The long-term fiscal impact of funding cuts to Danish public fertility clinics

Connolly, Mark P.; Postma, Maarten J.; Crespi, Simone; Andersen, Anders Nyboe; Ziebe, Søren

Published in:
Reproductive Biomedicine Online

DOI:

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2011

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

Copyright
Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment.

Take-down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.
The long-term fiscal impact of funding cuts to Danish public fertility clinics

Mark P Connolly a,b,*, Maarten J Postma a, Simone Crespi c, Anders Nyboe Andersen d, Søren Ziebe d

a PharmacoEpidemiology and PharmacoEconomics (PE2), Department of Pharmacy, University of Groningen, Groningen, The Netherlands; b Global Market Access Solutions, Health Economics, Ch. De Penguéy 66, 1162 St-Prex, Switzerland; c Global Health Outcomes, Merck, Kenilworth, NJ, United States; d The Fertility Clinic, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark

* Corresponding author. E-mail addresses: m.connolly@rug.nl, mark@gmasoln.com (MP Connolly).

Mark Connolly is a health economist with over 10 years of academic and consulting experience. He is currently a guest lecturer at the University of Groningen in health economics and is the managing director of Global Market Access Solutions in Switzerland.

Abstract This study evaluated the fiscal impact attributed to recent policy changes that limited funding to public fertility clinics in Denmark. Taking into consideration that introducing patient co-payments will influence the numbers of couples treated, the number of children born every year from assisted reproductive technology will be affected. To reflect the government perspective, the model assessed the average life course of a cohort of assisted-conception singletons taking into consideration age-specific, per-capita government transfers (e.g. education, health care, family allowances, education, pensions) and lifetime gross tax contributions to derive the discounted net tax contribution from assisted-conception singletons. An investment of €11,078 in a mother aged <40 to achieve an assisted-conception singleton was valued at €154,100 in cumulative discounted net tax revenue when the child reaches age 50. A reduction in the number of live births generated additional savings of €67-112 million due to reduced government transfers by age 25. However, by age 50, because of fewer children born and consequently fewer tax payers, a €74-123 million loss to government was estimated. The projected discounted net tax revenue attributed to assisted-conception children suggests that publicly funded treatment provides economic benefits to government over the lifetime of the conceived children.

© 2011, Reproductive Healthcare Ltd. Published by Elsevier Ltd. All rights reserved.

KEYWORDS: economics, generational accounting, health investment, IVF, reproductive medicine, tax
Introduction

The age of austerity is underway across Europe as governments seek to minimize spending on public programmes to rein in government debt accumulated during the current/recent economic crisis and prepare for the looming fiscal effects of ageing populations (Onaran, 2010). This is particularly relevant within health services seeking to find ways to prioritize care and identifying the most cost-effective services to maximize health gains with limited resources (Elshaug et al., 2009). However, a recent publication describing the relationship between public spending on social and health services warns of the potential implications of cost cutting on all-cause mortality (Stuckler et al., 2010).

Public funding challenges for assisted reproductive technology are not new, with only six of 57 countries recently surveyed providing fully funded treatments (Jones et al., 2007). Explanations for limited funds for assisted reproduction include the perception of infertility as a low health priority and the questioning of infertility as an illness within the wider healthcare framework (Hooren et al., 2008; McWhirter and McQueen, 2000).

In June 2010 the Danish government signalled its desire to cut funding for both assisted as well as non-assisted reproduction treatments, such as intrauterine inseminations with husband or donor semen, with the aim of passing a greater share of costs onto the couples seeking care (Lovforslag, 2010). Despite overwhelming evidence that increasing patient co-payments leads to dramatic reductions in the number of treatment cycles (Griesinger et al., 2007), national insurers continually seek to push costs to consumers for a technology often considered controversial. In Germany, cutting funds to fertility treatments in 2004 resulted in an estimated 10,000 fewer births in 1 year (Thaele and Uszkoreit, 2007). In the Danish context, the price increase represents an approximate 500% increase in costs paid by infertile couples, from approximately €318 to €1840 per cycle of IVF and intracytoplasmic sperm injection (ICSI) (Lovforslag, 2010).

The aim of this study is to assess the short- and long-term fiscal consequences of introducing patient co-payments for assisted reproductive technology in Danish public fertility clinics. To accomplish this, this study derives the discounted cost per live birth of €11,078 and €26,100 of approximately €2675 which is broadly aligned with costs in other European countries (Connolly et al., 2009a). The framework is based on the methodology of generational accounting used by governments to evaluate lifetime tax burdens across generations based on social-benefit promises and who will be required to pay for them (Kotlikoff, 1992). The generational accounting methodology is used to estimate the long-term fiscal impact of policy changes on government accounts, in which demography is the underlying element that influences government costs; therefore, it is suitable for estimating the impact of funding fertility programmes accountable for ~9.0% of national births (Danish Fertility Registry, 2010).

The model is constructed using age-stratified per-capita transfers for a range of social benefits in Denmark. Furthermore, age-specific transfers to government in the form of tax revenues are accounted for in the model. Applying this framework, an annualized balance sheet was constructed at the individual level to establish the lifetime net tax contributions. All costs in the model have been converted from Danish Krones (DKK) to Euros (€) based on an exchange rate of €1 = 7.45 DKK. Broadly speaking there are four major life stages considered in the model: early child, education, working and retirement (Svensson et al., 2008).

Materials and methods

Ethics

The study described here involved no human subjects or collection of medical data, consequently no ethical approval was required for conducting the analysis.

Modelling framework

The model estimates whether publicly funded fertility treatments represents a good use of government resources by evaluating the lifetime net tax revenue of an assisted-conception child for a cohort of assisted-conception children born in Danish public clinics in 2009. To accomplish this, the model simulates the average life course of Danish citizens from the government perspective, taking into consideration direct fiscal transfers paid by government and age-specific tax receipts paid to government (Connolly et al., 2009a). The framework is based on the methodology of generational accounting used by governments to evaluate lifetime tax burdens across generations based on social-benefit promises and who will be required to pay for them (Kotlikoff, 1992). The generational accounting methodology is used to estimate the long-term fiscal impact of policy changes on government accounts, in which demography is the underlying element that influences government costs; therefore, it is suitable for estimating the impact of funding fertility programmes accountable for ~9.0% of national births (Danish Fertility Registry, 2010).

The model is constructed using age-stratified per-capita transfers for a range of social benefits in Denmark. Furthermore, age-specific transfers to government in the form of tax revenues are accounted for in the model. Applying this framework, an annualized balance sheet was constructed at the individual level to establish the lifetime net tax contributions. All costs in the model have been converted from Danish Krones (DKK) to Euros (€) based on an exchange rate of €1 = 7.45 DKK. Broadly speaking there are four major life stages considered in the model: early child, education, working and retirement (Svensson et al., 2008).

Costs per live birth

To assess the economic impact of public investments in assisted reproductive technology, it was necessary to calculate the cost per live birth using IVF/ICSI. Based on current practices which includes ovarian stimulation, pituitary desensitization, oocyte retrieval, embryo transfer, and physician costs, this study estimated an average cost per cycle of approximately €2675 which is broadly aligned with costs in other European countries (Connolly et al., 2010). The costs per cycle were then applied to treatment success rates for women aged <40 and ≥40 obtained from the Danish Fertility Society assisted reproduction registry (Danish Fertility Registry, 2010). More than 90% of treatments are in women aged <40, due to an age limit of 40 years in public fertility clinics. Based on success rates for 2009, this study derived a direct cost per live birth of €11,078 and €26,100.
for women aged <40 and ≥40, respectively. This value takes into consideration cycles that do not lead to live births and is comparable with previous Danish estimates (Ingerslev et al., 2005). In the absence of long-term data suggesting IVF/ICSI-conceived children face impaired abilities and downstream economic consequences, these children have been assumed to be similar to naturally conceived children (Leunens et al., 2008).

### Healthcare spending

Healthcare expenditure was obtained from Statistics Denmark. Age-specific data were derived from aggregate cost data by age and divided by population cohorts. The per-capita pharmaceutical expenditure reported by Statistics Denmark and adjusted for growth was applied every year (Gunnersen and Bisgaard, 2010). Long-term nursing costs for institutionalized and home care were included based on aggregated expenditure data from the Ministry of Social Affairs and divided by the age-cohort utilizing services to derive a per-capita cost applied from age 60 onwards (Schulz, 2010). Considering the importance of healthcare spending on government accounts, several inflationary parameters were explored in the sensitivity analysis.

### Family support

The age-specific child benefits provided to families was also included in the analysis (Gunnersen and Bisgaard, 2010). Furthermore, the ordinary child allowance (€630 per annum) and extra child allowance (€642 per annum) based on the proportion of children raised in single-parent homes were included (Gunnersen and Bisgaard, 2010; RDMFA, 2009). A fixed cost of €23,500 associated with maternity-leave and parental-leave benefits was accounted for the birth year (Gunnersen and Bisgaard, 2010).

A range of publicly subsidized childcare programmes are available in Denmark ranging from nurseries, municipal day care and school care schemes to recreation centres. From programme-specific expenditure and number of participants in each programme available from Statistics Denmark, this study derived age-specific per-capita childcare costs from birth to age 18 (Statistics Denmark, 2010).

### Education

Government costs for education at different ages were included in the model based on 9 years of compulsory education and with an optional 3 years of upper secondary education (Danish Ministry of Education, 2009). Costs for 29% of the population pursuing higher degrees were also included. The per pupil government education costs are shown in Table 1.

### Pension

The costs of publicly funded pension schemes were included, with age of retirement set at age 67, based on new retirement laws, and inflated at 2% over time (OECD, 2009). The early retirement scheme currently available was not included in this analysis because of uncertainty.
Fertility funding and net taxes in Denmark

regarding its availability in the future. Private pensions are not included as these are based on personal contributions and not government expenditure.

**Income**

Age-specific earnings were obtained from a survey of 3.3% of Danish households in 2007 (Danish Rational Economic Agents Model, 2007). Wages were inflated according to long-term productivity projections of 2% provided by the Ministry of Finance (2007).

**Tax revenue**

To derive annualized government tax receipts for an average Danish citizen, this study applied age-specific proportional income-tax payments and social contributions obtained from population survey data to age-specific wages (Danish Rational Economic Agents Model, 2007). The age-specific proportional tax rate was held constant over the lifetime of the model because of uncertainty regarding future tax rates. To account for other financial transfers to government, a 12.75% flat rate was applied to annual earnings to account for value added taxes (VAT), duties and property taxes (Gunnersen and Bisgaard, 2010).

**Other government transfers**

Government transfers for sickness benefits, unemployment benefits, cash benefits, rent subsidies and rent allowances to the elderly were included (Table 1).

**Economic parameters**

Government transfer payments and costs were assumed to grow annually with the rate of inflation. Since 1989, the rate of inflation in Denmark has averaged 2% and this was used as the base inflation rate (Gunnersen and Bisgaard, 2010). The growth in healthcare costs per capita was set at 3% to reflect current growth rates (Gunnersen and Bisgaard, 2010).

To reflect the present value of assisted reproduction treatment costs and all other government transfers and tax receipts, it was necessary to reflect future values in present-day value using discounting. The discount rate in the base case was 3%. However, within the current economic environment, the discount rate published by the Danish National Bank is 0.75% that was assessed in the sensitivity analysis (Danmarks Nationalbank, 2010).

**Calculating lifetime net tax revenues**

To reflect the net present value (NPV) of investment in assisted reproductive technology, this study depreciated treatment costs attributed to an IVF-conceived child over the lifetime of the child ($K_0$). Furthermore, at each year of life, this study derived age-specific net tax revenues from the government perspective based on government transfers and gross tax receipts and discounted these costs to the base year:

$$NPV = \sum_{t=0}^{T} \left( \frac{R_t - E_t}{(1 + r)^t} \right) - K_0$$

$R_t = \text{sum gross tax revenues accruing from the individual age} t$; $E_t = \text{sum government expenditures on the individual age} t$; $r = \text{discount rate}; T = \text{life expectancy}; K_0 = \text{direct IVF/ICSI costs}$.

For comparison, a similar calculation was performed for a naturally conceived child excluding assisted reproductive technology costs. The results describe the cumulative discounted net tax revenue by ages 25 and 50 as convenient time points. The model was developed in Microsoft Excel.

**Results**

The trace in Figure 1 depicts the cumulative discounted net tax revenue for an IVF/ICSI-conceived singleton and naturally conceived child. During the early years of life, children are net recipients of government transfers, noted by the negative accumulate debt from the perspective of government. After joining the work force and paying taxes, the accumulated negative balance starts to improve until reaching the break-even age, i.e. the age at which all government transfers to the child have been paid for in tax receipts. An average individual will continue to contribute more in tax receipts than receiving in government transfers until the age of retirement. During retirement, individuals will normally consume more in government transfers compared with working ages, which explains the downward sloping figure during retirement.

The cumulative discount net tax revenue attributed per IVF/ICSI-conceived and naturally conceived child by the age 25 and 50 years is shown in Table 2. At age 25, both IVF/ICSI-conceived and naturally conceived children are still in negative balance with the Danish government based on financial transfers received in relation to taxes paid, at $-€155,900$ and $-€145,150$, respectively. By age 50, after approximately 30 years of tax contributions, the net tax benefit for an IVF/ICSI-conceived child whose mother was aged <40 at the time of treatment and a naturally conceived child are €154,500 and €165,200, respectively. A nat-

![Figure 1](image-url)
Table 2  Discounted lifetime tax benefits per IVF/ICSI-conceived and naturally conceived child.

<table>
<thead>
<tr>
<th></th>
<th>Year 25 (€)</th>
<th>Year 50 (€)</th>
<th>Breakeven age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naturally conceived</td>
<td>-145,150</td>
<td>165,200</td>
<td>39</td>
</tr>
<tr>
<td>Assisted-conceived, mother aged &lt;40</td>
<td>-155,900</td>
<td>154,500</td>
<td>39</td>
</tr>
<tr>
<td>Assisted-conceived, mother aged ≥40</td>
<td>-170,500</td>
<td>139,900</td>
<td>41</td>
</tr>
</tbody>
</table>

An IVF/ICSI-conceived child generates slightly higher net taxes for the state because of the presumed zero cost of conception compared with treatment costs required for IVF/ICSI-conceived children. The breakeven ages for an IVF/ICSI-conceived child with mother aged <40 is similar to a naturally conceived child at age 39 and for IVF/ICSI-conceived children with mother aged ≥40 at time of treatment, increases by 2 years to age 41.

To test the robustness of the base case assessment, this study varied several parameters most likely to influence the results. By applying the current discount rate of 0.75% recommended by the Danish National Bank increase, the discounted future net tax revenue for IVF/ICSI-conceived and naturally conceived children increases to €568,400 and €579,400, respectively. Growth in healthcare costs and reduced productivity negatively impact the discounted net tax revenue (Table 3).

Price sensitivity of IVF/ICSI

To project the long-term fiscal impact associated with changes in fertility funding in Denmark, this study estimated the fiscal impact associated with reduced number of cycles and live births following funding changes. Given an estimated 1547 IVF/ICSI live births annually (Danish Fertility Registry, 2010), following implementation of the new policy, the model estimated a 30–50% reduction in annual IVF/ICSI births. Estimates of reduced number of births are in line with previous reports of price-elasticity of demand for IVF/ICSI and healthcare in general (Connolly et al., 2009a,b; Ringel et al., 2005)

The results in Table 4 describe the impact of reduced numbers of IVF/ICSI-conceived children in a single year in discounted net tax revenue for the Danish government resulting from the policy change. By year 25, the IVF/ICSI birth cohort still, on average, has a negative account with the government because of accumulated transfers in early life. However, by year 50, the IVF/ICSI birth cohort represents €246 million in net tax revenue for the Danish government. Under different scenarios of reduced births following the policy change, the government achieves additional savings of €67 million, €90 million and €112 million by year 25. However, by year 50 the reduced number of births represents a loss to the government of €74 million, €99 million and €123 million, depending on the reduced number of IVF/ICSI-conceived births that results following introduction of the new reimbursement system (Table 4).

Discussion

One of the most common explanations made by national insurers for failing to fund assisted and non-assisted reproductive technology is that fertility treatments are considered too expensive (McWhirter and McQueen, 2000), even though, by comparison, treatment costs are comparable to many other services provided by health services, and costs make up less than 0.25% of the healthcare budget (Connolly et al., 2010).

Ideally, subjective assessments of cost are best considered in relation to treatment benefits, which raises the question about the most appropriate economic framework for valuing benefits of a medical technology that creates human life. For example, applying conventional evaluation methods to assisted reproduction based on quality-adjusted life years fails to capture the externality of creating human life through medical technology. Furthermore, in the context of fertility treatments, quality-adjusted life years are only relevant in the context of how the treatment impacts infertile couples (NICE, 2004) and, when applied to fertility treatments, do not account for the economic consequences associated with creating a child. This is particularly relevant in Denmark where the contribution of assisted reproductive technology to maintaining total fertility rates is well documented (Jensen et al., 2008).

One of the most interesting features of the current analysis is how the introduction of patient co-payments will impact government accounts differently over time. These estimates are derived using an accepted methodological

Table 3  Sensitivity analysis of critical parameters in assisted reproduction health investment model for assisted reproduction for mothers aged <40.

<table>
<thead>
<tr>
<th>Parameters tested</th>
<th>Assisted-conception child</th>
<th>Naturally conceived child</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase discount rate to 0.75%</td>
<td>568,400</td>
<td>579,400</td>
</tr>
<tr>
<td>Healthcare costs grow 4%</td>
<td>136,100</td>
<td>146,900</td>
</tr>
<tr>
<td>Healthcare costs grow 5%</td>
<td>109,500</td>
<td>120,300</td>
</tr>
<tr>
<td>Productivity growth rate 1%</td>
<td>12,350</td>
<td>23,100</td>
</tr>
<tr>
<td>Productivity growth rate 3%</td>
<td>370,100</td>
<td>380,900</td>
</tr>
</tbody>
</table>
framework used by treasury departments to derive discounted net tax revenue for different age cohorts (Bonin and Patxot, 2004). Depending on the actual numbers of reduced births following the policy change, the government will actually achieve additional savings from reduced numbers of assisted reproductive technology children born and receiving government transfer payments (e.g. health, education, allowances, cash transfers). An estimated additional saving of €67—112 million can be achieved by year 25 following the new policy. Conversely, over a longer time horizon, because of fewer assisted-conception children born, this will translate into fewer future workers paying taxes, even after adjusting for unemployment. By year 50, discounted net tax losses to the Danish government of €74—123 million are estimated.

The analysis described here provides an alternative perspective to the issue of multiple pregnancies. Whilst the medical community agrees that multiples are an undesirable outcome, when viewed from an economic perspective the issue is less clear. Within the modelling framework described here, the ‘average cost per live birth’ is used as the government-investment component and assumes a cohort of singleton deliveries. Whilst many argue for including costs of multiples in this type of an analysis, a previous study in Denmark commission by the Danish National Board of Health concluded that, on the basis of ‘costs per live birth,’ double-embryo transfer was more cost-effective compared with single-embryo transfer (Ingerslev et al., 2005). Even after adjusting for increased health expenditure in twin pregnancies, when these costs are divided by two births, the ‘cost per live birth’ was lower compared with single-embryo transfer (Ingerslev et al., 2005). Had the current analysis factored in the costs and benefits of twin pregnancies, similar to those described by Ingerslev et al., twin pregnancies may appear to represent improved economic outcomes compared with singletons because two future tax payers would have been born. Therefore, to avoid inadvertently promoting multiple pregnancies based on future net tax revenues from twins, this analysis was limited to only singletons.

It is possible that the financial impact of cuts to fertility estimates described here are an underestimate because only IVF/ICSI live births in Danish public clinics were considered. The new policy will also impact patient treatment costs for frozen-embryo cycles and oocyte donation, as well as medication costs for treatment provided in public clinics. This would suggest that the reduction in assisted reproduction live births might be much greater than those discussed here and consequently will have a greater financial impact over many generations. Additionally, considering similarities between the proposed Danish policy and recently implemented funding changes in Norway, there is reason to believe that the actual number of assisted reproduction births will be greater than estimated here, resulting in an increased fiscal impact.

Applying a generational accounting framework to understand investments in reproductive technology and other health technologies offers advantages over traditional approaches for evaluating programmes. Firstly, the framework illustrates that concerns over cost are often short-term concerns and that cutting costs has far-reaching implications, both positive and negative. Furthermore, while those working in the profession of assisted reproduction often discuss costs specifically related to treatment, in the scheme of all other government expenses and lifetime tax contributions these costs are almost insignificant. Additionally, it is worth considering that the framework discussed here considers costs in relation to assisted reproduction; in reality a similar analytic framework could be applied to any medical technology that influences mortality, productivity and work-force participation. However, it is important to recognize that results obtained applying a generational accounting framework to investments in health do not reflect a precise forecast of the future. Rather, they reflect a potential fiscal scenario based on prevailing macro-economic conditions and the interaction of these variables over time (Prušič and Pavloška, 2010).

Secondly, the government perspective framework illustrates how government beliefs can be misaligned. In a recent survey conducted by the United Nations with government planners in Denmark, concerns over ageing populations were expressed (United Nations, 2003). Whilst concerns over ageing populations are reflected in one area of government, cuts within the health service to fertility services that reduces birth rates that could alleviate these concerns within other areas of government.

The debate in Denmark regarding public funding for fertility treatments focuses attention on what are societal priorities during an era of ageing populations, limited healthcare resources, stagnant economic growth and the role of the state in the provision of services. Whilst most people desire a comprehensive and equitable health service, societies also demand economic growth, increasing economic prosperity and shared tax burden. At present,
much of the debate centres on the role of government in the economy and, of relevance to this paper, the national health services: too much intervention may impair growth; too little intervention may lead to an inequitable society.

To some extent, the above concerns are reflected in the debate regarding the provision of fertility services by public providers. In many health services, infertility is a low-priority illness that increases costs for health services that are focused on unmet needs of present-day society. In contrast, many of the fiscal problems of the future are attributed to ageing populations, declining numbers of working-age adults and increasing age-dependency ratios, all of which are partially mitigated by assisted-conception children, which represents 4–5% of the future workforce in some countries (de Mouzon et al., 2010).

One of the underlying weaknesses of the current analysis is the type of people that are likely to be influenced by the introduction of user fees in Denmark. Previous studies have shown that co-payments will deter couples less able to afford treatment (Griesinger et al., 2007). Conversely, couples with increased financial resources to pay for treatment are more likely to receive care using private funds. Based on the observation that children born to parents with more wealth will likely accumulate more wealth themselves (Charles and Hurst, 2003), this could influence the current findings. Because the model considers average earnings in the future based on universal access, this would suggest that the smaller birth cohort of IVF children would be wealthier in the future and more likely to pay more government taxes.

The need to ration is unavoidable in all health services, as demand for healthcare is almost limitless and resources are finite to satisfy this demand. The question then arises where to cut funds. Whilst cutting assisted reproduction services can appear less controversial, the availability of public fertility clinics and the resulting children satisfies other government initiatives regarding family formation and alleviates concerns over ageing populations. However, making this leap requires making hard decisions now about what is important in the future. For many health services, this is a difficult leap for health services dealing with budgetary and political demands of the present.

Acknowledgements

The authors are grateful to Karin Erb for providing data on reproductive outcomes data from the Danish Fertility Society Registry in Denmark. Furthermore, the authors are indebted to Dr Marianne Frank Hansen from the Danish Rational Economic Agents Model for providing population survey data used in this analysis. The work described here was funded by Merck. No commercial products are discussed in this research.

References


Fertility funding and net taxes in Denmark


Royal Danish Ministry of Foreign Affairs (RDMFA). Fifth periodic report of Denmark concerning the international covenant on economic, social, and cultural rights. December 2009.


An abbreviated set of results discussed in this paper were presented at a special hearing to the Danish Parliament on 25 October 2010.

Declaration: The funding organization had no influence on conducting the analysis and reporting of the results, other than academic contributions provided by SC. MPC received research support from and has served as a consultant for Merck. MJP received research support from Merck. SC is an employee of Merck. ANA and SZ report no financial or commercial conflicts of interest.

Received 1 June 2011; refereed 15 August 2011; accepted 19 September 2011.