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The societal impact of Diabetes mellitus and diabetes care

Report 3: Type 2 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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Timetable for main phases of the project:

Calendar year 2002: Initial planning and preparation of project protocols

Development of epidemiological model data and cost structure

Calendar year 2003:

analyses

Using empirical data sets for validation and supplementary

First reporting of results

Calendar year 2004: Final analyses and reporting

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EXECUTIVE SUMMARY

As part of a larger project aiming at assessing the societal impact of diabetes and diabetes care, the present study presents a health economics assessment of Type 2 diabetes (T2D) in Denmark, with reference to the calendar year 2001.

From epidemiological modelling three contrasting scenarios have been established: The "Current" scenario, representing the real situation for T2D in Denmark; 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 T2D is not associated with any excessive risk of complications and mortality.

Costs of treating T2D in Denmark have been estimated from public registries and 'ad hoc' 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 have been 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 "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).

We conclude that from a societal view point it is costly to treat T2D in Denmark and that the largest cost driver is related to nursing and palliation due to chronic diabetes complications. The high costs, though, are associated with a significant number of patient-years, quality adjusted patient-years (QALYs) as well as production values in the formal sector and the informal sector from people with diabetes. We cannot conclude whether these patient years and QALYs are the direct result of the current treatment level because of almost no clinical knowledge of how a situation with no treatment (a "worst" scenario) at all would look. A reasonable estimate, though, of the marginal cost of current treatment per QALY is in the range between DKK 70.895 (marginal cost pr QALY of type 1 diabetes (20)) to DKK 105,529 (Average cost pr QALY in the current 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 suggests that there is a potential gain in patient-years and productivity, at considerably lower costs. Thus improved diabetes care as in the improved scenarion is associated with savings. Health care cost savings and non-health care costs savings per gained patient-year is 348,389 DKK and 220,432 DKK per gained QALY. In addition to the reported health gains diabetes treatment also provides additional societal gains in terms of production value of DKK Bill 9.208 in the formal sector and DKK Bill 9.845 if the informal sector is included. Considerable additional gains and reduction in costs would be observed under the hypothetical assumption that improved care eliminates complications, co-morbidity and premature mortality in T2D as outlined in the "ideal scenario". These results suggest that improvements in diabetes care would be beneficial to society.

It should be underlined that these results are gross and not net benefits because the related consumption is not included. To the extent that the production values exceed related increased consumption the net cost to society of diabetes treatment will be lower than the

reported costs. Hence, the reported costs per health gain presented below should be seen as conservative figures.

Finally the conclusion that the majority of societal costs of diabetes are non-health costs is robust. A combined sensitivity based on that a) only people +65 receive nursing and b) at a unit cost of 50% of the base line cost shows that non health care cost would still be more than 50% of the total societal costs of diabetes.

T2D in Denmark, year 2001. Summary of costs of treatment and effects in contrasting scenarios.

	·		
COST Mill DKK	Current	Improved	Ideal
Healthcare Resources	2241	2243	1105
Non-Healthcare Resources	9152	3738	0
Patients' time	483	512	138
Informal care-givers' time	22	21	1
Total cost	11898	6514	1244
EFFECTS			
Patients' years unadjusted	136.047	151.500	169.050
Patients' years quality adjusted	112.748	137.172	160.598
Production value incl the informal sector Mill DKK	10296	14757	18381
Production value registered as GDP Mill DKK	8825	12649	15755

DIFFERENCES BETWEEN SCENARIOS COST Mill DKK	Socio economic gains improved vs current	Socio economic gains ideal vs
Healthcare Resources	3	-1,135
Non-Healthcare Resources	-5,415	-9,152
Patients' time	29	-345
Informal care-givers' time	-1	-21
Total cost	-5,384	-10,654
EFFECTS		
Patients' years unadjusted	15,453	33,003
Patients' years quality adjusted	24,423	47,849
Production value incl the informal sector Mill DKK	4,461	8,085
Production value registered as GDP Mill DKK	3,824	6,930

Socioeconomic ratios:	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefits (production value - costs), mill DKK		
Production value registered as GDP	9.208	17.584
Production value including the informal sector	9.845	18.739
Marginal cost effectiveness ratio		
DKK/patient-year	-348.389	-322.812
Marginal cost utility ratio:		
DKK/QALY	-220.432	-222.652

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

T2D in Denmark, year 2001. Summary of costs of treatment and effects in contrasting scenarios. MILL US\$ PPP (8.46 DKK/US\$ PPP)

COST Mill US\$ (PPP)	Current	Improved	Ideal
Healthcare Resources	265	265	131
Non-Healthcare Resources	1082	442	0
Patients' time	57	60	16
Informal care-givers' time	3	3	0
Total cost Mill US\$ (PPP)	1406	770	147
EFFECTS			
Patients' years unadjusted		151.500	169.050
Patients' years quality adjusted	112.748	137.172	160.598
Production value incl the informal sector Mill US\$ (PPP)	1217	1744	2173
Production value registered as GDP Mill US\$ (PPP)	1043	1495	1862

DIFFERENCES BETWEEN SCENARIOS COST US\$ (PPP)	Socio economic gains current vs worst		Socio economic gains ideal vs current
Healthcare Resources	265	0	-134
Non-Healthcare Resources	1082	-640	-1082
Patients' time	57	3	-41
Informal care-givers' time	3	0	-3
Total cost Mill US\$ (PPP)	1406	-636	-1259
EFFECTS			
Patients' years unadjusted	136047	15453	33003
Patients' years quality adjusted	112748	24423	47849
Production value incl the informal sector Mill US\$ (PPP)	1217	527	956
Production value registered as GDP Mill US\$ (PPP)	1043	452	819

SOCIO ECONOMIC RATIOS	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefit gains (production value - costs)		
Production value registered as GDP: Mill US\$ (PPP)	1.164	2.215
Production value incl the informal sector : Mill US\$ (PPP)	1.088	2.078
Marginal cost effectivness ratio:		
US\$ (PPP)/patient-year	-41.181	-38.157
Marginal cost utility ratio:		
US\$ (PPP)/QALY	-26.056	-26.318

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

1. INTRODUCTION

Treatment for diabetes, incl. treatment with insulin and peroral agents, 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.

It is generally believed that the prevalence of Type 2 diabetes (T2D) is increasing worldwide (3). Therefore, T2D represents a large burden for patients and society and must be considered a major public health problem.

Novo Nordisk A/S has launched a project aiming at studying various aspects of the societal impact of diabetes and diabetes care. The first report in this series dealt with the general methodological considerations behind the project. The second report concerned T1D in Denmark, year 2001 (4).

The present report concerns a health economics appraisal of treatment and care of T2D 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 a hypothesized scenario, representing a realistic case for improvements in diabetes care yielding reductions in the mortality and the risk of complications; an extreme variant of this scenario with improvements is represented by the assumption that T2D confers no excessive mortality and morbidity. Providing each of these hypothetical scenarios is then contrasted with the scenario for the current (actual) situation, the basis for an evaluation of effects and benefits.

2. OUTLINE OF METHODOLOGY. SCENARIO BUILDING

The study focuses on T2D in Denmark, with reference to the year 2001. In addition to the scenario representing the current situation for T2D in Denmark year 2001, two contrasting scenarios have been created to investigate the impact of different levels of clinical outcome in T2D 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, affecting the actual size of the population of people with T2D (the prevalence), which has further implications for the amount of resources used during the year studied. The scenarios of interest are characterized as follows:

"Current" scenario

This scenario is assumed to reflect the current situation concerning T2D in Denmark, year 2001. The 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 except that effectively from the year 1985, all mean survival times in T2D 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 T2D 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. Thus, this scenario may with due reservation be used as a reference of what the potential is of further gains in productivity when compared with the "current" scenario.

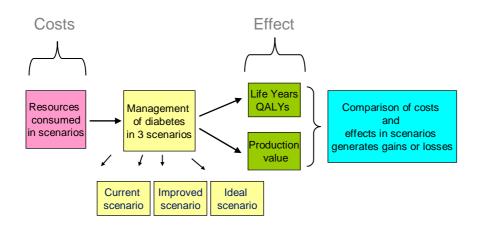
The epidemiological modelling under this scenario uses longevity in the general population to obtain the hypothetical numbers of patient-years (all falling in the class of no complications). Thereby, the number of patient-years estimated under this scenario is adjusted for the mortality level in the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

It should be stressed that the current population of patients with T2D in Denmark has obtained its size and age composition as a consequence of access to treatment for diabetes during many decades. Therefore, a comparison of patient-years experienced under the contrasting scenarios mentioned reflects the cumulative effect of access to care and treatment over previous decades and cannot be interpreted as an isolated effect for 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 T2D by age and complication status, and the associated cost and productivity items. Using the "Current" scenario as the reference, the "Improved" and "Ideal" scenarios, respectively, are evaluated with respect to

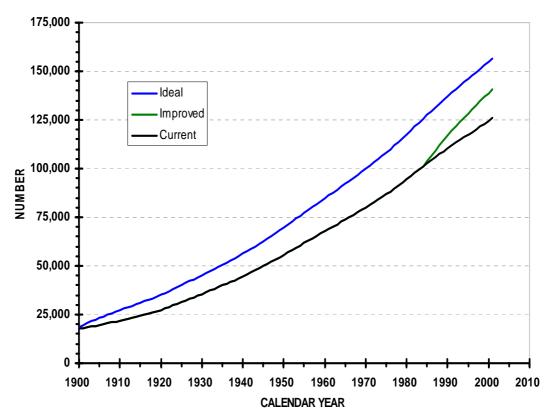
- The number of patient-years experienced with T2D
- The number of quality of life-adjusted patient-years experienced with T2D
- The costs of medical interventions in the hospital system and outside, including home nursing
- The cost consequences for the patients related to transport and informal care by relatives and others
- The foregone income from time lost due to sickness and reduced productivity by patients with T2D

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

Since there is no routine registration of diabetes in Denmark, any attempts to profile the population of patients with T2D must rest on available ad hoc empirical data, combined with epidemiological modelling and clinically based assumptions. Fortunately, new research initiatives have to a large extent compensated for the lack of routine registration of diabetes in Denmark. For the purpose of the present study it has been possible to combine epidemiological modelling with available empirical data. Annex 1 describes how the basic epidemiological profile relevant for the "Current" scenario has been established, guided by available data for the year 2001. Fig. 3.1 illustrates the resulting prevalence estimates under the various scenarios.

Fig. 3.1.Estimated prevalence (absolute numbers) for T2D in Denmark 1900-2001 (see Annex 1)



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 in the diabetic population 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 (7) and from the National Danish Hospital Activity Registration System ("Landspatientregistret") (8), as also described in Annex 2.

The data set from Århus County does not make it possible to distinguish between T1D and T2D in a reliable way. To compensate for this, we have used epidemiological modelling for T1D, leaving as T2D-related items all patient-years and costs not assignable to T1D. Reference is made to Annex 2 of Report 2 of the present series in which a detailed account has been given specifically to T1D.

Both the costs of treating T2D and the quality of life are strongly associated with the presence of long-term (chronic) complications of diabetes. For the purpose of the present study we have used a classification scheme for long-term diabetic complications as outlined in the text table below. Annex 1 provides the details on how this classification scheme has been used operationally.

Complication status	Patient profile of complications
State 0: No signs of chronic complications; No impairment in daily living function	No signs of complications present
State 1: Signs of minor/early chronic complications; No or only minor (insignificant) impairment in daily living function	Retinopathy, not including proliferative retinopathy; <i>and/or</i> Microalbuminuria; <i>and/or</i> Light neuropathy without open ulceration;
State 2: Presence of chronic complications, with significant impairment in daily living function	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)

Table 3.1 shows how the numbers of patient patient-years during the calendar year have been assumed to distribute by complication status. Furthermore, the patient-years have been grouped according to antidiabetic treatment (+ insulin and + peroral agents, respectively). See Annex 2 for further details.

Table 3.1 Estimated patient patient-years by current age and complication status under the contrasting scenarios

Scenario: "Current"

		Age group			
ALL PATIENTS	TOTAL	0-14	15-39	40-64	65+
No. of patient years, total	136,047	400	8,422	57,242	69,983
Complication state: 0	70,487	347	5,420	33,559	31,161
Complication state: 1	15,858	23	1,935	8,099	5,801
Complication state: 2	49,702	30	1,067	15,584	33,021

PATIENTS TREATED WITH INSULIN

No. of patient years, total	26,112	34	3,336	10,769	11,973
Complication state: 0	4,523	15	1,140	1,759	1,609
Complication state: 1	7,494	6	1,434	3,971	2,083
Complication state: 2	14,095	13	762	5,039	8,281

PATIENTS TREATED WITH PERORAL ANTIDIABETIC AGENTS

No. of patient years, total	62,560	25	1,745	27,030	33,760
Complication state: 0	32,532	25	1,393	16,121	14,993
Complication state: 1	7,258	0	219	3,850	3,189
Complication state: 2	22,770	0	133	7,059	15,578

PATIENTS TREATED WITH OTHER DRUGS

. ,					
No. of patient years, total	100,781	5	1,773	38,841	60,162
Complication state: 0	45,706	0	758	20,129	24,819
Complication state: 1	10,142	0	372	5,041	4,729
Complication state: 2	44,933	5	643	13,671	30,614

Scenario: "Improved"

			Age gro	up	
ALL PATIENTS	TOTAL	0-14	15-39	40-64	65+
No. of patient years, total	151,500	500	10,500	65,000	75,500
Complication state: 0	124,475	475	9,000	55,000	60,000
Complication state: 1	6,770	20	1,250	5,000	500
Complication state: 2	20,255	5	250	5,000	15,000

PATIENTS TREATED WITH INSULIN

No. of patient years, total	75,750	250	5,250	32,500	37,750
Complication state: 0	62,238	238	4,500	27,500	30,000
Complication state: 1	3,385	10	625	2,500	250
Complication state: 2	10,128	3	125	2,500	7,500

PATIENTS TREATED WITH PERORAL ANTIDIABETIC AGENTS

No. of patient years, total	136,350	450	9,450	58,500	67,950
Complication state: 0	112,028	428	8,100	49,500	54,000
Complication state: 1	6,093	18	1,125	4,500	450
Complication state: 2	18,230	5	225	4,500	13,500

PATIENTS TREATED WITH OTHER DRUGS

No. of patient years, total	118,541	4	3,088	49,750	65,700
Complication state: 0	94,500	0	2,250	41,250	51,000
Complication state: 1	5,075	0	625	4,000	450
Complication state: 2	18,966	4	213	4,500	14,250

Specifically for the scenario "Improved", the demographical model of T2D resulting in the "Current" scenario has been applied; however with the modification that effectively from year 1985 3.5 years have been added to all median survival times in T2D.

Scenario: "Ideal"

			Age gro	up	
ALL PATIENTS	TOTAL	0-14	15-39	40-64	65+
No. of patient years, total	169,050	550	12,500	75,000	81,000
Complication state: 0	169,050	550	12,500	75,000	81,000
Complication state: 1	0	0	0	0	0
Complication state: 2	0	0	0	0	0

PATIENTS TREATED WITH INSULIN

No. of patient years, total	84,525	275	6,250	37,500	40,500
Complication state: 0	84,525	275	6,250	37,500	40,500
Complication state: 1	0	0	0	0	0
Complication state: 2	0	0	0	0	0

PATIENTS TREATED WITH PERORAL ANTIDIABETIC AGENTS

No. of patient years, total	152,145	495	11,250	67,500	72,900
Complication state: 0	152,145	495	11,250	67,500	72,900
Complication state: 1	0	0	0	0	0
Complication state: 2	0	0	0	0	0

PATIENTS TREATED WITH OTHER DRUGS

No. of patient years, total	0	0	0	0	0
Complication state: 0	0	0	0	0	0
Complication state: 1	0	0	0	0	0
Complication state: 2	0	0	0	0	0

In 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, 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 T2D 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 life 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. A transformation of all cost items to US\$ (at the DKK/US\$ rate of 8.46) can be found in the appendix. Specific comments to the individual items are given below, when relevant.

Table 4.1. Overview of cost structure and valuation

COSTS and PRODUCTIVITY per patient-year

			Number of	units <i>per pat</i>	<i>ient-vear</i> hy	current age	group and c	omplication	state.					
		Cost per unit		0 - 14	ionic your by	ourrork ago	15 - 39	ompiloation.	olato.	40 - 64			65+	
Item	Unit	(DKK)	0	1	2	0	1	2	0	1	2	0	1	2
Healthcare Resources														
Added hospitalization costs	1000 DKK + overhead	1.150	8,586	8,967	14,229	9,389	10,993	33,631	1,645	9,557	25,676	0,000	0,000	10,891
Medication with insulin	1000 DKK	1.000	36,901	16,487	7,325	7,641	6,310	5,525	2,970	4,214	4,439	2,738	3,420	3,513
Medication with oral antidiabetics	1000 DKK	1.000	0,218	0,000	0,000	0,662	0,615	0,794	1,052	1,201	1,096	1,047	1,212	1,079
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. Abseenteism	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. Abseenteism	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 (see cost in us\$ in appendix) (All cost items 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)	1 visit	156
Medication with insulin	Empirical evidence (see Annex 2)	Consumption per patient year	4,124
Medication with peroral antidiabetic agents	Empirical evidence (see Annex 2)	Consumption per patient year	1,068
Medication with other drugs	Empirical evidence (see Annex 2)	Consumption per patient year, treated persons	3,798
Blood glucose monitoring	Life Scan (12)	By year, assuming 13 BGM per week exclusively for patients on insulin	6,371
Hospitalization	Empirical evidence (see Annex 2)	Costs per type 2 patient year	8,489 (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 (14, 26, 27)	Per year	360,000 (nursing home cost and hours of assistance at 421 DKK per hour)
Nursing assistance in own 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 (14, 26, 27)	Per year	280,320 (high) 118,800 (low) based on 421 DKK per hour
Physiotherapy	100% in group 2 (28)	Per year (12 visits)	3,384
Wheel chair	25% of complication group 2 (14,000 DKK ,10 year life time) (23)	Per year	1,400
Sticks	100% of complication group 2 (5000 DKK 10 year life time of stocks) (23)	Per year	500
Prosthesis crus	100% of crus amputations (50% over 65 year) (25000-30000, on average 27,500 DKK; 2 year lifetime of prosthesis) (22)	Per year	13,750
Prosthesis femur	100% of femur amputations (50% over 65 years) (30000-110000 on average 70,000 DKK; 2 year lifetime of prosthesis) (22)	Per year	35,500
Productivity			
Lost productivity during admissions (formal sector)	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 (19)	Per active working day	85
Lost productivity due routine controls	2 hour/day (19)	Per routine control	213
Gained productivity from improved survival	(19)	Per active working day formal/informal	851/425

Hospitalization 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 therefore the cost used in this study 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 Ministry of Health/Sundhedsministeriet, but has not been validated

Costs of consumption of peroral antidiabetic agents, insulin and other drugs

Costs of insulin treatment have been assessed as those costs left when insulin treatment for T1D has been accounted for (see Annex 2 for the details).

It is assumed that all costs related to treatment with peroral antidiabetic agents shall be assigned to the population of patients with T2D.

Costs of medication with drugs for prevention and treatment of long-term complications have been assessed as described in Annex 2, assuming that within categories by age and complication status, the cost per patient-year treated is identical for patients with T1D and T2D, respectively. 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:

- Number of GP visits during one year
 - o for new patients,
 - o for well-controlled patients with low cholesterol and
 - o well-controlled patients with high cholesterol.
- Laboratory tests

Further this item includes a number of visits to eye specialist 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

Lancets: 1,400 DKK

• Batteries: 50 DKK

It price of a glucometer is set at 235 DKK, with an expected life-time of 1 year.

Based on clinical experiences, it is assumed that – on average – during a patient-year with T2D in insulin treatment a home Blood Glucose Measurement is performed 13 times per week. Accordingly, the costs per patient-year in insulin treatment amounts to [(7.7+1.3)*13*52] +50+ 235 DKK= 6,371 DKK. Most likely, this represents an overestimate, but this effect is assumed to be out-weighted by the fact that no home BMG is assumed to take place during all other patient-years.

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 (13). 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. (14) 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 (27). The data reflects help to individuals across age groups (including people below 67 years of age), health, psychosocial 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)¹. (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 (13, 14, 26). 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 (25) 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.

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 there diabetes condition. In

¹ 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 (13)

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 pr 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 pr 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 pr 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 (24) 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. (23)

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 (22) 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 the "Improved" scenario

As mentioned before, this scenario is basically similar to the "Current" scenario in terms of patient population demography, with the exception that an additional 3.5 years of expected mean survival has been added with effect from the year 1985. Since this scenario is assumed to represent improved care, the resulting distributions by age group and complication status have been modified accordingly on the basis of best clinical judgment. Concerning costs, 20% have been added globally to hospitalization costs to reflect additional costs for reorganization of diabetes care. Furthermore, it is assumed - (based on suggestions from clinical experts: Critical Board Members (see introductory pages of this report)) – that such an improved scenario requires that 50% of all patients with T2D are treated with combined insulin and peroral agents, and that additional 40% of the patients are treated with peroral agents only

Re-organization in the improved scenario

As mentioned above 20% is added to hospitalization 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 (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 scenario "Ideal"

For the scenario "Ideal" it is assumed that all patient-years are experienced in the complication state 0, i.e. with no complications at all. It is assumed that T2D 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 with out any form of additional treatment and medication, thus relying on perfect self management etc. Another form of ideal scenario could take into considerations 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 a maximum acceptable societal cost level per gained QALY. Following the results for type 2 diabetes from the Danish Medical Technology Assessment report (16) this level is fixed at DKK 100,000 per gained QALY. The result of this calculation can be found in section 5. Results.

Assessment of effects

The effect from having T2D is expressed on the basis of numbers of patient-years experienced under the contrasting scenarios.

We have furthermore attempted to make an adjustment of the patient-years, by using a generic (non-disease specific) quality of life (QoL) instrument; the EQ-5D (1). 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 a single number that 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 or SF-36 (18) allowing 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. (1), all possible compound scores have been assigned a value between 0 and 1, with the value 0 indicating lowest possible level of QoL and the value 1 indicating maximal QoL.

Through an exercise a group of eight Danish experienced diabetes nurses have translated a number of typical diabetes health states into the descriptive health states as used in the EQ-5D questionnaire. In this way, we obtained EQ-5D weights to a number of health states that 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.

For the present study it is assumed that the population of T2D patients in the age segment 15-64 years who belongs to complication groups 0 and 1 have 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 of 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 year 2000 figures were updated to 2001 using a 4% rate of increase, based on the increase in income (19) resulting in 180,060 DKK/year (106 DKK per hour and 851 DKK per day). Finally, it was assumed that persons in complication group 1 had a reduced productivity of 10% during 50% of their working days.

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 GPs and similar out of hospital care both for patients and relatives, as well as income lost to society resulting from reduced productivity while working resulting 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 loosing 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 that are not engaged in productive market based work is assumed to produce in the home based sector.

Various approaches have been suggested for validating the home production. One approach is to assume a value equivalent to the opportunity cost of time as seen by 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 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 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 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) and the measures that result in a reduced number of future complications etc (prevention).

Diabetes management covers exercise, diet and medication and the issues 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 this into consideration in the study. As our study does not include screening or diagnosis of unknown diabetes patients the second definition is the most relevant for us.

Neither insulin nor oral anti-diabetic agents or other healthcare items in this study can be characterized as prevention. There are no costs included under hospitalization focused only on prevention. Insulin, oral anti-diabetic 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 characterized as prevention in our study is "medication with other drugs". A distinction is made between medication to patients in complication group 2 and to 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 characterized 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 anti-diabetic agents for people without complications (in complication group 0 and 1), are categorized as an investment in prevention.

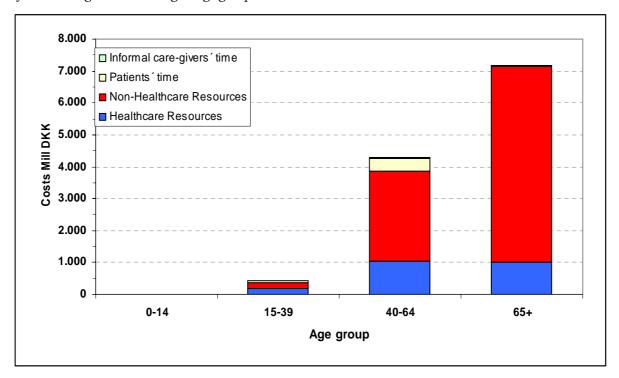
5. RESULTS

Costs

Tables 5.1, 5.2 and 5.3 show the detailed estimates of costs in the "Current", "Improved" and "Ideal" scenarios, respectively.

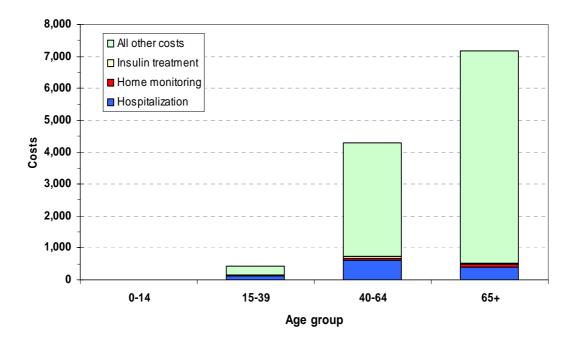
Particularly for the "Current" scenario, key results are summarized below in Fig. 5.1 and Fig. 5.2.

Fig. 5.1a. T2D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) per year by main categories according to age groups



Non healthcare costs are totally dominating and growing with age. The total costs of diabetes in age group 0-14 are so small compared to the rest of the age groups that it is not reflected in the figure 5.1a and b.

Fig 5.1b T2D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) per year by main cost drivers among healthcare costs according to age groups



Overall, hospitalization costs amount to about 10% of the total costs. The category "All other costs" is dominated by assistance to nursing (in nursing home as well as in own home) for patients with long-term complications (Fig. 5.1b)

Fig. 5.2a and b illustrates the same data, but now expressed per patient-year experienced in the calendar year 2001. Only in the age group 0-14 is healthcare dominating. The costs increase linearly by age, due to increasing non healthcare costs (i.e. 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 5.7 can answer that question.

Fig. 5.2a. T2D in Denmark, year 2001. "Current" scenario. Total costs (DKK) per patient-year by main categories according to age groups

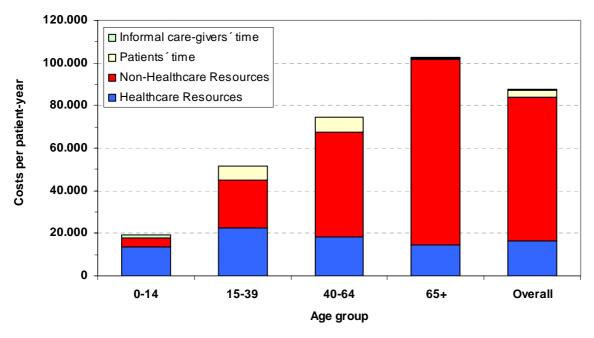


Fig 5.2b T2D in Denmark, year 2001. "Current" scenario. Total costs (DKK) per patient-year by main cost drivers among healthcare costs according to age groups

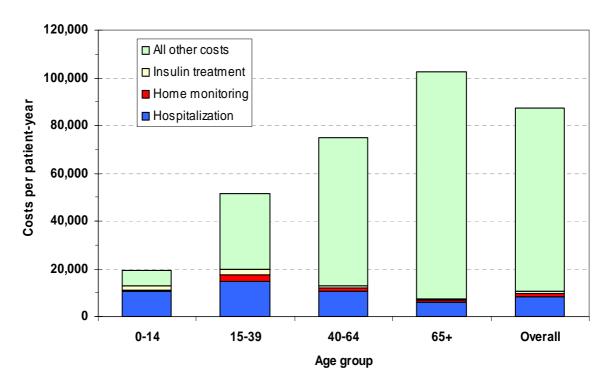


Fig. 5.3a. T2D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) per year by main categories according to complication status

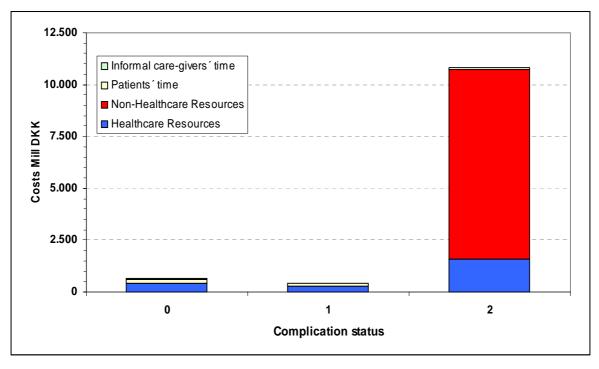


Fig 5.3b T2D in Denmark, year 2001. "Current" scenario. Total costs (mill. DKK) per year by main cost drivers among healthcare costs according to complication status

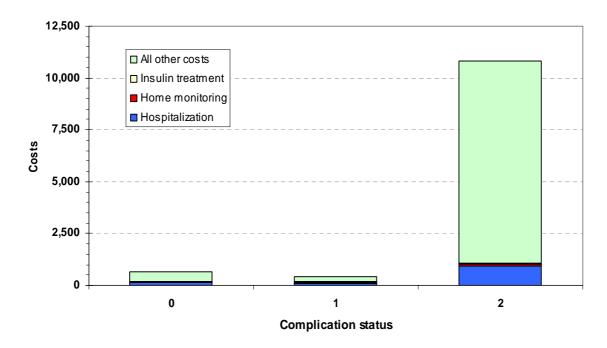


Fig. 5.3a and b illustrate the total costs by complication status. It is noteworthy that the patient-years experienced in complication group 2 (major complications) represent the largest costs. The most important driver of this large cost is non healthcare costs represented by nursing. The other major cost item is hospitalization.

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 costs per patient-year are more than 20 times greater for complication group 2 as compared with complication group 0 due to the very high level of non healthcare costs (nursing costs) in complication state 2.

Fig. 5.4.a T2D in Denmark, year 2001 "Current" scenario. Total costs (DKK) per patient-year by main categories according to complication status

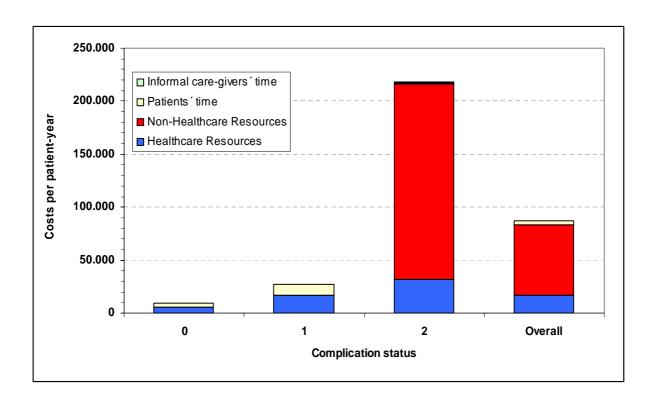


Fig 5.4b T2D in Denmark, year 2001. "Current" scenario. Total costs (DKK) per patient-year by main cost drivers among healthcare costs according to complication status

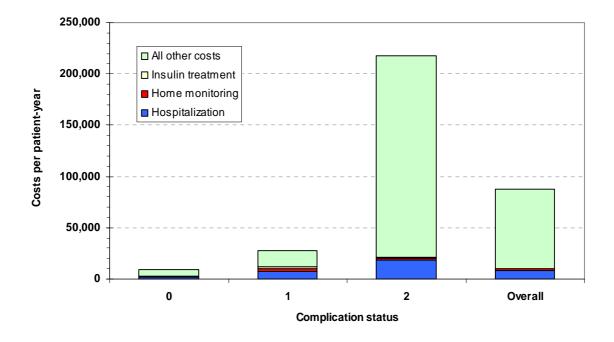


Table 5.1. Details of costs under the scenario "Current". By age group and complication status. All values in mill. DKK

		ı	0 - 14		ı	15 - 39		1	40 - 64		I	65+	ı
		0	1	2	0	1	2	0	1	2	0	1	2
TOTAL	11,898.2	4.8	0.5	2.5	102.7	75.9	254.6	389.2	307.0	3,581.6	141.8	51.9	6,985.8
Healthcare Resources	2,240.5	4.4	0.4	0.7	81.0	46.7	59.8	187.1	167.9	691.1	128.2	48.1	825.1
Added hospitalization costs	1,154.6	3.4	0.2	0.5	58.5	24.5	41.3	63.5	89.0	460.2	0.0	0.0	413.6
Treatment with insulin	107.7	0.6	0.1	0.1	8.7	9.0	4.2	5.2	16.7	22.4	4.4	7.1	29.1
Treatment with oral antidiabetics	66.9	0.0	0.0	0.0	0.9	0.1	0.1	17.0	4.6	7.7	15.7	3.9	16.8
Treatment with other drugs, added costs	380.8	0.0	0.0	0.0	1.4	0.9	3.3	64.1	19.6	79.5	73.5	14.8	123.8
Routine diabetes controls	196.1	0.3	0.0	0.1	4.2	3.0	2.5	26.2	12.6	36.5	24.3	9.1	77.3
Home monitoring	166.3	0.1	0.0	0.1	7.3	9.1	4.9	11.2	25.3	32.1	10.3	13.3	52.8
Physiotherapy	168.1	0.0	0.0	0.0	0.0	0.0	3.6	0.0	0.0	52.7	0.0	0.0	111.7
Non-Healthcare Resources	9,152.5	0.0	0.0	1.6	0.0	0.0	190.6	0.0	0.0	2,828.4	0.0	0.0	6,131.9
Added cost for nursing home	3,481.0	0.0	0.0	0.0	0.0	0.0	74.8	0.0	0.0	1,092.1	0.0	0.0	2,314.1
Annual cost for nursing assistance in the home, full-time	2,683.9	0.0	0.0	1.6	0.0	0.0	57.6	0.0	0.0	841.5	0.0	0.0	1,783.1
Annual cost for nursing assistance in the home, part-time	2,655.5	0.0	0.0	0.0	0.0	0.0	57.0	0.0	0.0	833.1	0.0	0.0	1,765.3
Wheelchair	52.1	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	5.5	0.0	0.0	46.2
Stocks	24.8	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	7.8	0.0	0.0	16.5
Protese crus	97.3	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	20.0	0.0	0.0	77.2
Protese femur	157.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	28.4	0.0	0.0	129.4
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	483.1	0.0	0.0	0.0	21.3	29.0	4.0	198.4	137.9	59.3	9.0	2.7	21.4
Transport and child care	25.0	0.0	0.0	0.0	۰. ا	0.6	0.5		2.2	6.7	4.5	4.7	44.0
routine visits	35.8	0.0	0.0	0.0	0.8	0.6	0.0	4.8	2.3	6.7	4.5	1.7	14.2
Transport and child care admissions	21.5	0.0	0.0	0.0	0.4	0.2	0.2	3.7	1.2	2.9	4.6	1.1	7.3
Loss of productivity during routine controls. Abseenteism	115.9	0.0	0.0	0.0	5.8	4.1	3.4	35.7	17.2	49.7	0.0	0.0	0.0
Loss of productivity during admissions	211.6	0.0	0.0	0.0	14.4	5.1	0.0	154.2	37.9	0.0	0.0	0.0	0.0
Loss of productivity related to discomfort during work	98.2	0.0	0.0	0.0	0.0	18.9	0.0	0.0	79.3	0.0	0.0	0.0	0.0
Informal care-givers' time	22.1	0.4	0.1	0.1	0.4	0.2	0.2	3.7	1.2	2.9	4.6	1.1	7.3
Transport and child care routine visits	0.1	0.0	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	21.5	0.0	0.0	0.0	0.4	0.2	0.2	3.7	1.2	2.9	4.6	1.1	7.3
Loss of productivity during routine controls. Abseenteism	0.5	0.4	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Production value	8,825.3	0.0	0.0	0.0	975.9	348.4	0.0	6,042.6	1,458.3	0.0	0.0	0.0	0.0
Registered as GDP	8,825.3	0.0	0.0	0.0	975.9	348.4	0.0	6,042.6	1,458.3	0.0	0.0	0.0	0.0
Including the informal sector	10,296.2	0.0	0.0	0.0	1,138.6	406.5	0.0	7,049.7	1,701.4	0.0	0.0	0.0	0.0

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

						45.00			40.04			0.5	
		0	0 - 14 1	2	0	15 - 39 1	2	0	40 - 64 1	2	0	65+ 1	2
			-					_					
TOTAL	6,514.5	17.0	0.6	0.4	232.2	49.9	61.4	939.2	207.0	1,191.3	553.9	5.5	3,256.2
Healthcare Resources	2,243.5	16.4	0.5	0.1	196.1	31.1	15.8	608.0	121.1	263.9	527.6	5.2	457.7
Added hospitalization costs	746.6	5.6	0.2	0.1	116.6	19.0	11.6	124.9	65.9	177.2	0.0	0.0	225.4
Treatment with insulin	260.6	8.8	0.2	0.0	34.4	3.9	0.7	81.7	10.5	11.1	82.1	0.9	26.3
Treatment with oral antidiabetics	140.4	0.1	0.0	0.0	5.4	0.7	0.2	52.1	5.4	4.9	56.5	0.5	14.6
Treatment with other drugs, added costs	389.7	0.0	0.0	0.0	4.0	1.5	1.1	131.3	15.5	26.2	151.0	1.4	57.6
Routine diabetes controls	155.1	0.4	0.0	0.0	7.0	2.0	0.6	42.9	7.8	11.7	46.8	0.8	35.1
Home monitoring	482.6	1.5	0.1	0.0	28.7	4.0	0.8	175.2	15.9	15.9	191.1	1.6	47.8
Physiotherapy	68.5	0.0	0.0	0.0	0.0	0.0	0.8	0.0	0.0	16.9	0.0	0.0	50.8
Non-Healthcare Resources	3,737.8	0.0	0.0	0.3	0.0	0.0	44.6	0.0	0.0	907.5	0.0	0.0	2,785.5
Added cost for nursing home	1,419.1	0.0	0.0	0.0	0.0	0.0	17.5	0.0	0.0	350.4	0.0	0.0	1,051.2
Annual cost for nursing assistance in the home, full-time	1,093.8	0.0	0.0	0.3	0.0	0.0	13.5	0.0	0.0	270.0	0.0	0.0	810.0
Annual cost for nursing assistance in the home, part-time	1,082.6	0.0	0.0	0.0	0.0	0.0	13.4	0.0	0.0	267.3	0.0	0.0	801.9
Wheelchair	22.8	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	1.8	0.0	0.0	21.0
Stocks	10.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	2.5	0.0	0.0	7.5
Protese crus	41.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.4	0.0	0.0	35.1
Protese femur	67.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	9.1	0.0	0.0	58.8
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	511.7	0.0	0.0	0.0	35.4	18.7	0.9	325.1	85. 1	19.0	17.4	0.2	9.7
Transport and child care routine visits	28.3	0.0	0.0	0.0	1.3	0.4	0.1	7.9	1.4	2.1	8.6	0.1	6.4
Transport and child care admissions	20.8	0.0	0.0	0.0	0.7	0.1	0.0	6.1	0.7	0.9	8.8	0.1	3.3
Loss of productivity during routine controls. Abseenteism	98.1	0.0	0.0	0.0	9.6	2.7	0.8	58.5	10.6	16.0	0.0	0.0	0.0
Loss of productivity during admissions	303.3	0.0	0.0	0.0	23.9	3.3	0.0	252.7	23.4	0.0	0.0	0.0	0.0
Loss of productivity related to discomfort during work	61.2	0.0	0.0	0.0	0.0	12.2	0.0	0.0	48.9	0.0	0.0	0.0	0.0
Informal care-givers' time	21.4	0.6	0.0	0.0	0.7	0.1	0.0	6.1	0.7	0.9	8.8	0.1	3.3
Transport and child care routine visits	0.1	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	20.8	0.0	0.0	0.0	0.7	0.1	0.0	6.1	0.7	0.9	8.8	0.1	3.3
Loss of productivity during routine controls. Abseenteism	0.6	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Production value	12,649.2	0.0	0.0	0.0	1,620.5	225.1	0.0	9,903.3	900.3	0.0	0.0	0.0	0.0
Registered as GDP	12,649.2	0.0	0.0	0.0	1,620.5	225.1	0.0	9,903.3	900.3	0.0	0.0	0.0	0.0
Including the informal sector	14,757.4	0.0	0.0	0.0	1,890.6	262.6	0.0	11,553.8	1,050.3	0.0	0.0	0.0	0.0

Table 5.3. 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	U-14 1	2	0	10 - 39	2	0	40 - 04 1	2	l 0	00+ 1	2
TOTAL	1,244.4	13.1	•		120.8	0.0	0.0	578.6	•		531.9		
Healthcare Resources	1,105.5	12.4			104.8			479.8			508.4		
Added hospitalization costs	0.0	0.0			0.0			0.0			0.0		
Treatment with insulin	280.2	10.1			47.8			111.4			110.9		
Treatment with oral antidiabetics	154.9	0.1			7.4			71.0			76.3		
Treatment with other drugs, added costs	0.0	0.0			0.0			0.0			0.0		
Routine diabetes controls	131.9	0.4			9.8			58.5			63.2		
Home monitoring	538.5	1.8			39.8			238.9			258.0		
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	138.3	0.0			16.0			98.8			23.5		
Transport and child care routine visits	24.1	0.0			1.8			10.7			11.6		
Transport and child care admissions	21.1	0.0			0.9			8.3			11.9		
Loss of productivity during routine controls. Abseenteism	93.1	0.0			13.3			79.8			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	0.7	0.7			0.0			0.0			0.0		
Transport and child care routine visits	0.1	0.1			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. Abseenteism	0.6	0.6			0.0			0.0			0.0		
Production value	15,755.2	0.0			2,250.7			13,504.5			0.0		
Registered as GDP	15,755.2	0.0			2,250.7			13,504.5			0.0		
Including the informal sector	18,381.1	0.0			2,625.9			15,755.2			0.0		

A summary of costs is presented in table 5.4. It is remarkable that the healthcare costs in absolute terms are similar for the "Improved" and "Current" scenarios. However, when expressed in total costs the costs are reduced by approx 50% as compared with the "Current" scenario. Large further reductions are seen, in absolute terms for the "Ideal" scenario. The numbers also underscore the considerable contribution from nursing (subsumed in "Non-healthcare resources") to the total costs, particularly in the "Current" scenario. (Se also figure 5.5)

Table 5.4. Summary of costs in the contrasting scenarios. Values are in mill. DKK

	Scenario			
	"Current"	"Improved"	"Ideal"	
Healthcare resources, mill. DKK	2,241	2,243	1,105	
Non-Healthcare resources, mill. DKK	9,152	3,738	0	
Patients' time, mill. DKK	463	512	138	
Informal care-givers' time, mill. DKK	22	21	1	
Total costs, mill. DKK	11,898	6,514	1,244	

Effects

Table 5.5 summarizes the estimated numbers of patient-years and QALYs, as well as the production value under each of the scenarios entertained.

Table 5.5. Summary of patient-years and income by working in the contrasting scenarios

	Scenario	Scenario		
EFFECTS	"Current"	"Improved"	"Ideal"	
Patient-years, un-adjusted	136,047	151,500	169,050	
Quality adjusted years (QALYs)	112,748	137,172	160,598	
Production value				
Registered as GDP, mill. DKK	8,825	12,649	15,755	
Including the informal sector, mill. DKK	10,296	14,757	18,381	

It is noteworthy that under the "Ideal" scenario T2D diabetes when treated appropriately is a disease completely without specific complications, and considerable more patient-years – with accompanying higher productivity – would be experienced (figure 5.5 and 5.6). The scenario "Improved" is placed somewhere in between the scenarios "Current" and "Ideal" in this respect.

Figure 5.5 Total cost and production value in scenarios

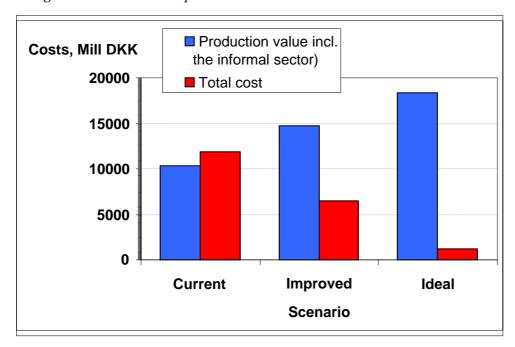
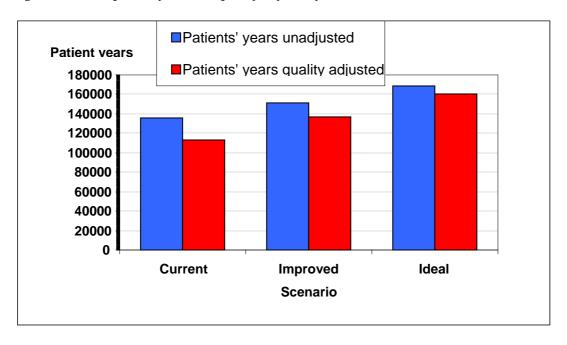


Figure 5.6 Total patient years and quality adjusted years in scenarios.



Health economics assessment

The estimated costs and effects, as reviewed above, have been summarized in a simple health economics evaluation as shown in Table 5.6. The hypothetical scenarios "Improved" and "Ideal" have been contrasted with the "Current" scenario in terms of differences. The "Current" scenario has not been evaluated against any "Worse" scenario, however, due to difficulties of establishing such a scenario for T2D.

Table 5.6. Summary results. All costs are in mill. DKK

Socioeconomic gains:	"Improved"	"Ideal"
	versus	versus
	"Current"	"Current"
COST (MILL DKK)		
Costs, total	-5.384	-10.654
Healthcare Resources	3	-1.135
Non-Healthcare Resources	-5.415	-9.152
Patients' time	29	-345
Informal care-givers' time	-1	-21
EFFECTS (mill DKK)		
Production value Mill DKK		
Registered as GDP	3.824	6.930
Including the informal	4.461	8.085
sector		
EFFECTS		
Patient-years		
Patient-years, un-adjusted	15.453	33.003
QALYs	24.423	47.849

The difference between the "Current" and "Improved" scenarios indicates that quite considerable gains through reduced costs are obtained at the same time as gains in patient-years, QALYs and production values are achieved.

The difference between the "Current" scenario and the "Ideal" scenario may be considered as the potential further gains which might be expected, should improved treatment and care of diabetes reach perfection. According to the estimates, a much lower level of costs would accompanied by a substantial further gain in patient-years, QALYs and as well as accompanying production value.

The final stage of the health economics assessment is summarized in Table 5.7, 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 5.7. Health economic evaluations. "Improved" and "Ideal" scenario compared to "Current" scenario

Key evaluation figures	"Improved" versus "Current"	"Ideal" versus "Current"
Cost-benefit (production value - costs), mill DKK		
Production value registered as GDP	9.208	17.584
Production value including the informal sector	9.845	18.739
Marginal cost effectiveness ratio:		
DKK/patient-year	-348.389	-322.812
Marginal cost utility ratio:	220 /22	222 (52
DKK/QALY	-220.432	-222.652

As described in the methodology report 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 "Improved" scenario as compared to the "Current" scenario, based on only productive gains, is (12,649-6,514)-(8,825-11,898)=9,208 mill. DKK when the human capital method is used to value the gains in years. This implies that benefits are measured in terms of productive gains only, disregarding the value of life per se. By including the value of household production, the net benefit increases to 9,845 mill. DKK. When the "Ideal" scenario is compared to the "Current", the net benefits in productive gains are 17,584 and 18,739 mill. DKK, respectively.

The marginal cost-effectiveness ratios are calculated as cost per added patient-year. The cost-effectiveness ratios are negative (DKK -348,349 and DKK -322,812), implying cost reductions as well as gains in patient-years when contrasting each of the alternative scenarios with the "Current" scenario. Finally, the cost-utility ratios show the cost associated with obtaining added quality adjusted patient-years in current treatment compared to the "Improved" (DKK

-220,432) and "Ideal" case (-222,652). In the present context this means the reduction in costs at the same time as quality-adjusted patient-years are gained. To the extent that the production value exceeds related 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 presented below should be seen as conservative figures.

We have not estimated the cost of a no treatment scenario (a "worst scenario") and what the effects would be in terms of type 2 patient years and QALYs, because there is very little clinical knowledge of how a situation with no treatment for type 2 would look. Thus no data are available for calculating the cost efficiency ratios (marginal costs) of current treatment pr gained patient year or 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). A reasonable estimate, though, of the marginal cost of current treatment per QALY is DKK 70.895 if we accept the cost effectiveness ratio from the type 1 study of Denmark (20) as a proxy for the marginal cost of current type 2 treatment. Alternatively we can use the average cost pr QALY of DKK 105,529 (DKK Mill 11,898/112,748 QALYs) in the "current scenario" as a proxy. In both cases a comparison with the figures reported in the literature suggests that the current resource allocation is beneficial to society. Consequently, the potential future allocation to diabetes treatment that will generate substantial savings would also be beneficial to society.

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 6 years before the year of impact for T2D. 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 1.34 for patients with T2D $((1 + 0.05) ^6 = 1.3401)$.

Based on the costs included for "treatment with other medication" this leads to a prevention cost of DKK mill 293 in the current scenario and DKK mill 408 in the improved scenario or DKK mill 74 and 104 in addition to the prevention costs already included in the base case. This amounts to an increase in the total healthcare costs by 3% in the current scenario and by 5% in the improved scenario. Of the total costs this amounts to less than 1 and 2 % respectively.

Alternative considerations in relation to the improved and the Ideal Scenario

The total healthcare costs are roughly the same in the "Current" and "Improved" scenario although the specific distribution on hospitalization, drugs, blood glucose monitoring etc is very different in the two scenarios. In the "Improved" scenario we have assumed that reorganization of the healthcare system in combination with an increased use of resources for an intensive form of poly-pharmacological treatment similar to the intensive poly-pharmacological discussed in the Danish Medical Technology Assessment report (16) leads to reduced hospitalization from less patients years with complications and an additional average life time of 3.5 patient years for people with T2D. The effects are 24,423 gained quality adjusted years of life and a reduction of the total cost of diabetes from DKK 11.9 Bill in the current scenario to DKK 6.5 Bill in the improved 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 10.7 Bill on the cost side and DKK 18.7 Bill in net benefits if the productivity effects are included) when a comparison is made to the current scenario. If only saving in *healthcare* costs is taken into account the savings are DKK 1.1 Bill. Thus the majority of the savings are savings in non-healthcare 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 what is the upper limit of the costs of such treatment for the treatment to be cost neutral when taking into account the associated resource savings and the health care effects attained in the ideal scenario. The gains in the "Ideal" scenario compared to the current scenario amounts to 47,849 QALYs and in terms of resources spent to savings of DKK Bill 10.654. This is equivalent to savings of 222,652 DKK per QALY gained. Hence, for the intervention to be cost neutral for the health care sector the cost of the new intervention may be as high as 222.700 per QALY gained. If we allow future treatments to generate costs and accept either the cost effectiveness ratio from the type 1 study of Denmark (20) of DKK 70,895 per gained QALY as a proxy for the marginal cost of current treatment type 2 diabetes, this would mean that the new intervention may cost as much as 293,000 DKK per QALY. Thus, on the basis of the savings in the ideal scenario it would be possible to use almost 10 times of what is currently used on health care (DKK 30,061 pr QALY) estimated for type 1 Diabetes in Denmark if such healthcare measures could lead to the elimination of all the current non-healthcare costs associated with the current disease pattern. If we use the average cost of type 2 pr QALY (DKK 105,529=Mill DKK 11,898/112,748 QALYs) as a proxy for the marginal cost of current treatment, this would mean that the new intervention may cost up to 330,000 DKK per QALY, and it would be possible to use more than 16 times of what is currently use of average health care resources pr QALY (19,876 pr QALY = Mill DKK 2,241/112,748 QALYs).

In the MTV report (16) two cost items are presented on the basis of international studies. These cost estimates could be used as examples of sophisticated treatment based on current medical knowledge. 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 are that complications are avoided just as assumed in the ideal scenario, but at the moment no firm evidence of such an outcome exist. If 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 per QALY for intensive poly-pharmacological blood glucose treatment substitution the healthcare cost of the ideal scenario) to make estimate of an alternative levels of cost in an ideal scenario, the total socio economic cost range between DKK 1.6 Bill (10,000*33,003 gained patient years in addition to the DKK Bill 1.1 in healthcare cost assumed in the ideal scenario) and 5 Bill (100,000*47,849 QALYs) of which healthcare cost amounts to 91%-97%. This should be compared to the total cost level in the ideal scenario of DKK 1.2 Bill. The savings compared to the total cost level in the current scenario then range between DKK 10.3 Bill (DKK Bill 11.9 – 1.6) and 7 Bill (DKK Bill 11.9 - 5). This leads to the conclusion that the results reached in the ideal scenario are relatively robust and that there are considerable potential socio economic savings to be found even from a rather expensive form of ideal treatment for type 2 diabetes.

6. DISCUSSION

The study design

This study represents a health economic analysis of the standard types of evaluation - cost-effectiveness analysis (CEA), cost-utility analysis (CUA) or cost-benefit analysis (CBA).

We have not, as it was the case in the study of Type 1 diabetes, outlined a "worst case" for Denmark Type 2 looking at how the survival and Quality of life would be impacted if no form of treatment of diabetes would be available. The reason for this is that very limited information is available of how such a situation would look. People with type 2 diabetes can live with the disease for many years without knowing it and medication with insulin is not key to survival as for type 1 diabetes.

First, the comparison of the present situation to an improved or ideal 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.

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.

Productivity gains and losses

A major effect of treatment of T2D patients is gain in patient-years. Derived effect may be increased productivity and costs in terms of use of time by informal care-givers. These issues are discussed in Report 1 and 2. (4)

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. Such derived consumption effects are not included in this study. The issue is discussed in the methodology report (report 1) (4).

Is the conclusion robust?

The non health care costs represent 77% of the total cost, thus indicating that the majority of societal costs of diabetes are non-health costs. This reflects an assumption that on average people with diabetes use some 64% more daily assistance and nursing (9 hour pr week) than the average receiver of such care (5.5 hours per week) in the general population. Two sensitivity analyses show that this conclusion is robust. First if we assume that the need for nursing attributable to diabetes was the same as for the average back ground population, the non health care cost due to diabetes would be 5.7 Bill DKK instead of 9.2 Bill DKK. Although this represents a substantial reduction in costs the non health care cost would still be 68% of the total cost.

A second sensitivity shows that a 34% reduction of people in need of nursing to only those above 65 years old in complication group 2 do not change this conclusion. Neither does reduction of annual unit nursing costs with 50%. A combined sensitivity based on that a) only people +65 receive nursing and care and b) at a unit cost of 50% of the base line cost shows that non health care cost would still be more than 50% of the total societal costs of diabetes.

7. CONCLUSION

Under the assumptions specified our study has demonstrated that it is costly to treat and care for T2D in Denmark. A very high part of the costs relates to nursing for elderly patients with long-term complications, but the high costs are associated with a significant number of patient-years and quality of patient-years and, in particular, productivity (income by working). Average cost pr QALY is DKK 105,500 in the current 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 the same time as the total costs would decrease, with improvements in diabetes care that it should be realistic to achieve.

Considerable gains and reduction in costs would be the case under the hypothetical assumption that improved care eliminates complications, co-morbidity and premature mortality in T2D as assumed in the ideal scenario. 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 as well as costs per health gain should be seen as conservative figures.

ANNEX 1: A demographical model of Type 2 diabetes in Denmark

There is no registration system in Denmark covering the population of patients with Type 2 diabetes (T2D). This makes it necessary to establish modelled populations from which the needed estimates of numbers of patient-years experienced in Denmark during the calendar year 2001 may be obtained under the scenarios specified before. Such modelled populations may be established when applying the basic principle:

Prevalence end of a year = Prevalence end of the year before + incidence during the year - deaths 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 T2D in Denmark has been developed, covering the period from year 1900 to 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.

The parameters of the model have been valuated so that the resulting prevalence estimates for the years 2000 and 2001 correspond in magnitude with the empirical data available from Århus County (see Annex 2). The establishing of the epidemiological models provides for estimations of patient-years in the contrasting scenarios.

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. A.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 Jylland (Nordslesvig) from German territory.

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

POPULATION SIZE AND STRUCTURE Millions 65+ 40-64 15-39 0-14 1920 1930 1970 1980 2000 1900 1910 1940 1950 1960 1990 **CALENDAR YEAR**

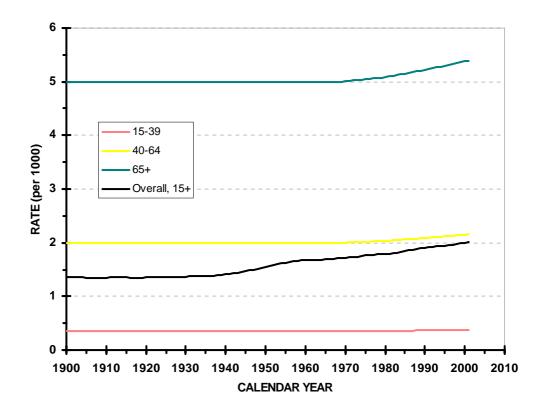
Estimation of incidence

There is no data available that reliably describes the trend in incidence of T2D in Denmark over time. We have therefore opted for the development of a parsimonious scenario, with constant incidence levels until about 1970, after which time the incidence has been slightly increasing.

The assumed incidence rates are shown in Fig. A2. It must be stressed that these age-specific incidence rates have been assumed under pure arbitrary grounds, but with the end results in mind that, combined with assumed mortality rates, the ending prevalence of diagnosed T2D in Denmark by the end of year 2001 should yield a number at around 125,000.

Note that, throughout the period 1900-2001, it is assumed that no cases of T2D in Denmark will be diagnosed under the age of 15 years.

Fig. A.2. Assumed trends in incidence rates of Type 2 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 T2D 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 T2D itself. Alternatively, estimates of remaining life expectancies from the time of diagnosis of T2D 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 diagnosis for a chronic and un-curable disease like T2D. 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 diagnosis. These numbers are based on the best available clinical evidence, due to the lack of reliable epidemiological information.

To establish a method that allows for realistic changes in life expectancy for patients with T2D, 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 back 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 T2D 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.

On pure arbitrary grounds, from year 1900 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 > 1900). The coefficient k_t is formally expressed as $k_t = k_{t-1} + (0.0509/ (year_t - 1900))$.

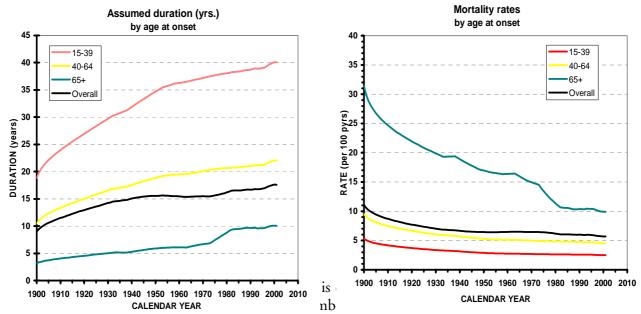
This formula ensures that the coefficient is given increasingly higher value as the time proceeds from 1900 – but also that the annual increment in the coefficient is becoming smaller and smaller. The constant of 0.0509 has been obtained as the value satisfying that, for the year 1975, the duration of disease is 0.75 times the expected remaining life time in the general population for any age at onset category.

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 T2D in Denmark for selected calendar years. Numbers in parentheses indicate values fixed by assumption.

Calendar	Coefficient	Estimated du	Estimated duration (yrs.) from onset at age:					
year	k,	0-14	15-39	40-64	65+	Overall	100 years)	
1900	0.551	24.1	18.8	10.5	3.3	9.0	11.1	
1925	0.696	36.3	28.3	15.8	4.8	13.6	7.4	
1950	0.730	44.4	34.7	18.9	5.9	15.5	6.4	
1975	(0.75)	48.2	37.7	20.5	7.4	15.6	6.4	
2000	0.764	51.3	40.1	22.0	10.1	17.6	5.7	

Figure A.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. A.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 2 diabetes for Denmark, 1900-2001.



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 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 T2D 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.

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 investigation of diabetes in the Århus County, Denmark, have been utilized for the purpose of the present project.

About the Arhus County diabetes investigations

As part of her Ph.D. study, Kristensen (5) investigated the potential possibilities of how to identify the total population of patients with diagnosed diabetes in Vejle County, Denmark. 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 to 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 whole Denmark, 2001

	Age group				
	0-14	15-39	40-64	65+	Total
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 back to 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:

Complication status	First year any of the diagnoses have been registered						
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 whole 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

	Age group				
All patients	0-14	0	0	0	TOTAL
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

	Age group				
All patients	0-14	15-39	40-64	>65	TOTAL
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

	Age group				
Type 1 patients	0-14	15-39	40-64	65+	TOTAL
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

	Age group				
Type 2 patients	0-14	15-39	40-64	65+	TOTAL
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 (8) 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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				_
	0-14	15-39	40-64	65+	Total
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 enables for aggregating 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 whole 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. ARHUS 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

Type 2 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		

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

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 for 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						
	0-14 15-39 40-64 65+ Tot						
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							
	0-14	Total						
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	AGE						
All patients	0-14	15-39	40-64	65+	Total		
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 .						
	0-14 15-39 40-64 65+ Total						
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 _						
	0-14	15-39	40-64	65+	Total		
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						
	0-14	15-39	40-64	65+	Total		
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 combing 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 for diabetic complications agents, regardless of complication status. Costs are in 1000 DKK

TOTAL DENMARK, YEAR 2001

	AGE GROUP						
	0-14	15-39	40-64	65+	Total		
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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 abovementioned 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 for diabetic complications agents, specific for complication status. Costs are in 1000 DKK

AARHUS COUNTY, YEAR 2001: The diabetic population

All patients	AGE GROUP				
	0-14	15-39	40-64	65+	Total
Total costs	1	1,195	21,442	23,078	45,716
Costs, independent of diabetes	0	29	2,175	5,426	7,630
Costs, ascribed to diabetes	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				
	0-14	15-39	40-64	65+	Total
Total costs	0	294	8,422	7,995	16,711
Costs, independent of diabetes	0	19	1,275	2,416	3,710
Costs, ascribed to diabetes	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				
	0-14	15-39	40-64	65+	Total
Total costs	0	198	2,584	1,601	4,383
Costs, independent of diabetes	0	7	309	448	763
Costs, ascribed to diabetes	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 GROU	AGE GROUP				
	0-14	15-39	40-64	65+	Total	
Total costs	1	703	10,436	13,483	24,622	
Costs, independent of diabetes	0	4	591	2,562	3,157	
Costs, ascribed to diabetes	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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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				
	0-14	15-39	40-64	65+	Total
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

APPENDIX

Valuation of cost items in US\$ (All cost are added costs)

Cost component	Sources: data; assumption;	Unit	Unit price (US\$ PPP)
Medical costs	professional opinion		•
Routine diabetes control (inclusive	Interview with GP/leaflet	1 visit	18.5
laboratory tests)	(11)/laboratory list prices	1 1/310	10.9
Medication with insulin	Empirical evidence	Consumption per	487
		average patient year	
Medication with peroral anti	Empirical evidence	Consumption per	128
diabetic drugs		average patient year	
Medication with drugs for	Empirical evidence	Consumption per	447
prevention and management of		average patient year	
complications			
Blood glucose monitoring	Life Scan (12)	By year, assuming 13	753
		BGM per week	
		exclusively for patients on insulin	
		on insulin	
Hospitalization	Empirical evidence	Costs per average	1,003 (incl. 15%
•		patient year	overhead)
Cost of nursing and appliances			
Nursing home	15% of complication group	Per year	42,553
	2 live in nursing homes and		
	received 15 hours of		
	assistance pr week (14, 26,		
Niiiil	27) 85% of complication group	D	22 125
Nursing assistance in home	2 has either high need (13	Per year	33,135 14,043
	hours a week) or low need		14,043
	(5,4 hours a week) 15% has		
	no assistance (14, 26, 27)		
Physiotherapy	100% in group 2 (28)	Per year (12 visits)	400
Wheel chair	25% of complication group	Per year	165
	2 (10 year life time) (23)	-	
Stocks	100% of complication	Per year	59
	group 2 (10 year life time of		
D 1	stocks) (23)	D.	4 (25
Prothese crus	100% of crus amputations	Per year	1,625
	(50% over 65 year) (2 year		
Prothese femur	lifetime of prothese) (22)	Per year	4,196
Fromese lemur	100% of femur amputations (50% over 65 years) (2 year	rer year	4,190
	lifetime of prothese) (22)		
Productivity	meenic of produces, (22)		
Lost productivity during admissions	Average income for people	Per admission day	101
1	employed in 2001 (19)	,	
Lost productivity during admissions	50% of the value in the	Per admission day	51
(informal sector)	formal sector (19)	,	
Restricted activity day	10% reduced productivity	Per active working day	5
	in 50% of working time		
	(19)		
Lost productivity routine controls	2 hour/day (19)	Per routine control	13
Gained productivity from improved	(19)	Per active working day	101/51
survival		formal/informal	

The average DKK/US\$ PPP conversion rate is 8.46 for the year 2001.

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