of … on the disease, a numerical results … Here, we will have won. I am not sure that it had to wait for that matter, to say that, it's a good thing. So, evaluate, I think the assessment is useful.*

At the same time, approaches to the organisation of evaluation were questioned, highlighting in particular the absence of consensus on common criteria or the lack of consideration of the patient perspective: *But…it is the beginning? There is no assessment based on the patient's point of view….*

Evaluation can further be interpreted as a means of penalising providers, especially with regard to the authorisation for a hospital or clinic to manage cancer patients (*autorisation d'activité en cancérologie*).

> *For me, the authorisation should be evaluated or it [...] was applied as a sanction. [...] And we had visitors from ARS completely alien to cancer, completely foreign to many things, probably also in medicine, which, in the establishment, came up with the grid proposed by the INCA. [...] They have really taken the wrong way. They took it as binding criteria. [...] I think it's the epitome if the evaluation loses its original purpose and becomes law.*

More commonly, evaluation was perceived as a control tool, for example, as a means to controlling the medical profession:

> *While there is a clear cause and then there is a hidden cause. When you see the assessment on drug consumption services is an assessment that is now extremely fussy ... The obvious cause is to save money. The hidden cause it to reduce the number of centres that practise carcinogenic trying to try to ensure, to make changes that will reduce the staff involved in cancer research. (Of) that I am absolutely convinced.'*

Other concerns centred on policy priorities identified by the interviewees in relation to healthcare expenditure. While there was agreement that cost of care is important, there was concern about the validity of the methods used to assess these. Interviewees also highlighted the importance of taking into account quality in the evaluation. This quality is associated with improved care and research. However, the link between these two dimensions and organisation of services was not always clear to the respondents:

> *It's useful, it is clear. [...] I think the assessment allows you to change practices and improve them. So I do not know what to say. It's all three ... [The] order for me would be: analyse, design of reforms and implement. I mean it's [a] quality approach.*

> *[T]his is a management tool of the organisation or a management tool improving care, therefore, it can be seen only as useful as soon as the objectives, if you have no goals, group compared with patients in relation to organisations, misjudged it is seen as an administrative constraint.*

Similar to what was observed for non-cancer networks, evaluation, while considered important, is seen to pose methodological challenges on the ground, and while national frameworks are considered useful, the level of support provided tends to be seen to be insufficient:

> *I think today there are difficulties that exist in the networks ... is the methodological support daily. Because the INCa, it is far. The ARS* [regional health agency]*, it does not support the methodology. And every day, there are many networks that are relatively poor compared to that. It is how we had built, methodological support.*

Furthermore, respondents noted that evaluations would probably be best performed by external evaluators, so as to maintain objectivity:

> *'I'm not qualified to answer this question. I think it's always useful either an external structure. Since it is more honest. If it [the facility] which evaluates one of its services, one would think that there are conflicts of interest. [...]. So I think it should be something external. Second, I think it should be at least partly medicalised. And partly also be examined by health economists.'*

To summarise, while evaluation was seen by all interviewees as of importance, activity reports were considered to be disconnected from the daily reality of care. In some cases, the actors claimed to make them more relevant to their practice. In this chapter we only present key observations of the interview study, but overall we find evidence of a 'blurred' image of evaluation, reflecting the different perspectives and expectations at different layers of the system, different skill sets and differences in the understanding of the values and uses of evaluation.

8.5 Discussion

The analyses presented in this chapter sought to explore the impact of selection bias on the evaluation of diabetes provider networks and to describe and analyse methods that are currently being used for the evaluation of different types of networks.

Assessing the impact of selection bias on the effectiveness of diabetes provider networks

Discussing the assessment of the impact of selection bias on the evaluation of diabetes provider networks first, our study demonstrated how, in France, patient selection takes place upon enrolment in a disease management initiative such as a diabetes provider network. In brief, the enrolled population tends to be of younger age, have a more recent diagnosis of diabetes and worse glycaemic control than a comparable control group. We highlight how failure to control for differences at baseline led to a before-after evaluation overestimating improvements in HbA1c levels and body mass index while underestimating deterioration in renal function in diabetic patients.

We demonstrate how, where no longitudinal data on a control population is available, calibration may provide a very useful tool for the evaluation of disease management

interventions, ensuring that findings are applicable to the entire target population. Indeed, calibrated evaluation gives an estimate of the impact that the intervention (that is, the enrolment in the diabetes provider network for one year) would have on a reference population, compared with the impact on patients inside a provider network. The raking ratio and logit method yielded similar results and seem equally recommendable for calibration. In order to ensure generalisation of results to the entire target population, it seems preferable to include in the calibration a maximal number of variables with relevance to the natural history of the disease under consideration. As the reduction of variables to a limited set of variables has an impact on the findings, it should be carefully applied. If it has to be done for technical reasons, this reduction should take the specific disease context into account (for example it should not drop all risk factors, disease and treatment characteristics).

Our quantitative analysis was based on a set of observable variables. However, we lacked data on important patient characteristics such as socioeconomic status and co-morbidities. Therefore, our analysis will not have seen the full picture of patient selection. At the same time, the data used reflects data available in the context of French provider network evaluation, and the method tested here can inform future real-world evaluations of provider networks.

Implications for improving access and to reduce patient selection

Selection is in part a matter of subjective judgement. In the French context, almost 90 percent of patients who join a provider network are selected by the physician whose decisionmaking is influenced by medical and also non-medical factors like socioeconomic status, race, language and gender.[114] As noted above, patients enrolled in either of the two provider networks were significantly younger, had a significantly shorter time since onset of the disease and had worse glycaemic control than the reference population. However, we cannot judge if this selection is justified or not. A first step to address selection is to raise awareness of this phenomenon and of the characteristics on which the selection is done (younger patients, worse glycaemic control, etc). A second step is to develop future research using qualitative methods to better understand the decisionmaking process behind the selection.

Analysing methods that are currently being used for the evaluation of different types of networks

The analysis of methods that are currently being used for the evaluation of different types of provider networks showed that there appears to be a gap or 'mismatch' with what is being recommended at national level and what is being implemented in practice, based on the data analysed in this study. Generally, the methods used for the external evaluation of provider networks in the sample of diabetes and non-cancer networks were based on descriptive techniques and satisfaction surveys, except for the few provider networks performing quantitative evaluation. The evaluations lacked clear indicators allowing to measure if the set objectives had been met. These objectives varied greatly, reflecting the heterogeneity of provider networks. At the same time, administrative stipulations for evaluation practice only give uniform and rather vague indications on the evaluation methods to be used. We therefore recommend a better match of evaluation methods and provider network characteristics by giving more specific indications by provider network subtypes, based on the disease type.

Our qualitative analysis of diabetes and non-cancer provider networks included only 12 such networks, thus representing just a small sample of existing provider networks in France. It would have been preferable to have a larger sample, but access to data presented a major obstacle, as external evaluations are not available in the public domain. We tried to include as wide a range of diseases, regions and network sizes as possible in order to reduce any potential bias that might have arisen because of the small sample size. Furthermore, the analyses for diabetes and non-cancer provider networks was based on data that were as recent as 2009. It is important to note that the situation has evolved since then. Most importantly, an evaluation grid provided recently by the Ministry of Health is increasingly being used in addition to existing evaluations (annual activity report, triennial external evaluation). This means that (re)funding decisions for provider networks will be based on a combined picture obtained by these three evaluation documents. The conclusions and recommendations of this study have thus to be perceived in light of these developments.

CHAPTER 9 Evaluation of disease management in the Netherlands

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9.1 Introduction

This chapter reports on the testing and validation of evaluation methods and metrics on data from a diabetes disease management intervention implemented in the Dutch health system (WP9). In the Netherlands, the rising burden of chronic disease and the increasing recognition of deficiencies in traditional care for patients with chronic conditions have prompted the introduction of the 'programmatic approach' to chronic disease management. This involved the implementation of integrated chronic care financing and delivery in the form of provider networks in primary care ('care groups') who contract with health insurers on the basis of a 'bundled payment' for the complete package of care for a specific condition.[115] The system currently covers diabetes type 2, chronic obstructive pulmonary disease (COPD) and vascular risk. The implementation of disease management is part of a structural and ongoing redesign of the organisation of chronic care, building on earlier successful shared care projects supported by a strong primary care sector.[116,117]

The overarching aim of the analyses presented in this chapter was to advance current methods of disease management evaluation by testing and validating two complementary analytical approaches to examine what (combination of) components of disease management interventions work(s) and for whom. Using data from existing regional care programmes for diabetes type 2 in the Netherlands, it sought to explore the extent to which the use of meta-analysis and meta-regression methods can improve current approaches to evaluation of disease management interventions in the Netherlands. Furthermore, analyses sought to gain insight into the basic elements of the regional diabetes care programmes and to assess care professionals' perspectives on current disease management evaluation approaches, focusing specifically on the difficulties and risks of evaluation in routine practice.

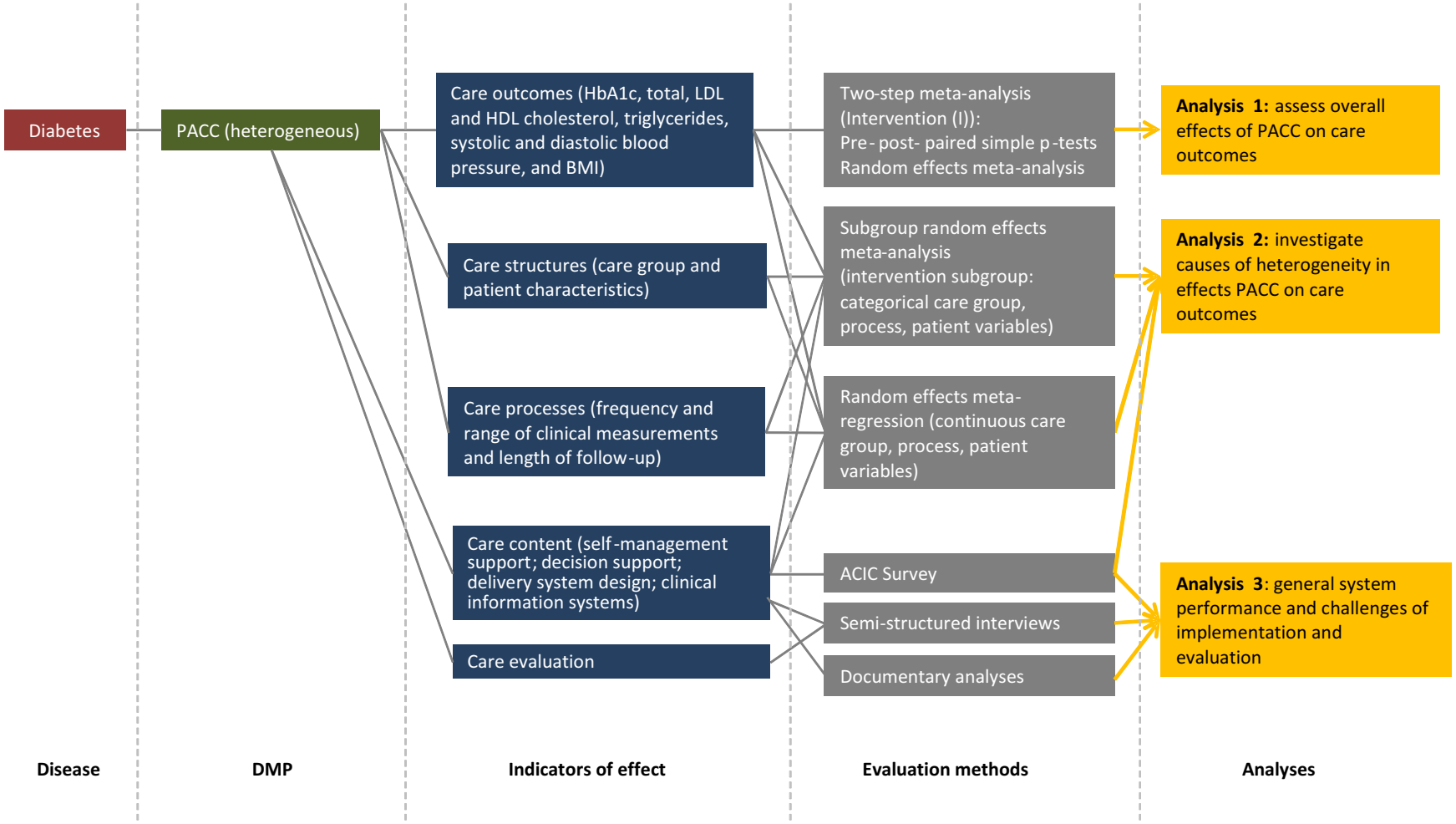

Figure 9.1 Overview of evaluation methods and metrics applied to a diabetes disease management intervention in the Netherlands

9.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in the Netherlands

Under the bundled payment system, care groups assume clinical and financial responsibility for all patients in their integrally funded disease management programme, who are enrolled automatically by their general practitioner (GP). Following experiments in diabetes care, the number of care groups providing diabetes care bundles grew exponentially to almost 100 groups by March 2010, covering nearly all regions of the Netherlands and about 75 percent of Dutch GPs.[118] The minimally required services to be covered by bundled payment contracts are stipulated in the national care standard for generic diabetes type 2.[119] This standard is based on existing evidence-based guidelines for GPs and includes general and disease-specific modules. The former focus on patient education, self-management and health behaviours; the latter comprise a defined frequency of GP visits, regular foot and eye examinations and laboratory testing. The standard defines the types of services rather than the personnel, so stimulating task redistribution from GPs to nurses and/or practice assistants. Performance indicators, primarily related to disease-specific modules, enable health insurers to monitor service-levels and quality of care.[116,118] For services that go beyond general practice, care groups may subcontract dieticians, physical therapists, specialists, and/or other relevant providers. [120,121]

9.3 Methods

Data collection and preparation

Data were collected from 18 Dutch care groups, including nine so-called 'frontrunners' which formed part of the pilot programme funded by the Dutch Organisation for Health Research and Development (ZonMw) and evaluated by the National Institute for Public Health and the Environment (RIVM).[115,120] We selected nine additional non-frontrunner care groups, that is to say regional care initiatives providing diabetes management without (financial) support from the pilot programme. These were diverse in geographical location and size. The 18 care groups represented nearly all regions of the Netherlands, covering a diabetic population of 106,623. We included all patients with diabetes type 2 with at least one registered visit during a 20 or 24 month period between January 2008 and December 2010, inclusive. Persons with diabetes type 1 (n=1,567) were excluded, because they are treated primarily by specialists.

Data were collected at individual and care group levels, using a mixed-model design, combining qualitative and quantitative data across the stages of the research process.[122] Patient-level data included various patient characteristics, care processes and clinical outcomes although only two care groups were able to provide data on the full range of relevant indicators. Most common missing data across groups were indicators concerning diabetes medication use (9 groups), the frequency of clinical measurements (4 groups), and the presence of co-morbidity (4 groups). The plausibility of data was verified through range checks; extreme outliers were removed based on expert cut-off points.

For non-frontrunner care groups, we further obtained care group level data using the Dutch version of the Assessing Chronic Illness Care (ACIC) survey.[123] The ACIC scores,

which could range from 1 (least optimal) to 4 (most optimal), reflect providers' perspectives on the level of implementation of components of high-quality diabetes care according to the Chronic Care Model (CCM), alongside their level of integration (see Section 2.2, page 7).

We cross-validated the survey through semi-structured interviews and a documentary analysis of care groups' diabetes care protocols and annual reports. Survey and interview participants represented a selection of 27 healthcare professionals, including one manager, one GP and one nurse/practice assistant per care group. The interviews were also used to gain insight into the main characteristics of the care groups and to assess care professionals' opinions about disease management evaluation with relation to: (1) determining and measuring the goals of diabetes care; (2) function and possibilities of evaluation; (3) type and range of quality indicators; and (4) indicator development.

Definition of variables

Quantitative data were classified into (a) structure (care groups: frontrunner status, size of the patient population, care bundle price, level of cooperation with specialists; patient characteristics: age, disease duration, diabetes medication type and use, baseline health status, co-morbidity, smoking status); (b) processes (frequency of clinical outcome measurements, number of registered outcome indicators and length of follow-up in months); and (c) outcomes (change in HbA1c, cholesterol, LDL and HDL cholesterol, triglycerides, blood pressure and body mass index). Outcome analyses excluded patients with missing data on registration of baseline and/or follow-up measurements; on registration of the care group, process and/or patient characteristics; and/or the time period between baseline and follow-up measurement was less than three months. The maximum length of follow-up per patient was 23 months.

Analytical approach

The quantitative analysis used meta-analysis and meta-regression techniques to assess the differential effects of disease management for diabetes over time. The meta-analysis employed a two-step approach to analyse the individual patient data (IPD) on eight clinical outcomes clustered by care group.[124,125] First, we conducted paired-sampled t-tests (two-sided; α=0.05) in SPSS® 18 to calculate the group-specific mean differences in clinical values between baseline and follow-up and standard deviations. Second, these estimates were synthesised with the Review Manager[126] into pooled mean differences and 95 percent confidence intervals; because of significant heterogeneity we applied the random effects meta-analysis model developed by DerSimonian and Laird.[127] Using this model, we weighted the aggregate effects by the inverse of their variances while assuming random treatment effects across care groups. To quantify the heterogeneity in effects between groups, we calculated the I^2 statistic (which can range from 0 to 100 percent, with larger values showing increasing heterogeneity) on the basis of the chi-square (χ^2) test.[128] We conducted subgroup analyses to examine the consistency of intervention effects across diabetes care structures and processes, grouping most continuous variables into two or three categories as derived from the literature (age[129,130] and disease duration[131]) or median values (care group size, care bundle price, measurement frequency, length of follow-up). Measurement range was dichotomised (eight clinical outcomes or fewer); where possible, baseline clinical values were categorised according to the target range values in the diabetes care standard.[118]

We used multivariable meta-regression analysis to further investigate the potential effect modifiers known for all 18 care groups as well as the three-way interactions between these covariates on the care group, process and patient level and intervention effects.[132,133] Univariable meta-regression was used to examine those covariates known for the nine non-frontrunner care groups only (care bundle price, level of specialist collaboration, and the ACIC scores). We applied the PROC MIXED command in the SAS® 9.2 Software, which use a random effects iterative method to provide a maximum likelihood estimate of the regression parameters. Continuous covariates, such as age and disease duration, were included as such in the meta-regression. For each outcome, we calculated the intraclass correlation coefficient (ICC), that is, the percentage of total heterogeneity that occurs between care groups. Explained heterogeneity was expressed as the percentage change in between-group variance ($\tau 2$) and/or within-group variance ($\sigma 2$). We examined collinearity with the variance inflation factor (VIF). A VIF value of greater than ten is generally taken as an indication of serious multi-collinearity.

The analysis of qualitative data (interviews, documentary analysis) used data matrices and bracketing that couples brackets (in other words fragments) of corresponding information from transcripts or texts to the basic concepts under study.[134] In the first instance, the brackets consisted of so-called thick descriptions, that is, literal passages from the interviews and documents. These were later summarised into 'thin' descriptions. The content of care groups' DMPs and providers' views on disease management evaluation were derived from, and compared on, the basis of the matrices containing thin descriptions.

9.4 Findings

The 18 groups considered in this analysis varied in terms of size of the patient population (348 to 18,531 patients). Care bundle prices, known only for the nine non-frontrunners, also differed substantially (€299 to €458). One third of the non-frontrunners engaged in more extensive cooperation with specialist care providers; for most groups, the collaboration with specialists was limited to a consultation function for GPs.

Across the 18 care groups, we included 105,056 patients with diabetes type 2 in our analyses. About half the patients were female; the average age was 65.7 and average disease duration 4.8 years. Further details are shown inTable 9.2.

Table 9.1 Characteristics of the study population

Patient characteristics	Patients for whom characteristic is known (total =105,056)	Estimate
	% (N)	Mean ± SD
Baseline age (18 groups)	99.9 (105,013)	65.7 ± 11.9
Baseline diabetes duration (14 groups)	71.9 (75,498)	4.8 ± 5.6
	% (N)	% (N)
Sex (18 groups)	99.3 (104,369)	
Male		49.3 (51,421)
Female		50.7 (52,948)
Medication (7 groups)	65.0 (68,298)	
No		36.0 (24,606)
Yes		64.0 (43,692)
Type of medication (7 groups)	41.6 (43,692)	
Oral		80.5 (35,163)
Insulin		7.9 (3460)
Both		11.6 (5069)
Co-morbidity[1] (16 groups)	94.5 (99,278)	
None		84.2 (75,357)
One or more		15.8 (14,165)
Smoking status (18 groups)	74.6 (78,384)	
Non or ex-smoker		81.6 (63,943)
Current smoker		18.4 (14,441)
	% (N)	Mean ± SD
Baseline HbA1c (mmol/mol) [target ≤53] (18 groups)	71.5 (75,127)	50.2 ± 9.8
Baseline total cholesterol (mmol/l) (18 groups)	58.4 (61,376)	4.5 ± 1.0
Baseline LDL (mmol/l) [target < 2.5] (18 groups)	55.9 (58,697)	2.6 ± 0.9
Baseline HDL (mmol/l) (17 groups)	51.8 (54,456)	1.2 ± 0.4
Baseline triglycerides (mmol/l) (18 groups)	58.1 (61,078)	1.8 ± 0.9
Baseline SBP (mmHg) [target ≤140] (18 groups)	69.9 (73,437)	140.4 ± 18.0
Baseline diastolic blood pressure (mmHg) (18 groups)	69.6 (73,115)	78.60 ± 9.6
Baseline BMI (kg/m^2) [target < 25] (18 groups)	60.3 (63,341)	29.7 ± 5.2

NOTE: [1]Included were four major co-morbidity associated with diabetes mellitus: angina pectoris, myocardial infarction (MI), stroke, transient ischemic attack (TIA).

With regard to care processes, blood pressure was found to be most frequently measured (n=4) during the patient-specific follow-up periods of 3 to 23 months, followed by BMI (n=3), and HbA1c (n=2). Cholesterol-related endpoints were measured least often (n=1). Across groups, the proportion of patients with registrations of all included endpoints (n=8) ranged from 44.4 to 86.7 percent (mean: 62.3 percent). Median length of follow-up varied from 11 to 12 months. The mean non-frontrunner ACIC scores were fairly high on average; with highest scores for self-management support (3.12±0.27), followed by delivery system design (3.09±0.35), decision support (2.78±0.31), clinical information systems (2.57±0.21) and the level of integration of the components (2.50±0.16).

Table 9.22 presents the findings of the random-effects meta-analysis across 18 care groups, presented per clinical endpoint. Overall, we found a small, non-significant increase in HbA1c levels between baseline and follow-up, while significant reductions in mean levels were observed for total cholesterol, LDL cholesterol, triglycerides and systolic and diastolic blood pressure. There was a modest, statistically significant increase in mean HDL cholesterol levels, and a small, non-significant decline in mean body mass index.

Table 9.2 Results of the overall random-effects meta-analysis

Endpoint	Care groups (N)	Patients (N)	Mean difference [95%CI]	Heterogeneity (I^2)
HbA1c (%)	18	75,127	0.17 [-0.60; 0.93]	98%*
Total cholesterol (mmol/l)	18	61,376	-0.10 [-0.14; -0.06]*	90%*
LDL (mmol/l)	18	58,697	-0.09 [-0.13; -0.05]*	93%*
HDL (mmol/l)	17	54,456	0.02 [0.00; 0.03]*	92%*
Triglycerides (mmol/l)	18	61,078	-0.05 [-0.07; -0.03]*	75%*
SBP (mmHg)	18	73,437	-0.95 [-1.25; -0.64]*	57%*
DBP (mmHg)	18	73,115	-0.80 [-0.93; -0.67]*	34%
BMI (kg/m^2)	18	63,341	-0.04 [-0.10; 0.02]	0%

NOTE: * Statistically significant ($p<0.05$)

Except for body mass index, all clinical outcomes showed moderate to high statistical heterogeneity, from 34 percent for diastolic blood pressure (non-significant) to 98 percent for HbA1c, suggesting that the intervention effect on these outcomes is inconsistent across care groups. Additional subgroup analyses found that non-frontrunner care groups appeared to achieve somewhat better results on the majority of clinical outcomes, as did larger care groups (>5,363 patients). The variance in effects on different outcomes between subgroups based on these characteristics was, however, rarely significant. Subgroup analyses for care bundle price and level of specialist collaboration were inconsistent across outcomes. Those for process characteristics demonstrated greater improvements in all clinical outcomes among patients with a measurement frequency greater than the median for each endpoint. Significant between-group variance was, however, identified only for total and LDL cholesterol. Analyses further showed that for half of the endpoints, patients with a length of follow-up of less than one year achieved somewhat better average results than patients observed for 12 months or longer. The results for measurement range were inconclusive.

Most notably, subgroup analyses for patient characteristics suggested that the diabetes disease management intervention appeared to be considerably 'more effective' for patients with poor baseline clinical values in that the intervention led to improvements while for those with good baseline values the potential for further improvement remained limited. Across the 18 care groups, patients with a baseline HbA1c of ≥75 mmol/mol achieved a mean reduction in this clinical measure of 16.8 mmol/mol during follow-up, whereas those within target range for HbA1c (≤53 mmol/mol) at baseline experienced a slight deterioration in glycemic control (1.79 mmol/mol). This is further illustrated in Figure

9.2, which demonstrates how glycaemic control improved in the majority of patients, but particularly so in those with highly uncontrolled diabetes, of whom about two-thirds achieved HbA1c levels of less than 75 mmol/mol during the follow-up period. Compared with the total study population, patients with poor baseline HbA1c levels were significantly younger but had a longer disease duration (7.5±7.48 years; P<0.0001).

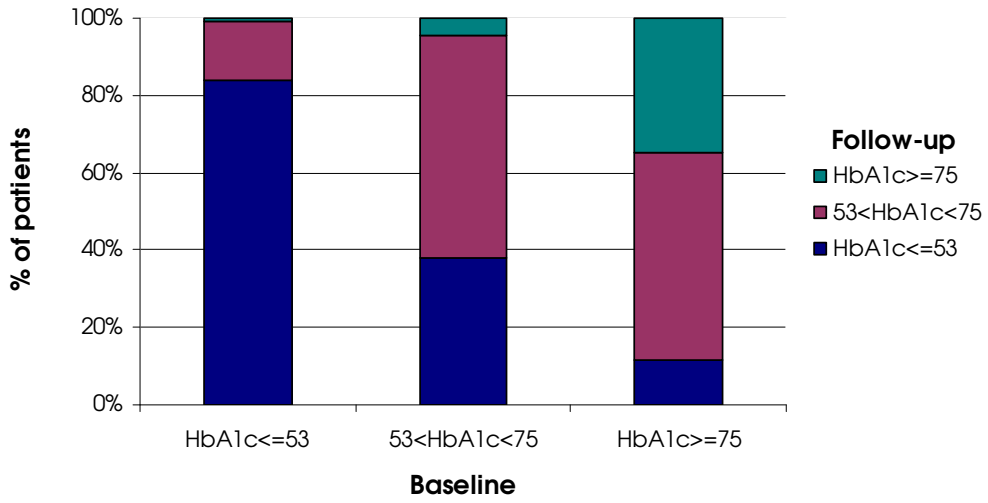

Figure 9.2 Glycaemic control between baseline and follow-up in three subgroups of patients based on the care standard target values for HbA1c

Similar observations were made for LDL cholesterol levels and systolic blood pressure, that is, those with poor baseline values tended to show the greatest improvements (data not shown).

To better understand the potential causes of heterogeneity in observed effects, we conducted several meta-regression analyses which indicated that the vast majority of variance in effects occurs within care groups rather than between groups. This is further illustrated in Table 9.3, which demonstrates the changes in between- and within-group heterogeneity in effects on clinical outcomes after correcting for potential effect modifiers, with the direction of effects indicated (positive or negative).

Table 9.3 Directions of meta-regression coefficients and associated changes in between-group (τ2) and within-group (σ2) variance in effects

	HbA1c	TC[Ŧ]	LDL	HDL	TRIG[π]	SBP	DBP	BMI
Care group characteristics								
Frontrunner status (n=18)	+	+	+	+	-	-	-	-
Care group size (n=18)	+	+	+	+	-	-*	-*	-
Change in τ^2	-6.8%	-6.7%	-1.3%	-12.2%	-8.2%	-21.3%	-45.9%	-59.2%
Non-frontrunner characteristics								
Care bundle price (n=9)	-*	-	-	-	-	-	-	N/A
Change in τ^2	-50.6%	-7.5%	-5.8%	-3.7%	-2.2%	-17.0%	1.2%	N/A
Specialist collaboration (n=9)	-	+	+	-	-	-	-	N/A
Change in τ^2	-21.9%	-7.5%	-9.1%	-2.1%	-5.0%	-1.4%	-5.5%	N/A
Process characteristics								
Measurement frequency (n=14)	-	-*	-*	+	-*	-*	-*	-
Measurement range (n=18)	-*	-	-	+*	-*	+*	+	+
Length of follow-up (n=18ps)	+*	+*	+*	+*	+*	+*	+*	+
Change in τ^2	26.0%	-18.3%	-37.0%	23.0%	50.1%	15.6%	-6.2%	15.6%
Change in σ^2	-0.1%	1.0%	0.7%	-9.6%	2.1%	5.2%	3.9%	1.8%
Care components[‡]								
Self-management support (n=9)	+	-	-	+	-	+	+	N/A
Change in τ^2	-0.4%	-0.3%	-0.5%	-0.5%	-0.3%	-0.7%	-38.0%	N/A
Decision support (n=9)	+	+	+	-	+	+	-	N/A
Change in τ^2	-0.8%	-35.5%	-20.4%	-7.2%	-14.4%	1.7%	-12.3%	N/A
Delivery system design (n=9)	-	-	-	+*	-	-	-	N/A
Change in τ^2	0.01%	-0.3%	-10.7%	-59.2%	-0.1%	-2.7%	9.2%	N/A
Clinical information systems (n=9)	-	-	-	-	-	+	+	N/A
Change in τ^2	-5.1%	-27.2%	-25.4%	-1.5%	-0.02%	3.2%	3.9%	N/A
Integration of care components (n=9)	-	-	-*	+	-	-*	-	N/A
Change in τ^2	-2.9%	-29.2%	-49.9%	-36.1%	-8.6%	-62.3%	3.5%	N/A
Patient characteristics								
Age (n=18)	-*	+*	+*	+*	-*	+*	-*	-*
Disease duration (n=14)	+*	-	-	+	-*	+	-*	+*
Baseline clinical value (n=18)	-*	-*	-*	-*	-*	-*	-*	-*
Co-morbidity (n=16)	+*	-*	-*	-*	+*	-*	-*	+
Smoking status (n=17)	+*	-	-	-*	+*	-	-*	-*
Change in τ^2	-12.5%	0.3%	-33.9%	-49.8%	-39.0%	74.8%	154.2%	22.3%
Change in σ^2	-23.5%	-20.5%	-21.7%	-3.3%	-21.5%	-29.9%	-27.0%	3.4%

NOTE: +=positive regression line/slope; -=negative regression line/slope; *Statistically significant (p<0.05); [Ŧ]TC=total cholesterol; [π]TRIG=triglycerides

Correcting simultaneously for care group characteristics (frontrunner status and size) reduced between-group variance in effects by between 1.3 and 59.2 percent, depending on the outcome considered. However, the positive effect of the intervention on systolic (SBP) and diastolic blood pressure (DBP) appeared to increase with the size of care groups' patient population as indicated by linear relations identified for these potential effect modifiers (Table 9.3). One other important finding was that the intervention effect on HbA1c levels appeared to be significantly better in care groups with higher care bundle prices. Furthermore, the identification of linear relationships between length of follow-up and all endpoints except for BMI, suggests that as the duration of care increases, the positive effect of the diabetes disease management intervention on clinical outcomes reduces. Likewise, a greater measurement frequency of clinical endpoints was associated with progressively better results on these measures.

Simultaneously correcting for known patient characteristics across the 18 care groups resulted in considerable reductions in the majority of within-group variance in effects of the intervention. Significant and consistent linear relationships were identified between baseline values of all clinical outcomes (except for HDL cholesterol) and the effects on those outcomes, suggesting that the impact of the intervention becomes progressively better as patients' baseline values are poorer.

Finally, we examined potential three-way interactions between diabetes care structures, processes and outcomes. One of those interactions was consistent across all included endpoints, suggesting that the benefit that patients have from more frequent measurements of clinical endpoints is negatively related to their baseline values. Thus, the poorer a given patient's baseline values of a particular endpoint, the more beneficial frequent measurement of that clinical outcome is in terms of achieved improvements.

In a separate set of qualitative analyses, we conducted interviews with representatives of nine care groups (three per care group) to gain insight into professionals' perspectives on current approaches to disease management evaluation. This showed that the majority of respondents: (1) agreed that the indicators used to determine the quality of diabetes care should coincide with the goals of a specific care programme, and (2) believed that this was the case in their care group. Most interviewees disagreed that the goals of diabetes care, and, alongside, the indicators for evaluation, should be based on the wishes of the patient; those who did agree argued for more shared-decisionmaking. As to the function and possibilities of evaluation, most respondents reported that they were able to derive whether improvements in organisational structure are necessary (especially through regular audits and benchmarks), but more than half stated that they did not have insight into the effects of all components of their care programmes. Self-management support and multidisciplinary cooperation were considered as difficult to evaluate. With regard to type and range of quality indicators, the vast majority of respondents believed that the focus should be on outcomes as well as processes and structures, and that parameters concerning patients' knowledge and behaviour should be a standard part of evaluating diabetes care. To date, however, evaluation focused mostly on clinical outcome measures and, to a somewhat lesser extent, service levels. Quality of life and patient satisfaction were also regarded as important, although to a lesser degree than clinical outcomes. Just over half of the respondents agreed that a limited number of parameters was necessary to gain insight into the quality of diabetes care. More than half of respondents also believed that

important indicators of good diabetes care, such as patients' self-efficacy and quality of life were currently not being measured; two-thirds of respondents reported experiencing difficulties in evaluating disease management for diabetes. Although these difficulties were often of a practical nature, relating to shortcomings in ICT or insufficient time for registration, providers also noted that the trend of quality measurement in primary care was relatively new and they are still in the learning phase, trying to determine how to measure quality, by what indicators and how to analyse large amounts of data.

9.5 Discussion

Interpreting the evaluation results

Measuring the effects of population-based, multi-component interventions such as the Dutch care groups for diabetes is a complex undertaking. It is therefore not surprising that the majority of professionals interviewed for this study reported difficulties with disease management evaluation. To advance the methods currently used, this study tested two analytic techniques, meta-analysis and meta-regression, on data from 105,056 patients across 18 diabetes care groups. Given that experimental comparisons were not possible, due to the nation-wide roll-out of the diabetes DMPs and the unsuitability of using historic controls[135], combining these two techniques allowed for in-depth assessment of treatment effects.

Where most observational study designs provide 'grand means', the use of meta-analysis and meta-regression methods enables estimation of the consistency of effects across different care structures (that is to say care settings/groups and patients) and processes, as well as investigation of the potential interactions between covariates on these levels. In the case of the Dutch diabetes management intervention, a simple pre-post comparison, for example by means of a paired-samples t-test, would have led to the conclusion that effects on patients' health are modest at best. While our overall meta-analysis showed similar results, the findings also indicated that the effects of the diabetes care programmes are moderate to highly heterogeneous among care groups. We conducted subgroup meta-analyses to investigate whether specific characteristics of care groups, care processes and patients contribute to this inconsistency in treatment effects. Most notably, these analyses revealed that patients with poor baseline clinical values achieve significant and clinically relevant health improvements after a median follow-up of 11 to 12 months. Findings also suggest that more promising improvements in health are associated with a higher than median measurement frequency of clinical outcomes. In addition, patients observed over less than one year show greater improvements in half of the clinical outcomes than patients with a length of follow-up of one year or more.

Meta-regression analyses allowed us to further investigate the potential effect modifiers related to care groups, processes and patients, without the need to create subgroups. In addition, meta-regression enabled us to investigate multiple variables simultaneously and to examine potential three-way interactions between care group, process and patient characteristics. Consistent linear relationships between treatment effects and care group characteristics were not identified, even though the subgroup meta-analyses demonstrated a trend towards better clinical results in non-frontrunner care groups and large care groups, as compared with their respective counterparts. Meta-regression did confirm there to be a

significant interaction between measurement frequency and treatment effects, in that patients' outcomes become more promising as clinical measures are registered more often. More frequent measurement of clinical outcomes appears to be especially beneficial for patients with poor baseline clinical values, who in general were shown to benefit most from disease management in terms of effects on clinical outcomes.

This finding is supported by a recent meta-analysis of the international literature conducted by Pimouguet et al. (2011)[136], which, given that the vast majority of patients included in our study had good first-year values, provides a plausible explanation for the small average effects of the Dutch diabetes DMPs. In line with previous studies[102,137] as well as the results from our subgroup-analyses, the meta-regression analyses also verified that length of follow-up interacts with treatment effects: as the duration of care increases, the positive results of the DMPs appear difficult to maintain. Although for many of the variables included in our meta-regression models, linear relationships with intervention effects were not identified, correcting for all known patient characteristics in particular significantly reduced the majority of heterogeneity in effects within care groups. This implies that these features influence the effects of disease management on clinical outcomes.

Meta-analysis and meta-regression: lessons learned

Meta-analysis and meta-regression constitute valuable techniques for evaluating complex, large-scaled DMPs on the basis of data from everyday health care practice. Although missing values were numerous in the Dutch datasets, these techniques enabled us to make as much use of the available evidence as possible, since we had to exclude patients missing a specific characteristic or outcome only from the analyses including those variables. More importantly, the differentiated findings that result from using these analytic approaches better inform chronic care redesign than the single effects across many patients measured in most current DMP evaluations. Meta-analysis of meaningful subgroups of patients can show, among others, who benefits most from disease management or what care processes are most effective. Meta-regression can identify linear relationships between (multiple) covariates and treatment effects and, more importantly, enables researchers to combine data on treatments and target populations, so as to answer the basic question of 'what works best for whom'. To date, our knowledge regarding how to best treat specific subgroups of the chronically ill remains limited, as most studies of disease management, regardless of design, focus on overall, summarised effect estimates. Moreover, most randomised controlled trials are conducted in academic settings and provide limited insight into the impact of disease management in the every-day practice of healthcare.

More generally, our differential, 'real-life' findings plead for a move from standardised to tailored disease management for diabetes, in which the components and processes of care are determined by the characteristics of patients. Intensive disease management, characterised by frequent monitoring of clinical measures, was shown to be especially useful for improving clinical values in poorly controlled diabetic patients. For those in relatively good health, a less physician-guided form of care that emphasises self-management might be equally effective, and probably less costly, to maintain glycaemic control. The characteristics relevant for tailoring disease management likely go beyond those investigated in our study and include, for example, patients' level of education and socio-economic status, which influence their health behaviours.[138] Future studies should

investigate the existence of interactions between such characteristics and the effects of population-based DMPs. In so doing, the use of longitudinal data is crucial, given the interactions identified between length of follow-up and the effects of disease management on clinical measures. Moreover, mixed methods are recommended to improve our insight into how specific local conditions, such as, for instance, the bundled payment system for chronic care implemented in the Netherlands, influence the outcomes of disease management.

CHAPTER 10 Evaluation of disease management in Spain

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10.1 Introduction

This chapter reports on the testing and validation of evaluation methods of a nurse-led intervention for cardiovascular disease in Spain (WP10). It has been estimated that cardiovascular diseases are responsible for 15 percent of total healthcare costs and 14 percent of lost productivity due to premature death in Spain.[139] The burden that these conditions placed on the healthcare system has led health authorities and several organisations and institutions to put into action diverse initiatives aimed at reducing the impact of this disease.[140] Preventive strategies that produce the greater medium- and long-term social benefits are those that include primary prevention, targeting individuals who have no known vascular disease. Secondary prevention strategies attempt to diagnose and treat existing diseases in its early stages before it results in over clinical condition preventing the progression of the disease.

In the analyses presented in this chapter, we examined one such preventative initiative that has been implemented throughout Spain. The intervention under consideration was not offered within a randomised controlled trial setting and the overarching objective for work presented here was therefore to identify an appropriate and unbiased control group so that the effects of interventions can be adequately evaluated. We carried out a series of before-and after studies using regression discontinuity analysis and propensity score matching, and tested different control group designs to analyse global risk and cardiovascular risk factors after a one-year intervention.

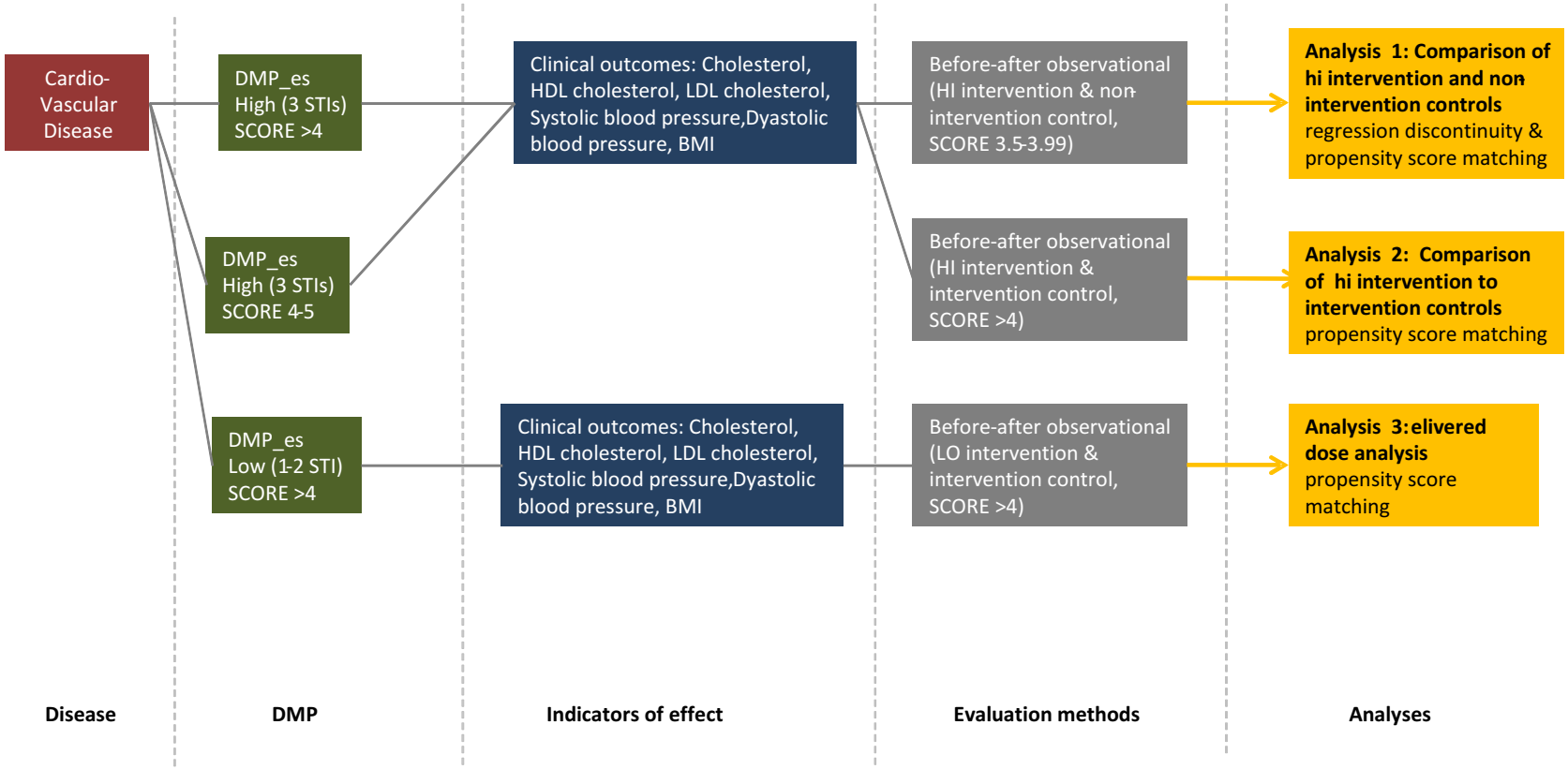

Figure 10.1 Overview of evaluation methods applied to a nurse-led intervention for cardiovascular disease in Spain

10.2 Disease management intervention that formed the basis for testing and validating evaluation methods and metrics in Spain

Ibermutuamur is a Mutual Fund for Workers Injuries and Occupational Diseases (*Mutua de Accidentes de Trabajo y Enfermedades Profesionales (MATEP)*), which has developed a plan for the prevention of cardiovascular risk, now successfully implemented through their network of healthcare professionals. A specific value of this intervention is that workers who attend the preventive services of Mutual Funds in Spain, such as *Ibermutuamur,* are usually young and healthy; they typically do not frequently consult healthcare services and are thus unlikely to be identified to be at risk of cardiovascular disease through routine checks within the health service.

Participation in the programme included a telephone follow-up conducted by a trained nurse using a Structured Telephone Interview (STI) after one, four and eight months from the initial medical checkup. The STI included questions to try to determine whether the individual had read the preventive recommendations provided with the results of the medical checkup; the level of knowledge of the individual with regard to his/her cardiovascular risk factors and his/her overall cardiovascular risk level as assessed by the SCORE (European Coronary Risk Evaluation[141]) risk chart; the degree to which the individual followed the preventive recommendations provided (including giving up smoking); and whether the individual had noticed the appearance of clinical symptoms of cardiovascular disease (coronary, cerebro-vascular or peripheric arterial). Twelve months after the initial checkup, individuals were given another medical checkup and cardiovascular risk factors were compared. Twenty-four months after initial checkup, and with no interviews after the third STI (which is carried out eight months after the initial medical checkup), individuals are given another medical checkup, and the SCORE values and cardiovascular risk factors are compared.

10.3 Methods

Data collection and preparation

Between May 2004 and May 2007, all individuals attending *Ibermutuamur* who were found to have a moderate to high cardiovascular risk (as measured using the European Systematic Coronary Risk Evaluation or SCORE), were offered participation in the intervention. Out of the asymptomatic individuals, approximately 2,700 met the following inclusion criteria: moderate-high SCORE; at least two complete consecutive medical checkups carried out between 10 and 14 months of each other. Individuals were excluded if they: had a previous cardiovascular disease; received treatment for high blood pressure, hypercholesterolemia diabetes mellitus, or antiplatelet drug treatment.

The medical checkup included a medical record and physical examination, two blood pressure measurements, body mass index (BMI), and analyses of biochemical parameters (glucose, triglycerides, cholesterol, uric acid, creatinine, etc).

Using these data, we generated two 'high intervention' groups and two control groups. Thus the two 'high intervention' groups comprised all individuals who received the complete intervention of three structured telephone interviews (STIs) and who had a

moderate to high SCORE. One group comprised individuals with moderate to high SCORE, where the SCORE level was greater than 4. The second group comprised individuals with moderate to high SCORE, where the SCORE level was between 4 and 5.

As regards the control groups, we first created an *intervention control group,* which comprised all individuals with a moderate-to-high SCORE (SCORE above 4) and principally met the criteria for inclusion in the intervention groups. However, individuals included were those who could not be contacted for the STI because of incorrect contact information or lack of response to telephone calls that were made on at least three different occasions by the trained nurse. A second *non-intervention control group* was generated, which included patients who had a low SCORE value of less than 4, and therefore did not meet the principal criterion for inclusion in the intervention. However, we only included those individuals whose SCORE value was very close to that of the intervention group (between 3.5 and 3.99).

Analytical approach

We carried out three sets of analysis:

Comparing high intervention and non-intervention controls using regression discontinuity analyses and propensity score matching

The main characteristic of the regression discontinuity design is that the assignment to the intervention arm is carried out using a value (cut-off point) of a variable (or several) that is calculated before the implementation of a certain programme. In the case of two groups as considered here, the application of a cut-off point implies that all individuals on one side of the cut-off point are assigned to one arm (intervention) and all those on the other side are assigned to the other arm (control). As noted above, the continuous variable used in this analysis to assign individuals to the intervention or control group was the SCORE; those above the cut-off point of 4 (between 0.04 and 0.05) were assigned to the intervention group and those below 4 (between 0.035 and 0.0399) were assigned to the non-intervention control group.

We further applied propensity score matching using the nearest neighbour algorithm, based on logistic regression, to match individuals in the non-intervention control group to those in the intervention group. The variables used in the logistic regression model were: sex, age, occupation, smoking habits, total cholesterol, height, weight, creatinine levels, systolic and diastolic blood pressure. Some pairs could not be matched because some of these variables had missing values in some individuals (Figure 10.2).

Once the matching was carried out, the comparison between the two groups was done using unilateral contrasts. In the case of continuous variables, Student's t test was used if the variable was normally distributed, and non-parametric tests were used when the variable did not follow the normality hypothesis. For qualitative variables, the Chi-squared was used. A p-value of 0.05 was used as the limit for statistical significance.

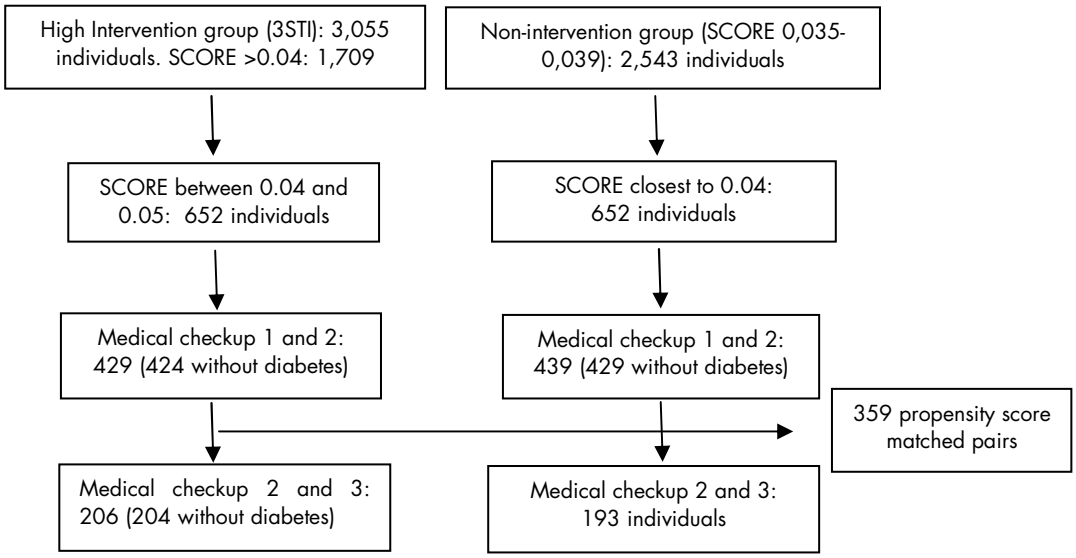

Figure 10.2 Flow chart: Comparing high intervention and non-intervention controls using regression discontinuity analyses and propensity score matching

Comparing high intervention with intervention controls using propensity score matching

This analysis set out to carry out propensity score matching to compare the high intervention group which included those who received three structured telephone interventions to the intervention control group, involving individuals eligible for receiving the intervention but were not contactable (Figure 10.3). We applied the same propensity score matching procedure and analytic technique as described in the preceding section.

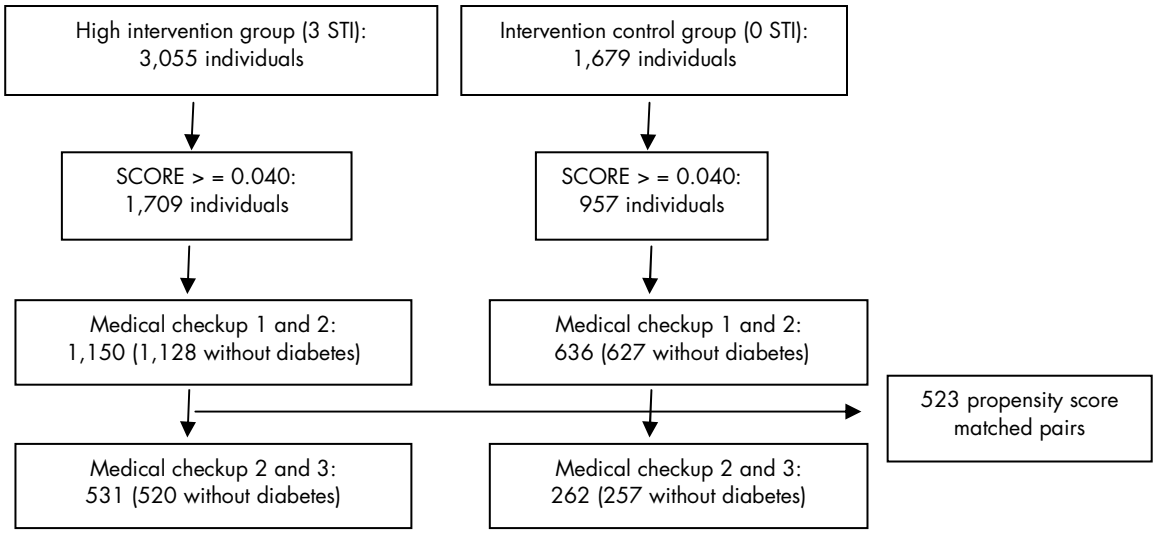

Figure 10.3 Flow chart: Comparing high intervention group to intervention control group using propensity score matching

Delivered dose analysis

A final set of analyses sought to evaluate the progression of independent cardiovascular risk factors, according to the intervention dose (n=0 structured telephone interventions vs. n=1 STI vs n=2 STI vs n=3 STI). Specifically we aimed to compare intervention effect in the intervention control group (moderate to high SCORE; number STI n=0) with the low intervention group (moderate to high SCORE; number STI n=1 or 2 (Figure 10.4). We applied the same propensity score matching procedure and analytic technique as described in the preceding section.

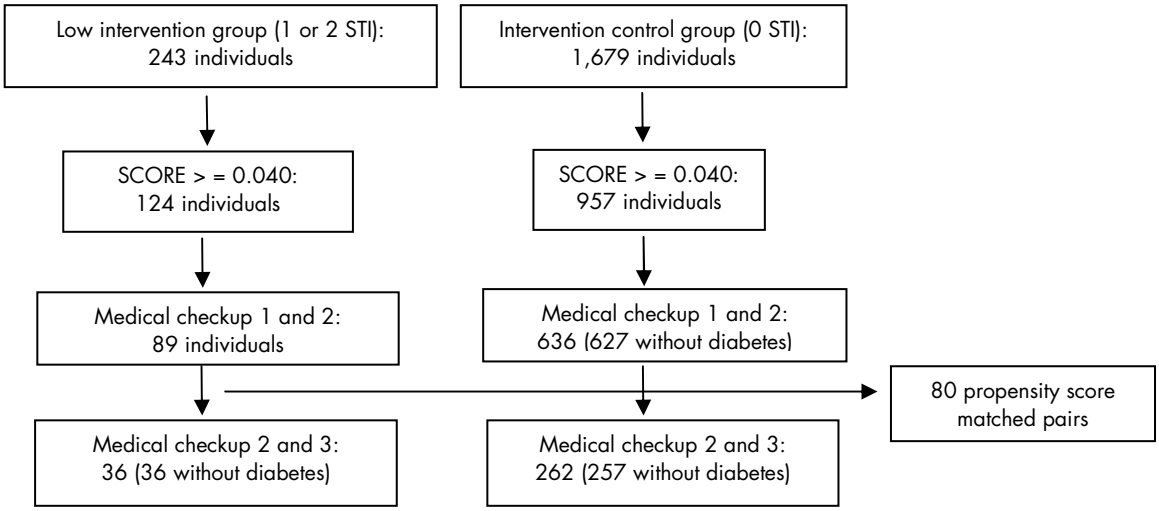

Figure 10.4 Flow chart: Delivered dose analysis

10.4 Findings

The general characteristics of the two intervention groups and the two control groups, before any propensity score matching was carried out, are shown in Figure 10.5. We found that groups were very similar with regard to their gender, with most individuals in the study (98.1 percent to 99.3 percent) being male. There was a slightly higher proportion of blue-collar workers in the low intervention group and in the two control groups that did not receive an intervention compared with those in the high intervention group. There were more smokers in the low intervention group (73 percent) as compared with the high intervention groups (both the subpopulation of individuals with SCORE between 4–5, 60.6 percent, as well as the overall population with SCORE above 4, 69.2 percent) and the two control groups (72.2 percent in the intervention control group and 63.6 percent in the non-intervention control group).

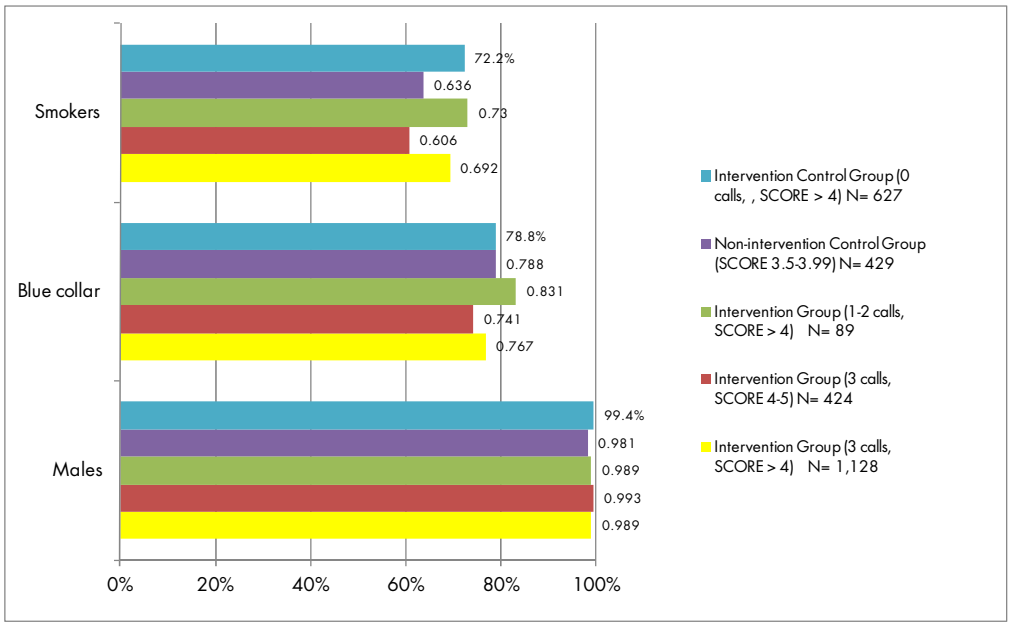

Figure 10.5 General characteristics of intervention and control groups

Figure 10.6 to Figure 10.11 illustrate the findings of the three sets of analysis, comparing high intervention and non-intervention control, high intervention and intervention control and low intervention and intervention control (delivered dose analysis) on major cardiovascular risk factors. We found levels of total cholesterol to be higher for individuals in the high intervention vs. intervention control and low intervention vs. intervention control, in particular in the first medical checkup (MCU) (Figure 10.6). This is because the relevant analyses did not impose restrictions on the SCORE value.

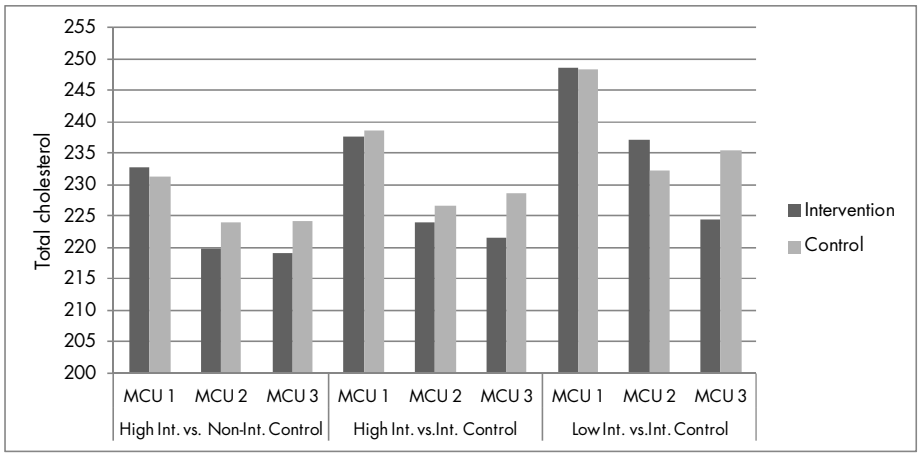

Figure 10.6 Total cholesterol among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

Importantly, in all three analyses, in the first medical checkup, total cholesterol values were very similar for the intervention and control groups as would be expected after having carried out the propensity score matching procedure. However, at the time of the third

medical checkup, total cholesterol levels had fallen everywhere, and tended to be lower in the intervention group compared with the control group.

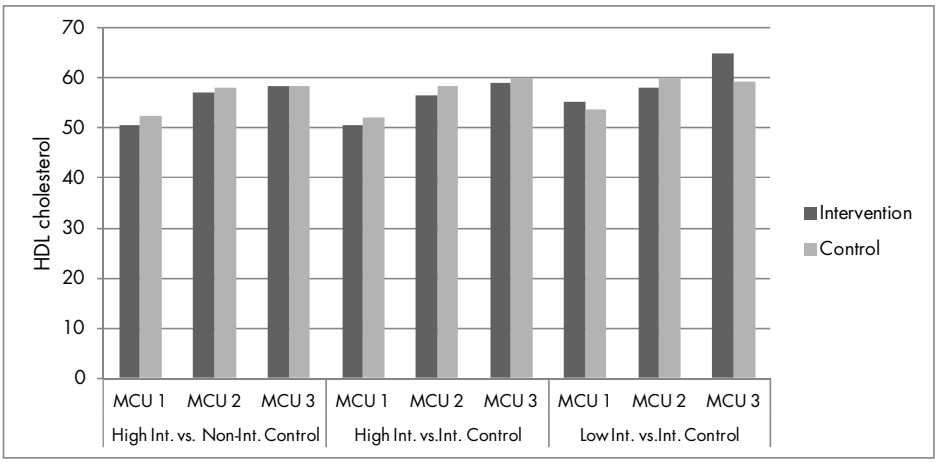

Figure 10.7 HDL cholesterol among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

Figure 10.7 illustrates findings for HDL cholesterol, demonstrating for all three analyses that there was a trend for levels to increase in the three successive medical checkups, both in the intervention arms and control arms.

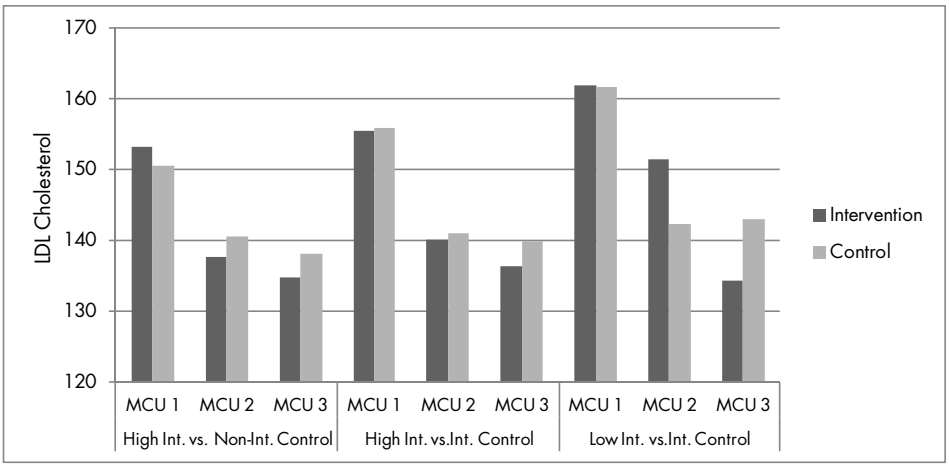

Figure 10.8 LDL cholesterol among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

In the case of LDL cholesterol (Figure 10.8), and similar to what we saw for total cholesterol, we observed levels to be higher for individuals in the high intervention vs. intervention control and low intervention vs. intervention control analyses (attributable to

lack of restrictions on the SCORE value). There was a decreasing trend in LDL cholesterol levels in each of the three medical checkups in the three analyses, with those in the intervention group tending to show lower values compared with the control group; the greatest differences were seen in the analysis comparing the low intervention group with the intervention control group, although only so upon the third medical checkup.

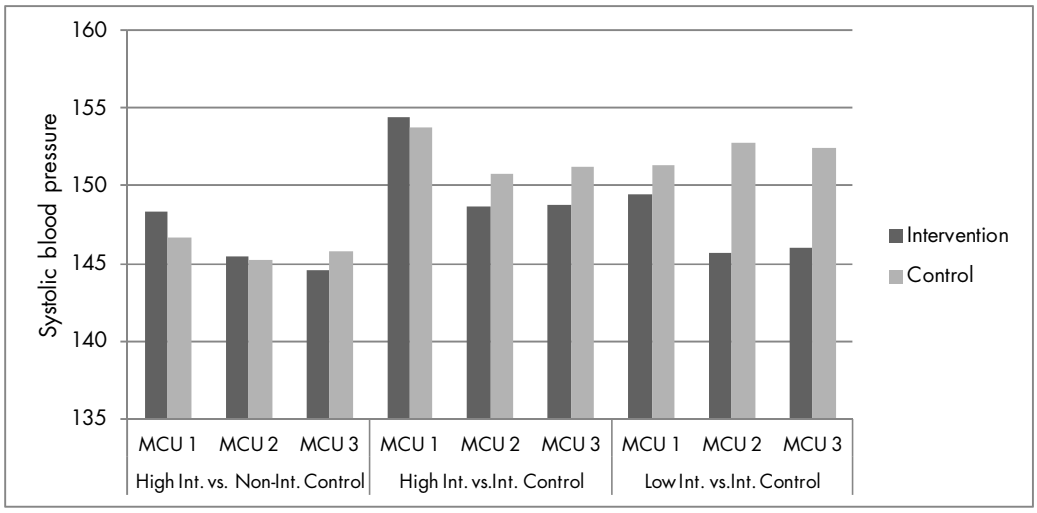

Figure 10.9 Systolic blood pressure among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

Similar to what was observed for LDL cholesterol, blood pressure was found to be higher among individuals in the high intervention vs. intervention control and low intervention vs. intervention control (Figure 10.9, Figure 10.10). Again, this was because we did not apply restrictions on the SCORE values in these groups.

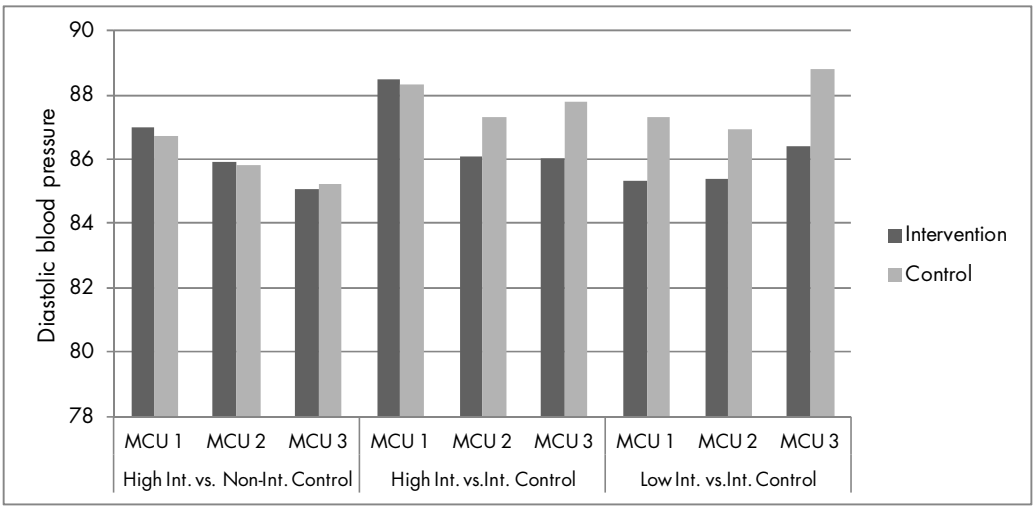

Figure 10.10 Diastolic blood pressure among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

Blood pressure levels tended to fall over the course of the three medical checkups among intervention groups in all three analyses, although findings for diastolic blood pressure were less consistent (Figure 10.10). For systolic blood pressure, the largest change was seen in the low intervention group compared with the intervention control.

Finally, we did not observe notable changes in body mass index for any intervention or control group, or across the three medical checkups (Figure 10.11).

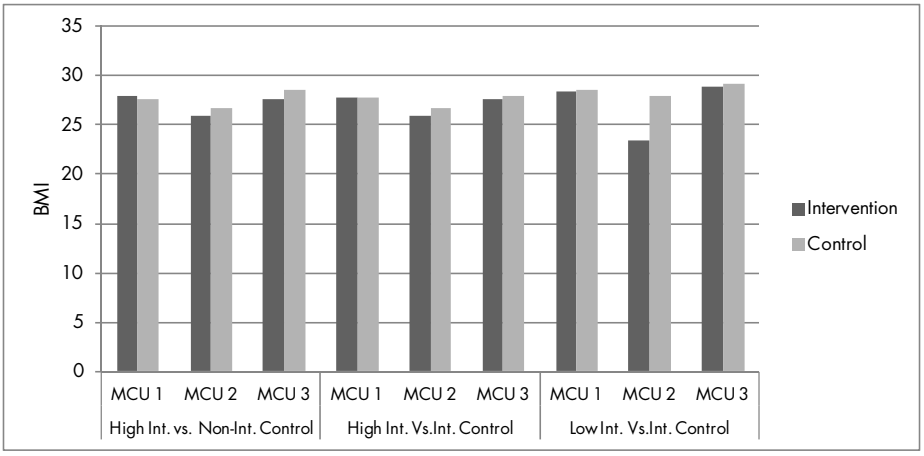

Figure 10.11 Body mass index among different intervention and control groups

NOTE. MCU – medical checkup; High Int – high intervention group; Non-Int Control – no intervention control; Int. Control – intervention control; Low Int – low intervention

Comparing high intervention and intervention controls

When examining specifically the high intervention group (STI n=3; SCORE >4) and the intervention control group (STI n=0; SCORE >4), we found for all clinical parameters except HDL cholesterol the percentage decline between the first and the third checkup to be greater in the intervention group. However, the size of the effect was smaller for total cholesterol and LDL cholesterol after propensity score matching (Table 10.1). For HDL cholesterol, there was an increase in the percentage change between the first and the third medical checkup; this effect strengthened after propensity score matching.

Table 10.1 High intervention (3 STI, SCORE >4) and Intervention control group (0 STI, SCORE >4)

	N Intervention Group A	N Control Group B	Mean differences MCU2-MCU1 Group A	Mean differences MCU2-MCU1 Group B	Confidence interval	p
Before propensity score matching						
Total cholesterol (mg/dl)	1128	625	-16.16	-13.22	[-6.33; 0.44]	0.088
HDL cholesterol (mg/dl)	1059	575	6.42	6.79	[-1.53; 0.77]	0.521
LDL cholesterol (mg/dl)	1038	582	-18.40	-16.23	[-5.27; 0.92]	0.169
BMI (kg/m2)	967	529	-1.95	-1.08	[-1.25; -0.50]	0
SBP (mmHg)	1126	623	-5.12	-3.93	[-3.003; 0.621]	0.197
DBP (mmHg)	1126	623	-2.23	-1.40	[-1.85; 0.20]	0.113
SCORE	1125	622	-0.0049	-0.0033	[-0.0046; 0.0012]	0.079*
After propensity score matching						
Total cholesterol (mg/dl)	523	522	-13.74	-12.08	[-5.85; 2.53]	0.436
HDL cholesterol (mg/dl)	502	482	5.84	6.25	[-1.80; 0.98]	0.560
LDL cholesterol (mg/dl)	491	490	-16.12	-14.68	[-5.10; 2.23]	0.441
BMI (kg/m2)	519	522	-1.82	-1.09	[-1.18; -0.30]	0.001
SBP (mmHg)	522	520	-5.61	-2.96	[-4.91; -0.38]	0.022
DBP (mmHg)	522	520	-2.40	-1.01	[-2.66; -0.11]	0.033
SCORE	522	519	-0.0055	-0.0012	[-0.0079; -0.0007]	0.009*

NOTE. MCU – medical checkup

Thus, following propensity score matching procedure increased the positive effect of the intervention with regards to HDL cholesterol, systolic and diastolic blood pressure and body mass index, compared to the control group while it reduced the effect of the intervention with regards to total cholesterol and LDL cholesterol. This suggests that the intervention had a 'true' effect in terms of improving HDL cholesterol level and lowering systolic and diastolic blood pressure and body mass index. Intervention effect with respect to total cholesterol and LDL cholesterol was less obvious. This may be explained by the fact that it is often easier to reduce a high blood pressure than a high cholesterol level and that the intervention was perhaps more effective on the first but not the second.

Comparing high intervention and non-intervention controls

When comparing the high intervention group with SCORE levels 4–5 and the non-intervention group with SCORE levels 3.5–3.99, we observe similar trends to those reported in the preceding paragraph. Thus, the percentage decline in LDL cholesterol between the first and third medical checkup in the intervention group became smaller after propensity score matching while an observed decline in total cholesterol in both intervention and control groups remained very similar following matching (Table 10.2). There was an increase in the percentage change between the first and the third medical checkup in HDL cholesterol in the intervention group; this effect became smaller following propensity score matching. Conversely, for diastolic and systolic blood pressure and body mass index, following matching, we found for the intervention group to show a greater reduction in percentage change between the first and the third medical checkup compared to the non-intervention control group.

Table 10.2 High intervention (3 STI, SCORE 4–5) and Non-intervention control group (0 STI, SCORE 0,035–0,039)

	N Intervention Group A	N Control Group B	Mean differences MCU2-MCU1 Group A	Mean differences MCU2-MCU1 Group B	Confidence Interval	p
Before propensity score matching						
Total cholesterol (mg/dl)	424	428	-14.24	-7.97	[-10.34; -2.19]	0.03
HDL cholesterol (mg/dl)	393	397	7.07	6.18	[-0.73; 2.52]	0.280
LDL cholesterol (mg/dl)	398	403	-17.22	-11.16	[-10.19; -1.93]	0.004
BMI (kg/m2)	364	388	-1.93	-0.89	[-1.64;-0.44]	0.01
SBP (mmHg)	424	428	-2.39	-1.35	[-3.33; 1.24]	0.37
BMI (kg/m2)	424	428	-1.04	-1.04	[-1.39; 1.38]	0.992
SCORE	424	427	0.0004	0.0029	[-0.0049; 0]	0.011*
After propensity score matching						
Total cholesterol (mg/dl)	359	358	-12.89	-7.30	[-9.98; -1.21]	0.13
HDL cholesterol (mg/dl)	340	333	6.45	5.68	[-0.98; 2.52]	0.390
LDL cholesterol (mg/dl)	340	340	-15.18	-10.24	[-4.93; 2.22]	0.026
BMI (kg/m2)	356	356	-1.93	-1.08	[-1.45;-0.25]	0.006
SBP (mmHg)	359	359	-2.92	-1.53	[-3.,81; 1.03]	0.261
BMI (kg/m2)	359	359	-1.06	-0.95	[-1.63;1.39]	0.879
SCORE	359	358	0.0000	0.0028	[-0.0053; -0.0002]	0.013*

NOTE. MCU – medical checkup

This second analysis suggests that the intervention had a greater positive effect on systolic and diastolic blood pressure and body mass index but not on total cholesterol, and only a small effect on LDL and HDL cholesterol levels. This may be explained by the observation that the initial values at baseline (at the first medical checkup) were lower in both intervention and control groups, because we applied a stricter definition on the SCORE

levels for inclusion (SCORE 4–5 in the intervention group and 3.5–3.99 in the non-intervention control group) so the potential for improvement is likely to be smaller.

Delivered dose analysis

Finally, when comparing the low intervention group that received one or two structured telephone interviews (STI) only (SCORE >4) with the intervention control group (STI n=0; SCORE >4), we find that, following propensity scoring, the intervention appears to have had a strong positive effect on the low intervention group compared with the intervention control group on all clinical parameters (total cholesterol, HDL cholesterol, LDL cholesterol, systolic blood pressure, diastolic blood pressure) except for body mass (Table 10.3). This analysis was, however, challenged by a very small sample size following matching, making it difficult to draw sound conclusions as to the effectiveness of the low intervention.

Table 10.3 Low intervention (1-2 STI, SCORE >4) and Intervention control group (0 STI, SCORE >4)

	N Intervention Group A	N Control Group B	Mean differences MCU2-MCU1 Group A	Mean differences MCU2-MCU1 Group B	Confidence Interval	p
Before propensity score matching						
Total cholesterol (mg/dl)	89	625	-9.71	-13.22	[-4.36; 11.38]	0.382
HDL cholesterol (mg/dl)	71	575	3.62	6.79	[-6.05; -0.31]	0.030
LDL cholesterol (mg/dl)	71	583	-11.,07	-16.23	[-2.06; 12.39]	0.161
BMI (kg/m2)	87	529	-4.90	-1.08	[-4.83; -2.82]	0
SBP (mmHg)	89	623	-4.08	-3.93	[-4.37; 4.08]	0.945
BMI (kg/m2)	89	623	0.39	-1.40	[-0.71; 4.29]	0.161
SCORE	89	622	-0.0014	-0.0033	[-0.0057; 0.0094]	0.832*
After propensity score matching						
Total cholesterol (mg/dl)	80	79	-9.35	-23.90	[-0.56; 28.54]	0.042
HDL cholesterol (mg/dl)	69	72	3.63	5.41	[-5.97; 2.41]	0.402
LDL cholesterol (mg/dl)	69	70	-11.36	-16.64	[-4.92; 15.48]	0.308
BMI (kg/m2)	80	80	-4.95	-1.16	[-5.10; -2.48]	0
SBP (mmHg)	80	80	-4.19	3.41	[-12.66; -2.55]	0.003
BMI (kg/m2)	80	80	-0.29	1.96	[-5.65; 1.14]	0.191
SCORE	80	79	-0.0022	-0.0001	[-0.0149; -0.0107]	0.133*

NOTE. MCU – medical checkup

10.5 Discussion

The analyses presented in this chapter used different approaches to generate intervention and control groups for the evaluation of a preventative intervention in Spain, using routinely collected data. We found that the sub-groups analysed were similar with respect

to their general characteristics (gender, smoking habits and type of work). As expected, the proportion of smokers (60.6 percent) in the intervention group with score between 4 and 5 was lower than in the non-intervention control group (score between 3.5 and 3.99), 63.6 percent, as smoking is a risk factor that intervenes in the SCORE calculation. In general, we found that the effect of the intervention, as measured by the percentage change in different clinical parameters considered in the first medical checkup compared to the third medical checkup, appeared to be greater after the propensity score matching was carried out. The aim of carrying out this matching procedure was to generate an intervention and control group as similar as possible with respect to all variables except for those individuals in the intervention arm receiving the intervention (that is to say Structured Telephone Interviews).

Assessing interventions in daily practice using real world data is increasingly considered a necessity. However, in observational studies, where there may not be a control group, or there is one that may be biased, the process of evaluating the real effects of an intervention becomes a methodological challenge. One of the first methods we used to try to overcome possible biases was the regression discontinuity technique but this procedure cut our sample size to one third of the original sample size (from 1,709 individuals to 652), so potentially reducing the power of analyses conducted. However, although the sample was reduced, this led to a more homogeneous group of individuals with regard to their cardiovascular risk characteristics; furthermore, the technique led to a reduction in sampling bias, in particular in the control group. However, we also selected only those individuals in the intervention group who had a moderate risk (SCORE between 4 and 5) and not a high risk (SCORE>5) and it may be possible that there is a greater effect of the intervention in the higher risk individuals than in the moderate risk individuals.

The next procedure we carried out in order to match our intervention group to our control group based on their cardiovascular risk factors as well as sex and occupation, was the propensity score matching technique (using the nearest neighbour algorithm). This procedure reduced our sample size by about 20 percent, although it provided an intervention and control group that initially shared some common characteristics (blood pressure, cholesterol level, etc) making it easier to assess the true effect of the intervention in the corresponding arm.

Therefore, the main lesson learned from the analyses presented here is that, in observational studies, in order to identify an adequately non-biased control group and gain internal validity we risk losing external validity. We consider it important to keep in mind that the research question being asked has to determine the appropriate research design, strategy and tactics to be used. Both randomised controlled and observational design can provide appropriate answers if questions are appropriately framed.

Based on the analyses presented here, we recommend that it will be important to keep in mind that evaluation has to be an integral part of the planning process that will eventually lead to the implementation of interventions in healthcare. If an evaluation is not designed from the beginning of an intervention it will be challenging to identify the true intervention effect where analyses have to be undertaken retrospectively. Using different statistical methods we can conclude, on the basis of analyses presented in this chapter, that the nurse-led intervention using telephone follow-up of individuals indentified at risk for

developing cardiovascular disease had a modest effect, a finding that was only observed after the matching methods used in the analyses.

CHAPTER 11 Summary and conclusions

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The report presents the overall findings of the work carried out within the DISMEVAL project. In this final chapter, we review the main lessons learned from the work undertaken and we also include a brief section discussing the insights gained in light of DISMEVAL's overarching aim to advance knowledge for evaluation approaches. The learning from these various work streams led to development of a set of recommendations for the evaluation of chronic disease management, which has been published as a separate report alongside this final report.[11]

11.1 Reviewing approaches to chronic disease management in Europe

Based on the collection of data on approaches to chronic disease management in 13 European systems and on methods and metrics used to evaluate these approaches using a structured survey instrument, we found that most countries have sought to create a regulatory and policy framework to respond to chronic disease during recent years. These generally aim to promote approaches that better integrate care and improve coordination between sectors and levels of care but countries differ with regard to their vision towards controlling and managing chronic disease. Likewise, approaches to chronic disease management vary in scope and nature across Europe. While our review did not attempt to present a comprehensive inventory of all approaches being implemented in a given country, some of the key observations were that:

- the majority of countries tend to focus on care models for populations with defined conditions, most frequently diabetes type 2, and involve some form of GP-led care coordination
- nurse-led approaches are becoming more common although there are differences in the degree to which nurses can operate independently
- patient access is typically granted in line with access to usual care although many approaches are being implemented in selected geographical regions so potentially limiting access to defined population groups
- the majority provide some form of patient self-management support, although the level and scope of support offered varies

- the overall the use of clinical information systems for chronic disease management tends to be the least developed strategy in most approaches.

Based on the survey data collected within DISMEVAL, we also examined whether and how chronic disease management models and programmes, or their equivalent that have been or are being implemented in European countries, are being evaluated. We find that while most initiatives reviewed had undergone some form of evaluation or had evaluation plans in place, the nature and scope of evaluations varied, with differences in objectives, design, the performance metrics used, the length of observation and approaches to data collection. We identified a range of challenges posed to the more systematic use of evaluation of complex healthcare interventions such as disease management in European health systems, such as a perceived lack of an evaluation culture in some settings, alongside lack of financial and human resources to conduct systematic evaluation. We note that evaluation of approaches to disease management reviewed would likely benefit analytically from increased use of sophisticated statistical techniques, but also conceptually from drawing more explicitly on one of the many possible theories of behaviour change to better link the choice of performance measures to the goals of the intervention (and of the evaluation). There may also be scope to more systematically draw in mixed-methods approaches to help place observed quantitative findings into the context within which the intervention under evaluation is embedded. More information is needed about the characteristics of the intervention and its intended populations, requiring greater specification of the wider context so as to improve comparisons and potential transferability across settings and countries in Europe.

In order to place survey findings reviewed in the preceding section into the wider context, we carried out interviews with key informants in a sample of countries that formed the core group of the DISMEVAL project (Austria, Denmark, France, Germany, the Netherlands and Spain). This provided an opportunity to learn how representatives from different sectors are approaching chronic care, and their perception of the policy framework for providing a strategic response to chronic disease. Some of the reported challenges included a continued focus of chronic care on complications management, with some movement towards more systematic disease management, and an overall lack of coordination between levels; failure to integrate risk minimisation and disease prevention with other components along the care spectrum; misalignment of financial incentives that tend to reward 'cure' over prevention; and a disjoint between intent, at national level, to enhance coordination and integration, and ability at regional or local level to translate these ambitions into practice. While some of these observations are perhaps not specific to chronic care as such, they emphasise the need for the development of a coherent response to chronic disease that takes account of the various tiers in the system and along the care continuum, with involvement of professionals, who exert a large degree of control in healthcare organisations such as primary care practices and hospitals. As we and others have argued elsewhere, failure to engage them in the reform process is likely to hamper sustainable change.[39,51,55]

11.2 Testing and validation of methods and metrics for the evaluation of chronic disease management

The testing and validation of methods and metrics for the evaluation of chronic disease management comprised studies carried out in six countries and using data from existing interventions. These were: disease management programmes for diabetes type 2 in Austria and Germany, 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 and for diabetes 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 study.

As interventions and the setting in which they were implemented varied, so did their approaches to testing and validation approaches to evaluation. Thus, country studies aimed to:

- quantify differences in effect sizes of structured care within a diabetes disease management programme using randomised and non-randomised controlled and non-experimental designs (Austria)
- test different approaches to identify treatment-control matches in non-experimental settings and quantify the likely impact on the effect estimate of an interdisciplinary and sectoral intervention for patients with chronic obstructive pulmonary disease or diabetes (Denmark)
- compare different methods to adjust for confounding in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme (Germany)
- test for selection bias for participating in a structured care programme for diabetes (Germany, France)
- employ advanced methods of disease management evaluation in non-experimental settings to better understand differential effects of structured care components on subpopulations (Netherlands, Spain).

Secondary goals of each analysis further included evaluating the effects of the intervention under study on patient outcomes more generally (all countries), alongside better understanding of the usefulness of current approaches to evaluation in the context of intervention practice (France, Netherlands) and to derive recommendations for further development of interventions and evaluation practice. We here provide an overvide of the main findings of country reports.

Evaluating the diabetes disease management programme in Austria using an uncontrolled design overestimates treatment effects

In Austria, the evaluation of the effect of the diabetes disease management programme 'Therapie Aktiv', using a randomised controlled design, found a reduction in HbA1c levels of 0.13 percent after one year. This effect was not statistically significant while measures of

process quality such as regular eye and foot examination and patient education improved significantly. In contrast, using an uncontrolled before-after design, treatment effect was estimated at a significant reduction in HbA1c levels of 0.41 percent in the intervention group. Extrapolating these findings to clinically relevant endpoints such as number needed to treat to avoid one case of myocardial infarction or one diabetes complication over a period of ten years, the uncontrolled before-after design overestimated treatment effect by a factor of three. This suggests that randomised controlled trial should be considered as the main means for evaluating treatment effect of a structured care intervention. The use of cluster randomisation provides a pragmatic approach to DMP evaluation, which is particular to settings where a randomised controlled trial is not feasible.

Different approaches to identify treatment-control matches in a non-experimental intersectoral intervention for patients with chronic obstructive pulmonary disease in Denmark provide different estimates of treatment effect

In Denmark, the evaluation of the effect of an interdisciplinary and intersectoral rehabilitation programme for patients with chronic obstructive pulmonary disease (COPD) found effect sizes to vary with the method of constructing control groups for the intervention-control and the difference-in-difference analysis. For example, propensity score matched sampling lowered the magnitude of the predicted intervention effect for COPD-specific hospital bed days when compared with controls created by random sampling. Likewise, control groups not matched by disease severity overestimated the effects of pulmonary rehabilitation on COPD-specific hospital contacts and bed days.

The study considered the method of control group construction and matching using propensity scoring and the use of difference-in-difference analyses to assess intervention effect to be optimal to evaluate the impact of interventions in non-experimental setting. As for the impact of the overall programme, the case study provided evidence that the intervention might have decreased the pace of disease progression in the intervention group, which was reflected in a non-significant increase in COPD hospital contacts, bed days, ambulatory visits and emergency room visits in the intervention group while these indicators significantly increased in the entire sample.

Different methods to adjust for baseline differences in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme in Germany result in similar effect measures

In Germany, the evaluation of intervention effect of a diabetes disease management programme (DMP) in a non-experimental setting found that different matching and/or weighting methods used resulted in similar effect measures for the outcome variables analysed. It highlighted how the applicability of available statistical methods and tools to perform a sound evaluation of programme effects is conditional on the availability of reliable baseline data prior to enrolment in the intervention, to enable adjustment of differences between intervention and control group. Therefore, a great effort should be made to collect detailed and valid data to maximise the usefulness of routine data for evaluation.

As for the impact of the overall programme, the case study confirmed the findings of other studies that participation in the diabetes DMP improved process parameters in diabetes

care especially those related to the monitoring of the disease. However, intensified care in the programme was accompanied by higher overall costs, primarily because of higher prescription costs. In order to draw valid conclusions about DMP effects on clinical endpoints such as mortality or micro- and macrovascular complications, a longer study period consistent with what is known about the time course of the disease should be chosen.

Patient selection for participating in a structured care programme for diabetes in Germany and France leads to over- and/or underestimation of findings of effect of the intervention

The evaluation of the diabetes disease management programme in Germany also observed a significant reduction of mortality in the intervention group. This effect was likely attributable to GPs systematically excluding patients from joining the programme who were more likely to die in the near future. Adjusting for baseline variables reduced this effect compared with the unadjusted analysis. Future analyses should include further adjustment for variables suited to predict short-term mortality risk. Furthermore, a longer observation period would be required to assess whether the mortality difference diminishes over the years.

Evidence of patient selection into the intervention was also observed in the case study for France, which examined patient characteristics of those enrolled with a diabetes provider network. These patients were found to be of younger age whose diabetes was diagnosed more recently but showed evidence of worse glycaemic control than patients in the reference population. By comparing a standard uncontrolled pre-post evaluation design with a pre-post design after calibration with the reference population at baseline, the analysis further showed that the uncontrolled evaluation design overestimated intervention effect on a number of clinical outcomes, including improvements in HbA1c levels and body mass index while underestimating deterioration in renal function in diabetic patients.

Advanced methods of disease management evaluation in non-experimental settings in the Netherlands and Spain help understand the differential effects of care components on subpopulations and so inform further development of structured care approaches

Given that most randomised controlled trials are conducted in academic settings and provide limited insight into the impact of disease management in the everyday practice of health care, in the Netherlands, the evaluation of integrally financed, regional disease management programmes for diabetes used a variety of approaches to better understand the effects of different programmes. It found that applying methods that permit for subgroup analyses provide important new insights into differential component effects. Thus, while the overall analysis of intervention effects found only modest impacts of the care programmes on the health status of patients with diabetes type 2, subgroup analyses revealed disease management to be considerably more effective for patients with poor baseline clinical values. As the vast majority of patients included in the analyses had good baseline values of most clinical endpoints, this differentiation provided a plausible explanation for the modest overall effects of the intervention. This suggests that further development of the intervention should move towards a more tailored approach to diabetes care, in which the characteristics of patients directly determine the processes of

diabetes care, including self-management support. Such a move will, however, require improvements in the current systems for data registration to provide valid and reliable information on patients' health status to determine care intensity.

Similarly, in assessing the effect of a nurse-led intervention targeting a working-age population at risk of cardiovascular disease in Spain, the use of advanced methodological approaches that permit for subgroup analysis in a non-experimental setting provided important new insights into the effects of the intervention.

Taken together, observations emerging from the six country reports suggest that in non-experimental settings, the creation of statistical controls or adjustment using propensity or matching methods was feasible using routine data sets. Application of such methods consistently provided different estimates, generally smaller, of intervention effectiveness. While the literature suggests that more aggressive methods such as boosted regression may provide a more suitable means for matching, results from studies presented here that compared alternative matching methods found results to be similar. Analyses presented here also provided insights into programme effectiveness without introducing an external control by examining variation across interventions such as in the Nethrelands, or by excluding patient populations close to the inclusion threshold (Spain).

11.3 Challenges and lessons learned

The DISMEVAL project set out to enhance our understanding of the use of various approaches to the evaluation of disease management in Europe, to identify examples of best practice and lessons learned and to provide evidence-based recommendations to policymakers, programme operators and researchers on evaluation approaches that may be most useful in a given context. As noted earlier, the learning from the various work streams has been published as a separate report alongside this final report.[11]

The work carried out within DISMEVAL set out on the premise that experimental research designs, particularly randomised controlled trials, are generally considered to be the most rigorous way of determining the effectiveness of a given intervention.[37] The Austrian case study in DISMEVAL has illustrated how it can be feasible to employ a randomised design in routine settings where the context allows for such a design to be applied (Chapter 5). However, use of an experimental design may not be possible (or desirable) for population-wide disease management interventions, which are frequently implemented in an operational setting and do not usually have a control group available, such as in Germany and the Netherlands. For example, in the Dutch case study use of an experimental approach was not possible due to the nation-wide roll-out of structured care approaches for diabetes and the unsuitability of using historic controls (Chapter 9). Furthermore, although randomised studies are generally considered to form the most rigorous means to assess intervention effect, the scientific rigour of required designs limits the generalisability of findings to larger and inherently more heterogeneous populations of, for example, chronically ill patients. Selection bias poses a threat to randomised designs as it does for non-randomised designs as we have highlighted (Chapter 5).

Observational study designs are more suitable for 'real-world' disease management evaluations, keeping their methodological limitations in mind. Given that disease

management is essentially a population-based care strategy, advancing observational study designs is crucial to come to strong conclusions on how to best target subgroups of chronically ill patients in the daily healthcare practice. The DISMEVAL project has identified and tested a wide range of methods that can be employed in situations where randomisation is not possible, emphasising that rigorous evaluation is still possible even where baseline or predefined control groups are not available. Project work further highlighted, through the introduction of statistical controls for selection or statistical matching, how findings were substantially different from simple comparisons of patients receiving a given disease management intervention and those who do not. Thus, the DISMEVAL project has shown how the use of randomisation or other methods of control is necessary to accurately assess the impact of such interventions. It also identified a range of methods that can be employed successfully to implement such controls.

Different (combinations of) care components and processes might be effective for managing chronic disease in patients with varying age, disease duration, health status, co-morbidity, education level, socio-economic status and so on. Contrary to most methods aimed at evaluating disease management interventions, which focus on assessing a single treatment effect, meta-analysis and meta-regression allow for investigations of which patient groups will benefit most from which treatment. Therefore future evaluation work drawing on such approaches can provide insight into what works for whom in the area of disease management, a question that randomised trials thus far have been unable to answer.[142] In addition, meta-regression analyses can be adjusted for baseline (prognostic) factors, which can increase the power of the analysis to detect a true treatment effect and allows adjustment for confounding factors, which is a particular advantage for analyses of observational data.

Overall, evidence presented here confirms the substantial heterogeneity across disease management interventions. This highlights how a given evaluation needs to be not only summative, but include formative components to understand how interventions and programmes can be improved. Such consideration is particularly important against the background that the implementation of disease management is essentially a process of social change, it is important to combine quantitative data on effects with qualitative information concerning contexts. Use of mixed methods can ensure that disease management evaluation provides insight into how specific local conditions influence the outcomes of a given programme.

Work undertaken within DISMEVAL on evaluation metrics and methods was limited to disease-specific programmes, mirroring much of the existing research evidence that has focused on the management of a few specific diseases, such as diabetes. Interventions studied here tended to target those with good baseline status on key measures. There appeared to be little improvement on key scores for these baseline patients, and measures based on average improvements in scores tend to average those patients among whom improvement is possible with those among whom further improvement should not be expected. There is a need for further serious consideration to the identification of appropriate measures of success for disease management interventions that takes account of these differential impacts. Importantly however, there has been less focus on individuals with coexisting conditions or multiple health problems[143,144], even though it is this rapidly increasing population, with multiple disease processes and with diverse and sometimes

contradictory needs, who pose the greatest challenge to health systems.[145] Furthermore, as we have shown, the impact of chronic disease management interventions will depend, to a considerable extent, on the specific features of the healthcare setting within which they are introduced, and this observation seems to hold both within and between care systems. However, this work has shown how it can be possible to learn from the experiences of others.

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APPENDICES

Appendix A: Template for data collection

DISMEVAL

Work package 2: Organisational approaches to chronic disease management in Europe

TEMPLATE FOR DATA COLLECTION

COUNTRY: _____

CONTACT PERSON/S _____

_____

_____

Objectives of the work package

1) To review organisational approaches to managing (chronic) conditions that have been developed and/or implemented by different countries in Europe since 2005.
2) To assess whether and how countries evaluate the approaches to (chronic) disease management.

Description of work

The work package seeks to extend earlier work by systematically collecting information on approaches to (chronic) disease management and evaluation strategies in a range of European countries so as to provide a systematic and comprehensive overview of approaches to (chronic) disease management in the European Union.

Partners will be required to collect data and information according to a common template, which is set out below. The template is divided into 3 broad areas:

i. The health system and policy context
ii. Type and format of approaches to managing chronic disease
iii. Approaches to evaluation

Definitions

Chronic diseases are defined as diseases 'which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by nonreversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care.' [146] This includes a range of health problems such as diabetes, coronary heart disease, depression, chronic obstructive pulmonary disease, progressive multiple sclerosis, chronic heart and renal failure as well as HIV/AIDS. In the framework of this research we also consider cancer, as in some settings approaches to chronic disease management may also target certain cancer sites such as breast cancer (for example breast cancer disease management programmes in Germany; cancer networks in France) and we would therefore encourage authors to also include these approaches, if deemed appropriate. Please note that we restrict the scope of this study to managing people with established disease as opposed to primary disease prevention and health promotion.

Sources

We ask partners to adopt an evidence-based approach by making use of the best data available, using all relevant sources. Suitable data sources include:

- completed/ongoing research projects related to chronic disease
- policy documents related to chronic disease
- routine statistics, surveys and census data related to chronic disease.

Data should be compiled in consultation with organisations involved in the management of chronic disease such as central government departments, health authorities (or their equivalent), arm's length bodies/subordinate agencies and academic and training organisations.

Where appropriate and necessary, additional information should be gathered through interviews with key stakeholders and reviews of work in progress such as pilot-projects, Green/White Papers, consultation documents, committee reports, parliamentary hearings, proposals, etc.

Additional information of relevance for selected countries may be obtained from the following sources:

- The European Observatory's Health System Profiles series: provide specific country information related to various aspects of health services. (http://www.euro.who.int/en/who-we-are/partners/observatory/publications/health-system-reviews-hits/full-list-of-hits)
- 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 (http://www.euro.who.int/__data/assets/pdf_file/0008/98414/E92058.pdf): provides further information on Denmark, England, France, Germany, the Netherlands, Sweden as well as Canada and Australia.
- Hofmarcher M, Oxley H, Rusticelli E. *Improved health system performance through better care coordination*. OECD Health Working Paper No. 30. Paris: OECD, 2007 (http://www.oecd.org/dataoecd/22/9/39791610.pdf): provides some further information on care coordination across OECD countries.

Instructions for completing the template

- Please follow the list of points/questions as closely as possible by inserting the requested information in the space provided. Use additional space where necessary.
- Please provide definitions where relevant.
- Please provide references for data sources used.
- Where data are not available and/or not reliable or where a particular point/question is not answerable, please describe where and why this is the case.
- **Please also note that each partner has been allocated a total of 3 person-months to compile the data according to this template** (covering work packages 2 and 3)**.**

DETAILED TEMPLATE FOR DATA COLLECTION

SECTION 1. THE HEALTH SYSTEM CONTEXT

This section aims to provide an overview of the overall policy context and the health sector within which chronic disease management is being addressed and delivered.

1.1 Please provide a succinct and brief description (<u>of no more than 800 words</u>) of how health care is provided in your country. Please consider:

(a) The administrative structure of the health care system (eg national health service, social health insurance, level of decentralisation [centralised – regionalised], etc)
(b) How the system is financed and managed
(c) Who determines the country's health policies and what are their drivers
(d) The interaction (if any) between primary and secondary care
(e) Reimbursement of individual service providers.

Descriptions will differ depending on the individual country's context. The two examples in Box 1 provide some guidance for a succinct country account.

1.2 Please provide a brief description of the major health care reforms that have been introduced/implemented since 2005 (or before, if considered seminal), as they relate to addressing chronic disease.

(Please add rows if necessary/applicable and tick one or more boxes as applicable)

#	Name/title of reform, year introduced	Focus of the reform as it relates to chronic disease	Further detail
(x)		**1** ☐ Prevention **2** ☐ Treatment **3** ☐ Management **4** ☐ Other:	

1.3 Please provide information on current legal, regulatory and policy frameworks specifically aimed at organising approaches to chronic disease management. Consider national, regional and local implementation (eg national or regional health plans; regional provider networks, etc) .
(Please add rows if necessary/applicable and tick one or more boxes as applicable)

#	**Name of framework or document *and* issuing authority** (ministry, government agency or authority, other)	**Status of framework or policy document**	**Level of implementation**	**Further detail:** Please provide a brief summary of the aims and scope of frameworks (use one example if there are several). If there are several such plans/frameworks, is there any attempt to coordinate those plans? Please explain.
(x)		1 ☐ Adopted (eg strategy or White Paper, regulation) 2 ☐ Proposed (eg Green Paper) 3 ☐ Topic discussed but no official policy proposed (eg parliamentary report) 4 ☐ Passed as law 5 ☐ Other	1 ☐ National 2 ☐ Regional 3 ☐ Local 4 ☐ Other	

Please provide a summary (of no more than 500 words) of the current 'vision', strategy and goals for controlling and managing chronic diseases (including markers of success) and the degree to which the focus is on management, treatment and/or prevention.
(*Please expand box if necessary*)

SECTION 2. ORGANISATIONAL APPROACHES TO CHRONIC DISEASE MANAGEMENT

This section aims to provide a detailed description of the services and models of care provided to patients with chronic diseases in your country.

Please consider the definitions listed in the 'Glossary of terms' below.

Care pathway/s (syn. clinical pathway; care map; integrated care pathway): Task-oriented care plan/s which specify essential steps in the care of patients with a specific clinical problem and which describe the patient's expected clinical course. 'Care plans offer a structured means of developing and implementing local protocols of care based on evidence-based clinical guidelines.' [147]

Case management: Intensive monitoring of a person with complex needs by a named case manager – usually a (specialist) nurse – through the development of care or treatment plans that are tailored to the needs of the individual patient who is at high risk socially, financially and medically. [148] Patients are assigned a case manager who oversees and is responsible for coordinating and implementing care for vulnerable people most at risk.

Chronic care model (CCM): Conceptual framework developed by Ed Wagner and colleagues [149]. This model presents a structure for organising health care to improve outcomes among patients with chronic illness. The four key components are (1) self-management support, (2) delivery system design, (3) decision support and (4) clinical information systems. [145]

Coordinated care (syn. care management): Involves the development and implementation of a therapeutic plan designed to integrate the efforts of medical and social service providers, often involving designated individuals to manage provider collaboration.

Disease management (programme) (DM(P)): Definitions of disease management (programmes) vary substantially. However, DM tend to share some common features: (a) an integrated approach to care/ coordination of care among providers, including physicians, hospitals, laboratories, and pharmacies; (b) patient education; and (c) monitoring/collection of patient outcomes data for the early detection of potential complications [148]. DM programmes do not normally involve general coordination of care. They also not normally include preventive services such as flu-shots.

Integrated care: Describes types of collaboration, partnerships or networks between providers of health and social care services that work together to meet the multidimensional needs of an individual patient/client or a category of persons with similar needs/problems. [150,151]

Managed discharge: Refers to arrangements for the transfer of an individual from hospital to an appropriate setting (primary care; community care) to ensure that any rehabilitation, recuperation and continuing health and social care needs are identified and met.

Multidisciplinary team(s)/care: An 'extension' of case management that also normally involves the development of treatment plans tailored to the medical, psychosocial and financial needs of patients. Its key feature is the utilisation of a broader range of medical and social support personnel (including physicians, nurses, pharmacists, dieticians, social workers and others) to facilitate transition from inpatient acute care to long-term, outpatient management of chronic illness [148].

Nurse-led clinic: A formalised and structured health care delivery arrangement in which a nurse with advanced competence to practise in a specific health care area (nurse practitioner, clinical nurse specialist, specialist nurse) acts as the first point of contact of care. The nurse manages patients either independently and/or interdependently with other members of a health care team in at least 80 percent of their work. The key interventions are nursing therapeutics, which encompass assessment and evaluation; health teaching/counselling, treatment and procedures, and case management. (NB. Nurse-led clinics are different from nurse-led care insofar as the former describe a formalised and structured delivery arrangement, whereas the latter also includes other arrangements, eg case-management, liaison nurses, discharge nurse etc). [152]

Provider network/s: refers to a group of providers bringing together different levels of care (eg health and social care or primary and secondary care).

2.1 **What *types of models/programmes/approaches/components* are being used to manage patients with chronic conditions?** If the relevant model/programme/approaches/components in your country do not fit any of these types described, please use the 'Other' category and provide a definition. Where models/programmes/approaches/components differ from those described in the Glossary above, or within your country or for a given disease, please use the extra space provided to describe accordingly the relevant model/programme/approach.
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

#	Name of model/programme/ approach/component	Type(s): The model/programme/ approach/component may refer to several types. Please indicate by ticking the appropriate boxes	Is the model/programme/ approach/component disease-specific? Please specify	Does the model/programme/ approach/component target certain groups? Please specify	Please provide reference or contact details
(x)		1 ☐ Care pathway/s 2 ☐ Case management 3 ☐ Chronic care model 4 ☐ Coordinated care 5 ☐ Disease management (programme) 6 ☐ Integrated care 7 ☐ Managed discharge 8 ☐ Multidisciplinary team/s 9 ☐ Nurse-led clinic 10 ☐ Other nurse-led care: 11 ☐ Provider network/s (please specify which providers are involved): 12 ☐ Other:	1 ☐ Diabetes ☐ type 1 ☐ type 2 2 ☐ Asthma/chronic obstructive pulmonary disease (COPD) 3 ☐ Cardiovascular disease ☐ Chronic heart failure (CHF) ☐ Ischaemic heart disease (IHD) ☐ Stroke ☐ Other 4 ☐ Breast cancer 5 ☐ Other cancer: ☐ 6 ☐ Generalist 7 ☐ Other	1 ☐ Children 2 ☐ Over-65s 3 ☐ 'High-intensity' users 4 ☐ Ethnic minorities 5 ☐ No specific target group 6 ☐ Other:	

2.2 **Please describe the actors who were the driving force behind developing and introducing models of care provided to patients with chronic diseases. Please refer back to each of the models/programmes/approaches/components listed under 2.1 above (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Key actors involved	**Please describe this process** (eg top-down vs. bottom-up approach; who took the initiative and brought the issue onto the agenda, etc)	**What was the scientific rationale for choosing this particular model/programme?** (eg choice was based on an analysis of level of activity required; adaptation of model in place elsewhere, etc)
(x) Name of model/programme/approach/component:		
1 ☐ Patient groups **2** ☐ Professional associations **3** ☐ Governmental agencies **4** ☐ Pharmaceutical companies **5** ☐ Funders (such as social health insurance funds) **6** ☐ Other		

2.3 **Please describe the key strategies used to manage chronic disease within each of the models/programmes/approaches/components described in (2.1); please consider the following four components and describe adopted elements under each [[153]](#)(with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Key strategies of models/programmes/approaches/components		Please describe
(x) Name of model/programme/approach/component:		
Self-management support	1 ☐ Patient education 2 ☐ Active involvement in developing care/treatment plan and goal setting 3 ☐ Regular assessment and documentation of self-management needs and activities 4 ☐ Provision of self-management tools 5 ☐ Routine assessment of problems and accomplishments 6 ☐ Other	
Delivery system design	1 ☐ Clearly defined roles of staff 2 ☐ Regular staff meetings 3 ☐ Use/development of integrated care-pathways 4 ☐ Individualised care plan 5 ☐ Medicines management for co-morbidities 6 ☐ Case finding 7 ☐ Follow-up (in person; telephone; email) 8 ☐ Case management 9 ☐ Other	
Decision support	1 ☐ Evidence-based guidelines 2 ☐ Provider education 3 ☐ Access to specialist expertise and experience 4 ☐ Other	

Key strategies of models/programmes/approaches/components		Please describe
Clinical information systems	1 ☐ Reminder systems on patient notes and monitoring systems 2 ☐ Disease registries 3 ☐ Monitor performance of practice team 4 ☐ Provider feedback 5 ☐ Electronic booking systems 6 ☐ Shared information system 7 ☐ Other	
Other	1 ☐ 2 ☐ 3 ☐ 4 ☐	

2.4 **Which *providers* are involved in the delivery of each of the models/programmes/approaches/components described in (2.1) (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Provider/s involved	Please describe
(x) Name of model/programme/approach/component:	
1 ☐ GPs/equivalent 2 ☐ Generalists 3 ☐ Specialists/consultants 4 ☐ Nurses 5 ☐ Allied health professionals 6 ☐ Pharmacists 7 ☐ Hospitals 8 ☐ Other	

2.5 **How are *patients* involved in the delivery of each of the models/programmes/approaches/components described in (2.1) (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Patients' level of involvement	Please describe
(x) Name of model/programme/approach/component:	
1 ☐ Patients are actively involved in developing a care/treatment plan, goal setting and decisionmaking	
2 ☐ Patient needs are regularly assessed and there is a follow-up system customised to patient needs (in person, telephone, email) (as opposed to unsystematic/hypothetical assessment and follow-up)	
3 ☐ Patient self-management support is limited to distribution of information material	
4 ☐ Patient self-management support, involves active patient support by appropriately trained staff	
5 ☐ Support mechanisms such as mentoring and peer support or group programmes form an integral part of routine care (as opposed to being available on referral only or not available at all)	
6 ☐ Self-management support mechanisms generally take account of patient characteristics such as age, sex, ethnicity, socio-economic aspects such as low income, etc	
7 ☐ Other	

2.6 **How is each of the models/programmes/approaches/components described in (2.1) *financed* (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Financing	Please describe
(x) Name of model/programme/approach/component:	
Source/s of funding 1 ☐ Funded from usual sources 2 ☐ Additional funding has been set aside 3 ☐ Other:	
Use of financial incentives 4 ☐ Yes, targeted at: ☐ physicians/providers ☐ patients ☐ funders, eg sickness funds ☐ other 5 ☐ No	
Source of financial incentives 6 ☐ Funded from usual sources 7 ☐ Additional funding has been set aside 8 ☐ Other:	
Incentives other than financial 9 ☐ Peer pressure 10 ☐ Networking 11 ☐ Access to guidelines, journals, etc 12 ☐ Other:	

2.7 **Please describe the *setting* in which each of the models/programmes/approaches/components described in (2.1) take place (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Setting of models/programmes/approaches/components				
(x) Name of model/programme/approach/component:				
1 ☐ Within GP practice (or equivalent)	2 ☐ Network of (GP-) practices	3 ☐ Community	4 ☐ Hospital	5 ☐ Other (please describe)

2.8 **Please describe the *quantity and distribution*, in terms of number and percentage of patients, of models/programmes/ approaches/components described in (2.1) (with appropriate reference to the number and name of the model/programme/ approach/component referred to in question 2.1) (for example, in the NHS/England, each primary care trust (PCT) had to introduce some sort of case management until 2008; in Germany, by June 2007 there were over 14,000 accredited disease management programmes (DMPs): ~ 1950 for type 1 diabetes; 3325 for type 2 diabetes; ~ 2850 for breast cancer; ~3000 for IHD).**
(Please add rows where necessary/applicable)

Quantity and distribution of models/programmes/approaches/components
(x) Name of model/programme/approach/component:

2.9 **What *percentage of GP practices* (or equivalent), in terms of number or % practices, have adopted some sort of disease management programme (or equivalent, as described in Section 2.1) (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable)

Percentage of GP practices (or equivalent) which have adopted some form of models/programmes/approaches/components
(x) Name of model/programme/approach/component:

2.10 **What *percentage of funders* is involved in/encouraging uptake/implementation of relevant models/programmes/approaches/components described in (2.1), if applicable (eg pilot projects by PCTs, sickness funds)? (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1)**
(Please add rows where necessary/applicable and use additional space if needed)

Percentage (%) of funders involved in/encouraging uptake/implementation of relevant models/programmes/approaches/components
(x) Name of model/programme/approach/component:

2.11 ***Population coverage*: what proportion of people (in terms of number and/or percentage) with chronic conditions is covered by/has access to models/programmes/approaches/components described in (2.1), if applicable (eg by July 2005, DMPs in Germany covered a total of 1.6 million patients)? (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1)** *(Please add rows where necessary/applicable and use additional space if needed)*

Population coverage of chronic care models/programmes or equivalent
(x) Name of model/programme/approach/component:

2.12 ***Equity/access*: what mechanisms (if any) are in place to ensure *equitable access* to the models/programmes/approaches/components described in (2.1), if applicable? Is this a matter of concern? (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1)**
(Please add rows if necessary/applicable and use additional space if needed)

Mechanisms in place to ensure equitable access to models/ programmes/approaches/components
(x) Name of model/programme/approach/component:

2.13 **Please illustrate a *'typical' patient journey* for each of the patients described below.**

(A) A 54-year-old woman with type 2 diabetes and chronic obstructive pulmonary disease who has a leg ulcer and moderate retinopathy. The patient is also slightly overweight (BMI of 27). She has been unemployed for three years and receives social assistance benefits; she lives on her own.

(B) A 76-year-old retired engineer with chronic heart failure, severe asthma and high blood pressure. He lives with his 73-year-old wife who cares for him, while herself suffering from arthritis. They live on the third floor in a housing block and are increasingly housebound due to their illness. They are determined to remain independent; their grandson, who is living nearby, does the daily shopping for them.

Please consider:

- How are patients with chronic diseases typically diagnosed (and by whom)?
- Access to specialist care
- Access to medication and self-management tools, etc

If possible/applicable, contrast this journey for 'usual care' with 'structured care/disease management/equivalent' (you may wish to illustrate this using a patient flow diagram).

SECTION 3. APPROACHES TO EVALUATION

3.1 **Please describe whether and how current models/programmes/approaches of/to care for patients with chronic diseases as described in (2.1) are evaluated (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).** *(Please add rows where necessary/applicable)*

Approaches to evaluation	Please describe
(x) Name of model/programme/approach/component:	
Aims and scope of the evaluation	
Who is carrying out the evaluation? *(eg external/internal; formal/informal)*	
Who is the evaluation for? *(eg providers, funders, government)*	
What is the frequency of the evaluation? *(eg annual, routine, ad-hoc, other)*	
What is the focus of the evaluation? *(eg structure, process, outcome, impact, other)*	
What is the budget allocated to evaluation?	
What is the timeframe of the evaluation?	
What is the scientific output of the evaluation?	

3.2 **Please describe the approaches that are being and/or will be used to evaluate and improve current models/programmes/approaches of/to care for patients with chronic diseases described in (2.1) (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1).**
(Please add rows where necessary/applicable and tick one or more boxes as applicable)

Approaches to evaluation	Please describe
(x) Name of model/programme/approach/component:	
Evaluation design 1 ☐ Observational	***Pleased consider:*** • *Statistical approach to controlling for selection: Is the control an average across all beneficiaries or selected sample of beneficiaries?*

Approaches to evaluation	Please describe
2 ☐ Non-experimental 3 ☐ Randomised controlled trial 4 ☐ Before-after study 5 ☐ Pre/post with control, with statistical controls for selection 6 ☐ Pre/post with control, without statistical controls for selection 7 ☐ Post-only with control, with statistical controls for selection; 8 ☐ Post-only with control, without statistical controls for selection 9 ☐ Pre/post without control 10 ☐ Qualitative evaluation methods 11 ☐ Other:	• *Post only: Any comparison made?* • *Benchmark for comparison? (Source)* • *Also, are there likely to be multiple trials/evaluations* • *Other details*
Indicators of programme effect 1 ☐ Cost 2 ☐ Utilisation 3 ☐ Structural measures: ☐ establishment of disease registry ☐ reminder systems ☐ other: 4 ☐ Process measures: ☐ referral rates ☐ regular monitoring ☐ clinical measures ☐ knowledge ☐ other:	
Source of data being used 1 ☐ Routine data 2 ☐ Newly collected data 3 ☐ Other:	

3.3 **How is success (or failure) of the models/programmes/approaches of/to care for patients with chronic diseases described in (2.1) defined (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1)?**
(Please add rows where necessary/applicable)

Definition of success or failure of models/programmes/approaches to care for patients with chronic disease
(x) Name of model/programme/approach/component:
Please consider whether success and/or failure is linked to incentives and/or penalties. What are these?

3.4 **What feedback mechanisms are in place to enable use of the evaluations of the models/programmes/approaches of/to care for patients with chronic diseases described in (2.1) to inform health policy (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1 above)?**
(Please add rows where necessary/applicable)

Feedback mechanisms to enable use of evaluations to inform health policy
(x) Name of model/programme/approach/component:

3.5 **To what degree is the evaluation of chronic care models/programmes/approaches an integral part of the overall performance assessment framework of the health care system?**
(Please use additional space if needed)

3.6 **Please describe existing and potential barriers to implementing appropriate policies on the evaluation of models/programmes/approaches to care for patients with chronic diseases.**
Examples may include:

- staff shortages
- lack of funding
- resistance from policymakers/health professionals/funders
- (lack of/limited) availability of valid and reliable data/information, etc.

(Please use additional space if needed)

SECTION 4. SYSTEM MARKERS OF SUCCESS OR FAILURE FOR ORGANISATIONAL APPROACHES OF CHRONIC DISEASE MANAGEMENT

4.1 **How has the introduction/implementation of models/programmes/approaches to care for patients with chronic diseases described in 2.1 impacted on the *overall performance of the health care system*? Please consider for each (with appropriate reference to the number and name of the model/programme/approach/component referred to in question 2.1 above) measures of *(i) efficiency, (ii) effectiveness, (iii) acceptability, (iv) accessibility and (v) equity*.**

Please describe
(x) Name of model/programme/approach/component:

4.2 **Please provide a reflection on the key features and critical success factors of chronic disease management in your country in the table provided. Please find below an example of how such an assessment might look.**

	Strengths	**Weaknesses**	**Opportunities**	**Threats**
Policy content				
Policy consistency				
Short- vs. long-term perspective				
Influence of electoral cycles				
Impact of institutional framework				
Impact of macro-economic conditions/constraints				

4.3 **What is the level of commitment towards continuous improvement of what is provided? Please consider the following components as proxy measures of level of commitment [154].**

(Please use additional space if needed)

Level of commitment towards continuous improvement of what is provided	**Please describe**
1 ☐ Investment in *human capital*	*eg development of a sustainable educational infrastructure enabling flexible alignment of training programmes with health service needs and work practices to produce the appropriate mix of people with the right mix of skills, et.*
2 ☐ Investment in *intellectual capital*	*eg frequency and/or institutionalisation of audit/evaluation; support and encouragement of innovation; development of supportive infrastructure enabling production of 'intelligence' through health information systems, analytical capacity, translation of research findings into practice, guideline development, etc*
3 ☐ Investment in *physical capital*	*eg strategic approaches to the efficient use of health technology to avoid/minimise duplication of services; systematic assessment of the implications of new technology for patient pathways and required reconfigurations of services resulting from this, etc*
4 ☐ Investment in *social capital*	*eg supporting and fostering the development of multidisciplinary teams; team-work; cooperation across sectors; improving working environments for healthcare staff through encouraging active participation in the implementation of change; etc*

Appendix B: Chronic disease management in Europe

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

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
Austria							
Ambulatory after-care of stroke patients, Salzburg	1989	To facilitate access to specialised ambulatory care for stroke patients and so enable timely rehabilitation and reduce hospital costs through early discharge	Stroke patients	Team of therapists ('neuro-rehabilitation' team)	Service principally accessible to all stroke patients across Land Salzburg; lack of therapists in remote areas reduces access	In 2009, the service covered ~ 450 patients who can access service upon referral only	Salzburg health fund (95%) plus 3% patient co-payment (deductible for home visit)
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	There are no published data on the number of patients covered by the programme	Regional SHI fund Styria; Graz model also supported by Styria health fund (2009)
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 (re-)admissions and complications and improve the quality of life	Chronic heart failure	Trained nurse	Programme comprises five trained nurses operating across Land Salzburg	Access to the service is through referral; there are no published data on the number of patients covered	Regional SHI fund and Land Salzburg at about 50% each
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 patients	GP	Implemented across Upper Austria and involving all hospitals that provide acute stroke care, medical emergency services and 3 rehabilitation centres	There are no published data on the number of stroke patients who have benefitted from the programme so far	Regional SHI fund Upper Austria and Upper Austria health fund (50% each)
'Therapie Aktiv' diabetes disease management programme	2006	To improve the quality of life and extend life for people with chronic disease, to place the patient at the centre of care and to make efficient use of healthcare resources and also reduce hospitalisations	Diabetes type 2	DMP physician (GP/family physician)	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 enrolled in DMP across Austria (~4.3 percent of all people with diabetes type 2)	Regional SHI fund and state at about 50% each; programme development funded by regional SHI funds

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
Denmark							
SIKS project - Integrated effort for people living with chronic disease	2005	To support people with chronic conditions (COPD, diabetes type 2, chronic heart failure, IHD, balance problems) through coordinated rehabilitation	Diabetes type 2, asthma/COPD, chronic heart failure, IHD, balance problems among elderly	Multidisciplinary team at healthcare centre / hospital (determined by severity of condition)	Initially implemented in Østerbro healthcare 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	During 2005–2007 about 80,000 patients were covered by the SIKS project; access is through referral following diagnosis (~90% of participating physicians refer patients on)	Combination of usual sources and government grant for 2005–2007 project period; full funding from usual sources from 2007
Regional disease management programmes	ongoing	A combined interdisciplinary, intersectoral and coordinated effort for a specific chronic condition that ensures the use of evidence-based recommendations, a precise description of tasks and coordination of and communication between all parties involved	Diabetes type 2, COPD (in preparation: CVD, dementia, musculoskeletal disorder)	DMP GP	Early stage; DMPs for COPD and diabetes type 2 implemented in Capital Region (end 2010); DMPs for other conditions and/or in other regions are planned or being developed	As programmes have only started very recently, the number of patients covered is limited to a small number in the Capital Region	Central government funding pool for the development of DMPs of DKK 438 million during 2009–2011
Integrated clinical pathways	2008 (cancer), 2010 (heart disease)	To ensure fast and optimal treatment and management of patients with cancer/heart disease	Heart disease, cancer	Care ('pathway') coordinator (specialist nurse)	As a national programme, integrated clinical pathways will be implemented across Denmark	It is anticipated that the integrated clinical pathways will cover ~40,000 CVD patients per year and all cancer patients	Funded from usual sources (taxation)
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 (eg diabetes, mental health, pain, learning difficulties)	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	EEP CIC states that ~80,000 people have taken part in EEP courses between 4/2007 and 12/2010	Funded from usual sources within the NHS by means of PCTs/SHAs purchasing the course for their population from EEP CIC
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	In principal, all NHS patients in England should have access to community matron services	Funded from usual sources within the NHS

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
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, and to prevent/delay the 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	Around 264,000 people were covered by services provided by projects	Services delivered by pilots funded from usual sources (health services: NHS, social services: local authorities)
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 scare resources	Generalist and disease-specific (eg 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	Population coverage of schemes varies; access to services limited to (target) populations in pilot sites	Services delivered by pilots funded from usual sources (health services: NHS, social services: local authorities)
Estonia							
Quality management in primary healthcare	2003 (completion of GP system)	Chronic disease management as a concept not established but indirectly embedded in the overall structure and organisation of the healthcare system	Diabetes type 2, cardiovascular disease (chronic heart failure, IHD)	GP	Quality management framework for diabetes and chronic CVD implemented across Estonia and covering all GP practices	Principally all persons with diabetes/chronic CVD are covered by virtue of statutory health insurance; access to care is free of charge	Funded from usual sources (Estonian Health Insurance Fund, EHIF); additional funding within quality management framework for diabetes/CVD care
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 healthcare system	Multiple sclerosis, Parkinson's disease, schizophrenia, COPD	Specialist (centre); co-morbidities managed by GP in coordination with specialist	Implemented across Estonia as part of usual care	Principally all persons with diagnosed disease covered by virtue of statutory health insurance; access to care is free of charge	Funded from usual sources; additional funding for Parkinson's association for patient education and support
France							
Health action by teams of self-employed health professionals (ASALEE)	2004–2007	To improve healthcare 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	The project covered around 1,500 patients	URCAM (regional statutory health insurance fund); usual sources
Sophia diabetes care programme	2008	To improve the coordination, efficiency and quality of diabetic care	Diabetes type I and 2	GP, 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	Experimental phase aimed at reaching 136,000 patients with diabetes; by end 2010, 62,000 had joined (~2.5% of all people with diabetes); 2010 expansion aims to	Funded from usual sources (statutory health insurance (CNAM))

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
					across France by 2013	reach 400,000 patients	
Health networks							
Diabetes networks: REVESDIAB	2001	To improve the quality of care for people with diabetes type 2	Diabetes type 2	Pathway coordinator: GP 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	REVESDIAB is based in the Paris region covering about 3,000 patients with diabetes; overall, in 2007, around 500,000 people with diabetes were enrolled in diabetes networks (~20% of people with diabetes in France)	FIQCS fund established by 2007 health reform
Coordination of professional care for the Elderly (COPA)	2006	To better integrate service provision between health and social care; to reduce inappropriate healthcare use, including ER and hospital utilisation; to prevent long-term nursing home institutionalisation	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	By end 2007, ~250 elderly people had been referred to COPA; it is being implemented in other parts of Paris and there is interest in other regions of France and Belgium also	FIQCS fund established by 2007 health reform
Measures in the 2003–2007 Cancer Plan							
Protocol for disease communi-cation 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 decisionmaking 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	By 2007, > 92,000 patients had been supported through a dedicated 'dispositif d'annonce' (~30% of all patients newly diagnosed with cancer); ~23,000 had received a personalised care programme (PPS) (~7% of patients)	Funded from regional budgets within MIGAC envelope (specific budget to finance activities of 'public utility') as part of usual care (hospital reimbursement) within SHI
Multi-disciplinary team meeting (RCP)	2004	To promote the systematic use of multidisciplinary team in the development of cancer care plan 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	By 2007, ~500,000 RCP had been recorded while the number of newly diagnosed cancer patients was 345,000 (partly reflecting repeat RCP for some patients pre-/post treatment); ~45% of cancer cases were recorded by RCPs	Funded from regional budgets within MIGAC envelope (specific budget to finance activities of 'public utility') as part of usual care (hospital reimbursement) within SHI

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
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	Not known	FIQCS fund established by 2007 health reform
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	GP	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	Not known	GPs and nurses funded from usual sources within SHI; networks funded through FIQCS established by 2007 health reform
Germany							
Disease management programmes	2003	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	Diabetes types 1 and 2, IHD (+ heart failure), breast cancer, asthma/COPD (obesity module in preparation)	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 diabetes type 2 (57% on IHD)	In November, 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 (70–85% of diagnosed diabetics in the SHI system)	Funded from usual sources (statutory health insurance (SHI))
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)	GP/family physician	By the end of 2007, 55 GP contracts had been concluded with GP participation varying among regions	Proportion of SHI insured people enrolled varies between 5.9 million (8.5% of all SHI insured) in 2007 to 19% in 2010	Principally from usual sources (SHI) but with contract arrangements permitting flexible GP payment different from usual care GP reimbursement
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	SHI insured do not have to register with an MVZ (or indeed any GP) so it is difficult to assess number covered by this model; Polikum provides services to ~ 100,000 patients	Funded from usual sources (SHI)
Integrated care: Healthy Kinzigtal	2005	To establish more efficient and organised healthcare 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)	By the end of 2008, ~4 million SHI members were enrolled with an integrated care contract (~6% of all SHI insured); Healthy Kinzigtal covers ~ 7,000 people (25% of all SHI members in the region)	Principally funded from usual sources (SHI) but with contract arrangements permitting flexible reimbursement; start-up funds (time-limited)

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
Community nurses: Care assistant in family practice (VerAH)	2005	To support GP services in under-served areas	Generalist (although typically targeting over 65s)	Practice assistant	Incorporated in selected GP models, see above	Incorporated in selected GP models, see above	Principally funded from usual sources (SHI) within GP contracts
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): GPs/groups of GPs, 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	Gradual expansion of the project covering 160,000 residents in the region of Veresegyház in 1999 to 2 million in 2005	Principally funded from usual sources (SHI); additional funding for administrative costs and prevention programmes (capitation for care coordinator)
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. By January 2010, there were around 850 trained asthma nurses across Hungary; the number of pulmonary dispensaries is around 160 (2007)	Precise data on population coverage is lacking; in theory the coverage should be 100%	Principally funded from usual sources with nurse training and payment as well as equipment (eg spirometer for patients) and printed materials funded by pharmaceutical companies
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 (eg GP 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	In principle, all diagnosed patients should be covered by treatment protocols; access is likely to vary across regions, reflecting inequalities in overall access to care	Funded from usual sources (SHI)
Gluco.net	2009	To provide a decision-support tool to guide patients in the monitoring and analysis of their blood sugar levels	Diabetes types 1 and 2	Internet-based self-management support tool	In principle, available to every patient with diabetes through the internet	Not known	Initially funded from service user subscriptions (annual fee of €35) but since 2010 available free of charge
Multifunctional community centres	Ongoing	To improve efficiency in the healthcare 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	Centres are not yet in operation; it is anticipated that 30–35% of small regions, and their residents, will be covered by the programme	Principally funded from usual sources; infrastructure investments from EU funds; additional funding from local government determined by services provided
Diabetes care management programme	Various	To improve the care of patients with diabetes type 2 through a range of measures,	Diabetes type 2	Diabetes specialist (physician, nurse)	Extent to which programme has been implemented by specialist diabetes outpatient	~ 20,000 patients with diabetes type 2 in Budapest are covered by ~40	Principally funded from usual sources with pharmaceutical and medical devices

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
		with nurse-led care at its core			units is not well understood; in 2008, there were 176 specialist diabetes units, including 41 in Budapest	specialist diabetes outpatient units; not all units provide all programme components	companies covering extra costs including payment to doctors and nurses, equipment & operational costs
Italy							
Leonardo Pilot Project, Puglia	2004–2007	To improve the quality and effectiveness of healthcare for those with chronic conditions and to facilitate systematic integration into the existing organisational framework set by local health agencies	Diabetes types 1 and 2, 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	Project covered just under 1,160 patients for a project duration of 18 months at the local health agency Asl di Lecce	Funded jointly by regional funds, MoH 'Special Programmes' fund, local health system & Pfizer Italy (contributing InformaCareTM software)
Integration, Management and Assistance for diabetes (IGEA)	2006	National strategy to support the implementation of disease management for diabetes type 2 at regional level	Diabetes type 2	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	Because of gradual implementation of the programme, patient enrolment is ongoing; there are no precise figures on the proportion of the population covered by IGEA	Funded from usual sources (SSN), complemented by national and regional funds earmarked for prevention
Project Raffaello, Marche and Abruzzi	2007	Research project 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	Diabetes types 1 and 2, cardiovascular risk	Specialist nurse	The research project involves 16 clusters of GPs participating in the experimental arm of the study	The research project is limited to a defined group of patients recruited for participation, a total of 900 patients in the regions of Marche and Abruzzi	Jointly funded by regional funds allocated to healthcare, additional funds by MoH 'Special Programmes' fund and co-financing by Pfizer Italy
From On-Demand to Proactive Primary Care, Tuscany	2009	A three-year strategy towards the development of a new organisational approach to healthcare that emphasises proactive patient care	Hypertension, diabetes, chronic heart failure, COPD, stroke	Multiprofessional teams ('module') (GP 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	~50 modules cover ~500,000 residents; initially targeting diabetes and heart failure; other conditions to be added; expected coverage with full implementation: 1.1 million with chronic disease in Tuscany	Funded from usual sources (SSN) with regional regulation stipulating allocation of resources to project implementation of EUR 8,883,000 over of three years

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
Latvia							
General primary healthcare system	1996/98 (PHC reform)	Not applicable	Generalist	GP	Chronic disease management embedded within primary care and as such involves all GPs; a 2010 evaluation of the PHC system found low levels of quality of chronic care as assess by regular examination of patients with diabetes type 2 (25% of all GPs) or asthma (5%)	Chronic disease management embedded within primary care and therefore covering virtually the entire population; severe financial pressures have however meant that ~45% of the population cannot access services because of required co-payments (2008)	Funded from usual sources (taxation)
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	GP/specialist (depending on condition)	Clinical guidelines should in principle be implemented across health services in Lithuania; precise data are not available	In principle, all diagnosed patients should be covered by care plans based on clinical guidelines	Funded from usual sources (statutory insurance)
Improving intersectoral collaboration	from 2004	To improve collaboration between health and social care	Generalist and disease-specific (diabetes, CVD, cancer, chronic renal failure, multiple sclerosis, depression, HIV/AIDS)	Nurse	Principally implemented in all 60 municipalities of Lithuania	Precise data on population coverage are lacking; access to case management varies by condition and likely across municipalities	Funded from usual sources (statutory insurance), social care funded by local government; plans to introduce more coordinated financing of multidisciplinary team activities
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	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)	Precise number of patients receiving care within stroke services not known; however, according to the Dutch Heart Foundation, the 69 stroke services present in the Netherlands since 2003 are distributed to a level that should sufficiently cover all stroke patients (around 191,000 in 2007)	Funded from usual sources: basic health insurance (GP and hospital services); AWBZ (eg rehabilitation centre; nursing home) and WMO (home care); shared care nurse is funded by all three schemes

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
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	Diabetes type 2	Core team of GP, specialist diabetes nurse and endocrinologist	In 2006, a total of 63 of 90 GPs (70%) in the Maastricht region participated in the Matador programme	In 2006, about 3,000 patients with diabetes in the Maastricht region were covered by the Matador programme	Usual sources for providers including GPs, specialists, dieticians and other health professionals; specialist diabetes nurses funded under previous Exceptional Medical Expenses Act
Primary care chain for diabetes type 2 / Heuvelland	2007	The primary care chain for diabetes type 2 describes the whole continuum of care for diabetes patients and is financed on the basis of the bundled payment system	Diabetes type 2	GP	All regional GPs are members of RHZ Heuvelland and as such participate in the 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	By the end of 2009, the programme covered some 7,600 patients with diabetes type 2 in the Maastricht/Heuvelland region	Funded from usual sources (mandatory insurance), principal contractor is the health insurer UVIT on the basis of a bundled payment contract
National care standard for vascular risk management	2010	Describes the minimum requirements for appropriate, patient-centred care along the care continuum from prevention and early detection to treatment and rehabilitation	Vascular risk	Central care giver (determined by programme)	Compared with diabetes, 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, whereas 17 were preparing to contract.	Precise number of patients receiving care within vascular risk management not known; limited to those receiving services through the two established programmes	Funded from usual sources (mandatory insurance) on the basis of a bundled payment contract
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	Precise number of persons being case-managed not documented	Funded from usual sources through the Andalucía government
Expert Patients Programme, Catalonia	2006	To promote patient self-management of their conditions; improve quality of life, knowledge, habits and lifestyle; involve patients in their care and increase satisfaction	Heart failure, anticoagulant 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)	Programme has been extended to other territories as well as Barcelona city, including Metropolitan South, Girona and Central Catalonia	Funded from usual sources through the Catalan Health Institute (the largest public health services provider in Catalonia, provides 75% of the Catalan population with primary care services)

Name	Year implemented	Aim/general description	Target population	Principal coordinator	Distribution	Uptake	Funding
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 development	Primary care physicians/GPs	In 2010, the Delta network comprised 160 primary care physicians (10–20% generalists, internists, GPs); in Vaud canton, the network includes 20 physicians	Accessible to any resident opting for the Delta network insurance scheme; in 2010, Delta covered about 60,000 insurees in the canton of Geneva (total population: around 450,000) and 2,000 insurees in Vaud canton	Financed within the Delta network insurance scheme principally following usual fee-for-service reimbursement but within a capitated scheme with re-insurance for expensive cases
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 healthcare stakeholders involved in diabetes care	Diabetes types 1 and 2	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	Diabaide was to cover 30% of the estimated population of with diabetes in Nyon-Morges region (~6,000). By 2009, 720 patients (12%) had been reached (~100–150 new patients/year)	Funded by the canton of Vaud (~50%) and from care activities charged to the patient and reimbursed by their health insurers (~50%)
Breast cancer clinical pathway, Lausanne University Hospital and Lausanne University	2008–2009	To improve the quality and efficiency of healthcare	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	Programme currently covers ~35% of new breast cancer patients in the canton of Vaud; aim is to treat 40% of new breast cancer patients, with a minimum of 150 patients to be included each year.	Financed by Lausanne University hospital

Table B.2 Components of chronic disease management used in 13 European countries

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Austria				
Ambulatory after-care of stroke patients, Salzburg	Team of therapists led by senior therapist and physician in each district acting as programme lead; regular team meetings and meetings of project leaders	Access to team of occupational therapists, speech therapists and physiotherapists in one-to-one and group settings; social activities; information through events	Continuing education and training of therapists; access for therapists to monthly group supervision meetings	Not specified
Care coordination / Interface management Styria	Care coordinator acts as key contact for patients, hospital and the patient's GP; regular meetings of the coordinator with providers outside hospital; case finding	Involvement of patients and their carers in planning of the discharge and subsequent care arrangements including information and practical assistance such as arrangement of devices and services	Checklist to identify patients requiring support by the care manager; use of the Blaylock Risk Assessment Screen (BRASS) index in Graz for case finding	Not specified
KardioMobil Home care for patients with chronic heart failure	Support of patients along defined protocol of three home visits by trained nurse; nurse also acts as key point of contact for patients and as care coordinator in collaboration with GP and specialist outpatient clinic	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	Continuing education for KardioMobil nurses on aspects of medication, quality assurance, communication with clinicians, IT, etc	Not yet integral part of the programme; plans to implement an electronic information system that allows for the sharing of patient data within the programme
Integrated stroke care Upper Austria	Development of integrated care pathways; regular ('peer group') meetings; defined roles for participating providers	Information (stroke awareness campaigns, brochures distributed in GP practices and hospitals, dedicated website, targeted lectures)	Practice guidelines (eg check list 'stroke' for GPs); development of integrated care pathways based on evidence-based guidelines	Common 'data warehouse' that compiles information on stroke patients collected by participating organisations; provider feedback to monitor and improve processes and outcomes
'Therapie Aktiv' disease management programme	Patient management through coordinating physician with conditions for referral between levels of care; regular follow-up of the patient (in person)	Education through group instruction; involvement in goal setting and timelines, with agreed targets signed jointly; regular follow-up	Care pathways developed by the Austrian Society of Diabetes (ÖDG); mandatory provider training programmes for DMP-physicians; annual advanced training sessions and quality circles	Standardised documentation of clinical and diagnostic measures and treatment; nationwide monitoring is planned but regular feedback reports to participating physicians have yet to be established
Denmark				
SIKS project Integrated effort for people living with chronic disease	Clear definition of roles and tasks of participating health professionals; multidisciplinary team supports the delivery of rehabilitation; regular patient follow-up; regular inter-organisational meetings	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	Evidence-based clinical guidelines developed by SIKS working groups; regular provider education and training	Monitoring of practice team performance; systematic collection of clinical and other data; use of municipal IT platform Sundhedsportalen; providers may operate their own database

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Regional disease management programmes (generic model as proposed by NBH)	Clearly defined roles of participating health professionals; development of individualised integrated care plans; GP is principal care coordinator with support by specialist and by case manager (usually specialist nurse) for complex patients; regular follow-up	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	Clinical guidelines developed by a working group and based on national and international clinical guidelines; provider training in relevant disciplines of chronic disease, including lifestyle interventions, self-management support and in education competencies and motivation techniques	Harmonised IT systems allow for data sharing and communication as well as consistent data collection; quality monitoring according to the Danish Quality Model (DDKM)
Integrated clinical pathways	Clear definition of responsibilities (diagnosis, treatment, rehabilitation); development of individualised care plans; designated care coordinator; regular follow-up with intervals depending on condition	Not specified	National clinical guidelines	Not specified
England				
Expert Patients programme	Not applicable	Education of patients by lay instructors aimed at strengthening competencies and skills to cope with chronic illness including development of care plans	Not applicable	EEP also available as online classes
Community matron	Clear definition of roles with specialist nurse as case manager, coordinating with GP, community and social care services; medicines management; case finding using standardised risk assessment	Education provided by specialist nurse; involvement in development of care plan and goals; regular assessment and documentation of needs and activities	Training of nurses within national competency frameworks and guidance	May include use of PARR tool to identify patients at risk of re-hospitalisation; availability of IT support/information sharing variable across PCTs
Partnerships for Older People Project (POPP)	Varied: community-based multi-agency teams; development of integrated care pathways; multidisciplinary health and social care teams; designated roles, including community matrons and case workers (social/'hybrid' workers); case finding; regular follow-up	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;	Varied: health and/or social care staff training; volunteer training; skill sharing and training; access to specialist expertise	Varied: integrated IT systems connecting primary and secondary care, or primary and social/community care; use of telehealth technology and case finding software; use of wireless technology for mobile units
Integrated care pilots	Varied: development of care pathways; managed discharge; case management, led by senior/specialist nurses; use of integrated community teams providing a single point of access for patients	Varied: patient education and provision of self-management tools by senior nurses; training in self-management of medicines	Varied: health and/or social care professional training, particularly regarding generic skills that enable more effective work on multidisciplinary teams or in a rapid-response capacity; access to specialist expertise	Varied: case finding software such as PARR; a few sites aim to establish a single integrated IT system for primary and community care, while others make use of telecare services and remote health monitoring

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Estonia				
Quality management in primary healthcare	Case finding; development of individualised care and treatment plans; routine follow-up	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	Evidence-based diagnosis, treatment and disease management guidelines; provider education as part of continuous professional development in primary and specialist care; quality management activities	GP practice information system according to mandatory guidelines including electronic medical records, booking and reminder systems; IT system linked to country-wide patient and treatment system of all healthcare providers (available online from 2009)
Chronic disease management at the primary/ secondary care interface	Case finding; development of individualised care and treatment plans; routine follow-up	Education (specialist); involvement in development of care plan; regular assessment and follow-up; mentoring/peer-support through patient associations (eg Multiple sclerosis, Parkinson's disease); support at home by nurse or social worker where necessary	Evidence-based diagnosis, treatment and disease management guidelines; provider education as part of continuous professional development in primary and specialist care	GP practice information system according to mandatory guidelines including electronic medical records, booking and reminder systems; IT system linked to country-wide patient and treatment system of all healthcare providers (available online from 2009)
France				
Health Action by Teams of Self-employed Health Professionals (ASALEE)	Clearly defined roles for staff with nurses responsible for screening for cognitive problems and cardiovascular risk factors in individuals >75	Education on disease provided by trained nurse	Not specified	Reminder systems on patient notes and monitoring systems
Sophia diabetes care programme	Clear definition of roles: regular individualised (need-based) phone intervention by trained nurse with GP remaining care coordinator; stratification of patients according to risk to determine frequency of intervention	Advice and information on self-management of disease and health behaviour; facilitating communication with health professionals; access to dedicated programme website	Evidence-based guidelines	Risk stratification software
Health networks				
Diabetes networks: REVESDIAB	Clear definition of roles of multidisciplinary healthcare team; development of individualised care plan by core team; discussion forum and quality circles; regular follow-up	Information and education (eg 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	Evidence-based guidelines and care protocols; provider training within continuous medical education	Shared information system involving a database collecting routine clinical indicators and used for evaluation and quality control; patient-held care folder to support monitoring; some systems operate reminder functions; GPs do not have routinely access to centralised patient information
Coordination of professional care for the Elderly (COPA)	Clearly defined roles with trained nurse as case manager; development of individualised care plan; occasional multidisciplinary team meetings (GP, geriatrician, carers); case finding	Involvement in developing treatment plan and goal setting	Provider training in geriatric assessment (InterRAI MDS-HC) to inform care plan and case finding	Database for evaluation and documentation; to be integrated in the clinical routine in future

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Measures of the 2003–2007 Cancer Plan				
Protocol for disease communication and promotion of shared decisionmaking (Dispositif d'annonce)	Roles of staff are clearly defined with support provided by nurse, psychologist or social worker; personalised follow-up	Access to dedicated time informing about the illness and support; involvement in decisionmaking; access to psychological and social support; regular assessment of patient needs; follow-up	National recommendations on patient communication developed by the HAS/INCA	Systems have been established to enable sharing of cancer patient records (Dossier communiquant en cancérologie, DCC); however, implementation has varied across regions
Multidisciplinary team meeting (RCP)	Development of individualised care plans (PPS); staff roles are clearly defined with 'médecin référent' preparing draft treatment plan for discussion with team; weekly team meetings for each cancer speciality and every two weeks to discuss individual cancer patients	As implemented within dipositif d'annonce	Regional guidelines/recommendations on cancer practice based on national recommendations issued by HAS/INCA	Systems have been established to enable sharing of cancer patient records (Dossier communiquant en cancérologie, DCC); however, implementation has varied across regions
Regional cancer networks	As implemented within RCP; in addition: regular (monthly, six-monthly) meetings of providers in form of workshops for each group of specialties of regional importance, eg variation in practice, regional guidelines	As implemented within dipositif d'annonce	As implemented within RCP	Systems have been established to enable sharing of cancer patient records (Dossier communiquant en cancérologie, DCC); however, implementation has varied across regions
Local cancer or local multipathology networks	Participation of GPs in multidisciplinary consultation; development of monitoring plan by GP covering episodes between hospitalisations, treatment at home and monitoring after-care	As implemented within dipositif d'annonce	As implemented within RCP with an element of provider education at local level (GPs, home care nurses) as means to implement regional guidelines; access to specialist expertise in hospital	Access of GPs to electronic patient records of participating patients
Germany				
Disease management programmes	Coordination of three care levels: according to specified conditions for referral between levels of care; regular patient follow-up	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	Evidence-based guidelines as developed by the German Institute for Evidence-based Medicine and Institute for Quality and Efficiency in Health Care; participating physicians have to meet defined training standards and may have to attend further training; further training and/or quality circles on a regular basis	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

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
GP contracts	GP acts as gatekeeper to specialist care; case management led by qualified nurse/practice assistants is encouraged	Annual checkups; advice on preventive measures and information; assessment of cardiovascular risk factors (‘*arriba*’) supports shared decisionmaking on treatment options	Treatment guidelines by association of family physicians; requirement to participate in (continuous) professional training, selected DMPs and in at least four quality circles per year; training in psychosomatic medicine and rehabilitation care	(Optional) use of electronic medical record (‘patient passport’); externally created feedback reports for physicians; requirement to implement a quality management system
Medical care centres	Teams of health professionals coordinate the care for patients, further supported by design of the centre; regular team meetings; involvement in integrated care contracts; acts as centre of a geriatric network	Education programmes (eg weight reduction, stress management, smoking cessation), and practical instruction (eg self-monitoring of insulin therapy)	Continuous professional education for physicians and nurses; in-house training centre offers variety of training events that are also accessible to physicians outside the centre; and a research programme into range of diseases/clinical areas	Shared electronic patient file accessible to all physicians involved in care; shared electronic booking system to help reduce patient waiting times
Integrated care / Healthy Kinzigtal	Clearly defined roles with identified care coordinators; integrated provider network and designated management organisation responsible for provider coordination; case finding	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	Treatment guidelines for > 15 diseases; providers and experts from the participating SHI funds collaborate in working groups develop guidelines and care pathways	Quality management system and electronic patient records; regular analysis of patient data using predictive modelling to identify high-cost risks
Community nurses: Care assistant in family practice (VerAH)	Delegation of tasks to practice assistants and performed under the supervision of the GP; usually forms part of GP contract	Access to trained case managers	Part of GP contract as described above	Part of GP contract as described above
Hungary				
Care coordination pilot	CCO responsible for care delivery to an enrolled population; regular meetings of providers; medicines management; case finding and follow-up; case management; systematic screening	Education by specialised nurses; involvement in developing treatment plan and goal setting; access to self-management tools; regular assessment of problems/accomplishments	Use of local care pathways and of evidence-based guidelines developed by CCO and discussed and with local providers	NIHFA database on healthcare utilisation to analyse provider performance and feedback; to create patient profiles to identify need
Asthma disease management programme	Asthma nurse is patient’s first point of contact, and case manager; regular staff meetings; responsibility of all care decisions remain with treating physician	Patient education on asthma; access to self-monitoring tools; involvement in treatment plan, goal-setting, decisionmaking; regular assessment of problems/accomplishments	Use of treatment plans based on evidence-based guidelines and training of providers, in particular asthma nurse	Use of a national registry of asthma patients maintained by National Institute of Pulmonology; nurses keep detailed records of each patient

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Treatment (and financing) protocols	Not applicable	Information material on cancer, hypertension and other CVD; self-management support by patient associations and by healthcare staff pre-discharge for hospitalised patients (cancer, CVD)	Use of treatment guidelines/protocols developed by professional associations on the basis of best available evidence with variation in quality of guidelines; provider education for some conditions, organised at national level and frequently supported by pharmaceutical companies	National disease registries are in place for cancer, asthma/COPD, cardiovascular disease
Gluco.net	Not applicable	Access to web-based software that permits automatic upload of self-monitoring data and feedback	Not applicable	Not applicable
Multifunctional community centres	Community centre integrates primary, specialist care and social care; development and use of integrated care pathways	Patient education may be provided	Not applicable	Implementation of integrated information system is a requirement
Diabetes care management programme	Clear definition of roles of healthcare staff; regular staff meetings to discuss problematic cases; regular follow-up of patients; use of discharge 'social nurses' who coordinate social support (cash and in kind)	Education provided by a diabetes nurse; access to self-monitoring devices (glucometer); regular follow-up to routinely assess problems and accomplishments, both in person and by telephone	Evidence-based treatment guidelines developed and regularly updated by the Hungarian Diabetes Association and the training of healthcare staff, in particular specialist diabetes nurses	Planned; strategies envisaged include reminder systems, electronic booking system and provider feedback
Italy				
Leonardo Pilot Project, Puglia	Care manager works with GP to deliver individual patient's care plan; staff roles are clearly defined; regular staff meetings; flow charts describe activities set out in the care plan; medicines management	Education based on the 'eight priorities' approach defined by Lorig; systematic assessment of patient needs (in person/ by telephone) and follow-up	Evidence-based principles of care management and scoring systems and training of staff (care managers in counselling and communication techniques; GPs in use of the programme software); specialist expertise is available where required	Software, InformaCareTM: reminders for providers; data collection for performance assessment; continuous monitoring of progress; information sharing. Electronic booking system in place
Integration, Management and Assistance for diabetes (IGEA)	Use of integrated care pathways; specialist nurse develops individualised care or treatment plans; team composition varies in accordance with individual patient's needs	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	Evidence-based guidelines for the management of diabetes type 2 and two-stage provider training: training-the-trainers stage at national and regional level and individual provider education with feedback for programme improvement	Registries of patients with diabetes enrolled in the programme although format varies by region; document 'The information system' sets out the principles for the development of information systems

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Project Raffaello, Marche and Abruzzi	Care manager works with GP to deliver individual patient's care plan; staff roles are clearly defined; use of case finding through measures of primary prevention	Participation in devising care plan and decisionmaking; 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	Provider education (training-the-trainers and individual provider training for GPs and care managers); access to specialist expertise and experience is mentioned but specialists do not play an active role in the team; pre-implementation simulation to assess impact of proposed care strategy on existing organisation	Software developed for care managers: regular reminders for GPs on scheduled tests and appointments; communication between patient and staff members; ensure adherence to evidence-based guidelines; evaluation of clinical outcomes
From On-Demand to Proactive Primary Care, Tuscany	Clinical pathways delivered by GP-led teams; periodic meetings with community health doctor at the local health agency (ASL); staff roles clearly defined including flow-charts; staff nurse for case management and counselling	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	Evidence-based guidelines to inform clinical pathways and comprehensive programme of peer education for all professionals involved and single groups of professionals on specific issues; access to specialist expertise; nurse training	Databases on enrolled patients to monitor performance of practice team in regular meetings; information sharing among team members through lead GPs electronic system; electronic booking system in place
Latvia				
General primary healthcare system	Plans to second nurses to work with GP in chronic care, education about self-management; health promotion and disease prevention and to develop home health care	Not specified	Quality criteria for general practitioners are defined by law, these include indicators on the periodic assessment of patients with conditions such as asthma or diabetes	Not specified
Lithuania				
Clinical guidelines	Development of individualised care plans common for diabetes and depression, required for cardiovascular disease	Routine assessment of clinical indicators	(Evidence-based) clinical guidelines; provider education in cases (eg depression) with support from private sector (pharmaceutical companies); access to specialist expertise	Electronic booking systems piloted; provider feedback on service delivery through database held by territorial patient fund ('SVEIDRA')
Improving intersectoral collaboration	Case finding by nurse; case management pilot (HIV/AIDS, some mental health problems)	Routine assessment of problems and accomplishments; access to psychosocial rehabilitation services in some cases (mental health)	Access to specialist expertise	Not documented
Netherlands				
Stroke Service Delft	Common elements: hospital stroke unit; specialist multidisciplinary team of caregivers; protocol-based care; agreements about patient referral; regular multidisciplinary staff meetings in the various settings; structured follow-up by specialist nurses of stroke patients following discharge to their home	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)	Shared care protocols and national multidisciplinary care for stroke guideline developed by over 70 professionals and representing 26 societies or institutions dealing with stroke patients; special staff training;	Electronic patient record 'Portavita Stroke Application': permits documentation and sharing of information; tracking and registering of medications; requesting, planning and registering of (complementary) examinations; workflow support

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Matador disease management programme	Stratification of patients into three levels of care intensity and clinicians (GP, diabetes specialist nurse, endocrinologist); staff roles clearly defined; specialist diabetes nurse liaison between hospital and primary care for all patients; regular core team meetings	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	Use of Matador-protocol; access to specialist expertise with endocrinologist supervising specialist diabetes nurse and acting as consultant to GP plus training	Not integrated; data on patient contacts and outcomes collected n GP and hospital information systems
Primary care chain for diabetes type 2 / Heuvelland	Stratification of patients into four regular modules plus two modules for (complex) problems; staff roles and responsibilities are defined; GP oversees referral to secondary care and ensures follow-up	Regular checkups that include education on self-management by practice nurses / specialised diabetes nurses, depending on the level of need	Nationally defined standards for diabetes care and multidisciplinary care protocol; referral criteria to other care providers clearly stipulated criteria; internist acts as consultant to specialised diabetes nurse on patients with (complex) problems	Disease-specific electronic patient record ('MediX') contains checkup and referrals data within care programme, allows for information sharing and automatisation of care protocols, can be linked to laboratory data and functional measurements
National care standard for vascular risk management	Defined staged process; staff roles and responsibilities clearly defined; central care giver is first point of contact and coordinator of care and is trained in vascular risk management skilled in supporting self-management and oversees referrals	Involvement in shared decisionmaking, development of care plan and goal setting; acquire self-management competencies through 'task-oriented communication'; motivational interviewing; and/or 'emotional-oriented communication'	Multidisciplinary care standard for vascular risk management; if necessary, experts can be consulted	IT systems are used to register, share and interpret patient data as part of vascular risk management, both at individual and group level
Spain				
Case management, Andalucía	Case managers are integrated into primary care teams; each team consists of family doctors, nurses, social workers and physiotherapists; development of a plan for healthcare assistance that identifies resources, with the case manager acting as liaison between the patient and the health service	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 by their patients	Not specified	Not specified
Expert Patients Programme, Catalonia	Multidisciplinary team (family doctor and a nurse or a social worker) select and train the EP, set up the patient groups, act as observers during the sessions or as leaders where necessary and include the information for the subsequent evaluation	Education of patients by lay instructors aimed at strengthening competencies and skills to cope with chronic illness including development of care plans	Not specified	Not specified

Name	Delivery system design	Self-management support	Decision support	Clinical information systems
Switzerland				
Physician network Delta, Geneva	Primary care physicians act as gatekeeper to specialist care; chronic disease management programmes for diabetes, heart failure and asthma under development	Regular information (two information letters per year), detailing provisions for access to health promotion and disease prevention consultations and activities; website	Organisation of regular quality circles for all physicians participating in the network	Not specified
Diabaide diabetes care network	Clear definition of staff roles and tasks; monthly team meetings and weekly coordination meetings; the development of care plans; scheduled patient follow-up including telephone contact at least once a year	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	Care protocols that are developed according to international and Swiss guidelines; specialist physicians are involved in the programme	Shared electronic medical record permitting (restricted) information sharing among health professionals ('customised' access); includes an electronic booking system
Breast cancer clinical pathway, Lausanne University Hospital and Lausanne University	Detailed description of clinical pathway; regular meetings with staff and project leads; and planned, predetermined and structured face-to-face consultations; regular assessments of pathway implementation	Written information; regular reassessment of the patient's situation; shared-decisionmaking; support by trained nurses and social workers; possible access to peer support groups	Adapted (inter)national guidelines; provider education of physicians and nurses involved in the programme; hospital specialists are entirely integrated in the programme; further support through written documentation detailing care pathway	Database and biobank; providers feed back on delays, number of new cases per month, volume of reoperation, or frequency of a given surgeon acting as main operator in relation to the total number of breast cancer operations

Appendix C: Assessment of existing approaches to evaluate disease management in Europe

Table C.1 Summary of study designs for evaluations of chronic disease management approaches in 12 European countries

Controlled design	RCT	Observational	Longitudinal cohort	Pre-post (before-and-after)	Post-only	ROI	Qualitative	Other**
Yes	'Therapie Aktiv' (A); Disease management programmes (D); Expert Patients Programme (ENG);Project Raffaello (I)	Prosper Net integrated care contracts (D)	Disease management programmes (D); GP contracts (D); Gesundes Kinzigtal integrated care contracts (D); National care standard for vascular risk† (NL)	'Therapie Aktiv', completed^ and planned (A); Evercare programme (ENG); From on-demand to proactive primary care** (I); Multifunctional community centres (H); Delta physician network (CH)	ASALEE (F); Care Coordination Pilot (H); Stroke Service Delft (NL)			
No ***with external comparison***				SIKS project** (DK); Capital region disease management programme (DK); Quality management in primary care – DM2, CVD (EE); CDM - MS (EE); Integrated Care Pilots* (ENG); DIABAIX^ (F)	REVESDIAB (F); COPA (F); multidisciplinary team RCP (F); disease management programmes (D); IGEA project (I)		Partnerships for Older People Project** (ENG)	
No ***without external comparison***		Prosper Net integrated care contracts (D); Community nurses – rural areas (D)	Disease management programmes (D); Gesundes Kinzigtal integrated care contracts (D); Primary care chain – DM2 (NL)	Treatment (and financing) protocols (H); Leonardo Pilot Project (I); Diabaide* (CH); Matador* programme (NL); Primary care chain for DM2 (NL)	Interface management Syria (A); Breast cancer clinical pathway (CH); Expert Patients Programme (ENG); REVESDIAB (F); DIABAIX (F); COPA (F); multidisciplinary team RCP (F); disease management programmes (D); GP contracts (D), medical	Gesundes Kinzigtal integrated care contracts (D)	Integrated care – stroke (A); CDM - MS (EE); Expert Patients Programme (ENG); organisation of access to supportive care (F); IGEA project (I); multidisciplinary	

Controlled design	RCT	Observational	Longitudinal cohort	Pre-post (before-and-after)	Post-only	ROI	Qualitative	Other**
					care centres (D)		team RCP (F)	
Use of comparator not specified		Kardiomobil (A)		Integrated care stroke Upper Austria (A)				CDM – COPD, PD, Schizophrenia (EE); Quality management in primary care – CVD, DM2 (EE); Care Coordination Pilot (H)

NOTE: †, design included cost/benefit as a key measure but design was not specified as ROI; ^, control group used in post-only comparison; *, design included cost modelling or cost-effectiveness analysis; **, designs included mixed methods. Abbreviations: A, Austria; CDM, chronic disease management at interface of primary and secondary care; CH, Switzerland; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; D, Germany; DK, Denmark; DM2, diabetes mellitus type 2; EE, Estonia; ENG, England; F, France; H, Hungary; I, Italy; MS, multiple sclerosis; NL, The Netherlands; PD, Parkinson's disease; RCT, randomised controlled trial; ROI, return on investment

Table C.2 Summary of indicators of programme effect used in documented evaluations in 12 countries in Europe

Measures of effect: structure	
Registry[a]	Development of a specific database or disease registry constituted a measure of the structure of a chronic disease management initiative (Breast cancer clinical pathway (CH); IGEA project (I); From on-demand to proactive primary care (I))
Reminder	Leonardo Pilot Project (I)
Other[b]	Integrated care – stroke (A); CDM – COPD, PD, Schizophrenia (EE); Quality management in primary care – DM2, CVD (EE); Expert Patients Programme (ENG); Partnerships for Older People (ENG); Integrated Care Pilots (ENG); REVESDIAB (F); COPA (F); Multi-functional community centres (H); IGEA project (I); Primary care chain for DM2 (NL); Stroke service Delft (NL)
Measures of effect: process	
Referral rates[c]	'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Diabaide (CH); Gesundes Kinzigtal integrated care contracts (D);GP contracts (D); Disease management programmes (D); SIKS project (DK); CDM – COPD, PD, Schizophrenia, MS (EE); Quality management in primary care – DM2, CVD (EE); COPA (F); DIABIX (F); Care Coordination Pilot (H); Multi-functional community centres (H); Leonardo Pilot Project (I); IGEA project (I); Primary care chain – DM2 (NL); Matador programme (NL)
Monitoring[d]	'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Diabaide (CH); Disease management programmes (D); CDM – COPD, MS, PD, Schizo-phrenia, (EE); Quality management in primary care (EE); REVESDIAB (F); COPA (F); IGEA project (I); From on-demand to proactive primary care (I); Leonardo Pilot Project (I); Primary care chain – DM2 (NL)
Clinical[e]	Integrated care – stroke (A); 'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Diabaide (CH); Gesundes Kinzigtal integrated care contracts (D); Disease management programmes (D); SIKS project (DK); CDM – COPD, MS, PD, schizophrenia (EE); Quality management in primary care – DM2, CVD (EE); ASALEE (F); DIABIAX (F); Care Coordination Pilot (H); Multi-functional community centres (H); Leonardo Pilot Project (I); Project Raffaello (I); From on-demand to proactive primary care (I); IGEA project (I); Matador programme (NL); Primary care chain – DM2 (NL); Stroke service Delft (NL); National care standard for vascular risk (NL)
Knowledge[f]	'Therapie Aktiv' (A); Interface management Syria (A); Gesundes Kinzigtal integrated care contracts (D); SIKS project (DK); Integrated Care Pilots (ENG); Primary care chain – DM2 (NL)
Other[g]	
Self-management	Gesundes Kinzigtal integrated care contracts (D); Expert Patients Programme (ENG); Leonardo Pilot Project (I); Primary care chain – DM2 (NL); Matador programme (NL)
Other	'Therapie Aktiv' (A); Integrated care upper Austria (A); Disease management programmes (D); Gesundes Kinzigtal integrated care contracts (D); Expert Patients Programme (ENG); Integrated Care Pilots (ENG); Treatment (and financing) protocols (H); IGEA project (I)
Measures of effect: outcome	
Health status[i]	Integrated care – stroke (A); Therapie Aktiv (A); Breast cancer clinical pathway (CH); CDM - MS (EE); Evercare (ENG); Multi-functional community centres (H); Treatment (and financing) protocols (H); IGEA project (I) Project Raffaello (I); Stroke service Delft (NL)
Satisfaction	'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Diabaide (CH); Community nurse – rural areas (D); Gesundes Kinzigtal and Prosper Net integrated care contracts (D); SIKS project (DK); CDM – MS, PD, Schizophrenia (EE); Quality management in primary care – DM2, CVD (EE); Expert Patients Programme (ENG); REVESDIAB (F); COPA (F); Project Raffaello (I); Leonardo Pilot Project (I); Primary care chain – DM2 (NL); Stroke service Delft (NL); National care standard for vascular risk (NL)
Quality of life	'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Disease management programmes (D); SIKS project (DK); Expert Patients Programme (ENG); Partnerships for Older People (ENG); Multi-functional community centres (H); National care standard for vascular risk (NL); Stroke service Delft (NL); Primary care chain – DM2 (NL); Matador programme (NL)

Cost[h]	Breast cancer clinical pathway (CH); Diabaide (CH); GP contracts (D); Gesundes Kinzigtal and Prosper Net integrated care contracts (D); Disease management programmes (D); SIKS project (DK); CDM - COPD, MS, PD, schizophrenia (EE); Quality management in primary care – DM2, CVD (EE); Expert Patients Programme (ENG); Partnerships for Older People (ENG); Integrated Care Pilots (ENG); ASALEE (F); REVESDIAB (F); COPA (F); Care Coordination Pilot (H); Treatment (and financing) protocols (H); Project Raffaello (I); Matador programme (NL); Primary care chain – DM2 (NL); Stroke service Delft (NL); National care standard for vascular risk (NL)
Utilisation[i]	'Therapie Aktiv' (A); Breast cancer clinical pathway (CH); Diabaide (CH); GP contracts (D); Disease management programmes (D); Gesundes Kinzigtal integrated care contracts (D); CDM – PD, COPD, MS, schizophrenia(EE); Quality management in primary care – DM2, CVD (EE); Evercare (ENG); Expert Patients Programme (ENG); Partnerships for Older People (ENG); Integrated Care Pilots (ENG); REVESDIAB (F); COPA (F); Care Coordination Pilot (H); Multi-functional community centres (H); Treatment (and financing) protocols (H); Project Raffaello (I); IGEA project (I); Matador programme (NL); Primary care chain – DM2 (NL); Stroke service Delft (NL); National care standard for vascular risk (NL)

NOTES:

[a] Development of a specific database or disease registry constituted a measure of the structure of a chronic disease management initiative.

[b] Specified in a variety of ways.

[c] Specified as: referrals; frequency of recommending (the initiative) to patients; number of new patients in the programme (ie recruitment); referral to ocular fundus examination and performance of laboratory tests (eg cholesterol); fist set of laboratory tests for 70% of all patients; frequency of physician contacts; average time of transfer (ie number of days from date of draft personalised health plan in current year per number of enrolled and benefited from the draft personalised health plan); number of patients screened who enrol in the intervention; number of GPs visited per member; number of specialists visited per member and percentage of these with referral.

[d] Specified as: number and type of consultations; waiting times for treatment, consultation, surgery, diagnostic procedures; number of patients receiving at least one action to prevent complications and/or therapeutic education; number of patients whose case was presented in a multi-professional coordination meeting at least once a semester (every 6 months) per total of patients; consultation rate; percentage of members with checkups.

[e] Specified as: metabolic control (decrease of Hb1Ac by more than 0.5 percent); Hb1Ac level; blood pressure (systolic and/or diastolic); total cholesterol; high-density lipoprotein; body mass index (BMI); glomerular filtration rate; morbidity rate; triglycerides; volume of performed thrombolysis; prescription frequency of disease-specific medication (eg anti-hypertensives, lipid-lowering agents, anti-diabetic drugs). The documented evaluations in Italy reported specific threshold levels for each of the disease-specific clinical measures in the set of indicators proposed by the National Centre for Disease Prevention and Control national guidelines.

[f] Process measures of knowledge were reported as either patient disease-specific knowledge, or level of provider knowledge/ awareness of the intervention.

[g] Specific 'other' process measures varied widely in this open response category, but tended to include self-care/ self-management or behaviour change (eg smoking habits, healthier nutrition, physical activity increase, participation in social activities) effects. Additional examples of 'other' process measures included: transport time, reach, adverse events, drop-out rates, productivity loss, provider motivation, and provider estimates of demand/popularity among patients.

[h] Cost effects were rarely specified but some indicators were described as: total expenditures; expenditure per patient (or cost per insured member); operating costs; average cost per patient; revenues; sick days per member and prescription costs per member. The economic perspective (eg societal) was also specified for some examples. In Denmark, measures of 'resource use' (eg productivity loss/time out of work and inpatient care, specialist consultation, prescription drugs) were reported as process measures rather than indicators of programme effect.

[i] Utilisation effects were specified as: amount of hospital days; hospital admissions; total number of hospitalisations per number of patients in a network; number of patients hospitalised more than once in the current year per number of patients of a provider network.

[i] Some respondents described measures referring to overall health status as a possible indicator of programme effect and these were reported as quality-adjusted life years (QALY), (inpatient) mortality, and/or survival (outside hospital).

ABBREVIATIONS: A, Austria; CDM, chronic disease management between primary and secondary care; CH, Switzerland; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; D, Germany; DK, Denmark; DM2, diabetes mellitus type 2; EE, Estonia; ENG, England; F, France; H, Hungary; I, Italy; MS, multiple sclerosis; NL, the Netherlands; PD, Parkinson's Disease

Appendix D: Interview topic guide

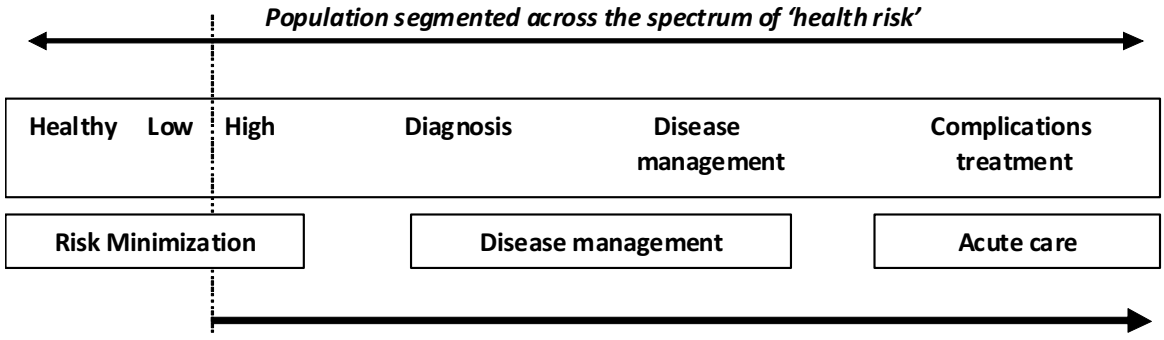
DEVELOPING AND VALIDATING DISEASE MANAGEMENT EVALUATION METHODS FOR EUROPEAN HEALTH CARE SYSTEMS

SEVENTH FRAMEWORK PROGRAMME

1. Consider the following Figure, which presents a range of activities, from minimising the probability that those with risk factors will develop established chronic disease, to the management of highly complex cases:

   - Looking at the Figure below, where would you see the major approaches that your country has taken to controlling chronic disease?

   - Which area/s is/are less developed and why?



2. Please talk us through an example of your choice of what you would consider a successful approach to chronic disease management in your country.

3. Please talk us through an example of your choice of what you would consider a less successful approach to chronic disease management in your country.

4. What do you think needs to happen in your country to appropriately address chronic disease?

5. What do you perceive to be the main challenges or barriers to this happening?

6. Is there anything other information you would like to add?

7. Can you suggest any key documents we should consult?

8. Who else do you think we should talk to who would provide important additional insight into this topic?