

## CHAPTER 2

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### **Managed and protocolized care for type 2 diabetes patients in primary care. An analysis of resource use and costs**

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## ABSTRACT

**Aims:** To evaluate the care process and costs of managed, protocolized, and usual care for type 2 diabetes patients from a societal perspective.

**Methods:** In two distinct regions of the Netherlands, managed and protocolized diabetes care were implemented. Managed care was characterized by a central organization, coordination, responsibility and central annual assessment. Protocolized care had a partly centralized organization structure. Usual care was characterized by a decentralized organization structure. The care process (guidelines adherence) and costs were compared between managed (n=253), protocolized (n=197), and usual care (n=333).

**Results:** Compared to usual and protocolized care, in managed care more patients were treated according to diabetes guidelines. Secondary health care use was higher in patients under usual care compared to managed and protocolized care. Compared to usual care, direct costs were significantly lower in managed care (€-1.181 (95% CI: -2.597 to -334)) while indirect costs were higher (€758 (95% CI: -353 to 2.701), direct, indirect and total costs were (non-significantly) lower in protocolized care.

**Conclusions:** Compared to usual care, managed care was significantly associated with a better process of the diabetes care, less consultations in secondary care and lower health care costs. Same trends were seen for protocolized care, however not significant.

## INTRODUCTION

The increasing prevalence of diabetes is associated with a high impact on health care use and costs.<sup>1</sup> Innovations to improve the quality of care, manage the increasing demand for health care and control the growth of health care costs are needed.<sup>1,2</sup> There is growing awareness that tackling the growing societal and economic burden of diabetes will require nothing less than a transformation of health care, from a system that reacts to acute episodes of illness to one that pro-actively maintains health.<sup>3-5</sup> Multiple deficiencies exist in the current management of diabetes, 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 of which discrepancies exist between care as recommended and care as received by patients.<sup>6-8</sup>

In recent years, targeted programs have become important means for improving the quality of diabetes care and overcoming existing deficiencies.<sup>7-9</sup> A wide array of approaches exists such as the Chronic Care Model,<sup>10,11</sup> and managed care.<sup>12</sup> A common aspect of chronic care programs is their underlying assumption that increasing the quality of care will result in improved health outcomes. Studies evaluating the effects and costs of diabetes care including elements of the Chronic Care Model showed inconsistent results.<sup>4,9,13-20</sup> Mostly, these studies did not include a control group or information on costs from a societal perspective.

In two distinct regions of the Netherlands, diabetes care was implemented in primary care with a different level of organization in each region. In the first region, managed diabetes care based on the Chronic Care Model was implemented, characterized by a central organization, coordination, responsibility and a central annual assessment. In the second region, protocolized care was implemented in primary care, with a central organisation and coordination, and decentralized responsibility and annual assessment. The care process (adherence to diabetes guidelines) and costs of managed diabetes care and protocolized diabetes care were investigated and compared to usual diabetes care, characterized by a decentralized organizational structure.

## MATERIALS AND METHODS

The process of the diabetes care of patients receiving managed care, patients receiving protocolized diabetes care and patients receiving usual diabetes care was compared and evaluated according to the Dutch guidelines for type 2 diabetes.<sup>21</sup> According to these guidelines, patients should visit their general practitioner (GP) practice four times a year for a diabetes assessment, in which weight and fasting blood glucose are measured.

R1 Blood pressure should be measured when antihypertensive medication is used. Foot  
R2 screening should be performed in patients at risk for developing an ulcer. Patients' well-  
R3 being, lifestyle and medication use should be discussed. Once a year, the assessment has  
R4 to be extended with measurement of among others, blood pressure, lipids and HbA<sub>1c</sub> and  
R5 screening for complications. To perform screening for retinopathy, the patient has to be  
R6 referred to a specialist in ophthalmology.

### R8 **Usual care**

R9 Usual diabetes care has a decentralized organisation structure and patients' own GP  
R10 is responsible for the diabetes care. Patients of all GPs should receive diabetes care  
R11 according to the Dutch guidelines for type 2 diabetes.<sup>21</sup> For the usual care group,  
R12 diabetes patients of a representative sample of 17 GPs throughout the Netherlands were  
R13 invited for participation in our study. The GPs in the usual care group are affiliated to  
R14 the Continuous Morbidity Registration sentinel stations of The Netherlands Institute  
R15 for Health and Services Research.<sup>22</sup> This network of general practices represents 0.8% of  
R16 the Dutch population and is representative at a national level for age, sex, geographic  
R17 distribution and population density. The possibility exists that GPs in the usual care  
R18 group participate in some form of disease management for type 2 diabetes patients.

### R20 **Managed diabetes care**

R21 According to the Chronic Care Model, improvement of care can be achieved by  
R22 separating acute care from the planned management of chronic diseases, offering the  
R23 patient education about the disease and supporting self-management. A computerized  
R24 information system is used as a reminder system to comply with evidence-based  
R25 guidelines, for planning individual patient care and for feedback to caregivers about  
R26 their performance.<sup>3,4</sup>

R27 In 1996, managed care was implemented in the Diabetes Care System (DCS) in the  
R28 West-Friesland region of the Netherlands, based on the Chronic Care Model. In contrast  
R29 with usual care, in which the GP is responsible for the diabetes care, the DCS is responsible  
R30 for the performance and quality of the diabetes care and organizes the diabetes care  
R31 centrally and coordinates the care between all care providers. Using a centrally organized  
R32 database, clinical information of patients is accessible to involved health care providers.  
R33 Starting at diabetes diagnosis, patients treated by the DCS receive an annual extended  
R34 diabetes assessment at the specialized Diabetes Care Centre, in addition to the diabetes  
R35 care by patients' GP. During this assessment BMI, blood pressure, HbA<sub>1c</sub>, lipid levels,  
R36 fasting glucose level and kidney function are measured. Screening for cardiovascular  
R37 diseases, retinopathy and complications of the foot is performed at the centre. Patients  
R38 have a central role in their care and self-management is stimulated by providing  
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education and information programs. Moreover, individual care plans are discussed with the patient and patients were stimulated to make their own choices with respect to treatment options and lifestyle behaviour. Diabetes nurses visit participating GPs twice a year to provide 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**

In 2007, in 12 GPs in the Amstelland region of the Netherlands protocolized care was implemented. This form of care mainly focuses on the adherence to guideline for type 2 diabetes. In addition to usual care, a web-based database is used for the registration of diabetes-related data, which is also applied to monitor mean values of risk factors and whether patients received diabetes care in line with the Dutch guideline for type 2 diabetes. Education is offered to all involved health care professionals to increase their expertise in the field of type 2 diabetes. In contrast to managed diabetes care, all assessments were performed in patient's own GP practice and there was no centrally organized assessment.

Presence of specific elements per type of diabetes care are presented in more detail in Appendix A.

### **Patient selection**

Type 2 diabetes patients, aged between 40 and 75 years and capable of understanding the Dutch language were eligible for this study. From July 2007 to May 2009, diabetes patients were invited to participate in this study.

The study population consisted of three subpopulations. For the managed care group, a random sample of 643 patients was invited for this study and 313 (49%) patients participated. For the protocolized care group, a random sample of 802 patients was invited of which 293 (37%) patients were included. For the usual care group, a random sample of 1098 patients was invited and 485 (44%) patients participated. Patients with type 1 diabetes were excluded, which was defined as diabetes with onset before the age of 40 in combination with insulin treatment (managed care: n=3; protocolized care: n=4; usual care: n=13). After exclusion of patients without a completed cost diary both at baseline and one year after baseline, 215 patients receiving managed care, 197 patient receiving protocolized care and 333 patients under usual care were eligible for the analyses. Patients who did not complete two cost diaries were younger (64 vs. 65) and were less likely to be married or living together (73 vs. 80) compared to patients completed two cost diaries. Other characteristics of the included participants were similar to those who had not completed two cost diaries.

R1 All participants provided written informed consent. Ethical approval for the study  
R2 was obtained from the Ethical Review Committee of the VU University Medical Center  
R3 Amsterdam.

### R4 **Measurements**

R5 Information on marital status, educational level, work status, smoking habits, diabetes  
R6 duration, type of treatment (dietary advice or medication) and performance of  
R7 assessments and screenings was obtained by self-administered questionnaires.  
R8

### R9 **Costs**

R10 All participants were asked to complete a prospective cost diary during three months  
R11 starting at baseline and during three months one year later. The cost diary is considered  
R12 a valid method to obtain information on costs.<sup>23</sup> If we did not receive a completed cost  
R13 diary and the patient did not respond to a reminder, or in case of an incomplete diary, we  
R14 tried to collect data through a telephone interview.  
R15

R16 Information on costs from a societal perspective was obtained including direct health  
R17 care costs, direct non-health care costs and indirect costs attributable to type 2 diabetes.  
R18 The cost diary included questions regarding visits to health care providers related to  
R19 diabetes care. Patients also reported visits, if any, to the GP, mental health care providers  
R20 and complementary health professionals. Patients were asked to specify visits to other  
R21 medical specialists and therapists. Performed laboratory tests, use of home care and  
R22 hospitalization were also reported. Finally, indirect costs were measured by asking the  
R23 patient about loss of productivity (absenteeism of paid and unpaid work). Dutch unit  
R24 prices were used to calculate costs of resource use (Appendix B).<sup>24</sup>  
R25

### R26 **Statistical analysis**

R27 Characteristics of the population are presented as means (SD), median (interquartile  
R28 range) or proportions according to diabetes care group. To investigate the process of  
R29 diabetes care, the proportion of patients that received the assessments or screenings as  
R30 recommended by the Dutch guidelines for type 2 diabetes was calculated.

R31 The cost diary at baseline and one year after baseline was used to interpolate health  
R32 care use and costs during one year.

R33 The proportion of patients visiting each health care provider (Chi<sup>2</sup> tests) and mean  
R34 number of visits per patient for that specific health care provider (Mann-Whitney test)  
R35 was calculated. Despite the skewed distribution of health care use and costs in our  
R36 population, mean number of visits and mean costs were reported because this is the  
R37 most informative measure from an economic perspective.  
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We differentiated between direct health care costs, direct non-health care costs and indirect costs. Direct health care costs consisted of costs concerning visits to health care providers, laboratory tests, use of home care, hospitalizations. Direct non-health care costs concerned costs of visits to health care providers not paid by patients' health insurance. Indirect costs were costs related to loss of productivity (paid and unpaid work).

Regression analysis was performed with direct health care and non-health care costs, indirect costs, total direct and total costs as outcome, estimating differences in costs between managed and usual care and between protocolized and usual care. Multivariate regression models were used to estimate differences in costs adjusted for confounding factors. Because of the skewed distribution of the costs, bootstrapping methods (5000 replications) with the bias-corrected and accelerated approach were used to estimate 95% confidence intervals (CI's) around the differences in costs.<sup>25</sup>

## RESULTS

Mean age of diabetes patients was 65 years. Compared to patients under usual care, a lower proportion of patients receiving managed care had high education (7.6 vs. 18.6%) and a lower proportion of patients receiving protocolized care had low education (48.2 vs. 59.5%). The use of glucose lowering medication use was highest in patients receiving managed care (88.2%) compared to patients receiving protocolized (76%) care or usual care (79.9%) Patients receiving protocolized care (5.6%) or usual care (13.3%) were more likely to consult a specialist in internal medicine for diabetes care compared to patients receiving managed care (1.0%, Table 1).

A significantly higher proportion of patients receiving managed care reported that they received information about self-control of feet, screening of the feet and measurement of weight compared to protocolized and usual care. Compared to usual care, in more patients in the managed care group screening of retinopathy was performed and a higher proportion of patients in the protocolized care group reported screening of nephropathy (Figure).

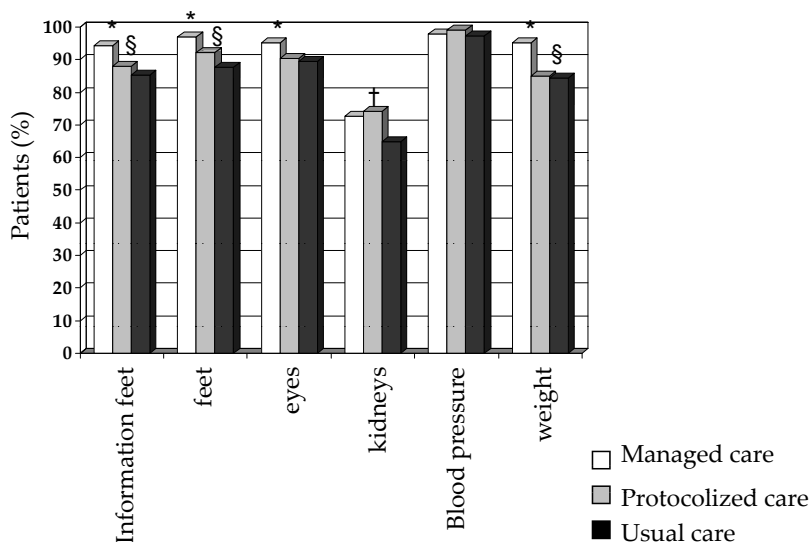
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**Table 1.** Baseline characteristics of the population stratified by diabetes care group

	Managed care (n=215)	Protocolized care (n=197)	Usual care (n=333)	P value usual care vs	
				Managed care	Protocolized care
Men (%)	52.1	53.8	51.1	0.81	0.54
Age (years)	64.6 (7.4)	65.5 (7.5)	64.4 (7.0)	0.66	0.07
Diabetes duration (years)	6 (2-11)	5 (3-10)	6 (3-10)	0.85	0.74
Married/living together (%)	81.1	78.2	80.4	0.84	0.54
Educational level (%)				<0.01	0.04
- low	52.8	48.2	59.5		
- medium	39.6	28.4	21.9		
- high	7.6	23.4	18.6		
Paid job (%)	17.9	26.4	18.6	0.84	0.04
Retired (%)	47.2	45.7	44.4	0.53	0.78
Disabled (%)	9.4	3.6	6.0	0.14	0.22
Smoking status (%)				0.48	0.25
- current	16.8	12.3	16.2		
- former	55.1	55.2	52.0		
- never	28.1	32.5	31.8		
Treatment (%)				0.05	<0.01
- diet only	11.8	24.0	20.1		
- oral medication	67.3	64.1	56.8		
- insulin	8.1	1.6	10.0		
- insulin and oral medication	12.8	10.4	13.1		
Treated in secondary care (specialist in internal medicine)	1.0	5.6	13.3	<0.01	0.01

Values are presented as mean (SD), median (interquartile range) or proportions.





**Figure.** Proportion of patients reporting that they received a specific medical examination during the last year. \* Indicates a significant difference ( $P < 0.05$ ) between managed and usual diabetes care. † Indicates a significant difference between protocolized and usual care. § Indicates a significant difference between managed and protocolized care.

Patients receiving protocolized care had more consultations with the diabetes nurse compared to patients receiving managed care or usual care. The dietician was more frequently visited by patients in the managed care group compared to patients in the protocolized or usual care group. Fewer patients in the managed care group visited specialists in internal medicine and ophthalmology, and the mean number of these consultations was lower in this group compared to the protocolized and usual care group (Table 2).

Direct and total direct health care costs were significantly lower in the managed and protocolized care group compared to the usual care group. After adjustment for confounding factors, differences in direct costs decreased but direct costs remained statistically significantly lower in managed care compared to usual care. Costs due to productivity loss (indirect costs) were comparable in the protocolized and usual care group, but was higher in patients receiving managed care compared to protocolized and usual care, although not statistically significant. Differences in indirect costs increased after adjustment for diabetes duration, marital status, educational level and retirement. Total costs were lower in managed care and protocolized care compared to usual care although not statistically significant (Table 3).

**Table 2.** Resource use and productivity loss stratified by diabetes care group.

Consultation of ..	Managed care N=215		Protocolized care <sup>‡</sup> N=197		Usual care <sup>‡</sup> N =333	
	% ≥1 visits	Mean (SD) # of visits	% ≥1 visits	Mean (SD) # of visits	% ≥1 visits	Mean (SD) # of visits
General practitioner	77.8	7.6 (8.6)	80.0	5.7 (6.9)	78.4	6.1 (6.9)
Diabetes nurse	74.5 <sup>ab</sup>	3.8 (3.8) <sup>b</sup>	82.6	4.3 (3.5) <sup>a</sup>	84.5	3.7 (2.8)
Dietician	38.4 <sup>ab</sup>	1.4 (2.4) <sup>ab</sup>	20.5	0.9 (2.2)	21.9	0.9 (2.4)
Podiatrist	19.4 <sup>b</sup>	0.7 (1.8) <sup>b</sup>	9.2 <sup>a</sup>	0.4 (1.6) <sup>a</sup>	24.3	1.2 (2.9)
Physical therapist	25.9	5.3 (13.8)	30.3 <sup>a</sup>	7.3 (18.1) <sup>a</sup>	21.0	3.9 (11.9)
<i>Specialist in</i>						
- Internal medicine	6.9 <sup>ab</sup>	0.4 (2.0) <sup>ab</sup>	15.4 <sup>a</sup>	0.6 (1.7) <sup>a</sup>	28.9	1.5 (2.8)
- Ophthalmology	17.6 <sup>ab</sup>	0.8 (2.5) <sup>ab</sup>	47.7	1.5 (2.5)	52.0	1.8 (2.6)
- Cardiology	15.7	0.6 (2.5)	15.4	0.7 (1.9)	15.2	0.7 (2.3)
- Neurology	5.1	0.2 (0.9)	6.2	1.6 (0.7)	6.4	0.6 (4.0)
- Nephrology	1.4	0.0 (0.4)	3.6	0.2 (1.3)	1.8	0.1 (0.4)
Other specialism	25.9	1.4 (3.1)	27.7	1.4 (2.9)	32.8	1.6 (4.0)
Hospitalization	9.7	0.7 (3.0)	10.3	1.1 (4.7)	12.5	2.7 (14.8)
Absenteeism paid work	8.8	4.9 (27.8)	10.8	2.8 (14.1)	10.0	3.1 (15.2)
Absenteeism unpaid work	13.9	12.3 (50.0)	9.7	18.2 (127.4) <sup>a</sup>	18.2	20.7 (70.6)

Data are expressed as proportions of patients who used the specific resource and mean (SD) resource use per patient during one year.

<sup>a</sup> Significantly different (P<0.05) from usual care.

<sup>b</sup> Significantly different (P<0.05) from protocolized care.

**Table 3.** Mean (SD) direct costs and total costs (€) during one year according to diabetes care group and mean differences (95% Confidence Intervals) in direct costs and total costs (€) between managed care, protocolized care, and usual care (reference category).

	Managed care (n=215)	Protocolized care (n=197)	Usual care (n=333)	Mean differences in costs between managed and usual care (95% CI)	Model 1	Model 2	Mean differences in costs between protocolized and usual care (95% CI)	Model 1	Model 2
Direct health care costs	1259 (2712)	1568 (3288)	2607 (8678)	-1348 (-2593 to -531)	4 (-10 to 25)	8 (-6 to 29)	-1057 (-2333 to -201)	7 (-10 to 33)	6 (-13 to 33)
Direct non-health care costs	17 (102)	19 (127)	13 (92)	-1344 (-2606 to -541)	461 (-524 to 2277)	758 (-353 to 2701)	-1050 (-2336 to -191)	-78 (-782 to 836)	-788 (-2042 to 47)
Total direct costs	1276 (2715)	1587 (3293)	2620 (8680)						
Indirect costs	1727 (8808)	1125 (4548)	1328 (4840)						
Total costs	3003 (9457)	2711 (5690)	3949 (10328)	-882 (-2415 to 932)			-1128 (-2682 to 86)		-884 (-2281 to 323)

Model 1: adjusted for age and sex

Model 2: further adjusted for diabetes duration, marital status, educational level, retirement

## DISCUSSION

Overall, a significantly higher proportion of patients in the managed care group received the assessments and screenings recommended by diabetes guidelines compared to usual care.

Patients in the managed and protocolized care group had fewer consultations with health care professionals in internal medicine compared to usual care. Patients receiving managed care compared to patients receiving protocolized or usual care also had less frequently visited specialists in ophthalmology. Total direct costs were significantly lower for patients receiving managed care compared to usual care. Same trends were seen for protocolized care, however not statistically significant. Indirect costs were higher in patients receiving managed care than in patients receiving protocolized and usual care. Total costs were lower in managed and protocolized care compared to usual care but not statistically significantly different.

In general, patients receiving managed or protocolized care had fewer consultations with health care professionals in secondary care compared to patients receiving usual diabetes care, contributing to lower health care costs. Particularly, in the managed care group, the proportion of patients that consulted a specialist in internal medicine or ophthalmology was low. In the managed care group, a high number of patients was disabled and more patients reported sick leave compared to patients in the protocolized and usual care group. It has been shown that persons with lower educational level are at increased risk for sick leave,<sup>26</sup> which might be an explanation for the high indirect costs in this group, in which only 7.6% of the patients had high educational level.

Studies evaluating diabetes care based on principles of different managed care models showed inconsistent results regarding health outcomes and process of the diabetes care.<sup>13-15,18,27</sup> Studies comparing costs of usual diabetes care with costs of diabetes care including at least three elements of the Chronic Care Model, showed cost savings<sup>15</sup> or no differences in costs.<sup>14</sup> In these studies, information on costs was obtained by claims paid for covered health care use. Detailed information on health care use or costs from a societal perspective was unavailable.

To obtain information on health care use to calculate costs of care, self-administered three-month cost diaries were used. Self-reported information might have led to an underreporting of health care use due to recall bias.<sup>28</sup> However, because of the prospective design of the cost diary, recall bias and underreporting of data is unlikely. Previous research comparing data obtained by cost diaries with data retrieved from insurance companies showed that cost diaries are a feasible and valid tool to measure costs.<sup>23</sup> Furthermore, the use of the cost diary at baseline and one year after baseline to calculate health care use and costs leads to more reliable estimates than a single measurement.

Using this method, we were also able to obtain indirect costs and costs not covered by health insurance companies. Patients who did not complete two cost diaries were excluded for this study, which might have resulted in a selection of healthier diabetes patients. However, except for age and marital status, other characteristics did not differ statistically significantly between included and excluded patients.

Due to the cross-sectional design of the study, causal relations between managed or protocolized care and long-term results cannot be determined.

We acknowledge that managed as well as protocolized care were implemented in a good functioning Dutch primary care system which might have resulted in smaller differences between patients receiving managed or protocolized care and patients treated according to usual care. However, we do believe that the results of our study can be extrapolated to other countries and other health care systems with high referral rates to secondary care.<sup>30</sup>

Our results indicate that a part of health care use can be substituted by the implementation of, in particular, managed care resulting in fewer consultations with specialists in secondary care. This substitution of secondary care by primary care was not associated with a lower quality of care compared to usual care. Instead, managed care performed better regarding the process of care. More patients in the managed care group received the assessments and screenings according to diabetes guidelines, which might have resulted in the detection of complications in an early stage, and early initiation of appropriate treatment, which could consequently reduce the number of complications in the long run.

To conclude, the implementation of managed diabetes care, with a high level of centralization, embedded in primary care resulted not only in a better process of the diabetes care but also in lower health care costs. The combination of better process of care and reduced costs is of great importance especially for a highly prevalent chronic disease as type 2 diabetes, which makes this form of managed care a promising strategy to treat the growing population of diabetes 2 patients.

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