

The societal impact of Diabetes
mellitus and diabetes care

Report 2:

Type 1 diabetes in Denmark year 2001

af

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Foreword

The present Working Paper is one in a series of five papers (WP 2005:4; WP 2005:5; WP 2005:6 WP 2006:1; WP 2006:2) on the societal impact of diabetes mellitus and diabetes care. The work was initiated by Novo Nordisk A/S, Corporate Health Partnerships and conducted of a team consisting of the four authors. An external evaluation was made by an invited Critical Board. The team received a number of valuable suggestions from the board, and most of these are included. Still, the content of the final reports is the responsibility of the authors alone. The project was financed by Novo Nordisk A/S.

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Source of Data: Data is from Århus County collected from public registries in a database, covering the years 2000 through 2002.

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Timetable for main phases of the project:

<i>Calendar year 2002:</i>	Initial planning and preparation of project protocols
	Development of epidemiological model data and cost structure
<i>Calendar year 2003:</i>	Using empirical data sets for validation and supplementary analyses
	First reporting of results
<i>Calendar year 2004:</i>	Final analyses and reporting

TABLE OF CONTENTS

PROJECT ORGANISATION	2
EXECUTIVE SUMMARY	4
1. INTRODUCTION.....	8
2. OUTLINE OF METHODOLOGY. SCENARIO BUILDING.....	9
Strategy of analysis.....	11
3. EPIDEMIOLOGICAL DATA	12
4. COST STRUCTURE, EFFECTS AND METHODS OF VALUATION	16
Overview	16
Cost structure and valuation	16
Assessment of effects.....	24
Assessment of productive gains	25
Prevention Costs.....	26
5. RESULTS	28
Costs.....	28
Effects	38
Health economics assessment.....	39
Prevention costs	42
Alternative considerations in relation to the Ideal Scenario	42
6. DISCUSSION	44
7. CONCLUSION	46
ANNEX 1: The demographic evolution of Type 1 diabetes in Denmark	47
ANNEX 2: Data obtained from the Århus County diabetes investigations.....	53
8. REFERENCES	67

EXECUTIVE SUMMARY

As part of a larger project aiming at assessing the societal impact of diabetes and diabetes care, this study presents a health economics assessment of Type 1 diabetes (T1D) in Denmark, with reference to the calendar year 2001.

From epidemiological modelling four contrasting scenarios have been established: The “Current” scenario, representing the real situation for T1D in Denmark; the “Worst” scenario, representing the hypothetical situation that insulin has never been available; the scenario “Improved”, representing a situation believed to represent realistically possible improvements in diabetes care; and, the “Ideal” scenario, representing the hypothetical variant of the “Improved” scenario in which T1D is not associated with any excessive risk of complications and mortality.

Costs of treating T1D in Denmark have been estimated from public registries and ‘ad hoc’ studies and enquiries, together with clinically based estimates. Cost and effects are estimated for each of the scenarios. Costs are structured in Healthcare resources, Non-Healthcare resources, Patients’ time, and Informal caregivers’ time. Effects are quantified in terms of patient-years, quality-adjusted patient-years and productivity (income by working with and without the value of household production). The reference point of the analysis is the current scenario. Gains on the cost and effect side have been estimated from contrasting each of the scenarios “Worst”, “Improved” and “Ideal” with “Current”. Please note that these gains are not additive, however –The Table below summarizes the results in Mill DKK and Mill US\$ (PPP).

The study concludes that from a societal view point it is costly to treat T1D in Denmark, but that the high costs result in a significant number of increased patient-years and quality of patient-years (QALYS) compared with a situation without treatment (“worst scenario”). Health care costs and non-health care costs per gained patient-year are 62,379 DKK and 70,895 DKK per gained QALY. In the literature willingness-to-pay for a QALY is reported as lying in the broad range of 90.000 DKK to 4 million DKK (1, 2) suggesting that the current resource allocation to diabetes treatment is beneficial to society. In addition to the reported health gains (patient-years and QALYs) diabetes treatment also provides additional societal gains in terms of production value of DKK Bill 1,001 in the formal sector and DKK Bill 1,331 if the informal sector is included. It should be underlined that the results are gross and not net benefits because the related consumption is not included. To the extent that production value exceeds increased consumption, the net cost to society of diabetes treatment will be considerably lower than the reported costs. Hence, the reported costs per health gain should be seen as conservative figures.

Our study also suggests that there is a further potential gain in patient-years and productivity, at lower total costs (lower non-health care costs), as in the improved scenario with improved diabetes care. Considerable gains and reduction in costs would be observed under the hypothetical assumption that improved care eliminates complications, comorbidity and premature mortality in T1D as outlined under the ideal scenario. These results suggest that improvements in diabetes care would be beneficial to society.

T1D in Denmark, year 2001. Summary of costs of treatment and effects in contrasting scenarios. Mill DKK

COST Mill DKK	Worst	Current	Improved	Ideal
Healthcare Resources	11	426	427	215
Non-Healthcare Resources	219	688	438	0
Patients' time	1	95	87	22
Informal care-givers' time	2	3	3	1
Total cost Mill DKK	232	1212	955	238
EFFECTS				
Patients' years unadjusted	1,041	16,744	17,286	19,987
Patients' years quality adjusted	677	14,493	15,534	18,988
Production value incl. the informal sector) Mill DKK	0	2,311	2,626	3,414
Production value registered as GDP, Mill DKK	0	1,980	2,251	2,926

CHANGES BETWEEN SCENARIOS	Socio economic gains current vs. worst	Socio economic gains improved vs. current	Socio economic gains ideal vs. current
COST Mill DKK			
Healthcare Resources	415	1	-211
Non-Healthcare Resources	469	-250	-688
Patients' time	94	-8	-73
Informal care-givers' time	2	0	-2
Total cost Mill DKK	980	-257	-974
EFFECTS			
Patients' years unadjusted	15,703	542	3,243
Patients' years quality adjusted	13,817	1,041	4,494
Production value incl. the informal sector) Mill DKK	2,311	315	1,103
Production value registered as GDP Mill DKK	1,980	270	946

<i>SOCIO ECONOMIC RATIOS</i>	"Current" versus "Worst"	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefit gains (production value - costs)			
Production value registered as GDP: Mill DKK	1,001	527	1,919
Production value including the informal sector: Mill DKK	1,331	572	2,077
Marginal cost effectiveness ratio:			
DKK/patient-year	62,379	-473,926	-300,207
Marginal cost utility ratio:			
DKK/QALY	70,895	-246,822	-216,626

By convention negative signs before an estimated ratio indicates a positive gain. Numbers might not add up due to rounding.

T1D in Denmark, year 2001. Summary of costs of treatment and effects in contrasting scenarios. Mill US\$ (PPP) (8.46 DKK/US\$)

COST US\$ (PPP)	Worst	Current	Improved	Ideal
Healthcare Resources	1	50	50	25
Non-Healthcare Resources	26	81	52	0
Patients' time	0	11	10	3
Informal care-givers' time	0	0	0	0
Total cost Mill US\$ (PPP)	27	143	113	28
EFFECTS				
Patients' years unadjusted	1,041	16,744	17,286	19,987
Patients' years quality adjusted	677	14,493	15,534	18,988
Production value incl. the informal sector) Mill US\$ (PPP)	0	273	310	404
Production value registered as GDP Mill US\$ (PPP)	0	234	266	346

CHANGES BETWEEN SCENARIOS COST US\$ (PPP)	Socio economic gains current vs. worst	Socio economic gains improved vs. current	Socio economic gains ideal vs. current
Healthcare Resources	49	0	-25
Non-Healthcare Resources	55	-30	-81
Patients' time	11	-1	-9
Informal care-givers' time	0	0	0
Total cost Mill US\$ (PPP)	116	-30	-115
EFFECTS			
Patients' years unadjusted	15,703	542	3,243
Patients' years quality adjusted	13,817	1,041	4,494
Production value incl. the informal sector) Mill US\$ (PPP)	273	37	130
Production value registered as GDP Mill US\$ (PPP)	234	32	112

<i>SOCIO ECONOMIC GAINS: RATIOS</i>	"Current" versus "Worst"	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefit gains (production value - costs)			
Production value registered as GDP: Mill US\$ (PPP)	157	68	246
Production value incl. the informal sector : Mill US\$ (PPP)	118	62	227
Marginal cost effectiveness ratio:			
US\$ (PPP)/patient-year	7,373	-56,020	-35,485
Marginal cost utility ratio:			
US\$ (PPP)/QALY	8,380	-29,175	-25,606

1. INTRODUCTION

Insulin has been available in the developed world for almost 80 year. Together with a constant improvement of the knowledge of how to prevent and manage the complications of diabetes this has had a huge impact on the survival of people with diabetes and, in particular, the quality of life of people with diabetes. Despite this, diabetes still represents a serious disease. Insulin treatment is an absolute requirement for preserving life in Type 1 diabetes (T1D). In addition, insulin treatment is important for improving metabolic control in other diabetic patients for whom alternative treatment has failed, or where access to peroral antidiabetic agents may be limited. Thus, insulin represents an essential component in diabetes care.

It is generally believed that the incidence (and, hence, the risk) of T1D is increasing worldwide (3). Furthermore, improving prognosis will add to an increasing prevalence of T1D. Albeit of relatively minor quantitative importance, as compared with the other main type of diabetes (Type 2 diabetes, T2D), T1D represents a large burden for patients and society since the disease frequently develops early in life – with subsequent life-long need for treatment and control.

Novo Nordisk A/S has launched a project aiming at studying various aspects of the societal impact of diabetes and diabetes care. This is the second report in a series of 5 reports. The first report in this series (4) dealt with the general methodological considerations behind the project. The third, fourth and fifth report deals with type 2 diabetes in Denmark and type 1 and type 2 diabetes in Bangladesh.

The present report concerns a health economics appraisal of treatment and care of T1D in a developed nation, using Denmark in the calendar year 2001 as framework. Specifically, we aim at developing a model for a developed country with a full scale treatment of diabetes patients as realistically as possible, with estimation of patient-years (with and without adjustment for quality of life) and costs. We then establish hypothesized contrasting scenarios, representing both an alternative with no access to insulin treatment at all, as well as an alternative in which improvements in treatment and care of T1D yields reductions in the mortality and the risk of complications; an extreme variant of this scenario with improvements is represented by the assumption that T1D confers no excessive mortality and morbidity. Each of these hypothetical scenarios is then contrasted with the scenario for the current (actual) situation, providing the basis for evaluations of effects and benefits.

2. OUTLINE OF METHODOLOGY. SCENARIO BUILDING

The study focuses on T1D in Denmark, with reference to the year 2001. In addition to the scenario representing the current situation for T1D in Denmark year 2001, three contrasting scenarios have been created to investigate the impact of different levels of availability of insulin treatment in T1D and the clinical outcome in T1D as well as the costs related to the health states arising from such assumptions. Each scenario is related to year 2001 and outlines a specific situation, with consequences for the actual size of the population of people with T1D (the prevalence), and further implications for the amount of resources used during the year studied.

The scenarios of interest may be characterized as follows:

”Worst” scenario

This scenario is assumed to reflect the situation for T1D in Denmark, year 2001, if insulin treatment had never been available. The scenario is based on estimates of patient-years experienced during the calendar year 2001 under this assumption.

”Current” scenario

This scenario is assumed to reflect the current situation concerning T1D in Denmark, year 2001. The scenario, representing the key reference scenario, is based on estimates of patient-years actually experienced during the calendar year 2001 in Denmark.

”Improved” scenario

This scenario has been established to investigate the consequences of possible and realistic improvements in diabetes care (with implications for the number of patient-years and corresponding distributions by age group and complication status). As described in the first methodology report, such improvements in diabetes care concerns a range of items including the enhancement of communication between people with the condition and their healthcare professionals; the improvement of communication and coordination among all healthcare professional groups; the promotion of effective self-management; the removal of patient and healthcare professional barriers to effective therapy; and, enabling improved psychosocial support for people with the condition.

This scenario is based on the same demographical model as the “Current” scenario; however with the change that effectively from the year 1985, all mean survival times in T1D have been extended with an arbitrary amount of 3.5 years. The scenario is based on estimates of patient-years experienced during the calendar year 2001 under this assumption.

”Ideal” scenario

This scenario represents a hypothetical variant of the “Improved” scenario by assuming that improvements in treatment and organization of diabetes care, as specified in the “Improved” scenario, result in a situation where T1D does confer neither any excess mortality nor any excess morbidity. This way, the “Ideal” scenario represents a sensitivity

analyses at the extreme upper boundary of gains in appraisals addressing costs and effects associated with improvements in treatment and care of T1D.

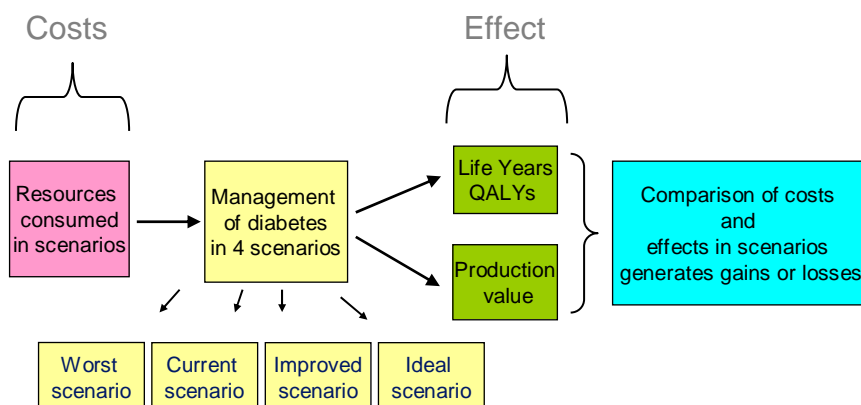
The epidemiological modelling under this scenario uses longevity in the general population to obtain the hypothetical numbers of patient-years (all falling in the class of no complications). Thereby, the number of patient-years estimated under this scenario is adjusted for the mortality level in the general population.

It should be stressed that the current population of patients with T1D in Denmark has obtained its size and age composition as a consequence of access to insulin and other forms of treatment during many decades following the introduction of insulin in the early 1920's. Therefore, a comparison of patient-years experienced under the contrasting scenarios mentioned reflects the cumulative effect of access to care and treatment, incl. insulin, over previous decades and cannot be interpreted as an isolated effect of insulin treatment during the year 2001.

Strategy of analysis

Fig. 1. Strategy of analysis

Illustration of Methodology



In summary, the main building stones of our study are scenarios and, for each of them, estimate of the population of people with T1D by age and complication status, and the associated costs and productivity items. Using the “Current” scenario as the reference, each of the other scenarios are evaluated with respect to

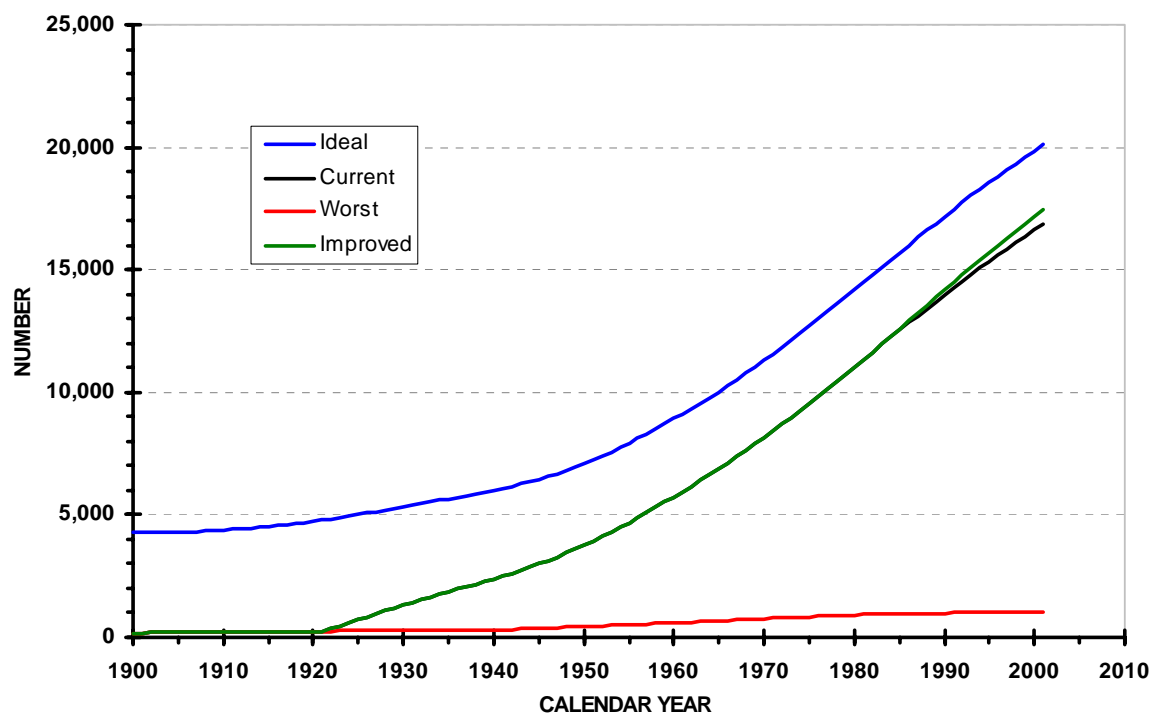
- The number of patient-years experienced with T1D
- The number of quality of life-adjusted patient-years experienced with T1D
- The costs of medical interventions in the hospital system and outside, including home nursing
- The cost consequences for the patients related to transport and informal care by relatives and others
- The foregone income from time lost due to sickness and reduced productivity by patients with T1D

These items will be dealt with in accordance with up-to-date methodology in epidemiology and health economics, as reviewed in the first report of this series.

3. EPIDEMIOLOGICAL DATA

By means of the methodology outlined in Annex 1 it has been possible to obtain estimates of the size of the prevalence population of patients with T1D in Denmark for each calendar year during the period 1900-2001. Different scenarios concerning patient survival/mortality have been entertained. The summary results are presented in Fig. 3.1. Under the “Current” scenario, the prevalence population amounted to 16,617 patients ultimo 2000 and 16,871 patients ultimo 2001. Therefore, the best available number of patient-years (all age categories combined) experienced during the year 2001 under this scenario is 16,744 (= (16,617+16,871)/2 years). Similarly, the number of patient-years that might have been experienced in Denmark during the year 2001 if insulin treatment had never been available (“Worst” scenario) is 1,041 years (= (1,039+1,043)/2). Under the “Improved” scenario the number is 17,286 years (= (17,146+17,427)/2). Under the “Ideal” scenario, the number of patient-years would be 19,987 (= (19,859+20,115)/2).

Fig. 3.1. Trends in estimated prevalence (absolute numbers) of type 1 diabetes in Denmark,



The number of patient-years experienced during a given calendar year is furthermore characterized by four *age at onset* categories (0-14; 15-39; 40-64, 65+ yrs.) in the modelling (Annex 1). However, for the present study stratification by four *current* age categories is needed. Based on judgment of how long time a patient is assumed to stay in the same age interval as the age at onset interval before moving to higher age intervals or death, distributions by current age have been obtained for each scenario.

Both the costs of treating T1D and the quality of life are strongly associated with the presence of long-term (chronic) complications of diabetes. There is no routine data available in Denmark to permit a characterization of the patient population by complication status. Therefore, attempts have been made in the present study to divide the prevalence population (stratified by age groups) of patients with T1D in Denmark for 2001 in three distinct categories of complication status, as indicated in the following Table:

Complication status	Patient profile of complications
<i>State 0:</i> No signs of chronic complications; No impairment in daily living function	No signs of complications present
<i>State 1:</i> Signs of minor/early chronic complications; No or only minor (insignificant) impairment in daily living function	Retinopathy, not including proliferate retinopathy; <i>and/or</i> Microalbuminuria; <i>and/or</i> Light neuropathy without open ulceration;
<i>State 2:</i> Presence of chronic complications, with significant impairment in daily living function	Overt nephropathy, incl. end stage renal disease; <i>and/or</i> Proliferate retinopathy and/or blindness; <i>and/or</i> History of stroke and/or myocardial infarction; <i>and/or</i> History of amputation (regardless of level)

Annex 2 describes how data from an ongoing epidemiological investigation of diabetes in Århus County, Denmark, following the design of Kristensen (5, 6), have been used to estimate how the patient-years distribute by age-group and complication status in the current scenario. The same data set has been used as “pilot-points” for the epidemiological modelling described above. Supplementary data have been acquired from the National Danish Medicines Agency and from the National Danish Hospital Activity Registration System (“Landspatientregistret”), as also described in Annex 2. Table 3.1 shows how the numbers of patient-years during the calendar year 2001 have been assumed to distribute by complication status, with reference to the various contrasting scenarios.

Table 3.1. Estimated patient-years by current age and complication status in contrasting scenarios

Scenario: "Current"

<i>Complication status</i>	0-14	15-39	40-64	65+	Total
State 0	960	5,134	2,615	500	9,209
State 1	60	400	4,675	850	5,985
State 2	0	300	750	500	1,550
Total	1,020	5,834	8,040	1,850	16,744

Scenario: "Worst"

State 0	0	0	0	0	0
State 1	0	0	0	0	0
State 2	275	390	300	76	1,041
Total	275	390	300	76	1,041

Scenario: "Improved"

State 0	970	5,300	3,500	936	10,706
State 1	55	350	4,250	725	5,380
State 2	0	250	500	450	1,200
Total	1,025	5,900	8,250	2,111	17,286

Scenario: "Ideal"

State 0	1,235	8,502	7,750	2,500	19,987
State 1	0	0	0	0	0
State 2	0	0	0	0	0
Total	1,235	8,502	7,750	2,500	19,987

Annex 1 describes the epidemiological modelling used to provide information on the patient-years experiences in the "Current" scenario.

Specifically, for the “Worst” scenario of the present study, the mean duration from diagnosis to death has been assumed to take the value of 1.5 years regardless of age at onset, with corresponding mortality rates at 66.7 deaths per 100 patient-years, throughout the period 1900-2001. Patients in the “Worst” scenario are assumed not to live long enough to develop late complications to T1D. However, since it is assumed that the patients, during their short course of diabetes, will be disabled and in the need of intensive palliative support, all patient-years have been assigned to the complication state with most severe impairment, i.e., state 2.

For the “Improved” scenario it has already been mentioned that the “Current” scenario has been modified by adding 3.5 years to all mean survival times from diagnosis, with effect from 1985 and onwards.

For the “Ideal” scenario, trends in mean duration (and, hence, mortality) have been assumed to follow the general population values for given age-at-onset and calendar time at onset. This ensures that the patients in this scenario have mortality levels identical with those of the general population. Furthermore, by assumption all patient-years have been assigned to the complication state without any impairment, i.e. state 0.

4. COST STRUCTURE, EFFECTS AND METHODS OF VALUATION

Overview

There are several types of costs involved in the care and management of T1D for both the individual and the healthcare system. Moreover, survival may involve need of treatment for later complications. These types of costs are automatically included in the present study, as we have chosen a one-year window, and thereby included patients who may be at all possible stages in the life-course of their illness.

With regard to *costs of treatment* we follow the US Panel (9) and distinguish between costs of using

- healthcare resources
- non-healthcare resources
- patients' time
- informal care-givers' time

Concerning *effects* we use three approaches (10):

- (patient) life years gained
- quality of patient-years gained
- productivity gains measured in monetary units

The three approaches should be seen as alternative ways of expressing the effects rather than additive measures as there may be overlaps between them.

Cost structure and valuation

The details of the cost structure are shown in Table 4.1. The corresponding valuation of items is summarized in Table 4.2, referring to the "Current" scenario. Specific comments to the individual items are given below, as relevant.

Table 4.1. Overview of cost structure and valuation

COSTS and PRODUCTIVITY per patient-year

			Number of units <i>per patient-year</i> by current age group and complication state:											
Item	Unit	Cost per unit (DKK)	0 - 14			15 - 39			40 - 64			65+		
			0	1	2	0	1	2	0	1	2	0	1	2
Healthcare Resources														
Added hospitalization costs	1000 DKK + overhead	1.150	8,5860	8,9670	14,2290	9,3890	10,9930	33,6310	1,6450	9,5570	25,6760	0,0000	0,0000	10,8910
Medication with insulin	One year's treatment	3.609	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0
Medication with oral antidiabetics	1000 DKK	1.000	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Medication with other drugs added costs	1000 DKK	1.000	0,000	0,000	0,822	1,795	2,449	5,092	3,182	3,880	5,817	2,961	3,126	4,045
Routine diabetes controls	One average visit	156	5	10	15	5	10	15	5	10	15	5	10	15
Home monitoring	One year's activities	6.371	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0
Physiotherapy	One year's cost	3.384	0,000	0,000	0,000	0,000	0,000	1,000	0,000	0,000	1,000	0,000	0,000	1,000
Non-Healthcare Resources														
Added cost for nursing home	One year's cost	280.320	0,000	0,000	0,000	0,000	0,000	0,250	0,000	0,000	0,250	0,000	0,000	0,250
Annual cost for nursing assistance in the home, full-time	One year's cost	360.000	0,000	0,000	0,150	0,000	0,000	0,150	0,000	0,000	0,150	0,000	0,000	0,150
Annual cost for nursing assistance in the home, part-time	One year's cost	118.800	0,000	0,000	0,000	0,000	0,000	0,450	0,000	0,000	0,450	0,000	0,000	0,450
Wheelchair	One year's cost	1.400	0,000	0,000	0,000	0,000	0,000	0,250	0,000	0,000	0,250	0,000	0,000	1,000
Stocks	One year's cost	500	0,000	0,000	0,000	0,000	0,000	1,000	0,000	0,000	1,000	0,000	0,000	1,000
Protese crus	One year's cost	13.750	0,000	0,000	0,000	0,000	0,000	0,007	0,000	0,000	0,093	0,000	0,000	0,170
Protese femur	One year's cost	35.000	0,000	0,000	0,000	0,000	0,000	0,003	0,000	0,000	0,052	0,000	0,000	0,112
Shoes	One year's cost	600	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
Patients' time														
Transport and child care routine visits	Cost per visit	29	0	0	0	5	10	15	5	10	15	5	10	15
Transport and child care admissions	Cost per admission day	18	0	0	0	4	6	8	6	8	10	8	10	12
Loss of productivity during routine controls. Absenteism	Cost per day of visit	213	0	0	0	5	10	15	5	10	15	0	0	0
Loss of productivity during admissions	Cost per working day	851	0,00	0,00	0,00	3,12	3,12	0,00	5,40	5,50	0,00	0,00	0,00	0,00
Loss of productivity related to discomfort during work	Cost per working day	85	0	0	0	0	115	0	0	115	0	0	0	0
Informal care-givers' time														
Transport and child care routine visits	Cost per visit	29	5	10	15	0	0	0	0	0	0	0	0	0
Transport and child care Visits during admissions	Cost per visit	18	1	2	3	4	6	8	6	8	10	8	10	12
Loss of productivity during routine controls. Absenteism	Cost per day of visit	213	5	10	15	0	0	0	0	0	0	0	0	0
Production value														
Registered as GDP	One year's aver. income	240.080	0,00	0,00	0,00	0,75	0,75	0,00	0,75	0,75	0,00	0,00	0,00	0,00
Including the informal sector	One year's aver. income	210.070	0,00	0,00	0,00	1,00	1,00	0,00	1,00	1,00	0,00	0,00	0,00	0,00

Table 4.2. Specification of evaluation of individual cost items (All costs are added costs)

Cost component	Sources: data; assumption; professional opinion	Unit	Unit price (DKK)
Medical costs			
Routine diabetes control (inclusive laboratory tests)	Interview with GP/leaflet/laboratory list prices (11)	Pr visit	156
Medication with insulin	List price: DKK 240.58 per 1000 unit (kU), supported by prices published by Lægemiddelstyrelsen	Consumption per year pr person based on a consumption of 15 kU	3,609
-Medication with other drugs	Empirical evidence (see Annex 2)	Consumption per year, treated persons	3,798
Blood glucose monitoring	Life Scan (12)	By year, assuming 13 BMG per week	6,371
Hospitalisation	Empirical evidence (see Annex 2)	Costs per type 1 patient year	11,502 (incl. 15% overhead)
Cost of nursing and appliances			
Nursing home	15% of complication group 2 live in nursing homes and received 15 hours of assistance pr week. (33,34)	Per year	360,000 (nursing home cost and hours of assistance at 421 DKK per hour)
Nursing assistance in home	85% of complication group 2 has either high need (13 hours a week) or low need (5,4 hours a week) 15% has no assistance (33,34)	Per year	280,320 (high) 118,800 (low) based on 421 DKK per hour
Physiotherapy	100% in group 2 (35)	Per year (12 visits)	3,384
Wheel chair	25% of complication group 2 (DKK 14000 DKK, 10 year life time) (37)	Per year	1,400
Sticks	100% of complication group 2 (5000 DKK, 10 year life time of sticks) (37)	Per year	500
Prosthesis crus	100% of crus amputations (50% over 65 year) (25000-30000 DKK on avg. 27500 DKK, 2 year lifetime of prosthesis) (36)	Per year	13750
Prosthesis femur	100% of femur amputations (50% over 65 years) (30000-110000 DKK on avg. 70000 DKK, 2 year lifetime of prosthesis)) (36)	Per year	35000
Productivity			
Lost productivity during admissions	Average income for people employed in 2001 (19)	Per admission day	851
Lost productivity during admissions (informal sector)	50% of the value in the formal sector (19)	Per admission day	425
Restricted activity day	10% reduced productivity in 50% of working time	Per active working day	85
Lost productivity due to routine controls	2 hour/day	Per routine control	213
Gained productivity from improved survival	(19)	Per active working day formal/informal	851/425

Hospitalisation costs

Annex 2 describes how costs related to hospital activities in the population of patients with diabetes mellitus have been obtained empirically from an ongoing investigation in Århus County (5, 6). The costs have been valuated by the National Danish Hospital Activity Registration System (“Landspatientregistret”) (8) using tariffs from the Diagnosis Related Group (DRG) system. Furthermore, the costs have been adjusted for those expected to occur independently of diabetes (see Annex 2) and the cost used in this study therefore represent the added costs. An estimate of 15% taking account of capital costs of hospital infrastructure has been added to these figures. This estimate is a best guess from the Ministry of Health but has not been validated.

Costs of consumption of insulin and other drugs

Cost of insulin, the IMS¹-weighted average list price (pharmacy selling price incl. VAT) in Denmark was 240.58 DKK per K-units insulin (1000 units). Using this average price and assuming a consumption of 15 K-units of insulin per patient-year (41 units per day, according to clinical practice and the National Danish Medicines Agency (Lægemiddelstyrelsen) (7) the annual cost of insulin for a patient-year was DKK 3,609.

It is assumed that no patients with T1D have used peroral antidiabetic agents.

Concerning added costs related to medication with other drugs Annex 2 describes how empirically based estimates have been obtained from the ongoing investigation in Århus County. These drugs include: C02 (antihypertensive agents); C03 (diuretics); C07 (beta-receptor blockers); C08 (Calcium antagonists); C09 (ACE inhibitors); C10 (lipid-lowering drugs).

Routine visits to GPs

The data used for estimating the cost of a routine visit to general practitioners were obtained through an interview with a Danish GP and supplemented by an information leaflet (11) from The Danish Medical Association (“Den Danske Lægeforening”).

The items included:

- No of GP visits during one year
 - for new patients,
 - for well-controlled patients with low cholesterol and
 - well-controlled patients with high cholesterol
- Laboratory tests

¹ IMS: IMS Health is supplier of market research, business analysis, forecasting to the pharmaceutical industry.

Further this item includes a number of visits to eye specialists and foot therapist for persons in complication group 1 and 2.

Home blood glucose monitoring

Prices related to consumption and costs of strips/meters have been obtained from LifeScan (12) and assuming Blood Glucose Monitoring three times a day. The approximate annual costs are:

- Strips: 8,400 DKK (= 7.7 DKK per strip)
- Lancets: 1,400 DKK (= 1.3 DKK per lancet)
- Batteries: 50 DKK

It is assumed that a glucometer costs 235 DKK, and has an expected life-time of 1 year.

Based on clinical experiences, it is assumed that – on average – a patient with T1D performs a Blood Glucose Measurement 13 times per week. Accordingly, the costs per patient-year amounts to $[(7.7+1.3)*13*52] + 50 + 235$ DKK = 6,371 DKK.

Nursing

Data and background

It has not been possible to find data about the actual social circumstances of individuals with severe diabetes complications (comp 2) in terms of housing, need for daily assistance, nursing etc. In the following paragraph an estimate of the cost of daily assistance for people in complication group 2 is made on the basis of the actual frequency of living in nursing homes and hours of permanent home assistance (Danish: Varig hjemmehjælp) in the Danish population as well as the cost in Denmark for year 2001.

The majority of people in this study that currently have diabetes complications are more than 40 years old. 31% are between 40-65 years old and 66% are more than 65 years old. People with major complications are all in comp 2. The large majority of people with complications in group 2 will need more extensive assistance to manage their daily lives than people with a similar age profile without diabetes. This is also reflected in the QALY values for group 2, 0.65, which means that these people have 20%-30% less QALY than people with a similar age and a social profile with no or only minor (insignificant) impairment in daily living functions (comp 0 and 1). People in group 0 and 1 are considered to be in a social condition almost identical to that of people without diabetes with a similar age and social profile. Thus no added social cost in terms of need for daily assistance is assumed for people in comp 0 and 1. They are assumed to consume assistance in the home, nursing etc. on a level identical to the rest of the population and therefore do not incur added costs due to diabetes.

Complication group 2 is defined as: Presence of chronic complications, with significant impairment in daily living function due to

- Overt nephropathy, incl. end stage renal disease; *and/or*
- Proliferative retinopathy *and/or* blindness; *and/or*
- History of stroke *and/or* myocardial infarction; *and/or*
- History of amputation (regardless of level)

Current practise:

The current practise for care of old aged people or people with disabilities is to help people stay in their own home as long as possible. Only people that irrespective of comprehensive municipal assistance cannot stay in their own home due to severe disabilities or problems related to age or other health status are referred to nursing homes or to other sheltered housing. Thus residents in nursing homes are increasingly people with serious disabilities of the sort that diabetes incurs.

In 2001 9% (61500 persons) of the population above 67 year of age lived in a nursing home: Furthermore 25% of people above 67 year of age received municipal assistance with daily necessities in their own home or in nursing homes/other sheltered living. Approx 50% received less than 2 hour a week while some 14% received between 8-20 hours and 7% more than 20 hours assistance pr week. The average amount of hours of assistance in 2001 was 5.5 hours per week for those who received assistance. Among 60% of those above 80 years of age the average amount of assistance in 2001 was 12 minute per day or 1 hour and 24 minutes per week (33). The data reflects help to individuals across age groups (including people below 67 years of age), health, psycho-social circumstances and handicap status. (The data from some municipalities do include transport time between clients/users).

The average annual total cost of assistance in the home is 120,000 DKK per user (all ages) receiving assistance with daily care (24.0 Bill DKK divided by 201,258 users)². (Hourly cost of assistance in 2001 was 24 Bill divided by 1,096,977 hours per week times 52 weeks equals 421 DKK per hour of assistance). The cost of nursing homes per inhabitant over 67 years is DKK 33,000 (Annual cost of nursing homes: 2.031 Bill DKK (2001) divided by 65100 inhabitants (14, 33). The actual care with daily activities received in the nursing homes is included under assistance in the home.

Added costs

The estimates of added costs are based on well documented knowledge that the frequency of complications among people with diabetes is higher than in the general population without diabetes and that diabetes complications do cause impairment of the daily living conditions.

According to the MTV report (39) 0-2% of people with diabetes experiences a leg amputation. Leg amputations due to diabetes amount to 30-60% of all amputations, and are between 5-15 times more frequent than for people without diabetes. Furthermore, even if the percentage of type 2 diabetics that experience end-stage fatal renal disease (ESRF) is relatively low (4-8 %) compared to 30-33% among type 1 patients the absolute number of people that need dialysis is large due to the large number of people with type 2 diabetes. People with diabetes amounts to 22 % of all patients in dialysis in 2001 and 50% of these had type 2. Further more according to the MTV report no data exists in a general diabetes population regarding frequency of retinopathy. The available data is based on patients in screening programmes or patients referred to eye specialists. These people are expected to have a higher frequency of reduced sight than that general background population. The frequency of reduced sight (defined as 0.3 to 0.1 ability to see) was 7% of the diabetes population.

² assuming that 61500 persons living in a nursing home and those receiving home nursing is a sub group of the 201,258 users of 171,743 receiving assistance in the home.

Estimates of Added costs

To obtain the added cost of nursing due to diabetes we have to make some assumptions about the added need due to diabetes compared to a similar person without diabetes and how many of the people receiving assistance do so due to their diabetes condition. In general there is a rising risk to be in need of assistance in the home or living in a nursing home with age independent of diabetes, but with diabetes the probability is larger because of the complications. We do not differentiate between people above and below 67 years of age.

The average receiver of permanent nursing assistance in the general population gets 5.5 hours per week. This average includes both people with and without diabetes. The average number of hours of assistance that would have been incurred independently of the diabetes condition has been estimated as 1.4 hours per week based on the average assistance received by the 50% of all users that receive less than 2 hours assistance per week. (The cost is calculated to 30,649 DKK based on 1,4 hours of assistance per week). There are not assumed any added costs for people with diabetes in comp group 0 and 1 even though with rising age people with diabetes in a good shape do need assistance with medication that people in the same age groups without diabetes do not need.

The diabetes prevalence among people above 65 years old in this study is 9.4%. Based on best available knowledge about the complications related to diabetes it is fair to assume that more than 9.4% of those +65 years old that lived in a nursing home in 2001 do so due to their diabetes situation and that among people with handicaps those with diabetes amounts to substantially more than the same age groups of the population without diabetes. We assume that 11% of all persons living in nursing homes in 2001 live in a nursing home or in other sheltered housing due to their diabetes condition. They are considered to be in need of a high level of assistance estimated at 15 hours per week (or 2.1 hours per day) assistance attributable to diabetes. We assume that if a person with diabetes lives in a nursing home they do so due to the diabetes conditions as a reflection of a high level of disability and a high level of need for assistance with daily necessities. The cost can therefore be regarded as a cost attributable to the diabetes condition.

Transformed to the study this leads to an assumption that 15% of the group in complication level 2 is living in a nursing home. Consequently 85% in complication group 2 are assumed to live in their own home and of these 85% is assumed to get some formal assistance in the home while 15% do not get any assistance at all. The majority of those that do receive assistance in the own home (45% of all in comp 2) do receive part time assistance (5.4 hour per week due to diabetes). Further more 25% of all in comp 2 (30% of those living in their own home) need substantial assistance (13 hours per week or 1.8 hours per day). Assistance in the home or in the nursing home is assumed to cover all kinds of support that a disabled person needs (home nurse assistance with medication and other medical care due to diabetes, help with daily necessities, cleaning and personal care, shopping, assistance to leave the home etc.).

On average this leads to an assumption that people with diabetes who do get home assistance due to diabetes on average receive 1 hour and 19 minutes per day or 9 hour per week in assistance or 64% more than the average per receiver in the general population of

assistance in the home. 40% of all people above 65 years old with diabetes is assumed to receive assistance in the home compared to 25 % in the general population above 67 years.

Appliances

Appliances are wheel chairs, sticks (stocks), prostheses (femur and crus). Many other items as suggested by the MTV report (38) such as dogs for blind people at a price of up to 160.000 DKK are not included. Furthermore cost of handicap cars, diabetes education, IT and other electronic equipment such as electronic books for blind people are also omitted.

Due to uncertainty and lack of information of the actual consumption of appliances among people severely hit by diabetes complications we have chosen only to include a few selected appliances listed above. Furthermore, the prices of the items included vary quite substantially. This is primarily due to the many different possible solutions. According to the Danish Catalogue of Disability Appliances (Hjælpemiddelkataloget) prices vary from a few thousands for a simple manual wheel chair to a more advance manual chair at a price of more than 20,000 DKK or to an electric wheel chair at a cost around 50.000 DKK. (37)

We have chosen a conservative estimate of the cost of wheel chair at a price of 14000 DKK to be depreciated over 10 year life time resulting in a yearly cost of 1400 DKK for a wheel chair. Regarding the prostheses the same argument applies. According to experts at the Steno Diabetes Center (36) the cost of a femur prosthesis can vary from 30.000 to 110 000 DKK depending on material and whether a special knee has to be created, and for a crus prosthesis between 25,000 to 30,000 DKK.

No appliances are included for people that have minor complications.

Modifications of cost medication and other costs in the scenarios “Worst”, “Improved” and “Ideal”

For the scenario “Worst” it is assumed that all patient-years are experienced in the complication state 2, i.e. the most severely impaired patients. It is further assumed that during the short life-span with T1D the patients spend 75% of the time in nursing homes and the remaining 25% in hospitals for intensive and terminal care. Accordingly, the time spent in hospital has been assigned a DRG-load corresponding with the load of a 65+-year old patient in complication state 2 under the “Current” scenario. In the “Worst” scenario, no costs have been allocated to insulin treatment, routine control visits and home monitoring. By assumption, all patients in the age group 15-64 years are out of the work force because of their disease.

For the scenario “Improved” the distributions of the patient-years by current age and complication status have been obtained on the basis of best available clinical evidence. Since this scenario invokes costs for improvements in diabetes care, with corresponding additional costs to re-organization of care and more intense medication, we have added 20% globally to hospitalisation costs per patient-year and 100% to costs per patient-year in the category ‘other drugs than insulin and peroral antidiabetic agents’.

Re-organization in the improved scenario

As mentioned above we add 20% to hospitalisation cost reflecting re-organization of diabetes care. The required reorganization of diabetes care involves multiple structural and procedural changes in the healthcare system to move from an acute to a chronic model of care and to adopt a person centred consultation rather than a disease-centred care model. The process for enabling this change depends to a large extent on effective changes in the collaboration of the healthcare sector. Dawn (Dawn stands for Diabetes, Awareness, Wishes and Needs) (15) is a study of the psycho social aspects of diabetes care and is used in the improved scenario to reflect the necessary changes. The DAWN call to action for improved diabetes care is facilitated globally by Novo Nordisk in collaboration IDF (International Diabetes Federation)

The key focus areas for improved diabetes care in the DAWN call to action are:

- Enhance communication between people with the condition and their healthcare professionals
- Improve communication and coordination among all healthcare professional groups
- Promote effective self-management
- Removal of patient and healthcare professional barriers to effective therapy
- Enable improved psychosocial support for people with the condition

Modifications of the “Ideal” scenario

For the scenario “Ideal” it is assumed by definition that all patient-years are experienced in the complication state 0, i.e. with no complications at all. It is assumed that T1D is managed exclusively on an out-patient basis; thus, no added costs related to hospital admissions have been invoked in this scenario. Otherwise, assessment of costs in the “Ideal” scenario is identical with that of the “Improved” scenario.

The ideal scenario is a highly hypothetical scenario because it assumes that a perfect situation can be achieved in principle without any form of additional treatment and medication, thus relying on perfect self management etc. Another form of ideal scenario could take into consideration some form of substitution treatment that could deliver a similar epidemiological situation as described in the ideal scenario but at a cost. Nobody knows what such a treatment would be like or what it might cost, but we have calculated the total cost to society on the basis of the existing cost level per gained QALY. Following the results for type 2 from the Danish Medical Technology Assessment report (16) we have assumed a level fixed at DKK 100,000 per gained QALY. The result of this calculation can be found in section 5.

Assessment of effects

The effect from having T1D is expressed on the basis of numbers of patient-years experienced under the contrasting scenarios.

We have furthermore attempted to perform an adjustment of the patient-years, using a generic (non-disease specific) quality of life (QoL) instrument; the EQ-5D (17). The reason for choosing EQ-5D is that it has been extensively validated in a wide range of countries. This makes it possible to compare data across countries. Yet another reason for choosing the EQ-5D is that the instrument yields an index (in contrast to profiles). This makes it possible to directly generate Quality Adjusted Patient Life Years (QALYs), a measure that makes it possible to include changes in QoL into health economic calculations. This is not possible from profiles as they only present QoL in a number of health dimensions rather than as a single number which is necessary in order to adjust patient-years for quality. Recent work has been made, however, to give preference weights to various dimensions of other health status of instruments like SF-36 (18), which allows for calculation of an index value.

EQ-5D identifies the health-related quality of life of a person on a preference based scale between 0 (death/worst imaginable health state) and 1 (best imaginable health state). Hence, any kind of health state can then be translated into a numerical value between 1 and 0. This number can then be used to adjust the length of a person's life with this health state measure. In practice the number of patient-years or months lived in any given state will be multiplied by the number representing the health state. If a person has a reduced health state, e.g. limited mobility due to a car accident, then the value of this health state may be, e.g., 0.64. The quality adjusted value of five years lived in this state is then $5 \times 0.64 = 3.20$ i.e. each year is valued as 0.64 of the value of 1 year lived with full health.

Specifically EQ-5D operates in five dimensions, *Mobility*, *Personal care*, *Ordinary daily activities*, *Pain/discomfort*, and *Anxiety/depression*. Within each dimension, score 1 means no problems at all while score 3 means severe problems. By means of regression analysis, as suggested by Greiner et al. (17), all possible compound scores have been assigned a value between 0 and 1, indicating lowest possible and maximally possible levels of QoL, respectively.

A group of eight experienced Danish diabetes nurses have translated a number of typical diabetes health states into the descriptive health states as used in the EQ-5D questionnaire. This way, we obtained EQ-5D weights to a number of health states which are typical for diabetes patients.

According to these results we have used the QoL-coefficients of 0.95, 0.85 and 0.65 for patient-years experienced in complication states 0, 1 and 2, respectively, and regardless of age-grouping

Assessment of productive gains

The impact on society can be measured through the productive contributions from the population of patients who are in a condition which allows them to work on equal terms with the rest of the population. The monetary measure of the productive time is based on an average wage rate.

For the present study it is assumed that the population of T1D patients in the age segment 15-64 years and belonging to complication groups 0 and 1 has approximately the same labour employment rate as the rest of the population (75%) (19). Non-employment may be temporary due to unemployment, maternity leave or education, or permanent due to early retirement or invalidity pension.

The basis for calculating the monetary value of gained (or lost) productivity is the average income in 2001. The total wage income for all employed persons in Denmark during 2000 was 5.94 billion DKK and 2.57 mill persons were employees (19) resulting in an average annual wage income of 231,000 DKK/year. As a consequence of the assumption that only 75% of the population in the age group 15-64 years have labour employment we adjust this figure with 75% to reflect the average income level in our study. 75% of this figure is 173,135 DKK/year. As a working year in 2000 was equivalent to 1,693 working hours; this corresponds to a value of 102 DKK per hour or 767 DKK per day.

The figures from year 2000 were updated to 2001 using a 4% rate of increase, based on the increase in income (Statistics Denmark, 2002 and 2003), resulting in 180,060 DKK/year (851 DKK per day).

The gains in production or income due to survival of patients are adjusted due to absence from work caused by hospital admissions and visits to GP and similar out of hospital care both for patients and relatives, as well as income lost to society resulting from productivity reductions during work from the diabetes condition. The study assumes that persons with diabetes in complication group 1 experience 10% lower productivity in 50% of the working time.

These calculations also include the production in households. By not including the production in the household sector into the analysis there is a risk of losing an important element represented by informal care (the care for patients by family members in their home) and the impact from other household based production. The base case assumes a labour market participation rate of 75% among the group (age 15-64) with a potential for participation in market based activities. The 25% of the population who is not engaged in productive market based work is assumed to produce in the home based sector.

Various approaches have been suggested for valuing the home production. One approach is to assume a value equivalent to the opportunity cost of time as seen by the individuals, which is the net wage (wage after tax). Another approach is to value the production by the market value of the home production – what would it cost to buy the corresponding goods and services on the market. There are reasons to believe that the last approach will overestimate the true value (see the discussion section below). Consequently, we have used the first approach and assume that the home production can be valued by the opportunity cost of time by adding approximately 12.5% based on the assumption that the value of non market activities is 50% of the market wage for the 25 % of the population not engaged in market based work. For patients above the age of 64 it is assumed that the value of home production is zero, although the opportunity cost of their time must be assumed to be greater than zero.

Prevention Costs

As described in this report the focus of the study is a one year time window. As a consequence an issue of interpretation may arise if the cost and effect of certain measures take place with a time lag. This leads to a distinction between measures that result in an immediate impact on survival and quality of life (treatment) while other measures result in a reduced number of future complications etc (prevention).

Diabetes management covers exercise, diet and medication and the issue of differentiation between preventive costs and treatment costs is not clear cut. Prevention could be defined as preventing people from going from a state of impaired glucose tolerance to a state of diagnosed diabetes. Alternatively it could be defined as "preventing a person with well

controlled diabetes without complications from getting complications". The distinction is somewhat arbitrary, but we find it essential to take it into consideration in the study. As our study does not consider screening or diagnosis of unknown diabetes patients the second definition is the most relevant for us.

Neither insulin, nor oral antidiabetic agents or other healthcare items in this study can be characterized as prevention. There is no cost included under hospitalisation that is for prevention. Insulin, oral antidiabetic medication and monitoring as well as routine diabetes control are also regarded as treatment. Home monitoring is included as a tool to ensure proper insulin treatment and routine diabetes controls (including visits to eye doctors as well as to other specialist) are important elements in proper treatment. Physiotherapy is included primarily as treatment for people with serious foot problems. The only cost item that can be characterised as prevention in our study is "medication with other drugs". A distinction is made between medication to patients in complication group 2 and to patients in complication groups 0 and 1. Patients in complication group 2 have already had some form of stroke or cardiovascular event and the medication is part of treatment of the event, while among the patients in group 0 and 1 the medication can be characterised as prevention of events that will transfer the patient to complication group 2. To take account of this, costs related to "treatment with other drugs" than insulin and peroral antidiabetic agents for people without complications (in complication group 0 and 1), could be categorised as an investment in prevention.

5. RESULTS

Costs

Tables 5.1, 5.2, 5.3 and 5.4 show the detailed estimates of costs in the four scenarios “Current”, “Worst”, “Improved” and “Ideal”, respectively.

Particularly for the “Current” scenario, key results are summarized below in Fig. 5.1 and Fig. 5.2.

Fig. 5.1a. T1D in Denmark, year 2001. “Current” scenario. Total costs (mill. DKK) for year 2001 by main categories according to age groups

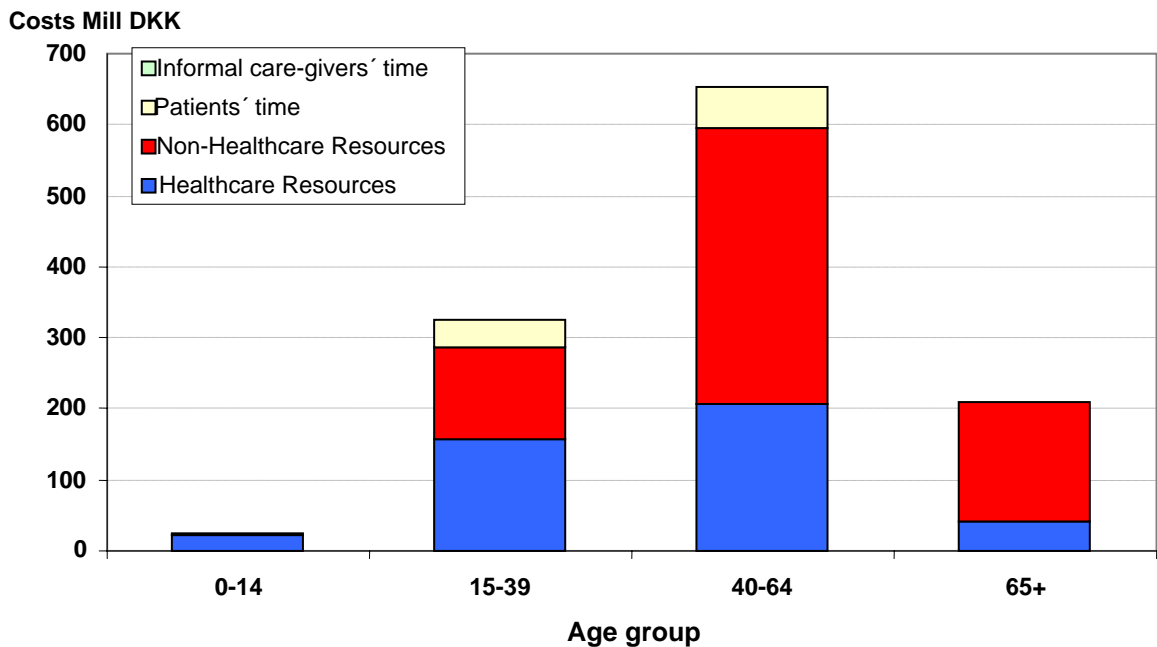


Figure 5.1.a illustrates the four main cost groups used in the analysis. Non healthcare amounts to 57% of the total costs and healthcare to 35% of all costs. In particular non healthcare costs are important among age group 40-65 and 65+ with a share of 60% and 80% respectively while healthcare cost dominates among the young generations.

Fig 5.1b *T1D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) for year 2001 by main cost drivers in healthcare according to age groups*

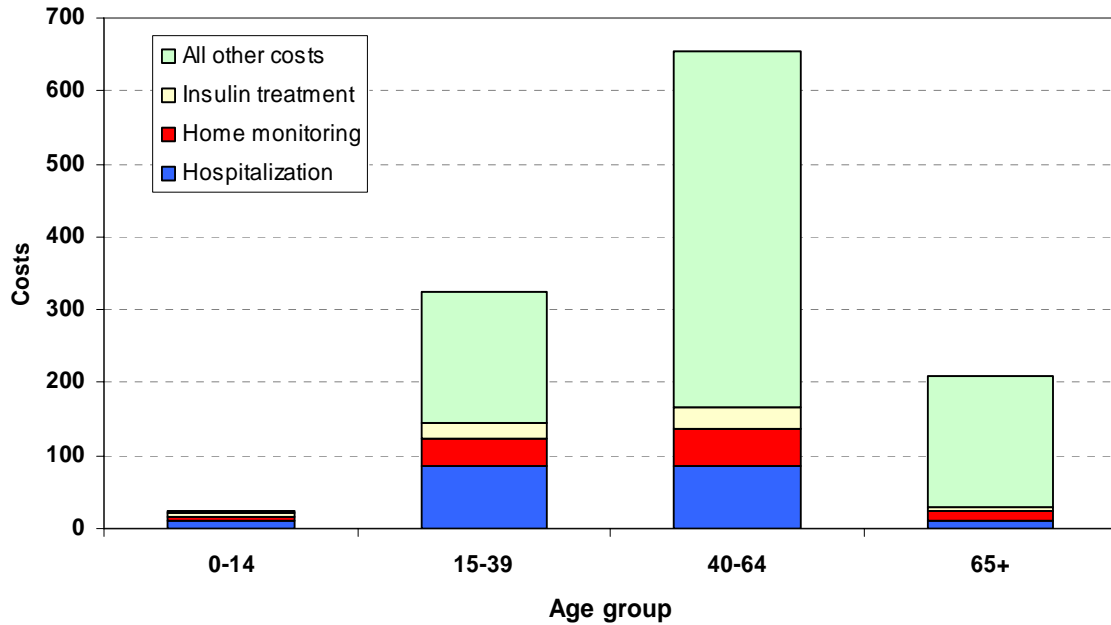


Figure 5.1b focuses in particular on the most important healthcare items. Overall, hospitalisation costs amount to 16% of the total costs, relatively largest for the age group 0-14 years. The main costs driver is represented by “All other costs”, which is dominated by costs for nursing and is relatively largest for the age group 65+ years (Fig. 5.1b).

Fig. 5.2a and b illustrate the same data as in 5.1a and b, but now expressed per patient-year experienced in the calendar year 2001. The costs increase linearly by age, due to increasing nursing costs. It should be noticed that the average cost per patient-year is merely a descriptive statistics, that is, it cannot be inferred from the figures that patient-years are gained due to the costs. Only the marginal or incremental cost as shown in table 5.8 can answer that question.

Fig. 5.2a. T1D in Denmark, year 2001. "Current" scenario. Total costs (DKK) per patient-year by main categories according to age groups

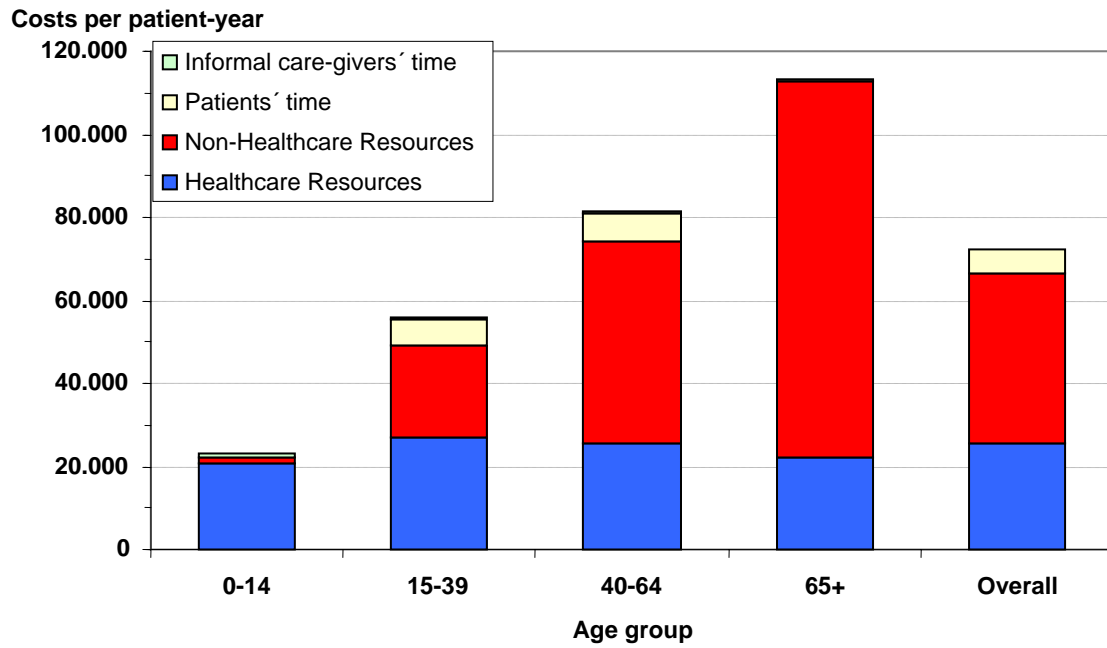


Fig. 5.2b T1D in Denmark, year 2001. “Current” scenario. Total costs (DKK) per patient-year by main cost drivers in healthcare according to age groups

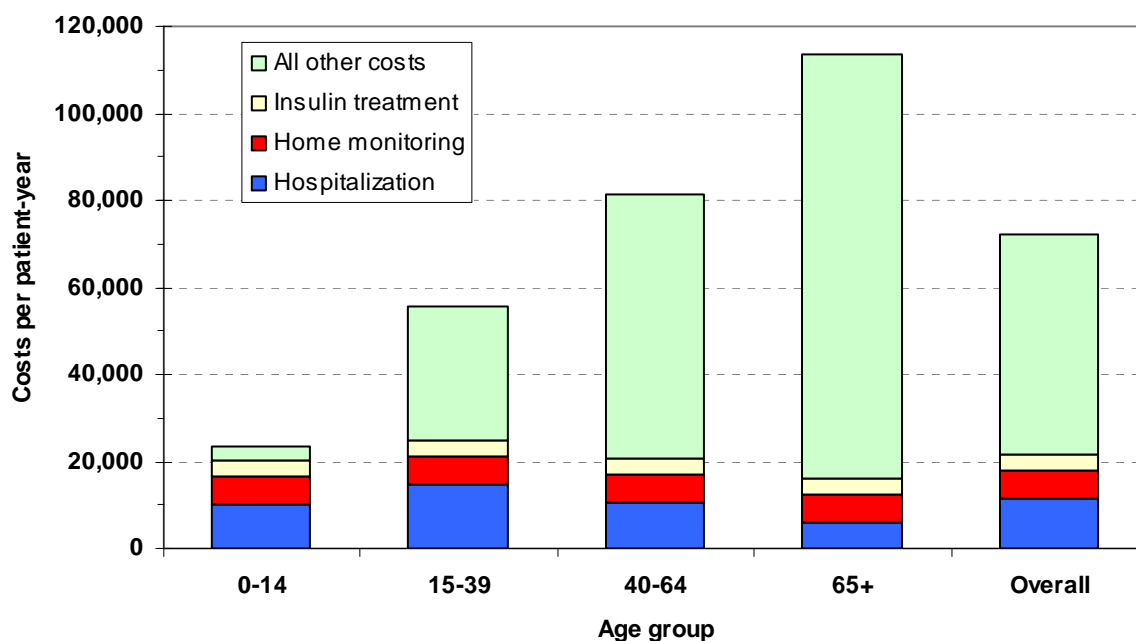
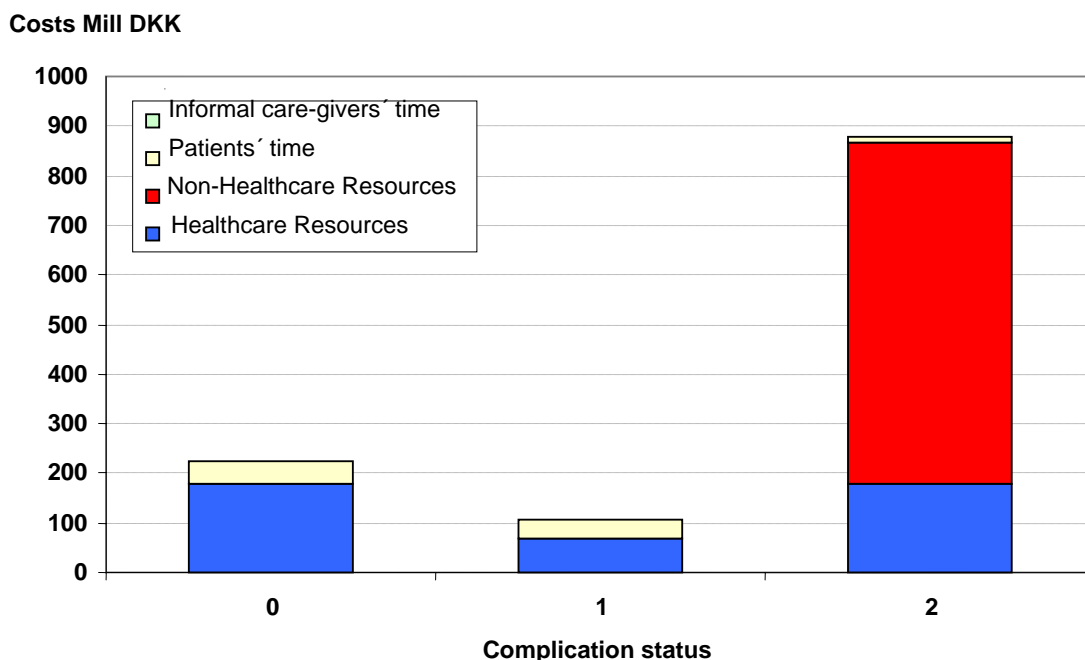


Fig. 5.3a. T1D in Denmark, year 2001. “Current” scenario. Total costs (mill. DKK) for year 2001 by main categories according to complication status



The dominating cost component “non healthcare resources” is concentrated in complication group 2. In complication group 0 and 1 healthcare resources are totally dominating.

Figure 5.3b *T1D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) for year 2001 by main cost drivers in healthcare according to complication status*

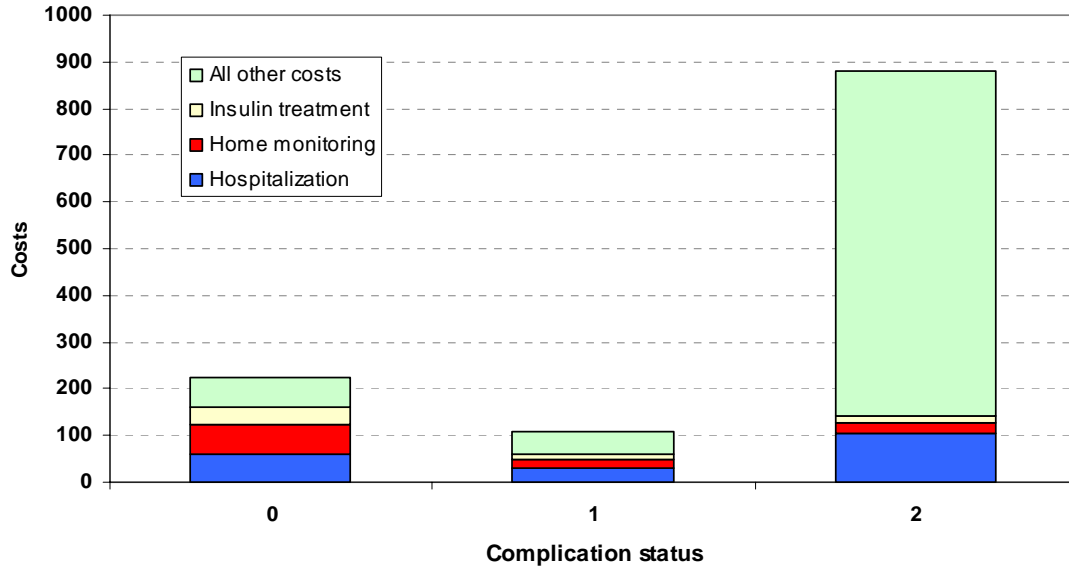


Fig. 5.3a illustrates the total costs by complication status. The patient-years experienced in complication group 2 (with severe impairment) carry the highest cost due to high nursing costs. Fig 5.3b illustrates the dominating role of hospitalisation among healthcare costs types in particular in complication group 2 as illustrated in figure 5.3b. In complication group 0 home monitoring, though, is equally important.

Fig. 5.4 illustrates the same data, but now expressed by costs per patient-year. The large impact of having clinically important complications is underscored. Thus, the cost per patient-year is more than 10 times greater for complication group 2 as compared with complication group 0.

Fig. 5.4. T1D in Denmark, year 2001. "Current" scenario. Total costs (DKK) per patient-year by main categories according to complication status

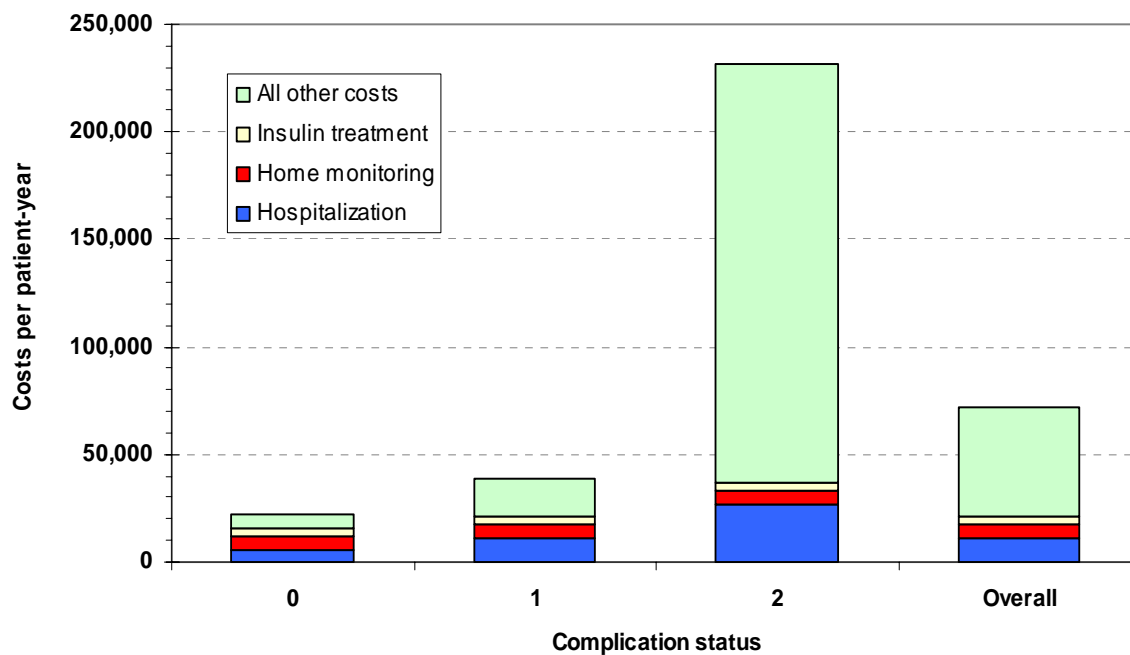


Table 5.1. Details of costs under the scenario "Current". By age group and complication status. All values in mill. DKK

		0 - 14			15 - 39			40 - 64			65+		
		0	1	2	0	1	2	0	1	2	0	1	2
TOTAL	1,211.9	20.0	2.1	1.7	96.8	54.0	174.0	96.9	49.7	507.0	11.2	1.8	196.7
Healthcare Resources	425.8	18.9	1.9	0.6	81.8	33.5	41.7	68.6	29.4	108.2	10.8	1.8	28.8
Added hospitalization costs	192.6	9.0	0.9	0.3	40.5	17.2	28.0	8.9	13.0	63.5	0.0	0.0	11.3
Treatment with insulin	60.4	3.3	0.3	0.1	13.5	4.9	2.6	17.0	4.3	7.8	3.0	0.5	3.2
Treatment with oral antidiabetics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Treatment with other drugs, added costs	32.3	0.0	0.0	0.0	0.9	0.6	2.2	9.0	2.8	11.0	1.9	0.3	3.4
Routine diabetes controls	21.1	0.7	0.1	0.0	2.9	2.1	1.7	3.7	1.8	5.0	0.6	0.2	2.1
Home monitoring	106.7	5.8	0.5	0.1	23.9	8.7	4.6	30.0	7.5	13.7	5.3	0.8	5.7
Physiotherapy	12.8	0.0	0.0	0.0	0.0	0.0	2.5	0.0	0.0	7.3	0.0	0.0	3.0
Non-Healthcare Resources	687.9	0.0	0.0	1.1	0.0	0.0	129.5	0.0	0.0	390.2	0.0	0.0	167.1
Added cost for nursing home	264.6	0.0	0.0	0.0	0.0	0.0	50.8	0.0	0.0	150.7	0.0	0.0	63.1
Annual cost for nursing assistance in the home, full-time	204.9	0.0	0.0	1.1	0.0	0.0	39.2	0.0	0.0	116.1	0.0	0.0	48.6
Annual cost for nursing assistance in the home, part-time	201.8	0.0	0.0	0.0	0.0	0.0	38.8	0.0	0.0	114.9	0.0	0.0	48.1
Wheelchair	2.3	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.8	0.0	0.0	1.3
Stocks	1.9	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	1.1	0.0	0.0	0.5
Protese crus	4.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	2.8	0.0	0.0	2.1
Protese femur	7.5	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	3.9	0.0	0.0	3.5
Shoes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Patients' time	94.8	0.0	0.0	0.0	14.8	20.3	2.7	27.8	20.1	8.2	0.2	0.1	0.6
Transport and child care routine visits	3.7	0.0	0.0	0.0	0.5	0.4	0.3	0.7	0.3	0.9	0.1	0.0	0.4
Transport and child care admissions	2.0	0.0	0.0	0.0	0.3	0.1	0.1	0.5	0.2	0.4	0.1	0.0	0.2
Loss of productivity during routine controls. Absenteism	23.6	0.0	0.0	0.0	4.0	2.9	2.3	5.0	2.5	6.9	0.0	0.0	0.0
Loss of productivity during admissions	40.7	0.0	0.0	0.0	10.0	3.6	0.0	21.6	5.5	0.0	0.0	0.0	0.0
Loss of productivity related to discomfort during work	24.8	0.0	0.0	0.0	0.0	13.3	0.0	0.0	11.5	0.0	0.0	0.0	0.0
Informal care-givers' time	3.4	1.1	0.2	0.1	0.3	0.1	0.1	0.5	0.2	0.4	0.1	0.0	0.2
Transport and child care routine visits	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Transport and child care visits during admissions	2.0	0.0	0.0	0.0	0.3	0.1	0.1	0.5	0.2	0.4	0.1	0.0	0.2
Loss of productivity during routine controls. Absenteism	1.2	1.0	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Production value													
Registered as GDP	1,980.5	0.0	0.0	0.0	675.2	244.7	0.0	848.1	212.5	0.0	0.0	0.0	0.0
Including the informal sector	2,310.6	0.0	0.0	0.0	787.8	285.5	0.0	989.4	247.9	0.0	0.0	0.0	0.0

Table 5.2. Details of costs under the scenario "Worst". By age group and complication status. All values in mill. DKK

		0 - 14			15 - 39			40 - 64			65+		
		0	1	2	0	1	2	0	1	2	0	1	2
TOTAL	232.4			60.2			87.5			67.6			17.0
Healthcare Resources	10.5			2.0			4.2			3.5			0.8
Added hospitalization costs	3.3			0.9			1.2			0.9			0.2
Treatment with insulin	0.0			0.0			0.0			0.0			0.0
Treatment with oral antidiabetics	0.0			0.0			0.0			0.0			0.0
Treatment with other drugs, added costs	3.7			0.2			1.7			1.6			0.3
Routine diabetes controls	0.0			0.0			0.0			0.0			0.0
Home monitoring	0.0			0.0			0.0			0.0			0.0
Physiotherapy	3.5			0.9			1.3			1.0			0.3
Non-Healthcare Resources	218.9			57.8			82.0			63.1			16.0
Added cost for nursing home	218.9			57.8			82.0			63.1			16.0
Annual cost for nursing assistance in the home, full-time	0.0			0.0			0.0			0.0			0.0
Annual cost for nursing assistance in the home, part-time	0.0			0.0			0.0			0.0			0.0
Wheelchair	0.0			0.0			0.0			0.0			0.0
Stocks	0.0			0.0			0.0			0.0			0.0
Protese crus	0.0			0.0			0.0			0.0			0.0
Protese femur	0.0			0.0			0.0			0.0			0.0
Shoes	0.0			0.0			0.0			0.0			0.0
Patients' time	1.3			0.0			0.7			0.5			0.1
Transport and child care routine visits	0.0			0.0			0.0			0.0			0.0
Transport and child care admissions	1.3			0.0			0.7			0.5			0.1
Loss of productivity during routine controls. Absenteism	0.0			0.0			0.0			0.0			0.0
Loss of productivity during admissions	0.0			0.0			0.0			0.0			0.0
Loss of productivity related to discomfort during work	0.0			0.0			0.0			0.0			0.0
Informal care-givers' time	1.7			0.5			0.7			0.5			0.1
Transport and child care routine visits	0.0			0.0			0.0			0.0			0.0
Transport and child care visits during admissions	1.7			0.5			0.7			0.5			0.1
Loss of productivity during routine controls. Absenteism	0.0			0.0			0.0			0.0			0.0
Production value													
Registered as GDP	0.0			0.0			0.0			0.0			0.0
Including the informal sector	0.0			0.0			0.0			0.0			0.0

Table 5.3. Details of costs under the scenario "Improved". By age group and complication status. All values in mill. DKK

		0 - 14			15 - 39			40 - 64			65+		
		0	1	2	0	1	2	0	1	2	0	1	2
TOTAL	955.1	23.1	1.3	0.5	142.2	22.9	101.4	122.0	47.7	307.4	17.0	1.8	167.8
Healthcare Resources	427.2	21.9	1.2	0.2	122.2	15.3	28.4	85.8	30.5	75.6	16.4	1.7	27.9
Added hospitalization costs	185.5	11.5	0.6	0.1	64.8	7.6	18.6	13.6	13.2	44.3	0.0	0.0	11.3
Treatment with insulin	62.4	3.5	0.2	0.0	18.0	1.8	1.4	21.7	3.6	4.5	4.5	0.4	2.7
Treatment with oral antidiabetics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Treatment with other drugs, added costs	42.5	0.0	0.0	0.0	3.6	2.0	3.6	7.6	5.8	11.6	3.0	0.5	4.9
Routine diabetes controls	18.5	0.8	0.1	0.0	3.9	0.8	0.9	4.7	1.6	2.9	1.0	0.2	1.8
Home monitoring	110.1	6.2	0.3	0.0	31.9	3.2	2.5	38.2	6.4	8.0	8.0	0.7	4.8
Physiotherapy	8.1	0.0	0.0	0.0	0.0	0.0	1.4	0.0	0.0	4.2	0.0	0.0	2.5
Non-Healthcare Resources	437.8	0.0	0.0	0.3	0.0	0.0	71.4	0.0	0.0	226.9	0.0	0.0	139.3
Added cost for nursing home	168.2	0.0	0.0	0.0	0.0	0.0	28.0	0.0	0.0	87.6	0.0	0.0	52.6
Annual cost for nursing assistance in the home, full-time	129.9	0.0	0.0	0.3	0.0	0.0	21.6	0.0	0.0	67.5	0.0	0.0	40.5
Annual cost for nursing assistance in the home, part-time	128.3	0.0	0.0	0.0	0.0	0.0	21.4	0.0	0.0	66.8	0.0	0.0	40.1
Wheelchair	1.6	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.4	0.0	0.0	1.1
Stocks	1.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.6	0.0	0.0	0.4
Protese crus	3.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.6	0.0	0.0	1.8
Protese femur	5.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.3	0.0	0.0	2.9
Shoes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Patients' time	86.8	0.0	0.0	0.0	19.7	7.5	1.5	35.5	17.0	4.8	0.4	0.7	0.5
Transport and child care routine visits	3.2	0.0	0.0	0.0	0.7	0.1	0.2	0.9	0.3	0.5	0.2	0.0	0.3
Transport and child care admissions	1.9	0.0	0.0	0.0	0.4	0.1	0.1	0.7	0.1	0.2	0.2	0.0	0.2
Loss of productivity during routine controls. Absenteism	20.2	0.0	0.0	0.0	5.3	1.1	1.3	6.4	2.1	4.0	0.0	0.0	0.0
Loss of productivity during admissions	46.9	0.0	0.0	0.0	13.3	1.3	0.0	27.6	4.7	0.0	0.0	0.0	0.0
Loss of productivity related to discomfort during work	14.7	0.0	0.0	0.0	0.0	4.9	0.0	0.0	9.8	0.0	0.0	0.0	0.0
Informal care-givers' time	3.2	1.2	0.1	0.0	0.4	0.1	0.1	0.7	0.1	0.2	0.2	0.0	0.2
Transport and child care routine visits	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Transport and child care Visits during admissions	1.9	0.0	0.0	0.0	0.4	0.1	0.1	0.7	0.1	0.2	0.2	0.0	0.2
Loss of productivity during routine controls. Absenteism	1.2	1.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Production value													
Registered as GDP	2,250.7	0.0	0.0	0.0	900.3	90.0	0.0	1,080.4	180.1	0.0	0.0	0.0	0.0
Including the informal sector	2,625.9	0.0	0.0	0.0	1,050.3	105.0	0.0	1,260.4	210.1	0.0	0.0	0.0	0.0

Table 5.4. Details of costs under the scenario "Ideal". By age group and complication status. All values in mill. DKK

		0 - 14			15 - 39			40 - 64			65+		
		0	1	2	0	1	2	0	1	2	0	1	2
TOTAL	238.4	14.8			102.4	0.0	0.0	93.6			27.6		
Healthcare Resources	215.1	13.3			91.5			83.4			26.9		
Added hospitalization costs	0.0	0.0			0.0			0.0			0.0		
Treatment with insulin	72.1	4.5			30.7			28.0			9.0		
Treatment with oral antidiabetics	0.0	0.0			0.0			0.0			0.0		
Treatment with other drugs, added costs	0.0	0.0			0.0			0.0			0.0		
Routine diabetes controls	15.6	1.0			6.6			6.0			2.0		
Home monitoring	127.3	7.9			54.2			49.4			15.9		
Physiotherapy	0.0	0.0			0.0			0.0			0.0		
Non-Healthcare Resources	0.0	0.0			0.0			0.0			0.0		
Added cost for nursing home	0.0	0.0			0.0			0.0			0.0		
Annual cost for nursing assistance in the home, full-time	0.0	0.0			0.0			0.0			0.0		
Annual cost for nursing assistance in the home, part-time	0.0	0.0			0.0			0.0			0.0		
Wheelchair	0.0	0.0			0.0			0.0			0.0		
Stocks	0.0	0.0			0.0			0.0			0.0		
Protese crus	0.0	0.0			0.0			0.0			0.0		
Protese femur	0.0	0.0			0.0			0.0			0.0		
Shoes	0.0	0.0			0.0			0.0			0.0		
Patients' time	21.8	0.0			10.9			10.2			0.7		
Transport and child care routine visits	2.7	0.0			1.2			1.1			0.4		
Transport and child care admissions	1.8	0.0			0.6			0.9			0.4		
Loss of productivity during routine controls. Absenteism	17.3	0.0			9.0			8.2			0.0		
Loss of productivity during admissions	0.0	0.0			0.0			0.0			0.0		
Loss of productivity related to discomfort during work	0.0	0.0			0.0			0.0			0.0		
Informal care-givers' time	1.5	1.5			0.0			0.0			0.0		
Transport and child care routine visits	0.2	0.2			0.0			0.0			0.0		
Transport and child care Visits during admissions	0.0	0.0			0.0			0.0			0.0		
Loss of productivity during routine controls. Absenteism	1.3	1.3			0.0			0.0			0.0		
Production value													
Registered as GDP	2,926.3	0.0			1,530.9			1,395.5			0.0		
Including the informal sector	3,414.1	0.0			1,786.0			1,628.0			0.0		

A summary of costs is presented in Table 5.5. The costs in the “Current” scenario are much higher than the estimated costs in the “Worst” scenario, i.e. the hypothetical situation without access to insulin treatment. Also, the costs in the “Improved” scenario are somewhat higher than in the “Current” scenario. On the other hand, the costs in the “Ideal” scenario are substantially lower than the estimated costs in the “Current” scenario.

Table 5.5. Summary of costs of treating T1D in the contrasting scenarios

	Scenario			
	“Current”	“Worst”	“Improved”	“Ideal”
Healthcare resources, mill. DKK	426	11	427	215
Non-Healthcare resources, mill. DKK	688	219	438	0
Patients’ time, mill. DKK	95	1	87	22
Informal care-givers’ time, mill. DKK	3	2	3	1
Total costs, mill. DKK	1,212	232	955	238

Effects

Table 5.6 summarizes the estimated numbers of patient-years and QALYs, as well as the production value) in each of the scenarios entertained.

Table 5.6. Summary of patient-years and income by working in the contrasting scenarios

	Scenario			
	“Current”	“Worst”	“Improved”	“Ideal”
Effects				
Patient-years, un-adjusted	16,744	1,041	17,286	19,987
Quality adjusted patient-years (QALYs)	14,843	677	15,524	18,988
Production value				
Registered as GDP, mill. DKK	1,980	0	2,251	2,926
Including the informal sector, mill. DKK	2,311	0	2,626	3,414

The striking feature is that many more patient-years are estimated for the “Current” scenario as compared with the “Worst” scenario (Figure 5.6). This is accompanied by a substantial productivity in the “Current” scenario against zero (0) productivity in the “Worst” scenario. (Figure 5.5) The number of patient-years, QALYs and the productivity are only marginally better in the “Improved” scenario as compared with the “Current” scenario. It is also noteworthy that in the “Ideal” scenario (assuming T1D diabetes is a disease without any specific complications, assumed treated as in the “Improved” scenario) considerable at more patient-years – with accompanying higher productivity – would be experienced.

Figure 5.5 Total cost and production value in scenarios

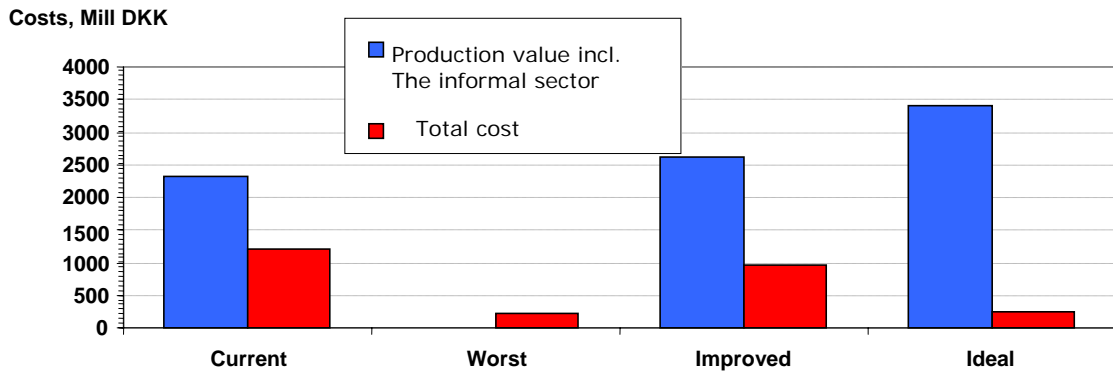
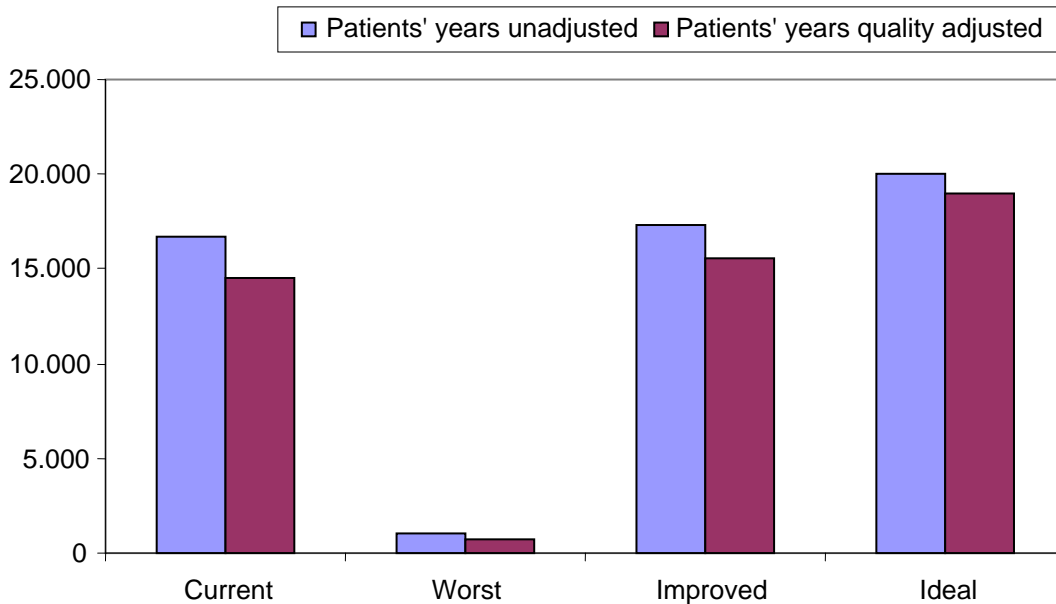


Figure 5.6 Total patient-years and quality adjusted years in scenarios.



Health economics assessment

The estimated costs and effects, as reviewed above, have been summarized in a simple health economics evaluation as shown in table 5.7. Each of the hypothetical scenarios “Worst”, “Improved” and “Ideal” has been contrasted with the “Current” scenario in terms of differences.

Table 5.7. Summary results. All costs are in mill. DKK

Socioeconomic gains:	"Current" versus "Worst"	"Improved" versus "Current"	"Ideal" versus "Current"
Costs, total	980	-257	-974
Healthcare Resources	415	1	-211
Non-Healthcare Resources	469	-250	-688
Patients' time	94	-8	-73
Informal care-givers' time	2	0	-2
Production value			
Registered as GDP	1,980	270	946
Including the informal sector	2,311	315	1,103
Patient-years			
Patient-years, un-adjusted	15,703	542	3,243
QALYs	13,817	1,041	4,494

It is evident that the increased costs for the "Current" scenario, as compared with the "Worst" scenario, must be seen against a substantial gain in patient-years and QALYs. Most of all, the productivity gain is more than twice the amount of increased costs.

Under the assumptions specified, it may seem surprising that the gains in patient-years, QALYs and productivity, respectively, are relatively modest in the scenario "Improved" when considered the additional healthcare resources needed to accomplish these gains compared to the "Current".

The difference between the "Current" scenario and the "Ideal" scenario may be viewed as the potential further gains that might be expected, should improved and care of diabetes reach perfection. According to the estimates, a much lower level of costs would yield a substantial further gain in patient-years and accompanying productivity

The final stage of the health economics assessment is summarized in table 5.8, showing the net benefits and cost-effectiveness and cost-utility ratios when contrasting the "Current" scenario with each of the alternative scenarios. Note that the benefits, hence also the net benefits, have been estimated at two levels, depending on whether or not the estimated production value has included the contribution from the informal sector. Note also that, by convention a negative sign before an estimated ratio actually indicates a positive gain.

Table 5.8. Health economic evaluation. Various scenarios compared.

<i>Key evaluation figures</i>	"Current" versus "Worst"	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefit gains (production value - costs)			
Production value registered as GDP: Mill DKK	1.001	527	1.919
Production value including the informal sector : Mill DKK	1.331	572	2.077
Marginal cost effectiveness ratio:			
DKK/patient-year	62.379	-473.926	-300.207
Marginal cost utility ratio:			
DKK/QALY	70.895	-246.822	-216.626

As described in the methodology report (4) and discussed in the discussion section none of these ratios take into consideration the issue of increased consumption as a derived effect of an improved health outcome.

Net benefits of the “Current” scenario as compared to the “Worst” scenario, based on only productive gains, is $(2,311 - 0) - (1,212 - 232) = 1,331$ mill. DKK when the production value includes the contribution from the informal sector. This implies that benefits are measured in terms of productive gains only, disregarding the value of life per se. Without the contribution from the informal sector, the net benefit decreases to 1,001 mill DKK. When the “Improved” scenario is compared to the “Current” scenario, the net benefits are 572 and 527 mill. DKK, respectively, with and without the contribution from the informal sector. Finally, when the “Ideal” scenario is compared to the “Current” scenario, the net benefits in productive gains are 2,077 and 1,919 mill. DKK, respectively, for the two ways of assessing the production value.

The marginal cost-effectiveness ratios are calculated as cost per added patient-year. Total cost per gained patient-year is 62,379 DKK and 70,895 DKK per gained QALY in the current versus the worst scenario. The cost-effectiveness ratios are positive when contrasting the “Worst” scenario with the “Current” scenario, implying that the gains in patient-years is associated with increased costs. To the extent that the production value exceeds increased consumption, the net cost to society of diabetes treatment will be lower than the reported costs. Hence, the reported costs per health gain should be seen as conservative figures. In the literature willingness-to-pay for a QALY is reported as lying in the broad range of 90.000 DKK to 4 million DKK (1, 2) suggesting that the current resource allocation to diabetes treatment is beneficial to society.

When contrasting each of the improved and ideal scenarios with the “Current” scenario the cost-effectiveness ratios are negative, implying cost reductions as well as gains in patient-years. Finally, the cost-utility ratios show the added costs of obtaining added quality adjusted patient-years in current treatment compared to the “Worst” case while the “Improved” and “Ideal” context means reduction in costs at the same time as quality-adjusted patient-years are gained..

Prevention costs

As described earlier in this report the focus of the study is a one year time window. As a consequence an issue of interpretation may arise if the cost and effect of certain measures takes place with a time lag. This leads to a distinction between measures that result in an immediate impact on survival and quality of life (treatment) while another part of the measures results in a reduced number of future complications etc (prevention).

To investigate the impact of an investment in prevention on the result an additional analysis is made. Discounting is made to take account of the time lag between the year of investment and the year of impact. Thus it is assumed that the share of annual costs of diabetes that can be regarded as an investment took place 20 years before the year of impact for T1D. As a consequence of the static character of the analysis the calculation do not included an accumulation of the investment costs. A discount rate of 5% p.a. is applied. The calculation assumes that the costs in earlier years are the same as in year 2001.

Thus the investment in prevention cost is increased with a factor 2.65 for patients with T1D $(1+0.05)^{20} = 2.6532$

Based on the costs included for ”treatment with other medication” this leads to a total prevention cost of DKK mill 21 in the current scenario and DKK mill 60 in the improved scenario or DKK mill 13 and 37 in addition to the prevention costs included in the base case. This amounts to an increase in the total healthcare costs of 3% in the current scenario and 9% in the improved scenario. Of the total costs this amounts to 1% and 4 % respectively.

Alternative considerations in relation to the Ideal Scenario

The ideal scenario is based on the assumption that an ideal situation is achieved for clinical outcomes with levels of treatment and care as specified in the “Improved” scenario. Thus, the “Ideal” scenario represents an outer limit for what maximum socio economic gains that could be reached under these circumstances. The savings associated with such a scenario are remarkable (DKK 974 Bill on the cost side and DKK 1.919 Bill in net benefits if the productivity effects are included) when a comparison is made to the current scenario. If only savings in *healthcare* costs are taken into account the savings are DKK 0.2 Bill. Thus the majority of the savings are savings in non-health care costs associated with complications.

It may be difficult to imagine how such a perfect situation could be brought about without some form of costly treatment not known to us today. Alternatively, a sophisticated form of treatment leading to an elimination of the complications and reduced quality of life associated with the current disease patterns could be assumed. The question to be asked is

then how much this future treatment may cost when taking into account the associated resource savings and the health care effects attained in the ideal scenario. The gains in the “Ideal” scenario relative to the current scenario amounts 4,494 QALYs and in term of resources spent to some 974 million DKK. This is equivalent to savings of 216,700 DKK per QALY gained Hence, for the new intervention to be cost neutral for the health care sector the cost of the new intervention may be as high as 216,700 DKK per QALY gained. If we allow future treatments to generate costs and accept a cost-effectiveness ratio of 70.895 DKK per QALY (equivalent to that of the current scenario when it is compared to the worst scenario), this would mean that the new intervention may cost in the range of 300,000 DKK per QALY. This corresponds to a 10 doubling of the current health care investment per QALY gained when comparing the current with the worst case scenario (426 million DKK-11 million DKK)/(14,493 person years-677 person years=30,061). This estimate should be judged as being conservative since it ignores the productivity gains assuming that such health care measures lead to the elimination of all non-healthcare costs associated with the current disease pattern.

Following the measures for type 2 discussed in the Danish Medical Technology Assessment report (16) two cost estimates are presented on the basis of international studies. Even if these cost estimates relate to Type 2 Diabetes we use them as examples of cost levels for sophisticated treatment. International studies indicate that intensive poly-pharmacological blood glucose treatment costs DKK 100,000 per gained QALY and intensive poly-pharmacological blood pressure treatment DKK 10,000 per gained patient-year. A prerequisite for these figures is that complications are avoided just as we have assumed in the “Ideal” scenario, but at the moment no firm evidence of such an outcome exist. We use these figures (DKK 10,000 per gained patient-year for intensive poly-pharmacological blood pressure treatment in addition to the other healthcare cost in the ideal scenario and 100,000 pr QALY for intensive poly-pharmacological blood glucose treatment substitution the healthcare cost of the ideal scenario) to make estimate of alternative levels of cost in an ideal scenario for type 1. The total socio economic cost derived from using these estimates range between DKK 0,03 Bill (10,000 * 3,243 gained patient-years plus healthcare costs in the ideal scenario DKK 215 Mill) and 0,5 Bill (DKK 100,000* 4,733 gained QALYs) of which healthcare cost account for between 91%-95% of the total cost estimate. This should be compared to the total cost level in the ideal scenario of DKK 238 million DKK of which healthcare costs amount to 90%. The savings compared to the total cost level in the current scenario of DKK 1.2 Bill (of which 35% is healthcare costs) then range between DKK 0.7 Bill (DKK 1.2 – 0.5 Bill) and 0.9 Bill (DKK 1.2 – 0.3 Bill). This leads to the conclusion that the results reached in the ideal scenario are relatively robust and that there are potential socio-economic savings to be found even from a rather expensive form of ideal treatment.

6. DISCUSSION

The study design

This study is presented as a health economic analysis of the standard types of evaluation - cost-effectiveness analysis, cost-utility analysis or cost-benefit analysis, although we have some reservations: First, the comparison of the present situation to a worst case scenario involves a rather big change whilst most economic evaluations - are made for smaller changes. The results show a rather substantial increase in patient-years as well as production gains. It is conceivable that as a consequence, some adjustments will take place at a macro level in the society, but any conclusion would be rather speculative. Second, the “worst case” scenario is somewhat artificial, at least in the context of a developed country.

Some of the controversial issues related to either of the standard types of evaluation are relevant to our study, and therefore some of these are discussed in the following.

Cost structure and valuation

To obtain cost estimates of the various medications and appliances used by patients and healthcare providers in treatment we have gathered data from companies like Life scan selling appliances for blood glucose monitoring. Such data are based on the companies' assessment of the yearly consumption for instance of strips for blood glucose monitoring. We have critically investigated the figures and when necessary amended the level of consumption to a level that we find realistic.

A major effect of treatment of T1D patients with insulin is gain in patient-years. Derived effect may be increased productivity and costs in terms of use of time by informal caregivers. These issues are discussed in Report number 1 (4).

Productivity gains and losses

A major effect of treatment of T1D patients with insulin is gain in patient-years. A derived effect may be a cost in terms of use of time by informal care-givers. It is generally accepted that individuals' time - whether work time or leisure time, or used in paid work or non-paid work - has an opportunity cost. Still, practical details on how to account for these costs in economic evaluations are controversial (22).

Until recently, the value of forgone time was termed indirect costs - a term that was derived from cost-of-illness tradition which has no connotation to economic evaluation. Moreover, the term caused some confusion as it is also used in the accounting literature to mean something different. Consequently, the term “productivity costs” has been coined to denote the value of time forgone.

Literature on methods on economic evaluations in healthcare, e.g. Drummond et al (10), recommends the inclusion of productivity costs and gains when the societal perspective is used. The approach is controversial, however, when applied to cost-effectiveness analysis where a calculation is made of the net cost per unit of outcome, measured in physical terms. It has been argued by (23) that as outcome measures in health economic evaluations is a health category, the opportunity cost of gained health is health forgone, not

consumption. In response, Koopmanshap and Rutten (25) have argued that budgets are arbitrary divisions in the allocation of resources, so productivity changes should be included. At this point of time, the issue seems unsettled.

A related argument concerns inclusion of productivity gains or costs in cost-utility analyses. When calculating the QALYs gained we move from a traditional welfare economic approach, based on individual utility maximization, to a so-called extra “welfarist” approach (26) where the implicit or explicit aim is to maximize the number of QALYs gained in a population. If we follow this route and focus more on aggregate health in society rather than individual utility, the productivity costs or gains can be seen as non-health effects. As the maximand— is health gains under the extra welfarist approach, one may argue that there is no place for productivity costs or gains in health economic evaluations. This point of view has been challenged in the literature, however, (22).

It should be stressed again that the current population of patients with T1D in Denmark has obtained its size and age composition as a consequence of access to insulin treatment during many decades following the introduction of insulin in the early 1920’s. Therefore, a comparison of patient-years experienced under the contrasting scenarios mentioned reflects the cumulative effect of access to insulin treatment over previous decades and cannot be interpreted as an isolated effect of insulin treatment during the year 2001.

Derived consumption

Another derived effect from increased number of patient-years is the added consumption that these patients have. The value to the rest of the society of a given intervention for a group of patients is the production value minus consumption. The issue is discussed in the methodology report (4). Due to lack of data we have abstained from making analyses thereof.

7. CONCLUSION

Under the assumptions specified our study has demonstrated that from a societal point of view it is costly to treat T1D in Denmark, but that the high costs is associated with a significant number of increased patient-years and quality of patient-years and, in particular, a gain in productivity (income by working), as compared with the hypothetical situation where insulin treatment would not have been available. To the extent that production value exceeds increased consumption, the net cost to society of diabetes treatment will be considerably lower than the reported costs. Hence, the reported costs per health gain should be seen as conservative figures. Total cost per gained patient-year is 62,379 DKK and 70,895 DKK per gained QALY in the current versus the worst scenario. In the literature willingness-to-pay for a QALY is reported as lying in the broad range of 90.000 DKK to 4 million DKK (1, 2) suggesting that the current resource allocation to diabetes treatment is beneficial to society.

Our study also suggests that there is a further potential gain in patient-years and productivity, at lower total costs (lower non-health care costs), with improved diabetes care (“the improved scenario”). Considerable gains and reduction in costs would be observed under the hypothetical assumption of “the Ideal scenario” that improved care eliminates complications, co-morbidity and premature mortality in T1D.

ANNEX 1: The demographic evolution of Type 1 diabetes in Denmark

There is no registration system in Denmark covering the population of patients with Type 1 diabetes (T1D). This makes it necessary to establish modelled populations from which may be obtained the needed estimates of numbers of patient-years experienced in Denmark during the calendar year 2001 under the scenarios specified before. Such modelled populations may be established when applying the basic principle:

$$\text{Prevalence}_{\text{end of a year}} = \text{Prevalence}_{\text{end of the year before}} + \text{incidence}_{\text{during the year}} - \text{deaths}_{\text{during the year}}$$

Accordingly, the prevalence population may be established by successive annual addition of new (incident) cases and subtraction of deaths. This approach requires assumed incidence and mortality rates, together with background demographic data for each of the calendar years covered by the total period to be modelled.

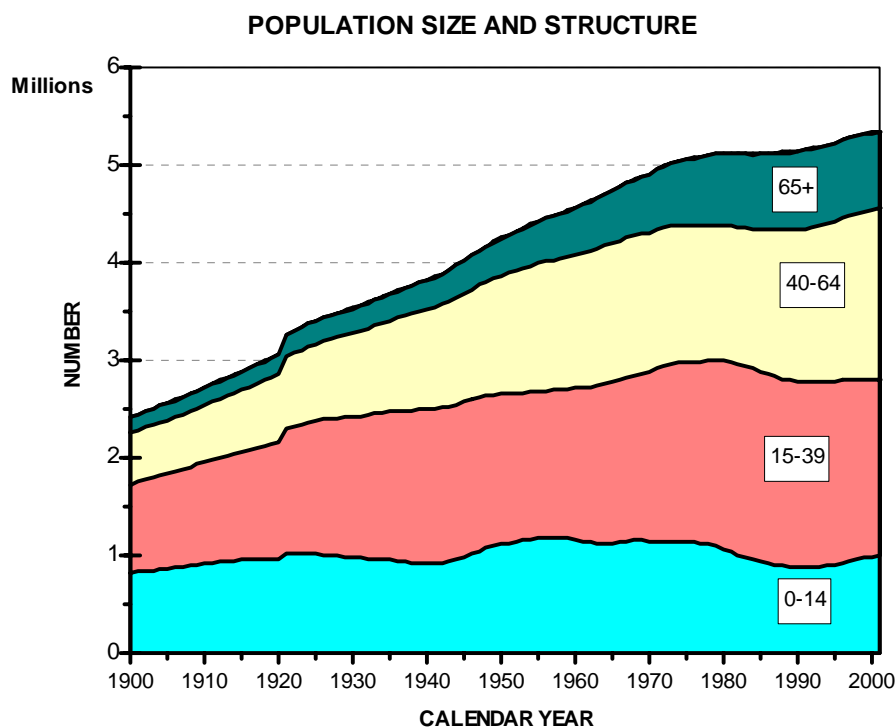
For the present purpose a model of T1D in Denmark has been developed, covering the period from year 1900 through year 2001. The following categorization of age has been used: 0-14 yrs.; 15-39 yrs.; 40-64 yrs.; 65+ yrs. No attempts have been made to distinguish between males and females.

Demography of the Danish population 1900-2001

Denmark has a longstanding tradition for enumeration of the population. Previously, the data were based on total population censuses carried out at intervals of five years. Since the establishment of the unique and totally comprehensive Central Person Registration system in the late 1960's, data on the population size, structure and movements are published annually. Based on the registration of deaths, also mortality statistics are available, including life tables and estimates of remaining years of life for given current age level and for given calendar year.

Fig. A1.1 below shows the trend in the size and age composition of the Danish population since 1900, as summarized from data published by Danmarks Statistik (21). The most prominent feature is a steadily increasing population size until about 1975, followed by a stable size until about 1990. The increase in population size is most of all seen in the adult population whereas the population of children has been rather stable during the whole period. It should be noted that the rather steep sudden increase in population size in the beginning of the 1920's reflects the reclaim of the part of Southern Jutland (Nordslesvig) from German territory.

Fig. A1.1. The Danish population 1900-2001



Estimation of incidence

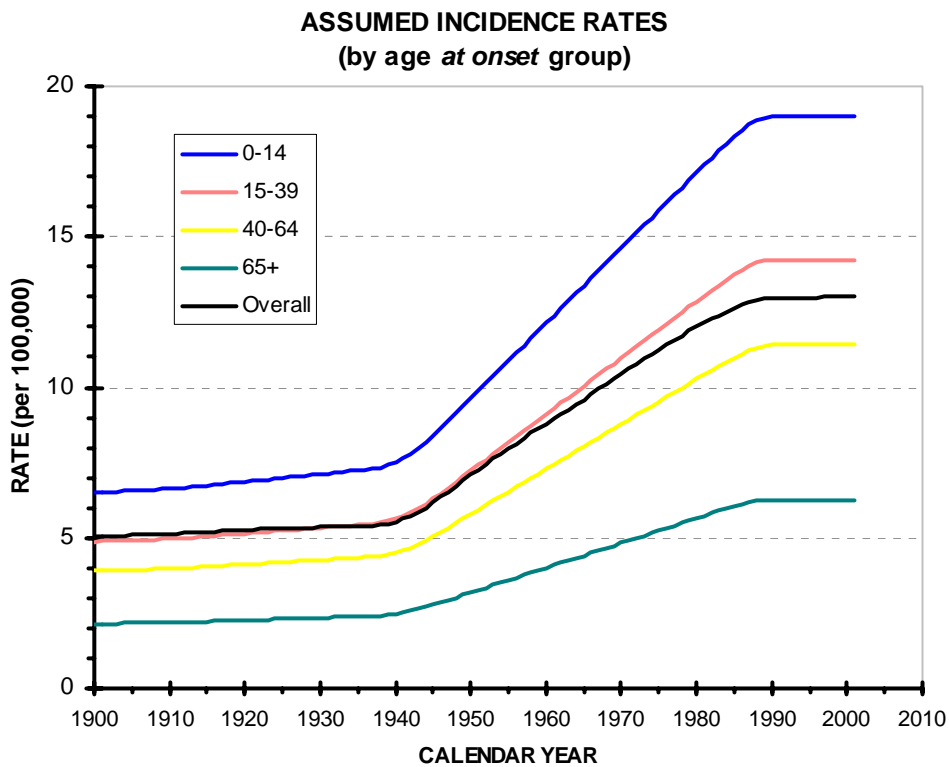
It has been established that the incidence of T1D, at least concerning childhood onset disease, exhibits secular trends in Denmark like in many other countries. Before the introduction of insulin for treatment of the disease, life expectancy of the patients was very short. Therefore, deaths among patients with T1D would to a large extent reflect the incidence of the disease. Based on death registrations in Denmark immediately before the introduction of insulin, the results presented by Heiberg & Heiberg (1924) (26) indicate that the incidence of Type 1 diabetes must have been several folds less than the current level. Other studies have demonstrated that the incidence of childhood onset T1D rose steadily from the early 1950's until about 1990 (27) whereas the incidence thereafter has levelled off if not stabilized at a level corresponding with 16-18 new cases per 100,000 children annually (28, 29). Therefore, it seems realistic to assume the secular trend in the incidence of Type 1 diabetes among children aged 0-14 as shown in Fig. A1.2 (blue line).

It is generally believed that even though T1D may be present at any age, the peak incidence is around puberty. Accordingly, the incidence in the age groups 15+ years is lower than in childhood. In accordance with the results of a Danish study (30) the incidence rates for the age groups 15-39, 40-64 and 65+ years have been scaled relative to the known (or assumed) value for the age group 0-14 years:

	AGE AT ONSET (yrs.)			
	0-14	15-39	40-64	65+
Scaling of incidence	1	3/4	3/5	1/3

The resulting assumed incidence rates for the age groups 0-14, 15-39, 40-64 and 65+ during the period 1900-2020 are shown, together with the overall (un-adjusted) rate, in Fig. A1.2. Applying these rates to the age-grouped data for population size produces for each calendar year the absolute number of new cases of T1D for each year.

Fig. A1.2. Assumed trends in incidence rates of Type 1 diabetes in Denmark, 1900-2001, by major age-at-onset groups



Estimation of mortality

It is difficult to get access to reliable mortality rates in T1D because official mortality statistics only publish numbers of deaths judged to be caused by the disease, thereby missing deaths among patients with the disease but classified as dead due to other causes than T1D itself. Alternatively, estimates of remaining life expectancies from the time of diagnosis of T1D may be used to obtain mortality rates, due to the close inverse relationship between mortality and mean duration of the disease: The mortality rate expresses the number of deaths per patient-year experienced and the inverse expression (the number of patient-years to be experienced before one death occurs) reflects the mean life expectancy from time of diagnosis for a chronic and in-curable disease like T1D. Accordingly, in the present context mortality rates, specific for age-at-onset groups, have been derived from estimated values of the number of years, a patient on average lives from time of diagnosis.

It has been estimated in Danish mortality studies (31) that in the 1970's and 1980's newly diagnosed cases with onset in the age groups 0-14, 15-39, 40-64 and 65+ years had survival times at about 45-50, 35-40, 20-22 and 5-9 years, respectively. On the other hand, the average life expectancy (regardless of age at onset) must have been very short before insulin became available, and is in the present estimation assumed to take the value 1.5 years (regardless of age at onset).

To establish a method that allows for realistic changes in life expectancy for patients with T1D, from the pre-insulin era up to the current times, an adjustment parameter has been incorporated. The principle is to take the estimated remaining life time for the general Danish population (as available for the calendar years from year 1900) within each age at onset class (0-14; 15-39, 40-64, 65+ yrs.) and then to adjust these estimates with an appropriate coefficient in order to model the remaining life time for patients with T1D within these age at onset categories. Finally, these estimated values of disease durations for each age at onset category have been converted to age-at-onset specific mortality rates (by taking the respective reciprocal values) and applied to the prevalence population referring to the calendar year given.

First, until the year 1922, the remaining expected disease duration from diagnosis for patients with T1D has been fixed at 1.5 years for all age at onset categories, corresponding with a global mortality rate at 66.7 deaths per 100 patient-years.

Second, from year 1922 and onwards the estimated duration for the general population for a given age at onset category has been multiplied with a coefficient, k_t (where t refers to the calendar year t , $t > 1921$). The coefficient k_t has been derived on pure arbitrary grounds from the formula

$$k_t = k_{t-1} + (0.2109/(\text{year}_t - 1921)).$$

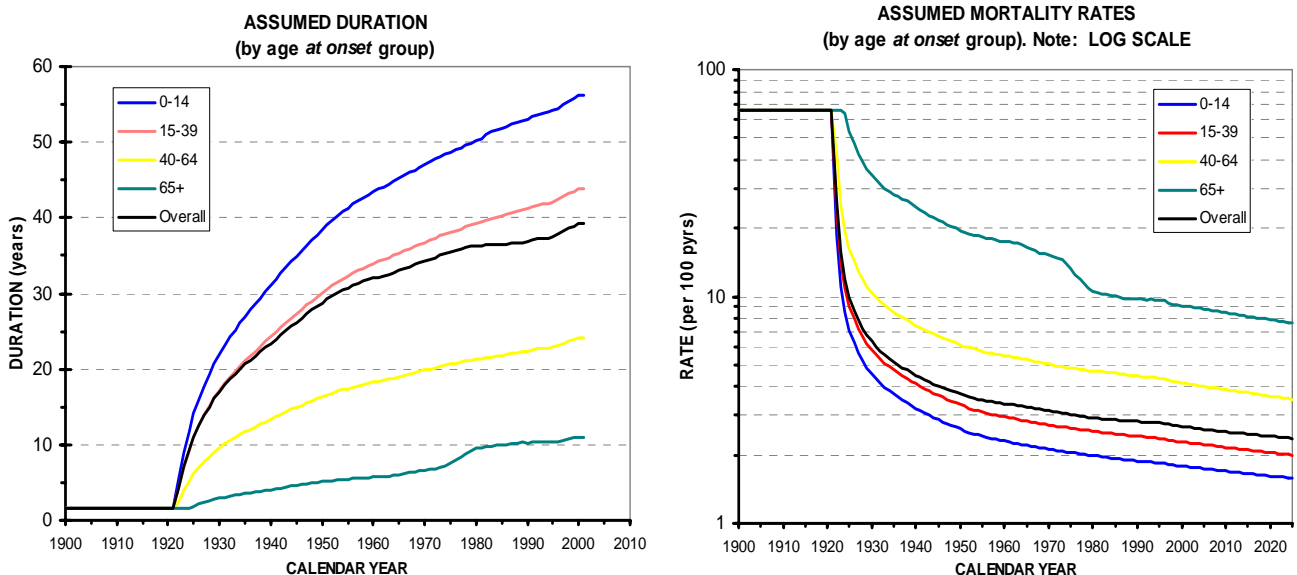
This formula ensures that the coefficient is given increasingly higher value as the time proceeds from 1922 – but also that the annual increment in the coefficient is becoming smaller and smaller. The constant of 0.2109 has been obtained as the value satisfying that, for the year 1975, the duration of disease is 0.75 times the expected remaining life time in the general population for any age at onset category, as suggested in Green & Hougaard (31).

An overview of the quantification of the parameters is given in the Table below, illustrating the arrays of average life expectancy and corresponding mortality rates in T1D in Denmark for selected calendar years. Numbers in parentheses indicate values fixed by assumption.

Calendar year	Coefficient k_t	Estimated duration (yrs.) from onset at age:					Overall mortality rate (per 100 years)
		0-14	15-39	40-64	65+	Overall	
1900	(0)	1.5	1.5	1.5	1.5	1.5	66.7
1925	0.271	14.1	11.0	6.1	1.9	11.1	9.9
1950	0.632	38.4	30.0	16.3	5.1	28.8	3.7
1975	(0.75)	48.7	38.1	20.7	7.6	35.5	3.0
2000	0.836	56.1	43.9	24.1	11.0	39.2	2.7

Figure A1.3 shows furthermore the secular trend, for each age-at-onset group and overall, in average life expectancy (left panel) and the corresponding mortality rates (right panel, observe the logarithmic scale).

Fig. A1.3. Assumed secular trends, for age-at-onset groups as well as overall, in average life expectancy (left panel) and corresponding mortality rates (right panel) in type 1 diabetes for Denmark, 1900-2001. Observe the log scale used for mortality rates.



Building up the prevalence population

The prevalence of T1D at the end of a year is estimated from the prevalence at the end of the preceding year, combined with the number of incident patients and the number of deaths in the patient population during the calendar year concerned. This is done successively over the total period of years covered by the modelling, starting with year 1900. The number of incident cases is obtained from the assumed incidence rates, combined with demographical data on population size and structure for the year. The number of deaths is obtained from the assumed mortality rates applied to the prevalence population of the preceding year.

Thus, the only information needed to start building up the prevalence population from 1900 and onwards is an estimate of the size of the prevalence population at the starting point (that is, start of the year 1900). This estimate has been obtained by running a sequence of 100 cycles of successive years with incidence rates and mortality rates as well as population size and structure for the year 1900, starting with a prevalence size at 0. After 10-20 cycles of the length of one calendar years, a state of epidemiological equilibrium is reached (that is, the number of new patients equals the number of deaths at a stable level of prevalence). This number of prevalent patients (n=183) has been used as the initial number, from which the prevalence for all successive years have been built by means of the annual incident and dead patients.

It may not be realistic to assume that T1D exhibited epidemiological equilibrium in 1900, but a long range of sensitivity analyses have demonstrated that even starting out with a prevalence population at 0 in 1900 the prevalence soon reaches the same levels as obtained with the one applied. The explanation for this is the high mortality in the pre-insulin era that has made incidence as the major determinant of the size of the prevalence population.

ANNEX 2: Data obtained from the Århus County diabetes investigations

Since there is no nationwide registration of patients with diabetes in Denmark, all data relevant for an epidemiological characterization of diabetes as well as activities and costs related to diabetes care must be compiled from modelling and *ad hoc* studies.

This Annex describes how data and results from an ongoing survey of diabetes and diabetes-related activities in the Århus County, Denmark, have been utilized for the purpose of the present project.

About the Århus County diabetes investigations

As part of her Ph.D. study, Kristensen investigated the potential possibilities of how to identify the total population of patients with diagnosed diabetes in Vejle County, Denmark (5). Making use of the unique personal identification code (Central Person Register number) assigned to all Danish citizens, Kristensen searched a series of public health registration systems including

- Registrations of admissions to hospitals
- Handling of a prescription with an antidiabetic drugs
- Ophthalmologic examinations specifically addressing patients with diabetes
- Choropodist visits specifically addressing patients with diabetes
- Biochemical investigations on blood sugar and glycosylated hemoglobin (HbA1c)

After verification of the diagnosis of diabetes, primarily by means of information from general practitioners, it was made possible to define an algorithm that with a high degree of sensitivity and specificity identified all patients with known diabetes in a given administrative region (5, 6).

Subsequently, the design and algorithm have been applied to Århus County that represents a 12% sample of the total Danish population (Table A2.1). Currently, all data from public registries of the kind mentioned above have been aggregated in a database, covering the years 2000 through 2002 (6). By collaborative arrangement, all relevant data pertinent for the calendar year 2001, un-identifiable at individual level, have been available for the analyses performed as part of the present project.

It must be stressed that, currently the data cannot be sub-grouped by diabetes type. However, information on current treatment and complication status is available.

Table A2.1. The demography of Århus County and entire Denmark, 2001

	Age group				Total
	0-14	15-39	40-64	65+	
Århus County	119,795	230,790	202,617	83,920	637,122
Whole Denmark	994,513	1,805,823	1,757,048	791,828	5,349,212
Århus County, % of Denmark	12.0	12.8	11.5	10.6	11.9

Size and composition of the population of patients with diabetes, Denmark year 2001

Age-specific information on the prevalence of known diabetes is available for Århus County with reference to December 31 for each of the years 2000, 2001 and 2002. The average values of the point prevalence for years 2000 and 2001 provide the estimated numbers of patient-years experienced within age classes during the calendar year 2001.

For all patients, complete registration of all admissions and outpatient visits to Danish hospitals since 1977 has been obtained from the Danish Hospital Activity Registration System (“Landspatientregistret”) (8, 6). Discharge and activity diagnoses have been used to determine the year at which any patient may have progressed from complication status 0 (no signs of diabetic complication) to complication status 1 (minor signs of diabetic complications but without significant impairment of daily activities) and complication status 2 (presence of overt complication, with significant impairment of daily activities), respectively, as summarized in the text Table below:

<i>Complication status</i>	<i>First year any of the diagnoses have been registered</i>
State 2	Nephropathy/end stage renal disease/dialysis; acute myocardial infarction; stroke; amputation; proliferative retinopathy/blindness; diabetes with complication(s)
State 1	Simplex (mild) retinopathy

Those patients not specifically assigned to complication status 1 or 2 have been assigned to complication status 0 by default. The distribution of the patient-years experienced during year 2001 in Århus County is shown in Table A2.2 (upper panel). Using the data in Table A2.1, the corresponding numbers for the entire Denmark have been estimated (Table A.2.2, next-upper panel).

Table A2.2. Estimated size and composition of the population of diabetic patients in Århus County and Denmark, year 2001. T1D: Type 1 diabetes; T2D: Type 2 diabetes

ÅRHUS COUNTY 2001: Patient-years experienced in total patient population

<i>All patients</i>	Age group				TOTAL
	0-14	0	0	0	
Complication state: 0	152	1,172	4,413	3,390	9,127
Complication state: 1	13	421	1,070	628	2,132
Complication state: 2	6	229	2,045	3,595	5,875
No. of patient years	171	1,822	7,528	7,613	17,134

DENMARK 2001: Estimated patient-years in total patient population

<i>All patients</i>	Age group				TOTAL
	0-14	15-39	40-64	>65	
Complication state: 0	1,262	9,170	38,269	31,986	80,687
Complication state: 1	108	3,294	9,279	5,926	18,606
Complication state: 2	50	1,792	17,734	33,921	53,496
No. of patient years	1,420	14,256	65,281	71,833	152,790

DENMARK 2001: Break-down of estimated patient-years experienced by diabetes type

<i>Type 1 patients</i>	Age group				TOTAL
	0-14	15-39	40-64	65+	
Complication state: 0	915	3,750	4,710	825	10,200
Complication state: 1	85	1,359	1,180	125	2,749
Complication state: 2	20	725	2,150	900	3,795
No. of patient years (a)	1,020	5,834	8,040	1,850	16,744

<i>Type 2 patients</i>	Age group				TOTAL
	0-14	15-39	40-64	65+	
Complication state: 0	347	5,420	33,559	31,161	70,487
Complication state: 1	23	1,935	8,099	5,801	15,857
Complication state: 2	30	1,067	15,584	33,021	49,701
No. of patient years (b)	400	8,422	57,241	69,983	136,046

a: Marginal number of patient-years obtained from epidemiological modelling

b: Number of T2D-patient-years obtained by subtracting T1D-results from total patients

The data set from Århus County does not provide reliable information on the distribution of patients and patient-years by diabetes type. To overcome this, we have used the model data for Type 1 diabetes in Denmark, as described in Annex 1. Accordingly, the part of the total patient-years that are to be assigned to Type 1 diabetes distribute as shown in Table A2.2 (next-lower panel). The distribution by complication status within age classes has been controlled by the distribution for the overall patient population of Århus County (Table A2.2, upper panel) under the assumption that, within age classes the patient-years distribute in the same way for the two types of diabetes.

Having assigned patient-years to Type 1 diabetes, all the remaining patient-years have been assigned to Type 2 diabetes by subtraction from the total numbers (Table A2.2, bottom panel).

Estimating added costs related to hospital admissions

As mentioned previously, hospital admissions back to 1977 have been traced in the Danish National Hospital Activity Registration System (“Landspatientregistret”) (8) for each individual patient registered in the Århus County diabetes investigations. For the calendar years 2000, 2001 and 2002 it has furthermore been possible to obtain the official valuation in DKK for each admission, based on the current Diagnosis Related Grouping (DRG) system. Thereby, all costs related to hospital admissions in the diabetic population during 2001 can be linked to the individual patients and grouped by age and complication status.

Because the present project concerns the *added* costs attributable to diabetes, it is necessary to adjust for hospital admission costs that would have occurred in the diabetic population independently of the diagnosis of diabetes. Upon specific request, the Danish National Hospital Registration System has provided age-specific accumulation of costs related to hospital admissions during the year 2001. Since the size and age-composition of the total Danish population is known for the year 2001 from vital statistics, and the estimated size and composition (with associated hospital admission costs) of the population of Danish patients with diabetes are obtained by extrapolations from Århus County (see Table A2.4 below), it is possible to estimate the hospital admission costs per person-year that have been experienced within age-groups for the year 2001, for the diabetic and non-diabetic population segments, respectively (Table A2.3).

The bottom line of Table A2.3 shows, expressed in costs per patient-year, those values that have been used to adjust for costs unrelated to diabetes.

Table A2.3. Costs related to hospital admissions in Denmark, year 2001, overall and broken down by diabetes status. Costs are in 1000 DKK.

DENMARK, YEAR 2001: Total population

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	3,101,750	6,517,252	11,056,044	12,686,771	33,361,816
Person-years	994,513	1,805,823	1,757,048	791,828	5,349,212
Cost per person-year	3.119	3.609	6.292	16.022	6.237

Source: The Danish National Hospital Activity Registration System ("Landspatientregistret")

DENMARK, YEAR 2001: Diabetic population

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	16,920	232,588	995,169	1,254,193	2,498,870
Patient-years	1,420	14,256	65,281	71,833	152,790
Cost per patient-year	11.919	16.315	15.244	17.460	16.355

Estimates based on extrapolations from Århus County

DENMARK, YEAR 2001: Non-diabetic population

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	3,084,829	6,284,664	10,060,875	11,432,578	30,862,947
Person-years	993,093	1,791,567	1,691,767	719,995	5,196,422
Cost per person-year	3.106	3.508	5.947	15.879	5.939

The Århus County data set provides total costs per patient-year within age group and complication classes. After adjustment for costs unrelated to diabetes, the estimated costs have been obtained as shown in Table A2.4. It should be stressed that for the age group 65+ years in complication states 0 and 1, a value of 0 has been used for the added costs per patient-year, since it appears that the diabetic patients in these categories represent less costs than their non-diabetic peers.

It has been assumed that the estimated added costs per patient-year, specified for age-groups and complication states, are identical for Type 1 and Type 2 diabetes.

*Table A2.4. Added costs related to hospital admissions in the population of diabetic patients.
Costs are in 1000 DKK*

AARHUS COUNTY, YEAR 2001: Diabetic population

All patients	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	2,038	29,725	114,760	132,923	279,446
Person-years	171	1,822	7,528	7,613	17,134
Cost per patient-year	11.919	16.315	15.244	17.460	16.309
Added costs per patient-year	8.813	12.807	9.297	1.581	10.073

Comp.status 0	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	1,777	15,116	33,502	27,709	78,104
Person-years	152	1,172	4,413	3,390	9,127
Cost per patient-year	11.692	12.897	7.592	8.174	8.557
Added costs per patient-year	8.586	9.389	1.645	0.000	2.321

Comp.status 1	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	157	6,105	16,589	8,978	31,829
Person-years	13	421	1,070	628	2,132
Cost per patient-year	12.073	14.501	15.504	14.296	14.929
Added costs per patient-year	8.967	10.993	9.557	0.000	8.692

Comp.status 2	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	104	8,505	64,668	96,236	169,513
Person-years	6	229	2,045	3,595	5,875
Cost per patient-year	17.335	37.139	31.623	26.769	28.853
Added costs per patient-year	14.229	33.631	25.676	10.891	22.617

Costs related to treatment with insulin

Treatment with insulin is essential for all patients with Type 1 diabetes, but may be required to obtain improved glycaemic control in patients with Type 2 diabetes as well. Furthermore, insulin treatment is specific for patients with diabetes and it can be assumed that no person will be treated with insulin unless the diagnosis of diabetes has been established.

The Århus County data set provides data for the number of patient-years treated with insulin, grouped by age and complication status, during the calendar year 2001. For each insulin prescription purchased, the sales price has been registered. Since each prescription is linked to a specific patient, this makes it possible to aggregate costs of insulin treatment across age-groups and complication states, as shown in Table A2.5, upper panel.

For the purpose of the present project, data on patient-years treated with insulin – and the associated costs – are necessary for Type 1 and Type 2 separately. This has been accomplished as follows. First, the estimates from Århus County (Table A2.5, upper panel) have been extrapolated to the entire Denmark, using the information in Tables A2.1 and A2.2. Second, it has been assumed that all patient-years in the class of Type 1 diabetes, regardless of age and complication status, are associated with a cost of DKK 3,609 (see main text of this report). Accordingly, the residual patient-years treated with insulin – and associated costs - are assigned to the category of Type 2 diabetes by default.

The resulting estimates, grouped by diabetes type as well as by age-groups and complication status are shown in Table A2.5, lower panels.

Table A2.5. Costs related to treatment with insulin. Costs are in 1000 DKK.

ÅRHUS COUNTY, YEAR 2001: Treatment with insulin

Costs, in 1000 DKK	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Complication state: 0	467	2,843	2,563	782	6,655
Complication state: 1	50	1,783	2,421	803	5,057
Complication state: 2	20	872	3,474	3,427	7,794
TOTAL	537	5,499	8,457	5,013	19,506

Patient-years treated	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Complication state: 0	112	625	746	258	1,741
Complication state: 1	11	357	594	234	1,196
Complication state: 2	4	190	829	973	1,996
TOTAL	127	1,172	2,169	1,465	4,933

DENMARK, YEAR 2001: Treatment with insulin

Type 1 diabetes

All patients	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs	3,681	21,055	29,016	6,677	60,429
Patient-years, treated	1,020	5,834	8,040	1,850	16,744
Cost per patient-year	3.609	3.609	3.609	3.609	3.609

Type 2 diabetes

All patients	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs:	777	21,971	44,325	40,619	107,692
Patient-years, treated	34	3,336	10,769	11,973	26,113
Cost per patient-year	22.626	6.585	4.116	3.393	4.124

Comp.status 0	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs	3,302	13,534	16,998	2,977	36,812
Patient-years, treated	915	3,750	4,710	825	10,200
Cost per patient-year	3.609	3.609	3.609	3.609	3.609

Comp.status 0	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs:	576	8,713	5,224	4,406	18,919
Patient-years, treated	15	1,140	1,759	1,609	4,524
Cost per patient-year	38.901	7.641	2.970	2.738	4.182

Comp.status 1	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs	307	4,905	4,259	451	9,921
Patient-years, treated	85	1,359	1,180	125	2,749
Cost per patient-year	3.609	3.609	3.609	3.609	3.609

Comp.status 1	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs:	104	9,050	16,734	7,124	33,013
Patient-years, treated	6	1,434	3,971	2,083	7,495
Cost per patient-year	16.487	6.310	4.214	3.420	4.405

Comp.status 2	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs	72	2,617	7,759	3,248	13,696
Patient-years, treated	20	725	2,150	900	3,795
Cost per patient-year	3.609	3.609	3.609	3.609	3.609

Comp.status 2	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs:	97	4,208	22,367	29,089	55,761
Patient-years, treated	13	762	5,039	8,281	14,095
Cost per patient-year	7.325	5.525	4.439	3.513	3.956

By assumption: The cost of treating one patient-year with Type 1 diabetes is fixed at DKK 3,609

Treatment with peroral antidiabetic agents

Treatment with peroral antidiabetic agents is relevant for patients with Type 2 diabetes, with or without supplementing insulin treatment. For practical purposes it may be assumed that, currently in Denmark, treatment with peroral antidiabetic agents is restricted to patients with Type 2 diabetes. Furthermore, administration of peroral antidiabetic agents is specific for patients with diabetes and it can be assumed that no person without diabetes will be treated with such drugs.

The Århus County data set provides data for the number of patient-years treated with peroral antidiabetic agents, grouped by age and complication status, during the calendar year 2001. For each prescription purchased, the sales price has been registered. Since each prescription is linked to a specific patient, this enables aggregating costs of peroral drug treatment across age-groups and complication states, as shown in Table A2.6, upper panel.

To obtain estimates for whole Denmark, year 2001, the data from Århus County have been extrapolated by means of the information pertinent to the segment of patient-years with Type 2 diabetes in Tables A2.1 and A2.2. The resulting estimates are shown in Table A2.6, lower panels.

Table A2.6. Costs related to treatment with peroral antidiabetic agents. Costs are in 1000 DKK

ÅRHUS COUNTY, YEAR 2001: Treatment with peroral agents

Costs, in 1000 DKK	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Complication state: 0	1	118	1,955	1,663	3,737
Complication state: 1	0	17	533	410	960
Complication state: 2	0	13	892	1,781	2,687
TOTAL	1	149	3,380	3,854	7,383

Patient-years treated	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Complication state: 0	3	178	1,859	1,589	3,629
Complication state: 1	0	28	444	338	810
Complication state: 2	0	17	814	1,651	2,482
TOTAL	3	223	3,117	3,578	6,921

DENMARK, YEAR 2001: Treatment with peroral agents

Type 2 diabetes All patients	AGE				Total
	0-14	15-39	40-64	65+	
Total costs	5	1,163	29,313	36,363	66,844
Person-years, treated	25	1,745	27,030	33,760	62,560
Cost per patient-year	0.218	0.666	1.084	1.077	1.068

Comp.status 0	AGE				Total
	0-14	15-39	40-64	65+	
Total costs	5	922	16,953	15,694	33,575
Person-years, treated	25	1,393	16,121	14,993	32,532
Cost per patient-year	0.218	0.662	1.052	1.047	1.032

Comp.status 1	AGE				Total
	0-14	15-39	40-64	65+	
Total costs	0	135	4,623	3,864	8,622
Person-years, treated	0	219	3,850	3,189	7,259
Cost per patient-year	0.000	0.615	1.201	1.212	1.188

Comp.status 2	AGE				Total
	0-14	15-39	40-64	65+	
Total costs	0	106	7,737	16,804	24,647
Person-years, treated	0	133	7,059	15,578	22,770
Cost per patient-year	0.000	0.794	1.096	1.079	1.082

Costs related to drug-treatment and prevention of complications

Diabetes mellitus, regardless of type of diabetes, is associated with chronic complications including hypertension, dyslipidaemia, cardiovascular diseases and renal complications. Therefore, patients with diabetes are frequently treated with antihypertensive agents, lipid-lowering drugs and agents to protect kidney function. Many subjects without diabetes are also treated with such drugs. For the purpose of the present project, estimates of added costs related to treatment with these drugs, have been obtained as follows.

The Århus County data set provides data for the calendar year 2002 on all prescriptions, purchased to subjects registered as having diabetes, in the following drug categories (ATC-codes):

C02 (antihypertensive agents); C03 (diuretics); C07 (beta-receptor blockers); C08 (Calcium antagonists); C09 (ACE inhibitors); C10 (lipid-lowering drugs). For each prescription (which is linked to a specific patient and thus assignable to age-group and complication status) the sales price is registered, permitting an estimate of the total costs experienced in the diabetic population in Århus County during the year 2002.

From the National Danish Medicines Agency “Lægemiddelstyrelsen”) the sales statistics, specific for age-groups) are available for all ATC codes (7). The latest year available for the present project is the calendar year 2000.

When extrapolating the patient-years and costs for the diabetic population of Århus County to whole Denmark (using Tables A2.1 and A2.2) and combining this information with the data available from the Danish Medicines Agency, it is possible to estimate the costs related to treatment with the drugs mentioned, specified for the diabetic and non-diabetic population segment, respectively (Table A2.7). Furthermore, using the age-specific costs per person-year in the non-diabetic population segment as a reference, the *added* costs (attributable to diabetes) may be estimated for the diabetic population, as also shown in Table A2.7.

Table A2.7. Costs related to drug-treatment and prevention of complications, regardless of complication status. Costs are in 1000 DKK

TOTAL DENMARK, YEAR 2001

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	476	37,951	674,768	730,867	1,444,063
Person-years	994,513	1,805,823	1,757,048	791,828	5,349,212
Cost per person-year	0.000	0.021	0.384	0.923	0.270

Source: The National Danish Medicines Agency ("Lægemiddelstyrelsen"), year 2000

DENMARK, YEAR 2001: Diabetic population

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	7	9,353	185,941	217,750	413,051
Costs, independent of diabetes	1	228	18,863	51,193	70,284
Costs, ascribed to diabetes	6	9,126	167,078	166,558	342,768
Patient-years	1,420	14,256	65,281	71,833	152,790
Total costs per patient-year	0.005	0.656	2.848	3.031	2.703

Estimates based on extrapolations from Århus County

DENMARK, YEAR 2001: Non-diabetic population

	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	469	28,598	488,827	513,117	1,031,011
Person-years	993,093	1,791,567	1,691,767	719,995	5,196,422
Cost per person-year	0.000	0.016	0.289	0.713	0.198

The information in the Århus County data set has been combined with the above-mentioned adjustment for costs, estimated to be experienced independently of diabetes, as shown in Table A2.8.

Table A2.8. Added costs related to drug-treatment and prevention of diabetic complications, specific for complication status. Costs are in 1000 DKK

AARHUS COUNTY, YEAR 2001: The diabetic population

All patients	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	1	1,195	21,442	23,078	45,716
Costs, <i>independent of diabetes</i>	0	29	2,175	5,426	7,630
Costs, <i>ascribed to diabetes</i>	1	1,166	19,267	17,652	38,086
Person-years, treated	1	383	5,107	6,545	12,036
Added cost per patient-year, treated	0.822	3.121	4.199	3.526	3.798

Comp.status 0	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	0	294	8,422	7,995	16,711
Costs, <i>independent of diabetes</i>	0	19	1,275	2,416	3,710
Costs, <i>ascribed to diabetes</i>	0	276	7,147	5,579	13,001
Person-years, treated	0	164	2,647	2,700	5,511
Added cost per patient-year, treated	0.000	1.795	3.182	2.961	3.032

Comp.status 1	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	0	198	2,584	1,601	4,383
Costs, <i>independent of diabetes</i>	0	7	309	448	763
Costs, <i>ascribed to diabetes</i>	0	192	2,275	1,153	3,619
Person-years, treated	0	81	666	512	1,259
Added cost per patient-year, treated	0.000	2.449	3.880	3.126	3.481

Comp.status 2	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Total costs	1	703	10,436	13,483	24,622
Costs, <i>independent of diabetes</i>	0	4	591	2,562	3,157
Costs, <i>ascribed to diabetes</i>	1	699	9,845	10,920	21,466
Person-years, treated	1	138	1,794	3,333	5,266
Added cost per patient-year, treated	0.822	5.092	5.817	4.045	4.676

It is assumed that, for given age-class and complication status, the added costs related to drug-treatment for complications are identical for Type 1 and Type 2 diabetes, respectively. However, for the purpose of the present project it is necessary to obtain estimates of patient-years actually treated with these drugs, specified not only for age and complication status but also for diabetes type. This has been accomplished by assigning the total added costs within age-groups and complication status (Table A2.8) to Type 1 and Type 2 diabetes, respectively, proportionately with the weights represented by the corresponding number of patient-years (Table A2.2, lower panels). The results are shown in Table A2.9.

Table A2.9. Estimated distribution of patient-years treated with drugs for diabetic complications, by diabetes type, age-group and complication status. Denmark year 2001

DENMARK, YEAR 2001: Estimated number of diabetic patient-years treated with other drugs

All patients	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Complication state: 0	0	1,283	22,954	25,476	49,713
Complication state: 1	0	634	5,775	4,831	11,240
Complication state: 2	8	1,080	15,557	31,449	48,094
TOTAL	8	2,997	44,287	61,755	109,047

Type 1 diabetes	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Complication state: 0	0	525	2,825	657	4,007
Complication state: 1	0	261	734	102	1,098
Complication state: 2	3	437	1,886	834	3,161
TOTAL	3	1,223	5,446	1,593	8,266

Type 2 diabetes	AGE GROUP				Total
	0-14	15-39	40-64	65+	
Complication state: 0	0	758	20,129	24,819	45,706
Complication state: 1	0	372	5,041	4,729	10,142
Complication state: 2	5	643	13,671	30,614	44,933
TOTAL	5	1,774	38,841	60,162	100,782

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