Early retirement and the influence on healthcare budgets and insurance premiums in a diabetes population

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Objectives: To contribute to current discussions about budget impact modeling, two different approaches for the impact of a new pharmaceutical product were analyzed: firstly considering the impact on annual healthcare expenditures only, and secondly additional inclusion of lost insurance premiums due to possible early retirement in patients with chronic diseases.

Methods: The dynamic model calculates the budget impact from two different perspectives: (a) the impact on healthcare expenditures and (b) on expenditures as well as on health insurance revenues due to premiums. The latter approach could especially be useful for patients with chronic diseases who have higher probabilities of early retirement. Early retirement rates and indirect costs were derived from published data. Healthcare premiums were calculated based on an average premium and a mean income. Epidemiological input data were obtained from the literature. Time horizon was 10 years.

Results: Results in terms of reimbursement decisions of the budget impact analysis varied depending on the assumptions made for the insurance premiums, costs, and early retirement rate. Sensitivity analyses revealed that in extreme cases the decision for accepting a new pharmaceutical product would probably be negative using approach (a), but positive using approach (b).

Conclusions: Depending on the disease and population of interest in a budget impact analysis, not only the healthcare expenditures for a health insurance have to be considered but also the revenue side for an insurance due to retirement should be included.

Keywords: decision analysis, budget impact, pharmacoeconomics, health economics, health insurance

Introduction

The use of economic evaluation in determining resource allocation is well established in a number of health services (Drummond and McGuire 2001). There is growing recognition that a comprehensive economic assessment of a new healthcare intervention at the time of launch requires both cost-effectiveness analysis (CEA) and a budget impact analysis (BIA).

BIA for new pharmaceutical products provides estimates of the likely impact of the new drug on healthcare decision-makers short- and longer-term annual budgets. It is an essential part of a comprehensive economic assessment of a new pharmaceutical product and is increasingly required (National Research Council 1991), along with CEA, before national or local formulary approval and/or reimbursement.

National regulatory agencies such as the National Institute for Clinical Excellence (NICE) in England and Wales (NICE 2004), the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia (PBAC 2002), the Co-ordinating OFFICE for Health Technology Assessment in Canada (CCOHTA 1997), the French Transparency Committee (Colleges Des Économistes De La Santé 2004) and the Pharmaceutical Benefits Board in Sweden (Pharmaceuticals Benefits Board 2003) as well as managed care organizations (MCOs) in the USA, now require that companies submit estimates of both the cost-effectiveness and

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the likely impact of the new healthcare interventions on national or health plan budgets to support the reimbursement or formulary inclusion (Trueman et al 2001).

Standard methods for performing and presenting the results of CEAs are well accepted (NICE 2004), but the same progress has not been made for BIAs (Kuntz and Weinstein 2002). Several factors, which are not generally needed for CEA, should be part of a comprehensive BIA including the size of the treated population, incidence and prevalence estimations, and market penetration rates for the new drug as well as for the main comparators. A review of the recent literature indicates that there are only a limited number of published budget impact analyses (Cairns 2001) and these vary greatly in the methods used.

It is recommended that a comprehensive approach to budget impact estimation be adopted, with the results being presented from both a societal perspective as well as from more limited perspectives depending on the needs of the decision-maker.

Recently, Trueman et al (2001) have proposed an initial framework for standardization of BIAs.

This paper analyzes the potential impact of early retirement on healthcare payer's annual budgets due to a chronic and progressing disease such as diabetes mellitus. The study is first based on a theoretical analysis before a hypothetical new product in diabetes treatment is applied.

Materials and methods

The budget of a healthcare payer like the social insurance payers in Germany or the private ones in the US, for instance, are mainly dependent on their expenses as well as their revenues (Zweifel and Breyer 1997). The expenses are mainly dependent on the development of the diseases of the insureds and the related costs whereas the revenue is highly influenced by the premium an insured is paying. Once an insured is being (early) retired the real amount paid for premiums is much lower in comparison to the premiums when an insured is working full-time due to the lower income.

The following paragraph shows the theoretical impact of early retirement as well as the impact of the drug price on the equilibrium equation for a general health insurance. The next step is to analyze a hypothetical example with a diabetes population.

Methods

The cost of illness, including the treatment costs as well as the complication costs due to a given disease, is the main driver on the healthcare payer budgets. The calculation of the cost of illness comprises the direct costs for complications (CoC)

and the treatment costs (CoT) for the given diseases i in the years t, respectively (with i = 1, .., N and t = 1; …; T). The costs of illness (CoI) for n patients are calculated according to the following equation E1:

$$CoI_{it} = \sum_{i=1}^{N} \sum_{t=1}^{T} (CoC + CoT)_t \cdot n_i \qquad (E1)$$

Additionally it is assumed that the number of complications c as well as the severity s of these are the drivers for the CoC and the market share for product A MS_A, with an influence of price for competitors p_{A+1}, as well as the price p_A for the drugs A (A = 1, …, Z) are the drivers for the CoI. Furthermore the numbers of patients n treated in the disease population i is mainly dependent on the prevalence i_p and incidence i_i of the disease as well as the mortality rates m_i within that population. The model is assumed to be dynamic, and hence with a higher mortality rate, fewer survivors have to be treated. Hence equation (E1) can be rewritten as

$$CoI_{it}(c, s, d_c(MS, p)) =$$
$$\sum_{i=1}^{N} \sum_{t=1}^{T} \left(CoC(c,s) + \sum_{A=1}^{Z} CoT_A(MS(p_{A\pm1}), p)_A \right)_t$$
$$\cdot n_i(i_p, i_i, m_i)_t \qquad (E2)$$

The revenue side R of a healthcare payer balance sheet is driven by the premiums h the n insureds are paying.

$$R_t = \sum_{t=1}^{T} h_t \cdot n \qquad (E3)$$

It is furthermore supposed to take the net present value of all revenues into account. Assuming that the income Y of the insureds are influencing the real cash flow h of the revenue side and the mortality rates have an impact on the number of insureds, equation (E3) can be rewritten as following

$$R_t = \sum_{t=1}^{T} h(Y)_t \cdot n(m) \qquad (E4)$$

Due to the nature of some diseases early retirement is widely spread in some population parts (Stock et al 2005). Retirement r as a whole has a significant influence on the income Y of that population. Assuming that no other factors have an impact on the income level equation (E4) can be adapted to (E5)

$$R_t = \sum_{t=1}^{T} h(Y(r))_t \cdot n(m) \qquad (E5)$$

For social insurance based systems such as the German healthcare system, the insurance companies are mainly non-profit organizations (with the exception of the private companies). Hence the premiums for the insureds are in an equilibrium (without a need for an increase) if the revenue of the payers is equal to the costs of these. Assuming that there is only one healthcare payer in a given country equations (E2) and (E5) represent the equilibrium of the healthcare payer company:

$$\sum_{t=1}^{T} h(Y(r))_t \cdot n(m) =$$
$$\sum_{i=1}^{N} \sum_{t=1}^{T} \left(CoC(c,s) + \sum_{A=1}^{Z} CoT(MS(p_{A \pm 1}), p)_A \right)_t$$
$$\cdot n_i(i_p, i_i, m_i)_t \tag{E6}$$

To simplify the interpretation of (E6) this is rewritten to equation (E7)

$$\sum_{t=1}^{T} h(Y(r))_t \cdot n(m) -$$
$$\sum_{i=1}^{N} \sum_{t=1}^{T} \left(CoC(c,s) + \sum_{A=1}^{Z} CoT(MS(p_{A \pm 1}), p)_A \right)_t$$
$$\cdot n_i(i_p, i_i, m_i)_t = 0 \tag{E7}$$

First derivations with respect to retirement r and the drug price p for a new product c are as follows

$$\frac{\partial}{\partial r} = \frac{\partial Y}{\partial r} \cdot \frac{\partial h(Y(r))_t}{\partial Y} < 0 \tag{E8}$$

$$\frac{\partial}{\partial p_i} = -\sum_{i=1}^{N} \sum_{t=1}^{T} n_i(i_p, i_i, m_i)_t \cdot \left[\frac{\partial CoT_A}{\partial MS_A} \cdot \frac{\partial MS_A}{\partial p_A} \right.$$
$$+ \frac{\partial CoT_A}{\partial p_A} + \frac{\partial CoT_{A-1}}{\partial MS_{A-1}}$$
$$\left. \cdot \frac{\partial MS_{A-1}}{\partial p_A} + \frac{\partial CoT_{A+1}}{\partial MS_{A+1}} \cdot \frac{\partial MS_{A+1}}{\partial p_A} \right] \tag{E9}$$

$$\forall A \neq 1; A \neq Z$$

Equation (E8) shows the following: When the retirement rate r changes, the income is also changed and this could be assumed to be negative. This assumption can be easily explained: Y decreases when r increases. Certainly in markets with perfect competition and private insurance this might even be assumed to be positive when assuming an increasing demand for a larger amount of insurance coverage, whereas this assumption might even not be assumed in the most liberal healthcare market, the US, where elderly people or retired people are usually then covered by MediCare and no more by competing healthcare plans.

When the retirement rate r is increasing the real income will be decreased. The second part of equation E8 is showing the impact of income Y on the premium function h, which could be positive: Due to the higher income it is assumed that the real amount of premiums is increasing, when assuming such a healthcare system as the one in Germany where a decreasing revenue side can be assumed with an increasing retirement rate.

In equation (E9) it is analyzed in which way a new product with price p_i has an influence on the insurance equilibrium equation (E7). The number of patients n is decreasing the right-hand side of the equilibrium function (E7) due to the sign of the first derivative. Additionally the costs of treatment CoT_A are of interest, whereas the sign here is mainly dependent on the price level as well as on the market share MS_A (first two parts in the bracket). Furthermore the change in costs of treatment and market share of the comparators of product A, namely A−1 and A+1, have an influence on the sign of that first derivative. Hence the sign of this equation is not clear and has to be analyzed case by case. The sign is mainly dependent on the price level of the comparator drugs and their market share. These findings are only valid for the case $A \neq 1$ and $A \neq Z$. One special case is an innovative product without any comparators (A = 1). Then the costs of treatment are changing with the price (increase) and the whole first derivative with respect to p_i is becoming negative. This would then have an influence on the revenue side which has to be increased to still fulfill the equilibrium criteria in equation (E7).

Results

After the theoretical analysis of an impact of early retirement and also price changes for a product A, a hypothetical comparison follows. The market i is assumed to be the one for type 2 diabetes mellitus patients. The comparison is based on the epidemiological finding of the UKPDS, where glycemic control was analyzed with the options of diet, sulfonylurea, metformin, and insulin therapy (UKPDS 1998).

In a usual budget impact analysis two scenarios are compared, which are usually assumed to be a world with the new possible treatment option and other available treatments and one without that new option, which is usually the environment

Table 1 Base assumptions for the three budget impact scenarios

Parameter	Base case scenario	Best case scenario	Worst case scenario
Average yearly income (€)[a]	35,517	35,517	35,517
Average yearly income lost due to early retirement (€)	14,207	14,207	14,207
Retirement rate for current Tx (%)	5.0	5.0	5.0
Retirement rate for current Tx and new option (%)	5.0	2.5	7.5
Premium (percentage of yearly income)[a]	14.0	14.0	14.0
Covered population - in both arms	83,000,000	83,000,000	83,000,000
Number of treated patients[a]	107,070	107,070	107,070
Prevalence (%)[a]	6.45	6.45	6.45
Incidence per year	1,000	500	2,000

[a]in the "Current Tx" and "Current Tx & NEW option" arm.

of the current market. The market share is changed due to the fact that this new option will be available on the market.

For this hypothetical analysis it is assumed that a pharmaceutical company will develop an innovation of a so-called oral antidiabetic (OADs), which is assumed to be more effective in comparison with the OADs currently available on the market. However, the insulins are still the state of the art after OADs are no more working properly in the patients in terms of HbA1c adjustment.

For the following analysis direct costs for various diabetes complications were derived from O'Brien et al (1998) whereas it was directly assumed that these US data could also be valid for the German circumstance (see Table 1). Prevalence data as well as early retirement data were derived from literature (Stock et al 2005). The main assumptions for this analysis are summarized in Table 2. Assumed complication rates derived from UKPDS 33 are summarized in Table 3. The market for diabetes was assumed to consist just of insulin drugs and oral antidiabetics (OADs). The efficacy of the hypothetical new option on the market was assumed to be 20% better in terms of outcomes in comparison with

the standard OADs. Hence the following two scenarios are analyzed: The world without the new option with the market share distribution in the following way. 38% of patients are getting a subcutaneous insulin and the rest of the treated patients are getting the OADs. All other patient groups treated with any other possibility are not taken into account. The market share over time is changed in the way that the insulin market will have a market share of 40% after 1 year and hence the OAD market is declining by that amount. The world with the new option has the same starting point for the insulin and the OADs, whereas the new option is assumed to have no market share at all. The following three scenarios (defined on the view of a pharmaceutical company) are analyzed for the comparator world including the hypothetical new treatment (Table 4):

- Base Case: The retirement rate was assumed to be 5% for both scenarios. Additionally the following market shares were assumed:
  - Market share for insulin after 4 years: 45%
  - Market share for OADs after 8 years: 10%
  - Market share for the new option after 8 years: 45%

Table 2 Diabetes-related complication costs derived from literature

Cost item	Costs per event (€)	Source
Hypoglycemia	384	*Diabetes Care* 1995
Retinopathy/Macular edema	71	O'Brien et al 1998
Blindness in one eye	4365	O'Brien et al 1998
Cataract	2250	Internal expert assumption
Micro-/Macroalbuminuria	78	O'Brien et al 1998
End-stage renal disease	77,735	O'Brien et al 1998
Neuropathy	273	O'Brien et al 1998
Peripheral arterial disease	6867	DRG handbook 2000
Diabetic foot syndrome	3421	O'Brien et al 1998
Myocardial infarction	34,597	O'Brien et al 1998
Heart failure	12,038	DRG handbook 2000
Angina pectoris	3102	O'Brien et al 1998
Stroke	50,858	O'Brien et al 1998

Table 3 Cumulative diabetes complication rates derived from UKPDS (1998) for the world with and without the new option ("Current treatment" vs "Current treatment & NEW option"). The complication rates are reported for the hypothetical diabetes cohort of 107,070 at year 0 (see assumptions)

Complication	"Current treatment"									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Hypoglycemia	2478	5274	7257	8861	10,060	11,087	11,782	12,331	12,772	10,649
Ophthalmic disorders (retinopathy, macular edema, blindness, cataract)	12,376	23,052	31,963	39,641	46,598	52,785	58,389	63,589	68,376	72,850
Kidney system, (Micro-, macroalbuminuria, end-stage renal disease)	4835	9460	14,175	18,373	22,431	26,438	30,321	33,827	37,141	39,842
Nerve system (neuropathy, peripheral arterial disease, diabetic foot syndrome)	4613	9042	13,571	18,124	22,578	26,874	30,963	35,442	40,158	44,560
Cardiovascular system	3094	58839	8651	11,365	14,038	16,619	19,142	21,398	23,713	26,014
Mortality	5845	11,442	16,574	21,279	25,920	30,118	34,032	37,834	41,378	44,782

Complication	"Current treatment & NEW option"									
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Hypoglycemia	2831	5092	6999	8688	9876	10,945	11,672	12,279	12,915	13,387
Ophthalmic disorders (retinopathy, macular edema, blindness, cataract)	11,513	21,403	29,638	36,704	43,064	48,508	53,467	58,008	62,184	66,029
Kidney system (Micro-, macroalbuminuria, end-stage renal disease)	4460	8687	12996	16872	20,596	24,244	27,787	30,993	34,047	36,536
Nerve system (neuropathy, peripheral arterial disease, diabetic foot syndrome)	4286	8348	12,423	16,517	20,489	24,283	27,819	31,706	35,773	39,509
Cardiovascular system	2931	5564	8180	10,722	13,251	15,717	18,076	20,173	22,303	24,419
Mortality	5484	10,732	15,519	19,979	24,438	28,395	32,121	35,824	39,304	42,625

Table 4 Market share for the three possible treatments over time for the three budget impact scenarios

Market share	Current market share	Target market share (Base / Best / Worst)	Time to reach the target
Insulin: Current Tx[a]	38	40	1
OADs: Current Tx[a]	62	60	1
Insulin: Current Tx + new option	38	45 / 30 / 50	4
OADs: Current Tx + new option	62	10 / 0 / 31	8
New option	0	45 / 70 / 19	8

[a]Assumption: fixed market in terms of scenarios.

- Best Case: The retirement rate was assumed to be 2.5% for both scenarios. Additionally the following market shares were assumed:
  - Market share for insulin after 4 years: 30%
  - Market share for OADs after 8 years: 0%
  - Market share for the new option after 8 years: 70%
- Worst Case: The retirement rate was assumed to be 7.5% for both scenarios. Additionally the following market shares were assumed:
  - Market share for insulin after 4 years: 50%
  - Market share for OADs after 8 years: 31%
  - Market share for the new option after 8 years: 19%

The price for subcutaneous insulin was assumed to be €89, for the OADs €286 (see Table 5). The base, best, and worst case analyses were run within some stratification groups for the incidence cases and drug costs for the new option (see Table 1).

The budget impact for the base case analysis, 1000 incident cases and drug costs of €500, ranged from €58,860,034 (best case) to €99,108,673 (base case) cumulative after 10 years (Table 7). Assuming that the premium assumption of 14% p.a. was an equilibrium of the costs and the expenses (see equation E7) the difference between the yearly premiums of the world with and without the hypothetical new drug ranged between 0.0034 and 0.0122, which was a proportional difference between 2.3% and 8.9% after 10 years. It turned out that the direction of the difference of the yearly premiums and the budget impact result would influence the decision makers in the same way. The new treatment option is not only more effective and has a positive impact on the healthcare payer's budget (in terms of cost reduction), but has also a reduction in the yearly premiums as a result due to the improvement of the early retirement rate. This conclusion can also be drawn for the third sensitivity analyses (drug price: €1500). The only scenario where the hypothetical new drug is dominant in terms of budget impact and premium change is the analysis with an assumed drug price of €500.

The second analysis was done by taking the same assumptions as before but changing the incidence rate from 1000 new cases per year to 500 new cases per year. For the base case analysis (drug costs €500) it can be seen that the budget impact is negative which means that the current treatment possibilities (insulin and OADs) are cheaper than the current treatment inclusive of the hypothetical new treatment (see Table 6). But when reviewing the yearly premiums based on the early retirement rate and the costs per year, the decision-maker should go with the new treatment due to lower yearly premiums, between 0.0046 (proportional: 2.6%) and 0.0167 (proportional: 10.0%). The same conclusion can be drawn when doing the analysis for a yearly drug price per patient of €1500. Interestingly the influence on the decision-maker is changed when including a drug price for the hypothetical new option to €500. With that price the budget impact is improved in terms of cost reduction with the new treatment as well as a lower premium per year.

The third analysis was run for the three scenarios described above and an incidence rate of 2000 new cases per year (see Table 8). Also for this stratification analysis it turns out that the impact of the early retirement rate is much

Table 5 Yearly drug costs (€) for the three pharmaceutical treatment options on the market

Cost item (€; yearly)	Base case scenario	Best case scenario	Worse case scenario
Insulin	286	286	286
Oral antidiabetics (OADs)	89	89	89
New option	1,000	500	1,500

Table 6 Budget Impact and premium differences for the three scenarios (base, best worse case) and for the corresponding (new option) cost groups for the incidence group 1000 patients per year. Budget Impact as well as premium differences are "Current Tx" vs "Current Tx & NEW"

Incidence per year: 1,000	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
New option costs: €500										
Budget Impact: Base Case	8,8847,518	14,172,088	24,553,377	36,123,442	44,348,912	49,426,880	60,670,863	70,756,833	85,102,459	99,108,673
Budget Impact: Best Case	4,968,733	5,573,514	12,102,680	20,062,508	24,303,277	25,193,357	32,636,192	38,612,245	49,164,357	58,860,034
Budget Impact: Worse Case	7,117,511	12,480,246	20,742,754	29,663,493	36,593,758	41,611,688	50,223,934	58,257,157	68,769,327	79,312,377
Premium difference (%): Base Case	0.0013 (0.1)	0.0028 (1.8)	0.0045 (2.9)	0.0059 (3.7)	0.0071 (4.4)	0.0082 (5.1)	0.0089 (5.7)	0.0091 (5.9)	0.0088 (6.0)	0.0085 (6.1)
Premium difference (%); Best Case	0.0024 (1.6)	0.0045 (3.0)	0.0068 (4.4)	0.0087 (5.5)	0.0103 (6.5)	0.0118 (7.5)	0.0127 (8.2)	0.0129 (8.6)	0.0126 (8.8)	0.0122 (8.9)
Premium difference (%); Worse Case	0.0001 (0.1)	0.0008 (0.5)	0.0016 (1.0)	0.0022 (1.3)	0.0027 (1.6)	0.0032 (2.2)	0.0036 (2.3)	0.0036 (2.3)	0.0035 (2.3)	0.0034 (2.3)
New option costs: €1,000										
Budget Impact: Base Case	−11,008,614	−26,070,717	−36,652,501	−46,415,326	−59,806,876	−76,750,125	−88,377,410	−101,887,136	−112,177,201	−123,979,141
Budget Impact: Best Case	−28,738,462	−62,164,812	−89,744,421	−115,808,158	−145,612,915	−179,171,899	−207,231,445	−237,830,339	−265,435,969	−295,744,857
Budget Impact: Worse Case	−513,781	−2,483,397	−1,653,996	−279,004	−1,012,490	−3,858,233	−3,693,205	−4,510,308	−3,303,420	−2,494,335
Premium difference (%): Base Case	0.0013 (0.8)	0.0028 (1.8)	0.0045 (2.8)	0.0059 (3.6)	0.007 (4.3)	0.0081 (5.0)	0.0088 (5.6)	0.0089 (5.8)	0.0087 (5.9)	0.0084 (6.0)
Premium difference (%); Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0068 (4.3)	0.0086 (5.4)	0.0102 (6.4)	0.0116 (7.4)	0.0125 (8.1)	0.0127 (8.5)	0.0125 (8.7)	0.0121 (8.8)
Premium difference (%); Worse Case	0.0001 (0.0)	0.0008 (0.5)	0.0015 (0.9)	0.0021 (0.9)	0.0026 (1.6)	0.0031 (1.9)	0.0034 (2.1)	0.0035 (2.2)	0.0034 (2.2)	0.0032 (2.2)
New option costs: €1500										
Budget Impact: Base Case	−30,339,519	−65,342,035	−96,289,765	−126,743,112	−161,193,055	−199,692,095	−233,500,675	−269,927,604	−304,028,352	−340,790,018
Budget Impact: Best Case	−61,920,432	−128,931,651	−190,022,909	−249,467,842	−312,759,498	−380,302,119	−443,174,072	−509,669,424	−574,607,786	−644,072,811
Budget Impact: Worse Case	−7,619,847	−16,475,553	−22,482,132	−28,010,518	−35,849,128	−46,093,119	−53,685,334	−62,674,272	−69,947,658	−78,024,111
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0045 (2.8)	0.0059 (3.6)	0.007 (4.3)	0.0081 (5.0)	0.0088 (5.6)	0.0089 (5.8)	0.0087 (5.9)	0.0084 (6.0)
Premium difference (%); Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0068 (4.3)	0.0086 (5.4)	0.0102 (6.4)	0.0116 (7.4)	0.0125 (8.1)	0.0127 (8.5)	0.013 (8.7)	0.0121 (8.8)
Premium difference (%); Worse Case	0.0001 (0.0)	0.0008 (0.9)	0.0015 (0.9)	0.0021 (1.3)	0.0026 (1.6)	0.0032 (1.9)	0.0034 (2.1)	0.0035 (2.2)	0.0034 (2.2)	0.0032 (2.2)

Table 7 Budget Impact and premium differences for the three scenarios (base, best worse case) and for the corresponding (new option) cost groups for the incidence group 500 patients per year. Budget Impact as well as premium differences are "Current Tx" vs "Current Tx & NEW"

Incidence per year: 500	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
New option costs: €500										
Budget Impact: Base Case	8,322,292	13,200,602	22,984,763	33,912,459	41,579,302	46,191,844	56,745,854	66,153,332	79,673,949	92,831,737
Budget Impact: Best Case	4,602,027	4,602,027	10,534,066	17,851,526	21,533,668	21,958,321	28,711,182	34,008,745	43,735,848	52,583,097
Budget Impact: Worse Case	6,592,285	11,508,759	19,174,141	27,452,510	33,824,149	38,376,653	46,298,925	53,653,656	63,340,817	73,035,440
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0045 (2.8)	0.0059 (3.6)	0.007 (4.3)	0.0081 (5.0)	0.0088 (5.6)	0.0089 (5.8)	0.0087 (5.9)	0.0084 (6.0)
Premium difference (%): Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0068 (4.3)	0.0086 (5.4)	0.0102 (6.4)	0.0116 (7.4)	0.0127 (8.1)	0.0127 (8.5)	0.0125 (8.7)	0.0121 (8.8)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0008 (0.5)	0.0015 (0.9)	0.0021 (1.3)	0.0026 (1.6)	0.0031 (1.9)	0.0034 (2.1)	0.0035 (2.2)	0.0034 (2.2)	0.0032 (2.2)
New option costs: €1,000										
Budget Impact: Base Case	−11,008,614	−26,002,120	−36,453,342	−46,000,992	−58,886,072	−74,875,789	−85,752,481	−98,107,186	−107,540,589	−118,061,822
Budget Impact: Best Case	−28,738,462	−62,009,423	−89,219,944	−114,620,480	−143,187,163	−174,725,971	−200,609,303	−228,166,314	−252,589,238	−278,662,119
Budget Impact: Worse Case	−513,781	−2,475,995	−1,671,224	−372,342	−1,138,886	−3,899,416	−3,928,150	−4,886,497	−4,197,019	−3,927,155
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0046 (2.8)	0.0061 (3.7)	0.0076 (4.4)	0.0092 (5.3)	0.0104 (6.0)	0.0111 (6.4)	0.0115 (6.6)	0.0117 (6.8)
Premium difference (%): Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0069 (4.3)	0.009 (5.5)	0.011 (6.6)	0.013 (7.7)	0.0148 (8.7)	0.0158 (9.3)	0.0164 (9.7)	0.0167 (10.0)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0008 (0.5)	0.0016 (0.9)	0.0022 (1.3)	0.0028 (1.6)	0.0036 (2.0)	0.0041 (2.3)	0.0044 (2.4)	0.0046 (2.5)	0.0046 (2.6)
New option costs: €1,500										
Budget Impact: Base Case	−30,339,519	−65,176,386	−95,691,990	−125,316,374	−158,228,845	−194,222,406	−225,112,588	−257,516,882	−287,111,454	−318,067,899
Budget Impact: Best Case	−61,920,432	−128,613,390	−188,842,320	−246,641,851	−307,072,176	−370,175,648	−427,511,437	−486,532,420	−542,643,841	−600,872,385
Budget Impact: Worse Case	−7,619,847	−16,434,486	−22,363,688	−27,761,139	−35,280,174	−44,879,832	−51,912,247	−60,000,445	−66,465,838	−73,438,798
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0046 (2.8)	0.0061 (3.7)	0.0076 (4.4)	0.0092 (5.3)	0.0104 (6.0)	0.0111 (6.4)	0.0115 (6.6)	0.0117 (6.8)
Premium difference (%): Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0069 (4.3)	0.009 (5.5)	0.1104 (6.6)	0.0131 (7.7)	0.0148 (8.7)	0.0158 (9.3)	0.0164 (9.7)	0.0167 (10.0)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0008 (0.5)	0.0016 (0.9)	0.0022 (1.3)	0.0028 (1.6)	0.0036 (2.0)	0.0041 (2.3)	0.0044 (2.4)	0.0046 (2.5)	0.0046 (2.6)

Table 8 Budget Impact and premium differences for the three scenarios (base, best worse case) and for the corresponding (new option) cost groups for the incidence group 2,000 patients per year. Budget Impact as well as premium differences are "Current Tx" vs "Current Tx & NEW"

Incidence per year: 2000	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
New option costs: €500										
Budget Impact: Base Case	8,322,292	13,257,513	23,383,676	35,108,597	43,824,505	49,633,878	63,022,311	75,854,974	94,961,295	114,606,698
Budget Impact: Best Case	4,443,507	4,616,994	10,797,333	18,752,795	23,205,302	24,427,551	33,547,884	41,626,652	56,276,813	70,652,998
Budget Impact: Worse Case	6,592,285	11,561,286	19,479,943	28,324,620	35,467,645	40,931,960	50,784,880	60,506,065	73,878,853	87,937,344
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0043 (2.8)	0.0053 (3.5)	0.006 (4.1)	0.0065 (4.6)	0.0066 (5.0)	0.0062 (5.1)	0.0057 (5.0)	0.0051 (5.0)
Premium difference (%): Best Case	0.0023 (1.6)	0.0044 (2.9)	0.0065 (4.2)	0.0079 (5.3)	0.0088 (6.1)	0.0094 (6.9)	0.0095 (7.3)	0.009 (7.5)	0.0082 (7.4)	0.0074 (7.4)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0007 (0.5)	0.0014 (0.9)	0.0019 (1.2)	0.0022 (1.4)	0.0025 (1.7)	0.0025 (1.9)	0.0024 (1.9)	0.0021 (1.8)	0.0019 (1.8)
New option costs: €1,000										
Budget Impact: Base Case	−11,008,614	−26,002,120	−36,453,342	−46,000,992	−58,886,072	−74,875,789	−85,752,481	−98,107,186	−107,540,589	−118,061,822
Budget Impact: Best Case	−28,738,462	−62,009,423	−89,219,944	−114,620,480	−143,187,163	−174,725,971	−200,609,303	−228,166,314	−252,589,238	−278,662,119
Budget Impact: Worse Case	−513,781	−2,475,995	−1,671,224	−372,342	−1,138,886	−3,899,416	−3,928,150	−4,886,497	−4,197,019	−3,927,155
Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0046 (2.8)	0.0061 (3.7)	0.0076 (4.4)	0.0092 (5.3)	0.0104 (6.0)	0.0111 (6.4)	0.0115 (6.6)	0.0117 (6.8)
Premium difference (%): Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0069 (4.3)	0.009 (5.5)	0.011 (6.6)	0.0131 (7.7)	0.0148 (8.7)	0.0158 (9.3)	0.0164 (9.7)	0.0167 (10.0)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0016 (0.9)	0.0022 (1.3)	0.0028 81.6	0.0036 (2.0)	0.0041 (2.3)	0.0044 (2.3)	0.0044 (2.4)	0.0046 (2.5)	0.0046 (2.6)
New option costs: €1,500										
Budget Impact: Base Case	−30,339,519	−65,176,386	−95,691,990	−125,316,374	−158,228,845	−194,222,406	−225,112,588	−257,516,882	−287,111,454	−318,067,899
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Premium difference (%): Base Case	0.0013 (0.9)	0.0028 (1.8)	0.0046 (2.8)	0.0061 (3.7)	0.0076 (4.4)	0.0092 (5.3)	0.0104 (6.0)	0.0111 (6.4)	0.0115 (6.6)	0.0117 (6.8)
Premium difference (%): Best Case	0.0023 (1.6)	0.0045 (2.9)	0.0069 (4.3)	0.009 (5.5)	0.011 (6.6)	0.0131 (7.7)	0.0148 (8.7)	0.0158 (9.3)	0.0164 (9.7)	0.0167 (10.0)
Premium difference (%): Worse Case	0.0001 (0.0)	0.0008 (0.5)	0.0016 (0.9)	0.0022 (1.3)	0.0028 (1.6)	0.0036 (2.0)	0.0041 (2.3)	0.0044 (2.4)	0.0046 (2.5)	0.0046 (2.6)

higher for the yearly premium calculations than for the budget impact. The budget impact would speak in favor of the new hypothetical treatment for a price of €500 but not for the other two price options, whereas the premiums calculations would always lead to the conclusion that the new treatment should be reimbursed by the healthcare payer.

Discussion

The dependency of healthcare payers on their revenue based on the premiums paid by their insured population and the costs mainly influenced by the cost of complications and the costs of treatment (pharmaceutical costs) was analyzed within a budget impact modeling framework. Across the ISPOR members of the Budget Impact Analysis Task Force there is currently no consensus on whether the revenue side of the healthcare payers should also be taken into account within a budget impact analysis (ISPOR 2007). This study shows the theoretical implications of a new product if a change in the early retirement rate could be expected for a new product due to a higher efficacy in comparison with the standard treatment. The product price as well as the assumptions for the early retirement rate can change the equilibrium of a revenue-cost premium calculation for a healthcare payer as was derived in a theoretical model. Additionally a hypothetical comparison in diabetes patients was undergone. The theoretical results could be proved by this study. Some assumptions had to be done, for instance on the levels of drug prices, incidence and prevalence rates, as well as the event rates for some complications which were derived from a well-known study (UKPDS 1998). In general it turned out that the premium differences were always in favor of the new option opportunity, which could be due to the assumption of a 20% better influence on the complications. The negative influence of the new option in terms of budget impact was highly dependent on the assumed drug price and the early retirement rate.

The weakness of this theoretical study can be seen in the following points. The premium calculations are usually based on all diseases and hence on all patients as well as on the disease-free population of the given healthcare payer. Within this hypothetical example it was assumed that only one disease area (diabetes) was of interest when analyzing the impact on the annual premiums. It was assumed that the impact of all other diseases as well as the impact of the healthy population is hold constant when comparing the two worlds of interest: Current treatment versus current treatment and new option. Additionally the impact of these groups

was assumed to be constant over time and hence no new drugs would enter the market for other diseases from which a healthcare payer could benefit. Also, the early retirement rates were held constant over time, which means the impact of the new drug option and also the higher early retirement risk with a higher age were not taken into account. Within such a circumstance it can be seen that a new drug with a higher efficacy could lead to a benefit for the healthcare payer with two possibilities: On the one hand the new treatment possibility could reduce the costs and could hence result in an improvement for the budget impact for some scenarios, and on the other hand, which could go along with the budget impact argument, the new drug could lower the complication rates which would reduce the complication costs and the early retirement rate. The last point could lead to a possible decrease in the annual premiums due to a higher revenue. This last option is not only valid assuming a non-profit healthcare payer like the social insurance companies in Germany, for instance, but also for private insurance companies looking for profits. For the latter the profitability would increase by the difference of the annual premiums. The framework suggested here should be taken into account if there is any possibility of early retirement reduction due to a more effective treatment possibility. It is recommended that sensitivity analysis are not only done with the costs but also with the market share over time as well as with the incidence rates, based on epidemiological data. Further empirical research on the influence of premiums and costs on the decision-making process should be undertaken.

Acknowledgment

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