



CHAPTER 1

General introduction

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Type 2 diabetes (T2DM) is a highly prevalent disease with a high burden on patients, health care and society. Therefore, ways to optimize diabetes care for patients, to manage the increasing demand on the health care system and control health care costs, should be explored. The main focus of this thesis is the evaluation of costs and cost-effectiveness of managed diabetes care in primary care.

Burden of type 2 diabetes

Due to aging, an unhealthy lifestyle and improved care for chronic diseases, the worldwide prevalence of type 2 diabetes is estimated to increase from 366 million in 2011 to 552 million by the year 2030.¹ In the Netherlands approximately 740,000 people were suffering from T2DM in 2007. In 2025 this number is expected to increase to 1,3 million.^{2,3} The growing epidemic of type 2 diabetes has major implications for patients and for society. Persons with type 2 diabetes are at increased risk for micro- and macrovascular diseases compared to persons without type 2 diabetes,^{4,9} associated with a decreased health-related quality of life and mortality. The increasing prevalence of diabetes and diabetes-related complications leads to an increased use of health care and health care costs.¹⁰ In 2007 The Netherlands spent 1,0 billion euro on diabetes care,¹¹ which is 1,4% of total costs of health care in the Netherlands. Taking into account all costs related to diabetes complications and productivity losses, costs of diabetes might exceed 8,0 billion euro.¹²

Diabetes care

Patients with type 2 diabetes should receive diabetes care from their General Practitioner (GP) according to the Dutch GP guidelines for type 2 diabetes.¹³ These guidelines specify that patients should visit their GP four times a year for a diabetes assessment, in which traditional risk factors should be measured and screening of diabetes-related complications should be performed. Once a year, an extended diabetes assessment should be performed. In usual diabetes care patients' own GP is responsible for the diabetes care conform a traditional diagnosis-recipe model, in which the GP is in charge of the procedure of the diabetes assessments and patients' care plan.

Multiple deficiencies exist in the current management of chronic care, including a lack of care coordination, limited follow-up of patients over time, inadequate training in self-management skills and insufficient adherence to evidence-based guidelines by care providers. As a result, there are discrepancies between care as recommended and care as received by patients.^{14, 15} During recent years there has been a strong focus on improvement of diabetes care, resulting in the implementation of disease management programs for diabetes by care groups. To enable high quality diabetes care, the Dutch Diabetes Federation (NDF) developed the 'NDF Care Standard Diabetes Type 2' which

R1 describes the basics for good quality of diabetes care and guidelines for the treatment of
R2 diabetes patients. A recent study among health care professionals involved in the diabetes
R3 care showed that only 38% of the professionals had the NDF Care Standard available.¹⁶
R4 Furthermore, health care professionals reported deficits in the collaboration between
R5 different care professionals, unclear roles of health care professional in multidisciplinary
R6 teams and registration and exchange of patient outcomes. For example, a recent study
R7 showed that the registration of HbA1c, the most frequently used indicator for the quality
R8 of diabetes care, was missing in 24% of all diabetes patients.¹⁷

R9 It is widely recognized that there is a need for innovations to improve the quality of
R10 care to prevent micro- and macrovascular complications in patients with type 2 diabetes
R11 and to control the increasing demand for health care and growth of health care costs.¹⁸
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R13 **Innovations to improve primary care for type 2 diabetes patients**

R14 There is growing awareness that tackling the growing societal and economic burden
R15 of diabetes requires a transformation of health care, from a system that reacts to acute
R16 episodes of illness to one that pro-actively maintains health.¹⁹⁻²¹

R17 Furthermore, instead of the traditional diagnosis-recipe model, the introduction of
R18 personalized care should lead to further improvement of the diabetes care. Both the GP
R19 and the patient should be actively involved in the development of a personalized care
R20 plan. The patient him- or herself should have an important role in decision making and
R21 should agree with goals and outcomes regarding the care.

R22 In recent years, targeted programs have become important means for improving
R23 the quality of diabetes care and overcoming existing deficiencies.^{15, 22} A wide array
R24 of approaches exist such as the Chronic Care Model (CCM)^{23, 24} and managed care.²⁵
R25 According to the CCM, improvement of care can be achieved by separating acute care
R26 from the planned management of chronic diseases, offering the patient education about
R27 the disease and supporting self-management. A computerized information system can
R28 be used as a reminder system to comply with evidence-based guidelines, for planning
R29 individual patient care and for feedback to caregivers about their performance.

R30 The CCM model defined different aspects of care.^{23, 24}

- R31 - Effective self-management meaning that patients have a central role in
R32 determining their care, one that fosters a sense of responsibility for their own
R33 health.
- R34 - Decision Support based on explicit, proven guidelines and integrated into the
R35 day-to-day practice of the primary care providers in an accessible and easy-to-
R36 use manner.
- R37 - Delivery System Design with clear roles and tasks of care-providers to ensure
R38 the patient gets the care; making sure that all the clinicians who take care of a
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patient have centralized, up-to-date information about the patient's status; and making follow-up a part of standard procedure.

- Clinical Information System that can track individual patients as well as populations of patients.
- Organization of Health Care that create an environment in which organized efforts to improve the care of people with chronic illness take hold and flourish.
- To improve the health of the population, health care organizations reach out to form powerful alliances and partnerships with the community it functioned in.

In this thesis we distinguish between managed care, protocolized care and personalized care, beside care as usual which reflects 'average' diabetes care in the Netherlands.

Managed diabetes care

In 1996, the Diabetes Care System started in the West-Friesland region of the Netherlands, in which during subsequent years more and more elements of the CCM were introduced. The Diabetes Care System West-Friesland is a centrally guided diabetes care organization. Patients treated by the DCS receive an annual extended diabetes check-up at the specialized Diabetes Care Center, in addition to the diabetes care by patients' GP, according to the Dutch guidelines for type 2 diabetes. Patients have a central role in their care and self-management is stimulated by providing education and information programs. Individual care plans are discussed with the patient and patients are stimulated to make their own choices with respect to treatment options and lifestyle behaviour. The DCS coordinates the diabetes care between primary and secondary care. Using a centrally organized database, clinical information of patients is accessible to involved health care providers. Diabetes nurses visit participating GPs twice a year for feedback about their performance. Individual patients are evaluated and mean values of risk factors of the diabetes population of the GP are compared to the diabetes populations of other participating GPs.

Protocolized Diabetes Care

During recent years, a variety of disease management programs for type 2 diabetes have been implemented in a large number of GP practices throughout the Netherlands, resulting in care groups. The basis of these care groups are bundled payment contracts, with the aim to improve quality of diabetes care.

In a care group in the Amstelland region of the Netherlands, a diabetes care program was implemented which was less centrally organized compared to the diabetes care implemented in the DCS. This form of diabetes care, protocolized diabetes care, mainly focuses on the adherence to type 2 diabetes guidelines. In addition to usual care, a web-based database was used for the registration of diabetes-related data, which was also

R1 applied to monitor mean values of risk factors and whether patients received diabetes
R2 care in line with the Dutch guideline for type 2 diabetes. Education was offered to all
R3 involved health care professionals to increase their expertise in the field of type 2 diabetes.
R4 In contrast to managed diabetes care, all assessments were performed in patient's own
R5 GP practice and there was no centrally organized assessment.
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R7 **Personalized diabetes care**

R8 According to the Dutch guidelines for type 2 diabetes the frequency of routine visits to
R9 the GP, four times a year, is equal for all diabetes patients. This frequency is not based
R10 on evidence and might not be optimal for all patients. A more efficient way to assign
R11 different frequencies of assessments to patients should be based on patients' risk profile.
R12 Most diabetes patients are well-controlled regarding diabetes-related risk factors and are
R13 at low risk for developing complications, meaning that the assessment frequency could
R14 be reduced compared to patients at high risk for complications.

R15 One way to distinguish between diabetes patients at high or low risk for complications
R16 is the use of a prediction formula. Several risk prediction formulas for the estimation of
R17 a first cardiovascular disease, a common complication of diabetes, have already been
R18 developed.²⁶⁻²⁹ These risk algorithms are derived from long-term prospective cohort
R19 studies including a general population^{27,30} or type 2 diabetes patients only.²⁸ Using such
R20 algorithms, cardiovascular disease risk is assessed by means of a method that combines
R21 values for different risk factors to produce an absolute risk estimate within a defined
R22 time period. Before applying it to a population different from the one in which it was
R23 developed, an a priori assessment of the accuracy and validity of these risk algorithms
R24 should be performed in patients with and without diabetes.

R25 The aforementioned risk algorithms are designed to estimate risk of a first
R26 cardiovascular disease. Patients who develop a first cardiovascular disease, are at
R27 increased risk of future cardiovascular diseases compared to persons without a history
R28 of cardiovascular diseases. Less is known about predictors of a recurrent cardiovascular
R29 event.^{31,32} To be able to target stringent medical interventions to those with increased risk
R30 of developing a recurrent cardiovascular event, more information about the population
R31 at risk is needed to be able to identify high-risk patients.
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R33 **Long term impact of diabetes related interventions**

R34 Monitoring long-term results of diabetes-related interventions can be very time-
R35 consuming and expensive. Instead, simulation models can be used to support the
R36 evaluation of interventions by extrapolating trial outcomes to long-term effects and
R37 costs.³³
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In the existing Chronic Diseases Model (CDM) developed by the Dutch National Institute for Public Health and the Environment (RIVM), macrovascular diseases are extensively modelled.³⁴ To enable a complete assessment of long term cost-effectiveness of diabetes-related interventions, microvascular complications should be included in the model as well.

Aim of this thesis

Studies that investigated effects and costs of diabetes care models including elements of the CCM or managed diabetes care showed inconsistent results.^{15, 19, 22-25, 35-37} Furthermore, most studies focussing on the effectiveness of diabetes care did not investigate patients' opinion on the quality of care.

Therefore, the aim of this thesis was to investigate differences in costs, cost-effectiveness and patients experience between different care programs for patients with type 2 diabetes, that is, centralized diabetes management, protocolized diabetes care and usual diabetes care.

Furthermore, a simulation model was developed to estimate long-term cost-effectiveness of different forms of care for type 2 diabetes. Finally, we aimed to explore methods to initiate personalized diabetes care.

Outline of this thesis

We investigated short-term costs (chapter 2), cost-effectiveness (chapter 3) and patient experience (chapter 4) regarding managed or protocolized diabetes care compared to usual care for type 2 diabetes patients. Furthermore, methods to initiate personalized diabetes care were explored by validating several algorithms for cardiovascular risk prediction (chapter 5) and by investigating whether persons at high risk of a recurrent cardiovascular event can be identified (chapter 6). To enable a complete assessment of long term cost-effectiveness of diabetes-related interventions, microvascular complications were added to the existing Chronic Diseases Model. The microvascular complication modules of the resulting MICADO (Modelling Integrated CARE for Diabetes based on Observational data) model was described and validated in chapter 7.

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