Pharmaceutical care in diabetes

Quantifying and evaluating community pharmacy's support to patients performing blood glucose self-monitoring

Michiel Storimans

PHARMACEUTICAL CARE IN DIABETES

QUANTIFYING AND EVALUATING COMMUNITY PHARMACY'S SUPPORT TO PATIENTS PERFORMING BLOOD GLUCOSE SELF-MONITORING

MICHIEL JOHAN STORIMANS

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De **bruinstaart-hoornkolibrie** (Boissonneaua flavescens) op de voorkant behoort tot de familie der Trochilidae (kolibries). Het metabolisme van kolibries is het snelste van alle dieren. Een regelmatige inname van voedsel - soms tot meerdere keren hun eigen lichaamsgewicht aan nectar - is voor de kolibrie van levensbelang. Dag in, dag uit. De kolibrie is het symbool van wetenschappelijk onderzoek naar diabetes.

PHARMACEUTICAL CARE IN DIABETES

Quantifying and evaluating community pharmacy's support to patients performing blood glucose self-monitoring

Farmaceutische patiëntenzorg bij diabetes

Kwantificeren en evalueren van de ondersteuning van openbare apotheken aan patiënten die aan zelfcontrole van bloedglucose doen (met een samenvatting in het Nederlands).

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Ter verkrijging van de graad van doctor aan de Universiteit Utrecht
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Vanuit de toekomst
komt wind de waterval
uiteenwaaien ...

Natsuishi Ban'ya 1955

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CHAPTER 1

INTRODUCTION

Zo stevig als ie kan
knijpt de kleine zijn knuistjes dicht,
al zit er niets in

Shinohara Hōsaku 1905-1936

1.1 Background

Prevalence and incidence of diabetes mellitus

Diabetes is a chronic, metabolic disorder that is characterised by hyperglycemia resulting from defects in insulin secretion, insulin action or both. It is accompanied by disturbances in the carbohydrate, fat and protein metabolism.

The two most frequently diagnosed types of diabetes are type 1 and type 2 diabetes mellitus. Type 1 diabetes is associated with an absolute deficiency of insulin, due to a cellular-mediated auto immune destruction of the ß-cells of the pancreas. Type 2 diabetes has many pathophysiological mechanisms, ranging from predominantly insulin resistance with relative insulin deficiency to predominantly an insulin secretory defect with insulin resistance. The global prevalence of diabetes among adults is high, varying between 2.8 percent to 4 percent in the year 2000. This number is expected to grow, resulting in over 350 million persons with diabetes world-wide in 2030. [1, 2] In the Netherlands, the prevalence is estimated to be 3.6 percent and 4.4 percent among men and women, respectively, aged 20 years or over. [3] This corresponds to 482,000 persons (in 2000). It is estimated that another 300,000 people have undiagnosed hyperglycemia. [4]

The incidence is also high; for type 2 diabetes in the Netherlands this number is approximately 66,000 among persons aged 50 years or over (2000). [5] The incidence increases with age, which, together with ageing of the population and possibly also with the high prevalence of overweight and obesity [6], will lead to a serious growth in the demand for diabetes-related health care.

Burden of disease

Hyperglycemia is associated with many different symptoms, which can be classified into short-term or long-term complications. Acute symptoms of untreated diabetes include thirst, weight loss, polyuria and blurred vision. Severe hyperglycemia can result in fatal diabetic keto-acidosis. Long-term complications include retinopathy, nephropathy and neuropathy. Neuropathy is expressed, for example, as foot ulcers, potentially leading to amputations. Furthermore, type 2 diabetes mellitus is associated with a twofold to threefold increased risk of cardiovascular disease. [7]

Especially the long-term complications of diabetes are associated with high morbidity, high cost and decrease in quality of life. [8-11] In Europe, the average yearly direct cost per type 2 diabetes patient in 1999 were € 2,834 [12], with overall cost in the Netherlands of €431 million. [13] The overall yearly mortality among patients with diabetes is 2.9%, with the most common cause of death being related to cardiovascular diseases, especially in type 2 diabetes. [14] The impact of diabetes mellitus on public health is recognised by the Dutch Minister of Health. Diabetes has received special attention in Dutch health policy, which makes it the first disease explicitly mentioned in policy documents. [15, 16]

Management of diabetes and self-monitoring of blood glucose

Reducing hyperglycemia has been shown to be an important factor in the prevention of diabetes-related complications. [17, 18] Various treatments, pharmacological as well as non-pharmacological have been shown to reduce the glycosylated hemoglobin levels (A1c levels). Pharmacological treatment is categorised in oral hypoglycemic agents and insulin. Oral hypoglycemic agents represent various different classes of drugs, for example sulfonurea derivates, biguanides and thiazodilinediones. Since type 1 diabetes is associated with an absolute deficiency of insulin, only insulin is used as treatment. Type 2 diabetes patients may benefit from all glucose lowering drugs and also from life style changes, such as exercise and diet.

In addition to pharmacological treatment, education on self-management of diabetes is considered an integral component of all diabetes care plans. [19, 20] Various strategies of self-management education exist. [21] Nevertheless, it is now widely accepted that self-management should not be only focused on knowledge and skills, but that self-efficacy and coping skills are equally important to achieve the desired patient outcomes. [22] Education or training of type 2 diabetes mellitus patients in self-management is effective in reducing A1c levels, although research into the long-term effects of educational programmes is limited. [21, 23]

Behavioural change focuses on nutrition, physical activity and psychosocial coping skills. Self-monitoring of blood glucose (SMBG) is also considered an important aspect of diabetes self-management. [4, 20, 22] SMBG is a technique that allows patients to measure their own blood glucose value. Depending on the equipment used, the value is reported as either plasma of whole blood glucose concentrations in mmol per liter or mg per deciliter. The exact procedure of the measurement is also defined by the equipment used, but always includes the application of a small amount of capillary blood – generally less than 50 microliters – on a disposable reagent stick and measurement in a separate, electronic read-out device. These reagent sticks, also called test strips, are highly specific to glucose, due to enzymatic catalysation of the oxidation of glucose. The read-out device – the blood glucose meter – translates this reaction either by reflectance photometry or coulometry.

SMBG has two goals. First, it enables patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the life style they prefer. Second, it allows physicians to gather data for clinical decision-making. Especially the first goal is relevant, since the SBMG equipment has become much more accurate and user friendly in recent years. Apart from blood sampling using the finger tip method, technical developments have made it possible to sample blood from other sites, reducing patient discomfort. [24] Furthermore, improved sensitivity of the analysis has led to a sharp decrease in the sample size needed for SMBG.

Self-monitoring of blood glucose and patient outcomes

SMBG is advocated in many treatment guidelines. For example, the American Diabetes Association (ADA), but also the Dutch Diabetes Federation (Nederlandse Diabetes Federatie, NDF) state that SMBG enables patients with diabetes to achieve and maintain specific individual glycemic goals. [4, 25] Based principally on the results of the Diabetes Control and Complications Trial (DCCT) [18], it is recommended that most individuals with diabetes should attempt to achieve and maintain blood glucose levels as close to normal as is safely possible. SMBG is recommended for all insulin-treated patients with diabetes. It may be desirable in patients treated with sulfonylureas or other insulin secretagogues and in all patients not achieving glycemic goals. [25] In its Standard of Diabetes Care the NDF expresses that people with type 1 diabetes but also those with type 2 diabetes who aim for improving their glucose control, should be given access to SMBG equipment. [4]

Glycemic control

Opposite to these position statements stands the limited scientific evidence that SMBG improves patient outcomes. Since the protocol of the DCCT study (gathering data on effectiveness of intensive treatment in type 1 diabetes mellitus) did not include an arm of patients without SMBG, no conclusion can be drawn on the effectiveness of SBMG per se. After the publication of these results, only a few clinical trials have been published among type 1 patients. [26] Only one study compared SMBG against no monitoring at all. [27] The others compared SMBG to glucose monitoring in urine. The pooled effect of SMBG over glucose monitoring in urine was a 0.57% lower A1c value (95% confidence interval –1.07% to –0.06%). [26] Among patients with type 2 diabetes who use insulin, published evidence is limited as well. A recent review of the effect of self-monitoring among type 2 diabetes using oral hypoglycemic agents showed a small, significant improvement in A1c levels in two out of six studies, but the methodological quality of the studies was poor. A recent randomised controlled trial also showed no additional effect of SMBG on A1c reduction [28], but a French randomised controlled trial showed a 10.3 percent increase in the proportion of patients with a significant improvement in A1c levels (more than 0.5%) among patients using SMBG compared to usual care without SMBG. [29] Results from observational studies are inconclusive. [30-34]

Other outcomes

In two randomised controlled trials (RCT), quality of life was not affected by SMBG compared to urine glucose control or no self-monitoring. [35, 36] However, one RCT showed a marked improvement in general well-being in a comparable patient group after introduction of SMBG in combination with standardised meal-related instruction. [37] In contrast, an observational study among non-insulin treated patients, frequent SBMG (more than once per day) was associated with higher levels of distress, worries and depressive symptoms. [38] Among patients using insulin no association was found between these outcomes and the frequency of use of glucose test strip. [38] Furthermore, SMBG did not affect body weight in type 2 diabetes patients in one observational study. [39]

Notwithstanding the ongoing debate on the cost and effectiveness of SMBG, self-monitoring of blood glucose has become a part of daily routine for patients with diabetes mellitus, particularly among patients using insulin. In the Netherlands, this is to a large part the merit of the Dutch patient organisation for diabetes.

Performance of patients in SMBG

Patient errors in self-monitoring of blood glucose are common. [40-44] Using direct observation of the SMBG process among adults, about one-fifth of all users made at least one error. In children, this was more than 90%. Internal calibration against a reference test strip, to eliminate between-batch variability in the reagent, is a source of mistakes. Incorrect finger-pricking procedure and the use of expired test strips may also result in inaccurate blood glucose values. The relevance of these user errors on patient outcomes is unclear. In observational studies, no association was found between the number of errors and A1c level. However, the studies were not designed to detect differences between poor and good performers of SMBG. Moreover, other important outcomes, such as hypoglycemic events and unnecessary dose changes, have not been studied.

Prevalence of self-monitoring of blood glucose

This debate on the appropriateness of SMBG among patients with type 2 diabetes is also reflected in the data on prevalence of SMBG. In British and US studies, the proportion of patients with type 1 diabetes not performing SMBG varies between 16% and 60%. For type 2 diabetes this ranges from 43% to 95%. [30, 45, 46] However, it must be taken into account that studies often use different definitions of SMBG. This is the result of uncertainty on the optimal frequency of test strip use. [25]

There is no information available on the situation among Dutch patients with diabetes mellitus. Moreover, results from studies in other countries cannot be directly translated to the Dutch situation due to differences in the health care systems between the Netherlands and, for example, the United States or the United Kingdom. SMBG is relatively expensive; one test strip costs about 1 euro. Remuneration of SMBG equipment is, therefore, an important determinant of performing SMBG. [45, 47-49]

Pharmacist interventions and outcomes in patients with diabetes

During the last 20 years, the focus of community pharmacy has shifted from a product-centred approach to patient-centred activities. This was the result of a growing awareness that not only the quality of the drug itself, but also that of pharmacotherapy are key in the effectiveness and safety. These issues, for example medication surveillance and patient education on compliance, have found their way in daily practice in Dutch community pharmacies.

As a consequence of this shift, and due to the impact of diabetes on public health, the interest in interventions involving pharmacists in diabetes care has improved

substantially. A relatively large body of literature is available, describing the effect of these interventions on patient outcomes. As **Table 1** summarises, the type of interventions varies distinctively, ranging from medication review to developing and implementing pharmaceutical care plans. Although not all papers are equally detailed in the description of the intervention, the activities tested in the studies are rather divergent; patient counselling, training in self-management of diabetes, physical examination, drug therapy evaluation and management of periodic screening on complications are just a few of the distinct actions performed by the study pharmacist. In some interventions, there was direct contact between the pharmacist and the patient. In other studies the pharmacist had a role as a consultant of other healthcare providers. Interventions also differed in the responsibilities of the pharmacist. For example in a study by Odegard et al., the pharmacists were primarily responsible for improvement of treatment outcomes. [50] However, other interventions were performed and monitored by diabetes nurses. [51, 52]

Apart from the differences in how diabetes care is provided, the studies differ also in the outcome measures used to assess the effectiveness of interventions (see **Table 2**). Although A1c levels are measured in all studies, many other patient outcomes are considered, depending on the focus of the research. Besides patient outcomes, process

Table 1. The topics addressed in trials of diabetes care interventions including a pharmacist or community pharmacy as a component of the intervention. [a]

Type of intervention	Reference [b]
Individualised patient counselling/education	53, 54, *56*, *57*, *58*, *59*, **60**, **61**, *62*
Individualised patient counselling/education on cholesterol management	63
Group based patient counselling	*52*, 64
Training in self-monitoring	**53**, **54**, *56*, *57*, *62*, 64
Training in dietary regulation and exercise	*56*, *57*, 64
Training in other self-management skills	*56*, *57*, *62*
Physical examination	**53**, **54**, *57*, *62*, **63**, *65*
Drug therapy evaluation	*51*, *52*, *56*, *58*, *59*, *66*
Medication surveillance	51
Management of periodic screening	58
Development and monitoring treatment plan	**50**, **53**, **54**, *57*, **60**, *62*, **67** [c], *65*
Free blood glucose meter	**53**, **54**, *57*
Waiver for co-payments for diabetes related medication and supplies	**53**, **54**
Assessment of compliance	59
Referral	**50**, 52, **53**, **54**, **61**, **63**

[a] The search only includes studies referenced in PubMed until July 2005. The search terms used were "Diabetes mellitus" [MeSH] AND pharmacy, "Diabetes mellitus" [MeSH] AND pharmacist* and "Diabetes mellitus" [MeSH] AND "Community pharmacy services" [MeSH].

[b] The references in bold type refer to interventions by community pharmacist, the references in italic type to clinical pharmacist interventions. For references in normal font type, pharmacist position could not be determined.

[c] The treatment plan focused on collecting, discussing and goal setting of SMBG results.

outcomes are sometimes evaluated, often compared to the ADA Standards of care to patients with diabetes. The Asheville project, Sadur et al. and Wagner et al. also provided an overview of the cost of the intervention, but a cost-effectiveness study of a diabetes care intervention including a pharmacist has not yet been published. [51, 53-55] Thirteen of the 17 interventions measuring the effectiveness of the diabetes care interventions on A1c level, showed a statistically significant improvement. Still, the extent of the effect varied. Not all studies included a control group and the number of patients under observation was generally small (fewer than 100 patients per arm).

Of the other outcomes, only LDL-cholesterol levels and HDL-cholesterol levels were significantly lower among intervention groups in three out of four studies examing this

Table 2. Outcomes used to assess trials of diabetes care interventions including a pharmacist or community pharmacy as a component of the intervention. [a]

Outcomes	References
Patient outcomes	
A1c	50-60, 62, 64-68
Fasting blood glucose	56, 62, 66
Blood pressure	52, 56, 57, 60
Serum creatine	56
Microalbumin to creatinine ratio	56
Total cholesterol	52-56, 60, 63, 65
Triglyceride concentration	56, 60, 65
High density lipoprotein concentration	53, 54, 56, 60
Low density lipoprotein concentration	53, 54, 56, 58, 60, 65
HDL/LDL ratio	53, 54
Weight	56
Hypoglycemic and hyperglycemic events	56, 62, 66
Patient compliance with medication	50, 56, 59, 67, 61
Diabetes knowledge	50, 60
Confidence in self-management	50, 51
Quality of life or well-being	50, 55, 56, 67
Self-reported self-care practice	51, 61
Cardiovascular risk profile	63
Proteinurea	65
Depression	55
Chronic disease score	55
Other outcomes	
Cost and/or utilisation of health care	51, 53, 54, 55, 62
Adherence to treatment guidelines	53, 54, 55, 58, 63, 65, 68
Changes in drug therapy	52, 57, 60, 63
Medication appropriateness	50
Use of diabetes care	50, 57, 66
Satisfaction with diabetes care	51, 52, 55, 59
Implementation of pharmacist's recommendations by physician	61

[a] The search only includes studies referenced in PubMed until July 2005. The search terms used were "Diabetes mellitus" [MeSH] AND pharmacy, "Diabetes mellitus" [MeSH] AND pharmacist* and "Diabetes mellitus" [MeSH] AND "Community pharmacy services" [MeSH].

outcome. Results on blood pressure, adherence, hypoglycemic events and quality of life were inconclusive. Interventions did improve the adherence to guidelines, but the effects on direct medical cost, use of care and patient satisfaction were contradictory.

1.2 Reasons for this Thesis

Issues in providing diabetes services in community pharmacy

As illustrated in the overview on community pharmacy interventions in diabetes care, diabetes services include a wide variety of different care processes. It contains elements of patient counselling on knowledge and behaviours, group-based educational interventions, logistical support, dispensing and other activities. This is also reflected in international pharmacy practice guidelines. Although these guidelines generally review similar topics, they vary on the level of detail of the recommendations. [69-71] Consequently, no widely accepted quality indicators for these pharmacy services exist.

The variation in recommendations is further complicated by one of diabetes care's most essential characteristics: it involves many different healthcare professionals. The list includes internists, general practitioners, diabetes nurses, nurse practitioners, dieticians, podotherapists, (hospital) pharmacists, pharmacy technicians and of course the patients and their relatives. This collaboration needed to provide diabetes care is not incorporated in the quality indicators often used in (community) pharmacies.

As a result of the lack of accepted quality indicators, the transparency of the diabetes care processes in community pharmacies is limited. Both patients and remunerating parties are not able to objectively compare individual pharmacies on the level of service they provide to people with diabetes. Furthermore, Health Care Inspectorates do not have instruments to supervise the quality of diabetes care. Even more important for improvement of community pharmacy services is the fact that benchmarking is difficult without proper indicators.

Finally, the evidence underlying the development of quality indicator for these services is limited. This thesis aims to contribute to closing this knowledge gap.

1.3 Scope of this Thesis

Quality assessment of community pharmacy services

Approaches to assessment of pharmaceutical care draw upon the work of Donabedian. He proposed a model of quality assessment currently known as the structure-process-outcome (SPO) model (see **Figure 1**). In this model, the quality of health care is the result of the interaction between the structure, the process and the outcomes of care. Structure is defined

as the relative stable characteristics of the healthcare providers, their tools, resources and the physical and organisational setting in which they work. It not only includes the organisation that the providers work in, but also contains the financing and delivery of health care services (health insurance). A quality management system is another example of structure. Process is a set of activities that go on between a patient and a healthcare provider. Although Donabedian refers in his work to practitioners, the concepts are applicable to all people and organisations that perform activities with the primary objective to influence the health status of a patient. Process can be divided into two distinct areas: technical management and interpersonal process. Technical management relates to the medical science and technology used in the process of care. Interpersonal process encompasses the relationship between the patient and the healthcare provider and is governed by values and ethical principles. An outcome refers to a change in the patient's current and future health status, attributable to previous health care. Central to the model's assumption is that the structure of care influences the care process. The care process affects the patient's health status and therefore influences the outcomes of care. [72, 73]

This thesis focuses on the association between the structure of health care and the process of care. This association is key to develop effective quality improvement programmes. Intervention studies have provided some insight into the key determinants of the care process. However, the question how to implement successful interventions in other settings effectively and efficiently, is still unanswered. [74] Implementation research has shown that the identification of obstacles to change is one of the key elements. These obstacles are located on the individual level, the social context of the care provision and the organisational context. [75]

1.4 Objective of this Thesis

No data are available on community pharmacy's role in the education and support of patients performing SMBG. Practice guidelines, again, describe best practice situation. In daily routine, the feasibility of diabetes care recommendations and the actual

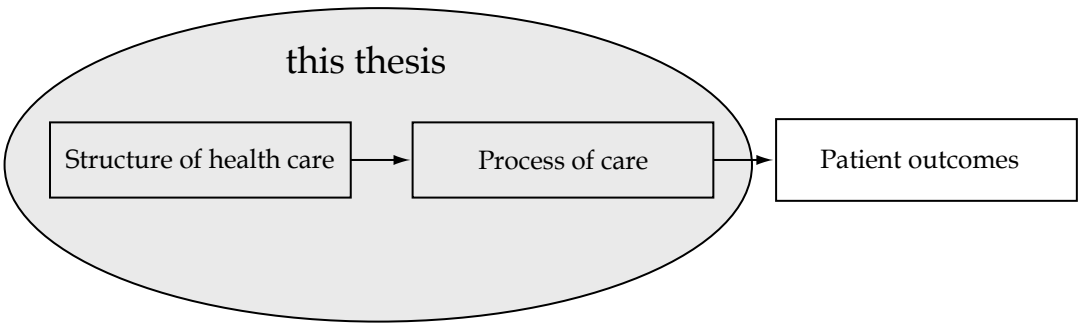

Figure 1. A schematic representation of the SPO-model.

implementation of these is diverse. [76, 77] Although it is likely that, as a result of this situation, large differences in self-monitoring services exist between community pharmacies, this is has not been the topic of much research.

The primary objective of the thesis is twofold:
- to describe the level and variation in the services provided to patients performing SMBG in Dutch community pharmacies (process of care);
- to describe the key determinants of these blood glucose self-monitoring services in community pharmacy (structure of care).

Secondary to these objectives, this thesis aims to contribute to the development of quality indicators of community pharmacy services.

1.5 Outline

The first objective is addressed in Chapter 2.1, in which a Dutch pharmacy dispensing database is used to identify differences in the proportion of patients with diabetes collecting SMBG equipment. Chapter 2.2 elaborates on this, using data from a survey among all Dutch community pharmacies on the services offered to patients performing SBMG, called self-monitoring services throughout this thesis. This chapter also discusses the relevance of definitions of self-monitoring services and diabetes care for pharmacy practice research.

In Chapter 3, the second objective is studied. It describes the factors associated with self-monitoring services. The chapter starts with a qualitative study into the perceived barriers and facilitators that community pharmacists experience when providing self-monitoring services (Chapter 3.1). Following (Chapter 3.2) is a study on the influence of geographical location on these community pharmacy services, using the same database as in Chapter 2.1. Data from the nationwide survey are used to assess the influence of local collaboration between healthcare providers involved in diabetes on the self-monitoring services of community pharmacies (Chapter 3.3). Chapter 3.4 describes patient characteristics associated with a patient's decision to collect SMBG equipment in a community pharmacy, instead of other sources of blood glucose test equipment.

The association between the frequency of use of blood glucose test strips and patient outcomes is studied in Chapter 4.

Finally, a general conclusion on the objectives of this thesis is drawn, in the light of the limitations of the study designs used. Furthermore, the implications of the findings in this thesis are discussed, especially for the development of quality indicators, together with recommendations for practice and further research (Chapter 5).

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CHAPTER 2

MEASURING COMMUNITY PHARMACY SERVICES

Hij kan de botten
in mijn lichaam zien zitten -
de blik van de valk

Akimoto Fujio 1901-1977

Dispensing of Glucose Testing Materials in Dutch Community Pharmacies

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ABSTRACT

Objective: To assess the proportion of patients with diabetes who collect blood glucose monitoring equipment for glucose testing in Dutch community pharmacy.
Methods: Data from the PHARMO-Record Linkage System, containing pharmacy dispensing records from 1991 - 1998, were used. The study population consisted of patients who received at least two prescriptions of insulin and/or oral hypoglycemic agents. Information on patient demographics, antidiabetic drug use and blood glucose monitoring equipment (blood glucose meters and test strips) was collected. Type of diabetes was determined for all incident users of antidiabetic drugs.
Main outcome measure: The proportion of patients per community pharmacy, who were dispensed blood glucose monitoring equipment at least once.
Results: The study population consisted of 11,358 patients with diabetes. The number of incident patients was 5,050, of whom 91.7% had type 2 diabetes. Twenty-nine pharmacies were included. The mean proportion of patients per pharmacy who took up test strips at least once was 30.1% (sd = 6.7%), and ranged from 19 to 46%. The proportion of patients who were dispensed test strips was almost three times higher among type 1 than among type 2 patients (54% versus 17%).
Conclusion: Dutch community pharmacies dispense blood glucose monitoring equipment to patients with diabetes mellitus relatively infrequently, compared to published data in other countries. Substantial differences between pharmacies in dispensing of test strips exist. Further research into the determinants of the use of test strips on a patient and pharmacy level is needed.

INTRODUCTION

Diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. [1] The prevalence of diabetes in the Netherlands is estimated to be 30 per 1,000 (2000). [2]

Normoglycemia has been shown to be an important factor in the prevention of diabetic complications. [3,4] In the treatment of patients with diabetes, self-management is recognised as a means of improving glucose control. The guideline of the American Diabetes Association states that diabetes self-management education is an integral component of medical care, for both type 1 and type 2 patients. [1] Self-monitoring of blood glucose (SMBG) is considered to be a cornerstone of diabetes care. [5,6] As part of the pharmaceutical care for diabetic patients, self-management and SMBG have also become an issue in pharmacy practice. Recent national and international position statements and guidelines make the role of community pharmacies in SMBG explicit. [7-9]

Although the guidelines promote the pharmacist's role in SMBG, data on the actual support that pharmacies offer patients with diabetes are limited. Remuneration data from the Dutch Health Care Insurance Board show that the cost associated with SMBG were more than € 75 million in 2002. From reports of the Foundation of Pharmaceutical Statistics (SFK) we estimated that around 60% of these cost are made in the community pharmacy. [10] In this study, the proportion of diabetic patients who collect SMBG equipment in the community pharmacy is investigated using a large database of pharmacy records. This proportion may be considered as an indicator of the potential role of Dutch community pharmacies in SBMG.

METHODS

Setting

We used prescription data from the PHARMO-Record Linkage System (RLS) covering the period 1991 – 1998. The PHARMO-RLS has been described in detail elsewhere. [11] In brief, the system includes pharmacy dispensing records from community pharmacies linked to hospital discharge records of all 450,000 community-dwelling residents of nine population-defined areas in the Netherlands from 1985 onwards. Since almost all patients in the Netherlands are registered with a single community pharmacy, independent of prescriber, pharmacy records are virtually complete with regard to prescription drugs. Records of dispensing of medical aids may be less complete, because SMBG equipment can be dispensed without a prescription. Still, a prescription is necessary for remuneration of SMBG equipment. Hence, in most cases dispensing of blood glucose meters and test strips is recorded in the patient's medication history.

Drug use was coded according to the Anatomical Therapeutic Chemical classification index of the World Health Organization. For test strips and blood glucose meters no standard index exists. They were selected by reviewing the complete history of medical aids, based on the description in the name-field together with the number of units dispensed.

Design and study population

Only the dispensing data from pharmacies in which data was collected from 1991 until 1998 were used in this study. Patients were included in the study population if they received at least two prescriptions for an oral hypoglycemic agent (OHA, ATC-code A10B), at least two prescriptions of insulin (ATC-code A10A) or one prescription of an OHA followed by one prescription of insulin in the period between January 1991 and December 1998 (n = 11,358).

The dispensing histories of drugs and SMBG equipment were collected from the period of January 1991 until December 1998. Retrievable information per prescribed drug and medical aid included the date of dispensing, the drug name and the dispensing pharmacy. Patient information per prescribed drug, blood glucose meter or test strip included gender and the date of birth. These data were used to determine the prevalence of SMBG equipment dispensed to patients with diabetes in community pharmacies. Patients were considered belonging to the diabetic population of a pharmacy if they filled at least two prescriptions for insulin or an oral hypoglycemic agent in that particular pharmacy.

The type of diabetes could only be determined for the incident patients. Therefore, a selection of all incident patients from the total diabetic population was made. All patients with at least six months of drug-dispensing records available before the first prescription of insulin or an OHA were included in this selection. Type 1 was defined as at least two prescriptions of insulin, no more than one prescription of an OHA and not older than 50 years at the start of insulin therapy. Insulin-using patients older than 50 years were not included as incident patients (n = 194), because it was considered unlikely that type 1 diabetes was diagnosed at an age of 50 or older. These patients could have had a very poor glycemic control at diagnosis, requiring immediate start of insulin. Type 2 was defined as at least two prescriptions of an OHA. [1, 6]

Analysis

Microsoft Visual FoxPro 6.0 was used for database management. The analyses were performed using Microsoft Excel 2000 and SPSS 10.0 for Windows.

RESULTS

Description of patients and pharmacies

The study population consisted of 11,358 users (46,504 person-years) of antidiabetic drugs. The median age at the day of the first registered dispensing of an antidiabetic drug in the PHARMO-RLS was 66 years (interquartile range (IQR) = 22 years). The median follow-up in the database after the first dispensing of an antidiabetic drug was 3.8 years (IQR = 5.1 years). For the incident patients, this was 2.7 years (IQR = 3.4 years). The proportion of men was 44.6%. The number of incident patients was 5,050, of whom 4,629 (91.7 %) had type 2 diabetes.

Dispensing data from 29 pharmacies were used. Fourteen pharmacies were not included in the analysis, because data on dispensing were not complete from 1991 until 1998.

The characteristics of the patient population with diabetes in a pharmacy are shown in **Table 1**. The mean number of patients with diabetes per pharmacy in the eight-year period varied from 182 to 823 (mean = 439; sd = 139). The mean age of the pharmacy's patients was 62.6 y (sd = 4.0 y; range 56.7 – 69.9 y). The mean proportion of type 2 patients among incident patients with diabetes per pharmacy was 92% (sd = 2.7%) and ranged from 84% to 96%.

Table 1. The characteristics of the population of patients with diabetes per pharmacy (29 pharmacies).

	Mean (sd)		Range
Patients with diabetes mellitus [a]	439	(139)	182 – 823
Incident patients with diabetes mellitus [a]	189	(57)	78 – 353
Age [b]	62.6	(4.0)	56.7 – 69.9
Male gender, %	44.3	(3.8) [c]	38 – 51
Type 2 diabetes mellitus, % [d]	92	(2.7) [e]	84 – 96

[a] At least two antidiabetic drug dispensed during follow-up.
[b] Age at the date of first recorded prescription of antidiabetic drugs. p-Value Kruskal-Wallis test <0.001.
[c] p-Value of Chi-square test < 0.001.
[d] Among incident patients.
[e] p-Value of Chi-square test is 0.043.

Test strips and blood glucose meters uptake

During the observation period, the pharmacies dispensed SMBG equipment on 33,464 occasions. This corresponds to 0.72 occasions per patient per year. A total of 33,020 times glucose test strips and 410 times (1.2%) a blood glucose meter was dispensed. In 34 cases (0.1%) the type of SMBG equipment could not be classified. Of all test strips, dispensing of blood glucose test strips (0.70 times per patient per year; 49 test strips per patient-year) was far more frequent than urine glucose testing (0.01 times per patient per year; less than one test strip per year per patient). A total of 3,593 patients (31.6%) were dispensed test

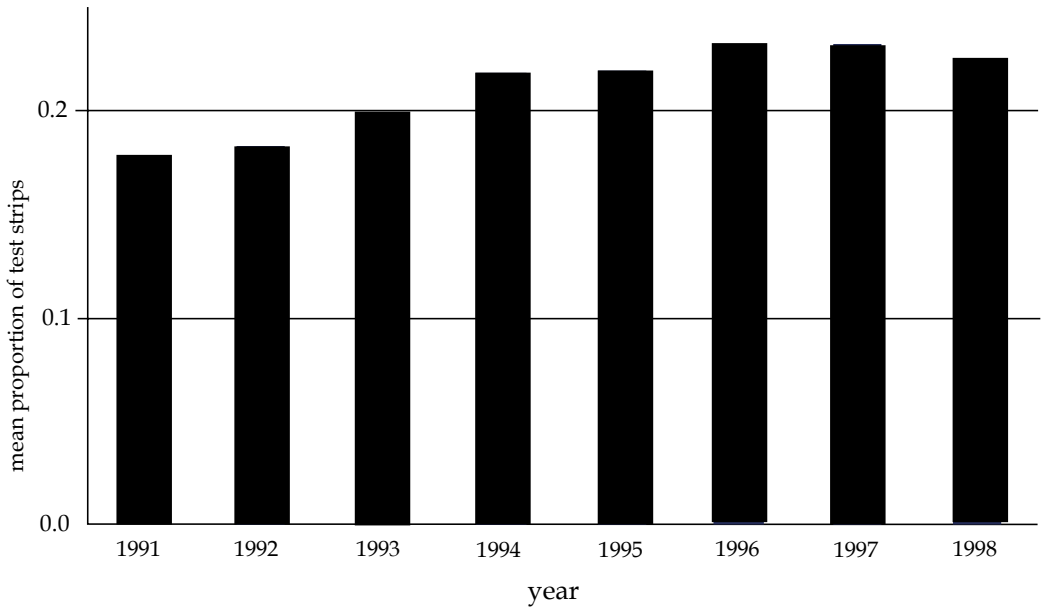

Figure 1. The mean proportion of patients with diabetes mellitus per pharmacy per year who received blood glucose test strips at least once.

strips at least once. When stratified by type of diabetes, the proportion of type 1 patients who received test strips at least once, was 54%. For type 2 patients this was 17%.

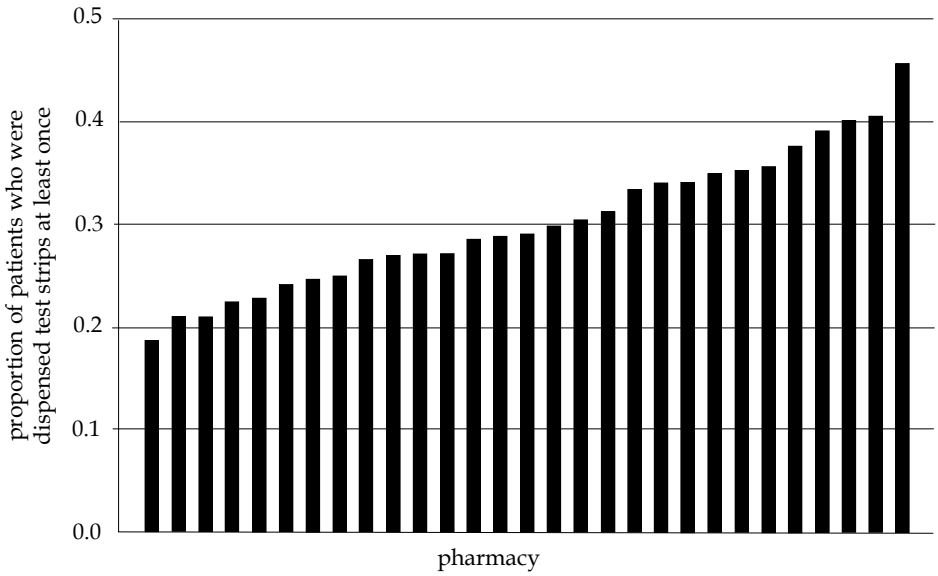

Figure 2. The proportion of patients with diabetes mellitus per pharmacy who were dispensed blood glucose test strips in a community pharmacy at least once during the period from 1991 until 1998. The proportions are ranked from low to high.

The mean number of dispensing of test strips was 142 (sd = 62) per year per pharmacy. For the blood glucose meters, this number was 1.8 (sd = 0.9). **Figure 1** shows the time trend in dispensing of test strips between 1991 to 1998.

The proportion of patients per pharmacy that were dispensed test strips at least once is displayed in **Figure 2**. The data are stratified per pharmacy and ranked from low to high to indicate the differences in dispensing. The mean proportion is 30.1% (sd = 6.7%). The substantial variation in dispensing of test strips on a pharmacy level is underlined by the wide range (19% - 46%).

DISCUSSION

This study shows that 70% of all patients who received at least two prescriptions of antidiabetic drugs between 1991 and 1998, did not obtain any test strips from community pharmacies. Comparative data to interpret the significance of this finding for pharmacy practice is limited. In a study using pharmacy prescription data from Tayside, Scotland (study period from January 1993 until December 1995, UK), Evans et al. reported that 16% of all type 1 patients and 21% of all type 2 patients using insulin obtained no test strips. [12] Data from the Northern California Kaiser Permanente Study (study period January 1996 until December 1996, USA), which also used pharmacy data, showed that 25% of all type 1 patients were not distributed any test strips. [13] For type 2 patients this was 43%. Our data show that the proportion of non-users in Dutch community pharmacies is higher for all patient categories. However, the organisation of the health care system in Scotland or the USA is not the same as in the Netherlands. Firstly, the remuneration of test strips in the Netherlands for type 2 patients was very limited during the study period, compared to the situation in the Kaiser Permante Study. Secondly, Dutch diabetic patients can acquire their SMBG equipment from third parties, for instance by mail order or from diabetes nurses. In the Kaiser Permanente Study, this was not very probable (AJ Karter, personal communication).

Because of the third party distribution, a low proportion of users of test strips in a pharmacy does not imply an unsatisfactory quality of care to diabetic patients. This non-pharmacy distribution is not recorded in the pharmacy dispensing database. Unfortunately, no data have been published on the market share of the community pharmacy, so extrapolating these findings to the frequency of use of test strips in all patients with diabetes is not possible. Furthermore, though SMBG is widely promoted as a means of patient empowerment, the evidence for the clinical effectiveness of the practice guidelines is still limited. In a meta-analysis by Coster et al., no significant reduction in HbA1c (A1c) was found in type 2 patients using SMBG compared to non-users. In type 1 patients, unconfounded studies do not provide convincing evidence for an effect of SMBG on A1c levels. [14]

The effectiveness of SMBG is also influenced by the usage patterns of test strips and the compliance of the patients. Studies suggest that adherence to SMBG is low [15, 16], although they vary in the definition of adherence. Furthermore, the optimal frequency of measurement is uncertain, especially in type 2 diabetes. [5] Some data has been published on incorrect use of test strips, potentially resulting in unreliable measurements. [17-19]

Blood glucose meters were dispensed among only 11% (410 individuals) of all users of test strips. However, a meter is required for viewing the result of a test strip measurement. This suggests that the data are incomplete with regard to the actual number of blood glucose meters dispensed. A possible explanation for this is the industry's practice of giving away free starter kits, including a blood glucose meter, some test strips and lancets for blood sampling. These free kits are not remunerated and hence are not recorded in the patient's dispensing history. Another reason might be that in some instances patients are given a meter on loan from the pharmacy. Especially when patients only require SMBG for a short period of time, for example during changes in pharmacotherapy, the pharmacy only records the dispensing of the test strips.

Of all prevalent cases of diabetes in the Netherlands, about 10 – 15% has type 1 diabetes. [2] The relatively low proportion of type 1 patients in our study is due to the definition of an incident patient and the fact that we did not have data on diagnosis. An incident patient is defined as at least six months of dispensing history before the first antidiabetic drug is dispensed. Because type 1 patients have in general less co-morbidity at the date of diagnosis and are younger at the time of diagnosis, they are less likely to be included as an incident patient than type 2 patients. This lowers the proportion of type 1 patients in the study population.

However, if we had included prevalent users of antidiabetic drugs, misclassification of insulin users would have occurred. About 25% of all type 2 patients use only insulin therapy to control their hyperglycemia. Furthermore, the underestimation of the number of type 1 patients, will only have a small effect on the proportion of users of test strips per pharmacy. Based on the prevalence of type 1 in the general population, an underestimation of 50% and distribution of test strips in community pharmacy to 75% of type 1 patients will lower the proportion of users of test strips by 4%. For the observed differences in dispensing of test strips between pharmacies, this will have even less effect.

The characteristics of the diabetic population varied between pharmacies, as shown by mean age, gender and to a lesser extent the proportion of type 2 patients. This might partially explain the observed differences in the prevalence of dispensing of test strips per pharmacy. Further research into the determinants of the use of test strips on a patient and pharmacy level is needed.

CONCLUSION

The prevalence of dispensing SMBG equipment to patients with diabetes by Dutch community pharmacies is relatively low. Substantial differences between pharmacies in the prevalence of dispensing of test strips exist. Whether this indicates that not all pharmacies provide best practice according to current guidelines needs further investigation.

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The Association Between Blood Glucose Self-Monitoring Support Provided by Community Pharmacy and Its Determinants is Dependent on the Definition of Self-Monitoring Support

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Submitted

ABSTRACT

Objective: To determine if the association between the level of community pharmacy diabetes services and six of its reported determinants is influenced by the definition of these services.

Study design and setting: Cross-sectional survey among 97% of all Dutch community pharmacies (1,642) registered in 2004. Seven definitions of self-monitoring support (support to patients performing self-monitoring of blood glucose) were constructed: one based on the Dutch pharmacy practice guideline (containing five activities related to patient counselling, calibration and dispensing), one based on patient counselling activities only and five definitions based on each separate activity. Associations between determinants and the different definitions of self-monitoring support were expressed as odds ratio (OR) and 95% confidence intervals (95% CI). All definitions were compared to the practice guideline definition. Multivariable models of self-monitoring support according to the different definitions were compared.

Results: The ORs of 14 of the 48 possible comparisons of different definitions were significantly different from one. The standardised difference ranged from 1.42 (95% CI: 1.01–1.90) to 3.05 (95% CI: 1.51-4.61). Three out of six predictive models retained different determinants compared to the multivariable model of self-monitoring support based on the guideline.

Conclusion: The association between self-monitoring support and its determinants is dependent on the definition of self-monitoring support.

INTRODUCTION

Pharmaceutical care interventions have shown that community pharmacists can have a significant impact on patient outcomes. [1-4] International and national guidelines encourage community pharmacies to take active interest in care for diabetic patients. [5-7]

What exactly comprises the community pharmacy services to diabetes patients is still widely discussed. Intervention studies aiming to improve diabetes care in community pharmacy all emphasise different activities. For example, Jaber et al. focused on improvement of diabetes care on patient counselling, while the Asheville project and Rothman et al. also included structured follow-up of patients in their diabetes care improvement program. [2, 4, 8] Pharmacy practice guidelines, although generally reviewing similar topics, vary on the level of detail of the recommendations. [5-7] Moreover, they only describe the best practice situation. In daily routine, the feasibility of these recommendations and the actual implementation is diverse. [9, 10]

This diversity in the aspects that constitute diabetes care is a key issue, especially for implementation research. Studies into implementing pharmaceutical care report, among other things, physical lay-out of the pharmacy, computer support, knowledge and competence as well as lack of time and reimbursement as key implementation factors. [11, 12] Moreover, the impact of these structural factors for successful implementation may not be the same for different aspects of (diabetes) care. For example, improving the pharmacy team's knowledge is likely to be an important aspect when implementing educational programs on life style changes. It is probably less relevant for areas in which, traditionally, pharmacies have more expertise, such as improving patient compliance.

The objective of this study was to determine if the association between structural pharmacy-related factors and the provision of support to patients performing self-monitoring of blood glucose (self-monitoring support) changes when different definitions of self-monitoring support are used.

METHODS

Setting and study design

We gathered data using a cross-sectional survey among all Dutch community pharmacies registered in January 2004 (n = 1,692). Data acquisition comprised two stages. First, semi-structured interviews were held with seven pharmacists to identify relevant structural factors potentially associated with self-monitoring support. These seven pharmacists also pre-tested the final survey and found it to be comprehensive. A pilot study was performed among 50 randomly selected community pharmacies to determine feasibility as well as a limited validation on variability in responses and comprehensibility. If an item was checked by less than 10% of the respondents, the item or the response categories were

rephrased or deleted. The results of these questionnaires were excluded from the final analysis. The questionnaire is included in Appendix 1.

In the second stage, a mailing was sent in February 2004 to all Dutch community pharmacies not involved in the pilot study. It was addressed to the senior pharmacist in the pharmacy. The invitational letter stated that the internet-based survey (respondents could fill in the questionnaire by accessing an exclusive internet site) was intended for the pharmacist responsible for the (diabetes) care activities. Participants could respond anonymously. After three weeks, all pharmacies received a reminder and a paper version of the survey, which could be returned at no cost.

Of all respondents, sites which functioned as an annex of another pharmacy (limited services available and only open a few hours per day) were excluded. In most regions only a few pharmacists dispense outside of office hours. This 'out of hours' service rotates among all pharmacies in that region. However, in some regions, a specialised 'out of hours' pharmacy has been created, which conducts all 'out of hours' dispensing. These pharmacies were excluded from the analysis as well.

Definition of self-monitoring support

Seven different definitions of self-monitoring support were constructed (see **Table 1**). All definitions were based on the Dutch pharmacy practice guideline. [5] This guideline defines five separate support activities in three areas of pharmacy services to patients performing self-monitoring of blood glucose (SMBG). These areas were: patient counselling, calibration of SMBG equipment, and providing blood glucose meters at no costs to patients performing SMBG for a short period. Patients in the Netherlands who use oral hypoglycemic agents usually do not receive (full) reimbursement of the blood glucose meter; therefore some pharmacists accommodate patients with one, to reduce initial costs of self-monitoring. Counselling was subdivided into three domains: choice of a suitable blood glucose meter, the operation of that blood glucose meter and performing the test procedure. Respondents were asked which support activities they performed. All responses were dichotomous (yes or no). Services that were not prompted by the pharmacy, for example patient counselling after a specific question from the patient, were excluded.

Definitions 1 to 5 represented the five separate aspects of self-monitoring support. For definition 6, we only included the aspects on patient counselling activities. As reference we used the practice guideline definition, comprising all five aspects of self-monitoring support (definition 7).

Pharmacy-related determinants

Apart from data on self-monitoring support, the 47-item questionnaire also gathered information on five structural factors that were mentioned in the first stage of the study as being essential to the implementation: availability of separate counselling area, having

Table 1. Description of the different definitions of blood glucose self-monitoring support based on the Dutch pharmaceutical care guideline for type 2 diabetes mellitus. [5, a]

	Description
Definition 1	The community pharmacy supports patients with the calibration of their blood glucose meters (45.8, 270)
Definition 2	The community pharmacy provides patient counselling on the type of blood glucose meter most suitable for them (41.9, 247)
Definition 3	The community pharmacy provides patients with an instruction on the operation of their blood glucose meter (69.5, 410)
Definition 4	The community pharmacy provides patient counselling on the procedure of blood glucose testing (64.7, 382)
Definition 5	The community pharmacy temporarily accommodates patients with a blood glucose meter at no cost (34.9, 206)
Definition 6	The community pharmacy performs at least three of the counselling activities mentioned in definitions 2 to 4 (65.1, 384)
Definition 7	The community pharmacy performs at least three of the activities mentioned in definitions 1 to 5 (55.3, 326)

[a] Between brackets the number of respondents who reported to provide self-monitoring support according to the definition % (n).

a pharmacy technician specialised in diabetes, perceived knowledge of the pharmacy's team on SMBG, perceived workload, and lastly existence of a regional agreement on the division of roles in self-monitoring support. These structural factors were reported as relevant in previous studies into barriers for implementation of pharmaceutical care and diabetes care. [11-16] Moreover, the factors represent key issues in many intervention programmes intended for improving diabetes care in community pharmacies (training, specialisation, improving collaboration).

Perceived knowledge of the pharmacy team on SMBG was collected with three statements concerning the ability of the pharmacy staff to provide self-monitoring support. Workload was collected as agreement to a statement on high workload being a reason not to provide support to all patients. All four items were scored on a four-point scale (entirely disagree to entirely agree). Because respondents might not always be the actual proprietor of the pharmacy, we only included respondents who agreed to a statement that they could independently determine the level of services in self-monitoring support.

Analysis

The results of the three questions regarding a team's knowledge showed significant correlation. Therefore, we calculated the sum score of all questions regarding knowledge, ranging from zero to nine. The sum score was categorised into three groups, representing the tertiles. The first tertile (a sum score of five or less) was used as reference.

For definitions 6 and 7, the total number of activities was calculated. Since no consensus on the relative importance of these activities exists, all activities were weighed equally. For the practice guideline definition, we classified a pharmacy as a low level service

pharmacy (LLS pharmacies; performing two or less of the five separate aspects) or a high level service pharmacy (HLS pharmacies; providing three, four or all of the aspects). Definition 6 was categorised as high level counselling services (two or all counselling activities) or low level counselling services (none or only one counselling activity).

To study the effect of different definitions on the associations with the structural factors, we first calculated odds ratios (ORs) for the association between the five structural factors and provision of self-monitoring support according to the different definitions using logistic regression. These ORs were compared both visually and statistically. However, since all ORs were derived from the same dataset, comparison using confidence intervals (95% CI) of the ORs was not possible. We therefore calculated a standardised odds ratio by dividing the OR for the association between a structural factor and the provision of self-monitoring support, according to definitions 1 to 6, by the OR for the association between that structural factor and providing self-monitoring support based on definition 7. A mean standardised OR was determined for 2,000 replications of the dataset using a bootstrapping method. The 95% CI of this standardised odds ratio were derived from the distribution of these replications. The mean standardised OR was calculated for every structural factor separately. Using this method we compared definitions 1 to 6 with the definition based on the practice guideline (definition 7).

The univariable models were extended to multivariable predictive models. We used backwards elimination based on changes in log likelihood ratio with a cut-off value of 0.10 and compared which structural factors remained statistically significantly associated with the provision of self-monitoring support.

RESULTS

Of all 1,642 pharmacies in the main study, 757 returned the questionnaire. After exclusion of annexes and 'out of hours' pharmacies, 724 (44%) remained. A total of 134 respondents did not agree with the statement that they could decide on the pharmacy's policy with diabetes care independent of the actual proprietors of the pharmacy.

Among the remaining 590 pharmacies, 65% of the respondents offered patient counselling on the testing procedure, 70% offered instruction on the operation of the blood glucose meter and 42% provided counselling on the choice of blood glucose meter. Calibration of blood glucose meters was reported by 46% of the respondents and providing a patient with a meter at no cost by 35% of the respondents. Using definition 7 (practice guideline), 45% pharmacies were classified as LLS pharmacies and 55% as high level service pharmacies.

Figure 1 reports the odds ratios of the univariable associations between the different definitions of self-monitoring support and the five structural factors. All associations but

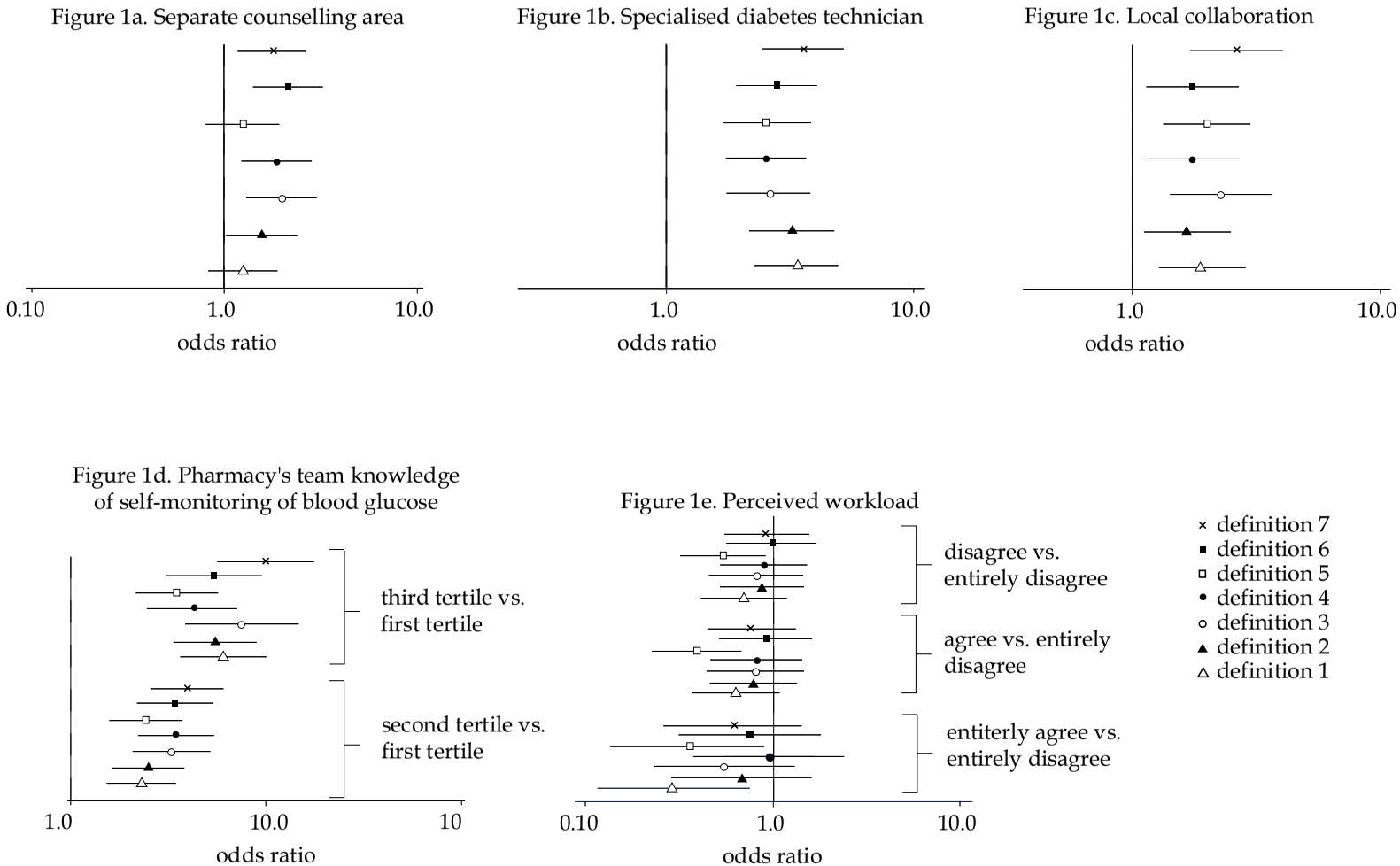

Figure 1. Crude association between structural factors and self-monitoring support according to different definitions (odds ratio and 95% confidence intervals).

that of 'perceived workload' were stronger for definition 7 than for the separate aspects or of the level of counselling services. This is shown by the OR being further away from 1. However, the associations are robust, indicated by the fact that for every structural factor, they all point in the same direction.

As **Table 2** illustrates, the standardised ORs shows that the strength of the associations of the self-monitoring support is not the same for the separate definitions. The association between self-monitoring support as described in definition 7 and the structural factors is often stronger than the association between the separate aspects of self-monitoring support and the structural factor. In 14 out of the 48 comparisons, these differences were statistically significant. Especially for 'knowledge', 'specialised diabetes technician' and 'local collaboration', the association with support as described in definition 7 is different compared to the association with its separate aspects. Interestingly, the strength of the association between the structural factors also varied amongst the separate aspects (definitions 1 to 5). Nevertheless, the differences were less pronounced (data not shown).

Limiting the definition of self-monitoring support only to patient counselling activities (definition 6), resulted in different associations with three out of the five structural factors compared to definition 7. Only the association with 'separate counselling area' and 'perceived workload' was not significantly different between these two definitions.

As can be seen in **Table 3**, the results of the multivariable model using different aspects of self-monitoring support led to dissimilar models. Only 'knowledge' was statistically significant in all models and 'workload' did not remain associated in any model. Compared to the multivariable model with self-monitoring support defined according to definition 7, only self-monitoring support defined as providing patients with a blood glucose meter at no cost and counselling on testing procedure were similar. In these three models, 'specialised diabetes technician', 'local collaboration' and 'knowledge' remained statistically significantly associated with the outcome. Models of the other aspects did not include 'local collaboration' or did include 'separate counselling area'. The aspects pertaining information on counselling activities all resulted in different multivariable models. Moreover, when we only included patient counselling activities in our definition, we observed a multivariable model that was different from definition 7 of self-monitoring support as well as from the models with self-monitoring support defined according to the separate aspects.

Correlation among the different aspects was relatively high. The minimal Spearman R^2 was 0.178 for the bivariate correlation between lending of blood glucose meter and counselling on the type of blood glucose meter. The highest R^2 was 0.667 for the correlation between counselling on the testing procedure and instruction on the operation of blood glucose meters. All correlations were statistically significantly different from 1.

Table 2. Ratio of the association between different structural factors and self-monitoring support according to definitions 1-6 and the association between different structural factors and self-monitoring support according to definition 7. [a]

	Def. 1	Def. 2	Def. 3
Separate counselling area			
available	1.45 (0.96 – 2.05)	1.15 (0.82 – 1.53)	0.90 (0.66 – 1.19)
not available	reference	reference	reference
Specialised diabetes technician			
available	1.10 (0.74 – 1.63)	1.13 (0.81 – 1.46)	1.42 (1.01 – 1.90)
not available	reference	reference	reference
Local collaboration on self-monitoring support			
available	1.43 (0.91 – 2.11)	1.60 (1.14 – 2.18)	1.17 (0.80 – 1.66)
not available	reference	reference	reference
Knowledge of self-monitoring [b]			
first tertile	reference	reference	reference
second tertile	1.77 (1.16 – 2.67)	1.61 (1.14 – 2.27)	1.22 (0.84 – 1.72)
third tertile	1.74 (0.84 – 3.05)	1.87 (1.13 – 2.92)	1.35 (0.78 – 2.14)
Perceived workload is a reason for not giving self-monitoring support to all patients			
entirely agree	2.46 (0.84 – 5.41)	0.98 (0.41 – 2.16)	1.17 (0.50 – 1.93)
agree	1.28 (0.72 – 2.12)	0.99 (0.64 – 1.42)	0.98 (0.62 – 1.56)
disagree	1.38 (0.80 – 2.15)	1.06 (0.70 – 1.54)	1.16 (0.73 – 1.75)
entirely disagree	reference	reference	reference

	Def. 4	Def. 5	Def. 6
Separate counselling area			
available	0.97 (0.72 – 1.29)	1.45 (0.94 – 2.10)	0.83 (0.64 – 1.06)
not available	reference	reference	reference
Specialised diabetes technician			
available	1.44 (1.05 – 1.95)	1.44 (0.91 – 2.10)	1.31 (1.00 – 1.73)
not available	reference	reference	reference
Local collaboration on self-monitoring support			
available	1.51 (1.08 – 2.03)	1.34 (0.84 – 1.92)	1.51 (1.15 – 2.06)
not available	reference	reference	reference
Knowledge of self-monitoring [b]			
first tertile	reference	reference	reference
second tertile	1.15 (0.79 – 1.60)	1.67 (1.04 – 2.66)	1.16 (0.82 – 1.53)
third tertile	2.43 (1.55 – 3.58)	3.05 (1.51 – 4.61)	1.86 (1.24 – 2.65)
Perceived workload is a reason for not giving self-monitoring support to all patients			
entirely agree	0.67 (0.27 – 1.18)	1.94 (0.79 – 4.52)	0.82 (0.41 – 1.38)
agree	0.97 (0.63 – 1.52)	2.02 (1.12 – 3.40)	0.86 (0.58 – 1.23)
disagree	1.05 (0.68 – 1.59)	1.77 (0.98 - 2.79)	0.95 (0.63 – 1.33)
entirely disagree	reference	reference	reference

Def. = Definition.

[a] Bootstrap-method with 2000 replications, mean (95% Bca confidence limits).

[b] first tertile (sum score: 0 – 5); second tertile (sum score: 6); third tertile (sum score: 7 – 9).

Table 3. Factors associated in a multivariable model using different definitions of self-monitoring support. [a]

Def.	Specialised diabetes technician [b]	Separate counselling area [b]	Work-load [b]	Local collaboration [b]	Knowledge of pharmacy team [b]
1	2.72 (1.74– 4.23)				2.07 (1.33 – 3.20) 4.47 (2.63 – 7.60)
2	2.51 (1.60 – 3.94)				2.20 (1.41 – 3.42) 4.12 (2.45 – 6.92)
3		1.69 (1.06 – 2.70)		1.93 (1.19 – 3.13)	2.95 (1.83 – 4.75) 6.16 (3.10 – 12.2)
4	1.90 (1.24 – 2.92)			1.46 (0.94 – 2.28)	2.98 (1.88 – 4.74) 3.35 (1.89 – 5.96)
5	1.73 (1.10 – 2.73)			1.66 (1.10 – 2.49)	2.28 (1.46 – 3.58) 2.43 (1.45 – 4.05)
6	1.92 (1.25 – 2.96)	1.71 (1.08 – 2.72)			2.86 (1.79 – 4.55) 4.66 (2.52 – 8.60)
7	2.40 (1.55 – 3.73)			2.11 (1.34 – 3.32)	3.54 (2.25 – 5.57) 6.49 (1.45 – 11.9)

Def. = definition.
[a] Backwards elimination, n = 478.
[b] Association only presented for factor that significantly improved multivariable the model (p-value of log likelihood ratio > 0.1)

Correlations between the separate aspects on self-monitoring support and the composite score on self-monitoring support ranged from 0.402 to 0.677 (all $p < 0.01$).

DISCUSSION

This is one of the first studies to assess the consequence of the fact that pharmaceutical care is not a single activity, but comprises many different aspects in pharmacy practice research. We found that associations between structural factors and separate aspects of self-monitoring support were often different from associations between structural factors and composite scores of self-monitoring support.

Variation in the associations with structural factors was not only observed for the five separate support activities defined in the practice guideline. Also when we compared two different ways to sum self-monitoring support (definition 6 and definition 7), the associations with the structural factors were statistically different.

These differences in the strength of the associations were observed in the univariable models. Furthermore, multivariable analysis resulted in dissimilar models. However, probably as a result of the strong correlation between the structural factors, the effect of different definitions of self-monitoring support was most pronounced for the univariable associations.

With respect to our findings, improvement of self-monitoring support is best achieved through investing in 'pharmacy's team knowledge' of SMBG. Since our results imply that this structural factor is associated with all separate aspects of self-monitoring support as well as with the definition based on the practice guideline, it is the most effective precondition to change. On the other hand, 'perceived workload' was not associated with any aspect of self-monitoring support, indicating that it is not relevant for the provision of community pharmacy support to patients with diabetes. However, due to the cross-sectional nature of this study, a longitudinal study is required to verify this.

We developed our own questionnaire, since to our knowledge, no validated questionnaire on structural factors in diabetes care or pharmacy's self-monitoring support exists. Because we had no gold standard to compare our results, we focused on the face-validity and content validity. The pilot study showed sufficient response and contrast on our main determinants and outcome variables.

Limitation

Response rates for this type of study are generally low, as it was with our questionnaire. Non-response can introduce a significant bias if for example pharmacists with no interest in pharmaceutical care decline to participate. However, had this been true, we would have expected a relatively high proportion of respondents who had participated in the nation-wide diabetes care improvement project. Yet, 48% of the pharmacists had participated in this nation-wide project, which is a similar response rate compared to the nation-wide participation rate of this improvement project (45%). [17]

Implications

We used self-monitoring support as an example of pharmaceutical care to diabetes patients, since it was considered a care activity that could be made operational without much risk for information bias. It is a relatively homogenous topic that has distinct aspects recognisable to all respondents. It is somewhat difficult to infer to what extent our conclusions apply to other fields of pharmaceutical care. Defining care on a higher hierarchical level would result in including more diverse activities. In that case, observed differences in associations between different aspects of care and structural factors would probably also become larger.

As our results show, the different activities comprising self-monitoring support cannot be compared with respect to the different structural factors associated with them. This implies that structural factors are inadequate quality indicators, at least when determining the quality of 'self-monitoring support' by community pharmacies. The opposite is also true. When measuring processes in a community pharmacy, it is imprudent to use a process that in fact comprises a plethora of activities. This also affects studies that use self-monitoring support as outcome variable, for example practice research of implementation strategies. Without proper and unequivocal definitions of

the observed process, incorrect conclusions on facilitators and barriers of diabetes care in community pharmacies could be drawn.

CONCLUSION

The association between structural factors and self-monitoring support varies when different definitions of self-monitoring support are used. However, this variation depends on which structural factor is studied. Our data do not answer the vital question of which definition is most appropriate for intervention and implementation studies. To clarify this, more research into the relation between the process of self-monitoring support and patient outcomes is needed. Still, we have shown that it is of pertinent importance that studies on implementation of diabetes care activities and diabetes care intervention research explicitly state which aspects comprise their definition of diabetes care.

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CHAPTER 3

KEY DETERMINANTS OF COMMUNITY PHARMACY SERVICES

Op het winters strand
raap ik gebroken schelpen,
door de zee aangespoeld.

Ueda Gosengoku 1933-1997

Community Pharmacists' Perceptions of Services to Patients Performing Blood Glucose Self-monitoring

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ABSTRACT

Objective: To describe the key elements that influence the provision of services by community pharmacists to patients performing self-monitoring of blood glucose (SMBG).

Setting and methods: Semi-structured group interviews with 18 Dutch managing community pharmacists. The interviews were transcribed verbatim and analysed through an inductive approach using open and axial coding. Interaction between the themes emerging from the transcripts was analysed using a constant comparison technique.

Key findings: Pharmacy team's competence, collaboration, competition and motivation were recurrent themes in all group interviews. Competence consisted of knowledge, experience and confidence. Collaboration described strategies in which community pharmacists worked together with other healthcare professionals. Competition consisted of actions of other persons or organisations aimed at supporting patients with SMBG. Motivation illustrated the actual or perceived results of the services for that particular community pharmacy.

Conclusion: Collaboration and competition were linked to competence by their ability to affect knowledge, efficiency and confidence. Pharmacies' competence in self-monitoring services was perceived as low, compared to their competence in drug dispensing and medication counselling activities. This was related to participants' motivation and their willingness to provide self-monitoring services.

INTRODUCTION

Diabetes is a chronic illness that requires continuing medical care to reduce the risk of long-term complications. [1-3] The two most frequently diagnosed types of diabetes are type 1 and type 2 diabetes. Both have hyperglycemia (elevated blood glucose levels) in common, but they differ in pathophysiological origin. An estimated 171 million people suffer from diabetes world-wide. [4] Especially long-term complications are associated with high morbidity, high costs and a decrease in quality of life. [5-9]

The self-monitoring of blood glucose (SMBG) is considered to be an integral part of the treatment plan of a patient with diabetes mellitus, especially for patients using insulin. [1,10] For a beneficial effect of SMBG on patient outcomes, proper self-monitoring technique, calibration and maintenance of blood glucose meters are essential. [1] At the same time, the self-monitoring process is also a common source of errors. [11-13] Therefore, patient education and regular assessment of a patient's skills and the quality of the SMBG equipment is needed.

National and international practice guidelines state that community pharmacists can support patients with counselling and follow-up on self-monitoring. [14-16] Even though various projects have been developed in the Netherlands to support community pharmacies in becoming involved in care for patients performing SMBG, relatively few have succeeded in implementing these services in daily practice. In a recent survey among 40% of the Dutch community pharmacies, Ploum et al. reported that only about one third of the pharmacies actively inquired into the patient's need for instruction on the use of the blood glucose meter. [17] Similar results were found using a cross-sectional survey among all Dutch community pharmacies. [18]

This suggests that many Dutch community pharmacists experience barriers for the implementation of this aspect of diabetes care. The aim of this study was to describe the key elements that influence the provision of services by community pharmacists to patients performing self-monitoring of blood glucose.

METHOD

Setting

Since decision-making in a community pharmacy in the Netherlands is primarily the responsibility of the managing pharmacist, this was our group of interest. If they were not able to participate, we invited the pharmacist who was most involved in diabetes care.

Participants were recruited from different departments of the Royal Dutch Society for the Advancement of Pharmacy. Community pharmacies are grouped in departments based on their geographical location. They were sampled on either affinity with diabetes care services or knowledge of the local diabetes care situation, by approaching pharmacists from a practice research network and members of the board of the departments. We aimed to also include pharmacists who were already providing self-monitoring services. Since previous studies have shown that the prevalence of these services is relatively low, we approached pharmacists who were likely to have implemented these services.

Group interviews

Four group interviews were performed. Letters were sent to 81 managing pharmacists, in which the general objective and the format of the study were outlined. When interested in participating, participants could fax or return the invitation in acceptance. Payment (€ 50) and travel expenses were offered. After two weeks, all non-respondents were contacted by telephone.

The group interviews were held at three different locations, all conveniently accessible for the participants. Discussions were scheduled to last about 120 minutes and were facilitated by an experienced moderator (psychologist) to minimise investigator bias. The principal investigator (MJS, pharmacist) was present at all group interviews. All discussions were semi-structured. In the first three group interviews, three self-monitoring support activities were discussed: offering follow-up on SMBG equipment and self-monitoring technique, patient counselling on first dispensing of a blood glucose meter and counselling on the interpretation of SMBG results. The order of the topics was rotated in every group interview. The services were discussed using a semi-structured topic guide, based on the quality improvement model of the European Foundation of Quality Management. [19] This model defines nine areas that are relevant for improvement of quality in an organisation divided into enablers (leadership, people, policy & strategy, partnerships & resources), process, and results (people results, customer results, society results and key performance results). This model has been proposed as useful in Dutch community pharmacies. [20] Based on preliminary results of the first three interviews, the last group interview focused on the participant's attitude towards the relevance of diabetes care for a community pharmacy. All discussions and interviews were audiotaped, transcribed and anonymised.

Analysis

The principal investigator checked all transcripts against the original recordings. Coding of the transcript of the first two group interviews was performed manually by the principal and the co-investigator (HT, pharmacist) separately. The coding was then compared and any discrepancies were discussed until consensus was reached. Subsequent coding was done by the principal investigator. Validity and consistency of the coding was verified by HT.

The transcripts of the first two group interviews were analysed in terms of concepts derived from literature on professionalisation [21-23] and implementation of pharmaceutical care. [24] Through an inductive approach of open and axial coding [25], we constructed a further coding system with which we coded all transcripts. Open coding is the process through which concepts are identified and their properties and dimensions are discovered. In axial coding categories (concepts that stand for central ideas in the data; generally, these categories are more abstract, containing several concepts) are linked on the level of these properties and dimensions. In the transcripts from the third and fourth session, no new themes were discovered, implying data saturation.

Competence, collaboration, competition and motivation were recurrent themes among all group interviews and participants. A constant comparison approach of the four sessions was used to study the interaction between these themes.

RESULTS

The study population included 18 community pharmacists from 8 of the 20 departments and 15 different urbanised areas. Community pharmacies in the Netherlands are relatively large. The provide their services to approximately 9,000 patients; the pharmacy teams consisted of five to six full-time positions for technicians and one to two pharmacists. One pharmacy sent their pharmaceutical manager. This is a position for senior pharmacy technicians, who have finished additional training. They are responsible for co-ordinating and improving routine work processes, including pharmaceutical care activities. **Table 1** describes the characteristics of the participants.

Competence

A recurrent theme in the group interviews was the pharmacy team's competence. Knowledge, experience and confidence were the main properties that linked competence to the provision of self-monitoring services.

All pharmacies dispensed SMBG equipment, but this was only on occasion and it was decreasing. Most of the pharmacies had just recently started organising follow-up events aimed at checking blood glucose meters and testing procedure. None of the pharmacies was providing counselling on the interpretation of SMBG results yet.

Pharmacists did not perceive the content and the process of self-monitoring services as difficult to master. Still, lack of knowledge was one of the elements that explained this limited involvement in self-monitoring services. As one pharmacist said:

With us, knowledge is not yet optimal to such an extent that you can very easily advertise, can elaborate. So, it's also not actively offered. [I, session 2, participant 2] (The original Dutch quotations are included in Appendix 2)

Table 1. Characteristics of the participants.

	Number of participants
Gender	
male	10
female	8
Years of practice in community pharmacy	
0 – 2	3
2 – 5	1
5 –10	4
more than 10	10
Function in community pharmacy	
managing pharmacist	12
second pharmacist	5
other	1
Type of income from pharmacy	
owner	6
salaried	12

Furthermore, as a result of this low prevalence of self-monitoring services, participants felt that not all technicians were able to build up enough routine. In turn, the limited experience with self-monitoring services negatively influenced their team's self-confidence in providing those services. For example, one participant explained:

The disadvantage is that it's happening less and less and that you can see that there's a shift taking place; that people often say, 'your good at that, you do it'. [II, session 3, participant 4]

Low patient demand for its self-monitoring services was both a consequence as well as a condition of the limited competence of a community pharmacy. A participant illustrated this vicious circle thus:

People don't ask because we don't offer; we don't offer because we don't always have the right answer to give. [III, session 2, participant 2].

For providing patient counselling on the interpretation of SMBG results, legal competence was important. Participants did not mind providing treatment advice, but were concerned this might lead to liability issues. As one pharmacist put it:

You should also be able to say, 'I'm allowed to say this.' You know, not have the patient come into the pharmacy when things go wrong and say, 'what did you have to interfere in this anyway; you've overstepped your bounds here.' If I knew I was allowed to say it, I'd read up on it. [IV, session 1, participant 2]

An external factor influencing competence was the relatively high number of different SMBG equipment available. Since these blood glucose meters each have a unique operation instruction, participants believed that broad assortment negatively influenced a pharmacy team's competence. Some of the pharmacists acknowledged this by actively restricting the number of types of equipment they dispensed.

Competence and workload

In these group interviews, workload was often used as an argument for pharmacists not striving for more involvement in self-monitoring services than they are currently providing. As one of the participants put it:

There's only so many hours in the day. [V, session 1, participant 3]

Due to the inexperience of pharmacy staff with self-monitoring services, pharmacists and pharmacy teams perceived the efficiency of these services as low. Participants often mentioned that technicians regularly asked for support from a colleague or the pharmacist. Since demand for counselling services was infrequent and prompted by patients, it was difficult to incorporate it into routine. The close relationship between competence and workload was underscored by the specialisation strategy that most pharmacists chose to raise the pharmacy's competence. In this process, one or two technicians received additional training to improve their skills in counselling on blood glucose meters and testing procedure. The resulting improvement in knowledge, experience and confidence makes more efficient use of the available workforce. As a pharmacist explained:

Those [technicians] that I do it with, have got so used to it. You can just see the confidence grow and the rest [of the technicians] have something like, 'that's what you do, so you do it, because you know how.' [VI, session 2, participant 3]

Collaboration

Participants had various strategies to change their level of competence. As mentioned above, specialisation was a way to concentrate experience and confidence. Improvement of knowledge through training of staff by specialised organisations or diabetes experts (patients) was brought up by many pharmacists. A few participants had a diabetes nurse working for them. Others started projects with colleagues to improve efficiency of the process of self-monitoring services. For follow-up on the SMBG equipment and testing procedure, many pharmacists used specialised nurses who are in secondment from the manufacturers of monitoring equipment. This service is often free for both the pharmacist and patients. Finally, the availability of diabetes care improvement projects with training and assisted implementation of protocols was mentioned as an approach to provide self-monitoring services.

Reasons for starting collaboration were related to competence. Pharmacists made use of experts in SMBG to improve their own team's knowledge, although this was not always an explicit motive. Explaining why he had hired a diabetes nurse to provide counselling on self-monitoring services one of the participants mentioned:

What it is of course, is what we can't offer is the quality of the diabetes nurse. She knows much more about it, maybe even more that I do; I don't doubt she does, actually. [VII, session 1, participant 2]

Collaboration was also motivated by wanting to improve efficiency. Because they did not have to re-invent the wheel themselves, it reduced the workload of self-monitoring services. Secondment from companies producing self-monitoring equipment was also a very good example of the association between competence and collaboration. As one participant put it:

So we then first started with the DiabetesCheck [a national diabetes care improvement project aimed at community pharmacies, organised by Zorgplan]. We started with the pills … We wanted to get that going before we started other projects. When the supplier said, 'you know, we can also start a follow-up event …' then we said to ourselves, 'now is the time to take the next step'. [VIII, session 1, participant 4]

Collaboration influenced the decision to start or continue with self-monitoring services. As one pharmacist said:

We at our pharmacy worked very well together with home care. But if that hadn't been there, I'm not sure it would have been so easy. Then you would really have to go against the current. [IX, session 4, participant 4]

Competition

Self-monitoring services, both dispensing as well as counselling and follow-up, are not legally restricted to a specific group or profession. As a result competition between pharmacist and other services was a recurrent theme in all group interviews. In dispensing test strips, pharmacists had to compete mostly with mail order companies. Counselling on use of SMBG equipment and testing procedure was seen as the domain of diabetes nurses. Counselling on interpretation of SMBG results was not offered partly because participants perceived this service as the professional role of the general practitioner.

Almost all participants reported that the competition had had an effect on their decision to start or continue offering self-monitoring services. Although their competence in these services was not directly increased or decreased by it, they considered their own self-monitoring services more as a back-up of the activities that other healthcare professionals provided. This was illustrated by one of the participants in the following statement:

Diabetes patients are of course patients who are already surrounded by a team of specialists. Especially the type 1. He is seeing an internist. He's already seeing a diabetes nurse, usually. And we're sort of a back-up in that. [X, session 4, participant 4]

This quote also illustrates the relevance of patient characteristics. Participants considered patients with type 1 diabetes as more actively involved in their disease than type 2 patients. The average age of type 2 patients is higher than among type 1 diabetes patients, which pharmacists link up with a patient's self-efficacy as well. The patient's competence together with their perception that type 1 patients are already supported by competent healthcare professionals was linked to a pharmacy's low participation in self-monitoring services for type 1 diabetes patients. Moreover, these patients are generally more complex. As a participant put it:

The tip of the iceberg, for me, are the type 1 diabetics, and children; everyone who's complex, you might say. The complex cases are for the hospitals. Those are the tippers. We do the normal patients. [XI, session 3, participant 2]

Competition was also the explanation for the observed differences between a pharmacy's role in providing services to patients treated in primary care and those under supervision by hospital-based healthcare professionals. Individual pharmacists could not invest resources into a collaboration with hospital-based diabetes care nurses as mail order companies were able to do. As a pharmacist said:

To them it's a core business and, naturally, to us it's a fringe activity. We as individual pharmacists can't spend all that time and energy on good marketing. [XII, session 4, participant 4]

Pharmacists perceived this advantage of the competition as unfair. In their opinion it also affected patient outcomes, since they felt they were more competent in counselling patients on the use of SMBG than mail order companies.

The realisation that competition was already performing well was not the only reason for not starting new self-monitoring services. Especially in patient counselling on interpretation of SMBG results fear of encroaching on another professional's domain recurred as an issue.

Motivation

Participants had diverse and often multiple motives for starting or continuing with the provision of self-monitoring services. The commercial consequences of self-monitoring services were mentioned as a motivating factor. These services gave them a means of distinguishing themselves from other competitors, including other community pharmacies. It was part of their strategy of business continuity. As two of them put it:

Earlier we talked about as to how far the [follow-up event] was a commercial goal as well. To me that is definitely a part of it. Marketing. Since it's a new pharmacy …, being able to present yourself as a care provider. [XIII, session 4, participant 2]

The discussion on FPZ-Plus [pharmaceutical care activities], that you're expected to be paid extra for that – that's still being worked on, but when it comes, I'd say 'let it come'. I'll have it on the computer then. [XIV, session 3, participant 2]

A more service orientated professional role concept, in which a participant saw the provision of self-monitoring services as an intrinsic responsibility towards diabetes patients was also referred to by the pharmacists. Fragmentation of services among different providers – as a result of competition – was a risk to patient outcomes, which they felt they were obliged to minimise.

On the one hand, I feel, like, it's not my job, but people can also get it [test strips] where they're not given any explanation. [XV, session 3, participant 4]

Job satisfaction was also a motive for providing self-monitoring services. This was not only relevant to the pharmacist. The pharmacy team's satisfaction was considered an important effect of self-monitoring services too. Participants saw their team's professional role concept – a positive attitude towards new roles as for example patient counselling – as an important item in implementing self-monitoring services. As one of them put it:

I have at times felt it to be a problem to still convince people of the fact that this is also part of the pharmacy's future, a bit of patient counselling. That these things can also bring some fun to your work; that it's not just something extra that's added and that's going to take time. [XVI, session 2, participant 2]

Not one motive was superior among the participants. All goals - financial, altruistic or strategic - were interrelated. It was even more complex as some participants referred to self-monitoring services as a means to improve the professional image of community pharmacies in general.

Direct financial consequences of SMBG were minimal. In the Netherlands, remuneration of community pharmacies for SMBG equipment varies per insurer, but generally only the dispensing of blood glucose test strips is compensated. Although the total sales of SMBG equipment is more than 100 million euro, financial gains or cost-effectiveness of SMBG did not seem to be a motive for community pharmacists to start or continue self-monitoring services. As one participant explained:

We ourselves asked in a questionnaire: would you change suppliers? A few indicate they would, but most are fixed on their mail order company. So the gain in that is very vague. [XVII, sessie 3, participant 1]

Prioritising

Although participants said they currently had only limited influence on a patient's SMBG behaviour, they felt that such a position was required if they aimed to become more involved in diabetes care. Some even indicated the provision of self-monitoring services

as a means to consolidate their future professional status. However, at the same time, they were hesitant to actually implement these services. Many participants mentioned that they were still 'not sure'.

Not just the absolute competence, but rather their competence in self-monitoring services relative to competence in other activities was key in this decision-making process. The level of priority of self-monitoring services was the result of a pharmacy's competence, collaboration, competition and potential benefits (see **Figure 1**) compared to more traditional activities. The exact position of this equilibrium varied per pharmacist and per self-monitoring service activity. In general, however, participants favoured counselling activities that were more closely related to drug use, an area in which they perceived themselves as highly competent. As one pharmacist explained:

Your core business, personally, I feel is the medication we dispense and the information that's needed for it – to give that. [XVIII, session 4, participant 1]

Especially for dispensing services and providing counselling, the large number of competitors was an important aspect of the decision to give priority to other activities. As a participant described it:

Meter use information is not a special trick: you don't have to be a pharmacist for it, or a technician. And in the health care business it's practice that everyone does his own special trick. [XIX, session 1, participant 2]

Boundary encroachment was mentioned in this context as well. Participants were hesitant to provide (new) services, particularly patient counselling on interpretation of results. This was felt to be an activity that would intrude on the domain of a healthcare professional with whom the pharmacist collaborated on drug dispensing activities. As shown by one of the pharmacists, responding to the statement from another participant that fear of encroachment was not an issue to her:

I entirely disagree, because you too have a relationship with that general practitioner. [XX, session 3, participant 3]

In contrast to the previous remarks on financial rewards, remuneration did play a role in balancing competences. Dutch community pharmacies have three major funding systems. First, they are remunerated for the number of prescriptions, receiving a fixed fee for every drug they dispense. Second, although the Dutch government does not allow pharmacists to sell drugs for more than the fixed maximum price, pharmacists can negotiate with wholesalers on reductions in cost price. The margin on over-the-counter drugs, cosmetics and medical aids is a third source of income for community pharmacies. At present, patient counselling on drugs or on SMBG is not reimbursed and de facto negatively influences a pharmacy's financial situation by utilising limited resources.

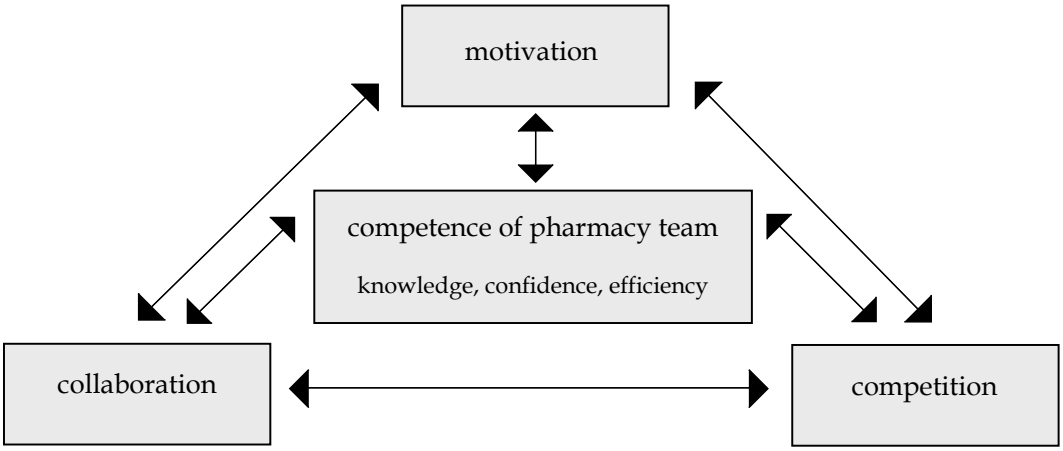

Figure 1. Recurrent themes and their relationship

In the end it [patient counselling] costs something that we're not paid for. There's a whole lot of good will with the pharmacist and the organisation, but you don't get anything in return. [XXI, session 3, participant 1]

This played a role in prioritising activities that more closely related to dispensing medication than self-monitoring services, underscoring the strategy to focus on 'core business'. As one pharmacist put it:

I've only got a pool of 10 technicians and they have to also run really the core business of the pharmacy, dispensing medication; that has to be taken care of too. [XXII, session 3, participant 3]

Of all activities, starting or continuing follow-up on patients performing SMBG, was most often mentioned by the participants. Its cost-benefit ratio was the most favourable. Through collaboration, this service could be performed with high efficiency. Both its strategic component as well as its effects on patients were the most easy to discern compared to the other services. Moreover, their role in this was acknowledged by patients and other healthcare professionals, which limited competition and boundary encroachment. As one of the pharmacists described her experience with announcing to general practitioners that her pharmacy was starting with a follow-up event of SMBG equipment:

Well, I mentioned it in passing. I haven't yet officially said I'm going to hold a follow-up event then, but the topic 'follow-up' has come up a few times. So I don't expect any problems with that, no; in itself they're OK with that sort of thing. [XXIII, session 2, participant 2]

DISCUSSION

In the provision of self-monitoring services by community pharmacists, competence was a recurring theme. Subordinate themes associated with competence were collaboration,

competition and motivation. The decision to start or to continue with these services was the result of a comparison of the service process against other pharmacy processes on these four themes.

Although our study was the first to focus on specific care activities, elements relevant to pharmacy practice have been the topic of previous research. [26-30] Rossing reviewed literature on barriers to pharmaceutical care. [24] She identified factors associated within the pharmacy (time, computer software and availability of data on patients' clinical status). Furthermore, the physical lay-out was also often mentioned in the studies. Apart from pharmacy-related factors, competence, pharmacy's focus on dispensing and their perception of the professional role of the pharmacist and his team recurred in most of the studies as a barrier or facilitator of pharmaceutical care provision. Last, supra-pharmacy factors (reimbursement, co-operation with general practitioners and patient expectations) were cited. In our group interviews, we saw a similar division of pharmacist-related factors (prioritising) and supra-pharmacy factors (effect of reimbursement and competition). However, pharmacy factors were not found to contribute directly to the provision of self-monitoring services, but affected the pharmacist's decision-making process.

The process of prioritising contained elements of professional role orientation as the decision-making process is governed by an individual's opinion of what a pharmacist should do. Previous work on individual professionalism showed that a community pharmacy's attempts at professionalisation are thwarted by its 'shop keeper image'. [21, 31] In our group interviews, participants did also struggle with this dualism as was apparent in their opinions on the reasons for the limited demand for self-monitoring services. Patients, but also other healthcare professionals, were often not aware of the pharmacist's potential in self-monitoring support. This unawareness is also observed in counselling services in, for example, England. [32] Moreover, concepts of boundary encroachment, limitation and exclusion [21] appeared in all group interviews.

Strengths and limitations

A limitation of a group interview such as ours is that the results may only describe what are considered to be 'acceptable' motives for (not) starting or continuing with self-monitoring services. We minimised this bias by using small groups (four to six participants). Furthermore, all participants were peers. Besides, the direct observation of the interviews showed that the participants felt comfortable in expressing their opinions. Moreover, we aimed for an overview of all potential elements in the decision-making process. We expected that the interaction in a group discussion would provide more elaborate results.

Due to our sampling technique, our participants tend to represent the more active, care-orientated pharmacists. As a result, community pharmacists who are not actively

involved in pharmaceutical care may experience other elements in the decision-making process. However, because of resource constraints and our group interview technique, it was considered that the early adopters of diabetes care should be the starting point of this project. For future research, it would be interesting to include laggers in a one-on-one interview, to improve the external validity of our conclusion.

We focused our study on the activities of community pharmacies in supporting patients with performing self-monitoring of blood glucose. Medical aids are interesting, because next to community pharmacies, other healthcare professionals and distributors are also involved in these activities, in contrast to dispensing of pharmaceuticals. Because of this, ours is one of the first studies to describe aspects of collaboration and competition in pharmaceutical care.

Implications

Due to the study design, generalisibility of the results is difficult. However, our results imply that barriers towards implementation of self-monitoring services in a community pharmacy are not only found at the level of the pharmacist, but also outside the zone of control of the pharmacist. If most of the 'active' pharmacists feel that their current competence in self-monitoring services is low and give priority to other activities, then the focus in less care-oriented pharmacies will be even less on provision of these services.

If community pharmacies are to take the objectives of the St Vincent Declaration seriously, implementation strategies should not only be aimed at improving a pharmacy's competence. This will become even more important considering the high incidence of type 2 diabetes mellitus, a group that seems more accessible for community pharmacists. Removing elements that negatively affect motivation, as for example remuneration, together with advertising collaboration schemes, is also essential. Still, individual pharmacists will not be able to accomplish this, suggesting that pharmacist organisations should take the lead.

CONCLUSION

Competence, collaboration, competition and motivation were recurrent themes among all group interviews and participants. Links between these themes were related to their ability to affect knowledge, efficiency and confidence. Participants felt more competent in drug dispensing and related medication counselling activities than in SMBG. This affected their motivation and their willingness to provide self-monitoring services.

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Geographical Region Influences Pharmacy's Dispensing of Blood Glucose Test Strips Independent of Differences in Patient Characteristics

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ABSTRACT

Background: Pharmacy practice guidelines promote the role of community pharmacy in self-monitoring of blood glucose. However, variation between Dutch pharmacies exists in the proportion of patients to whom test strips are dispensed.
Objective: To assess whether variations between community pharmacies in dispensing of blood glucose test strips can be explained by differences in patient characteristics and the region in which the pharmacy is located.
Setting: PHARMO-Record Linkage System containing drug dispensing histories from 40 community pharmacies of about 450,000 patients in the Netherlands.
Method: We performed a retrospective cohort-study. Data on prescription of all drugs and medical aids between 1991-2001 were extracted for all new users of antidiabetic drugs. Patients were excluded if the dispensing history did not allow classification of the type of diabetes or if the dispensing pharmacy could not be determined. The data were analysed using a Cox proportional hazard model.
Main outcome measure: Time to first test strips dispensed.
Results: We identified 8,233 starters of antidiabetic drugs. During a median follow-up of 2.1 years, 20% of the patients were dispensed test strips at least once. Community pharmacy was significantly associated with dispensing of test strips after adjustment for patient characteristics. This association was less apparent when stratified for geographical location of the pharmacy.
Conclusion: Community pharmacy is an independent determinant of the start of use of test strips. Differences in dispensing of test strips between pharmacies are dependent on geographical region. This suggests that implementing practice guidelines for diabetes care in community pharmacy requires different approaches in different regions.

INTRODUCTION

Diabetes is a chronic illness that requires continuing medical care and patient self-management to prevent acute complications and to decrease the risk of long-term complications. Reducing hyperglycemia has been shown to be an important factor in the prevention of diabetic complications. [1, 2] Besides pharmacological treatment, education on self-management of diabetes is considered an integral component of all diabetes care plans. [3, 4]

An important aspect of self-management is the self-monitoring of blood glucose (SMBG). SMBG enables both type 1 and type 2 diabetes patients to achieve and maintain specific individual glycemic goals. [5] National and international pharmacy practice guidelines recognise this and promote the role of community pharmacies in supporting patients performing SMBG. [6-9]

In a previous study, we found large differences in the rate of dispensing of test strips among pharmacies in the Netherlands. [10] This finding may indicate that not all pharmacies are able to implement the guidelines to the same extent. However, community pharmacies may differ substantially in their diabetic patient population (i.e. age, proportion of type 1 versus type 2 patients). It has been shown that patient characteristics are determinants of test strip use. [11, 12] Furthermore, regional differences may also be important to consider when comparing the diabetes care process. This is underscored by the results of the studies by Arday et al., who examined variation in diabetes care among states in the US. Variations in, for example, the rate of annual hemoglobin A1c (A1c)-testing, were significantly reduced when adjusted for differences in patient characteristics. Still, much variability remained unexplained, which might be due to differences in state characteristics. [13]

In this study, we assess whether variations between community pharmacies in dispensing of blood glucose test strips can be explained by patient characteristics and regional effects. Differences between pharmacies are important to study in order to identify barriers in dispensing of test strips which in turn may help to design and guide interventions to improve quality of diabetes care.

METHODS

Setting

We used data from the PHARMO-Record Linkage System (RLS) covering the period 1991 – 2001. The PHARMO-RLS has been described in detail elsewhere. [14, 15] In brief, the system includes pharmacy dispensing records from community pharmacies linked to hospital discharge records of all 450,000 community-dwelling residents of nine population-defined areas in the Netherlands from 1985 onwards. Since most patients

in the Netherlands are registered with a single community pharmacy, independent of prescriber, pharmacy records are virtually complete with regard to prescription drugs. Medical aid dispensing records may be less complete, because SMBG equipment can be dispensed without a prescription. Still, a prescription is necessary for remuneration of test materials. Hence, in most cases dispensing of test strips is recorded in the patient's medication history.

Drug use was coded according to the Anatomical Therapeutic Chemical (ATC) classification index of the World Health Organization. Because not all pharmacies use the standard index for SMBG equipment, a patient's complete dispensing history was reviewed. Dispensing records of test strips were selected based on the text description in the label-field together with the number of units dispensed.

Study design and population

We performed a retrospective cohort study among new users of antidiabetic drugs. All diabetes mellitus patients that filled at least two prescriptions of an antidiabetic drug (ATC-codes A10A or A10B) in the period of 1991 - 2001 were included in this study. Patients with less than 365 days of medication history before the first prescription of an antidiabetic drug were excluded (non-incident patients). Patients with gestational diabetes, defined as women younger than 50 years using insulin for less than 210 days with no prescription of an antidiabetic drug for at least one year after discontinuing insulin treatment, were also excluded. Type 1 diabetes mellitus was defined as at least two prescriptions of insulin, no more than one prescription of an oral hypoglycemic agent (OHA) and not older than 50 years at the start of insulin therapy. Type 2 diabetes mellitus was defined as at least two prescriptions of an OHA. A similar definition was used in previous studies with data from the PHARMO-RLS. [16] Patients of whom the type of diabetes could not be classified were excluded.

Data collection

Of all patients in the study population (n = 8,233), the dispensing histories of drugs and diabetes test materials were extracted from the database from the period of January 1991 until December 2001. Retrievable information per prescribed drug and medical aid included date of dispensing, drug name, dosage, number of prescribed dosage units and dispensing pharmacy. Patient information included gender and year of birth.

For all patients, the number of prescriptions of antidiabetic drugs per pharmacy was determined. Patients who collected antidiabetic drugs in two or more pharmacies were only included if they visited one of those pharmacies on at least three occasions to collect an antidiabetic drug. Furthermore, the patient had to fill at least 85 percent of all antidiabetic drug prescriptions in that pharmacy. The 'dispensing pharmacy' was defined as the pharmacy in which the patient collected the most prescriptions of antidiabetic drugs.

From the dispensing records, the type of antidiabetic drug treatment (oral hypoglycemic agents, insulin or both) was recorded as a time-dependent variable. Furthermore, data on use of chronic co-medication in the year prior to the first prescription of antidiabetic drug was collected. Use of co-medication was defined as at least one prescription of a drug in the year before the index date.

Analysis

Follow-up started at the first prescription of an antidiabetic drug and lasted until the first test strips was dispensed or at the end of follow-up, whichever came first. The Cox proportional hazard model was used to determine the association between the determinants and the time to the first test strip dispensed. The effect of 'dispensing pharmacy' was analysed separately by introducing it to a hazard model containing all patient characteristics. Finally, we assessed whether the effect of 'dispensing pharmacy' was modified by the geographical region in which the pharmacy was located. Analyses were performed using S-PLUS 6 Professional Edition for Windows, release 2.

The hazard ratio (HR) of 'dispensing pharmacy' was determined using one pharmacy as reference. This pharmacy's patient population showed the least deviation from the mean age, the total number of patients and the mean proportion of men. In the stratified analysis for geographical region, the reference pharmacy was the pharmacy with the most incident users of antidiabetic drugs in that region.

RESULTS

A total of 18,128 patients in the study population filled at least two prescriptions of antidiabetic drugs between January 1991 and December 2001. After exclusion of non-incident users and patients with gestational diabetes, the number of incident users of antidiabetic drugs was 8,878. Ninety-four patients were excluded, because data did not allow classification of the 'dispensing pharmacy'. Furthermore, another 551 patients were excluded because the type of antidiabetic drug treatment could not be determined (224 patients with a total of less than three prescriptions of antidiabetic drugs, all dispensed on the same day; 227 patients who filled at least two prescriptions of insulin, did not receive OHAs and were 50 years or older at start of follow-up).

Table 1 presents the patient characteristics of the final study population. A total of 8,233 patients were included (230 type 1 diabetes and 8,003 type 2 diabetes patients). The median age of the type 1 and type 2 patients was 33 years and 65 years respectively. The proportion of men in type 1 patients was 59.1%, for type 2 this was 47.5%. The number of incident users increased in the period 1992 – 2001, especially among type 2 patients. Use of co-medication in the year prior to their start of antidiabetic drug treatment was much higher in type 2 patients. The most commonly used drugs were benzodiazepines and cardiovascular medication (antihypertensives and cholesterol lowering drugs).

Table 1. Patient characteristics of incident users of antidiabetic drugs.

	Type 1 patients		Type 2 patients	
Number	230		8,003	
Age [a], median (IQR)	33	(27)	65	(20)
Proportion men, % (n)	59.1	(136)	47.5	(3,802)
Year of start of antidiabetic drug use, % (n)				
1992	3.5	(8)	4.9	(393)
1993	4.8	(11)	7.1	(570)
1994	7.4	(17)	8.0	(642)
1995	11.3	(26)	8.7	(697)
1996	17.0	(39)	8.8	(708)
1997	11.7	(27)	10.0	(802)
1998	17.0	(39)	12.0	(957)
1999	10.9	(25)	13.3	(1,062)
2000	11.8	(27)	14.3	(1,142)
2001	4.8	(11)	12.9	(1,030)
Use of co-medication (ATC-code), % (n)				
diuretics (C03, C07B or C07C)	7.0	(16)	31.7	(2,538)
beta blocking agents (C07 except sotalol)	7.0	(16)	26.4	(2,110)
ACE-inhibitors and AII antagonists (C09)	5.6	(13)	20.4	(1,633)
calcium channel blockers (C08)	2.6	(6)	15.8	(1,265)
cholesterol lowering drugs (C10A or B04A)	2.6	(6)	13.2	(1,054)
systemic corticosteroids (H02)	3.9	(9)	10.9	(869)
benzodiazepines (N05BA or N05CD)	15.2	(35)	26.9	(2,156)
antidepressants (N06A)	1.7	(4)	7.4	(595)
antipsychotics (N05A, except N05AN)	3.5	(8)	3.3	(263)

IQR = inter quartil range.
[a] Age in years at first prescription of an antidiabetic drug in the PHARMO-RLS database.

Use of test strips

During follow-up, patients received an average of 39.5 SMBG test strips per year (0.57 occasions of dispensing of test strips per patient per year). Of all 8,233 patients, 1,599 were dispensed test strips at least once (19.4%).

Patient characteristics by dispensing pharmacy

Data were collected in 40 community pharmacies in 17 geographical regions. The median registration period of a pharmacy in the database was 11 years (range 3.2 – 11 years). **Table 2** shows the characteristics of the diabetic population per geographical region and per pharmacy. Although only mean age differed statistically significant between 'dispensing pharmacy' ($p < 0.001$), age, sex and type of diabetes varied between pharmacies and, to a lesser extent, between regions. This variation reflects differences in the setting of the pharmacy, for example neighbourhood and regional demographics.

Determinants for dispensing of test strips in community pharmacy

Age and the year of start of antidiabetic drug use, as well as type of antidiabetic treatment were significantly associated with the time to the first test strips dispensed

(**Table 3**). The HR showed that older patients were less likely to receive test strips, also when adjusted for all other characteristics. There were no differences between male and female patients. There was a trend that patients who started antidiabetic drugs after 1997 had a higher chance of receiving test strips in the 'dispensing pharmacy' than before that time. Compared to type 1 patients, patients who used oral hypoglycemic agents (OHAs) were dispensed test strips almost five times less. In contrast, type 2 patients using insulin or both OHAs and insulin collected test strips more often (HR 3.75, 95% confidence interval (95% CI): 2.72 – 5.16 and HR: 1.83, 95% CI: 1.34 – 2.50, respectively). Use of specific co-medication in the year before the start of antidiabetic drug use was not associated with the outcome.

The variable 'dispensing pharmacy' improved the model ($p < 0.001$), and was independently associated with starting the use of test strip. Compared to patients in the reference pharmacy, the rate of dispensing of test strips to diabetic patients was significantly different in 14 pharmacies.

Regional effects on dispensing of test strips in community pharmacy

Variation in time to the first test strip dispensed between pharmacies in one region, was considerably less than between pharmacies in different regions (**Figure 1**). This

Table 2. Characteristics of the diabetes patient population per pharmacy in 17 geographical regions. [a]

	Overall	Region C	Region D	Region F
Number of pharmacies (patients)	40 (8,233)	4 (1,088)	5 (1,190)	5 (1,144)
Age [c]	62.9 (14.5)	62.8 (14.3)	62.8 (15.2)	59.1 (14.3)
Male [d], % (n)	47.8 (4.4)	47.8 (3.9)	47.3 (5.2)	48.8 (3.3)
Number of incident type 1 diabetes [e], mean (sd)	0.53 (0.34)	0.62 (0.51)	0.77 (0.49)	0.44 (0.14)
Number of incident type 2 diabetes [f], mean (sd)	19.1 (7.7)	24.9 (7.9)	21.0 (7.9)	20.4 (11.6)
	Region G	**Region H**	**Region I**	**Other [b]**
Number of pharmacies (patients)	7 (1,022)	5 (686)	3 (555)	11 (2,548)
Age [c]	62.5 (14.5)	65.2 (14.9)	62.4 (13.6)	64.3 (14.2)
Male [d], % (n)	48.5 (5.7)	45.8 (6.0)	48.6 (5.3)	47.9 (3.4)
Number of incident type 1 diabetes [e], mean (sd)	0.30 (0.25)	0.38 (0.30)	0.42 (0.05)	0.69 (0.28)
Number of incident type 2 diabetes [f], mean (sd)	17.4 (8.7)	12.1 (5.6)	16.4 (3.7)	20.4 (5.4)

[a] Data from regions with only one study pharmacy are pooled.
[b] Pooled data from 11 different regions with only one study pharmacy.
[c] In years. p-Value one-way ANOVA < 0.001.
[d] p-Value Chi-square is 0.126.
[e] Per year follow-up. p-Value one-way ANOVA is 0.110.
[f] Per year follow-up. p-Value one-way ANOVA is 0.257.

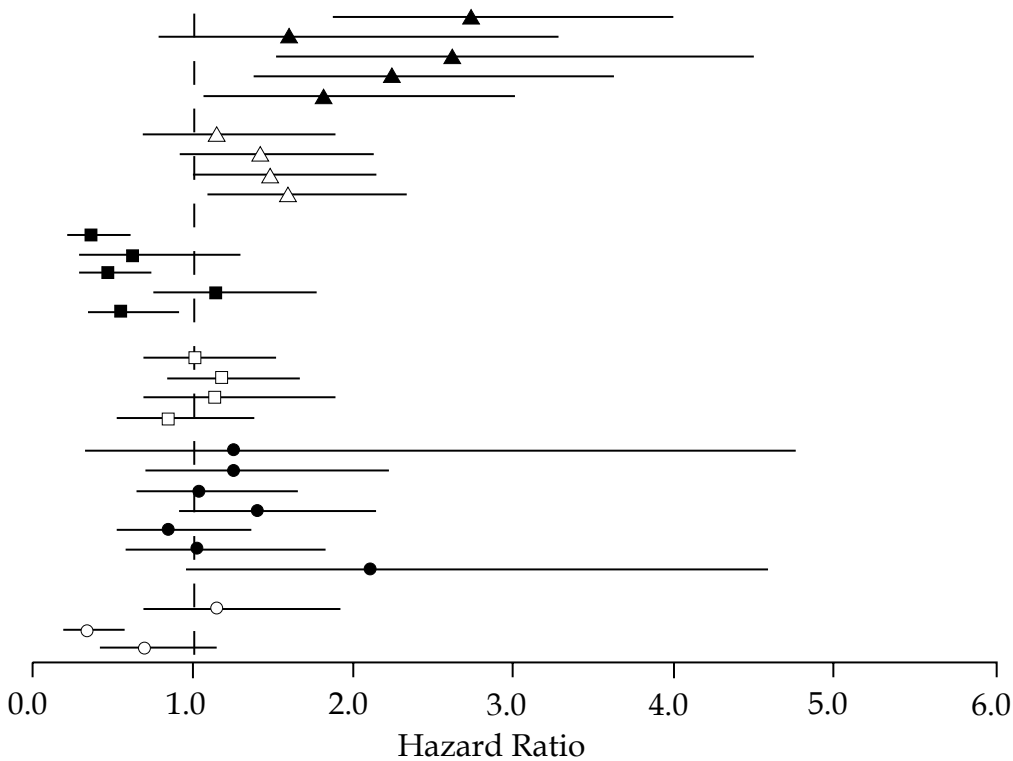

Figure 1. Association between 'dispensing pharmacy' and time to first test strips dispensed adjusted for age, gender, type of treatment, year of start of antidiabetic drug use and co-medication, clustered by geographical region. Different symbols represent different regions. Data from regions with only one study pharmacy have been omitted.

indicates that the differences between 'dispensing pharmacy' after adjusting for patient characteristics may also be dependent on the region.

When stratified for region, 'dispensing pharmacy' improves the model in only two out of six regions ($p < 0.001$ and $p = 0.012$). In these two regions, there were three pharmacies in which the chance of receiving test strips compared to the reference pharmacy, was statistically significantly different (data not shown).

DISCUSSION

We found that 20 percent of all incident users of antidiabetic drugs received test strips through community pharmacies at least once during a median follow-up of 2.1 years. After adjusting for variation in diabetes patient population, differences between pharmacies in dispensing of test strips remained. These differences became less apparent when we stratified for geographical region, suggesting that the role of the community pharmacy is significantly modified by the regional structure of care for patients performing SMBG.

Table 3. Association between patient characteristics and time to the first test strips dispensed.

	Crude HR (95% CI)		Adjusted HR (95% CI) [a]		'Pharmacy' adjusted HR (95% CI) [b]	
Age at start of antidiabetic drug use [c, d]	0.77	(0.74– 0.79)	0.91	(0.86 – 0.96)	0.89	(0.85 – 0.94)
Gender						
male	reference		reference		reference	
female	0.97	(0.88 – 1.07)	0.97	(0.86 – 1.09)	0.95	(0.85 - 1.08)
Year of start of antidiabetic drug use [c]						
1992	reference		reference		reference	
1993	1.09	(0.87 – 1.38)	0.92	(0.70 – 1.22)	1.05	(0.78 – 1.40)
1994	1.20	(0.96 – 1.51)	1.07	(0.82 – 1.41)	1.23	(0.91 – 1.65)
1995	1.28	(1.02 – 1.61)	1.08	(0.82 – 1.41)	1.30	(0.91 – 1.73)
1996	1.14	(0.90 – 1.45)	0.90	(0.69 – 1.19)	1.10	(0.82 – 1.48)
1997	1.23	(0.97 – 1.57)	1.04	(0.79 – 1.36)	1.25	(0.94 – 1.68)
1998	1.43	(1.12 – 1.81)	1.25	(0.96 – 1.63)	1.60	(1.20 – 2.14)
1999	1.30	(1.01 – 1.68)	1.17	(0.88 – 1.54)	1.34	(1.00 – 1.81)
2000	1.31	(1.00 – 1.71)	1.21	(0.91 – 1.63)	1.41	(1.03 – 1.93)
2001	1.73	(1.27 – 2.35)	1.63	(1.18 – 2.26)	1.80	(1.27 – 2.56)
Type of treatment [c]						
insulin use in type 1 DM	reference		reference		reference	
oral hypoglycemic agents	0.16	(0.13 – 0.21)	0.21	(0.16 – 0.29)	0.21	(0.15 – 0.28)
both insulin and OHA	3.08	(2.31 – 4.10)	3.75	(2.72 – 5.16)	4.57	(3.29 – 6.34)
only insulin in type 2 DM	1.49	(1.11 – 1.98)	1.83	(1.34 – 2.50)	2.30	(1.65 – 3.21)
Use of co-medication (ATC-code) [e]						
diuretics (C03, C07B or C07C)	0.81	(0.73 – 0.91)	0.90	(0.78 – 1.04)	0.91	(0.79 – 1.06)
beta blockers (C07, except sotalol)	0.87	(0.78 – 0.97)	1.03	(0.90– 1.18)	0.98	(0.85 – 1.13)
ACE-inhibitors (C09)	1.01	(0.89 – 1.14)	1.05	(0.90 - 1.22)	1.09	(0.93 – 1.27)
Ca-antagonist (C08)	0.94	(0.82 – 1.08)	1.04	(0.87 –1.23)	0.97	(0.93 – 1.27)
cholesterol lowering drugs (C10A or B04A)	0.98	(0.83 – 1.15)	0.96	(0.79 - 1.15)	0.97	(0.80 – 1.17)
corticosteroids (H02)	1.74	(1.39 – 2.20)	1.10	(0.90 – 1.35)	1.00	(0.80 – 1.24)
benzodiazepines (N05BA or N05CD) [c]	1.09	(0.98 – 1.22)	1.15	(1.00 – 1.32)	1.17	(1.02 – 1.34)
antidepressants (N06A)	1.07	(0.88 – 1.31)	0.88	(0.68 – 1.13)	0.89	(0.70 – 1.13)
antipsychotics (N05A, except N05AN)	1.15	(0.87 – 1.52)	0.94	(0.66 – 1.33)	0.98	(0.70 – 1.38)

OHA = oral hypoglycemic agent; DM = diabetes mellitus. HR = hazard ratio; 95% CI = 95% confidence interval.

[a] Adjusted for age, gender, year of start of antidiabetic drug use, type of treatment and all co-medication.

[b] Adjusted for age, gender, year of start of antidiabetic drug use, type of treatment, all co-medication and 'dispensing pharmacy'.

[c] Determinant is significantly associated ($p < 0.05$) with the outcome in the adjusted model.

[d] Per decade.

[e] Reference category is no use of that specific co-medication.

Several patient characteristics were significantly associated with test strip use. As expected from practice guidelines [5], we found that the type of antidiabetic treatment

was most strongly associated with collecting test strips. Type 1 patients were dispensed test strips almost five times more often than patients using only OHAs, but less often than type 2 patients using insulin in combination with OHAs. We also observed that type 2 patients using insulin were more likely to start using test strips compared to type 1. Our observations were in accordance with previous studies using frequency of SMBG as an outcome [11, 12, 17, 18], although comparative data on the effect of age and gender were inconclusive.

Arday et al. found large variations in diabetes care between U.S. states, which remained after adjustment for characteristics of state residents. [13] Although we performed our study in much smaller geographical areas, we observed a similar regional effect. Regional variation in rates of health care interventions is not restricted to diabetes care. Geographical variation has also been reported in, for example, treatment of acute myocardial infarction and surgical procedures such as knee arthoplasty. [19, 20] Although many different explanations for these geographic variations are proposed, it is believed that much variability is associated with differences in individual clinical practice. [21] SMBG among insulin users nears 100 percent, making physicians preferences a relatively unimportant factor. However, practice differences in the distribution of SMBG equipment could be relevant. In our study, region correlates well with different hospital referral areas. The key decision maker in choice of SMBG equipment – the diabetes nurse specialist – is often located in the hospital setting. Their practice pattern, for example based on collaboration with a certain supplier of testing materials, would affect dispensing of test strips of all community pharmacies within the referral area.

In some regions, we still observed significant differences between 'dispensing pharmacy' in the use of test strips after adjustment for variation in patient population. This suggests that pharmacy characteristics may have an effect on the proportion of test strip users. Although we had no additional data of these characteristics, previous studies report physical lay-out of the pharmacy, computer support, knowledge as well as lack of time and reimbursement as barriers to implementation of pharmaceutical care activities. [22, 23]

In the Netherlands, patients can acquire test strips through other distribution channels than community pharmacies, such as mail order companies or from diabetes nurses in specialised clinics. Since type 1 patients – in contrast to type 2 patients – are almost always treated by a specialist, the structure of diabetes care may differ. Therefore, it is possible that type 1 patients are less likely to receive test strips in a community pharmacy. This would result in a relatively higher probability of test strips dispensed to type 2 patients. The third party distribution also explains the finding that only one out of five patients receive test strips through a community pharmacy. Moreover, the low proportion of test strip use may also be explained by the inclusion of incident patients only and a median follow-up of 2.1 years.

The lack of information on distribution of test strips through other channels does not affect the generalisability of our study. Since we are interested in differences between pharmacies, it is not necessary to have data on every patient using test strips. Moreover, from reports of the Foundation of Pharmaceutical Statistics (SFK) we estimate that about 60% of the costs of SMBG are made in the community pharmacy, suggesting that our data still represent a large proportion of test strip users. [24]

A limitation of our study is the relatively low proportion of type 1 patients. Of all prevalent cases of diabetes in the Netherlands, about 10 – 15% has type 1 diabetes. [25] This discrepancy is due to the definition of an incident patient: at least one year of dispensing history before the first antidiabetic drug prescription is filled. Because type 1 patients have in general less co-morbidity at the date of diagnosis and are younger at time of diagnosis, they are less likely to be included as incident patient than type 2 patients. This lowers the proportion of type 1 patients in the study population. However, if we had included prevalent users of antidiabetic drugs, misclassification of insulin users would have occurred, because about 25% of all type 2 patients use only insulin therapy to control their hyperglycemia. Moreover, the association between the type of antidiabetic treatment and use of test strips is not likely to be influenced by this exclusion of some type 1 patients. For the observed differences between pharmacies, this would be even less important.

Because diabetic patients visit a pharmacy on average five to six times per year, community pharmacists are well placed to educate patients on diabetes. Dispensing of test strips provides an opportunity to support the patient with the complicated process of SMBG.

Furthermore, pharmacist-led intervention programs, including education and training of SMBG skills, showed a decrease in A1c-values attributed to the pharmaceutical care services. [26-30] Moreover, because of the observed differences between pharmacies, not all may experience the same barriers in dispensing of test strips. Since about 60 percent of all Dutch community pharmacies is owned by an individual pharmacist [31], this implies a significant effect of region-specific factors in the structure and process of the activities of the individual pharmacists .

For practice research, our findings suggest that the external validity of studies into dispensing of test strips might be limited if geographical variation is not taken into consideration. This might be true for other community pharmacy activities, especially those in which other healthcare providers also play a role. Therefore, it is important for studies on pharmaceutical care activities to include a representative sample of community pharmacies.

Although our study implies that regional characteristics are important in dispensing of test strips, our dataset did not provide information to further investigate these factors.

Future research should focus on elucidation of key factors in the dispensing process of SMBG equipment. This would facilitate the evidence-based implementation of diabetes care activities in community pharmacy.

CONCLUSION

Differences between pharmacies in the rate of dispensing of test strips are independent of differences in patient characteristics among pharmacies. However, this association depends on the geographical region of the pharmacy. Therefore, implementing practice guidelines for diabetes care in community pharmacies, will require different approaches in different regions. This study also underscores the complexity of determining relevant quality indicators for providing support to patients practising SMBG.

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Collaborative Services Among Community Pharmacies for Patients with Diabetes

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ABSTRACT

Background: Patients performing self-monitoring of blood glucose (SMBG) may benefit from community pharmacy services. However, wide-scale implementation of these services is limited. Many pharmacy characteristics (for example, physical layout of the pharmacy, knowledge and competence of the pharmacy team) are reported to be relevant when implementing these services. Still, the importance of local agreements on the division of roles with, for example, local general practitioners or diabetes nurses, is less clear.

Objective: To study the association between local collaboration and the level of services provided by community pharmacies to patients performing SMBG.

Methods: In 2004, we performed a cross-sectional survey among all 1,692 Dutch community pharmacies. Data were gathered on provision of services for SMBG, local agreements, and pharmacy characteristics. Data were analysed using logistic regression. The associations were adjusted for pharmacy characteristics.

Results: About 44% (724) of the community pharmacies returned the questionnaire. Pharmacies that were not involved in local collaborative services on patient counselling reported to provide fewer services compared with those that were involved in such agreements (odds ratio (OR): 0.26, 95% confidence interval (95% CI): 0.13 to 0.53). Similar findings were observed for agreements on calibration of SMBG equipment (OR: 0.17, 95% CI: 0.04 to 0.71). The associations remained after adjusting for pharmacy characteristics.

Conclusions: Local collaboration on the division of roles in diabetes care between healthcare professionals is independently associated with the number of pharmacy services provided to patients performing SMBG.

INTRODUCTION

Education on self-management of diabetes is considered an integral component of all care plans for patients with diabetes. [1] An important aspect of self-management is the self-monitoring of blood glucose (SMBG). This is recognised in national and international pharmacy practice guidelines, which promote the role of community pharmacies in supporting patients performing SMBG. [2-4] Pharmacist-led intervention programmes, including education and training of patients in SMBG skills, showed a decrease in hemoglobin A1c values attributed to the pharmaceutical care services. [5-8]

Community pharmacy's self-monitoring support focuses on patient counselling and calibration/checking of SMBG equipment. [2] To what extent these services are implemented is not known, but daily practice suggests large variation among pharmacies. [9-11]

The type and number of pharmaceutical services provided by community pharmacies are probably influenced by the characteristics of the local system for care of patients. Since diabetes treatment requires a team approach, [12] an important characteristic could be the presence or absence of a local collaboration among healthcare providers. The existence of a local agreement between different healthcare providers on the division of roles in supporting patients performing SMBG is an essential part of these collaborations.

The aim of this study was to determine whether such local agreements influence the provision of community pharmacy services to patients performing SMBG.

METHODS

Setting and design

We conducted a cross-sectional survey among all Dutch community pharmacies registered in January 2004. This study consisted of two stages. First, semi-structured interviews with seven pharmacists were held to identify relevant local and pharmacy-related factors potentially associated with the provision of services to patients performing SMBG. These pharmacists also pretested the final survey and found it to be comprehensive. A pilot study among 50 randomly selected community pharmacies was performed to determine feasibility, as well as a limited validation on the variability in the responses and its comprehensibility. To obtain enough contrast in responses on dichotomous questions, we required, a priori, that all response categories be checked by at least 10% of all respondents. If the item's response categories were checked less often, we either rephrased or deleted the response category or rephrased the item. The results of the pilot questionnaires were excluded from the final analysis.

In the second stage, a mailing was sent in February 2004 to all Dutch community pharmacies not involved in the pilot study. It was addressed to the senior pharmacist in

the institution. The invitational letter stated that the Internet-based survey was intended for the pharmacist responsible for patient care activities. Participants could respond anonymously. After three weeks, all pharmacies received a reminder and a paper version of the survey, which could be returned at no cost.

Of all respondents, the sites that functioned as an annex of another pharmacy (limited services available and open only a few hours per day) were excluded. In most regions, only a few pharmacists dispense outside of office hours. This 'out-of-hours' service rotates among all pharmacies in a particular region. However, in some regions, a specialised out-of-hours pharmacy has been created that conducts all out-of-hours dispensing. These pharmacies were also excluded from the analysis.

Survey

The questionnaire consisted of 47 items (see Appendix 1). Apart from the questions on the provision of pharmacy services to patients practising SMBG, it also gathered information on a large set of factors that were found to be associated with the provision of services in literature [13, 14] or derived from the semi-structured interviews during the first stage of the study.

Definition of self-monitoring services

Based on the Dutch pharmacy practice guidelines [2], we defined five separate support activities in three areas of pharmacy services for patients performing SMBG: patient counselling, calibration/checking of SMBG equipment, and providing blood glucose meters at no cost to patients performing SMBG for a short period. Since, in the Netherlands, patients who use oral hypoglycemic agents usually do not receive full reimbursement for the blood glucose meter, some pharmacists provide one to patients to reduce initial cost of SMBG.

Counselling was subdivided into three domains: choosing a suitable blood glucose meter, operating that meter, and performing the test procedure. Respondents were asked which support activities they performed. The total number of activities was calculated. Since no consensus on the relative importance of these activities exists, all activities were weighed equally. Services that were not prompted by the pharmacy, for example patient counselling in response to a specific question from the patient, were excluded.

Local agreements on SMBG

We inquired as to whether local agreements existed on two topics: patient counselling and calibration/checking of SMBG equipment. Based on the parties involved in the agreement, responses were classified as follows: no local agreements, local agreement without a pharmacy participating, and local agreement with a pharmacy participating. Of all agreements in which a community pharmacy participated, we evaluated

the description of the content of the agreement as provided by the respondent. We categorised them as containing either an active or passive role (for example, if it was agreed that the pharmacy would refrain from patient counselling). The different categories are summarised in **Table 1**.

Pharmacy characteristics

The pharmacy characteristics gathered were the number of pharmacists and technicians, current vacancies for a pharmacist or technician, the number of prescriptions per day, and the presence of a separate counselling area. The knowledge of the pharmacy team on SMBG as perceived by the respondent was determined using three statements concerning the ability of the pharmacy's staff to provide patient counselling. The workload was ascertained through agreement with a statement on workload being a reason for providing less counselling than desired. All of these items were defined as pharmacy characteristics, as they all were, to a certain extent, directly controllable by the community pharmacist. Because respondents might not always be the actual proprietor of the pharmacy, we also included a question on the pharmacist's perception of his or her independence to determine the level of services in diabetes care. Perceived knowledge, level of independence, and workload were scored on a four-point scale (entirely disagree to entirely agree).

Data analysis

Pharmacies reporting that they performed two or less of the five support activities defined in the practice guidelines were classified as low-level service (LLS) pharmacies. High-level service (HLS) pharmacies were those that performed three, four, or all of the support activities. The effect of local agreements was analysed in three different ways: (1) based on the parties involved in the agreement, with no local agreement as the reference group, (2) comparing any local agreement with no local agreement, and (3) comparing active involvement of a community pharmacy in a local agreement to passive involvement. All analyses were performed separately for the topic of the agreement.

Table 1. The classification of the local agreements.

Topic of agreement
A. patient counselling
B. calibration/checking
Parties involved in agreement
a. none (no local agreement)
b. agreement, community pharmacy not participating [a]
c. agreement, community pharmacy participating [a]
- active involvement
- passive involvement
[a] These categories were also grouped to form the category 'any local agreement'.

To study the effect of local agreements independent of pharmacy characteristics, we used two methods. First, we calculated changes in model statistics of a logistic regression model with the level of services as a dependent variable and all pharmacy characteristics as independent variables after addition of the factor 'local agreement'. Again, the effect of agreements was analysed in the three different ways mentioned above. Second, the crude odds ratio (OR) of pharmacies (HLS versus LLS) involved in agreements on calibration/ checking of SMBG equipment compared with no local agreement was compared with the OR after adjusting for different pharmacy characteristics. Respondents who agreed that they could not determine the pharmacy's policy on diabetes care independent of any possible proprietors of that pharmacy were excluded from this analysis.

Furthermore, the association of pharmacy characteristics with the provision of services was determined. The extreme categories in the questions regarding staff's knowledge and workload were used infrequently. Therefore, we analysed workload as a dichotomous variable. Knowledge was classified as sufficient when respondents agreed on two or more statements.

All associations were adjusted for having a diabetes care improvement project implemented in the respondent's pharmacy.

RESULTS

Of all 1,642 pharmacies in the main study, 757 returned the questionnaire. After exclusion of annexes and out-of-hours pharmacies, 724 (44%) remained. Data on local agreements on patient counselling were missing from 81 responses, resulting in 643 (39%) evaluable questionnaires. For analyses of local agreements on calibration/checking of SMBG equipment, 695 questionnaires were evaluable.

Local agreements and the provision of SMBG services by community pharmacies

Table 2 shows the characteristics of pharmacies offering LLS and those providing HLS. An average of one service was offered in LLS pharmacies, which primarily was counselling on the choice of a blood glucose meter or blood glucose testing procedure. HLS pharmacies provided an average of almost four activities.

Overall, the existence of any local agreement on patient counselling or calibration/ checking of SMBG equipment was reported by 31% (228) and 13% (91) of all pharmacies, respectively. Of all 724 respondents, 8% (58) did not know whether there was any co-operation on patient counselling; for agreements on calibration/checking this was 12% (83). A local agreement was often between general practitioners and pharmacists, diabetes nurses and pharmacists, or general practitioners and diabetes nurses if the agreement did not include a pharmacy.

Association between local agreements and level of services

Table 3 reports the associations between the three ways local agreements were analysed and the level of services. The respondents who reported a local agreement in which the pharmacy participated were more likely to provide HLS. In contrast, those who reported an agreement in which the pharmacy did not participate were less likely to work in an HLS pharmacy compared with no local agreement. This was significant only for agreements on patient counselling. Furthermore, pharmacies actively involved in the agreement were more likely to be HLS pharmacies. This observation was similar for agreements on calibration/checking, although the associations between agreements on calibration/checking and the level of services were more pronounced than the associations between patient counselling and the level of services.

Among the respondents who could determine their policy on self-monitoring support independent of the proprietors (82%, 590 pharmacies), adjusting for having a diabetes care improvement project implemented in the pharmacy attenuated most odds ratios by more than 10%. However, almost all odds ratios remained significant.

In sensitivity analyses using different definitions of LLS and HLS pharmacies, local agreements remained independently associated with the provision of services (data not shown).

Still, apart from local agreements, pharmacy characteristics were also associated with the level of services. A vacancy for a pharmacist, having a separate counselling area, and sufficient team knowledge of SMBG were more common among HLS pharmacies compared with LLS pharmacies.

Influence of pharmacy characteristics

When adjusted for all pharmacy characteristics, the association between local agreement on calibration/checking of SMBG equipment and the level of services remained. **Figure 1** demonstrates that, of all pharmacy characteristics, only adjustment for knowledge of SMBG had some effect on the association between local agreement and level of services. Still, it remained statistically significantly different from one. Similar findings were observed when analysing the association between local agreements on patient counselling or when using different ways to categorise local agreements (data not shown).

The independent effect of local agreement on the level of services is underlined by the changes in model statistics, although the results were less pronounced. Introducing local agreements (defined as the comparison between no local agreements to agreements with or without pharmacy's involvement) to a model containing all pharmacy characteristics improved the model significantly. The p-value of the likelihood ratio test was 0.029 and

Table 2. The characteristics of the pharmacies with a low and a high level of self-monitoring services. [a]

	n	Low level		High level	
Number of services provided, mean (sd) [b]	724	1.0	(0.87)	3.8	(0.72)
Proportion of times a service is actually provided [b, c]	507				
< 50		29	(49)	21	(70)
50-80%		54	(91)	50	(169)
> 80%		16	(27)	30	(101)
Local agreements, % (n)					
Local agreement on patient counselling	643				
any local agreement		57	(98)	55	(130)
no local agreement		33	(168)	38	(189)
don't know		10	(30)	8	(28)
Parties involved in agreement on patient counselling on SMBG [b]	585				
local agreement, pharmacy participating		20	(52)	34	(107)
local agreement, pharmacy not participating		17	(46)	7	(23)
no local agreement		63	(168)	59	(189)
Type of pharmacy-containing agreement on patient counselling on SMBG [b]	105				
pharmacy plays an active role		29	(9)	73	(54)
pharmacy plays a non-active role		71	(22)	27	(20)
Local agreement on calibration/checking [b]	611				
any local agreement		8	(26)	17	(64)
no local agreement		74	(241)	76	(281)
don't know		18	(58)	7	(25)
Parties involved in the agreement on calibration/checking of SMBG equipment [b]	611				
local agreement, pharmacy participating		6	(17)	16	(56)
local agreement, pharmacy not participating		3	(8)	2	(8)
no local agreement		91	(241)	81	(281)
Type of pharmacy-containing agreement on calibration/checking of SMBG equipment	47				
pharmacy plays an active role		64	(7)	86	(31)
pharmacy plays a non-active role		36	(4)	14	(5)
Pharmacy is part of health care centre	723	19	(56)	15	(50)
Pharmacy characteristic, % (n)					
Pharmacy is independent to determine policy on SMBG services [b]	724				
(entirely) disagree		22	(75)	15	(59)
(entirely) agree		78	(264)	85	(326)
Pharmacy team has sufficient knowledge of SMBG [b]	724				
(entirely) disagree		57	(173)	62	(43)
(entirely) agree		43	(166)	38	(342)
Separate counselling area [b]	719				
available		69	(233)	80	(306)
not available		31	(104)	20	(76)
Vacancy for pharmacists [b]	724	4	(14)	8	(31)

SMBG = self-monitoring of blood glucose.

[a] Due to missing data, not all numbers total 724.

[b] The characteristics that differed significantly (p value χ^2 or *t*-test < 0.05).

[c] Not included are 116 pharmacies that reported they provide no services.

0.048 for agreements on patient counselling and calibration/checking, respectively. Active compared with passive involvement in patient counselling also significantly improved the model (p-value of the likelihood ratio test was 0.004). Local agreements defined as any local agreement compared with no local agreement did not improve the model significantly (p-value > 0.30).

DISCUSSION

This study shows that a community pharmacy's involvement in local agreements is associated with the provision of more services to patients performing SMBG. The association was independent of pharmacy characteristics, but only for agreements on patient counselling. For agreements on calibration/checking of SMBG equipment, we observed similar effects. However, due to insufficient statistical power, not all of these observations were statistically significant.

The observed variation between pharmacists in the provision of services has been reported previously. A study in the US found that pharmacies show a large variation in the proportion of patients to whom diabetes education is provided. [15] The findings from that study and ours are supported by models of professional role orientation. Activities are influenced by pharmacists' professional self-perception, especially in newly developing roles such as diabetes care. [16] Even though practice guidelines exist, our results show that pharmacists are likely to form their role definition based on self-derived norms, leading to a wide range of professional behaviour.

The effect of local agreements on the level of services was smaller when restricted to agreements on patient counselling. This may be the result of agreements on calibration/checking being more easily obtained. In most of the latter agreements, only the pharmacy and the manufacturer of SMBG equipment were involved in contrast with multiple general practitioners and diabetes nurses in patient counselling. Interprofessional co-operation was found to be a barrier in the provision of pharmaceutical care in many studies. [13, 17, 18] Furthermore, patient counselling is a relatively new activity in community pharmacies compared with technical processes, such as calibration, which could be seen as a natural extension of calibration activities already performed by pharmacies. Pharmacists might feel less comfortable with starting or joining agreements on patient counselling.

An important aspect to consider is the cause–effect relationship between the level of services and local collaboration. Our results imply that involvement in local agreements improves the level of services and not vice versa. If a higher level of service would lead to more involvement in agreements, we would have found that the association between no local agreement and level of services would be the same as between not participating in a local collaboration and the level of service. However, we observed a significant difference in the odds ratios for no local agreement and local agreements in which a

Table 3. The association between local agreements as well as pharmacy characteristics and the provision of pharmacy services.

	Crude OR (95% CI)	Adjusted OR (95% CI) [a]
Implementation of diabetes care improvement project in daily care (n = 695)		
yes	3.72 (2.71 – 5.11)	NA
no	reference	
Local agreements (n)		
Local agreement on patient counselling on SMBG		
any local agreement (187)	1.30 (0.90 – 1.90)	1.14 (0.77 – 1.70)
no local agreement (279)	reference	reference
Parties involved in the agreement on patient counselling on SMBG	2.16 (1.38 – 3.37)	1.74 (1.09 – 2.78)
local agreement, pharmacy participating (132)	0.42 (0.23 – 0.78)	0.46 (0.24 – 0.87)
local agreement, pharmacy not participating (55)	reference	reference
no local agreement (279)		
Type of pharmacy-containing agreement on patient counselling on SMBG	6.32 (2.14 – 18.6)	5.00 (1.62 – 15.4)
pharmacy plays an active role (50)	reference	reference
pharmacy plays a non-active role (36)		
Local agreement on calibration/checking of SMBG equipment	2.38 (1.35 – 4.21)	2.06 (1.14 – 3.72)
any local agreement (71)	reference	reference
no local agreement (412)		
Parties involved in the agreement on calibration/ checking of SMBG equipment		
local agreement, pharmacy participating (60)	3.54 (1.79 – 7.00)	3.07 (1.52 – 6.20)
local agreement, pharmacy not participating (11)	0.66 (0.20 – 2.20)	0.53 (0.15 – 1.86)
no local agreement (412)	reference	reference
Type of pharmacy-containing agreement on calibration/checking of SMBG equipment		
pharmacy plays an active role (32)	7.00 (1.23 – 39.8)	8.20 (1.15 – 58.4)
pharmacy plays a non-active role (8)	reference	reference
Practice type of pharmacy		
part of health care centre	0.84 (0.52 – 1.36)	0.88 (0.53 – 1.47)
no part of health care centre	reference	reference

community pharmacy does not participate. This is supported by our finding that active involvement in a local agreement is more common among HLS pharmacies compared with LLS pharmacies. Moreover, most intervention studies show that strengthening co-operation results in the improvement of process. [19] Nevertheless, our results are based on a cross-sectional study, which limits its applicability. Since active involvement in local agreements may, in the future, become relevant in improving pharmaceutical care, longitudinal studies are warranted.

Response rates for this type of study are generally low, as it was with our questionnaire. Non-response can introduce a significant bias if, for example, pharmacists with no interest in pharmaceutical care ignore the questionnaire. However, if this was true, we

Table 3. – *continued.*

	Crude OR (95% CI)	Adjusted OR (95% CI) [a]
Pharmacy characteristics (n)		
Number of pharmacists (557) [b]	0.99 (0.79 – 1.25)	0.94 (0.73 – 1.21)
Number of technicians (534) [b]	1.02 (1.00 – 1.04)	1.02 (1.00 – 1.04)
Vacancy for pharmacist (565)		
vacancy	1.89 (0.93 – 4.22)	2.36 (1.07 – 5.24)
no vacancy	reference	reference
Vacancy for technician (564)		
vacancy	1.08 (0.67 – 1.74)	0.97 (0.59 – 1.61)
no vacancy	reference	reference
Number of prescriptions per day (565)		
small pharmacy	0.69 (0.46 – 1.05)	0.70 (0.44 – 1.08)
average pharmacy	reference	reference
large pharmacy	1.19 (0.78 – 1.81)	1.13 (0.73 – 1.75)
Separate counselling area (563)		
available	1.77 (1.20 – 2.61)	1.57 (1.04 – 2.38)
not available	reference	reference
Knowledge of SMBG (565)		
sufficient	9.79 (6.08 – 15.4)	8.20 (5.09 – 13.2)
not sufficient	reference	reference
Workload is reason to provide less patient counselling than planned (565)		
(entirely) agrees	0.81 (0.58 – 1.14)	0.94 (0.65 – 1.34)
(entirely) disagree	reference	reference

NA = not applicable; SMBG = self-monitoring of blood glucose; OR = odds ratio; 95% CI = 95% confidence interval.

[a] Adjusted for implementation of diabetes care improvement project in daily practice. All analyses were performed among the respondents who reported to determine the policy on diabetes care independent of the actual owners of the pharmacy.

[b] Per one full-time equivalent.

would expect a relatively high proportion of respondents who had participated in the nationwide diabetes care improvement project. Yet, the number was similar to the actual participation rate (48% and 45%, respectively). [20]

Non-response and self-reporting might lead to an overestimation of the absolute level of services, which is a common problem of surveys into professional behaviour. [21] We tried to minimise this bias by allowing the respondent to estimate the proportion of times a service was actually provided. Furthermore, our questionnaire was anonymous. Still, extrapolations of the number of pharmacies providing a certain activity must be interpreted with care, also with respect to the non-response. However, even if self-reported behaviour represents overestimation of the actual level of services, self-perceptions are important since they are likely to be linked to the motivation of pharmacists to either change their practice or make no changes. Moreover, since we performed only a limited validation of our questionnaire, our results must be interpreted in the light of the instrument used.

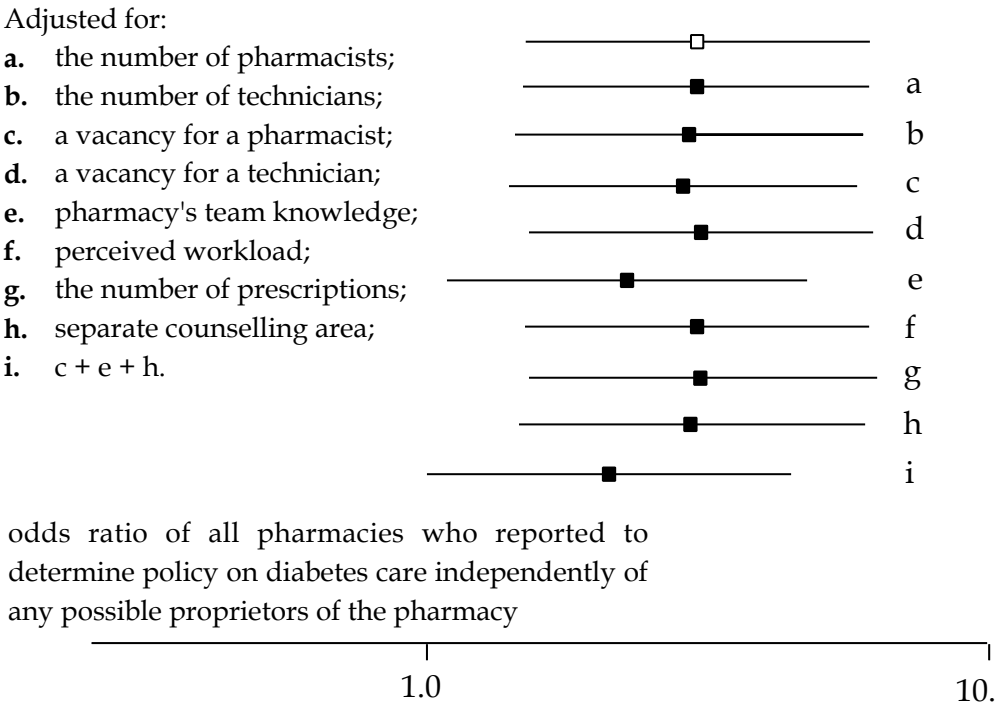

Figure 1. The effect of adjustment for pharmacy characteristics on the association between local agreements and the level of pharmacy services. The solid square represents the association (odds ratio) between local agreement (any versus no agreement) on calibration/checking of self-monitoring of blood glucose equipment and the level of services. Open squares represent the same association, but adjusted for one or a set of pharmacy characteristics.

CONCLUSIONS

Although the pharmacy's involvement in local agreements is an important determinant of the level of services provided to patients performing SMBG, it is not the only factor. To become an HSL pharmacy, other structural aspects related to the pharmacy must also be fulfilled. This indicates that interventions to overcome barriers in the pharmaceutical care of SMBG must be focused on internal processes as well as co-operation with other healthcare professionals. Moreover, it also suggests that the level of services is, to a large extent, directly controllable by the individual pharmacist.

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Membership of the Diabetes Patient Organisation Determines the Choice of Supplier of Blood Glucose Test Strips

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Submitted

ABSTRACT

Background: Distribution of blood glucose testing equipment is not restricted to a specific profession. If patients do not choose their supplier randomly, this will lead to a clustering of patients with specific characteristics and counselling needs.
Objective: To study if the characteristics of patients collecting test strips in a community pharmacy differ from those who receive their test strips through other channels.
Study design: A cross-sectional survey among a random selection of diabetes mellitus patients 18 years or older.
Method: Patients were recruited in 60 Dutch community pharmacies. They self-monitored their blood glucose at least once between January 2003 and March 2003. Respondents completed a 30-item self-administered questionnaire. Their self-reported current collection of blood glucose test strips in community pharmacy was compared to all other suppliers of blood glucose monitoring equipment. Data were analysed using multivariable logistic regression analysis.
Results: The patients who collected blood glucose monitoring equipment in community pharmacies were more likely to have type 2 diabetes, were older and less likely to perform self-regulation of insulin needs compared to those who acquire their equipment through other channels. They were also less likely to be a member of the diabetes patient organisation. Only this membership remained significantly associated in the multivariable analysis (odds ratio: 0.60, 95% confidence interval: 0.40 – 0.90). No statistically significant differences on indicators of disease severity or self-monitoring behaviour were found.
Conclusions: Apart from the membership of the diabetes patient organisation, we could not indicate any other characteristics of patients that were independently related to the supplier of equipment for self-monitoring of blood glucose.

INTRODUCTION

Diabetes is a chronic illness that requires continuing medical care to reduce the risk of long-term complications. [1-3] The two most frequently diagnosed types of diabetes are type 1 and type 2 diabetes. Both have hyperglycemia (elevated blood glucose levels) in common, but they differ in pathophysiological origin. An estimated 171 million people suffer from diabetes world-wide. [4] Especially long-term complications are associated with high morbidity, high cost and decrease in quality of life. [5-9]

Self-management of diabetes is recognised as an important aspect of the treatment. [1,10] Self-monitoring of blood glucose (SMBG) is considered a cornerstone of self-management. [1] SMBG is a technique that enables a patient to independently measure his or her current blood glucose level, using an electronic measuring device (blood glucose meter) and a disposable reagent (blood glucose test strip). The objective of SMBG is twofold: to gather data for clinical decision-making and to enable patients to monitor and react to changes in their blood glucose level. A survey among Dutch general practices reported that general practitioners (GPs), practice assistants, diabetic nurse specialists as well as practice nurses are involved in education on self-monitoring of blood glucose (SMBG). [11] In addition to these healthcare providers, community pharmacies may also play a role, as is promoted in national and international guidelines on pharmacy practice. [12, 13]

In the Netherlands, SMBG equipment such as blood glucose meters and test strips are distributed by community pharmacies, mail order companies and, to a lesser extent, by diabetes nurses. Patients are not obliged to acquire their SMBG equipment from a specific supplier. Although a patient does not need a prescription to obtain SMBG equipment, insurers do require it for reimbursement. Depending on the type of treatment for hyperglycemia, patients are entitled to a certain amount of test strips per quarter. Since the cost of SMBG are considerable, its use among non-reimbursed patients is limited.

If the selection of a supplier is not a random process, freedom of choice of supplier may lead to grouping of patients with specific characteristics. Research on this selection process is limited. Since clustering of patients with similar characteristics around GPs has been reported to exist in diabetes care [14], clustering of patients according to the distributor of SMBG equipment could be a relevant issue.

The aim of our study was to assess if the characteristics of patients acquiring test strips differ between suppliers of blood glucose monitoring equipment.

METHODS

Setting and study population

We used data from a survey among 1,547 patients of 18 years or over who collected at least two prescriptions of oral hypoglycemic agents (OHAs), two prescriptions of insulin or one prescription of insulin and one of an OHA between March 2002 and March 2003. These two classes of drugs are the only classes available to treat hyperglycemia, apart from changes in lifestyle.

Per pharmacy, we randomly selected 8% of the patients on glucose lowering drugs, using the complete, anonymous medication history of 60 Dutch pharmacies. These pharmacies were recruited through an advertisement in a professional journal. To ensure that we had enough respondents performing SMBG, 39 of the 60 pharmacies were randomly selected to include - at random - an additional five insulin users. Since it was the first study into determinants of suppliers, there was no information available on the potential differences. Power analysis was therefore not performed. We aimed to include 500 users of blood glucose test strips. The number of invitations was based on the expected response, but given the proportion of diabetes patients performing SMBG, the workload for participating pharmacies became too high. For that reason we asked two-thirds of the pharmacies (one pharmacy did not honour our request) to include additional insulin users. Previous studies show that insulin users are more likely to practice SMBG than patients using oral hypoglycemic agents. [15] The pharmacists included only those patients who were alive at March 1st, 2003. Furthermore, they excluded all patients who were known to have continuous nursing supervision (i.e. patients living in a nursing home or on a psychiatric ward) or did not understand Dutch. During March 2003, the participating pharmacists sent the selected patients a questionnaire, which could be returned to the researchers anonymously. The questionnaire is included in Appendix 3. After three weeks, a reminder was sent. Based on the results, we excluded all patients who did not perform a blood glucose measurement between January 2003 and March 2003. Furthermore, patients who reported to receive SMBG equipment from multiple sources were excluded as well as all questionnaires with missing data on the supplier of SMBG equipment.

Survey

We used a Dutch questionnaire – measuring the quality of care from a patient's perspective – from the Netherlands Institute for Health Services Research (NIVEL) as a starting point in developing our instrument. [16] We used its questions on demographics (age and gender), the duration of diabetes, the perceived diabetes status (rated as very poorly or poorly controlled, moderately controlled, well-controlled, or very well-controlled), the complications of diabetes (self-reported nephrological, neurological or visual problems) and the last known hemoglobin A1c (A1c). A1c is a widely used clinical marker for the seriousness of hyperglycemia. The questions on the current supplier of

the test strips, membership of the diabetes patient organisation, hypoglycemic events (a side effect of drug treatment), self-reported hospitalisation between January 2003 and March 2003, the brand of test strip and the usage pattern of blood glucose test strips were added.

Usage pattern of test strip use was defined in two ways: as the number of test strips per week and as the number of test strips per day together with number of days per week if a patient responded to perform glucose curves. Furthermore, we investigated if patients self-regulated their insulin need. Glucose curves and self-regulation were used as proxy for the two different objectives of self-monitoring.

Response categories existed of two or more options, of which the patient was instructed to tick the most appropriate one. With some questions, a patient could tick more than one response box. If relevant, the respondent could add a short explanation or comment. For year of birth, duration of diabetes, number of hypoglycemic events and frequency of glucose curves, patients could fill in the appropriate number. All these questions and those on the usage pattern of test strips explicitly related to the patient's situation in the previous two months.

All data were self-reported, except data on medication use between March 2002 and March 2003 and level of co-morbidity. The latter two were determined based on the patient's dispensing records. Co-morbidity was analysed using the chronic disease score [17], ranging from 0 for patients without co-morbidity to a maximum of 35. Dispensing history was also used to calculate the number of concurrent OHA dispensed to the patient.

For the outcome of interest (supplier of SMBG equipment) a patient could choose between community pharmacy, mail order company, diabetes nurse of other supplier. In our analyses, we classified all answers as either community pharmacy or other sources.

The questionnaire was pre-tested by ten diabetic patients practicing self-monitoring, who were recruited in three different pharmacies. Their community pharmacist considered these patients to be representative for other diabetic patients in the pharmacy. The questionnaire was found to be comprehensible and relevant.

Analysis

The association between the characteristics and the supplier of SMBG equipment was analysed with logistic regression. This technique is widely used to determine the strength of associations in cross-sectional data such as from our survey. Other (non-pharmacy) suppliers were used as the reference group. All factors that were significantly associated with supplier ($p < 0.05$) were studied further in a multivariable model to adjust for potential confounding among the remaining determinants. All data were analysed using SPSS, version 11.0.

Table 1. The characteristics and the associations between patient characteristics, indicators of disease severity and self-monitoring behaviour with the supplier of SMBG equipment. [a]

	Community pharmacy		Other suppliers		Crude OR (95% CI)
Number of observations	345		239		
Demographic characteristics, % (n)					
Age, mean (sd) [b]	63.5	(13.8)	59.9	(14.0)	1.21 (1.06 – 1.36) [c]
Gender					
male	52.8	(182)	46.4	(111)	1.27 (0.91 – 1.77)
female	46.4	(160)	51.9	(124)	reference
Type of antidiabetic drug treatment					
oral hypoglycemic agents	17.4	(60)	20.5	(49)	1.34 (0.91 – 1.96)
insulin	47.2	(163)	50.6	(121)	reference
both	34.5	(119)	27.6	(66)	0.91 (0.58 – 1.42)
Member of patient organisation					
yes	23.5	(81)	36.0	(86)	0.55 (0.38 – 0.79)
no	73.0	(252)	61.5	(147)	reference
Diabetes, % (n)					
Type of diabetes					
type 1	13.6	(47)	21.3	(51)	reference
type 2	73.9	(255)	66.9	(160)	1.73 (1.11 – 2.69)
Duration of diabetes, mean (sd) [b] (537)	12.6	(9.3)	13.7	(11.6)	0.99 (0.97 – 1.01)
Indicators of disease severity, % (n)					
Self-reported severe hypoglycemic event					
yes	13.6	(47)	15.1	(36)	0.88 (0.55 – 1.41)
no	84.9	(293)	82.4	(197)	reference
missing	0.6	(2)	1.3	(3)	
Value of last A1c measurement					
< 7.5%	15.9	(55)	21.3	(51)	reference
7.5-8.5%	36.2	(125)	35.1	(84)	1.38 (0.86 – 2.21)
> 8.5%	12.5	(43)	15.1	(36)	1.11 (0.62 – 1.99)
unknown	26.3	(91)	20.9	(50)	1.69 (1.01 – 2.82)
missing	8.1	(28)	6.2	(15)	
Self-reported visual, nephrological or neurological complications					
yes	35.4	(122)	40.6	(97)	0.81 (0.57 – 1.14)
no	58.6	(202)	54.4	(130)	reference
missing	5.2	(18)	3.8	(9)	

RESULTS

Response

Of the 1,547 patients that were sent a questionnaire, 72% (1,110) responded. Of those patients, 611 reported to have performed SMBG in the previous two months. Because of multiple suppliers, 28 questionnaires were excluded. Another five patients were excluded due to missing data on the supplier of SMBG equipment.

Univariable associations

Of all 578 included patients, 59% (342) collected their SMBG equipment in a community pharmacy. **Table 1** describes the association between the supplier and the various

Table 1. - *continued.* [a]

	Community pharmacy		Other suppliers		Crude OR (95% CI)
Indicators of disease severity, % (n)					
Perception of diabetes status					
poorly or very poorly controlled	6.7	(23)	3.8	(9)	1.66 (0.67 – 4.15)
moderately controlled	27.8	(89)	24.7	(59)	0.98 (0.54 – 1.78)
well-controlled	55.1	(190)	58.6	(140)	0.88 (0.51 – 1.51)
very well-controlled	11.6	(40)	10.9	(26)	reference
missing	0.0	(0)	0.8	(2)	
Chronic disease score [d] (578)	5.4	(2.9)	5.0	(3.0)	1.04 (0.98 – 1.10) [c]
Measuring a hypoglycemic or hyperglycemic event					
yes	66.1	(228)	71.1	(120)	0,.74 (0.49 – 1.12)
no	24.6	(85)	19.7	(47)	reference
missing	8.4	(29)	7.9	(19)	
Hospitalised between January 2003 and March 2003					
yes	7.6	(26)	5.4	(13)	1.40 (0.71 – 2.79)
no	90.4	(312)	91.6	(219)	reference
missing	1.2	(4)	1.7	(4)	
Self-monitoring behaviour, % (n)					
Self-regulation of insulin need [e]					
yes	34.2	(118)	41.8	(100)	reference
no	40.9	(141)	32.2	(77)	0.64 (0.44 – 0.95)
missing	7.5	(26)	5.9	(14)	
Average frequenct of SMBG					
< 1 per week	19.4	(67)	14.2	(34)	1.68 (1.01 – 2.77)
1 - 7 per week	36.8	(127)	33.5	(80)	1.35 (0.90 - 2.02)
> 1 per day	29.0	(100)	35.6	(85)	reference
missing	13.9	(48)	15.5	(37)	

OR = odds ratio; 95% CI = 95% confidence interval; SMBG = self-monitoring of blood glucose.
[a] In italic type all the factors that were significantly associated (p-value log likelihood < 0.05). Unless otherwise stated, n = 578. Due to missing data, not all numbers add up.
[b] In years.
[c] Per decade.
[d] Per point.
[e] 102 Patients did not use insulin but only oral hypoglycemic agents (OHA).

characteristics of the respondents. For every ten year increase of age, patients are about 20% more likely to acquire SMBG equipment in community pharmacies, compared to other suppliers (odds ratio (OR) 1.21, 95% confidence interval (95% CI): 1.06 – 1.36). Type 2 patients are almost twice more likely to receive their test strips through their pharmacy than through other suppliers compared to type 1 patients (OR: 1.73, 95% CI: 1.11 – 2.69). Only two other characteristics were significantly associated with the supplier. First, membership of the diabetes patient organisation was more common among those who collected their SMBG equipment through other channels than community pharmacies. Second, self-regulation was also more common among those respondents who reported to receive their SMBG equipment from other suppliers. When having a pharmacy as the supplier, patients were more likely to use test strips infrequently compared to

Table 2. The association between age, the type of diabetes, the membership of the diabetes patient organisation and self-regulation with the supplier of SMBG equipment.

	Crude OR (95% CI)	Adjusted OR (95% CI) [a]	Change in OR
Age [b]	1.21 (1.06 – 1.36)	1.14 (0.99 – 1.32)	-6%
Type of diabetes			
type 1	reference	reference	
type 2	1.73 (1.11 – 2.69)	1.03 (0.58 – 1.85)	-68%
Member of diabetes patient organisation			
yes	0.55 (0.38 – 0.79)	0.60 (0.40 – 0.90)	8%
no	reference	reference	
Self-regulation of insulin need			
yes	0.64 (0.44 – 0.95)	0.83 (0.54 – 1.28)	22%
no	reference	reference	

OR = odds ratio; 95% CI = 95% confidence interval; SMBG = self-monitoring of blood glucose.
[a] Adjusted for the three other variables in the Table.
[b] Per decade.

other suppliers. However, this characteristic was not significantly associated (p-value = 0.10). There was a trend in the value of the last A1c value, which seemed to be higher in patients who received test strips through a community pharmacy. They also tended to be hospitalised more often, used OHAs more often, were less likely to measure a hypo- or hyperglycemic event and perceived their diabetes status as worse than patients who were supplied by other sources. However, all these factors were not significantly different at $p < 0.05$.

Multivariable associations

The four characteristics found to be significantly associated with the supplier of SMBG equipment were to a certain extent related to each other. Only the strength of the association of age and the membership of the diabetes patient organisation with supplier did not change in a multivariable model (**Table 2**). The effect of self-regulation attenuated about 20%. The OR for the type of diabetes was most affected, changing from 1.73 to 1.03, indicating that the type of diabetes was not associated with the supplier of SMBG equipment. All associations except that of the patient organisation membership became non-significant in the multivariable model.

DISCUSSION

Our results show that diabetes patients do not choose a supplier of blood glucose test equipment randomly. They cluster on age, the type of diabetes, self-regulation of insulin need and the membership of diabetes patient organisation. When we adjusted for correlation between these determinants, only membership of the diabetes patient organisation remained statistically significantly different between patients who obtain

their SMBG equipment in a community pharmacy and those who acquire it through other suppliers.

The associations between these four characteristics and the supplier of SMBG equipment may be explained by two independent factors. First, those patients who are a member of the diabetes patient organisation may be more likely to have a non-pharmacy supplier due to the marketing strategy of mail order companies. For example, they advertise their services in the patient organisation's magazine. Community pharmacies, on the other hand, are less involved in promotion of dispensing of SMBG equipment. Second, it may be associated with differences in health care process between type 1 and type 2 patients. Almost all type 2 patients on oral hypoglycemic agents are treated by GPs. In some cases, GPs also treat type 2 patients using insulin. [10] However, type 1 patients are almost always monitored by an internal specialist. This can lead to differences in the setting in which patients are educated on performing SMBG. Patients educated in the outpatient setting may be more likely to be directed to a community pharmacy for their supplies. It may explain the observed differences in the characteristics between both groups. Type 1 patients are, on average, younger. Furthermore, type 1 patients are more likely to be a member of the diabetes patient organisation. Finally, self-regulation of insulin need is more relevant for type 1 patients, since they are more at risk of experiencing hypoglycemic events. [18] The associations with the type of drug treatment, the frequency of test strip use, hospitalisation and measuring a hypoglycemic or hyperglycemic event, though only at a non-significant level, is in line with this explanation. It is underlined by the observation that the type of diabetes became non-significant in the multivariable model; the effect of the type of diabetes could be explained almost completely by the three other characteristics that are related to the type of diabetes.

We are not aware of any national or international studies of differences in characteristics between patients who acquire test strips from different suppliers. Our results show that in the Netherlands, around 60% of the patients receive their SMBG equipment through a community pharmacy. Any (international) comparison with published health care consumption data is limited. In the public domain, data are not detailed enough to establish the cost on the level of dispensing. Moreover, the market share of community pharmacies in dispensing diabetes test equipment has been growing in the recent years. This makes any comparison sensitive to the time period observed.

In itself, clustering of diabetes patients on different providers of diabetes care is not novel finding. Studies into the quality of (diabetes) care consistently report case-mix bias and clustering effects, impeding comparison of providers. [14, 19] However, it has not been reported for dispensing of medical aids. Since the availability of SMBG equipment

and other medical aids from multiple suppliers is not unique to the Netherlands, our findings may also extend to other countries. This is even more relevant if a patient has the opportunity to decide between different suppliers.

Limitations

The questionnaire was only checked for face validity and not all questions were used in previous studies. This may have resulted in misclassification of patients, especially for more ambiguous domains such as a patient's perception. However, most of the questions we added where relatively straightforward, limiting the probability of misinterpretation. Still, misclassification may have occurred, although it is unlikely that patients who acquire test strips in a community pharmacy differ in this respect from those acquiring them from other sources. Such a misclassification would then only lead to an underestimation of the association between clinical status and supplier.

The association between the determinants of the supplier of SMBG equipment affects the statistical power of our results. Self-regulation of insulin use is more important among type 1 patients, the average age of type 2 patients is higher than for type 1 patients and insulin users are generally more involved in the patient organisation. Consequently, statistical analyses are hampered resulting in large confidence intervals.

A considerable part of observational research on the epidemiology of medical aids has been performed on self-monitoring of blood glucose. In most of the studies, exposure to SMBG is determined by self-report of patients. One of the limitations of this method is that it can introduce for example recollection bias and socially desirable answers. This is potentially also a drawback of our study design.

Implications for research

Routine data collections do not have the problem of self-reporting biases. However, our results show that data from pharmacy prescription databases cannot be generalised to all users of SMBG. Especially since test strip frequency has been found to be associated with age and type of diabetes [20, 21], results of studies of for example Evans [22] but also our previous work [15, 23], may not be directly extrapolated to a national level. To what extent this also plays a role in studies into other medical aids is unclear but warrants further research.

Implications for (pharmacy) practice

If the membership of the diabetes patient organisation is considered a proxy for patient empowerment, our results imply that grouping occurs of patients with specific counselling needs. Together with the fact that the testing procedure is a common source of errors [24], community pharmacies have to realise that patients acquiring test strips in their facility may require special attention. Since proper self-monitoring techniques, calibration and maintenance of blood glucose meters are essential to ensure a beneficial

effect of SMBG on outcomes [24-26], this makes evaluation of a patient's monitoring technique very important, both initially and at regular intervals. [1] Furthermore, if a community pharmacy opts to improve its market share, the optimal strategy should include co-operation with the diabetes patient organisation.

In conclusion, suppliers deliver equipment to different groups of patients, with potentially different barriers to performing SMBG correctly. Still, the disease severity was similar, indicating that the influence of any difference between supplier in patient support on patient outcomes is relatively limited. However, if providers of SMBG equipment are to be included in improving self-monitoring techniques, different implementation strategies may be essential.

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CHAPTER 4

PATIENT OUTCOMES OF COMMUNITY PHARMACY SERVICES

Een slang in de herfst -
met een blik als van een mens
kijkt hij naar me.

Yamaguchi Seison 1892-1988

Perceived Diabetes Status is Independently Associated with Glucose Monitoring Behaviour

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ABSTRACT

Aims: To investigate if patients' perceptions of their diabetes status is related to their blood glucose self-monitoring (SMBG) behaviour, independent of disease severity.
Methods: A cross-sectional study in 1,561 patients, 18 years or older, who filled at least two prescriptions for any glucose lowering drug between March 2002 and March 2003. Using a 30-item self-administered questionnaire, data on the self-monitoring behaviour (the frequency of test strip use and objective of self-monitoring), their perceived diabetes status and the disease severity were gathered. We used logistic regression to calculate odds ratios (OR) and their 95% confidence intervals (95% CI).
Results: About 54% of the patients (n = 841) returned evaluable questionnaires. Practicing SMBG was more common among patients who rated their diabetes status as poorly or moderately controlled compared to those who rated it (very) well-controlled (OR 1.93; 95% CI: 1.20 – 3.12). For type 2 patients, a better perceived diabetes status was more likely in those who performed SMBG infrequently compared to those who performed SMBG frequently (p-value for trend = 0.001). Self-reported factors of disease severity and personalised objectives did not affect these associations considerably.
Conclusions: Among type 2 diabetes mellitus patients, SMBG behaviour is associated with patients' perceptions of diabetes status, irrespective of the self-reported disease severity.

INTRODUCTION

Reducing hyperglycemia is an important factor in the prevention of diabetic complications. [1,2] Lowering blood glucose levels can be achieved through different pharmacological and non-pharmacological treatments. Patient education on self-management of diabetes is considered an integral component of all diabetes care plans. [3]

One of the elements of self-management is self-monitoring of blood glucose (SMBG). Self-monitoring behaviour varies among diabetes patients. A patient's clinical situation is a key element in the frequency of self-monitoring advised to patients. [4] For example, frequent monitoring was found to be more common in patients experiencing hypoglycemic events. [5] Furthermore, patients using insulin are more likely to use test strips frequently than those who use oral hypoglycemic agents (OHAs). [5-8] In particular, patients who self-regulate their insulin need are far more common among frequent test strip users. [5] In practice, these personalised objectives of self-monitoring (to gather data for clinical decision-making and to enable patients to monitor and react to changes in their blood glucose levels) are strongly correlated with the way type 1 and type 2 diabetes is treated. These conclusions are underlined by both national and international diabetes care standards, which state that SMBG is especially important in insulin treated patients. [4,9]

Still, other factors may also influence self-monitoring behaviour. For example, a patient's perception of the status of his or her diabetes could mediate the association between the clinical situation and self-monitoring behaviour. Personal illness models have been proposed as an important predictor of the level of self-management. [10] However, research into the relevance of patients' perceptions of their disease on self-monitoring is limited. Our aim was to determine if patients' perceptions of their diabetes status are associated with self-monitoring behaviour, irrespective of disease severity.

PATIENTS AND METHODS

Setting and study population

We conducted a cross-sectional survey of patients with diabetes mellitus, aged 18 years and older and living in the Netherlands. Community pharmacies were invited to participate in the study through the professional journal of Dutch pharmacists. Pharmacists were asked to send the complete, anonymised medication history between March 2002 and March 2003 of all patients who collected at least one prescription of an oral hypoglycemic agent (OHA) or insulin in that period. From this set we selected all current users of glucose lowering drugs, defined as all patients who received at least two prescriptions of OHAs, two prescriptions of insulin or one prescription of insulin and one of an OHA between March 2002 and March 2003. In each pharmacy, we made a random selection of eight percent of all current users. To make sure that we had enough respondents performing SMBG, we randomly selected 39 pharmacies to include

- at random - an additional five insulin users. Previous studies show that insulin users are more likely to practice SMBG than patients using oral hypoglycemic agents. [11] The pharmacists included only those patients who were alive at March 1st, 2003. Furthermore, they excluded all patients who were known to have continuous nursing supervision (i.e. patients living in a nursing home or psychiatric ward) or did not understand Dutch. The participating pharmacists sent the selected patients a questionnaire, which could be returned to the researchers anonymously. In the analyses, we also excluded all patients of whom the result on the question about the type of diabetes was missing.

Measurements

Even though a variety of instruments on measuring diabetes-related quality of life, diabetes self-care activities and effectiveness of treatment have been used in the literature, we chose to construct a new questionnaire for two reasons. First, most studies were performed in English-speaking populations, introducing linguistic difficulties, differences in social context and processes in diabetes care when translating the items. Secondly, none of the instruments measuring frequency of test strip use (our main outcome) have been validated. We used a Dutch questionnaire from the Netherlands Institute for Health Services Research (NIVEL) as a starting point in developing our instrument. [12] This instrument measures the quality of care from the perspective of people with diabetes.

Our questionnaire, consisting of 30 items, explored a patient's usage pattern of blood glucose test strips and its determinants. The questionnaire is included in Appendix 3. All patients who responded having used test strips in the period of 01-2003 to 03-2003 were classified as performing SMBG. In this group, we defined test strip users who performed SMBG infrequently (one or less than one test strip per day) and those who were frequent users (more than one test strip per day).

Since we were not primarily interested in the different domains of a patient's perception of his diabetes status, we measured this with a single question. Patients could rate their diabetes status as very poorly or poorly controlled, moderately controlled, well-controlled, and very well-controlled. Data on indicators of disease severity were also collected and comprised last known hemoglobin A1c levels (A1c), occurrence of severe hypoglycemic events (defined as an event requiring assistance of someone else), duration of diabetes and the presence of diabetes-related complications (self-reported nephrological, neurological or visual problems). Co-morbidity was analysed using the chronic disease score [13], ranging from 0 for patients without co-morbidity to a maximum of 35. We also asked patients how they responded when they observed a hypoglycemic or hyperglycemic value. We used the following indicators as a proxy for the individual objective of self-monitoring: the type of diabetes, the type of glucose lowering drug treatment, performing glucose curves and self-regulation of insulin needs. These

indicators were chosen because they were likely to be associated with different goals of SMBG. All questions explicitly related to the patient's situation in the previous two months. Furthermore, the questionnaire gathered data on patient characteristics.

The questionnaire was pre-tested by ten diabetic patients practicing self-monitoring, who were recruited in three different pharmacies. Their community pharmacist considered these patients to be representative for other diabetic patients in the pharmacy. The questionnaire was found to be comprehensible and relevant.

The pharmacy medication history was used to determine which glucose lowering drugs were prescribed between March 2002 and March 2003.

Analyses

In the first analysis we studied the association between self-reported diabetes status and performing SMBG (categorised as yes or no). We adjusted for potential confounders that have been associated with test strip use in previous studies: age, gender, the duration of diabetes, the type of glucose lowering treatment, self-reported A1c, complications and self-reported hypoglycemic events. [5-8, 14] In the second analysis, the study population was restricted to patients who reported to perform SMBG. We assessed the relation between self-reported diabetes status and the frequency of test strip use. Because of the small sample size and the skewed distribution of some of the variables, we limited the multivariate analyses of this second analysis to a maximum of three co-variables (the duration of diabetes, age and the type of blood glucose lowering treatment). Finally, we investigated to what extent the association between self-reported status of diabetes and the frequency of testing was influenced by (self-reported) markers of disease severity and individual self-monitoring objectives. All analyses were performed separately for type 1 and type 2 diabetes patients.

We used logistic regression to calculate these associations, expressed as odds ratios (OR) and their 95% confidence intervals (95% CI). All data were analysed using SPSS version 11.0.

RESULTS

Study population

We collected the medication history of 16,440 users of antidiabetic agents in 61 pharmacies. A total of 1,561 current users were sent the questionnaire. These randomly selected patients were comparable on age, gender and the type of antidiabetic drug use to the total population (data not shown).

About 68% of all questionnaires were returned. Twelve patients refused to participate in the study. Four patients reported to have gestational diabetes. Because of the

small numbers, this group was excluded from the analysis. Of the remaining 1,044 respondents, 841 patients met the inclusion criteria. Patients were excluded for two reasons: hospitalisation in the two preceding months (59 patients), missing data on the type of diabetes (82 patients) and incomplete information on the question regarding SMBG or recent hospitalisation (62 patients).

There was no statistically significant difference between the respondents and non-respondents in the proportion of men, the glucose lowering drug treatment or age. Patients excluded from the study were comparable to included respondents on gender, glucose lowering drug use and age.

Among all included patients, type 2 diabetes was most common (88%, see **Table 1**). Of type 2 patients, about 20% used insulin and another 20% used both insulin and OHAs during the study period. Nearly 7% of the type 2 patients and 23% of all type 1 patients reported a severe hypoglycemic event and about three out of ten patients responded to have at least one diabetes-related complication. Most patients rated their diabetes status as well-controlled. Still, a quarter of the type 2 patients and one third of the type 1 patients perceived it as moderately or poorly controlled. Among type 2 patients, 50% (371) had used test strips in the two months before filling in the questionnaire. All type 1 patients reported to perform SMBG.

Factors associated with performing SMBG

Since all patients with type 1 diabetes performed SMBG, no associations could be calculated. **Table 2** reports the association between the characteristics of type 2 patients (including the perception of the diabetes status) and whether or not a patient performed SMBG. The patients who reported a moderately or poorly controlled diabetes status were almost two times more likely to use test strips compared to the patients reporting to be well- or very well-controlled (OR: 1.93; 95%CI: 1.20 – 3.12; 30% versus 16%). Both the indicators of disease severity and type of glucose lowering treatment did only marginally influence the association between the perception of diabetes status and performing SMBG, as shown by the small difference between the crude and the adjusted OR.

Several other factors (younger age, recent change in glucose lowering drug treatment, the membership of the diabetes patient organisation, a higher chronic disease score) were also more common in patients performing self-monitoring.

Factors associated with frequency of test strip use

Among the 467 patients who performed SMBG, 239 used one or less than one test strip per day (infrequent users). We categorised 153 patients as frequent users (more than one test strip per day). Among type 1 patients, the frequent users of SMBG seemed to be more common in those who reported a poorly controlled and very well-controlled diabetes compared to well-controlled (see **Table 3**). However, these findings were not

Table 1. The characteristics of the included patients. [a]

	Type 1 diabetes		Type 2 diabetes	
Number of patients	97		744	
Patient characteristics, % (n)				
Male gender	51.5	(50)	49.5	(368)
Age, median (IQR) [b]	45.5	(22.75)	67.0	(16.0)
Member of patient organisation				
yes	71.0	(67)	12.8	(94)
no	29.5	(28)	82.2	(640)
Chronic disease score, median (IQR) [b]	3.0	(3.75)	5.0	(4.0)
Duration of diabetes, median (IQR) [b]	18.5	(18.0)	6.0	(9.0)
Use of blood glucose lowering drugs, % (n)				
Current blood glucose lowering drugs				
insulin	100	(97)	19.6	(146)
oral hypoglycemic agents	-		61.0	(454)
both insulin and oral hypoglycemic agents	-		19.4	(144)
Recent change in glucose lowering drug use [c]				
yes	19.1	(18)	30.7	(221)
no	80.9	(76)	69.3	(499)
Self-reported indicators of disease severity, % (n)				
Self-reported HbA1c				
< 7.5%	32.3	(30)	24.3	(170)
7.5 – 8.5%	45.2	(42)	32.9	(230)
> 8.5%	7.5	(7)	15.5	(108)
unknown	15.1	(14)	27.3	(191)
Self-reported presence of visual, nephro- or neuropathic complications				
none	34	(33)	26.7	(199)
at least one	66	(64)	73.3	(545)
Self-reported severe hypoglycemic event				
yes	22.7	(22)	6.6	(48)
no	77.3	(75)	93.4	(683)
Perception of diabetes status				
(very) poorly controlled	7.2	(7)	3.3	(24)
moderately controlled	25.8	(25)	19.5	(142)
well controlled	60.8	(59)	62.5	(455)
very well controlled	6.2	(6)	14.7	(107)
Currently performing self-monitoring blood glucose				
yes	100	(97)	49.9	(371)
no	-		50.1	(372)
Frequency of test strip use				
once or less per day	28	(27)	57	(212)
more than one per day	52	(50)	28	(103)
non classifiable [d]	21	(20)	16	(59)

[a] Due to missing data not all numbers add up to the total number of respondents. Type 1 and type 2 diabetes mellitus patients differ statistically significant on all characteristics, except gender and presence of complications (p-value < 0.05)

[b] IQR = interquartile range (absolute difference between 25th percentile and 75th percentile).

[c] Dosage change, switch to or addition of other glucose lowering drugs between 01-2003 and 03-2003.

[d] Data were not available or the reported data did not match with response on other questions on test strip usage pattern.

Table 2. The association between a patient's perception of his diabetes status, the type of glucose lowering drug treatment, patient characteristics as well as the self-reported disease severity with performing self-monitoring of blood glucose between January 2003 and March 2003 among type 2 patients. [a]

	Crude OR (95% CI)	Adjusted OR (95% CI) [b]
Patient's perception of diabetes status		
poorly or moderately controlled	2.17 (1.51 – 3.11)	1.93 (1.20 – 3.12)
well-controlled or very well-controlled	reference	reference
Patient characteristics		
Age [c]	0.83 (0.73 – 0.94)	0.70 (0.55 – 0.89)
Duration of diabetes [d]	3.91 (2.87 – 5.32)	1.07 (0.61 – 1.89)
Male gender	0.92 (0.69 – 1.23)	0.60 (0.36 – 1.01)
Diabetes patient organisation		
member	4.68 (2.76 – 7.92)	3.65 (1.94 – 6.88)
no member	reference	reference
Chronic disease score [e]	1.09 (1.03 – 1.16)	1.11 (1.03 – 1.20)
Glucose lowering drug treatment		
Glucose lowering treatment between 03-2002 and 03-2003		
oral hypoglycemic agents (OHA)	reference	reference
insulin alone/in combination with OHA	177 (70.6 –444)	166 (61.2 –451)
Dosage of glucose lowering treatment [f]		
recent change	1.52 (1.15 – 2.09)	1.63 (1.07 – 2.48)
no change	reference	reference
Self-reported indicators of disease severity		
Self-reported value of last hemoglobin A1c		
< 7.5%	reference	reference
7.5 – 8.5%	2.07 (1.26 – 3.41)	1.55 (0.73 – 3.31)
> 8.5%	2.47 (1.63 – 3.72)	1.44 (0.75 – 2.74)
unknown	2.54 (1.65 – 3.90)	0.99 (0.48 – 2.05)
Visual, nephropathic or neuropathic complications		
present	2.98 (2.11 – 4.22)	1.89 (0.95 – 3.24)
absent	reference	reference
Self-reported recent, severe hypoglycemic event		
present	6.41 (2.84 – 14.5)	2.51 (0.65 – 9.78)
absent	reference	reference

OR = odds ratio; 95% CI = 95% confidence interval.

[a] The number of observations is 727.

[b] The number of observations is 611; the number of events is 319. Odds ratios are adjusted for age, gender, the duration of diabetes, the type of glucose lowering treatment, self-reported A1c, complications and self-reported hypoglycemic events.

[c] Per decade.

[d] Per year.

[e] Per point.

[f] Dosage change, switch to or addition of other glucose lowering drugs between January 2003 and March 2003.

significant and no trend was observed. Because of the small number of type 1 diabetes patients, no further adjustments were made for other determinants.

For type 2 patients, the association between the frequency of testing and perceived diabetes status is summarised in **Table 3** and **Figure 1**. Self-reported diabetes status was associated significantly with the frequency of SMBG: 82% of all patients reporting a poorly controlled diabetes were frequent test strip users, compared to 30% of those who rated themselves as well-controlled (OR: 10.9; 95% CI: 3.02 – 39.7). Furthermore, 17% of the respondents with a very well-controlled diabetes status used test strips frequently (OR: 0.47; 95% CI: 0.20 – 1.13). Even though the latter result was not statistically significant, the Chi-square test for trend was ($p < 0.001$). Interestingly, the association did not change much when we adjusted for indicators of disease severity, performing glucose curves or the type of glucose lowering treatment.

Other factors strongly related to the frequency of SMBG were: performing self-regulation of insulin need and measuring a hypoglycemic or hyperglycemic blood glucose value. Frequent test strip use was also more common among those with a recent change in antidiabetic drug use. Older patients and users of OHAs were less likely to perform SMBG frequently.

Indicators of disease severity were not significantly associated with frequency of testing in this study. Adjustment for differences in age, the type of glucose lowering drug treatment and the duration of diabetes had a limited effect on most associations. Of the other determinants, only the type of glucose lowering drug treatment correlated significantly with the frequency of testing.

DISCUSSION

In this observational study, self-monitoring was associated with a patient's perception of diabetes status. Even after adjusting for recognised clinical factors for self-monitoring (disease severity and type of antidiabetic drug use), the patients who performed self-monitoring rated their status less positive than patients who did not perform SMBG. Furthermore, among type 2 patients the frequency of test strip use was also associated with a patient´s perceived diabetes status. This association too, did not change considerably when adjusted for disease severity and the personalised objectives of SMBG.

The observed importance of clinical status and personalised objectives is confirmed by previous studies. [5-8, 14, 15] However, associations of for example age and gender were not similar to associations found in other studies. Also among those studies, results are contradictory. This could be due to different definitions of the frequency of test strip use, different subpopulations and time periods. In itself, this inconclusiveness could illustrate that clinical determinants are not the only factors of self-monitoring frequency.

One aspect of the association between self-monitoring frequency and the perception of diabetes status could be the patient's mechanism for coping with negative results (blood

Table 3. The associations between patients' perceptions of diabetes status as well as other characteristics and the frequency of test strip use among type 2 diabetes patients.[a]

	Crude OR (95% CI)	Adjusted OR (95% CI) [b]
Type 2 diabetes (314) [c]		
Patients' perceptions		
Perception of diabetes status		
(very) poorly controlled (17)	10.9 (3.02 – 39.7)	10.6 (2.77 – 40.5)
moderately controlled (81)	1.38 (0.79 – 2.41)	1.55 (0.85 – 2.84)
well-controlled diabetes (174)	reference	reference
very well-controlled (42)	0.47 (0.20 – 1.13)	0.52 (0.21 – 1.29)
Patient characteristics		
Age [d]	0.79 (0.64 – 0.98)	0.71 (0.56 – 0.91)
Duration [e]	1.04 (1.01 – 1.08)	1.03 (0.99 – 1.07)
Male gender	0.95 (0.59 – 1.51)	1.02 (0.61 – 1.69)
Diabetes patient organisation		
member	1.74 (0.98 – 3.10)	1.35 (0.73 – 2.51)
no member	reference	reference
Chronic disease score [f]	1.02 (0.94 – 1.12)	1.04 (0.94 – 1.14)
Glucose lowering drug treatment		
Glucose lowering drug treatment between 03-2002 and 03-2003		
oral hypoglycemic agent	reference	reference
insulin	4.31 (2.01 – 9.94)	4.49 (1.98 – 10.2)
both	4.66 (2.19 – 9.21)	4.56 (2.06 –10.1)
Dosage of glucose lowering treatment [g]		
recent change	1.85 (1.14 – 3.01)	2.11 (1.23 – 3.64)
no change	reference	reference
Self-reported indicators of disease severity		
Self-reported value of last hemoglobin A1c		
< 7.5%	reference	reference
7.5 – 8.5%	1.03 (0.48 – 2.19)	0.97 (0.42 – 2.26)
> 8.5%	2.05 (0.87 – 4.84)	2.57 (1.00 – 6.64)
unknown	1.62 (0.75 – 3.51)	1.70 (0.72 – 4.00)
Visual, nephropathic, neuropathic complications	1.48 (0.91 – 2.40)	1.23 (0.73 – 2.10)
present	reference	reference
absent		
Self-reported recent, severe hypoglycemic event		
present	0.85 (0.39 – 1.86)	0.65 (0.29 – 1.48)
absent	reference	reference
Self-regulation of insulin need [h]		
yes	9.13 (3.48 – 24.0)	5.05 (2.59 – 9.82)
no	reference	reference
Measuring a hypoglycemic/hyperglycemic value		
yes	3.77 (1.92 – 7.40)	3.88 (1.91 – 7.87)
no	reference	reference

glucose values that are either too high or too low). Negative results might be interpreted by the patients as poor control. Since patients who monitor more often are more likely to find a blood glucose value that is out of the normal range, they are also more likely to perceive poorer control. In itself, a result indicating for example a hypoglycemic event, will probably induce more frequent measuring of blood glucose to evaluate the effectiveness of the patient's intervention. Current practice in the Netherlands

Table 3. – *continued.*

	Crude OR (95% CI)	Adjusted OR (95% CI) [b]
Type 1 diabetes (90) [c]		
Patients' perceptions		
Perception of diabetes status [i]		
(very) poorly controlled (6)	2.86 (0.31 - 26.2)	
moderately controlled (22)	0.57 (0.21 – 1.55)	
well-controlled diabetes (65)	reference	
very well-controlled (7)	3.43 (0.39 – 30.5)	

OR = odds ratio; 95% CI = 95% confidence interval; OHA = oral hypoglycemic agent.

[a] The odds ratios are shown for frequent users versus infrequent users.

[b] Adjusted for age, the type of glucose lowering drug treatment and the duration of diabetes.

[c] The numbers refer to the patients who scored that category.

[d] Per decade.

[e] Per year.

[f] Per point.

[g] Dosage change, switch to or addition of other glucose lowering drugs between January 2003 and March 2003.

[h] Only among patients using insulin. The number of observation is 44.

[i] p-Value for trend = 0.0001.

strengthens this circular relation; patients who are (clinically) well-controlled are advised to decrease the self-monitoring frequency, reducing the probability of finding a hypoglycemic or hyperglycemic value.

Though data on the association between patients' perceptions of their disease and self-monitoring behaviour is limited, similar effects have been reported on self-management. Ciechanowski et al. reported that self-management behaviour depended on a patient's cognitive model and how a patient rates the quality of provider communication. [16] Glasgow and co-workers found that personal model-cognitions about diabetes and its treatment were related to the level of self-management after controlling for the influence of patient demographics, [10]

Our aim was to determine if, apart from clinical indicators of self-monitoring behaviour, patients' perceptions were associated with self-monitoring behaviour. Our questionnaire has only been validated on comprehensibility and completeness of the response categories. Results of a question on diabetes status cannot be regarded as a complete personal illness model. However, our study was not designed to elucidate the mechanism in which the perception of diabetes status could influence self-monitoring behaviour. For this, further research into the domains of perceived diabetes status is warranted.

A limitation of our study is that most data were self-reported, which may have resulted in misclassification of respondents. Even so, data collection on performing SMBG, frequency of testing and patient characteristics is not very sensitive to misinterpretation.

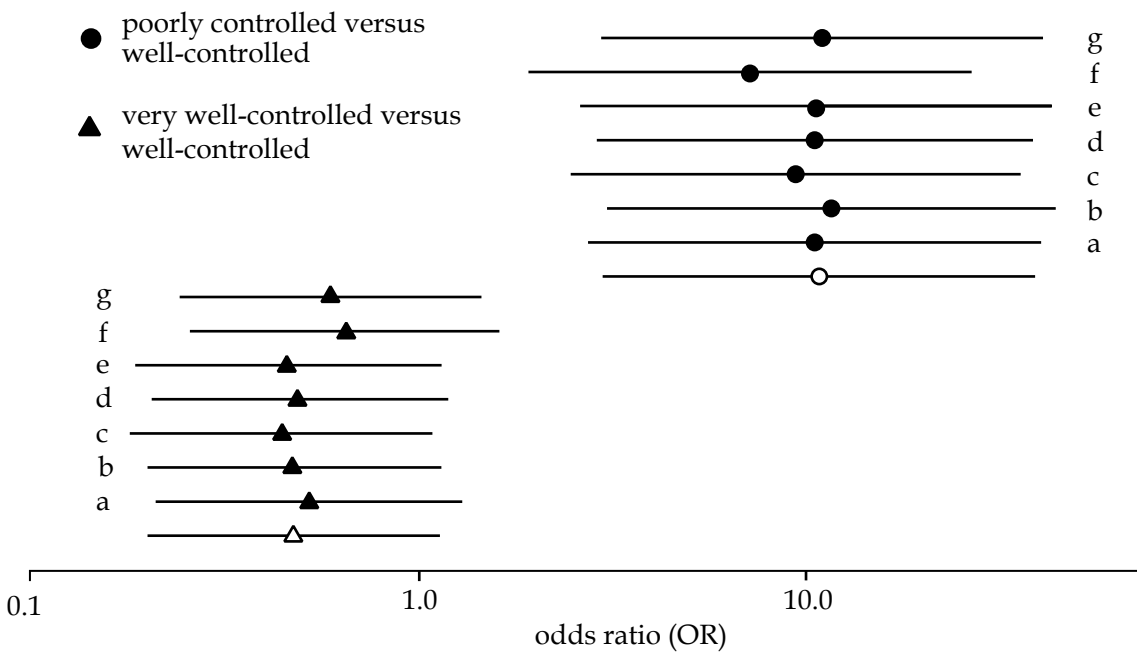

Figure 1. The effect of several indicators of disease severity on the association between frequency of SMBG and patient's perception of diabetes status among type 2 patients. The results are displayed as an odd ratio (OR) and 95% confidence interval on a logarithmic scale. The open circle and triangle represent the crude OR, the closed circles and triangles show the adjusted OR. The number behind the symbols refers to the different factors which were adjusted for: **a.** age, the type of glucose lowering drug treatment and the duration of diabetes; **b.** recent, severe hypoglycemic event; **c.** self-reported value of last A1c; **d.** self-reported presence of visual, nephropathic or neuropathic complications; **e.** b, c and d (all self-reported indicators of disease severity); **f.** measuring a hypoglycemic or hyperglycemic value; **g.** performing glucose curve.

Furthermore, it is not likely that classification of the self-monitoring behaviour is biased by the type or severity of diabetes.

The number of usable responses on the frequency of test strip use can also be considered a limitation. Due to insufficient contrast, we could not clarify the association among patients with type 1 diabetes. We also had to limit the number of factors for which we could adjust in the analyses of the association between self-monitoring frequency and the perception of diabetes status, since several determinants were highly correlated. Still, we observed a significant trend between perception of diabetes status and the frequency of SMBG. Furthermore, the effects of the adjustments all pointed in the same direction.

Our results show that a patient's self-monitoring behaviour corresponds to the instructions of healthcare providers. This indicates that they understand the implications of their self-monitoring results on their diabetes regulation. This appears to be true, irrespective of the reason that a patient performs SMBG. In addition, the providers of diabetes care should be aware that in type 2 diabetes frequent blood glucose testing might indicate that a patient perceives his diabetes status as poor. These patients might need extra attention, since their perception of the diabetes status does not necessarily have to correspond with more objective measures of disease severity.

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CHAPTER 5

DISCUSSION

Op dorre velden
in de heuvels in de verte
komt zonlicht terecht!

Takahama Kyoshi 1874-1959

5.1 Introduction

Pharmaceutical care was a reaction to the observed drug treatment failure in daily practice. [1] Pharmaceutical care originally was developed as a practice philosophy which aimed to improve a patient's quality of life. Today, this term is also used for other extended community pharmacy services focused on patient outcomes. As stated in the introduction, evidence exists of the effectiveness of pharmacy services in diabetes care. For other chronic diseases, for example asthma [2], and specific patient groups [3], there is also sufficient data to advertise implementation of these services. This is one of the reasons why in the Netherlands patient-centred activities, such as patient counselling on first dispensing and medication surveillance, are relatively common.

As a consequence of its broadscale implementation, assessment of community pharmacy services in diabetes is becoming more relevant. It is a means for patients and payers to select healthcare providers. It is an instrument for Health Care Inspectorates to supervise and control public health. For individual healthcare professionals, quality assessment can be used as a benchmark to compare their own practice against.

The structure-process-outcome model is a widely-used framework for developing quality indicators. [4, 5] Apart from its use in quality assessment, the model also underscores two basic relations in health care. The first is that the care process affects the health status of a patient. The changes in health status (outcome) are not a random effect. The second relationship is that between the structure of care and the care process. For example, the presence of a quality assessment system improves the probability of a 'good' process. The first association has been the objective of evidence based practice. With regard to pharmaceutical care in diabetes, many studies evaluate interventions involving pharmacists on clinical outcomes (hemoglobin A1c, lipid profile), economic outcomes and humanistic outcomes (quality of life, patient satisfaction). However, how structure affects the care process in community pharmacies has received less attention.

In this thesis, services provided to patients who perform self-monitoring of blood glucose (SMBG) are used as a model of community pharmacy services. The association between the process of these self-monitoring services and its key structural determinants have been studied.

The term 'community pharmacy services' used in this chapter refers to all activities aimed at individual patients or a group of patients, excluding the actual dispensing of prescription drugs. It includes, among other things, patient counselling, dispensing of over-the-counter drugs and medical aids and medication surveillance. In this discussion, 'pharmaceutical care' is considered (a set) of community pharmacy services and it refers to the activities defined by Hepler and Strand. [1]

5.2 Main Findings

Measuring community pharmacy services

With respect to measuring community pharmacy services, this thesis shows that substantial differences exist between community pharmacies in both dispensing of SMBG equipment as well as in the self-monitoring services they provide to their patients. Chapter 2.1 reports that the proportion of patients with diabetes who collected test strips ranged from 19% to 46% between community pharmacies. As **Figure 1** shows, the number of services offered by a community pharmacy to patients performing SMBG has a bimodal distribution (chapter 2.2). This underscores the large variation in self-monitoring services among pharmacies.

Apart from possible explanations, these variations between community pharmacies are important in their own right. First, it shows that self-monitoring services are an appropriate model to study the association between structure and process, since there is a contrast to make a quantitative approach possible. Second, it also signals that these services are an issue in pharmacy practice. Depending on the reader's position on the community pharmacy's role in SMBG, either a significant proportion does not achieve the desired level of pharmaceutical care or many pharmacies are wasting resources. Interestingly, after many years of increasing sales in medical aids through community pharmacies, 2004 saw a small drop of 0.5%, although the spending on glucose testing equipment kept growing. [6]

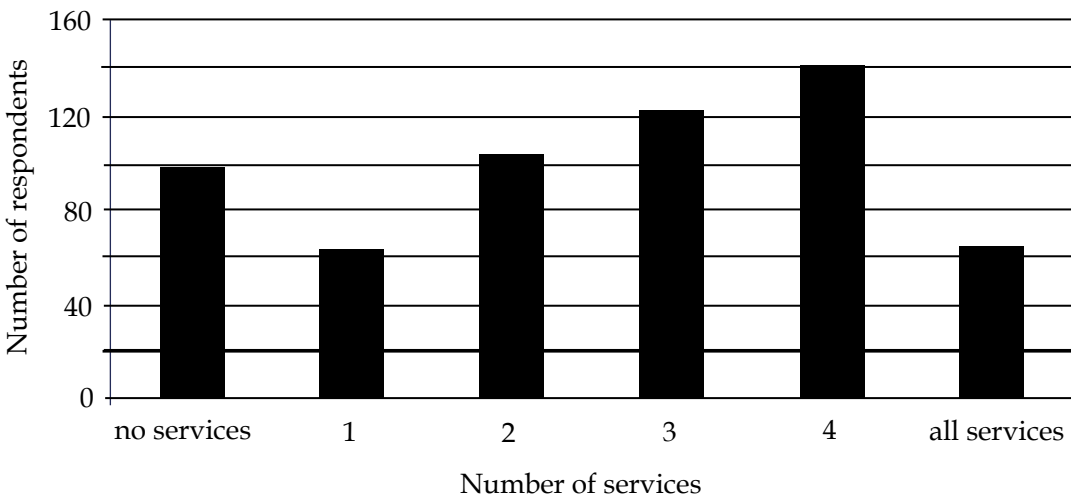

Figure 1. The histogram of the number of services as defined in the WINAp Pharmaceutical Care Standard for type 2 diabetes mellitus [32] provided by the respondent's pharmacy (n = 590).

Although this thesis is the first to show variation in care process in diabetes care in community pharmacies, differences in activities between pharmacies have been reported before. [7-9] However, none of these studies adjusted for confounding by other associated structural elements. Variation in care process has received much more attention in medical care. For example, practice variation has been demonstrated in end-of-life care [10], treatment of acute myocardial infarction [11], gynaecology [12] and hospital discharge for patients with chronic diseases. [13]

Key determinants of community pharmacy services

It is not completely unexpected to observe practice variations. One can think of many factors that are potentially associated with the care process in a community pharmacy.

Variations may not be the result of the community pharmacy per se, but can be the consequence of differences in patient characteristics. This patient mix-bias and provider clustering is an issue that has received much attention in the field of quality of care research, since it does bias the actual level of quality of care. [14, 15] As shown in chapter 3.2, patient-mix bias is also a relevant issue in community pharmacies. The mean age of diabetes patients differs significantly between the pharmacies. Since age is associated with the chance of receiving test strips, part of the association between pharmacy and dispensing of test strips is confounded. In quality assessment, this effect may have serious consequences. [16] Provider clustering is a bias that involves the fact that patients within a practice tend to share certain characteristics, as for example age, gender and health problems, because of provider characteristics. An example of this is the observation that the variation in disease severity among patients within a cardiology practice is smaller than the variation among all patients with cardiovascular disease. Because of this clustering, patients are not independent observations, affecting statistical analysis. However, patients in the Netherlands are free to choose which pharmacy dispenses their prescriptions. Their main motivation seems to be the proximity of the pharmacy. Internationally, a convenient location is also among the top criteria for choosing a pharmacy. [17, 18] It is therefore unlikely that clustering is related to aspects of the community pharmacy, but they represent neighbourhood demographics.

Data from chapter 3.4 does point at clustering of patients. Patients collecting test strips in the community pharmacy as opposed to those receiving their equipment through mail order are less likely to be a member of the diabetes patient organisation. Even though the study does not provide information on differences between pharmacies, it underscores the fact that patient characteristics are a determinant of the absolute level of community pharmacy services.

Patient characteristics could not explain all variation in the time to the first test strips dispensed, indicating that other determinants are relevant too. The geographical location

of the pharmacy and the pharmacy itself are associated with the time to the first test strip dispensed (chapter 3.3). From this follows the second conclusion: self-monitoring services are influenced by both pharmacy-related factors as well as determinants on a supra-pharmacy level. This conclusion is underlined by the results of chapters 3.1 to 3.3. The pharmacy's team knowledge on SMBG is associated with performing more self-monitoring services, as is the integration of a diabetes care improvement project in daily practice and having a job opening for a pharmacist. Chapter 3.3 underscores the supra-pharmacy factors (geographical location). However, in that study there was no additional information on which aspect of the region contributed to the variation. One of the possible explanations is provided in chapter 3.2, which shows that pharmacies providing more self-monitoring services are also more likely to participate in a local agreement on SMBG with other healthcare professionals.

As the results of our qualitative study (chapter 3.1) show, the provision of self-monitoring services is the result of pharmacist-related factors, as for example their motives and perceived competence. Although not specifically focussing on diabetes care in community pharmacies, (structural) factors potentially associated with pharmaceutical care in general have received some attention. A review of Rossing provides a good overview of perceived barriers or facilitators to pharmaceutical care: time and money, knowledge, computer software, communication and management skills and attitude of the pharmacist. [19] These structural factors are surprisingly consistent across different nations. [19, 20] This indicates that these factors are robust, which may alleviate research into determinants of the pharmacy care process. Nevertheless, chapter 3.1 also shows that pharmacist-related factors are influenced by aspects that are outside of their zone of control, such as competition and remuneration issues.

The elucidation of these supra-pharmacy determinants is a topic that is less studied. Regional effects have been previously reported for activities performed in community pharmacies. Norris observed regional variation in patient counselling on restricted medication. [8] Goel et al. studied the effect of location on advice given by pharmacists in Kenya. [21] These issues have received much more attention in medical care. [10, 11, 13, 22, 23] Especially among acute and surgical procedures, but also in diabetes care, much evidence exists that underscores the variation in care process between regions. [24]

Regional variation in care process has been attributed to many phenomena. Skinner et al. excluded patient mix as the most relevant factor, since the variation was only partly explained by differences in gender and race between regions. [22] For surgical procedures, local work force supply and bed supply are considered contributory causes. [11, 23] Other explanations are the variations in physicians' opinions of the best approach to health care. [11, 13]

It is not unlikely that the explanations in physician practice also hold true for pharmacists. Self-monitoring support by community pharmacies can be considered an evolving role. It is a relatively new task and it requires skills not originally considered part of a community pharmacy's domain. The resulting role ambiguity is common to occupations expanding their role to include new activities, explaining variation in professional behaviours. [25] This is underscored by the observations in chapter 3.3, in which even standards for self-monitoring services can not prevent disparity between community pharmacies.

Patient outcomes

The frequency of test strip use was associated with the perception of the patient of how well his or her diabetes was under control. The opinion that their diabetes status was poor was more common among patients who frequently monitored their blood glucose levels than among infrequent users of test strips, independent of other patient characteristics or determinants of disease severity. Although the association between SMBG behaviour and clinical markers of diabetes has been reported before [26, 27], the separate effect of patients' perception of diabetes status is not widely studied. Franciosi showed that among type 2 diabetes patients in Italy, who did not use insulin, health distress and worries were more likely among those who frequently performed SMBG (more than once per day) compared to those performing less than once per week. [28] Similar associations between patients' perceptions and diabetes self-management have been reported. [29, 30]

5.3 A Model for Community Pharmacy Services

This thesis focuses on activities of community pharmacies on a specific area, viz. SMBG. This model is chosen for three reasons. First, self-monitoring services are not exclusively the domain of community pharmacists. In the Netherlands, diabetes nurses, general practitioners (GPs) and nurse practitioners, as well as mail order companies are involved in the dispensing, counselling and follow-up of SMBG. [31] The resulting competition and need for collaboration are issues that are important in all chronic diseases, as for example asthma/COPD and rheumatoid arthritis. Moreover, with the increasing number of elderly persons and the association between age and morbidity, future care processes will have to involve multiple healthcare professionals working as a team.

Second, self-monitoring services are relatively well-defined in the Netherlands. Pharmaceutical care standards describe the activities. [32] This makes these services more easily recognisable, limiting bias in for example questionnaires into the actual provision of care activities. Especially this specific and concise topic distinguishes this thesis from previous studies into processes of care in community pharmacies and its determinants. [20, 33-35]

Last, supporting patients performing SMBG can be viewed as an evolving role, meaning that it has not yet been incorporated into routine care in all pharmacies. Pharmacists will have different perceptions and opinions on its relevance for their pharmacy. [25] The resulting variation in the services provided makes it possible not only to study the phenomenon qualitatively, but also to determine the association with its determinants quantitatively.

As this thesis shows, self-monitoring services is an appropriate model for research on implementation of care activities. Since these activities are surveyable, not fully implemented and show large variation between the study objects, it enables the study of the elements in implementation processes in community pharmacy. Although the external validity of this type of models is always difficult to determine, the findings suggest that self-monitoring services have much in common with other pharmacy processes.

5.4 Implications for Development of Quality Indicators

The results in this thesis imply that, when interpreting results of quality assessment of community pharmacy services, the possibility of patient-mix bias must be recognised. When comparing pharmacies based on the activities they do or do not offer, without adjusting for patient characteristics of that particular pharmacy, wrong conclusions might be drawn. This has been a major topic in medical care. [12, 36] As chapters 2.1 and 3.2 point out, a lower proportion of diabetes patients acquiring test strips in a community pharmacy, does not necessarily mean that the community pharmacy performs less.

Moreover, due to third party dispensing of test strips and other healthcare professionals involved in patient counselling on SMBG, the absolute level of community pharmacy services will probably not show a high correlation with patient outcomes. This points out an important limitation of using outcomes as a measure of pharmacy's performance. In the Netherlands, a pharmacist has only an indirect effect on individual pharmacotherapy. Changes in a patient's drug therapy are almost always made in collaboration with the prescriber. As a consequence, patient counselling and follow-up remain as the most important tools to alter a patient's health status. This does not imply that pharmaceutical services are ineffective. It indicates that – due to the many care interventions surrounding a diabetes patient – changes in the clinical outcomes are less valuable as quality indicators of pharmacies. This is possibly one of the reasons why pharmaceutical care interventions show conflicting results on (cost) effectiveness. [37-39]

Ideally, a quality indicator has several characteristics, which – when optimal – makes it both valid and reliable (see **Table 1**). Valid means the measure to which the result of the

Table 1. The characteristics of quality indicators. [a]

Ambiguity	degree of agreement on definitions and described exthaustively and exclusively.
Sensitivity	ability to detect good quality as indicator is present/positive
Specificity	ability to detect poor quality as indicator is absent/negative
Discriminance	detection of small changes in quality of care
Acceptability	importance of object measured by the indicator for the users of the indicator
Feasability	ease in which data on quality indicator can be made available
Evidence	availability of scientific evidence

[a] Derived from Mainz and Lawrence et al. [40, 41 42]

indicator describes the 'true' state of the structure, process or outcomes that the indicator pertains to. Reliable is the indicator's ability to provide similar results over repeated measurement under varying conditions.

At this moment, development of structure and process indicators for community pharmacy services depends mostly on consensus methods, with only limited data available on the content validity of the quality indicator. Furthermore, the feasibility of data collection plays an important role in the development of quality indicators; data available that are already routinely collected are preferred. Both factors may lead to suboptimal quality indicators. More research into the characteristics of quality indicators will provide insight into how these characteristics are related and describe common mechanisms of how structural factors relate to these care processes. The properties of self-monitoring services make is very useful as a model to study the theoretical basis of quality indicators. For example, chapter 3.3 provides evidence that the presence of a collaboration with other healthcare professionals discriminates between low level service pharmacies and high level service pharmacies. Since the activities are well-defined and vary between pharmacies, it allows for determining of the other characteristics with relative ease.

5.5 Recommendations

There is no denying that diabetes mellitus presents a major burden, both on the individual patients as on society. Although therapeutic options are improving, for example continuous insulin infusion, the cost will probably increase before the health-related quality of life improves. And even with superior pharmacotherapy, the need for self-management will only rise.

Both factors, high prevalence and more complicated self-management, will place high demands on healthcare professionals involved in diabetes care. Workload of GPs is already high and in some regions there is a shortage of diabetes nurses. Since most diabetes patients visit their pharmacy regularly to collect their medication, community

pharmacies are ideally placed to provide patients with services that will help them to self-manage their diabetes. [43]

From a patient's perspective, the type of diabetes is also an important determinant of self-monitoring services. As chapters 2.1, 3.2 and 4 show, the self-monitoring behaviour of patients with type 1 and type 2 diabetes varies. From a community pharmacy's point-of-view, there are no practical motives to support both types of patients differently. Projects integrating a diabetes nurse into a community pharmacy, for example through co-operation with pharmaceutical home care organisations, have been initiated to close potential knowledge gaps. Still, this shift would require an integration of two, currently separated, systems of care. Care for type 1 diabetes is mostly hospital based, whereas type 2 diabetes is predominantly treated in primary care. This makes the type of diabetes a relevant political issue when discussing community pharmacy's role in diabetes care.

Tailoring of interventions and follow-up

Projects aimed to improve community pharmacy services, either initiated by a national pharmacist association or by other organisations, should support the implementation of community pharmacy services by offering tailor-made implementation plans and coaching. For example, the DiabetesCheck programme in the Netherlands offered several different activities that community pharmacists could choose from, making it easier to anticipate patients' demands.

However, as this thesis shows, to implement these services in community pharmacies, having clear objectives is not enough. The intervention must also be attuned to fit in the local situation. Especially the social context of the self-monitoring services (intrusion on domain of other healthcare providers and competition with mail order companies for dispensing) is perceived as a barrier by some pharmacists. The differences in the participation in local agreements on counselling on SMBG and calibration/checking of SMBG equipment, together with the association of local agreements and level of services, emphasise that one single implementation scheme is unlikely to be efficient. Moreover, since implementation in daily routine of these relatively non-prevalent activities will probably take a long time, external coaching of the pharmacy may be an effective instrument.

These issues imply that only developing tools and educational programmes is not enough to change pharmacy practice. As described in chapter 3.1, obstacles on the individual level play a role. The pharmacist's opinion towards diabetes care in general can hamper implementation, but it can also facilitate initiation of self-monitoring services. It is not likely that all community pharmacists underscore the relevance of self-monitoring services for pharmacy practice. Therefore, pre-intervention assessment may prevent unnecessary investments of time and money in a project for which only a limited demand exists. For a community pharmacy such a feasibility assessment will also be a

useful instrument to assist in selecting community pharmacy services. A survey of the pharmacist's attitude towards a specific service and an evaluation of key determinants associated with that service can provide the likelihood for successful implementation.

Remuneration of self-monitoring services

The question remains if – in general – self-monitoring services are a rational investment for a community pharmacy. As a result of all factors previously mentioned, patient demand for these services will rise in such numbers that other healthcare professionals will probably not be able to support all patients. Diabetes care activities surrounding SMBG have been delegated from the internist, to the GP and diabetes nurse, followed by task reorganisation to nurse practitioners, home care nurses and practice assistants. This trend implies that, with proper educational programmes, community pharmacies will be able to perform self-monitoring services on the required level. Other pharmacy-related determinants, for example staffing and a separate counselling area are surmountable too. With an average of 200 diabetes patients per pharmacy and 50% of those patients performing SMBG, counselling and calibration services will take approximately 50 hours per year. Furthermore, a separate counselling area has become more or less the standard in newly established or renovated pharmacies in the Netherlands.

The supra-pharmacy determinants of SMBG are, at the moment, barriers that limit the adoption of self-monitoring services. Local agreements (chapter 3.3) and patient characteristics (chapter 3.4) are examples of determinants that include the interest of other individuals or organisations involved in the diabetes care process. The resulting field of tension may seriously impede the development of the role of community pharmacies in SMBG. For other diabetes care-related processes, for example lipid management, the situation will probably be similar. Fortunately, active involvement of community pharmacies in diabetes care collaboration can resolve this barrier.

However, if a community pharmacy is serious in achieving the targets of the St. Vincent Declaration [44], remuneration of SMBG counselling and calibration must be established. If the only organisational result of self-monitoring services is an improvement in employee and customer satisfaction, pharmacists will continue to prefer services with less competition (medication surveillance, patient counselling on inhalers). These services, too, are widely appreciated by both staff and patients. Individual pharmacists will almost certainly not succeed in negotiating remuneration, which leaves the responsibility for further development of self-monitoring services in the hands of pharmacy organisations and payers.

One could argue that the profit from the dispensing of blood glucose test strips and meters itself is enough incentive. If all diabetes patients performing SMBG collected their test strips in community pharmacy, the average turnover of SMBG equipment would approximately be € 6,000 in 2004. [45] However, third party distribution serves

about 40% of the patients who perform SMBG. Since especially type 1 patients, who test more frequently than type 2 patients, collect test strips from these third parties, the pharmacy turnover is probably about € 2,500 per year. This figure must be balanced against the sales margin and the overhead of personnel and stock control, probably seriously limiting the profitability. Furthermore, profits from dispensing will not encourage the provision of counselling and calibration services.

Lowering the incidence of diabetes mellitus and reducing its impact on patients already diagnosed has become a top priority in Dutch public health. [46] Stimulating the collaboration between healthcare providers and financial transparency are two of the strategies to reach the objectives. At the same time, the Dutch health insurance system is drastically reorganised. Effective as of January 1, 2006, all Dutch have the same compulsory insurance, covering basic medical needs, such as physician consultation, surgery and most medication. For extra services, people can arrange additional coverage, at their own expense. Insurers will have more authority and autonomy to contract healthcare providers for the care of their clients. All these changes make this current situation optimal for improving the pharmacy's position in supporting patients with diabetes in general and SMBG in particular. Nevertheless, this will need a focused and proactive shift in pharmacists' attitudes towards self-monitoring of blood glucose.

Self-monitoring services and improvement of patient outcomes

In this thesis, the effectiveness of self-monitoring services is not monitored. Therefore, the clinical basis to recommend self-monitoring services to patients in community pharmacies is still limited. Studies outside of the Netherlands indicate that SMBG does change blood glucose values and self-monitoring behaviour. [47] The effectiveness of the Dutch pharmaceutical care standard for type 2 diabetes is not known, but the impact of the activities of Dutch community pharmacies on patient outcomes in other chronic diseases is well studied. [2, 3, 48] Still, based on the result of chapter 4, it is likely that these services can at least have a signalling function for patients who perceive their diabetes status as poor.

Relationship between structure and process requires further research

This thesis does not provide the solution to all knowledge gaps and issues indicated in the previous sections. It presents an overview of key determinants of the provision of self-monitoring services and also signals the need for more research into the process of community pharmacy services and its 'building blocks'. From a pharmacist's perspective, for example, evidence of the effect of extra staff on the provision of care activities is needed to support him or her in developing the pharmacy's policy. However, for pharmacists as a group, studies into collaborations with other healthcare professionals are even more relevant. What is agreed upon in these collaborations? How are the responsibilities divided?

A factor that may influence the generalisability of the conclusion on the key determinants, is the choice of key (structural) determinants and the arbitrary distinction between structure and process. For example, knowledge of the pharmacy team can be considered both a structural factor as a process indicator. In this respect, the approach of Billups et al. is more elegant. [49] They assessed both categories of indicators as a whole. However, what is a consequence of a process in some circumstances is a is a condition in others. For example, lack of knowledge is a reason not to provide self-monitoring services. But by not providing these services, the team's knowledge with this aspect of care does not improve. Even though this is not relevant from a quality assessment point-of-view, the interrelationship is imperative for developing quality improvement programmes. Pharmacy practice research can contribute to the latter issue by clearly defining and studying how structural elements interact with the processes in community pharmacies.

As the starting point of the qualitative search for key determinants, the EFQM model for Business excellence was used. [50] This model describes nine classes of determinants related to quality improvement of (not-for) profit organisations. The choice was based on previous experience with that model. Furthermore, this quality improvement instrument has been adapted for community pharmacies. [51] However, it is not likely that other key determinants would have been found, if another model had been used. First, quality management systems generally have similar principles. Second, the determinants that are identified are relatively robust; both the qualitative and the quantitative approach shows comparable results. This robustness implies that differences in the initial models will have limited influences.

In addition, it is not known to what extent the association between structure and process observed in this thesis applies to other community pharmacy services. As mentioned in chapter 5.3, self-monitoring services share characteristics with many other community pharmacy services, but it still remains a model. The assumptions made in this thesis have to be verified in future research using, for example, patient counselling at the first dispensing of an antidiabetic drug as the care process.

An aspect that will require careful consideration in practice research is that of definition of process. As chapter 2.2 shows, different definitions of services may result in changes in the associations with key determinants. This issue is vital to the question why pharmacy practice research has not been able to implement highly effective interventions and develop quality indicators. Despite the work of Hepler and Strand, what exactly comprises pharmaceutical care in daily practice is unknown, hampering good quality studies into its effects. [52] As illustrated by, for example, the behavioural pharmaceutical care scale of Odedina et al. [33], many different behaviours and activities are recognised as being part of the care process. To define 'community pharmacy services' is even more

complicated. Pharmacy practice research will have to put continuous effort into making studies comparable with other work. Pharmaceutical care standards may facilitate this process, for they can be used as a reference or gold standard. However, one should recognise that due to differences in health care systems between countries, findings will primarily be relevant for the local situation.

Measurement of community pharmacy services and development of well-performing quality indicators are issues that have received considerable, international attention. Farris proposed the SPO model as framework to assess quality of pharmaceutical care. [53, 54] Since then, various tools and methodologies have been developed to assist researchers, policy makers and healthcare professionals in assessing and improving community pharmacy services. [55-57] Still, there is limited evidence that structural indicators can be used in quality assessment, since they have not been shown to increase the likelihood of either a good outcome, or a process that has previously been shown to yield better outcomes. [40] Even the many intervention studies on the effect of changes in structural factors on improvement of process only partly clarified the association. This was because these studies were aimed at demonstrating the effect on patient outcomes [2, 3, 48] and, therefore, structural determinants were controlled. The observational nature of this thesis allows an examination of the association in daily practice and to quantify it. Data from chapter 3 can be used to validate quality improvement tools. At this moment, many quality indicators in pharmacy practice are based on expert opinions, instead of evidence. [56] This makes validation essential, especially to which extent the indicator predicts how well a pharmacy is performing (predictive validity).

Finally, pharmacy practice research should not only focus on patient outcomes. The significance of structure on the provision of pharmacy services deserves more attention as a primary study objective. Although less relevant from a quality assessment point-of-view, the associations are imperative to the development and dissemination of evidence based improvement programmes.

The current developments in diabetes care provide an excellent opportunity for pharmacy practice to contribute to the quality of life of diabetes patients, especially those with type 2 diabetes mellitus. Considerable room for improvement exists in Dutch community pharmacies. However, a change will require a pro-active attitude, both from individual pharmacists as well as from the profession as a whole. The present focus on activities related to medication adherence and surveillance may not be enough to become an important player in diabetes care. To a diabetes patient, life is more than drugs. Pharmacists have to decide for themselves if they want this new, more elaborate role, but a choice is needed soon. Otherwise non-pharmacy organisations will probably make the community pharmacy's contribution on diabetes care mere fiction.

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Summary

Introduction

Diabetes is a chronic, metabolic disorder that is characterised by hyperglycemia resulting from defects in insulin secretion, insulin action or both. It is accompanied by disturbances in the fat and protein metabolism. Of the two most frequently diagnosed types (type 1 and type 2 diabetes mellitus), especially type 2 diabetes has a high prevalence, varying between 2.8 percent to 4 percent in the year 2000. The incidence is also high; in the Netherlands in 2000 this number was approximately 66,000 among persons aged 50 years or over. Together with a relatively high burden of disease, this has led to a serious growth in the demand for diabetes-related health care.

Apart from the pharmacological treatment of hyperglycemia, self-management by the patient is a cornerstone of the treatment plan. One aspect of this self-management is self-monitoring of blood glucose (SMBG). SMBG is a technique that enables patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the life style they prefer. Furthermore, it allows physicians to gather data for clinical decision-making.

However, SMBG is a relatively complex process that requires specialised equipment, counselling and follow-up. National and international pharmacy practice guidelines advocate that one of the community pharmacists' roles in diabetes care is to support patients with SMBG. The associated activities are called self-monitoring services throughout this summary. Still, to what extent these guidelines are actually implemented in daily routine is unknown.

The aim of this thesis is to assess the level and the variation in the services that Dutch community pharmacies provide to patients performing blood glucose self-monitoring (process of care). Furthermore, it describes the key determinants of these self-monitoring services (structure of care).

Chapter 2: Measuring community pharmacy services

Community pharmacies differed substantially in the proportion of patients with diabetes to whom they dispensed SMBG equipment. Using the PHARMO-Record Linking System, dispensing data of 29 community pharmacies were analysed. Patients who started using antidiabetic drugs – oral hypoglycemic agents (OHAs) or insulin – between 1991 and 1998 were included (n = 5,050). On average, 30% (relative standard deviation: 22%) of these patients, all 18 years and older, received test strips at least once in their pharmacy, but this figure ranged from 19 to 46%. Furthermore, type 1 patients were three times more likely to acquire SMBG equipment in a pharmacy than type 2 patients. Compared to published data in other countries, Dutch community pharmacies dispensed relatively few blood glucose test strips to patients with diabetes mellitus.

Apart from dispensing of SMBG equipment, community pharmacies also differed in the provision of self-monitoring services to patients with diabetes (Chapter 2.2). Data were obtained from a survey among 97% of all Dutch community pharmacies (n = 1,642) registered in 2004. Five separate activities were defined, based on the WINAp Pharmaceutical Care Standard for type 2 diabetes mellitus. Eligible respondents (39%, 590 pharmacies) varied substantially in the number of services provided to their patients. Sixty-five percent offered patient counselling on the testing procedure, 42% provided counselling on the choice of a blood glucose meter and 70% offered instruction on the operation of it. Calibration of blood glucose meters was reported by 46% of the respondents and providing a patient with a meter at no cost by 35%. A histogram of the total number of services showed a bimodal distribution.

Moreover, this study also examined to what extent the association between the level of self-monitoring services and six of its reported determinants was dependent on the definition of self-monitoring services that was used. For this purpose, seven definitions of self-monitoring services were constructed. All definitions were compared to the practice guideline definition. The odds ratios of 14 of the 48 possible comparisons of different definitions were significantly different from one. The standardised difference ranged from 1.42 (95% confidence interval: 1.01 – 1.90) to 3.05 (95% confidence interval: 1.51 – 4.61). Three out of six predictive models retained different determinants compared to the multivariable model of self-monitoring support based on the guideline. This showed that it is important for studies to explicitly state which aspects comprise their definition of diabetes care.

Chapter 3: Key determinants of community pharmacy services

A qualitative study among 18 Dutch managing community pharmacists investigated what they considered key determinants of self-monitoring services (chapter 3.1). Four semi-structured group interviews were held, which were transcribed verbatim and analysed through an inductive approach using open and axial coding. Pharmacy team's competence, collaboration, competition and motivation were recurrent themes in all group interviews. Competence contained elements of knowledge, experience and confidence. Collaboration described strategies in which community pharmacists worked together with other healthcare professionals. Competition consisted of actions of other persons or organisations aimed at supporting patients with SMBG. The participants perceived their pharmacy's competence in self-monitoring services as low, compared to their competence in drug dispensing and medication counselling activities. This was related to their motivation and their willingness to provide self-monitoring services.

The differences in dispensing of blood glucose test strips observed in chapter 2 were studied more extensively in chapter 3.2. This dataset (40 community pharmacies in 19 geographical regions), again from the PHARMO Record Linkage System, included data on 8,878 patients who started antidiabetic drug treatment between 1991 and 2001. In a time-dependent Cox proportional hazard model, patient characteristics (age, the year of

start of antidiabetic drug treatment, as well as the type of antidiabetic drug treatment) were significantly associated with the time to the first test strips dispensed. These results were similar to the results in chapter 2.1. 'Community pharmacy' was also associated with the time to the first test strips dispensed, independent of the patient characteristics. Moreover, variation in time to the first test strip dispensed between pharmacies in one region was considerably less than between pharmacies in different regions.

In chapter 3.3, collaboration between pharmacies and other healthcare providers was further evaluated using the data from the survey among all Dutch community pharmacies. All eligible respondents (724) were classified based on the number of self-monitoring services they provided (low level service or high level service pharmacies). The pharmacists who reported to be involved in a local agreement between healthcare providers on who provided the counselling of patients performing SMBG, were more likely to be high level service pharmacies (adjusted odds ratio: 1.74, 95% confidence interval: 1.09 – 2.78). In contrast, those who reported an agreement in which the pharmacy did not participate, were less likely to work in a high level service pharmacy compared to no local agreement at all (adjusted odds ratio: 0.46, 95% confidence interval: 0.24 – 0.87). Although similar in strength and direction, the association between level of self-monitoring services and local agreements on calibration/checking was not statistically significant.

Since patients are free to choose their supplier of SMBG equipment, the community pharmacy is not the only supplier. This may result in clustering of patients with specific characteristics and counselling needs. A survey among almost 1,500 patients with diabetes gathered information on patient characteristics, their SMBG behaviour and the supplier of their SMBG equipment used. Of all 1,100 respondents, 611 reported performing SMBG in the previous two months. Almost 60% of the patients (n = 344) acquired blood glucose test strips in their community pharmacy. Of the other suppliers, mail order companies were most often mentioned. Patients who collected their SMBG equipment in community pharmacies were more likely to have type 2 diabetes. They were also older and less likely to perform self-regulation of insulin needs compared to those who acquired their equipment through other channels. They were also less likely to be a member of the diabetes patient organisation. Only membership remained significantly associated in the multivariable analysis (odds ratio: 0.60, 95% confidence interval: 0.40 – 0.90). No statistically significant differences on indicators of disease severity or self-monitoring behaviour were found.

Chapter 4: Patient outcomes of community pharmacy services

Chapter 4 also used the data from the survey mentioned in chapter 3.4. The study focused on the association between patients' perceptions of their diabetes status and SMBG behaviour, independent of disease severity. Of all respondents, the questionnaires of 841 patients met the inclusion criteria. Among type 2 diabetes patients, those who reported

a moderately or poorly controlled diabetes status were almost two times more likely to use test strips compared to patients reporting to be well- or very well-controlled (odds ratio: 1.93; 95% confidence interval: 1.20 – 3.12). There was also a statistically significant trend that the patients who perceived their diabetes status as worse were more likely to frequently use test strips compared to those who used test strips infrequently. For type 1 patients, no association between the reported diabetes status and self-monitoring behaviour was observed, partly due to the small number of patients and the skewed distribution of the frequency of test strip use.

Conclusion

Dutch community pharmacies differ substantially in the services they provide to patients performing SMBG. This variation is the result of many factors: differences in patient characteristics between community pharmacies, pharmacy-related determinants (for example the pharmacy team's competence and the pharmacist's perceptions of SMBG) and supra-pharmacy determinants (regional differences in for example collaboration, competition and remuneration). Although these determinants have received much attention in medical care and quality assessment, few comparable studies have been performed in pharmacy practice research, especially on diabetes care.

Based on the results of this thesis, changes in the implementation strategy of community pharmacy services are recommended. Tailor-made implementation plans and coaching of community pharmacists may be needed, since the presence of key determinants on many different levels requires an intervention that must attuned to fit the local situation.

As long as community pharmacies are not reimbursed for self-monitoring services, most pharmacists will continue to prefer providing services in which they experience less competition, as for example medication surveillance and patient counselling on inhalers. At present, this makes the supra-pharmacy determinants of SMBG the most relevant barrier that limits the adoption of self-monitoring services.

Finally, this thesis signals the need for more research into the process of community pharmacy services and its 'building blocks'. A careful consideration of the definition of the care process is required in pharmacy practice research. Furthermore, knowledge of the association between the structure of care and the process of care is essential in developing quality indicators and quality improvement.

Samenvatting in het Nederlands

Diabetes mellitus

Diabetes mellitus is een chronische, metabole afwijking die wordt gekenmerkt door hyperglycemie. De hyperglycemie is het gevolg van afwijkingen in de insulinesecretie, de activiteit van insuline of een combinatie van beide. Diabetes gaat vaak samen met verstoring van de vet- en eiwitstofwisseling. Er bestaan verschillende types diabetes, waarbij de meest frequent gediagnostiseerde varianten type 1 en type 2 diabetes worden genoemd. De prevalentie van type 2 is hoog: 2,8 tot 4% van de wereldbevolking boven de 18 jaar in het jaar 2000. Ook de incidentie is groot. In 2000 werd de ziekte bij 66.000 mensen boven de 50 vastgesteld. Omdat diabetes tevens een hoge ziektelast heeft, zal er de komende tijd een sterke groei komen in de vraag naar diabeteszorgverlening.

Naast farmacologische behandeling van hyperglycemie is ook zelfmanagement door de patiënt een belangrijke peiler van het behandelplan. Een van de onderdelen van zelfmanagement is de zelfcontrole van bloedglucose, in het Engels afgekort met SMBG (self-monitoring of blood glucose). SMBG is een techniek die de patiënt in staat stelt om veranderingen in bloedglucosewaardes te registreren en hierop te reageren. Op deze manier zijn patiënten beter in staat om hun diabetes in hun dagelijks leven te integreren. Daarnaast is het een hulpmiddel voor behandelaars om de farmacotherapie te beoordelen.

SMBG is echter een ingewikkelde procedure, waarbij specifieke apparatuur, voorlichting en controle noodzakelijk zijn. Praktijkrichtlijnen in binnen- en buitenland geven aan dat openbare apotheken een rol kunnen spelen bij de ondersteuning van diabetespatiënten die zelf hun bloedglucose meten. De activiteiten die met deze ondersteuning zijn gemoeid worden in deze samenvatting aangeduid met 'zelfcontrole-ondersteuning'. Het is echter onduidelijk in welke mate zelfcontrole-ondersteuning in de praktijk is geïmplementeerd.

Het doel van dit proefschrift is om te bepalen in welke mate zelfcontrole-ondersteuning in Nederlandse openbare apotheken plaatsvindt. Daarbij zijn ook de verschillen in het zorgproces tussen apotheken belangrijk. Bovendien heeft dit proefschrift als doelstelling om de belangrijkste determinanten van zelfcontrole-ondersteuning te beschrijven (de zorgstructuur).

Hoofdstuk 2: Het meten van zelfcontrole ondersteuning door openbare apotheken

Openbare apotheken verschilden aanzienlijk in het aandeel diabetespatiënten dat SMBG-materialen via de apotheek geleverd kreeg. Met de gegevens van het PHARMO Record Linking System werden de aflevergegevens van 29 openbare apotheken geanalyseerd. Patiënten die tussen 1991 en 1998 startten met antidiabetica – zowel orale bloedglucoseverlagende middelen (Engelse afkorting: OHA) als insuline – werden

geïncludeerd (n = 5.050). Gemiddeld kreeg 30% (relatieve standaarddeviatie: 22%) van deze patiënten zijn teststrips in de apotheek, maar dit getal varieerde van 19 tot 46%. Type 1 patiënten hadden een drie keer grotere kans om teststrips te krijgen in de apotheek dan type 2 patiënten. Ten opzichte van resultaten uit buitenlandse studies werden in Nederlandse apotheken weinig teststrips verstrekt.

Naast de variatie in het afleveren van SMBG-materiaal, verschilden openbare apotheken ook in het aantal zelfcontrole-ondersteuningsactiviteiten (hoofdstuk 2.2). De onderzoeksgegevens werden verkregen door middel van een schriftelijke vragenlijst. Bijna alle Nederlandse apotheken (97% oftewel 1.642 apotheken) werden aangeschreven. Op basis van de WINAp Farmaceutische Patiëntenzorgstandaard bij diabetes mellitus type 2 werden vijf verschillende activiteiten gedefiniëerd. De respondenten (39%, 590 apotheken) verschilden aanzienlijk in het aantal zelfcontrole-ondersteuningsactiviteiten dat ze aanboden. Zesenvijftig procent bood voorlichting aan over de uitvoering van een bloedglucosemeting, 70% gaf voorlichting over de bediening en 42% van de respondenten ondersteunde patiënten bij de keuze van het merk bloedglucosemeter. Een periodieke controle van de bloedglucosemeter werd gerapporteerd door 46% van de apothekers en 35% van de respondenten bood patiënten die maar voor een korte tijd hun eigen bloedglucosewaarden hoefden te meten een gratis glucosemeter aan. Het histogram van het aantal activiteiten vertoonde een bimodale verdeling.

Deze studie onderzocht bovendien in welke mate de relatie tussen zelfcontrole-ondersteuning en zes bekende determinanten afhankelijk was van de definitie van zelfcontrole-ondersteuning. Voor deze studie werden zeven verschillende definities van zelfcontrole-ondersteuning geconstrueerd. Alle vergelijkingen tussen de definities werden gedaan ten opzichte van de definitie volgens de WINAp Farmaceutische Patiëntenzorgstandaard. Er waren in totaal 48 mogelijke vergelijkingen tussen de definities en de referentiedefinitie, waarvan er 14 statistisch significant verschilden van één. Het gestandardiseerde verschil liep van 1,42 (95% betrouwbaarheidsinterval (95%): 1,01 – 1,90) tot 3,05 (95% CI: 1,51 – 1,46). Drie van de zes predicitiemodellen behielden verschillende determinanten in vergelijking tot het multivariate model van zelfcontrole-ondersteuning volgens de referentiedefinitie. Dit toonde aan dat het belangrijk is om te weten welke activiteiten tot een bepaalde definitie van (diabetes)zorgverlening worden gerekend.

Hoofdstuk 3: Variabelen van zelfcontrole-ondersteuning

In hoofdstuk 3.1 werden 18 openbare apothekers gevraagd naar hun mening over de variabelen die belangrijk zijn voor zelfcontrole-ondersteuning. Hiervoor werden vier half-gestructureerde groepsinterviews gehouden. De interviews werden woordelijk uitgeschreven en de tekst werd geanalyseerd. Uit de uitspraken van de deelnemers werden algemene, terugkerende thema's gedestilleerd door middel van het coderen van tekstfragementen. De codes waren niet vooraf opgesteld, maar kwamen voort uit de

tekst (grounded theory approach). De thema's die in alle groepsinterviews naar voren kwamen waren: competentie van het apotheekteam, samenwerking, concurrentie en motivatie. Competentie bestond uit kennis, ervaring en zelfvetrouwen. Samenwerking beschreef strategiëen waarbij openbare apothekers samen met andere zorgaanbieders zelfcontrole-ondersteuning aanboden. Concurrentie bestond uit activiteiten van andere personen of organisaties dan de openbare apotheek die gericht waren op patiënten die aan SMBG deden. Deelnemers beschouwden zichzelf en hun apotheekteam niet voldoende competent om zelfcontrole-ondersteuning te verzorgen in vergelijking tot hun compententie in het ter hand stellen van geneesmiddelen en het geven van voorlichting over geneesmiddelen. Dit was weer gerelateerd aan hun motivatie en hun bereidheid om zelfcontrole-ondersteuning te verzorgen.

De verschillen in het afleveren van teststrips die aan de orde zijn gekomen in hoofdstuk 2 werden verder onderzocht in hoofdstuk 3.2. Dit databestand omvatte gegevens uit 40 openbare apotheken uit 19 geografische regio's en was wederom afkomstig uit het PHARMO Record Linkage System. Het bevatte gegevens van 8.878 patiënten die gestart waren met antidiabetica tussen 1991 en 2001. In een tijdsafhankelijke Cox proportioneel risico-model waren patiëntenkarakteristieken (leeftijd, het jaar dat de patiënt startte met antidiabetica, het soort geneesmiddel tegen diabetes) significant geassocieerd met de tijd tot het ophalen van de eerste teststrip. De variabele 'openbare apotheek' was ook geassocieerd met de uitkomstmaat, onafhankelijk van de patiëntkarakteristieken. Bovendien bleek de variatie tussen apotheken in verschillende regio's groter te zijn dan tussen apotheken in dezelfde regio.

Eén van de variabelen, samenwerkingsverbanden tussen apotheken en andere zorgverleners, werd uitgebreider onderzocht in hoofdstuk 3.3. Voor deze studie werd gebruik gemaakt van de gegevens uit de vragenlijst onder alle Nederlandse openbare apotheken (zie hoofdstuk 2.2). Alle bruikbare vragenlijsten (724 stuks) werden ingedeeld op basis van het aantal zelfcontrole-ondersteuningsactiviteiten (weinig zelfcontrole-ondersteuning of veel zelfcontrole-ondersteuning). Apothekers die veel aan zelfcontrole-ondersteuning deden gaven vaker aan dat ze lokaal een afspraak hadden over wie de SMBG voorlichting verzorgde dan zij die weinig activiteiten bij SMBG uitvoerden (gecorrigeerde odds ratio: 1,74, 95% CI: 1,09 – 2,78). Apothekers die aangaven dat er lokale afspraken over SMBG voorlichting waren waar zij niet bij waren betrokken, hadden bijna twee keer minder kans om in een apotheek te werken met veel zelfcontrole-ondersteuning ten opzichte van respondenten die aangaven dat er helemaal geen lokale afspraken waren (gecorrigeerde odds ratio: 0.46, 95% CI: 0.24 – 0.87). De resultaten voor afspraken over controle van SMBG-apparatuur waren van dezelfde grootte-orde, maar in dit geval niet statistisch significant.

Omdat patiënten in Nederland kunnen kiezen uit verschillende aanbieders van SMBG-apparatuur, is de openbare apotheek niet de enige aanbieder. Het mogelijke gevolg

hiervan is een clustering van patiënten met specifieke eigenschappen en voorlichtingsbehoeften. Door middel van een vragenlijst onder ongeveer 1.500 patiënten met diabetes werd informatie verzameld over patiëntenkenmerken, hun zelfcontrolegedrag en de leverancier van SMBG-materiaal. Van de 1.100 respondenten gebruikten er 611 een bloedglucosemeter in de twee maanden er voor. Ongeveer 60% (n = 344) haalde de SMBG-apparatuur in de apotheek. Van alle andere aanbieders werden postorderbedrijven het vaakst genoemd. Patiënten die de apotheek als leverancier opgaven hadden vaker type 2 diabetes. Daarnaast waren ze ouder, voerden ze minder vaak zelfregulatie uit en waren ze minder vaak lid van de vereniging van diabetespatiënten (DVN) dan de groep patiënten die teststrips buiten de apotheek om verkreeg. Lidmaatschap van de DVN was de enige variabele die significant geassocieerd bleef in een multivariaat model (odds ratio: 0,60, 95% CI: 0,40 – 0,90). Er werden geen statistisch significante verschillen gevonden in zelfcontrolegedrag en ernst van de ziekte.

Hoofdstuk 4: Patientenuitkomsten en zelfcontrole-ondersteuning

Met de gegevens van de vragenlijst uit hoofdstuk 3.4 werd ook gekeken of er een relatie bestond tussen de mening van de patiënt over zijn of haar diabetesinstelling en het zelfcontrolegedrag, onafhankelijk van de ernst van de ziekte. Van alle geretourneerde vragenlijsten voldeden er 841 aan de inclusiecriteria. Onder de patiënten met type 2 diabetes bleken de patiënten die vonden dat hun diabetes matig of slecht was ingesteld bijna twee keer zo vaak aan SMBG te doen dan degenen die hun instelling goed of zeer goed vonden (odds ratio: 1,93; 95% CI: 1,20 – 3,12). Er was een statistisch significante trend dat patiënten die vonden dat ze slechter waren ingesteld, vaker aangaven frequent teststrips te gebruiken. Onder diabetes type 1 patiënten waren deze verbanden niet waarneembaar. Dit kwam deels door het geringe aantal patiënten en de scheve verdeling van de frequentie van het gebruik van teststrips.

Discussie

Nederlandse openbare apotheken verschillen sterk in de dienstverlening aan patiënten die aan SMBG doen. Deze variatie is het gevolg van verschillende factoren: verschillen in de eigenschappen van de patiëntenpopulatie van de apotheken, apotheek-gerelateerde determinanten (zoals bijvoorbeeld de competentie van het apotheekteam en de perceptie van het belang van SMBG) en apotheekoverstijgende factoren (regionale verschillen in bijvoorbeeld samenwerkingsverbanden, concurrentie en vergoeding). Alhoewel deze determinanten veel aandacht hebben gehad in medische zorgverlening en kwaliteitsbeoordeling, zijn er weinig vergelijkende studies binnen het farmaceutisch praktijkonderzoek.

Op basis van de resultaten van dit proefschrift wordt een aantal aanbevelingen gedaan voor veranderingen in de strategie om ondersteuningsactiviteiten geïmplementeerd te krijgen. Implementatieplannen op maat en coaching van openbare apothekers is

noodzakelijk. De aanwezigheid van succesfactoren op verschillende niveaus vergt een interventie die aansluit bij de lokale situatie.

Zolang zelfcontrole-ondersteuning niet wordt vergoed zullen de meeste apothekers de voorkeur geven aan het verzorgen van activiteiten waarin zij minder concurrentie ervaren, bijvoorbeeld medicatiebewaking en inhalatie-instructie. Hierdoor zijn de apotheekonafhankelijke variabelen op dit moment de meest belangrijke barrières in de adoptie van zelfcontrole-ondersteuning door openbare apotheken in Nederland.

Tot slot geeft dit proefschrift aan dat er meer onderzoek gedaan moet worden naar de processen in openbare apotheken en de 'bouwstenen' van deze processen. Farmaceutisch praktijkonderzoek moet zorgvuldig beschrijven welke activiteiten tot het zorgproces worden gerekend. Daarnaast is kennis van de associatie tussen zorgstructuur en het zorgproces essentieel voor de ontwikkeling van kwaliteitsindicatoren en kwaliteitsverbetering.

Dankwoord

Het dankwoord is misschien wel een van de meest gelezen onderdelen van het proefschrift. Niets is leuker dan je eigen naam terug te zien in drukvorm, overladen met loftuitingen. Partners die jarenlang niet hebben begrepen waarom de promovendus ook ‘s avonds én in het weekend moest werken, ontvangen een welgemeend *mea culpa*. Verwaarloosde familie en vrienden wordt beterschap beloofd. Er wordt oprecht bedankt voor de luisterende oren en begrijpende blikken van collega’s die men kreeg na de veertiende afwijzing, nota bene van het 'Thai Journal of Irrelevant Research'.

Voor de schrijver is het dankwoord een bezoeking. Hoe formuleer je telkens weer een spitsvondige, overtreffende trap van waardering? Om scheve gezichten te voorkomen moet tactisch worden omgegaan met het aantal woorden tekst per persoon. Er wordt geschaafd en gestreept totdat de loftoezwaaiingen eerlijk verdeeld zijn. En natuurlijk puzzelt de auteur lang aan de volgorde van de vernoemingen. Uiteindelijk wordt het dus een uiterst vermoeiende opsomming van diplomatieke formuleringen.

Om die reden wil ik het in dit dankwoord anders doen. Ik zal kort beschrijven hoe ik de afgelopen vijf jaar heb beleefd.

Promoveren heb ik als een toets van doorzettingsvermogen ervaren. Vooral in het begin, toen het project nog moest uitkristalliseren, was de progressie minimaal. Ik heb vele concept onderzoeksvoorstellen geschreven, voordat het geheel uitmondde in het boek dat voor u ligt. Toen de onderzoekstrein eenmaal op de rails stond, kwam de vaart er gelukkig goed in. Logistiek was het soms een flinke klus. Met name de vragenlijstonderzoeken vergden flink wat organisatie en tijd. Maar met de hulp van studentassistenten en het secretariaat bleef altijd alles onder controle.

Ook de manuscripten kenden een tamelijk scheve verdeling. Toen het eerste artikel werd aangeboden was de onderzoekstijd al voor de helft op. Maar ook hier kan een parallel met een dieselmotor worden getrokken. De begeleiders werden de laatste maanden gebombardeerd met zowel concept- als definitieve teksten, waar ik nogal krappe deadlines aan had verbonden. De druk kwam deels ook doordat manuscripten soms een rondgang maakten langs de bureaus van verschillende editors - overigens waren de afwijzingen gerelateerd aan de match tussen het onderwerp en de focus van het 'journal', niet met de uitvoering van het onderzoek. Ook dat was een kwestie van doorzetten.

Het uitblijven van meetbare voortgang had voornamelijk een effect op mijn directe omgeving. Die vroeg zich wel eens af, waarom ik het in hemelsnaam nog leuk vond. Misschien heeft het te maken met een overdosis optimisme, maar ik ben altijd blijven geloven in een goede afloop.

Deze positivistische instelling werd deels ook gevoed door de prettige werksfeer op de afdeling. Mijn omzwervingen langs een aantal disciplinegroepen brachten me zo rond december 2000 naar de achtste verdieping van het Went-gebouw. Na een half jaar alleen te hebben geploeterd, was het een verademing te ontdekken dat sommige problemen al door anderen opgelost waren. Collega's waren nooit te beroerd om mij – tussen hun eigen drukke werkzaamheden door – de beginselen van FoxPro, statistiek, epidemiologie en wetenschappelijk schrijven te leren. De kritische vragen van mijn begeleiders zorgden er voor dat de manuscripten toch elke keer weer een beetje beter werden. Discussies met kamergenoten gaven mij de mogelijkheid om de resultaten van mijn onderzoek in het juiste farmaceutische en soms ook politiek-historisch perspectief te plaatsen. Het is jammer dat de faculteit geen traditie kent van proefschriftstellingen, want ik beschik nu over een heel arsenaal one-liners. (Alhoewel een enkele misschien niet voor publicatie geschikt is).

De kiem voor de invulling van het project werd gelegd tijdens de terugrit van een bespreking met het QIPC. Nadat onder andere palliatieve zorg als onderwerp was afgevallen, bleek diabetes en specifiek het zelfmanagementaspect van diabetes een vruchtbaar model om apotheekprocessen te bestuderen. Dat het onderwerp leefde, zag ik ook terug in mijn onderzoeken waarbij ik een bijdrage vroeg van patiënten en apothekers. De respons was altijd goed. Ondanks het feit dat er voor hen niet of nauwelijk iets tegenover stond, waren ze niet te beroerd om mijn vragenlijsten te beantwoorden, met mijn projecten mee te denken en medicatiegegevens na te lopen.

De veelzijdigheid van het onderzoek heeft mij altijd zeer aangesproken. Analyse op grote databestanden was net zo'n uitdaging als de ontwikkeling van een vragenlijst. Daarnaast heb ik ook nog kennis kunnen maken met kwalitatieve onderzoeksmethodes. De statistiek wisselde van zeer complex tot eenvoudige standaarddeviaties. Gelukkig was er voor alles wel iemand te vinden die bereid was mij wegwijs te maken in het woud van nieuwe technieken. Daarnaast ben ik ook altijd in de gelegenheid gesteld om mezelf te bekwamen in een verscheidenheid van onderwerpen. De cursussen, congressen en ook mijn onderwijsactiviteiten vormden een welkome afwisseling op die momenten dat het onderzoek tijdelijk even niet wilde vlotten.

Zonder alle anderen te kort te willen doen, wil ik tot slot toch een aantal mensen persoonlijk bedanken. Dit project was namelijk nooit van de grond gekomen zonder de inzet en het optimisme van Herre. Olaf bewaakte de methodologische kant van de promotie, waardoor het project werd geconcretiseerd. Kees heeft er voor gezorgd dat het project daadwerkelijk mogelijk werd. Hij gaf mij ook de ruimte om zelf mijn keuzes te maken. Dank ook aan mijn ouders, die me het zelfstandig werken hebben bijgebracht en mij in mijn keuzes hebben gesteund. Mijn broertje, en Kees, die de manuscripten op Engels controleerden en nooit in de stress raakten van de beperkte tijd die ik hen er voor gaf. De paranimfen, en mijn broertje, die mij ontzettend hebben geholpen om dit

document er uit te laten zien, zols het voor u ligt. Jesper, die had bedacht dat hij het beste tijdens de laatste vier maanden van het proefschrift geboren kon worden. En Roos, die niet altijd begreep wat mij zo aantrok in onderzoek doen, maar mij altijd met raad en daad heeft bijgestaan.

In de finale wil ik me tot u richten. Ik had willen afsluiten met de woorden van een of ander groot filosoof. Maar ik realiseerde me dat deze poging tot eruditie niet beschrijft wat voor mij promoveren is; eenzaam, maar niet alleen. Door uw bijdrage, groot of klein, inhoudelijk of ondersteunend, financieel of emotioneel, heb ik het tot de eindstreep gebracht. Dank.

APPENDIX 1

QUESTIONNAIRE CHAPTER 2.2 AND 3.3

TOELICHTING

Wij verzoeken u om de vragenlijst te laten invullen door de **apotheker** die het meest bij patiëntenvoorlichting is betrokken.

Lees de vragen rustig door. Alle vragen hebben betrekking op de huidige situatie. Vink het antwoord aan dat het beste met de situatie in uw apotheek overeenkomt. U kunt bij een aantal vragen een korte toelichting in het lege antwoordvak noteren.

Wij schatten in dat het invullen ongeveer 10-15 minuten kost. Wij verzoeken u de vragenlijst voor **9 april 2004** terug te sturen.

bescherming (persoons)gegevens
De vragenlijst is volledig anoniem. Alle informatie zal vertrouwelijk worden behandeld. De resultaten zullen alleen worden gebruikt voor wetenschappelijk onderzoek.

verzending vragenlijst
Als u de vragenlijst heeft ingevuld, kunt u deze in de bijgevoegde enveloppe doen en opsturen naar de Universiteit Utrecht. De enveloppe is al geadresseerd. Een postzegel is niet nodig.

Namens alle onderzoekers alvast hartelijk dank voor uw medewerking.

DEEL A. APOTHEEKKENMERKEN

1. **Hoe groot is het aantal full time equivalenten (fte) voor apothekers op dit moment?**
   Eventuele vacatures niet meenemen in de telling.
   …….…. fte
2. **Hoe groot is de vacatureruimte (in uren per week) voor een apotheker op dit moment?**
   Vul 0 uren per week in als er geen vacature is.
   …….…. uren per week
3. **Hoe groot is het aantal full time equivalenten (fte) voor apothekersassistenten op dit moment?**
   Eventuele vacatures niet meenemen in de telling.
   …….…. fte
4. **Hoe groot is de vacatureruimte (in uren per week) voor een apothekersassistent op dit moment?**
   Vul 0 uren per week in als er geen vacature is.
   …….…. uren per week
5. **Hoeveel recepten (WTG en niet-WTG) levert uw apotheek gemiddeld per dag af?**
   In het geval dat patiëntenbestand is gekoppeld met een andere apotheek, kunt u dan een inschatting geven van het aantal recepten dat in bij uw in de apotheek wordt afgeleverd?
   - □ minder dan 100
   - □ 100 - 250
   - □ 250 - 400
   - □ meer dan 400
6. **Heeft de apotheek een speciale ruimte voor het geven van persoonlijke adviezen of voorlichting**
   - □ nee
   - □ ja, een werkruimte (koffiekamer, kamer van de apotheker) wordt hiervoor gebruikt
   - □ ja, er is een aparte gespreksruimte
7. **Is de apotheek opgenomen in een AHOED-constructie of een gezondheidscentrum?**
   - □ ja
   - □ nee
8. **Is de apotheek een nevenvestiging van een andere apotheek (uitdeelpost)?**
   - □ ja
   - □ nee
9. **Is de apotheek uitsluitend een dienstapotheek?**
   De apotheek is alleen 's avonds en 's nachts open en kent geen dagopenstelling.
   - □ ja
   - □ nee
10. **Wat zijn de eerste 2 cijfers van de postcode van de apotheek?**
    Deze gegevens zijn niet terugvoerbaar op uw persoon of de apotheek en zullen alleen worden gebruikt voor onderzoek naar regionale verschillen.

    …….…

DEEL B. FPZ BIJ DIABETES

11. **Is er tussen januari 2000 en nu een project gestart in de apotheek om de zogverlening aan diabetespatiënten te verbeteren?**
    - □ nee
    - □ ja, de DiabetesCheck
    - □ ja, namelijk …….…
12. **Is dit project op dit moment ook geïmplementeerd in de dagelijkse werkzaamheden?**
    - □ ja
    - □ nee

13. Wordt er in de apotheek gewerkt volgens een eerste uitgifte protocol voor antidiabetica (insuline of orale hypoglycemische middelen)?
- □ nee
- □ ja, namelijk volgens ……

14. Is er in de apotheek een assistent die zich (enigszins) gespecialiseerd heeft in diabeteszorg?
- □ ja
- □ nee

DEEL C. ZORGVERLENING BIJ ZELFCONTROLE

Vraag 15 tot en met 24 hebben betrekking op situaties waarin de patiënt door de apotheek wordt benaderd met advies (dus zonder een directe vraag vanuit de patiënt). Ook als deze voorlichting bijvoorbeeld door drukte niet altijd aan alle patiënten wordt gegeven, kunt u 'ja' invullen.

15. Is het gebruikelijk in de apotheek om ongevraagd voorlichting (mondeling of schriftelijk) te geven over het belang van zelfcontrole van bloedglucose, bijvoorbeeld bij eerste uitgifte van een antidiabeticum of via een mailing?
Ook als deze voorlichting bijvoorbeeld door drukte niet altijd aan alle patiënten wordt gegeven, kunt u 'ja' invullen.
- □ ja, alleen aan insulinegebruikers
- □ ja, zowel aan insulinegebruikers als aan mensen met orale hypoglycemische middelen
- □ nee, *ga naar vraag 17*

16. Is er een protocol voor het geven van ongevraagde voorlichting over het belang van zelfcontrole?
- □ ja
- □ nee

17. Is het gebruikelijk in de apotheek om ongevraagd MONDELINGE voorlichting te geven bij aflevering van een bloedglucosemeter?
Ook als deze voorlichting bijvoorbeeld door drukte niet altijd aan alle patiënten wordt gegeven, kunt u 'ja' invullen.
- □ ja
- □ nee, *ga naar vraag 20*

18. Over welke onderwerpen wordt er voorlichting gegeven?
U kunt meerdere antwoorden aankruisen.
- □ keuze van type bloedglucosemeter
- □ werking van de bloedglucosemeter en eventuele extra functies
- □ uitvoering van een bloedglucosemeting
- □ calibratie van een bloedglucosemeting

19. Worden er protocollen gebruikt bij de voorlichting over bloedglucosemeters en zelfcontrole van bloedglucose?
- □ nee
- □ ja, protocol Uitgifte Bloedglucosemeter (DiabetesCheck)
- □ ja, namelijk ……

20. Nodigt de apotheek patiënten die een bloedglucosemeter gebruiken uit om de uitvoering van de meting te toetsen?
Ook als deze voorlichting bijvoorbeeld door drukte niet altijd aan alle patiënten wordt gegeven, kunt u 'ja' invullen.
- □ ja
- □ nee, *ga naar vraag 22*

21. Wordt er een protocol gebruikt bij de toetsing van de uitvoering van de bloedglucosemeting?
- □ ja
- □ nee

22. Nodigt de apotheek patiënten met een bloedglucosemeter uit om periodiek hun meter te laten testen, te ijken en/of te calibreren? *Ook als deze voorlichting bijvoorbeeld door drukte niet altijd aan alle patiënten wordt gegeven, kunt u 'ja' invullen.*
- □ ja
- □ nee, *ga naar vraag 24*

23. Wordt er een protocol gebruikt bij het onderhoud en de ijking van bloedglucosemeters?
- □ ja
- □ nee

24. In hoeveel gevallen lukt het om de bovenstaande voorlichting ook daadwerkelijk te geven?
- □ minder dan de helft van de gevallen
- □ 50 - 80% van de gevallen
- □ meer dan 80% van de gevallen
- □ niet van toepassing

25. Is er in het afgelopen half jaar een speciale activiteit geweest, waardoor er extra veel aandacht is geweest voor zelfcontrole (bijvoorbeeld een metercontroledag)
- □ nee
- □ ja, namelijk

26. Worden er in de apotheek leenmeters verstrekt aan patiënten die voor een korte periode aan zelfcontrole doen?
- □ ja
- □ nee

DEEL D. VERZOEK OM VOORLICHTING VANUIT DE PATIËNT ZELF

27. Hoe vaak komt het voor dat patiënten uit zichzelf met een vraag komen over bloedglucosemeters of bloedglucosemeting?
- □ minder dan eens in de twee maanden
- □ gemiddeld één tot twee keer per twee maanden
- □ vaker dan één keer per maand
- □ anders, namelijk ……

28. Is er een procedure voor het afhandelen van vragen vanuit de patiënt zelf?
- □ nee
- □ ja, een procedure voor het afhandelen van ……

DEEL E. REGIONALE SITUATIE EN SAMENWERKING BIJ ZELFCONTROLE

29. Kunt u inschatten hoeveel gebruikers van teststrips in uw apotheek deze niet bij u, maar via een andere kanaal bestelt? *Bijvoorbeeld via postorderbedrijven.*
- □ minder dan 20% van de gebruikers
- □ 20 - 50% van de gebruikers
- □ 51 - 80% van de gebruikers
- □ meer dan 80% van de gebruikers
- □ weet niet

30. Is er een (periodiek) spreekuur van een diabetesverpleegkundige in uw apotheek?
- □ ja
- □ nee
- □ dit gaat binnen enkele maanden van start

31. Is er een (periodiek) spreekuur van een podotherapeut of diëtist in uw apotheek?
- □ ja
- □ nee
- □ dit gaat binnen enkele maanden van start

Onderstaande vragen hebben betrekking op de lokale afspraken over de taakverdeling bij de begeleiding van diabetespatiënten die aan zelfcontrole doen. Wij verzoeken u de vragen ook in te vullen als er is afgesproken dat uw apotheek GEEN taken uitvoert.

32. Levert de apotheek alleen teststrips en bloedglucosemeters af van één producent/ leverancier van bloedglucosemeters? *U levert bijvoorbeeld alleen meters en teststrips van Roche of LifeScan.*
- □ ja
- □ nee

33. Zijn er lokale afspraken gemaakt over de vraag wie er VOORLICHTING geeft over het gebruik van bloedglucosemeters en de uitvoering van bloedglucosemetingen?
- □ nee, *ga naar vraag 36*
- □ weet niet, *ga naar vraag 36*
- □ ja

34. Welke partijen zijn betrokken bij deze afspraken over voorlichting?
U kunt meerdere antwoorden aankruisen.
- □ huisarts
- □ diabetesverpleegkundige (zelfstandig of in ziekenhuis)
- □ internist
- □ uw apotheek
- □ collega-apotheken
- □ patiëntenvereniging (DVN)
- □ andere organisaties, namelijk

35. Kunt u kort omschrijven wat deze afspraken inhouden?

36. Zijn er lokale afspraken gemaakt over de vraag wie het PERIODIEK ONDERHOUD en CALIBRATIE van de bloedglucosemeters uitvoert?
- □ nee, *ga naar vraag 39*
- □ weet niet, *ga naar vraag 39*
- □ ja

37. Welke partijen zijn betrokken bij de afspraken over onderhoud en calibratie?
U kunt meerdere antwoorden aankruisen.
- □ huisarts
- □ producent/leverancier van bloedglucosemeters
- □ diabetesverpleegkundige (zelfstandig of in ziekenhuis)
- □ uw apotheek
- □ collega-apotheken
- □ zorgverzekeraar
- □ andere organisaties, namelijk

38. Kunt u kort omschrijven wat deze afspraken inhouden?

DEEL F. SUCCESFACTOREN VOOR ZORGVERLENING BIJ ZELFCONTROLE

39. Ontvangt uw apotheek een financiële vergoeding voor het geven van ongevraagde voorlichting over zelfcontrole of het uitvoeren van calibratie en onderhoud?
Bijvoorbeeld door een bijdrage te vragen aan de producent/leverancier van bloedglucosemeters, de patiënt of de zorgverzekeraar.

- □ ja
- □ nee
- □ niet van toepassing

40. Wordt er in de apotheek SCHRIFTELIJK voorlichtingsmateriaal over zelfcontrole en/ of bloedglucosemeters meegegeven? *U kunt meedere antwoorden aankruisen.*

- □ nee
- □ ja, bij advisering bij de keuze van het type bloedglucosemeter
- □ ja, bij voorlichting over de werking van bloedglucosemeters en de uitvoering van een meting
- □ ja, bij het toetsen van de uitvoering van de bloedglucosemeting
- □ ja, bij de ijking en controle van de bloedglucosemeter

41. Is het gebruikelijk om handelingen rondom zelfcontrole van bloedglucose vast te leggen in het patiëntendossier?

- □ ja
- □ nee

42. Binnen het apotheekteam in voldoende kennis om patiënten te adviseren bij de keuze van een bloedglucosemeter.

- □ volledig mee eens
- □ mee eens
- □ mee oneens
- □ volledig mee oneens

43. Binnen het apotheekteam is voldoende kennis om patiënten uit te leggen op welke manier een bloedglucosemeting moet worden uitgevoerd..

- □ volledig mee eens
- □ mee eens
- □ mee oneens
- □ volledig mee oneens

44. Binnen het apotheekteam is voldoende kennis om bloedglucosemeters te ijken en te controleren..

- □ volledig mee eens
- □ mee eens
- □ mee oneens
- □ volledig mee oneens

45. Hoge werkdruk is voor het apotheekteam een reden om minder voorlichting over zelfcontrole te geven dan eigenlijk zou moeten..

- □ volledig mee eens
- □ mee eens
- □ mee oneens
- □ volledig mee oneens

46. De apotheek kan, zonder tussenkomst van (mede)eigenaren, zelfstandig en onafhankelijk haar beleid rondom diabeteszorg opstellen.

- □ volledig mee eens
- □ mee eens
- □ mee oneens
- □ volledig mee oneens

47. Hieronder kunt u eventuele opmerkingen noteren.

APPENDIX 2

ORIGINAL QUOTATIONS OF CHAPTER 3.1.

I	Bij ons is de kennis niet dusdanig optimaal nog dat je heel makkelijk kunt adviseren, kunt uitwerken. Dus het wordt ook niet actief aangeboden.
II	Het nadeel is dat het nu steeds minder gebeurt en dat je wel ziet dat je een verschuiving krijgt, dat er vaak wordt gezegd, jij kan dat heel goed, ga jij dat dan maar.
III	Mensen vragen niet omdat we het niet aanbieden, wij bieden het niet aan omdat we niet altijd het juiste antwoord erop weten.
IV	Je moet ook kunnen zeggen: dat mag ik zeggen. Niet dat de patient in de apotheek komt als het fout gaat en zegt: waar heb je je eigenlijk mee bemoeid, je bent buiten je boekje omgegaan. Als ik zou weten dat ik het zou mogen, zou ik me erin verdiepen.
V	Er zitten maar 24 uur in een dag.
VI	Diegenen (assistenten) met wie ik het doe, die zijn zo gewend geraakt. Je ziet gewoon dat de zekerheid groeit en de rest (van de assistenten) heeft zo iets van, jullie zijn daar mee bezig, doen jullie het maar, want jullie weten het.
VII	Het is natuurlijk zo dat, wat wij niet kunnen bieden is de kwaliteit van de diabetesverpleegkundige, die weet er veel meer van, misschien nog wel meer dan ik, daar twijfel ik eigenlijk niet aan.
VIII	Wij zijn toen eerst begonnen met de DiabetesCheck van Zorgplan. We begonnen eerst met de tabletten … Dat wilden we eerst goed op de rails hebben voor we aan andere projecten wilden beginnen. Toen de leverancier zei van, wij kunnen ook een metercontroledag beginnen … toen hadden we zoiets van, nu is het dus wel het moment om een stap verder te zetten.
IX	Bij ons hadden we een goede samenwerking met de thuiszorg. Maar als die er niet geweest was, weet ik niet of het zo makkelijk was gegaan. Dan moet je wel heel erg tegen de stroom inroeien.
X	Diabetespatienten zijn natuurlijk patienten die al omgeven zijn door een team van deskundigen. Zeker de type 1. Die zit bij een internist, die zit al bij een diabetesverpleegkundige vaak. En wij zijn daar een soort back-up.
XI	De top van de ijsberg zijn voor mij de type 1 diabeten en de kinderen, zeg maar alles wat moeilijk is. De moeilijke gevallen gaan naar het ziekenhuis. Dat zijn de piekers. De gewone patiënten hebben wij.
XII	Voor hen is het core business en voor ons is het natuurlijk een randgebied. Wij kunnen als individuele apotheker niet zo veel tijd en energie steken in goede marketing.
XIII	Er werd net al gepraat over de vraag in hoeverre dat (metercontroledag) ook een commercieel doel was. Bij mij speelt dat zeker mee. Marketing. Omdat het een nieuwe apotheek is, je kunnen profileren als zorgverlener.

Original quotations of chapter 3.1. - *continued*	
XIV	De discussie over FPZ –Plus dat daar extra betaald voor zou moeten worden, daar wordt nog steeds aan geknutseld, maar als het komt, dan heb ik zo iets van kom maar op. Dan heb ik hem in de computer zitten.
XV	Aan de ene kant heb ik zoiets van, het is niet mijn taak, maar mensen kunnen het (teststrips) ook krijgen waar ze geen voorlichting krijgen.
XVI	Ik heb wel als een probleem ervaren om mensen toch te overtuigen van het feit dat dit ook een stuk toekomst is van de apotheek, een stuk patientenbegeleiding. Dat dit soort dingen ook leuk kunnen zijn voor je werk, dat het niet alleen iets extra is dat er bij komt en wat veel tijd gaat kosten.
XVII	Wij hebben zelf in een enquete (de vraag) gesteld: zou u ook veranderen van leverancier? Een enkeling geeft dit aan, maar de meeste zijn honkvast bij hun postorderbedrijf. Dus die winst is heel onduidelijk.
XVIII	Je core business vind ik toch, de geneesmiddelen die we afleveren en de informatie die er bij nodig is, om die te geven.
XIX	Meteruitleg is geen uniek kunstje waar je apotheker voor moet zijn of apothekersassistente. En binnen de zorgverlening is het gewoon dat iedereen zijn eigen kunstje heeft.
XX	Absoluut niet mee eens, want jij hebt ook een relatie met die huisarts.
XXI	Het [patiëntenvoorlichting] kost uiteindelijk iets waar we niet voor worden betaald. Er is heel veel goede wil van de apotheker en de organisatie, maar je krijgt er niks voor terug.
XXII	Ik heb maar een pool van 10 assistenten en die moeten ook de normale gang, eigenlijk de basis van de apotheek, het leveren van geneesmiddelen, moet ook gewoon gebeuren.
XXIII	Nou ik heb het zijdelings genoemd, ik heb nog niet officieel gezegd dat ik die dag die metercontrole ga houden, maar het onderwerp metercontrole is wel al een aantal keren ter sprake gekomen. Dus daar verwacht ik geen geen problemen mee, nee, op zich dat soort dingen vinden ze wel goed.

APPENDIX 3

QUESTIONNAIRE CHAPTER 3.4 AND 4

Onderzoek Diabetes en bloedglucosemeting

Instructie bij het invullen van de vragenlijst
Deze vragenlijst is een onderdeel van een onderzoek naar bloedsuikermeting door mensen met diabetes. Ook als u **geen bloedsuikermetingen** uitvoert, verzoeken wij u de vragenlijst te beantwoorden. De vragenlijst bestaat uit 3 delen: deel A, deel B en deel C. Lees de vragen rustig door en **kruis** het antwoord aan dat het beste bij uw situatie past. Bij sommige vragen wordt speciaal naar een bepaalde periode gevraagd. Beantwoord de vraag dan zoals de situatie in die periode was, ook al was het voor of na die tijd anders.

Het invullen van de vragenlijst zal ongeveer 15 minuten in beslag nemen. Wilt u de vragenlijst a.u.b. zo snel mogelijk en uiterlijk voor **15 mei 2003** terugsturen?

Diabetespas
Voor het beantwoorden van enkele vragen, bijvoorbeeld over de bezoeken aan de arts en diabetesverpleegkundige, kunt u ook uw **Diabetespas** raadplegen.

Bescherming (persoons)gegevens
De vragenlijst is volledig anoniem. Alleen de apotheek die u de vragenlijst heeft gestuurd heeft uw adresgegevens. De onderzoekers kennen uw naam en uw adres dus niet. De resultaten zullen alleen worden gebruikt voor wetenschappelijk onderzoek.

Verzending vragenlijst
Als u de vragenlijst heeft ingevuld, kunt u deze in de bijgevoegde envelop opsturen naar de Universiteit Utrecht. De envelop is al geadresseerd en gefrankeerd. Een postzegel is dus niet nodig.

Namens alle onderzoekers alvast hartelijk dank voor uw medewerking.

DEEL A ALGEMENE VRAGEN

1. In welk jaar bent u geboren?

- □ In 19 ……

2 Wat is uw geslacht?

- □ man
- □ vrouw

3 Bent u lid van de patiëntenvereniging voor mensen met diabetes (DVN)?

- □ nee, ik ben geen lid van de diabetes patiëntenvereniging (DVN)
- □ ja, ik ben lid van de diabetes patiëntenvereniging (DVN)

DEEL B ALGEMENE VRAGEN OVER UW DIABETES

4 Hoe lang heeft u al diabetes?

- □ al ..... jaar
- □ weet niet meer

5 Welk type diabetes heeft u?

- □ type 2 / ouderdomsdiabetes
- □ type 1 / jeugddiabetes
- □ zwangerschapsdiabetes
- □ weet niet meer

6 Wanneer bent u voor het laatst op controle geweest voor uw diabetes?

- □ na 1 juli 2002
- □ tussen 1 januari 2002 en 1 juli 2002
- □ voor 2001
- □ weet niet

7 Met welke zorgverleners heeft u afgelopen jaar (dus tussen 1 maart 2002 en 1 maart 2003) vanwege uw diabetes contact gehad?

U kunt meerdere hokjes aankruisen.

- □ diabetesverpleegkundige
- □ diëtist
- □ huisarts
- □ oogarts
- □ podotherapeut
- □ specialist / internist
- □ anders, namelijk .....

8 Wanneer is bij u voor het laatst de HbA1c gemeten?

- □ tussen 1 januari 2002 en 1 maart 2003
- □ in 2001
- □ voor 2001
- □ weet niet meer

9 Weet u wat uw laatste HbA1c was?

- □ nee, dat weet ik niet meer
- □ ja, mijn HbA1c was namelijk:
- □ lager dan 7%
- □ tussen de 7% en de 8,5%
- □ hoger dan 8,5%

10 Door de diabetes kunnen er soms complicaties ontstaan. Kunt u aangeven of er complicaties bij u zijn geconstateerd? Zo ja, kunt u invullen wanneer (eventueel bij benadering) die complicatie bij u is vastgesteld?

- □ nee, er zijn geen complicaties vastgesteld
- □ ja, namelijk:
- □ voetafwijkingen, sinds …….
- □ oogafwijkingen, sinds …….
- □ nierafwijkingen, sinds …….
- □ zenuwafwijkingen (neuropathie), sinds …….
- □ hart-/vaatziekten, sinds …….
- □ hoge bloeddruk, sinds …….

11 Heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) een hypo gehad, waarbij u hulp van iemand anders nodig had?

- □ nee
- □ ja, dat is ……. keer gebeurd

12 Hoe goed is naar uw eigen mening uw diabetes ingesteld?

- □ zeer goed
- □ goed
- □ matig
- □ slecht
- □ zeer slecht

13a Is in de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) uw medicatie voor uw diabetes veranderd (bijvoorbeeld een ander diabetesmedicijn, een andere sterkte, meer tabletten of insuline)?

- □ nee, *ga verder met vraag 14*
- □ ja, de medicatie voor mijn diabetes is veranderd *ga verder met vraag 13b*

13b Van wie kreeg u het advies om uw medicatie te veranderen?

- □ van de diabetesverpleegkundige
- □ van de huisarts
- □ van de specialist / internist
- □ van iemand anders, namelijk ……..

14 Bent u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) in het ziekenhuis opgenomen geweest?

- □ nee
- □ ja

DEEL C VRAGEN OVER HET GEBRUIK VAN BLOEDSUIKERMETERS EN TESTSTRIPS

15 Heeft u ooit een apparaat gehad om zelf uw bloedsuiker mee te meten?

- □ nee *ga verder met vraag 31 op pagina 8*
- □ ja *ga verder met vraag 16*

16 Heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) uw

- □ nee *ga verder met vraag 31 op pagina 8*
- □ ja *ga verder met vraag 17*

17 Gebruikte u vóór 1 januari 2003 ook al een bloedsuikermeter?

- □ nee, de eerste keer was tussen 1 januari en 1 maart 2003
- □ ja, ook vóór 1 januari 2003 gebruikte ik al een bloedsuikermeter

18 Wie heeft u aangeraden om uw eigen bloedsuiker te meten?

- □ apotheek
- □ diabetesverpleegkundige
- □ huisarts
- □ specialist / internist
- □ vrienden of kennissen
- □ niemand, ik ben er vanuit mezelf mee begonnen
- □ weet niet meer
- □ anders, namelijk .....

19 Wie levert op dit moment de teststrips voor uw bloedsuikermeter aan u?

- □ apotheek
- □ diabetesverpleegkundige in het ziekenhuis
- □ huisarts
- □ postorderbedrijf (bijvoorbeeld Hermedico of MeMo)
- □ specialist / internist
- □ anders, namelijk .....

20 Hoe vaak heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) uw bloedsuiker gemeten?

- □ gemiddeld minder dan 1 keer *per week*
- □ gemiddeld 1 tot 6 keer *per week*
- □ gemiddeld 1 keer *per dag*
- □ gemiddeld 2 tot 4 keer *per dag*
- □ gemiddeld 5 tot 6 keer *per dag*
- □ gemiddeld meer dan 6 keer *per dag*

21a Heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) dagcurves gemaakt?

- □ ja, ik heb één of meer dagcurves gemaakt *ga verder naar vraag 21b*
- □ nee, ik maak geen dagcurves *ga verder naar vraag 22*
- □ weet niet meer *ga verder naar vraag 22*

21b Hoe vaak heeft u de afgelopen 2 maanden een dagcurve gemaakt?

- □ gemiddeld …… dag(en) per week
- □ ik ben net van tabletten naar insuline overgegaan en heb daarvoor
- □ (ongeveer) …… dagcurves gemaakt

21c Uit hoeveel metingen bestaat uw dagcurve?

- □ tijdens het maken van een dagcurve meet ik (gemiddeld) …… per dag

22 Heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) telkens op een vast tijdstip gemeten?

- □ nee, ik meet alleen op wisselende momenten en tijdstippen
- □ ja, ik meet altijd op een vast tijdstip, bijvoorbeeld voor de maaltijd
- □ ik meet zowel op een vast tijdstip als op wisselende momenten

23 Welk merk teststrips heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) gebruikt? *U kunt meerdere hokjes aankruisen als u verschillende teststrips heeft gebruikt.*

- □ Accu-chek sensor comfort of Accu-chek instant plus
- □ Elite strips
- □ Euroflash teststrips
- □ Gluco touch strips
- □ Glucocard memory strips
- □ Precision plus of Precision Xtra elektroden (Medisense)
- □ One touch of One touch ultra
- □ anders, namelijk ……..

24 Wie heeft u uitleg gegeven over de manier waarop u uw bloedsuikerwaarde moet meten? ***U kunt meerdere hokjes aankruisen als verschillende mensen u uitleg hebben gegeven.***

- □ apotheek
- □ assistente bij de huisarts
- □ diabetesverpleegkundige in ziekenhuis
- □ huisarts
- □ specialist / internist
- □ de patiëntenvereniging
- □ wijkverpleegkundige
- □ niemand, ik heb het mezelf aangeleerd
- □ anders, namelijk .....

25 Gebruikte u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) een PC (personal computer) om de meetwaarden te bekijken of te bewaren?

- □ nee, ik heb de meetwaarden niet met een PC bekeken of bewaard
- □ ja, ik heb de meetwaarden met een PC bekeken of bewaard

26 Kunt u aangeven hoe vaak u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) de waarde van een bloedsuikerbepaling heeft opgeschreven in een dagboek of agenda?

- □ ik heb geen waarden opgeschreven
- □ wel eens, maar minder dan de helft van de bloedsuikermetingen
- □ vaak, meer dan de helft van de bloedsuikermetingen
- □ altijd

27 Heeft u de afgelopen 2 keer dat u voor controle bij uw (huis)arts of diabetesverpleegkundige bent geweest, het dagboek met bloedsuikerwaarden meegenomen?

- □ ik neem altijd het dagboek mee
- □ ik heb het dagboek één keer meegenomen
- □ ik heb het dagboek beide keren niet meegenomen
- □ ik heb sinds kort diabetes en ben nog geen 2 keer op controle geweest
- □ weet niet meer

28 Werden bij uw vorige controlebezoek aan uw huisarts, specialist of verpleegkundige de meetwaarden met u besproken?

- □ nee, de meetwaarden zijn toen niet besproken
- □ ja, de meetwaarden zijn toen besproken
- □ weet niet meer

29a Heeft u de afgelopen 2 maanden (dus tussen 1 januari en 1 maart 2003) de bloedsuikermeting gebruikt om te bepalen hoeveel insuline u moet spuiten?

- □ nee, ik doe niet aan zelfregulatie *ga verder naar vraag 30a*
- □ ik gebruik geen insuline *ga verder naar vraag 30a*
- □ ja, ik doe aan zelfregulatie *ga verder naar vraag 29b*

29b Indien u aan zelfregulatie doet, hoe vaak heeft u de afgelopen 2 maanden een bloedsuikermeting uitgevoerd om te bepalen hoeveel insuline u moet spuiten?

- □ gemiddeld minder dan 1 keer per dag
- □ gemiddeld 1 keer per dag
- □ gemiddeld 2 tot 4 keer per dag
- □ gemiddeld 5 of 6 keer per dag
- □ gemiddeld meer dan 6 keer per dag

30a Is uw bloedsuikerwaarde de afgelopen twee maanden (dus tussen 1 januari en 1 maart 2003) te hoog of te laag geweest?

- □ nee *ga verder naar vraag 31 op pagina 8*
- □ ja *ga verder naar vraag 30b*

30b Wat doet u in het geval een meting te hoog of te laag is?
U kunt meerdere hokjes aankruisen.

- ☐ noteren in dagboek of agenda
- ☐ mijn eten aanpassen
- ☐ mijn beweging aanpassen
- ☐ mijn hoeveelheid medicijnen of insuline aanpassen
- ☐ contact opnemen met (huis)arts of diabetesverpleegkundige
- ☐ ik doe geen speciale dingen
- ☐ anders, namelijk ……..

31 Wilt u dat uw apotheek u een samenvatting van de onderzoeksresultaten opstuurt?

- ☐ ja
- ☐ nee

In de onderstaande ruimte kunt u opmerkingen of toelichtingen noteren.

Dit is het einde van de vragenlijst. Hartelijk dank voor het invullen. U kunt de lijst in de bijgesloten envelop terugsturen naar:

Onderzoek Diabetes en bloedglucosemeting
Faculteit Farmaceutische Wetenschappen
disciplinegroep Farmacoepidemiologie en -therapie
Antwoordnummer 8821
3500 ZK Utrecht

Een postzegel is niet nodig.

APPENDIX 4

CURRICULUM VITAE

Michiel Storimans was born on September 2, 1973 in Alphen aan den Rijn. In 1976, his family moved to Zeist, where he attended the Zeister Montessori School and, subsequently, the Montessori Lyceum Herman Jordan. In 1991, he received his VWO diploma. He started his propedeuse Pharmacy at the University of Groningen, which he completed in 1992. He obtained his doctoral degree four years later, with a specialisation in clinical pharmacology/hospital pharmacy under supervision of prof. dr. J.R.J.B. Brouwers. In 1998, Michiel graduated as a pharmacist. After his graduation, he accepted a position as 'junior docent' at the Faculty of Pharmacy of Utrecht University. He assisted post-doctoral pharmacy students in analytical chemistry and quality control. During this period he became interested in the concepts of quality assurance, both of products and pharmacy services. In September 2000, he was given the opportunity to develop and work on a PhD project entitled 'Quality assessment of pharmaceutical care'. This project was supervised by prof. dr. C.J. de Blaey, professor of pharmaceutical care and scientific director of the Scientific Institute Dutch Pharmacists (WINAp). This part-time position was combined with teaching activities on the topic of Quality Assurance. He currently works at IMRES b.v., Lelystad.

APPENDIX 5

LIST OF PUBLICATIONS

Abstracts

- Storimans MJ, Klungel OH, Talsma H, Floor-Schreudenring A, de Blaey CJ. Patients' opinions of their diabetes control is associated with the frequency of self- monitoring of blood glucose. Pharmacoepidemiol Drug Saf 2004;13 (suppl 1):S208-S209.
- Storimans MJ, Klungel OH, Talsma H, de Blaey CJ: Community pharmacy is an independent determinant of the dispensing of blood glucose test strips to diabetic patients. Br J Clin Pharmacol 2004;58:112.
- Storimans MJ, Klungel OH, Talsma H, Floor-Schreudenring A, de Blaey CJ. Patients' opinion of their diabetes control is associated with frequency of test strips use. Br J Clin Pharmacol. 2005;59:135.

Publications

- Storimans MJ, Talsma H, Klungel OH, Bouvy ML, de Blaey CJ. Collaborative services among community pharmacies for patients with diabetes. Ann Pharmacother. 2005;39:1647-52.
- Storimans MJ, Talsma H, Klungel OH, de Blaey CJ. Dispensing glucose test materials in Dutch community pharmacies. Pharm World Sci 2004; 26:52-55.
- Storimans MJ, Klungel OH, Talsma H, de Blaey CJ.Geographical region influences pharmacy's dispensing of blood glucose test strips. Ann Pharmacother 2004;38:1751-2.
- Buurma H, de Smet PA, van den Hoff OP, Sysling H, Storimans M, Egberts AC. Frequency, nature and determinants of pharmacy compounded medicines in Dutch community pharmacies. Pharm World Sci. 2003;25:280-7.
- Storimans MJ, Talsma H, Klungel OH, de Blaey CJ. Geographical region influences pharmacy's dispensing of blood glucose test strips independent of differences in patient characteristics. Pharm World Sci: accepted for publication.

Notities

Notities

Notities

The high prevalence and incidence of diabetes mellitus and its complications have led to a serious growth in the demand for diabetes-related health care in the Netherlands. National and international pharmacy practice guidelines advocate that community pharmacists can play a role in diabetes care. Since most patients regularly visit their pharmacy, pharmacies are ideally placed to support patients managing their own diabetes.

This thesis explores the services community pharmacies provide to patients with diabetes. It focuses on one particular aspect of self-management: self-monitoring of blood glucose. This technique enables patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the life style they prefer.

The studies reveal a significant variation in the services provided by community pharmacies. These differences are both patient-related and pharmacy-related. Moreover, regional elements, such as local collaboration and remuneration, also influence pharmacies' activities. The information obtained should facilitate pharmacists, policy makers and researchers to develop tailor-made improvement strategies and valid quality indicators of community pharmacy services.