Quality and costs of diabetes care –
comparison of two models in primary
health care

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ACADEMIC DISSERTATION

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This thesis is based on the following original publications:


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### Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>avtk</td>
<td>aikuisväestön terveyskäyttäytyminen</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>BP</td>
<td>blood pressure</td>
</tr>
<tr>
<td>CGM</td>
<td>continuous glucose monitoring</td>
</tr>
<tr>
<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
</tr>
<tr>
<td>EDIC</td>
<td>Epidemiology of Diabetes Interventions and Complications</td>
</tr>
<tr>
<td>FFA</td>
<td>free fatty acid</td>
</tr>
<tr>
<td>FinnDiane Study</td>
<td>the Finnish Diabetic Nephropathy study</td>
</tr>
<tr>
<td>FQN</td>
<td>Finnish Quality Network</td>
</tr>
<tr>
<td>GDM</td>
<td>gestational diabetes mellitus</td>
</tr>
<tr>
<td>GLP-1</td>
<td>glucagon-like peptide 1</td>
</tr>
<tr>
<td>GP</td>
<td>general practitioner</td>
</tr>
<tr>
<td>HbA₁c</td>
<td>haemoglobin A₁c</td>
</tr>
<tr>
<td>HC</td>
<td>health centre</td>
</tr>
<tr>
<td>HILMO</td>
<td>National Discharge Register of the Finnish National Institute for Health and Welfare</td>
</tr>
<tr>
<td>ICD-10</td>
<td>international classification of diseases, 10th revision</td>
</tr>
<tr>
<td>LADA</td>
<td>latent autoimmune diabetes in adults</td>
</tr>
<tr>
<td>LDL</td>
<td>low-density lipoprotein</td>
</tr>
<tr>
<td>MDI</td>
<td>multiple daily injections</td>
</tr>
<tr>
<td>MODY</td>
<td>maturity onset diabetes in young</td>
</tr>
<tr>
<td>NPH</td>
<td>neutral protamine hagedorn</td>
</tr>
<tr>
<td>PHC</td>
<td>primary health care</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SH</td>
<td>severe hypoglycaemia</td>
</tr>
<tr>
<td>SLGT2</td>
<td>sodium-glucose co-transporter</td>
</tr>
<tr>
<td>T1D</td>
<td>type 1 diabetes / diabetic</td>
</tr>
<tr>
<td>T2D</td>
<td>type 2 diabetes / diabetic</td>
</tr>
<tr>
<td>UKPDS</td>
<td>United Kingdom Prospective Diabetes Study</td>
</tr>
</tbody>
</table>
Abstract

Diabetes is a common chronic disease with growing prevalence in Finland like worldwide. It shortens the life expectancy and the quality of life. Despite the development in medication and devices there has been only modest improvement in the outcome, especially among type 1 diabetic patients.

The aim of this study was to compare the outcome of overall diabetes care in municipalities with different primary health care models of organising the follow-up of type 1 diabetes and type 2 diabetes with special treatment problems. The study also aimed at estimating the feasibility of various indicators of the standard of diabetes care.

The outcome, use and costs of health services connected with diabetes and its complications were compared in two suburban communities, Kouvola and Nurminajarvi. In Kouvola the follow-up of all patients had been based on family doctors already over 15 years whereas in Nurminajarvi the follow-up of T1D patients and the complicated T2D patients had been centralized to 1-2 doctors for the same time. The diabetic populations of these municipalities resembled each other.

In the centralized system T1D became cheaper for the municipality. Differences in the quality parameters were minor. Both these results were obviously due to more consultations of the specialist level in Kouvola. However, T1D patients were significantly more satisfied with the centralized follow-up model.

In conclusion, the centralized follow-up of the most demanding diabetes in PHC is cost-effective and results in high patient satisfaction. The centralized model is better in the follow-up of T1D but in T2D there were no differences between these two models.
1 Introduction

The prevalence of diabetes is rapidly growing in most countries of the world, including Finland (1). This phenomenon is closely connected with obesity, sedentary life style and energy-rich western diet (2, 3). In Finland, the incidence of type 1 diabetes is the highest among all nations (4, 5). The basic underlying causes for diabetes mellitus are still unknown, but both genetic and environmental factors are involved in the pathogenesis (6-13).

In Finland there have been national guidelines for diabetes care for many years including detailed instructions for diagnosis, treatment, treatment targets and follow-up of the patients (14). However, limited data exists to evaluate how different models of organising diabetes follow-up influence the quality, outcome and costs of diabetes care.

Treatment of type 1 diabetes is demanding and different from the treatment of type 2 diabetes. The quality of type 1 diabetes care as assessed only by HbA1c values has not improved during the past decades and there is still a vast excess mortality of type 1 diabetic patients compared with the whole Finnish population (15, 16-18).

Physicians do not become very experienced in type 1 diabetes care if the number of diabetic patients on their responsibility is limited. Diabetes specialist nurses have traditionally supported the family doctors, but an experienced doctor as a team leader is valuable.

This study tries to find answers to the question, if the centralized diabetes follow-up model in primary health care produces advantages to the society or to diabetic patients when compared with decentralized family doctor model. This kind of evaluation requires feasible indicators of the quality of diabetes care. Special attention is focused on the most traditional indicator, HbA1c. Also the prevalence of hypoglycaemias is evaluated because of their connection to increased mortality in many recent studies (19, 20).

Two municipalities with long histories of different models of diabetes follow-up in PHC were found for comparison. In Kouvola, the whole population had a family doctor who was determined by the residence address of the inhabitant. Every diabetic patient also had a family doctor according to this system. In Nurmijärvi, all type 1 diabetic patients and type 2 diabetic patients with special treatment problems were centralized to the follow-up of 1-2 physicians especially interested and trained in diabetes care. The diabetic populations of these municipalities were nearly same-sized.
2 Review of the literature

2.1 Types of diabetes

Diabetes is a group of diseases with elevated plasma glucose as a common feature. Hyperglycaemia leads to similar organ complications irrespective the reasons behind the elevated glucose levels (Table 1).

**Type 1 diabetes** (ICD-10 dg: E10) is an immunologic disease which originates from the destruction of the insulin producing β-cells of the pancreas (10). The reasons for this disease are under vigorous investigation but still much is unknown. Both a genetic tendency and some triggering factor are probably needed (7, 8, 11-13). Insulin replacement is required in the therapy of type 1 diabetes. In Finland, about half of all type 1 diabetic patients get the disease before the age of 15 years (4). In the Finnish population, the incidence of type 1 diabetes is higher than anywhere else in the world. A subtype of type 1 diabetes with slow progression in adult age is called LADA (latent autoimmune diabetes in adults) (21).

A typical feature of **type 2 diabetes** (ICD 10 dg: E11) is the reduced sensitivity of tissues to insulin (insulin resistance). During years or decades, worsening relative lack of insulin will develop leading to the need for insulin therapy. The lazy western lifestyle with too much food and too little exercise has been accused for the growing incidence of this disease, but there are also many risk genes increasing its probability (22, 23). This disease typically appears in middle-age or later, but currently it is met even among the school-aged children.

**MODY-diabetes** (Maturity Onset Diabetes in Young, ICD-10 dg: E13) is a single gene disease, which is diagnosed at young age, mostly before the age of 25 years. In Finland 2-4 % of all diabetic patients are estimated to have MODY-diabetes. There are currently about ten known subtypes of MODY. They are dominantly inherited in autosomal chromosomes but there are also new mutations without the same kind of diabetes in previous generations (24). These patients are usually very sensitive to insulin therapy and prone to hypoglycaemic episodes. They may have lowered insulin production or changes in the normal regulation of insulin secretion (25).

About 10 % of Finnish pregnant women have **gestational diabetes mellitus** (GDM; ICD-10 dg: O24.4), which means that diabetes is diagnosed the first time during pregnancy. It usually disappears after delivery, but the patient has an increased risk for later type 2 or type 1 diabetes, especially if she remains overweight (26, 27).
Table 1. Comparison of the two main types of diabetes (types 1 and 2)

<table>
<thead>
<tr>
<th></th>
<th><strong>Type 1 diabetes</strong></th>
<th><strong>Type 2 diabetes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients in Finland</td>
<td>40 000</td>
<td>300 000</td>
</tr>
<tr>
<td>Aetiology</td>
<td>Immunological process; usually caused by genetic susceptibility in addition to some environmental factor</td>
<td>Insulin resistance + beta cell apoptosis; usually connected with risk genes, overweight and sedentary life style</td>
</tr>
<tr>
<td>Heritability</td>
<td>2 – 6 %</td>
<td>40 (one of the parents) – 70 % (both parents)</td>
</tr>
<tr>
<td>Age at the time of diagnosis</td>
<td>50 % of cases under the age of 15 years, possible even in old age</td>
<td>Usually &gt; 40 years of age, possible even in the school age</td>
</tr>
<tr>
<td>Principles of the treatment of the glucose balance</td>
<td>Insulin replacement therapy mandatory due to total insufficiency of own insulin production</td>
<td>Depends on the severity of the disease: life style changes and oral hyperglycaemic agents, insulin, GLP-1 - agonists</td>
</tr>
<tr>
<td>Connection to other diseases</td>
<td>Risk of other autoimmune diseases is increased</td>
<td>Part of the metabolic syndrome in 80 % of cases</td>
</tr>
<tr>
<td>Prognosis</td>
<td>Shortens significantly the life expectancy (excess mortality especially to cardiovascular diseases)</td>
<td>Morbidity to cardiovascular diseases 2-4 fold compared with the population on average</td>
</tr>
<tr>
<td>Target of the treatment</td>
<td>Good glucose control without risk of hypoglycaemias. Efficient treatment of all risk factors of cardiovascular complications including hypertension and dyslipidaemia. Changes towards healthier life style.</td>
<td></td>
</tr>
</tbody>
</table>

There are also several reasons for secondary diabetes (ICD-10 dg: E13) that is caused by some other disease or medication or a disease of the pancreas. The pancreas can be resected due to a trauma or a tumour, thus causing diabetes. The most common reasons for pancreatitis are alcohol abuse and stones in the gall ducts. Other diseases causing secondary diabetes are Cushing’s disease, acromegaly and hemochromatosis. Common drugs behind secondary diabetes are glucocorticoids that stimulate gluconeogenesis in the liver and impair insulin sensitivity. The risk of diabetes is also increased by other commonly used drugs like beta-blockers, diuretics and statins (28).

There are still some rare diabetes types not mentioned above and some diabetic patients, whose disease is difficult to fit in any of these categories. New gene mutations leading to diabetes will surely be discovered.
2.2 Epidemiology of diabetes

The prevalence of type 2 diabetes is growing almost everywhere in the world. About 10% of the adult population in the developed countries has the disease (1). There are over 40,000 type 1 and over 300,000 diagnosed type 2 diabetic patients in Finland, with a population of about 5.4 million people (4, 29). It is also estimated that there are still at least 200,000 type 2 diabetic patients with an undiagnosed disease (29). These numbers are naturally approximations and are based on D2D study from the first half of the previous decade. There are, however, no clear reasons to believe, that the situation would have significantly changed. Another prediction is that the prevalence of type 2 diabetes may still double during the next 10-15 years (14). The incidence of type 1 diabetes has nearly doubled between the years 1988 and 2006 and is now about 62 new cases per 100,000 children under the age of 15 years. However, after the year 2006 the occurrence of new cases seems to have stabilized – at least for a period of five years (Figure 1).

![Figure 1. The incidence of type 1 diabetes in children under 15 years of age in Finland (cases per 100,000 children). Modified from Harjutsalo et al. 2013](image)

2.3 Organization and resources of diabetes care

The Finnish public health care has traditionally been divided strictly to primary health care (PHC) and hospital based specialist care. The latter has been given in local, central and university hospitals.
and their outpatient clinics. Diabetes is one of the most common and clearly the most expensive of our chronic diseases (29, 30). Most general practitioners working in PHC get some experience on the treatment and follow-up of diabetic patients in their practice. Only some of the most complicated type 2 diabetic patients are subject to regular consultation in hospital outpatient clinics.

In Finland, the proportion of type 1 diabetic patients followed-up in PHC varies in a large scale: in some places, the type 1 diabetic patients in PHC are gathered to GPs especially interested and educated in diabetes care. Elsewhere their follow-up can be scattered to family doctors just depending on the home addresses of the patients. Diabetes specialist nurses follow diabetic patients in some municipalities; elsewhere all diabetic patients in PHC may be in the care of team nurses who have also many other duties in their work. Regional diabetes centres with multiprofessional teams are currently established in some larger cities. They are not as vulnerable as smaller units, but they demand a population large and dense enough. So, the quality of care is not equal to all type 1 diabetic patients, and there may also be big differences between the costs and cost-effectiveness of various organization models.

In California Ho et al. (31) compared the outcome of diabetes care given by the physicians of a diabetes clinic versus a general practice clinic. According to this study recording of patients’ self-monitoring of blood glucose levels, foot examination, comprehensive eye examination, HbA_{1c} measurement, and referral to diabetic education took place more often in the diabetes clinic than in the general practice clinic.

The cost-effectiveness of diabetes care given by physicians versus diabetes oriented nurses has been compared in a short trial in the Netherlands with the conclusion that there were no differences between the results provided by the study groups (32). The influence of different working arrangements of diabetes specialist nurses to the treatment results of diabetic patients has been studied e.g. in Sweden (33). The results showed that organizing the care of type 2 diabetes in a structured way encourages better metabolic control in spite of less use of oral medication. The knowledge of the disease among the patients was better and the self-management more active thus favouring the implementation of local guidelines.

Overall, it has been shown that more PHC resourcing is associated with reduced hospitalisation in chronic diseases (34). However, the resourcing must be kept within sensible limits and the organization in PHC has to be as effective as possible.
2.4 Treatment principles of diabetes

Type 1 diabetes is a disease with insufficient own insulin production of the pancreas caused by an immunological process against the insulin producing β-cell mass. Total insulin deficiency leads to death in a few days. The treatment is based on insulin replacement therapy. The patient takes usually long-acting insulin analogue as injections once or twice daily and rapid-acting insulin with meals imitating the actions of a healthy pancreas (multiple daily injections, MDI). Alternatively rapid- or short-acting insulin is continuously infused subcutaneously with an insulin pump. The basal doses of insulin used in the pump are tailored according to an individual glucose profile and usually 2-4 different insulin infusion rates are used during 24 hours (35, 36). If needed, the patient can make temporary changes to the basal profile and the sizes of the meal insulin doses must be decided by the patient. Oral medications against hyperglycaemia are used only exceptionally in pure type 1 diabetes.

An important part of the treatment of type 2 diabetes is the correction of lifestyle factors. In practice, this means an increase in the amount of exercising and efforts to reduce overweight by healthy dietary changes. Optimally changes in the lifestyle are more efficient in the treatment of type 2 diabetes than any single drug alone. Medical treatment of hyperglycaemia in type 2 diabetes is dependent of the duration and the severity of the disease. The lack of insulin is usually only relative and worsens during the course of time. The amount of insulin in blood and tissues may be even higher than normal but its efficacy has decreased. The target of the treatment is to increase the amount of insulin in the organ system or to improve the insulin sensitivity of the tissues. The drugs may also increase glucose excretion through the kidneys (SGLT2-inhibitors) or decrease the amount of gluconeogenesis in the liver (Table 2). The choice of the treatment depends on the residual insulin secretion capacity, the function of kidneys, the age, weight, occupation and the overall capacity of the patient. The means and goals of the treatment of a type 2 diabetic patient are highly individualized. The first-line drug at the time of diagnosis in type 2 diabetes is metformin with only a few exceptions like severe renal insufficiency or alcoholism (37, 38). In the long run insulin becomes mandatory when the β-cell impairment has proceeded.

To decrease the amount of complications and the high risks of premature death in diabetic populations, it is very important to take efficient care of all risk factors for the vascular diseases in the treatment of both diabetes types (39, 40). The risks to developing diabetic complications have lowered significantly during the latest decades in the US and also in Finland (41, 42). The reasons and their relative proportions for this positive development are still speculative, but the disease
burden has not lightened because of the rapidly growing total number of new diabetic patients. The treatment of hyperglycaemia should not lead to a marked risk of hypoglycaemia (43-45).

Table 2. The mechanisms of the influences of drugs used in the treatment of glycaemia in type 2 diabetes

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Drug classes</th>
</tr>
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<tbody>
<tr>
<td>Insulin secretageous</td>
<td>Sulphonylureas</td>
</tr>
<tr>
<td></td>
<td>DPP4-inhibitors</td>
</tr>
<tr>
<td></td>
<td>GLP1-analogues</td>
</tr>
<tr>
<td>Insulin sensitizing</td>
<td>Thiazolidinediones</td>
</tr>
<tr>
<td>Glucosuric</td>
<td>SGLT2-inhibitors</td>
</tr>
<tr>
<td>Insulin replacement</td>
<td>Insulins</td>
</tr>
</tbody>
</table>

2.5 Long-term complications of diabetes

2.5.1 Microvascular complications (retinopathy, neuropathy and nephropathy)

The risk of diabetic microvascular complications increases with worsening glycaemic control (45, 46). The level of the risk is, however, not in straight correlation to the average glucose concentration. There are genetic factors that either protect against complications or increase the risk. In type 1 diabetes the FinnDiane Study Group has especially studied the genetic factors predisposing to nephropathy and retinopathy (47). Concerning to type 2 diabetes, 40 genes have already been found that predispose the diabetic patient to the disease and give an explanation to the varying clinical expression and risk profile of complications (22).

Small arteries also suffer from hyperglycaemia that gradually causes damage in neural tissues, retina and kidneys, especially in genetically prone diabetic people. The risk of all vascular complications increases with arterial hypertension and dyslipidemia and smoking. Sufficient results have not been achieved by the treatment of hyperglycaemia alone. For these reasons the goal in the care of diabetes is to get all the risk factors into optimal control.
The prevalence of diabetic retinopathy increases with the duration of the disease. In type 1 diabetes about 90% of all patients have at least slight background retinopathy after 20 years of the disease. About one third of type 2 diabetic patients have clinical findings of retinopathy already at the time of diagnosis (48). This means that they have had undiagnosed diabetes for several years. Eye fundus photographing aims to early detection of diabetic eye complications and to their treatment in proper time. The recommended time interval between the consecutive imaging of the eyes is maximally two years in type 1 and three years in type 2 diabetes (49). For diabetes in the pregnancy there are special guidelines (50). The eye complications are usually treated with laser-coagulation, intrabulbar injections or vitreal surgery, depending on the degree of the eye damage.

At least one third of type 1 diabetic patients have the first signs of nephropathy after 20 years of the disease. Currently, however, the incidence of new dialysis therapies connected to type 2 diabetes has exceeded the incidence of new dialyses patients in type 1 diabetes in Finland. Early detection is important also in diabetic nephropathy. The screening of nephropathy is based on measuring nocturnal albumin excretion yearly from the urine. In Finland, in type 1 diabetes the screening is recommended yearly after five years from the beginning of the disease (14, 51). Constant microalbuminuria is one criterion for the diagnosis of diabetic nephropathy but the disease can develop also without early albuminuria (52, 53). The careful follow-up and strict control of blood pressure are essential in slowing down the progression of renal insufficiency. The first-line choices of antihypertensive medication are angiotensin receptor blockers or inhibitors of the angiotensin converting enzyme (46).

Some signs of diabetic neuropathy develop into practically every diabetic patient in the course of years. Like retinopathy it is common already in the phase of diagnosis of type 2 diabetes. The symptoms and clinical findings of diabetic neuropathy are multiform. The diagnosis in PHC is usually done by examining the feet of the patient: the sense of touch with a monofilament and the sense of vibration with a tuning fork (128 Hz) should be tested from every diabetic patient at least yearly. The treatment of neuropathy is mostly symptomatic. The use of alcohol must be as restricted as possible, because alcohol and hyperglycaemia have additive negative influence on the neural tissue. Other possible causes of neuropathy, like hypothyreosis and B12-vitamin deficiency, must naturally be checked and treated when diagnosed.

The glycaemic control and the blood pressure must be checked and optimized, and the possible smoking ceased latest at the time of the first signs of microvascular complications. The follow-up studies of UKPDS and DCCT show that the difference in HbA1c values between the intensive and
standard care groups vanishes during 1-2 years after the cessation of the actual trial phase (54, 55). Good results in the care of hyperglycaemia do not keep without continual efforts.

2.5.2 Macrovascular complications

About 60% of all deaths of type 2 diabetic patients in Finland are due to cardiovascular diseases, while the proportion in the whole population is about 40% (15, 56). The excess mortality among the type 2 diabetic population has, however, decreased during the last decades (15). Unfortunately, this positive development does not concern type 1 diabetic patients (15). Diabetes increases the risk of atherosclerosis regardless of the type of the disease. Its clinical manifestations are coronary heart disease, stroke and peripheral vascular disease contributing partly to the ‘diabetic foot’. The relative risk for the arterial disease in working age is about 4 times in men and even 8 times in women with type 1 diabetes compared with all Finnish men and women of the same age. In type 2 diabetes, the risk ratio is about 2-4 but still very significant (15).

Smoking is still more common among type 1 diabetic patients than in the overall Finnish population. Smoking cessation is very important in the prevention of macrovascular complications. Hypertension and dyslipidemias are also more common in the diabetic population than in the non-diabetic population and they contribute to the increased risk of vascular diseases.

2.5.2 Diabetic foot

Hyperglycaemia causes glycosylation of many protein-based structures in the organ system. This phenomenon causes the reduced mobility of joints and elasticity of tendons and ligaments and is partly underlying the slow formation of the diabetic foot with a high arch and hammer toes (57). Glycosylation of proteins influences on the organ system in many ways increasing e.g. the risk of the ‘frozen shoulder’ and the ‘carpal canal syndrome’. On the whole, the diabetic foot is a complex combination of many pathological mechanisms related to chronic hyperglycaemia. Sensomotor neuropathy weakens the position sensing and causes numbness of the foot thus exposing the skin to wounds and abrasions. The balance of small muscles changes and all these together lead to alterations in the way of walking. This change in turn predisposes the sole to the formation of local thickening. Autonomic neuropathy causes reduction of sweating and dries the skin, which in turn is a partial cause to wounds that are prone to bacterial and fungal infections in hyperglycaemic surroundings with reduced arterial circulation. The peripheral infections are often very resistant to antibiotic therapy because of the weakened local immunological response due to the impaired blood flow (58).
2.6  Acute complications

2.6.1  Ketoacidosis and symptomatic hyperglycaemia

Diabetic ketoacidosis is caused by nearly total lack of insulin. Insulin deficiency increases lipolysis from the adipose tissue and free fatty acids (FFA) are used as a major fuel of metabolism. The incomplete burning of FFA produces a cumulative amount of ketone acids, which lower the pH of the blood. The metabolic disorder results in ketoacidosis when the pH of the blood is less than 7.30. Ketoacidosis is a life-threatening situation and requires urgent emergency care (59).

A subset of type 1 diabetic patients has ketoacidosis at the time of diagnosis. Later in the course of type 1 diabetes ketoacidosis may develop if the patient for some reason is left without insulin. Alcohol use and psychiatric disorders are obviously the main reasons why type 1 diabetic patients neglect their insulin injections. A severe infection can be a contributory factor by causing temporary insulin resistance. Theoretically a type 1 diabetic patient with insulin pump therapy has higher risk to ketoacidosis, because the pump usually contains only rapid-acting insulin with a small subcutaneous insulin reservoir. A disruption in the insulin dosing can lead to ketoacidosis already in a few hours if the patient does not notice the situation in due time. Insulin damaged e.g. by heat or frost can also cause ketoacidosis. The symptoms of diabetic ketoacidosis are nausea, pains in the chest and the stomach, shortness of breath (hyperventilation) and a decreasing level of consciousness. Ketoacidosis can develop without marked hyperglycaemia. There were 15 cases of death because of ketoacidosis in the year 2012 in Finland according to the Statistics Finland. Of the cases 11 were males and 4 females (60).

Hyperosmotic nonketotic coma can develop gradually in type 2 diabetes with a relative insulin deficiency, often during an infection. The hyperglycaemia causes a hyperosmotic situation with symptoms like somnolence and may gradually decrease the level of consciousness. The blood glucose concentration is usually very high, between 30 -100 mmol/l. This situation is very rare but severe with the death rate ranging from 20 to 50 % (59, 61).

Lactic acidosis may develop in patients with metformin use, especially connected with alcohol consumption and in renal insufficiency. Metformin use should be ceased in case of serious renal insufficiency and acute situations causing the risk of dehydration or ischaemia (38).

2.6.2  Incidence and significance of hypoglycaemias

Hypoglycaemia is principally determined as a situation where the plasma glucose concentration is less than 4.0 mmol/l. The hypoglycaemia is called symptomatic if the low plasma glucose value is
associated with hypoglycaemic symptoms (Table 3). First the symptoms are adrenergic consisting of tremor, sweating, palpitation and dyspnoea and in the next phase neuroglycopenic symptoms like inertia, sight disturbances, blurred speech and tiredness may dominate (62, 63). Hypoglycaemia may be totally asymptomatic if the counter regulatory response has vanished. Hypoglycaemia is usually classified severe, if the patient needs help from other people to recover (43). A patient, who is used to very high plasma glucose concentrations, may have typical hypoglycaemic symptoms if the P-glucose decreases rapidly from high to normal values. Thus the organ system recognises better the changing glucose level than the absolute number (64).

Table 3. Typical symptoms of hypoglycaemia in relation to plasma glucose concentration

<table>
<thead>
<tr>
<th>P-glucose</th>
<th>Symptoms of hypoglycaemia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>sympathoadrenergic / kolinergic</td>
</tr>
<tr>
<td></td>
<td>neuroglycopenic</td>
</tr>
<tr>
<td>2,5 – 4,0 mmol/l</td>
<td>palpitation, tremor, anxiety/euphoria</td>
</tr>
<tr>
<td></td>
<td>hunger, sweating, disturbances of sensing</td>
</tr>
<tr>
<td>&lt; 2,5 mmol/l</td>
<td>weakening of judgement, visual disturbances, tiredness, blurred speech, aggression, consciousness</td>
</tr>
</tbody>
</table>

Hypoglycaemias are almost inevitably connected to insulin treatment. However sulphonylurea treatment may also result in hypoglycaemia, especially when the patient has renal impairment. Almost all insulin treated diabetic patients have hypoglycaemias. Slight hypoglycaemic symptoms may happen several times a week in the life of a type 1 diabetic patient. There are some anamnestic features that are usually connected with a high risk of severe hypoglycaemias like long diabetes duration, hypoglycaemia unawareness, and strict glycaemic control, previous SH episodes and male gender (65-68).
In the DCCT trial, the incidence of serious hypoglycaemias (SH) was 61.2 episodes per 100 patient-years in type 1 diabetic patients with intensive insulin therapy (69). In insulin pump therapy, the incidence of SH seems to be lower than in MDI-therapy and continuous glucose monitoring (CGM) obviously still reduces the risk (70-74). At the same time the price of the care increases and the influence on the long-term cost-effectiveness still needs more studies.

The risk for hypoglycaemia has previously thought to be lower in type 2 diabetes and the estimates vary in a large scale. In retrospective studies, the incidence of SH in insulin-treated type 2 diabetic patients has been between 15 and 73 episodes per 100 patient years. In prospective studies, the incidence has been lower, probably because of the exclusion criteria in randomised controlled trials (75).

SHs carry much significance for diabetic patients. An acute SH may cause accidents and injuries. In old patients SHs increase the risk of cardiovascular events, mostly by activating antagonistic hormonal reactions. It has been estimated that even 10% of the deaths of type 1 diabetic patients are caused by hypoglycaemia (76). Recent studies also prove a connection between SHs and dementia or lowering of cognitive functions (77, 78). Even one SH can be the reason for a life-long fear that ruins the possibilities to good glucose balance for the rest of the life (79-82).

The economic burden of hypoglycaemias to the society comes partly from the use of emergency health care but mainly from the disability to work: sick days and lowered efficacy after the episode (83-86). Only the top of the iceberg is seen in the emergency rooms of hospitals: no more than about 30% of all SHs are treated by health care professionals and, e.g. in Helsinki, 89.9% of these patients got the treatment by the paramedics without transferring to hospital (86). Thus, only 3% of all SHs can be found in the Finnish Hospital Care Register HILMO; however, probably the majority of the most serious episodes (87).

Recent observations based on big study populations (ACCORD, ADVANCE, VADT) have led to new estimations for the HbA1c goals in recommendations for the care of diabetes (14, 88, 89). Low levels should be aimed at only when the risk of SHs is tolerable. The goals are now individual and are influenced by the age, occupation and renal function (14). On average, lower HbA1c levels correlate with lower risk of diabetic complications, but high visit-to-visit variability of HbA1c and fasting plasma glucose also seem to be predictive of adverse outcomes (90).

2.6.2 Hypoglycaemias and permission to drive

While driving a vehicle, hypoglycaemias always carry a marked risk of the health and safety of both the diabetic patient and other people in the traffic. The risk of insulin-treated diabetic patients to
traffic accidents has been showed to be higher than the risk of the rest of the population (91-96). Moreover, not only hypoglycaemias, but also high levels of plasma glucose decrease the cognitive capacity of the patient by causing somnolence and decreasing alertness. The European and Finnish regulations for diabetes and driving emphasize the role of hypoglycaemias and the motivation of the diabetic driver to measure her/his blood glucose always before the beginning of driving and every second or third hour of a prolonged driving session (97, 98). In Denmark the reporting of SHs by type 1 diabetic patients reduced by 55% when the new regulations were implemented and the proportion of the patients reporting of recurrent SHs decreased from 5.6% to 1.5% (99). The conclusion of the writers was that the new regulations may paradoxically weaken the safety in the traffic. SHs always cause a need for reanalysing the care of a diabetic patient and at least the reason for the episodes must be reconstructed. In case of driving heavy vehicles or in occupational driving, even slight hypoglycaemia induced changes in the level of consciousness are not allowed. Driving performance may be especially difficult to judge in the insulin-treated diabetic drivers with hypoglycaemia unawareness.

2.7 Use and costs of health services of diabetic patients

Kangas has calculated the costs of diabetes care in Finland (100). According to his data, diabetes with its complications was by far the most expensive chronic disease for the Finnish health care system already in the year 1989. The direct costs of diabetes care were in total 5.8 % of the health care costs of the whole Finnish population. In that time, the proportion of drug-treated diabetic patients was 1.9 % of the total population. 18 years later (year 2007) the proportion of the costs of diabetes care was 8.9% of the total health care expenses, but the method of calculation was slightly different (101). In an estimation of the global expenditure of diabetes care 12% of total health care costs were used in diabetes care in the year 2010 (102). The study covered people aged 20-79 years in 91 countries where appropriate data was available.

After the year 1989 the number of diabetic patients has more than doubled but fortunately the costs have not increased so fast (100, 101). This is probably due to the increasing proportion of newly diagnosed type 2 diabetic patients. Diabetes with complications is many times more expensive for the society than diabetes without complications (100, 101). This also emphasizes the fact that effective diabetes care from the early diagnosis is very important in order to postpone or avoid the development of expensive complications.
2.8  Outcome and quality of diabetes care

2.8.1  Glycaemic control of T1 and T2 diabetic patients in Finland

Valle et al. (16-18) have analysed the quality of diabetes care in Finland three times with the intervals of about eight years (1993, 2000-2001 and 2009-2010). The cross-sectional study was performed with the same principles each time in order to get comparable results. The target was to get the data of 50 consecutive diabetic patients (per care unit) over 15-year-old visiting outpatient clinics for routine diabetes follow-up. These studies are based on samples and questionnaires directed to hospitals and health care centres. An arrangement like this is susceptible to a selection bias. However, they form our best knowledge of the present-day situation in the care of the glycaemic control and other markers of diabetes care in Finland. The HbA₁c values were measured in local laboratories using varying HbA₁c assays. Differences in the distribution of HbA₁c assays between cross-sectional studies may have significant effect on the results observed.

Table 4. Cross-sectional quality of diabetes care in Finland between years 1993 and 2009-2010 as expressed by median values.  LDL = LDL-cholesterol, BP = blood pressure, BMI = body mass index.

<table>
<thead>
<tr>
<th>Year</th>
<th>Type 1 diabetes</th>
<th>Type 2 diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients n.</td>
<td>599</td>
<td>1165</td>
</tr>
<tr>
<td>HbA₁c, %</td>
<td>8,6</td>
<td>1165</td>
</tr>
<tr>
<td>LDL, mmol/l</td>
<td>2,7</td>
<td>3,1</td>
</tr>
<tr>
<td>BP, mmHg</td>
<td>130/80</td>
<td>150/84</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>25,0</td>
<td>29,0</td>
</tr>
</tbody>
</table>

In Valle’s studies the median of HbA₁c values in type 2 diabetes has lowered and was 6.7% during 2009-2010 (Table 4). The glycaemic control in type 1 diabetes patients has not, however, changed over the observation period of 16 years: the median stays on the level of about 8.5%.

2.8.2  Body mass index, blood pressure and LDL-cholesterol of type1 and type 2 diabetic patients in Finland

The median body mass index (BMI) is increasing in patients with type 2 diabetes from 1993 to years 2009-2010 (Table 4). Also the median blood pressure of type 1 diabetic patients has developed in the wrong direction.
2.8.3 Screening of microvascular diabetic complications

The eye fundus photographs had been taken in Finnish health care centres from 60.3% of all type 2 diabetic patients during the past two years in the year 2005. In most municipalities, this service is bought from private companies. Nocturnal albuminuria had been analysed from 42.2% of type 2 diabetic patients during the preceding year (Klas Winell, Finnish Quality Network, personal information). The corresponding data of type 1 diabetic patients in Finland is not available. The data of type 2 diabetic patients is based largely on patients at pre-planned visits in dedicated health care centres. The results may therefore be better than in the reality. The data of FQN is not published in peer reviewed scientific journals for critical evaluation. It is, however, the best available data of the treatment balance of Finnish type 2 diabetic patients.

2.9 Significance of the outcome of care for the diabetic patient and for the society

UKPDS proved in type 2 diabetes and DCCT in type 1 diabetes that a stricter glycaemic control reduces significantly the risk of microvascular and also slightly the macrovascular diabetic complications (103-105). The post-trial monitoring of both studies, however, showed that the intensive treatment group could not maintain the good glycaemic control achieved during the trial (54, 55): after the more active follow-up had ceased, the difference in HbA1c between the conventional and intensive care groups was rapidly lost. However, the incidence of new diabetic complications remained significantly lower during the whole post-trial follow-up of ten years in type 2 diabetic patients with intensive treatment during the trial period (106). This phenomenon, called the ‘metabolic memory’ or the ‘legacy effect’, suggests that even a short period of good glycaemic control may have a long lasting effect on the incidence of diabetic complications.

According to recent statistics, type 1 diabetic patients, who have not developed microalbuminuria during the first 15 years of their disease, have a life expectancy comparable with the general population (107). The concept of metabolic memory was also detected in the follow-up trial (EDIC) of type 1 diabetic patients primarily included in DCCT. The incidence of microvascular complications remained still smaller in type 1 diabetic patients with intensive therapy during DCCT although the difference in the glycaemic control between the study groups was lost after the end of DCCT (55).

A multifactorial approach with an intensive treatment of all known risk factors for diabetic complications has been emphasized during the recent years. Steno 2 trial proved the advantages of the simultaneous intensive therapy of hyperglycaemia, arterial hypertension and dyslipidemia (108-111).
2.10 Measures to compare the outcome and quality of diabetes care between different care units

The performance of diabetes care between various care units in Finland and in other countries has been tried to compare (31, 112-114). Because of the lack of national diabetes registers in most of the countries, the comparisons between different diabetes care providers have usually based on various-sized patient cohorts. This may create a selection bias between the study groups. Also the HbA1c determinations have not been done with the same standardized laboratory assay (112).

Recent guidelines have also stressed the individualized goals of diabetes care as indicated by individual target HbA1c depending on the clinical features of the patient (14). Good glycaemic control cannot be judged only by HbA1c values but also other clinical factors as the number and degree of hypoglycaemias and control of other cardiovascular risk factors (LDL-cholesterol, blood pressure, smoking etc.) must be taken into account. Based on these facts, the comparative studies using only HbA1c values as a measure of quality between different diabetes care units, may not be very informative (112, 114). In North Carelia, Finland, the quality comparison of diabetes care between the municipalities of the area has been brought forward: the whole area operates with the same data system, uses the same laboratory and has a covering patient register (115).

However, in Finland there is still neither a national indicator definition nor a follow-up system of the indicators – opposite to the UK, the United States, Australia and Sweden (116-119).

In diabetic populations there are usually about 10-20% of the patients who are outliers of contacts to the organized diabetes care system. These diabetic patients renew their drug prescriptions without a direct contact with the personnel. They are supposed to have mostly unsatisfying glucose control and an increased risk developing both acute and chronic diabetic complications. The coverage of regular diabetes follow-up among the diabetic population could maybe be used as one marker of good quality, too.

There are many guidelines and recommendations for the care of diabetes, both on national and international level (14, 120-122). Small differences in these alignments may exist, but the main principles are usually similar. One indicator for the good quality of diabetes care – at least at national level – could be the implementation of the current recommendations (123).

‘Soft measures’ to evaluate the quality of diabetes care should include the satisfaction and quality of life of the patients by using questionnaires especially targeted for diabetic patients. Previous studies have shown that diabetic patients are usually satisfied with their diabetes care if they think that the technical level of the care is high (124). Young type 1 diabetic patients in Ireland were satisfied with their diabetes care, even where they noted that aspects of those services were sub-
optimal (125). The results of diabetes care also seem to depend on the communication skills of the physician (126).

The costs and the cost-effectiveness of care have become more and more important issues during the past decades in the health politics of the society. The equally high-quality diabetes services have to be produced for all diabetic patients with limited expenses. At the same time the proportion of old people and the total number of diabetic patients are steadily growing and the possibilities to efficient, but often expensive new treatments are increasing. Thus the comparison of the quality of care in two health care units demands that the cost-effectiveness of the diabetes care models is also evaluated. The means for cost analysis have now improved with the DRG-based invoicing of the municipalities by the secondary and tertiary care units (including both inpatient and outpatient care) and the APR-based knowledge of the consistence of PHC visits (127, 128). The diagnoses for inpatient care periods are gathered and saved to the national HILMO-register on all levels of care and in the near future this will cover all of the outpatient visits. Methods of comparing the quality of diabetes care are summarized in Figure 2.

![Diagram](image)

**Figure 2.** Indicators for the comparison of the quality of diabetes care.
3 Aims of the study

The aim of the study was to assess whether the model of diabetes care in PHC (centralized or decentralized) has an effect on the quality of care, glycaemic control, diabetic complications, specialist consultations, use of hospital beds and overall health care costs in diabetic patients living in two municipalities with different organizations of diabetes care.

Special attention was paid to type 1 diabetes and:

I Quality indicators, especially HbA$_1c$ (study I)

II Incidence of observed serious hypoglycaemias (study II)

III Influence of serious hypoglycaemias on driver’s licence holding (study III)

IV Quality and costs of diabetes health care (study IV)
4 Patients and methods

4.1 Selection of the municipalities compared

Two municipalities with different organisations of diabetes care were selected for the comparison:

1. In Nurmijärvi, the diabetes care has been organized in the centralized model already for over 20 years. There have been 1 – 2 doctors with the responsibility of diabetes care during these years. Nurmijärvi is a growing municipality with 35922 inhabitants at the end of the year 2003 (39018 at the end of the year 2008) bordering the Finnish capital region from the north. There is no single city centre but three smaller population centres. The rest of the municipality is countryside and a marked proportion of the population belongs to old local families. Most of the immigrants are native Finnish families, whose parents work in the capital region. They search for more space for living with a lower housing price and safer surroundings for their children. The average age of the population in Nurmijärvi is low and the average educational level high.

2. In Kouvola, the diabetes care has been organized in the decentralized model based on family doctors for over 15 years. Kouvola was a town of nearly equal size with 31399 inhabitants at the end of the year 2003 (30633 at the end of the year 2008) and at the beginning of the study design. In the beginning of year 2009 it was fused with five other neighbouring municipalities. In this presentation ’Kouvola’ means the old Kouvola, where the diabetes care in PHC has been arranged in a decentralized model since the early 1990’s. The old Kouvola is located in the middle of an area of wood processing industry. It is also a node of railway-traffic. Typically, the workers of the factories have lived in the neighbouring municipalities and the white-collar people in the town of Kouvola. The population of Kouvola is decreasing due to structural changes in industry. Kouvola and Nurmijärvi were chosen for comparison because of many mutual features in these municipalities. In both health care centres there was also a covering register of the diabetic patients living in the municipality.

4.2 Determination of the diabetic cohorts

The study cohorts were determined in the same way in both municipalities. The customer lists of the public cost-free distribution points of diabetes care supplies were used to get the lists of diabetic patients. There are practically no diabetic patients who do not fetch their care supplies free of charge. The target populations consisted of all diabetic patients of Kouvola and Nurmijärvi who fulfilled the diagnostic criteria of diabetes mellitus and reached the age of 18 years by the end of the year 2004. This cohort was followed throughout the study (Figure 3).
Two diabetic populations as similar as possible were searched for the study. If possible, they would differ from each other just by the model of organization of diabetes care in PHC. Figure 3 shows the flow chart, how the numbers of the diabetic patients of these two municipalities were included in the studies.

The most obvious difference between the populations of these two municipalities was the age structure: the proportion of people in working age was similar in both municipalities but there were more children in Nurmijärvi than in Kouvola: 25% vs.15% of the whole population was under the age of 16 years. On the other hand, the number of old people was higher in Kouvola than in Nurmijärvi (20% vs. 10% were in the age group over 64 years). This difference did not have any impact on the diabetic populations, which were nearly of the same age and the same size and had a similar duration of the diabetes. 1776 diabetic patients over 18 years of age and living either in Kouvola (951) or Nurmijärvi (827) were identified from the Reimbursement Register of the Social Insurance Institution of Finland (KELA). They were eligible for reimbursement for antidiabetic medication. However, the number of diabetic patients over 18 years of age using the public free-of-charge distribution points of diabetes care supplies was much bigger: 1195 patients in Kouvola and 1170 in Nurmijärvi, altogether 2365 patients. The big difference is caused by the fact that at the time of the beginning of the study KELA admitted the reimbursement for antihyperglycaemic medication only after half a year of regular medication use. At that time there were also many people with recently diagnosed diabetes who had only lifestyle treatment with no medication, according to contemporary recommendations. They were, however, included in the study. Only the patients, who had returned the 36-item questionnaire, were included to the evaluation of severe hypoglycaemias. The anonymous register data of the use of health services was possible to be used of all the diabetic patients without separate permissions. Totally 16 patients denied the use of their health records (three of them at a later phase of the study) and they were excluded.

The diabetes specialist nurses or the nurses in the distribution points for diabetes care supplies gave an information brochure of the study during four months in the year 2005 to every patient who fulfilled the criteria. If the patient admitted the use of her/his patient records in PHC and the specialist level, she/he was asked to sign an informed consent. If the patient was not present personally, she/he got the forms with the supplies and was asked to return the forms with the signature or comments in a closed envelope, the postal fee of which was paid in advance.

The forms were posted to those diabetic patients of the target groups, who did not visit the distribution points during these four months. After one month, the same forms were posted still once more to those who had not yet responded to the first letter. The result of this last circuit was
not abundant – the exact number of questionnaires returned by different posting circuits was not recorded. The filling of the questionnaires was not superintended. The proportion of patients, who returned the questionnaire, was quite high, but the drug-treated patients of Nurmijärvi were more active than those of Kouvol (\( p < 0.001 \), Figure 3).

**Figure 3.** Recruitment of patients into the studies

4.3 **Data collected**

4.3.1 **Background information of the patients**

All the patients in the target cohorts were asked to answer a 36-item questionnaire (Appendix I) about their background and lifestyle and many other issues related to diabetes. It is shortened and modified from the avtk questionnaire of the National Institute for Health and Welfare with the permission of Professor Antti Uutela (129). The questionnaire included questions about the duration of diabetes, depressive symptoms, severe hypoglycaemias, smoking and alcohol use, amount of physical training and details of diet. The background included the profession, education, marital status and housing conditions.
4.3.2 Blood samples for simultaneous HbA\textsubscript{1c} measurement in the laboratories used by the health centres of the study municipalities – Study I

35 blood specimens of diabetic patients were divided for the simultaneous analysis of HbA\textsubscript{1c} in both laboratories used. This was done without any preceding notice to the laboratories, because the aim was to test the everyday routine analytics of HbA\textsubscript{1c} assays in both laboratories involved in the care of the diabetic patients of the study municipalities. The blood samples were taken in the laboratories of the two health centres into EDTA-vials without any pre-treatment according to the normal routines. All samples were sent to the analysing laboratories by their regular customers. Both laboratories had immunological analysis methods standardised against the IFCC reference method. The results were turned to the DCCT level using a coefficient. The laboratory used by Kouvola had a Roche Integra 800 analyser and Roche’s reagents. The laboratory used by Nurminjärvi had Olympus’ analyser and reagents.

4.3.3 Glycaemic control, LDL-cholesterol, blood pressure and body mass index of the patients and implication of the national guidelines for diabetes care – Study IV

The means of HbA\textsubscript{1c}, LDL-cholesterol, blood pressure and body mass index were calculated categorised by diabetes type and a comparison was made between the study municipalities. Moreover, an analysis was done, how the recommendations of national guidelines for diabetes care were met.

4.3.3 Incidence and risk factors of serious hypoglycaemias – Study II

In the Reimbursement Register of the Social Insurance Institution of Finland, there were altogether 1776 adult patients with reimbursed diabetes medication and living in the study municipalities at the end of the year 2003. Informed consent was obtained from 1437 of them (80.9%) to use their clinical data from different sources. The population for the analysis of self-reported severe hypoglycaemias consisted of those drug-treated patients who also filled and returned the 36-item questionnaire (n=1327). 686 of them had insulin treatment and were thus in the major focus of the study. All the patients were asked in the questionnaire if they had suffered from serious hypoglycaemias during the previous year (2005). If the answer was positive, they were asked to list the number of the hypoglycaemic episodes.

A cohort of 1469 study patients with informed consent to use their medical data was cross checked from the local paramedic registers for the alarms made because of hypoglycaemia. This cohort included patients with informed consent and diet therapy. Moreover, the HILMO registers were screened in order to find severe hypoglycaemias, which had led to emergency room visits or
hospital care. The criterion for serious hypoglycaemia was the need for another person’s aid to recover from the disorder (43, 130). The patient records were screened in order to find possible risk factors for recurrent hypoglycaemias.

4.3.4 Data of the driver’s licences of diabetic patients with recurrent serious hypoglycaemias – Study III

The targets of interest included the influence of recurrent severe hypoglycaemias on the validity of driver’s licences of the diabetic patients. The validity of driver’s licences is public data in Finland and can be used freely without a separate permission. This data was collected with the assistance of traffic authorities in both municipalities.

4.3.5 Use and costs of health care services of diabetic patients - Study IV

The use of the health care services of diabetic patients was divided into two categories: to those resulting from diabetes itself or its known complications and to those caused by other medical reasons.

The interest of the study was focused on the diabetes-related use of health care services (Appendix II). This data was collected from the years 2005-2010 from the National Hospital Discharge Register (HILMO) maintained by the Finnish National Institute for Health and Welfare. The HILMO register includes individual level data on inpatient care in PHC and private health care, as well as on all types of specialist care given in local, central and university hospitals. Considering the outpatient care in PHC, the period of review was one year (2005) because this data could not be analysed automatically. The number of PHC outpatient visits was collected manually from electronic medical records by one nurse in Kouvola and one nurse in Nurmijärvi. These nurses were employees of the health care centres but did not work in diabetes teams. They received special training and similar instructions and calculated the amount of outpatient visits (to doctors and diabetes specialist nurses) whose main content was diabetes or its complications. These results were multiplied by six and corrected to the price level of year 2010 in the final analysis.

The costs of diabetes care on secondary and tertiary level health care were the direct invoicing sums of the hospital outpatient visits and inpatient periods, based on DRG grouping. The visits in PHC were priced by using the APR prices counted for the diabetes care contacts of Kouvola health centre in the year 2009 (128).

The especially expensive patients, whose costs exceeded 100 000 € during six study years, were excluded from the calculation and comparison of the average diabetes care costs. Of these six
patients, four lived in Nurmijärvi (three with type 1 and one with type 2 diabetes) and two in Kouvola (one with both diabetes types). They were mostly patients in dialysis therapy due to end stage diabetic nephropathy. Their influence on the total costs would have been significant and incidental without any true connection to the quality of the diabetes care in PHC.

4.3.6 Satisfaction of type 1 diabetic patients – Study IV

A 12-item questionnaire was used to evaluate the satisfaction of type 1 diabetic patients with different domains of the care (Appendix III). The questionnaire was sent to 50 randomly selected type 1 diabetic patients living in both study municipalities who were under the follow-up of the health care centres. Of the selected type 1 diabetic patients 82% in Kouvola and 86% in Nurmijärvi returned the questionnaire. The questionnaire was planned by the researchers and the questions included four alternatives, half of which were positive and half were negative. A neutral alternative was not available in order to get honest opinions. There was also room for free-form text.

4.4 Statistical analyses

All results are given as means ± SD (standard deviation). Unpaired Student’s T-test was used for between-group comparisons, since the variables distributed normally (study I, study II). For qualitative parameters, the group differences were analysed with the chi-squared test (study II, study IV). Pearson’s correlation coefficient was used to test the dependence between the two variables (study I). The independent role of the risk factors for the episodes of SH was analysed by using multivariate stepwise logistic regression analysis (study II). The differences between the costs of diabetes care as well as the mean levels of the laboratory parameters and blood pressure were compared using the Mann-Whitney test for two independent non-parametric samples, because the outcomes did not distribute normally (study IV). The Bonferroni correction was used in the analysis of the patient satisfaction (study IV).

4.5 Ethics

The contacting procedure described above was approved by the Ethics Committee of the Department of Internal Medicine in Helsinki Uusimaa Hospital District. The Helsinki-Uusimaa and Kymenlaakso Hospital Districts approved the study protocol and granted permission to collect clinical data from patient records and paramedic service registers. The anonymous, crypted patient register information needed was used with the permission of the Finnish National Institute for Health and Welfare.
Every diabetic patient, who fulfilled the criteria to participate the study, was asked for an informed consent that justified their medical records at various health care organizations to be examined. In practice, the consent was mostly utilized to pick up the data of the use of the health centre services of the diabetic patients from the year 2005. The number and the mean of every patient’s diabetes-related laboratory tests, the means of blood pressure and BMI measures, the number of visits to diabetes specialist nurses, physiotherapists, doctors because of the diabetes, were calculated. The same information was searched from the specialist level medical records of the diabetics living in Nurmijärvi, if they announced themselves to be in the follow-up of hospital outpatient clinics. In Kouvola, the same data could be gathered from the health centre because of the mutual laboratory data system of all levels of public health care in the region.
5 Results

5.1 Demographic data of the diabetic populations studied

The diabetic populations in both study municipalities were of similar size, 1195 in Kouvola and 1170 in Nurmijärvi. The principal interest was focused on type 1 diabetes, which was the diagnosis of 171 patients in Kouvola and 170 patients in Nurmijärvi in the beginning (yr. 2005) of the study (Figure 3). Six years later, at the end of the study, these cohorts were exactly of the same size (n=165) because of six deaths in Kouvola and five in Nurmijärvi. In both municipalities about 40% of the type 1 diabetic patients were females and 60% males, and the average age was 44.1 years in Kouvola and 44.4 years in Nurmijärvi at the beginning of the study. Almost all of the patients were Caucasians. There was no difference between the average diabetes duration in these patient cohorts.

The sizes of the type 2 diabetic cohorts were much bigger but also similar in both study communities (n=958 in Kouvola and 932 in Nurmijärvi at the beginning of the study). Their average age was 66.1 years in Kouvola and 64.4 years in Nurmijärvi. Half of the patients were female both in Kouvola and in Nurmijärvi.

We excluded the patients with the diagnosis of secondary diabetes and those whose diabetes type could not be determined. Of the original study patients 41 had an injured pancreas due to a previous pancreatitis, trauma or pancreatic tumour. The remaining 93 patients did not give an informed consent or they could not be reached at all. None of the latter had used public health care during the study period because of their diabetes. The vast majority of them were obviously type 2 diabetic patients in an early phase of their disease.

5.2 Methodological comparability of the HbA1c-determinations used – Study I

There was a high correlation (r=0.96, p<0.001) between the HbA1c results of the immunological methods of two laboratories compared. However, the levels of the HbA1c results were significantly different (p<0.001) from low to high values: the results of the laboratory of Kuusankoski local hospital (used in Kouvola) were on the average 0.6 %-units lower than the results of the VITA-laboratory used in Nurmijärvi. The individual difference varied from 0.1% to 1.6%, and every single patient had a lower HbA1c value measured in the laboratory of Kuusankoski hospital than in the private VITA-laboratory. The mean difference was bigger on higher HbA1c levels (Figure 4). The difference of HbA1c results between the study laboratories was large enough to influence the clinical decision making in the treatment of diabetic patients. The number of samples analysed is low but even now the difference in the results is highly significant (p < 0.001).
Figure 4. The interlaboratory difference in HbA1c determinations according to the HbA1c level (the higher of the two results = the results of Nurmijärvi / VITA-laboratory). R = 0.96

5.3 Comparison of the glycaemic control in the study patients – Study IV

5.3.1 Type 1 diabetic patients

During the study year, in the type 1 diabetic patients of Kouvola, the median and mean HbA1c was 8.15 % and 8.16 ± 1.28 %, respectively. In Nurmijärvi, the median was 8.28 % and the mean 8.20 ± 1.28 %. There was no statistical difference of mean HbA1c values between the type 1 diabetic patients living in Kouvola and Nurmijärvi, but the possible influence of methodological differences in the HbA1c determinations must be taken into account as presented previously. If the difference observed between the HbA1c assays in blood samples taken during two days would have been constant through the whole study year, the mean HbA1c value of type 1 diabetic patients living in Nurmijärvi had been significantly lower than that in type 1 diabetic patients living in Kouvola (p<0.01).

The distribution of the HbA1c values of type 1 diabetic patients according to the targets defined by the Finnish guideline for the treatment of type 1 diabetes in the year 2005 is shown in Table 6. Thirty percent of type 1 diabetic patients living both in Kouvola and Nurmijärvi had good glycaemic
control according to the quality standards of the Finnish guideline for the care of type 1 diabetic patients (Table 5).

**Table 5.** The distribution of HbA1c values of type 1 diabetic patients according to the targets defined by the Finnish guideline for the treatment of type 1 diabetes in the year 2005

<table>
<thead>
<tr>
<th>HbA1c, %</th>
<th>Meaning</th>
<th>Kouvolta</th>
<th>Nurmijärvi</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 7.0</td>
<td>give attention to the possibility of asymptomatic hypoglycaemias</td>
<td>15.7 % n=17</td>
<td>16.7% n=21</td>
</tr>
<tr>
<td>7.0 - 7.5</td>
<td>good glycaemic control</td>
<td>14.9 % n=16</td>
<td>13.5 % n=17</td>
</tr>
<tr>
<td>7.5 – 8.5</td>
<td>fair glycaemic control</td>
<td>31.4 % n=34</td>
<td>34.1 % n=41</td>
</tr>
<tr>
<td>&gt; 8.5</td>
<td>consider, what should be done</td>
<td>38.0 % n=40</td>
<td>35.7 % n=45</td>
</tr>
</tbody>
</table>

5.3.2 *Type 2 diabetic patients*

The mean HbA1c values of type 2 diabetic patients living in the two municipalities did not differ significantly from each other (7.09 ± 1.11% in Kouvolta and 7.19 ± 1.11% in Nurmijärvi) (Table 6).

**Table 6.** The mean HbA1c values of type 2 diabetic patients living in the two municipalities according to the model of care

<table>
<thead>
<tr>
<th>Treatment modality (% of patients)</th>
<th>HbA1c, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kouvolta</td>
</tr>
<tr>
<td>Diet (11.7)</td>
<td>6.4 ± 0.6 n=76</td>
</tr>
<tr>
<td>Oral agents (52.7)</td>
<td>6.8 ± 0.9 n=363</td>
</tr>
<tr>
<td>Combination therapy (20.6)</td>
<td>7.8 ± 1.1 n=120</td>
</tr>
<tr>
<td>Insulin therapy (15.1)</td>
<td>7.9 ± 1.5 n=67</td>
</tr>
</tbody>
</table>

*p < 0.05 for difference between patients living in the study municipalities*
If the values of Kouvola are corrected upwards similarly as previously in type 1 diabetes using linear regression, the HbA1c values of Nurmijärvi would have been significantly lower than in Kouvola (p<0.001).

5.4 Incidence and risk factors of serious hypoglycaemias in study patients – Study III

5.4.1 Severe hypoglycaemias requiring paramedic or emergency room care

Altogether 100 episodes of SH needing emergency health care occurred in 47 patients of whom 35 had type 1 diabetes, 11 type 2 diabetes, and one with secondary diabetes. The incidence of SH needing paramedics or emergency room care was 30.5 and 1.3 per 100 patient years in patients with type 1 diabetes or type 2 diabetes, respectively. In type 2 diabetic patients SHs resulted in need of paramedics or emergency care only in 9% of SH episodes, whereas in type 1 diabetic patients 42% of SH episodes needed paramedic or emergency room care.

5.4.2 Incidence of self-reported serious hypoglycaemias

As expected, the risk of self-reported SH in type 2 diabetic patients was much lower than in type 1 diabetic patients (14.4 vs. 72.0 per 100 patient years, respectively). However, due to the much higher prevalence of type 2 diabetes, 154 (45.3%) of all 340 SH episodes were reported by type 2 diabetic patients. On average, type 1 diabetic patients suffered from SH once in 1.5 years, type 2 diabetic patients with insulin treatment once in four years. Of type 1 diabetic patients 72.7% and of type 2 diabetic patients with insulin therapy 87.9% did not have a single episode of SH during the observation year (2005). SHs in diabetic patients with oral medication were rare (6.0 episodes per 100 patient years) occurring mostly in elderly people with renal impairment. The incidence of SHs among type 2 diabetic patients with oral medication, diabetic nephropathy and age ≥ 70 years was 20.0 episodes per 100 patient years approaching the risk of insulin-treated type 2 diabetic patients (27.0 episodes per 100 patient years).

5.4.3 Clustering of self-reported hypoglycaemias – Study II

The distribution of self-reported hypoglycaemias is shown in Figure 5. Self-reported SHs were highly clustered (three or more episodes in a year) in 53 (7.7%) of insulin-treated patients. Thirty three (62.2%) of these patients had type 1 diabetes and twenty patients had type 2 diabetes. Eleven (19%) patients with clustering of SH were outliers of any regular diabetes follow-up.
5.4.4 Risk factors of severe hypoglycaemia – Study III

The incidence of self-reported SH among diabetic patients living in two municipalities was similar (24.3 episodes per 100 patient years in Kouvola and 22.8 episodes per 100 patient years in Nurmijärvi). Of all risk factors for SH included in logistic multivariate analysis—nephropathy, depression, physical activity and follow-up of patients in secondary or tertiary care units—were shown to predispose the diabetic patients to SH. In this study the HbA1c value did not have any correlation with the number of reported SH episodes.

5.5 Impact of recurrent serious hypoglycaemias on the validity of driver’s license – Study II

Of all 385 insulin treated patients without any reported SH 70 % owned a valid driver’s license. Moreover 20% of them had a valid driver’s license for driving with heavy vehicles at least 3.5 tons (group 2 driver’s license). Also of the 53 insulin treated patients with the recurrent episodes of SH 36 (68 %) had a valid driver’s license and even 11 (21 %) had a valid driver’s license for driving heavy motor vehicles. No one of them had been given any type of official driving restrictions due to severe hypoglycaemias.

5.6 LDL-cholesterol, blood pressure and body mass index of the study patients – Study III

The median LDL of type 1 diabetic patients living in Kouvola was 2.58 mmol/l and in Nurmijärvi 2.48 mmol/l, respectively (Table 7). In the Finnish guidelines for type 1 diabetes at the time of the study the target for LDL-cholesterol was ≤3.0 mmol/l.

Figure 5. Clustering of self-reported hypoglycaemias
There was no difference between the medians of the blood pressure values of type 1 diabetic patients living in Kouvola (139/80 mmHg) and in Nurmijärvi (137/78 mmHg). Type 1 diabetic patients living in Kouvola had lower BMI than those living in Nurmijärvi and this difference was even statistically significant. The weight of 975 diabetic patients had both been reported by the questionnaire and measured by the personnel: the self-measured weight was on average 1.42 kg lower. Of type 1 diabetic patients 35.3% were daily smokers in Nurmijärvi but only 21.4% in Kouvola. Alcohol use was as abundant among the diabetic patients of both municipalities.

The type 2 diabetic patients living in Kouvola had significantly lower mean and median blood pressure than those living in Nurmijärvi (Table 7), but there were no significant differences in LDL cholesterol or BMI between the type 2 diabetic patients.

Table 7. LDL-cholesterol, blood pressure and body mass index of the study patients

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Type 1 diabetes</th>
<th>Type 2 diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kouvola</td>
<td>Nurmijärvi</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/l) during the past 1.5 years</td>
<td>2.6 ± 0.6  n=93</td>
<td>2.6 ± 0.8  n=112</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.7 ± 0.8  n=441</td>
</tr>
<tr>
<td>BMI (kg/m²) during the past year</td>
<td>24.7 ± 3.8  n=99</td>
<td>26.3 ± 5.0*  n=101</td>
</tr>
<tr>
<td></td>
<td>30.4 ± 5.4  n=421</td>
<td>32.5 ± 6.1  n=405</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg) during the past year</td>
<td>140 ± 19  n=99</td>
<td>140 ±18  n=121</td>
</tr>
<tr>
<td></td>
<td>144 ± 18  n=566</td>
<td>146 ±17*  n=578</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg) during the past year</td>
<td>80 ± 10  n=52</td>
<td>82 ± 11  n=121</td>
</tr>
<tr>
<td></td>
<td>80 ± 10  n=565</td>
<td>83 ± 10**  n=578</td>
</tr>
</tbody>
</table>

* p<0.05, ** p<0.01 for the difference between patients living at study municipalities

5.7 Implementation of the national guidelines for diabetes care in the study patients – Study IV

In type 1 diabetic patients, the recommendations given in guidelines were generally better implemented in Nurmijärvi than in Kouvola (Table 8). The measurements recommended to be taken at every visit, were studied from a time period of one year. Measurements recommended to be included in yearly controls were studied from a time period of 1.5 years (nU-alb, foot.
examination, LDL-cholesterol). Eye fundus photographing arranged by a private company had better patient coverage in Kouvola than in Nurmijärvi, where eye fundus photographs were taken locally. In Kouvola, a smaller proportion of type 1 diabetic patients was followed up by PHC than in Nurmijärvi (49.4 vs. 61.4 %). Of type 1 diabetic patients 12.4 % living in Nurmijärvi and 19.0 % living in Kouvola had not had any diabetes control during the previous year (Table 9).

**Table 8.** Coverage of diabetes care in two communities. Only the patients who reported themselves to be in the follow-up of the health centres were included in the evaluation of the proportion of examined patients

<table>
<thead>
<tr>
<th>Measurement/Examination</th>
<th>Type 1 diabetes</th>
<th></th>
<th>Type 2 diabetes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kouvola n=84</td>
<td>Nurmijärvi n=105</td>
<td>Kouvola n=577</td>
<td>Nurmijärvi n=615</td>
</tr>
<tr>
<td>LDL-cholesterol during the past 1.5 years</td>
<td>71.4</td>
<td>84.8*</td>
<td>70.0</td>
<td>78.5**</td>
</tr>
<tr>
<td>BMI during the past year</td>
<td>51.2</td>
<td>77.1**</td>
<td>69.5**</td>
<td>61.3</td>
</tr>
<tr>
<td>HbA1c during the past year</td>
<td>89.3</td>
<td>94.3</td>
<td>93.2</td>
<td>90.7</td>
</tr>
<tr>
<td>Blood pressure during the past year</td>
<td>83.3</td>
<td>90.4</td>
<td>91.2*</td>
<td>87.0</td>
</tr>
<tr>
<td>Nocturnal albumin excretion during the past 1.5 years</td>
<td>58.3</td>
<td>74.3**</td>
<td>35.2</td>
<td>37.1</td>
</tr>
<tr>
<td>Eye fundus photographing (according to national guidelines)</td>
<td>73.8*</td>
<td>53.3</td>
<td>49.2**</td>
<td>35.1</td>
</tr>
<tr>
<td>Foot examination during the past 1.5 years</td>
<td>44.0</td>
<td>88.0**</td>
<td>43.5</td>
<td>43.2</td>
</tr>
</tbody>
</table>

*p<0.05, **p<0.01 for the difference between patients living in the study municipalities

In type 2 diabetic patients HbA1c and blood pressure recordings were carried out yearly in a majority of patients living in the study municipalities. Weight measurement for the calculation of BMI was done more often in type 2 diabetic patients living in Kouvola compared with those living in Nurmijärvi; whereas LDL cholesterol was measured more often in type 2 diabetic patients living in Nurmijärvi than in Kouvola. In both municipalities, the examination of nocturnal urinary albumin excretion rate (or U-alb/krea) had been measured only in one third of type 2 diabetic patients during the past 1.5 years. Eye fundus photographing was done more often in type 2 diabetic
patients living in Kouvola than in Nurmijärvi, and in both municipalities it covered less than half of the type 2 diabetic patients. Foot examinations during the past 1.5 years covered also less than half of the type 2 diabetic patients (Table 8).

5.8 Utilization and costs of diabetes or its complications related health care services – Study IV

5.8.1 Use of specialist consultations and hospital beds

As shown in Table 9 and Figures 8 and 9 both type 1 and type 2 diabetic patients living in Kouvola made significantly more outpatient hospital visits than those living in Nurmijärvi during the observation years 2005-2010.

Table 9. Use of primary or specialist care facilities, proportion of patients who had not participated any regular care and deaths of type 1 diabetic patients during the study years

<table>
<thead>
<tr>
<th></th>
<th>Kouvola (n=171)</th>
<th>Nurmijärvi (n=170)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of type 1 diabetic patients who had visited specialist level care because of diabetes or diabetes related complications at least once during the years 2005-2010</td>
<td>82.5*</td>
<td>67.6</td>
</tr>
<tr>
<td>Percentage of type 1 diabetic patients being in regular follow-up of health care centres during the study year 2005</td>
<td>49.4</td>
<td>61.4*</td>
</tr>
<tr>
<td>Percentage of all type 1 diabetic patients who had not visited a doctor because of diabetes during the study year 2005</td>
<td>19.0</td>
<td>12.4</td>
</tr>
<tr>
<td>Number of type 1 diabetic patients (%) who had died during the years 2005-2010</td>
<td>6 (3.5 %)</td>
<td>5 (2.9 %)</td>
</tr>
</tbody>
</table>

*p<0.05 for the difference between patients living in the study municipalities. The number of type 1 diabetic patients in the study municipalities is given in parentheses.

A slightly bigger proportion of both type 1 diabetic patients (37 vs. 33 %) and type 2 diabetic patients (39 vs. 36 %) from Kouvola than those from Nurmijärvi had used specialist level hospital beds during six study years because of their diabetes or its complications, but the difference was not significant. The hospital care periods of diabetic patients in Kouvola were on average shorter than those living in Nurmijärvi (Figures 6, 7).
Figure 6. Average number of specialist level inpatient periods in both diabetes types during years 2005 – 2010 in the study municipalities

Figure 7. Average number of specialist level inpatient days in both diabetes types during years 2005-2010 in the study municipalities
5.8.2 Costs of health care services – Study IV

The most used and nearest hospital offering specialist level care in Kouvola was the local hospital of Kuusankoski. Diabetic patients requiring more comprehensive care were treated in the central hospital of Kymenlaakso (Kotka), and only a few diabetic patients got treatment in Helsinki University Central Hospital. For diabetic patients living in Nurmijärvi, specialist level care was provided by the hospital of Hyvinkää, which has 5% higher prices of invoicing than Kuusankoski local hospital. Tertiary level care for patients living in Nurmijärvi was given in Helsinki University Central Hospital, where the prices were 10% higher than in Kymenlaakso Central Hospital. The average yearly costs of specialist level outpatient care in type 1 and type 2 diabetic patients living in the study municipalities are shown in Figures 8 and 9.

Figure 8. The average yearly costs of specialist level outpatient care of type 1 diabetic patients in the study municipalities during years 2005-2010.
The average yearly costs of specialist level outpatient care of type 2 diabetic patients of the study municipalities during years 2005-2010.

Regardless of these differences, the total health care costs of one type 2 diabetic patient during the years 2005 – 2010 were slightly smaller in Nurmijärvi than in Kouvola. Figures 10 and 11 summarize the average yearly costs per patient during the study years 2005-2010 from the use of outpatient and inpatient care in type 1 and type 2 diabetic patients living in the study municipalities.
Figure 10. Average yearly inpatient and outpatient costs of one type 1 diabetic patient in the study municipalities according to the health care level (years 2005-2010).

Figure 11. Average yearly inpatient and outpatient costs of one type 2 diabetic patient in the study municipalities according to the health care level (years 2005—2010).

Taken together in the both study municipalities the yearly average diabetes and diabetic complications related costs of health care services (discounted in the prices of year 2010) in type 1 diabetic and type 2 diabetic patients were about 2000 and 1000 €, respectively (Figures 10 and 11). In the care of type 2 diabetes about half of the costs came from PHC whereas about 75 % of the
costs of type 1 diabetes care came from specialist level. In type 1 diabetic patients there was a clear and significant difference in the costs of diabetes care between the two municipalities: the total yearly costs of the diabetes care of one type 1 diabetic patient were 2220 € in Kouvola and 1710 € in Nurmijärvi calculated in the year 2010 prices. The difference was caused by the fewer visits of type 1 diabetic patients from Nurmijärvi to hospital outpatient clinics. On PHC level the yearly costs of type 1 diabetes care were very similar in both of the municipalities: 522 € in Kouvola and 505 € in Nurmijärvi. Inside these costs more money was spent on inpatient care in Kouvola than in Nurmijärvi and on outpatient care in Nurmijärvi (Figure 12).

![Figure 12. Total average yearly costs of diabetes care per 1 patient during years 2005-2010 in year 2010 prices.](image)

The exceptionally expensive patients were excluded from the final analysis because of their incidental, but still very significant influence on the results. If these few patients had been included in the calculations, the total costs of specialist level care of type 1 diabetes had been 16% higher in Kouvola (2577 € per year) and 45% higher in Nurmijärvi (2479 € per year).

The costs of one type 2 diabetic patient were approximately half of the costs of one type 1 diabetic patient and about half of the costs came from PHC, the other half from specialist level care. However, based on the high prevalence of the disease, total costs due to the care of type 2 diabetes became more expensive to the society. The total health care costs of type 2 diabetic patients in a year were 32 € smaller in Nurmijärvi than in Kouvola and this difference was based on
the smaller costs in PHC. In the total costs of specialist level care, there was only an average difference of two euro in a year (Figure 11).

5.9 Satisfaction of type 1 diabetic patients with their health care services – Study IV

Type 1 diabetic patients were quite satisfied with their follow-up and other diabetes related services provided by PHC in both municipalities (Figure 13). The lowest level of satisfaction was given to the quality of foot care provided by PHC in Kouvola, and it differed significantly from that organized in Nurmijärvi. Type 1 diabetic patients were also more satisfied with the professional skills of the doctors working in the health centre of Nurmijärvi than in Kouvola. Type 1 diabetic patients reported also that it was significantly easier to make a contact with the personnel of PHC in Nurmijärvi than in Kouvola. Taken together type 1 diabetic patients were more satisfied with the diabetes care in PHC of Nurmijärvi than of Kouvola.

Figure 13. Satisfaction of type 1 diabetic patients with different sections of the diabetes care in the two health care centres. *p<0.05, **p<0.01 and ***p<0.001 for difference between the satisfaction in the study municipalities
6 Discussion

6.1 Key findings

This study evaluates the impact of two different models of diabetes care on the quality of the treatment and follow-up and health care costs of diabetic patients in two municipalities with similar populations of diabetic patients. The main target group is the type 1 diabetic population of our two study municipalities. However, the care of the type 2 diabetic population was also studied.

6.1.1 Key findings of study I

When comparing the results of diabetes care of these different care units, the validity of the means of comparison is inevitably faced. The traditional measure has been the use of the HbA\textsubscript{1c} values of various groups of diabetic patients (111). The study I showed that HbA\textsubscript{1c} has shortnesses in this meaning, if the determinations have been made by different analysis methods or in different laboratories. The average difference of 0.6 %-units is much wider than acceptable in everyday clinical work.

6.1.2 Key findings of studies II and III

Studies II and III analysed the distribution of severe hypoglycaemias in the Finnish diabetes care. The vast majority of all SHs were treated outside the hospital emergency care units by paramedic personnel, family members or other people. When all SHs were taken into account, their incidence was higher than in many other previous clinical trials (69, 131). Nearly half of all SHs occurred in type 2 diabetic patients – mostly due to the higher prevalence of type 2 diabetes. Predisposing factors for SHs were active exercising, depression and complicated diabetes defined by the presence of diabetic nephropathy. Diabetic patients followed up by the hospital outpatient clinics had a higher risk for SHs, which was probably related to their more serious disease. HbA\textsubscript{1c} level, type of basal insulin (NPH vs. glargine), amount of alcohol use or living alone did not correlate to the incidence of SHs. There was a strong tendency to clustering of SHs to a small minority of insulin-treated patients. These diabetic patients had valid driver’s licences as often as the whole diabetic population on average. This was the case even in the group 2 licences authorising driving of heavy vehicles. Despite recurrent SHs, one fifth of these patients had not visited a doctor because of their diabetes during the study year.
6.1.3 **Key findings of study IV**

The study IV compared the quality of the care of the diabetic populations of two municipalities with many different indicators. The satisfaction to the professional skills of the doctors among the type 1 diabetic patients seems to be much higher in the centralized care system. The satisfaction to the professional skills of the diabetes specialist nurses was, however, on a very high level in both care systems. The care of type 1 diabetic patients in PHC followed better the national recommendations in the centralized system, whereas there was not any significant difference with type 2 diabetes. The most important difference between these two organization models of diabetes care in PHC was the cost-effectiveness: the total costs of the care of type 1 diabetes and its complications were 500€/pt/year lower in the centralized care system. The difference resulted from the lower amount of specialist level outpatient visits. The difference in type 2 diabetes was small (32€/pt/year) but not without significance, as the amount of type 2 diabetic patients is big.

6.2 **Comparison with the previous literature**

6.2.1 **Reproducibility of HbA\(_{1c}\) – Study I**

The Study I gave new data about the limitations of HbA\(_{1c}\) determinations. A small Finnish study from the 1990's already showed that there is a significant variation in the reproducibility of the analysis results of even the liquid chromatography methods of HbA\(_{1c}\) determinations (132). A change smaller than 0.65 %-units, could be explained by the variation inside the analysis method, and just the changes over 0.65 %-units were clinically significant. After this, a lot of work has been done with the international standardizing of the HbA\(_{1c}\) analysis methods (133, 134). In the daily clinical practice, however, the accuracy of the analysis still remains approximately the same. It has, however, been known that HbA\(_{1c}\) tells only something about the average glucose level during the last 2-3 months, but nothing about the variation or hypoglycaemias. The ADAG-study determined the average glucose levels behind various HbA\(_{1c}\)-values, but the confidence intervals were wide (135). This study also showed that the same average plasma glucose can produce HbA\(_{1c}\) 6% to one patient and 8% to some other patient. The main reason for this phenomenon is the varying living time of red blood cells in the blood circulation. The longer the time, the higher HbA\(_{1c}\) is the result. This is because then the patient`s red cells are longer exposed to glucose.

Clinical situations that decrease the lifetime of red blood cells and thus cause abnormally low HbA\(_{1c}\) values are haemolytic anaemia, bleeding and blood transfusions from a healthy donor. On the other hand, HbA\(_{1c}\) values become incorrectly high when the medium age of red cells is abnormally high. Some possible reasons are iron deficiency anaemia, splenectomy, aplastic anaemia and
polycythemia (136). Hemoglobinopathies are not recognized by all analysis methods and may sometimes produce incorrect results. There are also small ethnic differences in HbA₁c levels and elderly people usually have higher values with the same glucose levels than younger people. Serious renal insufficiency is a source of error to HbA₁c analysis with many possible mechanisms: iron deficiency, haemolysis, erythropoietin deficiency and production of carbamylated HbA₁c. The daily use of big doses of acetosalicylic acid may disturb HbA₁c analyses by the formation of acetylated HbA₁c (136-138).

Labquality performs yearly five external quality assessment rounds for HbA₁c for clinical laboratories in Finland and other countries. The target values of the specimen used are determined by a European Reference Laboratory for Glycohemoglobin -unit in Holland. The approved IFCC reference method for the measurement of HbA₁c in human blood is published by Jeppson et al. 2003 (133). Both of the laboratories compared in study I participated in the quality assessment rounds of Labquality.

The work with standardization has not changed the fact that certain variation between different analysing methods exists and must be remembered in both benchmarking and clinical work. Labquality does not sign over the results of a single laboratory. Marked differences between the levels of the results of different analysing methods are still seen.

6.2.2 What is new about severe hypoglycaemias? - Studies II and III

The studies II and III give new data about the epidemiology and risk factors of severe hypoglycaemias. The incidence of SHs was higher than in some previous studies both in type 1 (69, 131) and insulin treated type 2 diabetes (67, 131, 139). This is likely due to the population-based study design and the high participation percent of the diabetic patients to the 36-item questionnaire. A few other earlier population based studies have shown quite high incidences. Donnelly et al. published in the year 2005 a population-based prospective hypoglycaemia trial from Scotland: the incidence of SHs was 1.15 events per patient per year in type 1 diabetes and 0.35 events per patient per year in insulin-treated type 2 diabetes (140). Akram et al. (75) published a literature survey in the year 2006 concerning the incidence of SHs in in insulin-treated type 2 diabetes. They found 11 studies with at least 50 patients and a follow-up period of at least six months. The incidence of SHs was higher in retrospective than in prospective studies and the variation was wide (15 - 73 events per 100 patient years). The proportion of patients having one or more episodes was between 1.4 to 15%.
Earlier studies have shown the correlation between depression and glycaemic control in diabetes (141-146). In this study there was also a statistical correlation between depression and the risk of SH. The direction of causality remains however obscure: do SHs cause depression or does depression lead to labile glycaemic control and SHs? The role of depression in diabetes still needs more research – is there some common metabolic background in these two conditions as previously suggested (147, 148)? Opposite to some other studies (149), increasing age was not a risk factor for SHs in this study. Instead, active exercising and complicated diabetes (indicated by the presence of diabetic nephropathy) seemed to be predisposing factors for SHs like in the most previous studies (139, 140, 149-153). The clustering of SHs to a minority of insulin treated diabetic patients has been observed already in some earlier studies (75). In a retrospective study from the year 2004 Pedersen-Bjergaard et al. reported even 130 SH episodes per 100 patient years in a cohort of 1076 type 1 diabetic patients. SH was reported from the preceding year by 36.7% of all patients and 5% of all accounted for 54% of the episodes (65).

Already mild hypoglycaemias increase markedly the risk of accidents when driving a vehicle (91-95). The study III showed that the instructions concerning diabetes and driving are poorly realized in the follow-up of Finnish diabetic patients.

6.2.3 Utilization and costs of diabetes care – Study IV

The study IV compared the outcome and costs of diabetes care when it is organised either according to a centralized model or based on family doctors in PHC. In California, a specialized diabetes clinic made better short-term results than a general practice clinic in diabetes care (31), but in this study no cost benefit analysis was done. In the Netherlands experienced diabetes specialist nurses made as good short-term results in diabetes care as general practitioners (32). This study examined the organisations of the Finnish health care system and that is why there exist only a few studies with even nearly the same kind of design (115). The organizations of the health care systems of different countries vary and thus national research is required. The example of Sweden shows the advantages of a national diabetes register in improving the quality of care (154). In North Carelia, a regional register system has been established and now benchmarking of the diabetes care between the municipalities is easier. The problematic areas can be recognized, which is the basis for improvements (115).

In both of the municipalities median HbA1c values of type 1 diabetic patients were lower than in Valle’s studies yrs. 1993-2010 (16-18). After the year 2005 the means of HbA1c values of type 2 diabetic patients have decreased according to Valle et al. and the Finnriski 2012 -study (155) - contrary to type 1 diabetes. Both these studies are based on samples of patients, which probably
do not represent the same kind of diabetic patients as the previous studies. This is due to the efficient screening of new patients, which in turn “dilutes” the study population emphasizing the proportion of diabetic patients in the early phases of their disease. The Finnriski 2012 study was based on a random sample of the population register. 59 % of the invited people took part in the study and the number of type 2 diabetic patients was 347. A method like this surely contains a possibility to a selection bias (156). In the editorial of the journal of the Finnish medical association, that published the Finnriski 2012 results, two leading Finnish diabetologists call for better means for evaluation of the quality of diabetes care (156).

In type 2 diabetes, small but significant differences were observed in the coverage of examinations recommended in national guidelines for diabetes care, all of them to the advantage of Kouvola. The blood pressures of the type 2 diabetic patients were significantly higher in Nurmijärvi. This data can be compared with the data obtained from the Finnish Quality Network (FQN). The work of FQN is based on yearly samples of care results, benchmarking, teaching and sharing of good practices and ideas. In the year 2005, the mean HbA1c, LDL-cholesterol and blood pressure of type 2 diabetes in FQN’s data were 7.10 ± 0.042 %, 2.56 ± 0.03 mmol/l, 141.38 ± 1.41 mmHg (systolic) and 80.47 ± 0.76 mmHg (diastolic), respectively (Klas Winell, FQN, personal information).

6.3 Significance of the findings in the Finnish health care system

6.3.1 The role of PHC in diabetes care

The financial resources for the health services are limited and grow slower than the requirements of the continuously increasing proportion of old population and the modern, but expensive health and medical technology. It is important to study how the treatment of common diseases could be arranged as cost-effectively as possible. It is important to find the best way to organize the follow-up of diabetic patients in PHC. The organization of diabetes care fulfils the criteria, when the patients feel well, are satisfied with their treatment and do not develop the complications of diabetes. On the other hand, diabetes treatment should not produce a marked risk of hypoglycaemias, which in turn always cause a risk for accidents, cardiac arrhythmias and even sudden deaths (157-161). Hospital inpatient care and severe hypoglycaemias are both very expensive for the society and they correlate to complicated diabetes and long diabetes history (162).

High-quality diabetes care in PHC is always comprehensive and takes care of all risk factors of cardiovascular diseases (108, 110). It is easier to motivate the patients to take good care of their
health, if they feel themselves to be well treated by the experts. Individual medical treatment plans are important in setting mutual targets, but they must be flexible and not too complicated.

The diabetic complications develop slowly in the course of years and decades. High-quality care does not produce instant profits and investments for the quality of care will award the society with a long delay. Type 2 diabetes is closely related with the way of living. The health care system has an important role in advising people to more healthy habits including the reduction of smoking, eating and alcohol use as well as the increase in physical activity (163-165). However, the support of many other sectors of the society is also needed to get closer to these targets.

6.3.2 *HbA1c as a marker of glycaemic control*

Physicians have been used to evaluate a patient’s glycaemic control mainly by the HbA1c-value. Changes to the treatment are seldom made, if HbA1c is under the target value and the patient feels well. This laboratory parameter, however, works the best in the follow-up of a single diabetic patient if the analysing laboratory and the method of analysis keep the same. The glycaemic control between two patients cannot be compared with each other only by the HbA1c values. Benchmarking of the quality of diabetes care can neither be done by comparing the means of HbA1c values, if they are not measured with the same analysis method HbA1c does not always reflect good glucose balance – there may also be recurrent hypoglycaemias and a wide variation of the glucose concentration (166-169). The limitations of HbA1c measurement have previously been poorly known among the Finnish doctors, but this study has provided new insight into the use of this parameter in the follow-up of diabetic patients. In the future, it is important to further standardize HbA1c.

6.3.3 *Severe hypoglycaemias as a threat to good diabetes care*

The efforts to bring the median HbA1c values as low as possible, and the patients near to normoglycaemia, reveal inevitably the opposite problem: the risk of severe hypoglycaemias. Recent large trials like Accord and VADT carried out in patients with type 2 diabetes strongly suggest that recurrent severe hypoglycaemias may be harmful for the health of diabetic people. In those trials, however, the incidence of hypoglycaemias was the highest in the patient group with the worst glucose balance when estimated with HbA1c level. Hypoglycaemias increase the risk of accidents, expose patients to cardiac arrhythmias, and cause in the long run declining of cognitive functions (170-172) and even increase mortality (19, 20, 45). According to a recent study, also in patients with type 1 diabetes, low HbA1c values may increase the risk of all-cause mortality (174, 175). Alterations in ECG and lowered myocardial blood circulation have already been shown during
hypoglycaemic periods (176-179). Continuous monitoring of tissue glucose has shown long hypoglycaemic nocturnal episodes in patients, whose HbA1c is under 7% (166). Before the time of the possibility to glucose monitoring, their glucose control would be appreciated as excellent.

In this population-based retrospective study the incidence of severe hypoglycaemias was higher than in random controlled trials, in which the patients with the biggest risk for SHs are usually automatically outside the study because of the exclusion criteria (75). This group includes people with alcoholism, psychiatric problems or antisocial behaviour, whose ability to commit to clinical investigations is questionable. The risk to SHs is connected tightly also to the insulin treatment of type 2 diabetic people and the risk increases, if the kidney function is impaired. The incidence of SH is generally lower in type 2 diabetes than in type 1 diabetes, but according to our study, nearly half of all SHs occurred in the group of type 2 diabetic people. However, the SHs are somewhat different in type 2 diabetes, because they seldom lead to calling paramedics or transportations to hospital emergency units. Perhaps the SHs of the younger type 1 diabetic patients more often occur in working places, schools, sporting areas, streets etc.

The number of insulin treated elderly people is rapidly growing. This result is an increasing burden to the health care system, especially for the home care (180). It is obvious that insulin-treated elderly people come sooner or later to a situation, where they no more can take the responsibility of their own insulin treatment anymore. To solve this problem new ideas and innovations are needed in the near future.

6.3.4 Influence of hypoglycaemias on driving licence eligibility

Recurrent hypoglycaemias cluster to a small proportion of all medically treated diabetic patients. It would be very important to recognize these patients and to make the required changes to their insulin treatment or other conditions that affect their glycaemic control. The current situation in Finland is problematic, because the data systems of the paramedics do not communicate with the patient record systems of the health care providers. Moreover, the majority of SHs is treated with the aid of other people without any interference of the health care system. The diabetic patients know about the doctors’ duty to notify the traffic authorities about the impaired driving ability. In this evaluation, the occurrence of hypoglycaemias plays the major role, especially if the warning symptoms are weak or absent (95, 98). This is obviously the reason why the diabetic patients often hide this problem from their diabetes doctors and nurses (99). A solution for this problem could be a separate ‘driving ability evaluation centre’ for the comprehensive estimations of driving capacity in borderline cases? The present situation may also jeopardize the well-functioning relation
between the patient and the doctor in the follow-up of the diabetes. It is, however, encouraging that 80% of insulin-treated diabetic patients did not have a single SH during the study year.

The Finnish regulations for health and follow-up demands of diabetic drivers were quite tight already in the year 2005 when the patient cohort for this study was collected. If the regulations were followed exactly, many of type 1 diabetic patients would most likely have lost their driving license. It is worrying that among the diabetic patients with three or more SHs during the study year, there were as many driver's license holders as among the diabetic population as a whole. Is the reason for this in the unawareness of the doctors about the SHs of their diabetic patients or their unwillingness to give restrictions for driving thus jeopardizing the doctor-patient relationship (181)?

6.3.5 Quality and use of primary health care services

The Study IV compared the outcome and quality of diabetes care in PHC when organized in a centralized model or when based on family doctors. The quality of diabetes care in PHC determines the total outcome a lot. The specialist level health care has to take the responsibility of the examination and treatment of advanced diabetic complications.

Only a small proportion of diabetic patients is in a proper follow-up in the private health care due to the expenses of the recommended laboratory testing. On the other hand, the possibilities of occupational health care to offer adequate diabetes care are limited. According to these facts, in Finland the public primary health care has the responsibility to take care of a vast majority of the treatment and follow-up of also type 1 diabetic patients. This includes the early diagnosis of developing diabetic complications in order to prevent blindness, amputations, renal failure, cardiac attacks, strokes etc.

In Sweden the follow-up of type 1 diabetic patients is centralized to areal diabetes specialist centres and the Swedish National Diabetes Register makes it possible to do benchmarking and gather knowledge of the whole Swedish diabetic population (119). The average glucose control of type 1 diabetic patients seems to be better than in Finland (182, 183).

If the quality of treatment in PHC is inadequate, the consequence may be an increased number of complications with high costs. It is also important that the follow-up system of diabetic patients reaches as many patients as possible. The treatment of type 1 diabetic patients in Finland is not on a satisfactory level and the results of care have not become better during the last decades. Especially in the decentralized diabetes care model in PHC a bigger proportion of type 1 diabetic
patients seem to have inadequate services. The dissatisfaction to the skills of the doctors produces more drop-outs of regular follow-up and the treatment adherence weakens.

6.3.6 Strengths and limitations of the study

Strength of this study is the long history of the models of organizing diabetes care in both of two municipalities. The target population was unselected and consisted of the whole adult-aged diabetic populations of these municipalities. The identification of the target population was based mostly on the patient lists of the public distribution points of diabetes care supplies in two municipalities. These lists were exceptionally well maintained in both cases. Thus the target population included significantly more patients than the Reimbursement Register of the Social Insurance Institute of Finland. Every person in the target group had some connection to the health centres as a diabetic patient. It is possible that a small group of people with diabetes diagnosis were not reached. This might theoretically be possible in the case that a diabetic patient had visited only the private health care or occupational health care because of the diabetes without even using the public diabetes supply distribution points. The diabetic patients get devices for the self-measuring of blood glucose almost routinely at the time of diagnosis. This is the case despite controversial evidence of the advantages of the practise in the early phases of type 2 diabetes. The devices and their test strips are fetched from the public distribution points also in the case of some other follow-up unit.

The participation rate of the patients was good in both study municipalities. Of all diabetic patients living in the study municipalities 67% gave an informed consent to use their health records and 61% of all returned our 36-item questionnaire considering their demographic data, lifestyle and various aspects of diabetes care. The use and costs of the specialist level health care could be calculated for all diabetic patients identified, regardless of the consent. The type 1 diabetic populations were same-aged in both municipalities. In type 2 diabetes there was a difference of 1.7 years in the average age – in Kouvola they were older. However, there was not a significant difference in the disease duration between the type 2 diabetic patients living in two municipalities. The duration of diabetes is considered more important than the age for the development of diabetic complications.

However, there are many variables other than the organization of diabetes care in PHC that affect the outcome and total costs of diabetes care. The ways and traditions of clinical practice on specialist level may differ markedly. Incidental factors like the migration of single patients with complicated diabetes may also influence much to the total use of health care services in the study municipalities. The effective treatment of end-stage diabetic renal disease, for instance, may produce extra quality-adjusted life years but the expenses are quite high. Implementation of new
practices like eye fundus screening, the insulin pump treatments or wide use of foot therapist visits can be expensive during the first years, and the possible savings come only after a delay of years.

The strength of study I, i.e. the comparison of the results of the HbA1c determinations of the laboratories, was the successful testing without preceding information to the laboratories. However, the comparability of the results of HbA1c determinations as part of everyday routine analytics could be estimated only once during the study year with this arrangement. Therefore it is a limitation of this study that we do not know whether the differences in HbA1c determinations were accidental or constant. It is, however, very unlikely that the moment of the widest difference between the results would be found by the first checking. A reference laboratory should have been recruited to find out, which one of the two laboratories gave “correct values” – now it remained obscure.

A significant proportion of patients with recurrent SHs would be excluded from randomised controlled studies (RCT) because of the assumed insufficient co-operation (184, 185). All possible data sources were used in order to find out the real incidence of SHs: questionnaires to all patients, paramedic registers, the health records of the local hospitals and the HILMO register data of the use of specialist level health services. These are the main strengths of the hypoglycaemia studies II and III. Participation of the diabetic patients including the questionnaires was active in both municipalities. However, there are also some limitations in these studies: questions about the timing and preceding symptoms of SHs would have been informative like an estimation of the amount of yearly kilometres driven by the patients. The memory of the diabetic patients may also be a source of error, concerning especially the patients with recurrent SHs. However, Akram et al. have studied the memory of diabetic patients concerning the number of SHs estimated prospectively or retrospectively: they noticed that the SHs of the latest year are still very well remembered (75). It is possible that different patients have understood the definition of SH in different ways. The question concerning the SHs was like this: “Have you had your blood glucose so low during the last 12 months, that you have needed help from other people to recover?” No / Yes, _ times (Appendix I). Also in some clinical trials SH has been defined differently by the need for parenteral glucose infusion or glucagon injection (92, 156, 166).

The definition of depression remained somewhat superficial: the diagnosis based only on one question in the questionnaire or the use of antidepressant medication. At the time of data sampling, the recording of the diagnoses of outpatient visits was a new duty to the doctors and often felt as an extra burden in their clinical work. This may have been a source for inaccuracies in ICD-10 coding.
Strength of study IV was that a vast majority of all diabetic complications are treated within the public health care system in Finland and the use of public specialist care is archived in the HILMO register. In this study the quality of diabetes care was measured from many directions and by using several different indicators.

The population-based design was the most significant strength in examining the production and the costs of services. Thus no statistical significances or standardising by age or gender is needed, like in sample-based studies when modelling the use and costs of services.

A limitation to study IV is that the public PHC system of Kouvola broke down in the year 2006 and the PHC was taken over by a private health service company. The change in producing the PHC services may have influenced the results during the latest years of the follow-up. However, diabetic complications needing specialist level health care develop slowly during years and decades. The private company, however, continued the decentralized diabetes follow-up model and made strong efforts to show that the quality of their work is on a high level. The amounts of produced outpatient services in PHC during the follow-up years 2005-2010 were estimated in relation to the production and costs of the year 2005. Thus a change of the producer of the services did not affect this part of the results.

The structure of the specialist level services in our two municipalities differed: the nearest and most commonly consulted hospital of Kouvola had 5% lower prices of invoicing than the nearest supporting hospital of Nurmijärvi, the hospital of Hyvinkää. The most demanding treatments of Kouvola were usually given in the central hospital of Kymenlaakso, which in turn had the same invoicing prices as the hospital of Hyvinkää. The patients of Kouvola were treated in the University Hospital of Helsinki only with exceptional needs, whereas the most serious cases of Nurmijärvi were routinely treated in the university hospital. Because of these structural features, the use of specialist level care became 5-10% more expensive for Nurmijärvi than for Kouvola. On the other hand, this may have lowered the threshold to specialist level consultations in Kouvola. During the years 2006 to 2010 there was a diagnosis number for every specialist level outpatient visit and inpatient period in the HILMO-register and the DRG-prices could be calculated. Every diagnosis code is surely not exactly the right one, but all of our patients had some type of diabetes. In the first year of the study, there were also some outpatient visits on specialist level without any diagnosis. Most of these visits had been made by patients living in Kouvola (648 outpatient visits or 17.7% of the total of 2465 visits to the specialities possibly concerned in the year 2005). The same proportion in Nurmijärvi was 5.4%. Approximately one third of these visits may have been done
due to diabetes or its complications. They were excluded from the calculations, but compared with all visits during six study years their proportion was small.

6.3.6 Which model of diabetes care is better?

In type 1 diabetes the centralized care model reaches a bigger proportion of the patients, who are more satisfied with their treatment than in the decentralized system. Moreover, the centralized care model diminishes the amount of the use and costs of specialist level health care. The influence of the centralized care model to the total costs of the health care of type 1 diabetic patients is strongly positive. In type 2 diabetes the difference is small but parallel, not without significance because of the high prevalence of the disease. The costs and quality of the supporting services like eye fundus photographing and foot care depend on the local arrangements, not on the follow-up model per se.

This study was based on a situation where two municipalities, with different diabetes care models already over 15 years, were identified. Moreover, the populations (and the diabetic populations) of the municipalities were almost as big and resembled each other in demographic features. The adult diabetic patient populations were followed as cohorts for a time interval of 6 years in order to get stronger results. Some sources of error are still remaining in a study design like this, but we, however, believe that the results are reliable.

The superior satisfaction with the centralized care model among the type 1 diabetic patients was a significant and clear result. Dissatisfaction with the skills of the doctors in Kouvolan was emphasized in the informal written answers: several patients wrote that they felt they knew more of their disease themselves than their doctor. The satisfaction to the foot care was very much bigger in Nurmijärvi, depending naturally on the fact that there was a foot therapist in Nurmijärvi but not in Kouvolan. The satisfaction to the work of the diabetes specialist nurses was on a very high level in both municipalities. This may mostly be due to the personal characteristics of these much appreciated people in both of the municipalities. Moreover, there was no difference in the satisfaction to the supporting services like eye fundus photographing, diabetes supplies distribution or laboratory services.

The regular follow-up of type 1 diabetic patients, according to the recommendations of existing Finnish guidelines, worked better in Nurmijärvi than in Kouvolan. On the contrary, there were not so marked differences in the follow-up of type 2 diabetic patients, who actually were mostly under the care of family doctors in both municipalities. In Kouvolan, the eye fundus photographing was done by a private company, which had developed an invitation system leading to better coverage. In
both municipalities the determination of nocturnal albuminuria was taken from fewer than 40 % of all type 2 diabetic patients – thus not reaching the targets. A very important part of the examination of a diabetic patient is to check the condition of the feet, at least once a year. Even this was neglected more often than in 50 % of the patients. Foot examination had been done properly only in type 1 diabetic patients living in Nurmijärvi. Regular foot examination is important also in the diagnosing of the diabetic neuropathy, since the diagnosis in PHC is mostly based on the abnormal findings of the feet.

It is difficult to find the reason for the high prevalence of smoking in type 1 diabetic patients in Nurmijärvi; the proportion of smokers is clearly higher than in the average population [16.5% in a population with similar age and gender distribution (186)] and also higher than in Kouvola. In every case, smoking seems to be a problem that needs special attention in the future follow-up of type 1 diabetes.

In the centralized diabetes care system of Nurmijärvi, a bigger proportion of type 1 diabetic patients was followed-up in PHC and there were fewer patients who were drop-outs of the regular follow-up.

Taken together, concerning to type 1 diabetic patients, the centralized care model in PHC seems to work better than the decentralized model but both models are equally good in the care of type 2 diabetic patients.

6.3.7 Centralizing produces savings

The very expensive patients with total costs above 100 000 € during six study years were excluded from the comparison of health care costs. At least the majority of these six type 1 diabetic patients with nephropathy had not previously been in the follow-up of the local PHC. Four of these expensive patients lived in Nurmijärvi and two in Kouvola.

The outpatient specialist care in type 1 diabetes was 38.3 % cheaper per one patient and 14.3 % cheaper in type 2 diabetes in Nurmijärvi than in Kouvola. The costs of one type 1 diabetic patient in outpatient specialist care were more than four times higher than the costs of one type 2 diabetic patient. The specialist level inpatient periods of Kouvola were somewhat shorter in both diabetes types. The total yearly costs of the treatment of diabetes and its complications per one diabetic patient were 510 € lower in type 1 and 32 € lower in type 2 diabetes in Nurmijärvi with the centralized care system than in Kouvola with the decentralized care. The difference in type 2 diabetes is small when calculated per one patient but considering the higher prevalence of type 2 diabetes, the total sum becomes significant. Altogether, the centralized diabetes care model of
Nurmijärvi seemed to produce yearly cost saving of 116 500 € when compared with the family doctor based follow-up system of Kouvola.

The savings produced by the centralized follow-up system of type 1 diabetes are nearly equivalent to the yearly costs of one general practitioner. If extrapolated to the whole country, the centralized follow-up of type 1 diabetic patients could produce savings of more than 10 million euro per year. The saved money can, of course, be used in many ways: recruiting of a new doctor can produce extra savings in the long run, but that is uncertain. A marked proportion of the savings can be lost by unsuccessful decisions. The very expensive patients with total costs above 100 000 € during the six study years were decided to be excluded from the comparison of health care costs. At least the majority of these six type 1 diabetic patients with nephropathy had not been previously in the follow-up of the local PHC. Four of these expensive patients lived in Nurmijärvi and two in Kouvola.
7 Summary and conclusions

- HbA\textsubscript{1c} is not a good measure in comparing the quality of diabetes care of different care units, especially if the analyses have not been done by the same analysis method in the same laboratory. Moreover, HbA\textsubscript{1c} does not detect hypoglycaemias or glucose variability.

- Almost half of all severe hypoglycaemias are suffered by type 2 diabetic patients. On average, type 1 diabetic patients suffer from severe hypoglycaemia once in 1.5 years and insulin-treated type 2 diabetic patients once in 4 years. Only the top of an iceberg is seen in the health care system, because most of all severe hypoglycaemias are treated at home or outside the hospitals by paramedics.

- Depressive symptoms, physical activity and diagnosed diabetic nephropathy correlate with the risk of severe hypoglycaemias – but not the level of HbA\textsubscript{1c}, use of alcohol or the type of basal insulin (glargine vs. NPH). Eighty per cent of all insulin-treated diabetic patients do not have severe hypoglycaemias. Hypoglycaemias cluster to a small minority of all diabetic patients.

- Patients with recurrent severe hypoglycaemias have valid driver’s licenses as frequently as the whole diabetic population on average. Many of them are outliers of the public diabetes care system having no visits to the health care system.

- The centralized diabetes follow-up model in PHC produces significant savings in the care of type 1 diabetes and smaller savings in the care of type 2 diabetes. The difference is mostly due to more frequent consultations of specialist level outpatient health services in the decentralized care model.

- Type 1 diabetic patients are more satisfied with the centralized follow-up system. The difference is especially notable in the satisfaction with the skills of doctors. The trust to the skills of diabetes specialist nurses is high in both models.
Conclusions

- Modern patients need high-quality care also in the PHC. This is difficult to offer, if every doctor tries to be expert in all specialities. It seems to be also economically sensible to share the work of the doctors in the PHC according to their special interests.

- The satisfaction inquiry confirms the old idea that the diabetes specialist nurses are a cornerstone of diabetes care. Every type 1 diabetic patient should have an easy way to consult a diabetes specialist nurse.

- An independent ‘driving ability centre’ system should be established for problematic driving permission estimations.

- Benchmarking of the quality of diabetes care needs new indicators, computerized data collection systems and national diabetes registers.

- The connection between diabetes and depression is worth more research.

- Avoidance of severe hypoglycaemias should be one of the main targets in diabetes care.
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Appendix I

ARVOISA TUTKIMUSHENKILÖ

Saamassanne potilastiedotteessa kuvattuun tutkimukseen liittyen keräämme oheisella kyselykaavakkeella taustatietoja, joiden toivomme täydentävän sairaskertomustiedoissanne mahdollisesti esiintyviä puutteita koskien diabeteksenne hoitoon keskeisesti liittyviä asioita. Saamiamme vastauksia käytämme hyväksi myös, kun selvitämme, millaiset asiat liittyvät diabeetikkojen hoitotasapainojen eroihin.

Toivomme Teidän suhtautuvan kyselyyn myönteisesti; aikaa vastaamiseen kulunee 10-15 min. Täytetyn kaavakkeen sekä allekirjoitetun suostumuslomakkeen voitte palauttaa terveyskeskuksen diabeteshoitajalle, tarvikejakeluun tai myöhemmin postitse palautuskuoreessa, jonka postimaksu on maksettu. Vaikka ette haluaisikaan vastata kyselyyn, voitte allekirjoittaa suostumuslomakkeen, jolloin annatte luvan diabetestietojenne keräämiseen tutkimusta varten. Kaikki antamanne tiedot käsitellään ehdottoman luottamuksellisesti ja tulokset julkaistaan muodossa, jossa kenenkään henkilökohtaisia tietoja ei voida jäljittää.

VASTAUSLOMAKE 2005

Tutkimuskeskuksen koodi: I__I__I

Potilaan koodinumero: I__I__I__I__I
1. Sivilisäty

1. naimisissa tai avoliitossa
2. naimaton
3. asumuserossa tai eronnut
4. leski

2. Millaista työtä teette suurimman osan vuodesta

1. maanviljelys, karjanhoito, metsätyö, emäntä
2. tehdas-, kaivos-, rakennus tai muu vastaava työ
3. toimistotyö, henkinen työ, palvelutyö
4. opiskelu tai koulunkäynti
5. kotiropua, kotiäiti, koti-isä
6. eläkeläinen
7. työttömä

3. Mikä on ammattinne?

___________________________

4. Kuinka monta henkeä kuuluu kotitalouteenne tällä hetkellä Teidät itsenne mukaan lukien?

I__I__I jäsentä

5. Kuinka moni kotitalouteenne kuuluvista on:

1. alle 7-vuotiaita? __________
2. 7-17 -vuotiaita? __________
3. 18-24 -vuotiaita? __________
4. 25-64 -vuotiaita? __________
6. Mikä on asumismuotonne?

1 kerrostalo
2 rivitalo / paritalo
3 omakotitalo
4 palveluasunto
5 laitos (vanhainkoti, vuodeosasto)

7. Arvioikaa mahdollisimman tarkasti, milloin diabeteksenne on todettu? (esim. kuukausi ja vuosi, pelkkä vuosi tai vuosikymmen, jos ette muista tarkemmin)


8. Mikä on diabeteksenne pääasiallinen hoitopaikka? (esim. sairaala, terveyskeskus, työterveyshuollon yksikkö tai yksityinen lääkäriasema; nimeltä mainiten)


9. Miten pitkään diabeteksenne hoito ja seuranta on toteutettu nykyisessä hoitopaikassa?

1 alle 1 vuoden ajan
2 1-3 vuoden ajan
3 3-5 vuoden ajan
4 5-10 vuoden ajan
5 yli 10 vuoden ajan

10. Arvioikaa mahdollisimman tarkasti, milloin olette viimeksi käynyt silmälääkärin vastaanotolla tai milloin silmänpohjanne on viimeksi valokuvattu?


11. Onko ammattihenkilö tutkinut jalkanne viimeksi kuluneen vuoden aikana (lääkäri, diabeteshoitaja, muu sairaanhoitaja tai jalkojenhoitaja)?

1 ei ole
2 on

12. Mikäli diabeteksenne pääasiallinen seuranta toteutuu terveyskeskuksessa tai sairaalassa, oletteko lisäksi käyttänyt yksityislääkärin palveluita diabeteksenne hoitoon liittyvissä asioissa viimeisten 12 kk:n aikana (ei koske silmälääkärillä käyntejä)?

1 en ole
2 olen, 1 kerran
3 olen, 2 kertaa tai enemmän

13. Oletteko viimeisten 12 kuukauden aikana käynyt jalkojenhoitajalla omalla kustannuksellanne?

1 en ole
2 olen, 1 kerran
3 olen, 2 kertaa tai useammin

14. Onko Teillä käytössä pieni päivittäinen asetosalisylaattilääkitys verenkiertohäiriöiden estoon (Aspirin, Disperin tai Primaspan 50-250mg/vrk)?

1 ei ole
2 on

15. Mikäli Teillä on ns. aikuistyyppin diabetes (tyyppi II) ettekä käytä asetosalisylaattilääkitystä, mikä on lääkkeen käyttämättömyteen syyynä?

1 allergia asetosalisyylihapolle
2 herkkä vatsa tai esim. sairastettu vatsahaava
3 muun verenhoennuslääkityksen (esim. Marevan tai Plavix) käyttö
todettu herkkyyys verenvuodoille
korkea ikä
6 runsas muu lääkehoito
terveydenhuoltohenkilöstö ei ole sen käyttöä suositellut
8 en ole itse halunnut käyttää sitä, vaikka sitä on minulle suositeltu
16. Onko Teillä viimeksin kuluneiden 12 kk:n aikana ollut niin matalia verensokereita (insuliinisokkeja), että olette joutunut turvautumaan toisen henkilön apuun?

1  ei ole
2  kyllä, _______ kertaa

17. Tupakoitteko?

1  en ole koskaan polttanut (siirtykää kohtaan 12)
2  en, lopetin _______ vuotta sitten
3  kyllä, satunnaisesti
4  kyllä, 1-10 savuketta vrk:ssa
5  kyllä, 11-20 savuketta vrk:ssa
6  kyllä, 20-30 savuketta vrk:ssa
7  kyllä, yli 30 savuketta vrk:ssa
8  kyllä, mutta poltan sikareita, piippua, itsekäärittyjä sätkiä tai nuuskaan (alleviivaa sopiva vaihtoehto)

18. Arvioikaa mahdollisimman tarkasti, kuinka monen vuoden ajan elämänne aikana olette yhteensä tupakoinut päivittäin?

____________________

19. Oletteko viimeksi kuluneiden 12 kk:n aikana käyttänyt mitään alkoholijuomia?

1  en
2  kyllä
20. Montako lasillista (tavallista ravintola-annosta) tai pullollista olette juonut edeltävän viikon (7 vrk) aikana seuraavia: Ellette ole juonut yhtään, merkitkää 0.

<table>
<thead>
<tr>
<th>Olutta (III tai IV)</th>
<th></th>
<th>pullollista (1/3 l)</th>
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<td>I__I__I</td>
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<tr>
<th>Long drink –juomia</th>
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<th>pullollista (1/3 l)</th>
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<tr>
<th>Väkevää alkoholia</th>
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<th>ravintola-annosta</th>
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<td>I__I__I</td>
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<thead>
<tr>
<th>Viiniä tai vastaavaa</th>
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<th>lasillista</th>
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<td>I__I__I</td>
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(alkoholipit. yli 5%)

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<tr>
<th>Siideriä tai kevytiiniä</th>
<th></th>
<th>lasillista</th>
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<tr>
<td>I__I__I</td>
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(alkoholipit. n. 5%)

21. Edellisessä vastauksessa kuvailitte alkoholin käyttönne viimeksi kuluneen viikon aikana. Käytättekö tavallisesti alkoholia tuohon viikkoon verrattuna

1. selvästi vähemmän?
2. hiukan vähemmän?
3. suunnilleen saman verran?
4. hiukan enemmän?
5. selvästi enemmän?

22. Mitä ajattelette omien ruokailutottumustenne terveellisyystä? Syöttekö mielestänne

1. erittäin terveisestä
2. melko terveisestä
3. hieman epäterveisestä
4. erittäin epäterveisestä
23. Onko joku viimeksi kuluneiden 12 kk:n aikana kehottanut Teitä muuttamaan ruokailutottumuksianne terveyssyistä?

1  kyllä, lääkäri
2  kyllä, diabeteshoitaja
3  kyllä, muu terveydenhuoltohenkilö
4  kyllä, perheenjäsen
5  kyllä, joku muu
6  ei kukaan

24. Pyrittekö rajoittamaan ns. kovien rasvojen (eläin- ja maitorasvat) käyttöä ruokavaliossanne?

1  kyllä
2  ei

25. Pyrittekö tietoisesti runsaaseen kuitujen määrään (hedelmät, vihannekset ja kokojyväviljatuotteet) ruokavaliossanne?

1  kyllä
2  ei

26. Miten usein lisätte suolaa ruokaanne pöydässä?

1  en juuri koskaan
2  yleensä silloin, kun ruoka ei maistu riittävän suolaiselta
3  jokseenkin aina ennen maistamista

27. Painatteko mielestänne

1  huomattavasti liian paljon?
2  jonkin verran liian paljon?
3  hiukan liian paljon?
4  sopivasti?
5  liian vähän?
28. Oletteko pyrkinyt pudottamaan painoanne viimeksi kuluneiden 12 kk:n aikana?

1  kyllä
2  ei

29. Kuinka usein harrastatte vapaa-ajan liikuntaa vähintään puoli tuntia niin, että ainakin lievästi hengästytte ja hikoilette?

1  päivittäin
2  4 – 6 kertaa viikossa
3  2 – 3 kertaa viikossa
4  viikottain - kuukausittain
5  muutaman kerran vuodessa tai harvemmin
6  en voi vamman tai sairauden takia harrastaa liikuntaa


1  työni on pääasiassa istumatyötä enkä kävele paljonkaan
2  kävelen työssäni melko paljon, mutta en joudu nostelemaan tai kantamaan raskaita esineitä
3  joudun työssäni kävelemään ja nostelemaan paljon tai nousemaan portaita tai ylämäkeä
4  työni on raskasta ruumiillista työtä, jossa joudun nostamaan tai kantamaan raskaita esineitä, kaivamaan, lapioimaan tai hakkaamaan jne.

31. Kuinka monta minuuttia kävelette tai pyöräilette työmatkoillanne (yhteensä meno- ja paluumatkalla)?

1  en ole työssä tai työni on kotona
2  kuljen työmatkan kokonaan moottoriajoneuvolla
3  alle 15min. päivässä
4  15 – 30 min päivässä
5  30 – 60 min päivässä
6  yli tunnin päivässä
32. Oletteko tuntenut itsenne jännittyneeksi, stressaantuneeksi tai kovan paineen alaiseksi viimeksi kuluneen vuoden aikana?

1 kyllä - elämäntilanteeni on miltei sietämätön
2 kyllä - melkoisesti enemmän kuin ihmiset yleensä
3 kyllä - jonkin verran mutta en käsittääkseni enempää kuin ihmiset yleensä
4 en ollenkaan

33. Oletteko tuntenut itsenne masentuneeksi viimeksi kuluneen vuoden aikana?

1 koko ajan
2 suurimman osan aikaa
3 huomattavan osan aikaa
4 jonkin aikaa
5 vähän aikaa
6 en ollenkaan

34. Häiritseekö jokin asia elämäntilanteessanne (huolet, muut sairaudet tms.) oleellisesti mahdollisuuksianne keskittyä diabeteksen hoitoon?

1 kyllä
2 ei

35. Onko oma terveydentilanne tällä hetkellä mielestä ette?

1 hyvä
2 melko hyvä
3 ei hyvä eikä huono
4 melko huono
5 huono

36. Mikä on pituutenne?

I__I__I__I_ cm

1 nyt tai vastikään mitattu
2 vanha tieto tai muistikuva
ja paljonko painatte?

I__I__I__I kg

1 nyt tai vastikään punnittu
2 arvioitu

Merkitkää vielä päivämäärä, jona täytitte kaavakkeen: _____ / _____ 200__ ja tarkistakaa, että olette vastannut kaikkiin kysymyksiin.

KIITOS VAIVANNÄÖSTÄNNE!
Appendix II

List of the ICD-10 diagnoses and procedures which were evaluated to be diabetes-related in the study IV:

I20-I25
I63-66, I69
I70-71, I74, I80, I83.0
J00-J15, J20, J22
E10-14, E65-68
F01
G63.2
H28*E10-14
H33-36
H43
L00-08
L92
M14*E10-14
M68, M75.0, G56.0
N17-19, N30, N10

Procedures;
ACB51, CKC10-50, CKD60-65, CKD91-95, XCD20, XCK10, FN, FWC00, FX_2 - FX_4, NFQ, NGQ, NGW10, NGS20, NGS99, NHQ, NHS, NHW10, PAF, PAH, PAQ, PAR, PA_, PDF, PDG, PDH, PDN, PDP, PDQ, PD_2, PD_3, PEF, PEG, PEH, PEN, PEP, PEQ, PER, PEU, PEW, PE1AT, PE1BT, PFH, PFP, PFQ, PFR, PFU, PF_, PG, PWC00, QDG, QWC00, QXG
Appendix III

HYVÄ DIABEETIKKO!


Kysymykset:

1. Miten tyytyväinen olette diabeetikkojen hoitotarvikkeiden (neulat, verensokerin määrittelyliuskat yms.) jakeluun toimivuuteen terveyskeskuksessa?  

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<tbody>
<tr>
<td>1</td>
<td>erittäin tyytyväinen</td>
</tr>
<tr>
<td>2</td>
<td>melko tyytyväinen</td>
</tr>
<tr>
<td>3</td>
<td>melko tyytymätön</td>
</tr>
<tr>
<td>4</td>
<td>erittäin tyytymätön</td>
</tr>
</tbody>
</table>
2. Miten tyytyväinen olette laboratoriopalveluiden toimivuuteen terveyskeskuksessanne?

1. erittäin tyytyväinen
2. melko tyytyväinen
3. melko tyytymätön
4. erittäin tyytymätön

3. Miten tyytyväinen olette diabeetikkojen silmätutkimusten toimivuuteen terveyskeskuksessanne?

1. erittäin tyytyväinen
2. melko tyytyväinen
3. melko tyytymätön
4. erittäin tyytymätön

4. Miten tyytyväinen olette diabeetikkojen jalkojen tutkimiseen ja hoitoon terveyskeskuksessanne?

1. erittäin tyytyväinen
2. melko tyytyväinen
3. melko tyytymätön
4. erittäin tyytymätön

5. Miten tyytyväinen olette saamaanne ravitsemusneuvontaan terveyskeskuksessanne?

1. erittäin tyytyväinen
2. melko tyytyväinen
3. melko tyytymätön
4. erittäin tyytymätön

6. Miten tyytyväinen olette diabetshoitajanne tavoitettavuuteen?

1. erittäin tyytyväinen
2. melko tyytyväinen
3. melko tyytymätön
4. erittäin tyytymätön
7. Miten tyytyväinen olette diabeteshoitajanne ammattitaitoon?

1 erittäin tyytyväinen
2 melko tyytyväinen
3 melko tyytymätön
4 erittäin tyytymätön

8. Miten tyytyväinen olette lääkärinne tavoitettavuuteen?

1 erittäin tyytyväinen
2 melko tyytyväinen
3 melko tyytymätön
4 erittäin tyytymätön

9. Miten tyytyväinen olette lääkärinne ammattitaitoon diabeteksenne hoitoa koskevissa asioissa?

1 erittäin tyytyväinen
2 melko tyytyväinen
3 melko tyytymätön
4 erittäin tyytymätön

10. Miten tyytyväinen katsoisitte kaiken kaikkiaan olevanne diabeteksenne ja siihen liittyvien asioiden hoitoon terveyskeskuksessanne?

1 erittäin tyytyväinen
2 melko tyytyväinen
3 melko tyytymätön
4 erittäin tyytymätön

11. Miten hyvin olette mielestänne tarvittaessa päässyt erikoissairaanhoidon arvioon diabeteksenne tai sen liitännäissairauksien hoitoon liittyvissä asioissa?

1 erittäin hyvin
2 melko hyvin
3 melko huonosti
4 erittäin huonosti
5 en koe diabetekseni hoidon vaatineen erikoissairaanhoidon palveluita
12. Vielä toivoisimme teidän arvioivan, miten tyttyväinen olette omaan panokseenne diabeteksenne hoidossa?

1. erittäin tyttyväinen
2. melko tyttyväinen
3. melko tyytymätön
4. erittäin tyytymätön

13. Lopuksi Teillä on mahdollisuus sanallisesti kertoa, mihin olette diabeteksenne hoidossa tyhtymätön ( tai tyttyväinen). Tutkimuksen keskeisenä tavoitteena on luonnollisesti kehittää diabeteksen hoitoa maassamme, jolloin potilailta saatava palaute on ensiarvoisen tärkeää.

______________________________

KIITOS VAIVANÄÖSTÄNNE!