RESEARCH AGENDA FOR HEALTH ECONOMIC EVALUATION

Country Case Studies

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David Tordrup, MSc

Nika Berlic, MSc

Ewa Bandurska, MSc

Fiona Thom, MSc

Allira Attwill, MSc

Dr. Roberto Bertollini, MD, MPH

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Abbreviations

CINDI	Countrywide Integrated Non-communicable Diseases Intervention Programme
CRC	Colorectal Cancer
COPD	Chronic Obstructive Pulmonary Disorder
CVD	Cardiovascular Disease
DH	Department of Health
EU	European Union
FIT	Faecal Immunochemical Technology
HC	Healthcare
HMT	Her Majesty's Treasury
HSE	Health Survey for England
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
IER	Institute for Economic Research
KCE	Belgian Healthcare Knowledge Centre
LA	Local Authority
NCD	Non-communicable Disease
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NIPH	National Institute of Public Health
NPV	Net Present Value
OECD	Organization for Economic Cooperation and Development
ONS	Office of National Statistics
PHE	Public Health England
PMIC	Pomeranian Model of Integrated care for COPD
PV	Present Value
QALY	Quality-Adjusted Life Year

RAHEE	Research Agenda for Health Economic Evaluation
RS	Republic of Slovenia
SVIT	Slovenian National Colorectal Cancer Screening Programme
WHO	World Health Organization

1 Introduction

The financial sustainability of publicly funded universal access health systems in Europe is currently endangered by the combined forces of among other things population ageing, technological progress and limited financial resources (Pammolli, Riccaboni & Magazzini, 2012), with chronic and non-communicable disease driving a significant proportion of costs (Busse et al., 2010). These developments raise increased demands on the effectiveness and cost-effectiveness of EU health systems, which must respond to both increasing health challenges and a more restricted budgetary context(EC, 2010).

In the Tallin Charter, adopted at the WHO European Ministerial Conference on Health and Health Systems in 2008, member states of the World Health Organization Regional Office for Europe (WHO/Europe) committed to improving population health by strengthening health systems and addressing major health challenges in the context of epidemiological and demographic change, widening socioeconomic disparity, limited resources, technological development and rising expectations (WHO, 2008a). In the 2013 follow-up meeting, Health systems for Health and Wealth in the Context of Health 2020, member states commitment to the Charter was reaffirmed (WHO, 2013).

The RAHEE project aims to outline a future research agenda for the EU on health economic evaluation, based on both gaps in the available evidence and the application of health economic evidence in practice. The main objectives are 1) to prepare an overview of the state of health economic evidence for a selection of high burden conditions in the European Union, based on a systematic assessment of the scientific literature, complemented by cross-cutting observations on methodological or other weaknesses that reduce the applicability of health economic evidence in practice; and 2) to identify difficulties in the translation of existing evidence on health interventions based on case studies in selected countries. A High Level Expert Panel consisting of public health officials, health economists and policymakers will formulate research recommendations for the EU based on this research.

The present report describes the results of the second objective above: Identification of difficulties in the translation of economic evidence in practice. This is achieved be examining the economic considerations underlying the planning of four different health interventions in England, Belgium, Slovenia and Poland, and identifying enabling conditions and barriers to the use of economic evidence in practice. The methods applied are given in section 2 of this report, and case study results are given in sections 4 to 7.

2 Methods

2.1 Identification of countries

Countries for the RAHEE case studies were identified during the 1st RAHEE Steering Committee meeting held in Brussels on 9th January 2014. Countries were selected on the basis of representation of different sub-regions of the EU, and of different health system organisation models.

2.2 Case study methods

The case study methods were defined in detail by individual study authors as appropriate, and are reported separately in the relevant sections. Overall, the case studies relied on reviews of published

articles and reports, and primary data collection through interactions with individuals involved in the planning of the health services studied.

3 Results: Overview of case studies

The case studies describe the following interventions: National colorectal cancer screening in Slovenia; regional integrated care for Chronic Obstructive Pulmonary Disorder in Pomerania, Poland; national cardiovascular health checks in England; and national/regional rotavirus vaccination in Belgium. The case studies include authors and/or key informants from the main institutions involved in the pre-implementation economic evaluation of the services, as given in Table 3.1 and described further in the methods of individual case studies.

Table 3.1 Case study authors and affiliations

Authors	Affiliation
Slovenia	
Nika Berlic*, Dr. Valentina Prevolnik Rupel	Institute for Economic Research, Ljubljana, Slovenia
Dr. Jožica Maučec Zakotnik, Dr. Dominika Novak Mlakar	National Institute of Public Health, Slovenia
Poland	
Ewa Bandurska*, Piotr Popowski, Marzena Zarzeczna-Baran	Public Health and Social Medicine Department Medical University of Gdansk
Iwona Damps-Konstańska, Ewa Jassem	Department of Allergology Medical University of Gdansk
England	
Fiona Thom*	Health Improvement Analysis Team, Department of Health
Belgium	
Allira Attwill*	World Health Organization, WEU, Brussels

*Notes: * lead author*

4 Economic evaluation of bowel cancer screening in Slovenia

Nika Berlic[*], dr Valentina Prevolnik Rupel[*], Jožica Maučec Zakotnik, MD[+], Dominika Novak Mlakar, MD[+]

[*] Institute for Economic Research, Slovenia

[+]National Institute of Public Health, Slovenia

4.1 Introduction

Data from the Slovenian Cancer registry indicate that the incidence and prevalence of colorectal cancer (CRC) has risen since 1961. In 2009 it was the second most common newly diagnosed cancer with 1,568 cases, and was the second most common cancer among men and third most common among women. According to the data from 2009, CRC is the second most common cause of cancer death in Slovenia (Mlakar et al., 2013, Žakelj et al., 2010, Žakelj et al., 2013). Comparing 1961 with 2010, it can be seen in Figure 4.1 that crude incidence rate has risen from 5 to 48.7 per 100,000 for colon cancer and from 6.1 to 35 per 100,000 for rectal cancer (SLORA 2014).

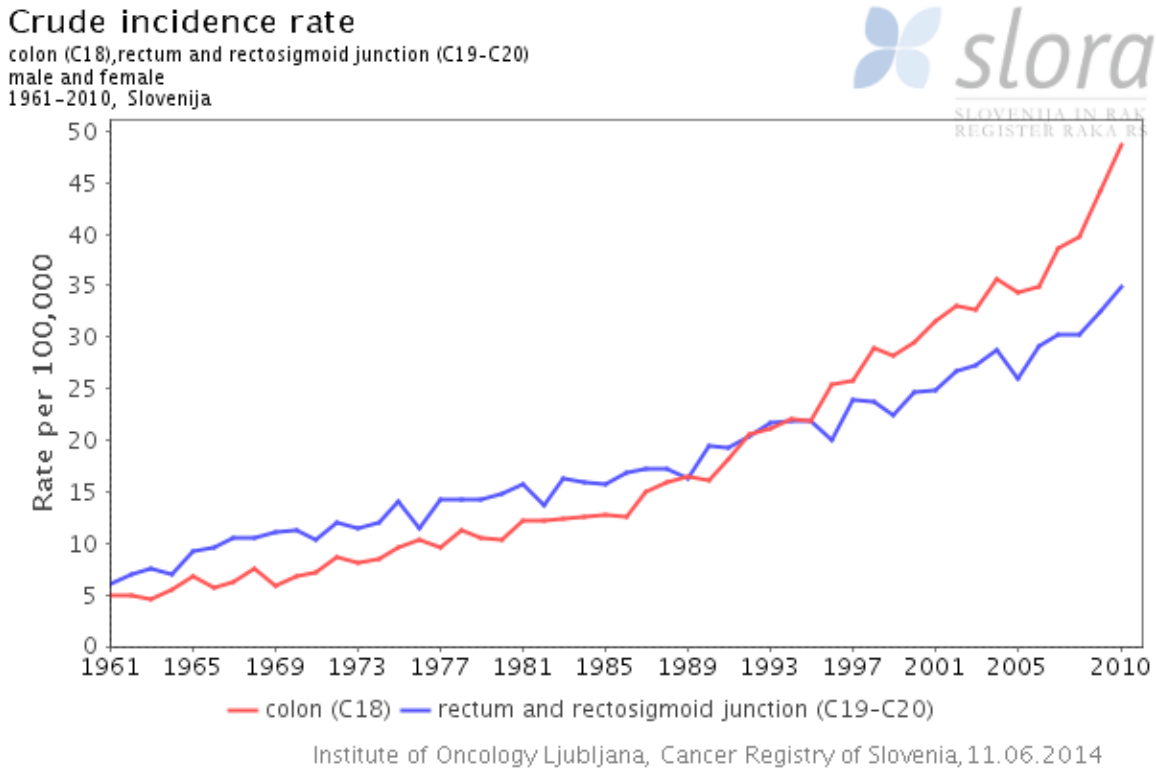

Figure 4.1: Crude incidence rate; Cancer Registry of Slovenia. Source: (SLORA 2014)

Similar changes were observed for prevalence (Figure 4.2). The data from Cancer Registry of Slovenia indicates that partial and lifetime prevalence[1] of cancer patients has risen from 88 colon cancer cases,

[1] Lifetime prevalence is defined as the number of all persons ever diagnosed with cancer and being alive at specific time date (usually the last day of calendar year). Partial prevalence is the number of all cancer patients, being alive at specific date (usually the last day of calendar year) and being diagnosed with cancer within a defined period of time before the date of calculation. One year partial prevalence includes patients, diagnosed with cancer one year before the date of calculation, patients included in 1-4 years prevalence were diagnosed within one and five years before calculation, ect. The partial prevalences in cancer are important, as they reflect the number of cancer cases in different course of disease, e.g. the one-year prevalence includes patients during their primary treatment, 1-4

two rectosigmoid junction cases and 177 rectal cancer cases within the observed year of 1961 to 5,177 colon cancer cases, 859 rectosigmoid junction cases and 3,232 of rectal cancer cases in 2010 (SLORA 2014).

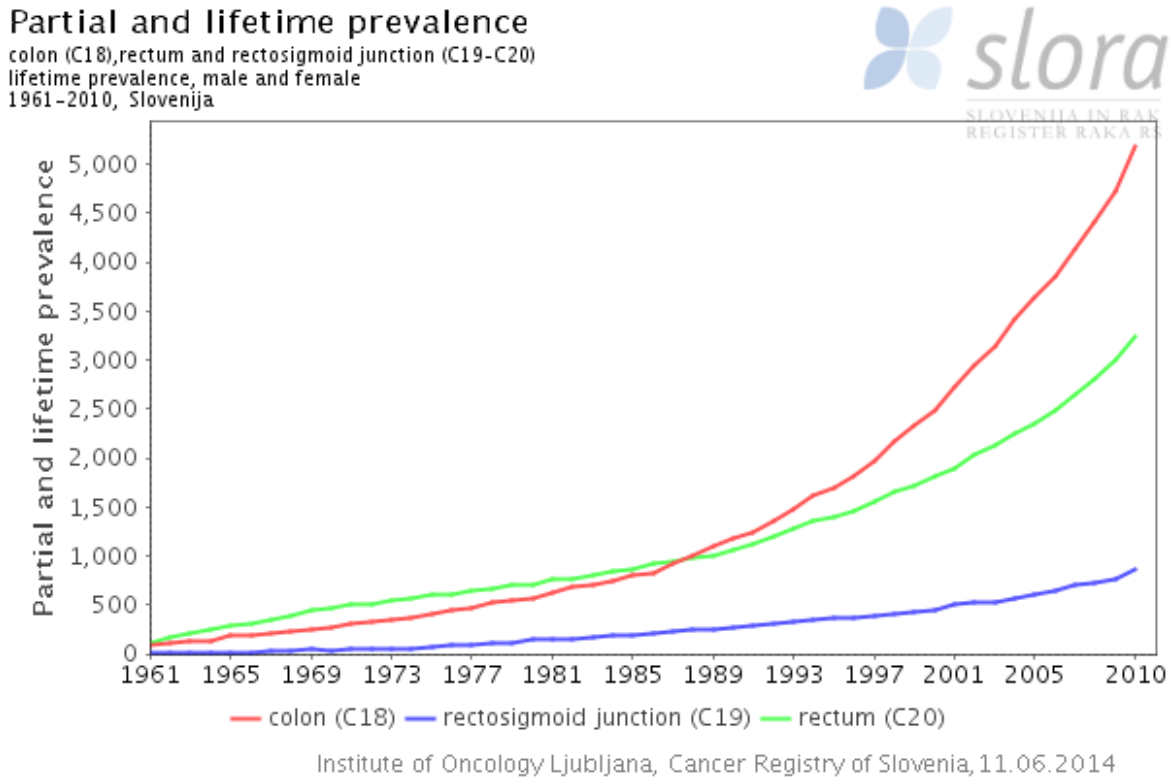

Figure 4.2: Partial and lifetime prevalence. Source: (SLORA 2014)

During this period the mortality rates also rose, from 9.6 to 22.7 per 100,000 for colon cancer and from 12.7 to 15.8 per 100,000 for rectal and rectosigmoid junction cancer as shown in Figure 4.3 (OECD, 2013, SLORA).

The increase in CRC mortality in Slovenia was reported also by the OECD (2013). The data, presented in Figure 4.4, allows for the comparison of Slovenian CRC mortality rate with that of other countries (OECD, 2013). Notably, the increased mortality rate in Slovenia between 2001 and 2011 was in contrast to decreased rates in most other OECD countries.

years prevalence those requiring regular clinical follow-up, while 5-9 and especially 10 and more years prevalence includes predominantly those considered cured from cancer.

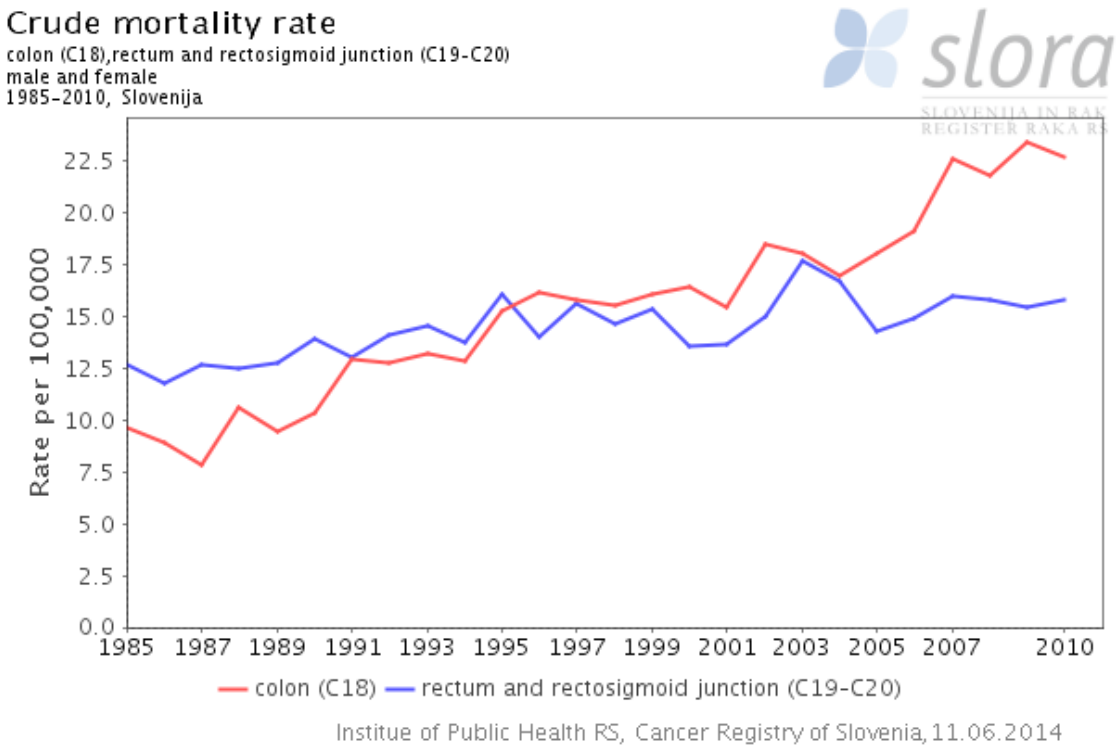

Figure 4.3: Crude mortality rate. Source: (SLORA 2014)

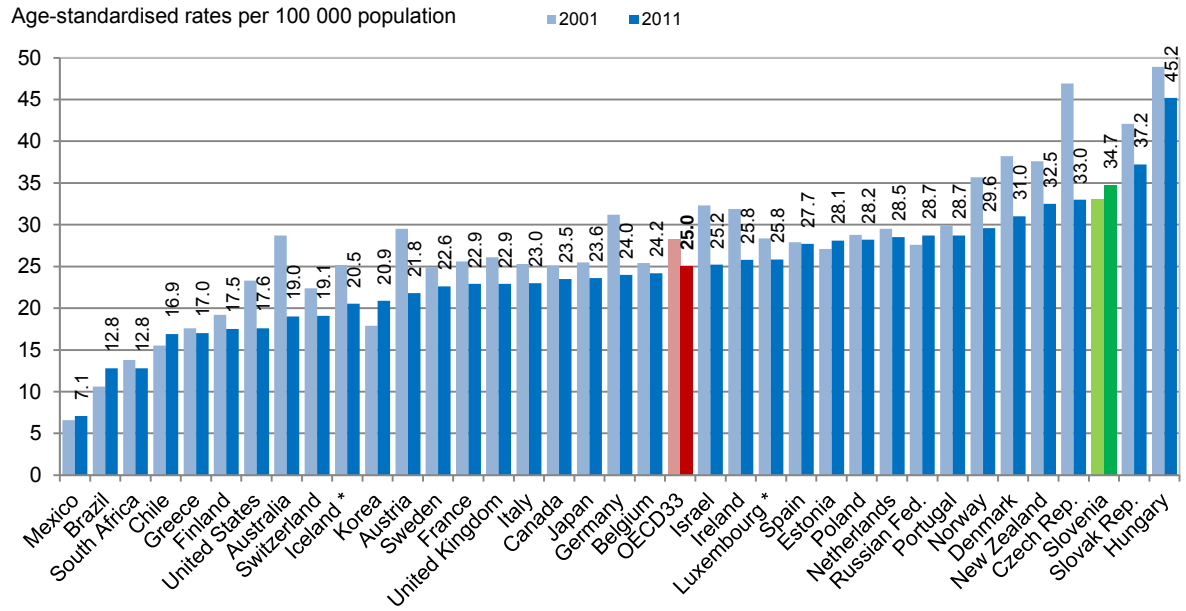

Figure 4.4: Colorectal cancer mortality, 2001 to 2011 (or nearest year); Comparison with other countries. Source: (OECD, 2013).

In 2006, in order to reduce the incidence and mortality rate of CRC in Slovenia, the National Institute of Public Health (NIPH) of the Republic of Slovenia[2] started an initiative for establishing organized screening on the national level. The inspiration for the initiative came from the "*Proposal for a Council Recommendation on Cancer Screening. Commissionof the European Communities. 2003/0093(CNS)*" (COMMISION OF THE EUROPEAN COMMUNITIES, 2003). Slovenia's EU presidency in 2008 and consequent enhanced political support for reduction of the cancer burden in Slovenia also favoured the establishment of a screening programme. Experts at NIPH, together with an economic expert from the Health Insurance Institute of Slovenia and a range of other specialists in Oncology and Gastroenterology, prepared a proposal for an organized, population-wide screening programme for CRC in Slovenia on the basis of experiences from other European countries, especially Finland, France and Italy. Data was obtained by visiting these countries and reviewing several articles (eg. (Berchi et al., 2004, Guittet et al., 2007, Herbert et al., 1995, Launoy et al., 1996, Launoy et al., 2005, Malila et al., 2005, Segnan et al., 2005)) (J.M. Zakotnik and D.N. Mlakar, personal communication, April 2014). The proposal was presented to the Slovenian government. Following government approval, the pilot project was implemented in 2008 (J.M. Zakotnik and D.N. Mlakar, personal communication, April 2014). The pilot proved to be efficient, and the Slovenian national colorectal cancer screening program (SVIT) was implemented on the national level in 2009, and has been successfully implemented for 5 years now. SVIT is perceived as one of the most effective preventative programmes in Slovenia. The aim of this study is to examine and present how economic evidence was used throughout the development and implementation of the programme.

4.2 Methods

Information on SVIT and CRC in Slovenia was obtained from a systematic literature review of peer-reviewed articles, a grey literature review, a review of Slovenian data sources, and personal communication (interviews) with experts from National Institute of Public Health Countrywide Integrated Non-communicable Diseases Intervention Programme (NIPH CINDI Slovenia) department, the founder of SVIT programme.

National Institute of Public Health, Slovenia:

- Dominika Novak Mlakar: Participated in the literature review of colorectal cancer (CRC) screening and the review of published experiences of similar programs abroad; shared experiences with CRC screening programs abroad (Italy, Finland, France); participated in the expert group to prepare the Slovenian CRC screening algorithm; participated in 2006 in the CRC screening proposal preparation for Health Council of the Ministry of Health of the Republic of Slovenia; participated in 2009 in the CRC screening implementation at the national level, and from 2009 onwards is part of the slovenian CRC screening Central unit.

[2] In 1994 Slovenia incorporated to the international Countrywide Integrated Non-communicable Diseases Intervention Programme network (CINDI network) and established a special unit, called CINDI centre that was part of the Health centre of Ljubljana. In November 2010, the CINDI centre renamed itself into the Department of Chronic Diseases and at the same time became part of a Centre for Health Promotion and Management of Chronic Disease at the National Institute of Public Health of RS (NIPH).

- Jožica Maučec Zakotnik: Founder of the SVIT programme; assumed leadership in the organisational, professional and financial initiation of the programme; present head of the SVIT programme.

Published literature was identified by following a two-step approach. The first step was to search relevant Slovenian scientific journals and publications for peer-reviewed articles on the subject of SVIT and CRC in Slovenia. Five relevant Slovenian journals were reviewed: Zdravniški vestnik (Slovenian Medical Journal), Onkologija (Oncology), Zdravstveno varstvo (Slovenian Journal of Public Health), Endoskopska revija (Endoscopic journal) and Radiology and Oncology. The second step included systematic literature search using one Slovene and six international online library databases: Slovenian Digital Library, PubMed/MEDLINE, EBSCO Host/Medline, JSTOR, Springer link, Science direct and Wiley online library. The search was performed for the period from 2006 (the start of Slovenian initiative for organizational CRC screening) to April 2014. The main search terms used were: *SVIT program, SVIT Slovenia, colorectal cancer in Slovenia, colon cancer in Slovenia, rectal cancer in Slovenia, economic analysis of SVIT program, evaluation of SVIT program*.

Inclusion criteria were:

1. Studies that included the SVIT programme and/or CRC in Slovenia.
2. Studies considering the economic aspect of the SVIT programme.

Of the five relevant Slovenian journals reviewed in the first step, three published articles which were identified as potentially relevant to the case study. Among the seven articles that were found in Slovenian Medical Journal, Oncology and Slovenian Journal of Public Health, three were included in the case study. No additional articles were found during the second step of databases searches.

Additional searches were undertaken using Google, where reports for SVIT, additional professional and educational materials of SVIT and international statistical reports (OECD) were found. Google was also used in order to access the central Slovenian statistical database for cancer (SLORA) and the Database of Statistical office of Republic of Slovenia. Information on incidence/prevalence and mortality in Slovenia was obtained from SLORA, whereas no additional information on CRC was found in the Database of the Statistical office.

Database	**Internet address**
SLORA – Slovenia and cancer – Cancer Registry of Republic of Slovenia	http://www.slora.si/en/
Statistical office of Republic of Slovenia	http://www.stat.si/eng/index.asp

Table 4.1: Slovenian database sources

On advice from NIPH CINDI another Google search was performed, which identified information published on the web site of the Ministry of Health of the Republic of Slovenia (MoH of RS) pertaining to the institutional procedures and requirements for the introduction of new health technologies.

Economic aspects of SVIT were not referred to in any of the literature identified by the systematic literature review and grey literature review, therefore personal communication was established with the founders of the programme at NIPH CINDI Slovenia. In March 2014, a preliminary meeting was held where general information was obtained. Subsequently on-line interviews (via e-mail) were conducted in April and in May 2014, the latter to clarify uncertainties and earlier statements. The questions used in the interview were: *Did you perform economic evaluation of the SVIT program? Was the idea for the SVIT program inspired from the experiences and best practices of other EU countries – of which ones? What kind of obstacles have you faced when implementing the program – were there any institutional, legal, financial or organizational problems/obstacles? Which stakeholders have taken part in the preparation of economic analysis that was performed before the implementation of the pilot project? What challenges did you face in preparing economic calculations, if there were any?* During the first meeting, NIPH CINDI Slovenia agreed to provide central documents detailing the economic evaluation of SVIT. One document was created before implementation of the programme, in 2006 (CINDI Slovenia, 2006b), while the other was created in 2010, after the pilot phase in 2008 and the first year of implementation in 2009.

Descriptive analysis was performed on different information sources. The literature review and personal communication was performed by one researcher in collaboration with other Slovenian experts from Institute for Economic Research (IER) and NIPH CINDI Slovenia. All relevant experts involved in the case study reviewed the present report and comments and suggestions were incorporated.

4.3 Results

The main goals of SVIT are: reduction of CRC morbidity and mortality by 20% to 30%, achieving optimal level 70% responsiveness of the screening program target group, increasing awareness of the CRC problem and opportunities of SVIT , increasing the percentage of disease detected in the early stage to over 50 %, assuring the quality of implementation of the program, improvement of the quality of CRC patient treatment, reducing the costs of treatment and burden on the medical services and improvement of the quality of life of CRC patients (Mlakar et al., 2013).

4.3.1 Institutional procedures and requirements

Currently, Slovenia does not have any special Regulation or Act on public health services (vaccination, screening, campaigns) or medical devices. For introduction of new medical devices or services a special Health Council at MoH of RS is accountable.

In accordance with the requirements of the MoH of RS for introducing new or modified health programmes, NIPH prepared a detailed economic calculation of the estimated costs and benefits of the intended organized CRC screening program in 2006.[3] The MoH of RS procedure was first defined in the document named: "*Process of assessment and integration of new or modified health programs and other innovations in methods of work in the health service schemes in the Republic of Slovenia",* which

[3] The costs in the document were presented in Slovenian previous currency (ie. SIT) and were recalculated into the current Slovenian currency (ie. EURO).

was adopted at 3/2005 session of Health Council on April 14th, 2005. Between 2005 and 2009, this document underwent numerous of changes and improvements, especially in area of economic evaluation of proposed health programmes. The most recent version underlines the importance of: a) the scientific merits of the programme in question, b) defining the number of patients who will benefit from the program, c) increasing the role of experts in Slovenia that are responsible for the professional doctrine in a particular medical field, and d) introducing elements of the assessment of cost-effectiveness. The Health Council, which was established under the MoH of RS and is involved in the decision-making process regarding allocation of public funds to health care, addresses the proposals for new or modified health programmes to ensure that they are feasible and equitable. The Health Council must make reasonable, responsible, transparent and independent decisions regarding the equity and feasibility of programmes, accounting for the maximum public health benefit of the programme, as well as the needs of individuals with regard to the degree of risk. Deliberation on a new or modified health programme or service is open for the public. This is ensured by inviting all national media representatives to be present at the session (Ministry of Health of the RS, 2010).

4.3.2 Economic evaluation of SVIT program in details

NIPH in document from 2006 predicted that the costs for organized screening on a national level for 5 years (2007 – 2011) would amount to 16.2 million EUR. They have predicted that the costs - after the pilot phase and first year of screening - would become stable and would amount to 3.8 million EUR per year, or approximately 7.6 million EUR for one screening round. The estimated costs were different for the pilot phase in 2007 (pilot phase started to implement in 2008[4]) and the first year of screening in 2008 (first year of screening began to implement in 2009). Costs for the pilot phase (in 2008) amounted to 945,749.14 EUR (and included also the purchase of the furniture for the Central unit), while the first regular screening year (costs estimation for 2009 in order to implement the programme in 2010) amounted to almost 3.9 million EUR, due to the purchase of essential screening equipment (ie. machine for automatic reading of tests) (CINDI Slovenia, 2006b, CINDI Slovenia, 2006a). Estimated SVIT screening costs per each year are presented in the Table 4.2, while the detailed estimation of costs per screening per year (selected year of 2009) that NIPH CINDI Slovenia prepared for the MoH of RS is presented in the item H/Table 13 in the Appendix (CINDI Slovenia, 2006a).

[4] The estimated costs were for the 5 year period of implementation of SVIT (2008 – 2012). These were predicted for 2007 – 2011 in order to receive budget one year prior to the actual implementation, with a purpose of achieving fluent implementation of the programme.

Estimated SVIT screening annual costs					
	2007	*2008*	*2009*	*2010*	*2011*
Labour costs [a]	151,155 €	154,329 €	157,570 €	160,879 €	164,257 €
Material costs [b]	613,905 €	1,224,027 €	1,224,444 €	1,224,027 €	1,224,027 €
Medical services [c]	/ €	2,403,606 €	2,403,606 €	2,403,606 €	2,403,606 €
Amortization [d]	/ €	27,125 €	27,125 €	27,125 €	27,125 €
Setup costs[e]	108,498 €	72,192 €	/ €	/ €	/ €
Total annual costs	**873,558 €**	**3,881,279 €**	**3.812.745** €	**3,815,637 €**	**3,819,015 €**

Table 4.2: Estimated SVIT screening annual costs

NIPH also estimated the expected savings of CRC screening, which included both direct and indirect elements (CINDI Slovenia, 2006b, CINDI Slovenia, 2006a). Within the assessment of direct cost benefits[5], costs of treatment for CRC and costs of necessary health services in cases of localized and extended disease were considered. The estimated direct cost savings for 5 years would amount to approximately 17.2 million EUR (CINDI Slovenia, 2006b, CINDI Slovenia, 2006a) as shown in Table 4.3.

Additional savings would result from the indirect cost benefits. Within indirect benefits reduction, life years gained and therefore savings of human capital and minor losses of income were taken into account. The calculation of income as the result of the CRC survival due to the screening program would amount to approximately 14.5 million for a 5 year period (see Table 4.4) (Zakotnik et al., CINDI Slovenia, 2006b, CINDI Slovenia, 2006a).

[5] Within the calculation of direct benefits the following medical services were taken into account: colonoscopy, procedures before the surgery, surgery, oncological treatment, specialized outpatient activity, spa medical treatment, medical visits in primary health care, salary compensation and palliative treatment. Costs of radiotherapy have been excluded from these calculations, because data weren't available.

Before the introduction of screening program	Annual data	Early detected cancer (localised cancer)	Late detection of cancer (extended cancer)
	Number of diagnosed in 2003	167	972
	Structure of diagnosed before the screening program	14.7 %	85.3 %
	Costs of medical services per individual, suffering from the diagnosis	10,253.14 €	29,955.54 €
	Estimation of annual costs of treatment	1,712,273.81 €	29,116,780.19 €
After 5 years implementation of screening program	Number of annual detected colorectal cancer using the predicted ratio (30 % - 70 %)	342	797
	Estimation of annual costs of treatment of colorectal cancer	3,506,572.71 €	23,874,561.54 €
	Total annual savings after 5 years implementation of the Svit program	**3,447,919.75 €** **(ie. approx. 17.2 million in 5 years)**	

Table 4.3: Direct cost savings due to the Svit colorectal screening program.

In 2010, NIPH together with Institute of Oncology Ljubljana prepared a short interim document with health and financial impacts following the implementation of SVIT in 2009. These post-implementation calculations were prepared on the basis of the results of the pilot phase in 2008 and results of national implementation of the program in year 2009. The document revealed that the direct costs of CRC treatment under the umbrella of screening program were halved from approx. 45.5 million before the implementation of screening program to approx. 20.7 million with the screening program. The details are presented in the item I/Table 14 in the Appendix (Zakotnik and Zakotnik, 2010). According to these calculations, annual cost savings (due to earlier detected disease, which represents lower costs of treatment) after 2 years of implementation of the program, would amount to approx. 3.5 million EUR (see the item J/ Table 15 in the Appendix) (Zakotnik and Zakotnik, 2010). After 5 years of implementation of the program the annual costs savings would amount already to approx. 20 million EUR (see the item K/Table 16 in the Appendix) (Zakotnik and Zakotnik, 2010) due to the earlier detected disease and consequently due to the reduction of disseminated disease over the years. The document from 2010 estimated higher costs savings in comparison to the document from 2006. This was due to the several reasons: firstly, results of the document from 2010 have shown that 70% of cancers are detected in early stages compared with the 30% predicted in 2006, and secondly, more significant savings additionally resulted from the decrease in incidence of CRC following detection and removal of pre-cancerous polyps. An in depth economic evaluation of SVIT has not yet been conducted due to lack of human and financial resources, and more importantly, due to the 3-year publication delay for data in the Slovenian cancer registry (since 2015 these data are reported with 4-year delay). The Cancer Registry is managed by the Institute of Oncology, which regularly prepares annual comprehensive reports on the cancer situation in Slovenia. In 2013, the Registry published the data for 2010, which

would not yet reflect the benefits of screening for the first screening round that took place in 2010 and 2011 (J.M. Zakotnik and D.N. Mlakar, personal communication, April 2014).

	Number of individuals
Number of all deaths due to colorectal cancer in 2003	711
Number of deaths among active population (20 – 64 years) due to colorectal cancer	155 (21.8%)
Number of individuals that are younger than 65, who died despite the screening	116
Number of individuals that are younger than 65, who survived due to the screening program. (According to the data and good practice of other EU countries NIPH predicted 25% reduction of mortality due to the screening.)	39
Estimation of mortality due to CRC among individuals that are younger than 65 (in case of no screening)	755 (155 per year, minus 166)
Estimation of individuals that are younger than 65, who would survive due to the screening program (estimation for 5 years)	194
Average gross income of 1 person in 5 years (age group of 20 – 64)	75,027.38 EUR
Estimated average gross income (in EUR) of individuals (age group of 20 – 64), who would survive due to the screening program	14,536,555.32[6]

Table 4.4: Estimated evaluation of income in 5 years period.

4.3.3 Results on the implementation of SVIT program

Although a formal economic evaluation of SVIT has not yet been performed, NIPH CINDI Slovenia publishes annual and semi-annual reports on the implementation of Slovenian organized screening. The reports include information on responsiveness of target population, on the national level and across all 9 regions (National Institute of Public Health, 2010, National Institute of Public Health, 2011, National Institute of Public Health, 2012).

According to the programme plan, the target group of 50 to 69 year old men and women is invited to the screening every two years. The system considers that on even years (eg. 2010) individuals born on even years (eg. 1944) are invited, while on the odd years (eg. 2011) individuals born on odd years (eg.

[6] Within estimation of human capital loss the average year's income and mortality rate were considered. Average gross income of 1 person in 5 years was amounted to 75,027.38 EUR.

1945) are invited. The approx. sample size for two years is 540,000 individuals, who are to be offered Feacal Immunochemical Technology (FIT/iFOBT) for the screening (Zakotnik et al.).

The screening programme is conducted according to the procedure described in Figure 4.5 (Mlakar et al., 2010).

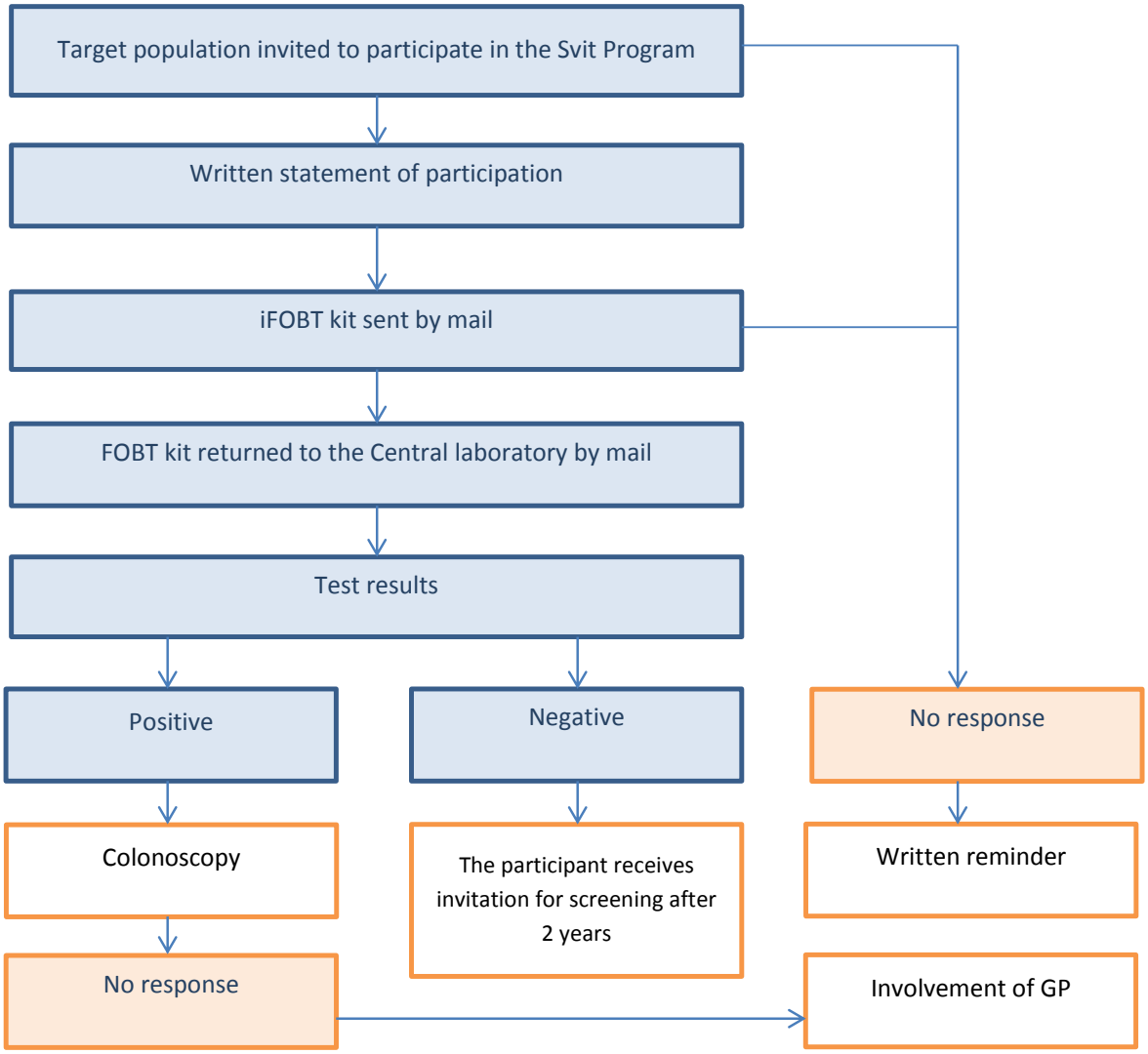

Figure 4.5: Screening Diagramme (Mlakar et al., 2010)

The SVIT reports (2008-2013) (National Institute of Public Health, 2010, National Institute of Public Health, 2011, National Institute of Public Health, 2012, National Institute of Public Health, 2013, Tepes et al., 2014), together with personal communication, revealed that the number of the invitations sent (if the pilot phase and the first year of screening were not included) amounted to between 250,000 to 310,000 individuals. Each year approximately 1000 invitations were undelivered due to a number of reasons, ie. unknown recipient, migrated recipient, if recipient doesn't take over the consignment or if the address of the recipient is incomplete. Responsiveness to the invitations that were delivered has

been stable at around 60% each year from 2010 onwards (the exceptions were 42 % in 2008 and 36 % in 2009), while the estimation of screened population in the last screening years stabilised to around 55% (27 % in 2009, 49 % in 2010, 53 % in 2011, 58 % in 2012 and 56 % in 2013. The responsiveness rate depends on the exclusion criteria and willingness to participate. Exclusion criteria are of two types: a) permanent (individuals are no longer invited to the screening), ie. in case of performed colonoscopy with removed polyps or in case of chronic inflammatory disease; and b) temporary, ie. in case of performed colonoscopy (without pathology) in the last 3 years. Percentage of individuals that were excluded due to the exclusion criteria decreased from 13 % in 2008 (pilot phase) to 6 % in 2013. The percentage of individuals, who did not want to participate, ranged between 0.11 % and 0.33 %. The data revealed that the percentage of individuals with positive tests each year is around 6 %, while the percentage of detected CRC cases ranges around 3 % (the data are available only for 2012 and 2013). Detailed data are presented in the item L/ Table 17 in the Appendix.

4.4 Discussion

Five years after implementation, SVIT has demonstrated many positive characteristics. Besides achieving the programme's primary objective, which was the reduction of prevalence of colorectal cancer and the mortality due to CRC, another important characteristic became evident: cost savings have occurred due to the implementation of SVIT. In 2006, when SVIT was introduced, NIPH CINDI Slovenia calculated that the annual costs for the organized screening on a national level would amount to 3.8 million Euro (4.9 million according to the more recent data in 2010[7]). The calculations from 2006 also predicted the expected cost benefits of CRC screening that were estimated as both direct and indirect. Within the assessment of direct cost benefits, the estimated cost savings amounted to approximately 17.2 million EUR over a 5 year period, while estimated indirect cost savings were approximately 14.5 million EUR over 5 years. Considering all these facts observed within the document prepared in 2006, the net savings due to the organized colorectal cancer screening were estimated to be approximately 15.5 million over 5 years (17.2 million of direct savings plus 14.5 million EUR of indirect savings minus 16.2 million EUR of predicted screening costs). According to the document from 2010, the annual cost savings after 5 years of implementation of SVIT were estimated to be approximately 20 million per year, which is significantly more than the estimate from 2006.

Comparing the screening costs and economic benefits calculated in the 2006 document and the 2010 document, some major differences exist. This may be due to several reasons, including: a) unknown and unpredictable costs incurred during the pilot phase which had not been included in the 2006 proposal (eg. biological drugs), b) the adoption of the Euro in 2007 which marked an increase in standard of living and costs of life essentials, and c) detection of pre-cancerous cases and larger estimations of early

[7] Higher treatment costs were due to the introduction of biological drugs. In the 2006 calculation, biologicals were not taken into account because they were not available at that time. Biologicals that prolong life are used only in the metastatic setting and correspond to the higher costs because of a longer treatment.

detected cases in the 2010 document, which lead to reduction of costs of CRC treatment. The exact comparison of these two documents could not be performed, because the document from 2010 was not as detailed as the document from 2006.

When observing institutional, organizational and legal factors that contributed to success, it might be worth mentioning the establishment of central unit (ie. SVIT centre) for CRC screening that is responsible for management of SVIT. All relevant information regarding CRC and screening is sent to the target population by the SVIT centre, which ensures: a) that all eligible target population is invited and well informed about the CRC, and the CRC screening process, b) that the screening process is conducted strictly according to the rules of procedure that are specified within the CRC screening programme in order to achieve quality assurance of the programme's implementation (the quality of process depends also on the communication, coordination etc.), c) an adequate and timely follow-up or treatment for those who need it and d) the availability of data.

Although the programme has been considered a success, one challenge remains unmet: the preparation of comprehensive economic ex-post evaluation of SVIT programme. Two major factors impeding a formal study of cost-effectivess are, the 4 year publication delay for data from the Cancer Registry of Republic of Slovenia (it is most reasonable to postpone the study until 2017, when newer data on CRC cancer mortality and incidence will be available, in order to cover the first 5 years of SVIT), and the insufficient budget space in the national public health sector to support the study.

4.5 Conclusions

Organized CRC screening can be a cost-saving and effective prevention instrument to tackle colorectal cancer, which is positively accepted by the public. Conclusions regarding the economic effectiveness of SVIT are complicated by the fact that the 2006 and 2010 documents assessing the program differ in certain cost and benefit estimates, in the currency used, and in the level of detail included. In addition, despite drawing on detailed data, the SVIT programme analysis did not include elements usually considered central to economic evaluation, including sensitivity analysis or a discussion of time horizon and discounting, probably because formal procedures did not require such elements. As soon the relevant data on the Slovenian central cancer database SLORA that publishes data with a 4-year delay would be available (year 2017), a comprehensive economic evaluation of SVIT (based on economic modelling) should be prepared in order to gain insight into the actual cost savings of the programme and obtain the most important successes and challenges within the area of CRC.

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4.7 Appendix

A. Estimation of costs before the surgery (f, g, h procedures are conducted only and always in case of rectum cancer) (CINDI Slovenia, 2006b).

Procedures before the surgery	Unit costs (same for localised or expended tumour) in EUR
a) laboratory	17.35
b) tumour marker CEA (carcinoma antigen)	12.07

c) ultrasound of the abdomen	43.65
d) roentgen	34.85
e) electrocardiography	5.51
TOTAL (a – e)	**113.43**
f) endoscopic ultrasound	832.48
g) computed tomography of abdomen	258.94
h) magnetic resonance of pelvis with contrast	540.74
TOTAL (f – h)	**1,632.16**
TOTAL	**1,745.59**

Table 2: Estimation of costs before the surgery.

B. Costs of surgical treatment (CINDI Slovenia, 2006b).

Type of surgery	Unit cost of surgical treatment in EUR
Anterior resection of rectum	6,676.68
Hemicolectomy	5,216.16
Colectomy subtotalis	5,424.80
Metastasectomy	5,633.45
Average cost of surgery	5,662.66

Table 3: Costs of surgical treatment.

C. Costs of oncological treatment (systematic treatment of patients) and specialist ambulatory activity (treatment with oncologist) (CINDI Slovenia, 2006b).

Cancer stage	Average unit costs of systematic oncological treatment in EUR
Localised cancer stage	/
Regional extension of tumour	12,954.40
Distant extension of tumour	19,246.34
Regional and distant	14,716.15

Table 4: Costs of systematic oncological treatment.

Location of tumour	Average unit costs of specialist ambulatory treatment in EUR
Regional extension of tumour	103.43
Distant extension of tumour	118.09
Regional and distant	107.54

Table 5: Costs of specialist ambulatory treatment.

D. Costs of health spa medical treatment (according to the rules of compulsory health insurance, patients can utilize 14 days of spa medical treatment) (CINDI Slovenia, 2006b).

Type of activity	Costs per unit in EUR

Nonmedical treatment day	38.48
Medical and therapeutic services (per day on average)	47.19

Table 6: Costs of health spa medical treatment.

NIPH made estimation of average costs of spa medical treatment. It amounted to 1,199.44 EUR for localized type of cancer and 863.79 EUR for regional extended type of cancer (CINDI Slovenia, 2006b).

E. Estimated costs of visits in primary health service (CINDI Slovenia, 2006b).

Cancer stage	Costs per person in EUR
Early diagnosis (localised cancer)	152,60
Extended disease	244,58

Table 7: Estimated costs of visits in primary health service.

F. Costs of sickness absence

According to The Health Care and Health Insurance Act (Official Journal of Republic of Slovenia, no. 72/06 - official consolidated text, 114/06 - ZUTPG, 91/07, 76/08, 62/10 - ZUPJS, 87/11, 40/12 - ZUJF, 21/13 - ZUTD-A, 91/13, 99/13 - ZUPJS-C, 99/13 - ZSVarPre-C and 111/13 - ZMEPIZ-1), the entitlement for the wage compensation during temporary absence from work have all policyholders, who are employed, persons performing independent economic or professional activity, owners of private companies, top athletes and top chess players and farmers, if they protected this right. Wage compensation is covered by the compulsory health insurance.

Reason for absence from work	Vesting percentage for the calculation of wage compensation for the first 90 calendar days	Vesting percentage for the calculation of wage compensation over the 90 calendar days
transplantation of living tissue and organs in favour of another person; the consequences of donating blood; isolation, ordered by a doctor;	90%	100%
occupational disease; occupational injury;	100%	100%
disease	80%	90%

injury outside of work; escort, ordered by a doctor;	70%	80%
care for a family member	80%	80%
blood donation	100%	-

Table 8: Vesting percentages for the calculation of wage compensation.

When preparing calculation of costs, NIPH considered average length of sickness absence, which for localised cancer represents 2.5 months and for extended cancer 8 months. Taken into account average salary compensation, the costs of salary compensation for sickness leave of 1 person with localised cancer amounts to 2,017.06 EUR, while sickness leave of 1 person with extended cancer amounts to 6,454.68 EUR (CINDI Slovenia, 2006b).

Expenditure of compulsory insurance for salary compensation (2005)	172,447.97 EUR
Number of working days lost in burden of Health Insurance Institute of RS (2005)	4,488,416 days
Average amount of salary compensation per days	38.42 EUR

Table 9: Salary compensation in 2005.

G. Costs of palliative care

Costs of palliative care per person were estimated on 49.35 EUR for localised cancer and 734.19 EUR for extended cancer (CINDI Slovenia, 2006b).

H. Calculation of costs made in 2009 for the given year of implementation of the SVIT program. Source: Health Center Ljubljana, CINDI Slovenia (CINDI Slovenia, 2006a).

Type of costs	**Detailed description of activity**	**Costs per unit (of gross)**	**Total costs (2009) in EUR**
Labour costs		pay ratio	
- medical specialist	1 person	11,810	
- other with BSc	3 persons	8,025	
- administration	2 persons	4,403	
Total			**157.569,84**
Material costs			
- space rental	1	15.857,15 €	15.857,15
- material costs	1	4.172,93 €	4.172,93
- accounting, financial and legal services	1	10.432,32 €	10.432,32
- purchase of tests kits	134856	349 €	470.454,08
- media activities	1	83.458,52 €	83.458,52
- invitation letter			173.344,66
- reminder 1			100.740,71
- sending the kits to			186.549,67

the target population			
- reminder 2			17.107,29
- letter 2			42.768,55
- letter 3			42.768,55
- letter of GPs			76.372,33
- preparation of the sample for 2010-2011	1	417,29 €	417,29
Total			**1.224.444,02**
Costs of services			
Laboratory – test analysis			168.823,23
Reporting to the Central unit			18.317,04
Colonoscopy			1.654.569,35
GPs' work			312.388,52
Lecturing on program screening			241.161,74
Results – analysis of the program			8.345,85
Total			**2.403.605,75**
Amortization	Cost value of equipment		
Computer equipment			7.303,14
Information system (program)			19.821,40
Total			**27.124,54**
Other costs			/
/			/
TOTAL			**3.812.744,15**

Table 10: Calculation of costs made in 2009 for the given year.

I. Health and financial impacts of the Program Svit, considering the discplacement of stage of the disease at detection of CRC and reduction of incidence (Zakotnik and Zakotnik, 2010).

Stages of disease	**Cost of treatment of CRC per person (in EUR)**	**State of stage of the CRC at diagnosis before the screening**	**Stage projection of CRC considering the results of pilot phase of Svit program (2008)**	**Cost of CRC treatment before the screening**	**Cost of CRC treatment after the screening**
Stage I (cancerous polyp)	260.00	0 (0 %)	270 (30 %)	0	70,200.00
Stage I	10,000.00	144 (12 %)	90 (10 %)	1,440,000.00	900,000.00
Stage II			135 (16 %)		1,350,000.00
Stage III	20,000.00	720 (60 %)	243 (26 %)	12,960,000.00	4,380,000.00
Stage IV (metastatic cancers at first diagnosis)	50,000.00	300 (25 %)	135 (15 %)	31,050,000.00	13,950,000.00
All metastatic cancers (primary	50,000.00	690	309		

and at lower stages)					
Unknown stage	/	36 (3 %)	27 (3 %)	/	/
Total (taken into account that 10 % of patients are not treated)	/	1200 (100 %)	900 (100 %) Reduced incidence due to the removed precancerous lesions (polyps)	**45,450,000.00**	**20,650,200.00**

Table 11: Health and financial impacts of the Program Svit, considering the discplacement of stage of the disease at detection of CRC and reduction of incidence.

J. Annual cost savings after 2 years of implementation of Program Svit (Zakotnik and Zakotnik, 2010).

	Data in EUR
Annual costs of CRC treatment (stage I – III) – without the Svit program	14,400,000.00
Annual costs of CRC treatment (stage I – III) with Svit program	6,700,200.00
Annual costs of Program Svit	4,900,000.00
Annual cost savings after 2 years	**3,498,000.00**

Table 12: Annual cost savings after 2 years of implementation of Program Svit.

K. Annual cost savings after 5 years of implementation of Program Svit (Zakotnik and Zakotnik, 2010).

	Data in EUR
Total annual costs of CRC treatment – without the Svit program	45,450,000.00
Total annual costs of CRC treatment – with Svit program	20,650,200.00
Annual costs of Program Svit	4,900,000.00
Annual cost savings after 5 years of implementation of the Svit program (approx.)	**20,000,000.00**

Table 13: Annual cost savings after 5 years of implementation of Program Svit.

L. Data from the annual reports (National Institute of Public Health, 2010, National Institute of Public Health, 2011, National Institute of Public Health, 2012, National Institute of Public Health, 2013, Tepes et al., 2014).

YEAR	**2008**[8]	**2009**	**2010**	**2011**	**2012**	**2013**
Number of invitations sent	9,189	171,494	310,404	275,211	280,686	248,011

[8] In 2008 the pilot phase was conducted. Age group in pilot phase: 64 - 68 years; only 3 Slovenian regions participated in the pilot phase, namely: Ljubljana region, Kranj region and Celje region.

Number of invitations delivered[9]	9,091	170,217	308,341	273,831	279,592	247,015
Number and percentage of returned written and signed statements of participation	3,807 (3807*100/9091 = 41.88 %)	61,337 (61337*100/170217= 36,03 %)	175,718 (175718*100/308341 = 56.99%)	159,654 (159,654*100/273,831 = 58.30%	174,241 (174241*100/279592 = 62.32 %)	148,427 (148427*100/247015 = 60.09 %)
Number and percentage of individuals that were excluded due to the exclusion criteria[10]	496 (496*100/3807= 13.03%)	7,120 (7120*100/61337 =11.61%)	22,569 (22569*100/175718 = 12.84%)	15,342 (15342*100/159654 = 9.61 %)	12,992 (12992*100/174241 = 7.46 %)	8,600 (8600*100/148427 = 5.79 %)
Number and percentage of individuals, who did not want to participate in the screening	15 (15*100/9091= 0.16%)	188 (188*100/170217 = 0.11%)	681 (681*100/308341= 0.22%)	908 (908*100/273831 = 0.33 %)	725 (725*100/279592 = 0.26 %)	371 (371*100/247015 = 0.15 %)
Number and percentage of sent iFOBT tests	3,117 (3117*100/9091 = 34.29%)	52,933 (52.933*100/170217= 31.10%)	154,631 (154631*100/308341 = 50.15 %	142,239 (142239*100/273831 = 51.94 %	162,585 (162,585*100/279592 = 58.15 %)	140,053 (140,053*100/247015 = 56.70 %)
Number of adequately tested **(ie. percentage of screened population)**	There is no data on number/ percentage of screened population for a pilot phase.	Samples: screened=44,080 44080*100/ (170217-7120) =27.03%	Samples: screened=140,271 140271*100/ (308341-22569) = 49.08 %	Samples: screened=135,727 135727*100/ (273831-15342) = 52.51 %	Samples: screened=154,329 154329*100/ (279592-12992) = 57.89 %	Samples: screened=133,751 133751*100/ (247015-8600) = 56.10 %
Number of individuals with negative	2,612 (92.33 % among	41,069 (94.39% among	130,559 (93.73% among	126,945 (94.05% among	144,339 (93.80 % among	152,122 (=93.85 % among

[9] Invitation can't be delivered to the recipient according to several reasons: if the recipient is unknown, migrated, if he doesn't take over the consignment or if the address of the recipient is incomplete.

[10] Exclusion criteria are of two types

1. permanent (individuals are no longer invited to the screening):
   - performed colonoscopy with removed polyps;
   - chronic inflammatory disease;
2. temporary (after a specified time, individuals are again invited to the screening):
   - performed colonoscopy (without pathology) in the last 3 years;

test result	individuals who returned samples that were adequate for the analysis)	individuals who returned samples that were adequate for the analysis)	individuals who returned samples that were adequate for the analysis)	individuals who returned samples that were adequate for the analysis)	individuals who returned samples that were adequate for the analysis)	individuals who returned samples that were adequate for the analysis)
Number (percentage) of individuals with positive test result	217 (7.67 % among individuals who returned samples that were adequate for the analysis)	2,441 (5.61 % among individuals who returned samples that were adequate for the analysis)	8,728 (6.27% among individuals who returned samples that were adequate for the analysis)	8,027 (5.95% among individuals who returned samples that were adequate for the analysis)	9,542 (6.20 % among individuals who returned samples that were adequate for the analysis)	8,197 (6.15 % among individuals who returned samples that were adequate for the analysis)
Number of performed colonoscopies after the positive test result[11]	193	1,622	7,488	7,872	9,016	7,969
Number (percentage) of detected colorectal cancer cases	/	/	/	/	275 3.11 % among individuals taken first colonoscopy in 2012	183 2,36 % among individuals taken first colonoscopy in 2013

Table 14: Data from the annual reports.

[11] Data reflect the fact that an individual can undertake more than one colonoscopy.

5 Pomeranian Program of Integrated Care for Patients with Severe COPD

Ewa Bandurska[*], Iwona Damps-Konstańska[+], Piotr Popowski [*], Ewa Jassem[+], Marzena Zarzeczna-Baran[*]

[*] Public Health and Social Medicine Department Medical University of Gdansk

[+] Department of Allergology Medical University of Gdansk

5.1 Introduction

Burden and classification of COPD in Poland

According to data presented by the World Health Organization (WHO), 65 million people have moderate to severe COPD worldwide. In Poland, there are about 2 million people suffering from COPD, one fifth of whom have the severe form of the disease, i.e. stage III or higher in the GOLD classification from 2010 (Bednarek et al., 2008; GOLD, 2013). The GOLD classification system assesses severity of symptoms, the degree of obstruction, the risk of exacerbation and the presence of comorbid disorders. The aim of this classification system is to facilitate the coordination of treatment with the real needs of individual patients.

The need for an integrated care model

COPD mortality in Poland is among the highest in Europe, which underlines the seriousness of the condition from a public health perspective (Zielński, 2007). Due to the high rate of COPD mortality, (21/100,000 citizens per year) (Górecka et al., 2012) and morbidity, as well as the need to rationalize direct medical costs, health authorities began to consider the introduction of innovative care for patients with COPD (Zielński, 2007). The recommendations of the World Health Organization from 2002 were taken into account, which highlighted the merits of the implementation of an integrated system of care for patients with advanced chronic diseases, including COPD (World Health Organisation, 2008), since a wide range of activities exist which could potentially lead to stabilization of the disease and an elongation of periods without exacerbations (Seemungal et al., 2000).

In 2009, intensive work was started on the creation of the Pomeranian Model of Integrated Care for Patients with severe COPD (PMIC) (Jassem et al., 2010). The program was based on, among other things, a pilot study carried out in Chojnice, Poland (Werachowska, 2013). The results of the pilot study demonstrated a high level of acceptance for this type of care and the need to introduce more systematic care. Findings indicated that 93% of the patients were satisfied, and 7% were very satisfied, with integrated care and 90% of patients expressed the hope that this kind of care would be available to them in the future (Werachowska, 2013). Consequently, the Pomeranian Program of Integrated Care for Patients with Severe COPD (PMIC) was created in 2011, owing to the commitment of the following institutions: University Clinical Center, Medical University of Gdansk, Office of the Marshal of the Pomeranian Voivodeship, Town Council of Gdansk, Polish Society for Health Programs and the *I like to Help* Foundation. The programme was scaled-up from the pilot and implemented as part of a systematic, regional plan to solve health problems in the Pomeranian Voivodeship.

Organization of the integrated care model

The main elements of PMIC as indicated by Damps-Kostańska et al. (2011) are:

Patient's eligibility

A patient can can qualify to receive care under PMIC if he/she: suffers from severe COPD (stage III or IV according to GOLD and Polish Society for Lung Disease criteria), has had at least 3 exacerbations in the past year, of which at least one required hospitalization, and has consented to joining the programme.

Implementation of a multidisciplinary care team

A team comprised of a pulmonologist, nurse, coordinator, patient assistant, physiotherapist, dietitian, social worker, and volunteers, cooperate with each other and with the relatives of the patient. The innovative element is to integrate the activities of medical and non-medical staff, and to provide home support for patients with poor self-management. The organization of the activities of the programme are presented in Figure 5.1. Section A describes the course of consultations following enrolment in the programme, while B shows the interactions between the patient, a coordinating nurse, and volunteers/patient assistants.

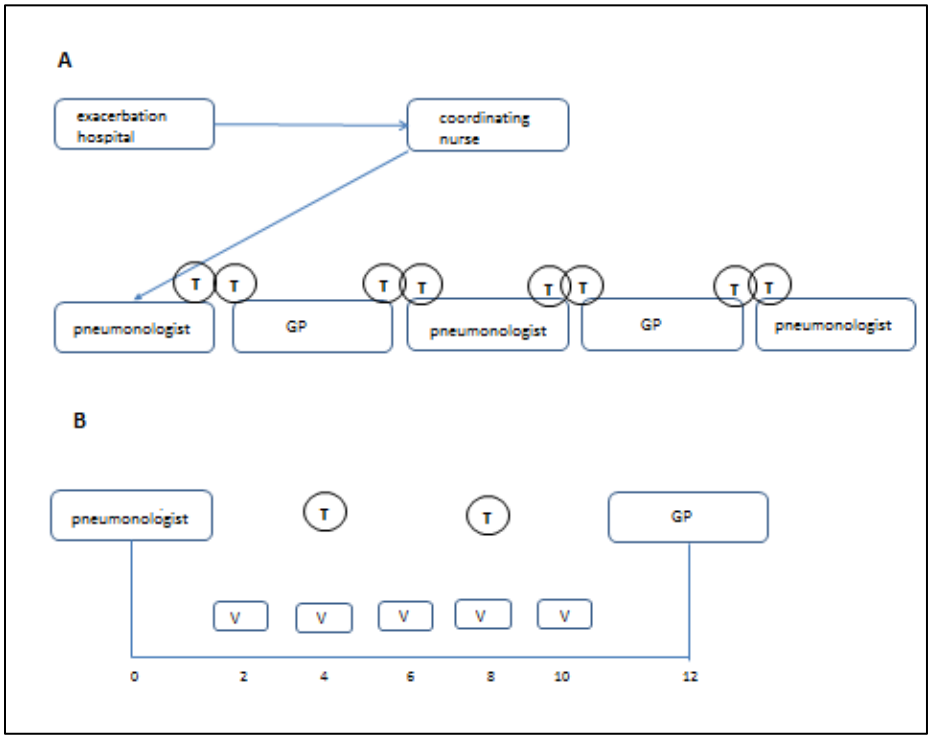

Figure 5.1 Organization of actions in PMIC (Based on Jassem et al, 2011)**.**

Notes: T =coordinating nurse consultation, V =volunteer and patient assistant contact

After an exacerbation (Figure 1, A), eligible patients are put in contact with the coordinating nurse if they give consent to join PMIC. This is followed by five consultations/visits:

- During the first visit (pneumonologist), the patient receives information on treatment recommendations, the course of action in case of exacerbations, and health education
- The second visit (general practitioner), after 3 months, is to monitor that the patient is adhering to medication and demonstrating adequate control of their symptoms The third visit (pneumonologist), after 6 months, involves evaluation of the course of treatment, changes to recommendations (if indicated), and education

- The fourth visit (general practitioner), after 9 months, involves the continuation of drugs, and control of stabilization
- The fifth visit (pneumonologist), after 12 months, summarizes and concludes the treatment.

Between the visits, patients are contacted by the coordinating nurse (Figure 1, B, T) who verifies whether patients have their drugs and are taking them properly, if they require any help at home, and whether they smoke. Also between the medical consultations, patients are visited by an assistant and volunteers every two weeks (Figure 1, B, V). The visit lasts for 2 hours and includes assistance with the use of the inhaler, measurement of vital signs such as blood pressure, heart rate, pulse oximetry, peak flow (if indicated), exercise and breathing improvement, as well as conversation.

Effectiveness and costs of integrated care vs hospitalization in the literature

Preventing hospitalization in COPD by way of integrated care has uncertain effectiveness. Two randomized studies (Hermiz et al., 2002; Monninkof et al., 2003) demonstrated no health benefit following implementation of integrated care systems, whereas iBourbeau et al. (2003) observed benefits of an integrated model(Monninkof et al., 2003; Bourbeau et al., 2003; Gallefoss, 2004; Hermiz et al., 2002). Casas et al. (2006) showed that patients who were managed in integrated care were less frequently hospitalized than those who were managed with standard care (1.5 hospitalizations per patient per year versus 2.6). However no significant difference in the mortality rate was observed (19% for integrated care versus 16% for standard care). It is difficult to determine why different studies report conflicting results, indicating the need for further research.

The assumption that integrated care would lead to a decrease in the number of exacerbations requiring hospitalization, which would in turn would result in a reduction of direct medical costs, was the basis for implementing integrated care in the Pomeranian Voivodeship . The cost of hospitalization is very high, so a decrease of between 10-20% would result in noticeable savings. The main focus was on direct medical costs. Indirect costs were considered less important because 91% of COPD patients in Poland are retirement age and only 6% require sick leave (Jahnz-Różyk et al., 2011). More recently,the idea of how indirect costs should be calculated has changed, more indirect cost data is taken into consideration in Poland (e.g. sick leave of close family members of COPD patients).

The main objectives of PMIC at the time of implementation were: to limit the number of exacerbation requiring hospitalization by 20%, and to improve patient satisfaction, quality of life and ability to cope with disease, as was achieved in the pilot study organized in Chojnice (Werachowska, 2013). The aim of this case study is to present PMIC, the data which provided the evidence base to start organizing integrated care in Poland, and the results of the an initial economic evaluation of the Pomeranian Program of Integrated Care for Patients with Severe COPD.

5.2 Methods

To date, no papers on the economic considerations of PMIC have been published. The present case study is based on the direct involvement of the authors in the establishment of the PMIC programme as follows:

Public Health and Social Medicine Department Medical University of Gdansk:

- Ewa Bandurska: Acquisition, analysis and interpretation of data
- Piotr Popowski: Participated in the expert group preparing PMIC in 2012, cooperated with National Health Fund
- Marzena Zarzeczna-Baran: Analysis and interpretation of data from National Health Fund

Department of Allergology Medical University of Gdansk

- Ewa Jassem: Leader of the expert group preparing PMIC in 2012, author of conception and design of PMIC, analysis and interpretation of data, sharing experiences about PMIC in Poland (May 2014- XXXIII congress of Polish Society for Lung Diseases), cooperation with National Health Fund in acquisition of data
- Iwona Damps-Konstańska: Participated in the expert group preparing PMIC in 2012, acquisition of data, coordination of the project, sharing experiences about PMIC in Poland (May 2014- XXXIII congress of Polish Society for Lung Diseases), cooperation with National Health Fund

5.3 Results

Data for the pre-implementation assessment of PMIC

The main method used to gather information about the scale of the COPD problem in Poland was a review of available literature. There was no complete, national data relating to the incidence rate of COPD, therefore estimated were based in the extrapolation of available epidemiological data from selected regions of the country (Malopolska and Mazovia). The studies were carried out by Niepsuj et al. (2002) and by Pływaczewski et al. (2003) The experiences of other countries in the area of integrated care was also analyzed (Lemmens, Nieboer & Huijsman, 2009; ZuWallack & Nici, 2010). An additional source of data were observations and conclusions drawn from the development of the *Health for Pomeranians Program*, relating to the very extensive cooperation that was formed between medical society representatives and local government authorities (Regional National Assembly). Finally, data on COPD incidence in the Pomeranian Voivodeship was also collected (Appendix section 5.7.1).

Political process for establishing the PMIC

The PMIC was constituted as one of the 12 goals of the strategic development plan for the health sector in the Pomeranian Voivodeship, *Health for the Pomeranian*s. The plan was created to meet the need for a coherent policy in the area of health. It includes disciplines, which due to the epidemiological situation, must be given priority in the organization of health services, financing of infrastructure and medical equipment, and availability of key medical services. The Health for Pomeranians program was created under the Declaration on Cooperation of 21 February 2005 on the development of the Pomeranian Program Disease Prevention and Treatment of Cardiovascular Disease and Cancer "Health for the Pomeranians 2005-2013." The collaboration agreement on the Health for the Pomeranians included the following partners: Pomeranian Voivodeship Office, Pomeranian Voivodeship NHF Office,

Convention of Starostes of Pomeranian Voivodeship, Regional Statistical Office in Gdańsk. The program became an integral element of the *Pomerania Program*[12].

In 2011, it was possible to determine the level of support and accessibility to social services[13] in the voivodeship thanks to cooperation started between social services offices. This was an important element in the preparation for the implementation of PMIC. Information meetings between pneumonologists, social workers and local government authorities were organized to find out about current situation and decide about further cooperation in the area of COPD (Damps-Kostańska & Jassem, 2013). The results of the consultations suggested an urgent need to implement PMIC, because the present organization of care was insufficient to maintain optimal health status of Pomeranian patients with severe COPD (Jassem & et al, 2011). A detailed schedule of the consultation meetings leading up to the establishment of PMIC with different specialists is given in Appendix section 5.7.2.

Economic data

The main health economic evidence taken into consideration at the inception of the PMIC consisted of the results of studies dealing with the direct medical costs of stable periods and exacerbations in Poland, Europe and globally. According to international evidence, besides health and social costs experienced by COPD patients, the condition is also associated with high economic costs to health systems (direct medical costs) and national budgets (indirect non-medical costs).

Direct medical costs of respiratory diseases account for around 6% of the total expenditure of health systems in the European Union, of which 56% of the costs are expenditures related to the treatment of COPD, approximately equal to 38.6 billion euros (Hoogendoorn, 2011). Detailed data are presented in Figure 5.2.

[12] Pomerania Heath is a wider approach to health of the citizens of Pomeranian Voivodeship and includes the Health for the Pomeranians Program

[13] Social workers are engaged in PMIC to support patients in activities of everyday life. This is important because COPD is a systemic disease and requires not only medical care.

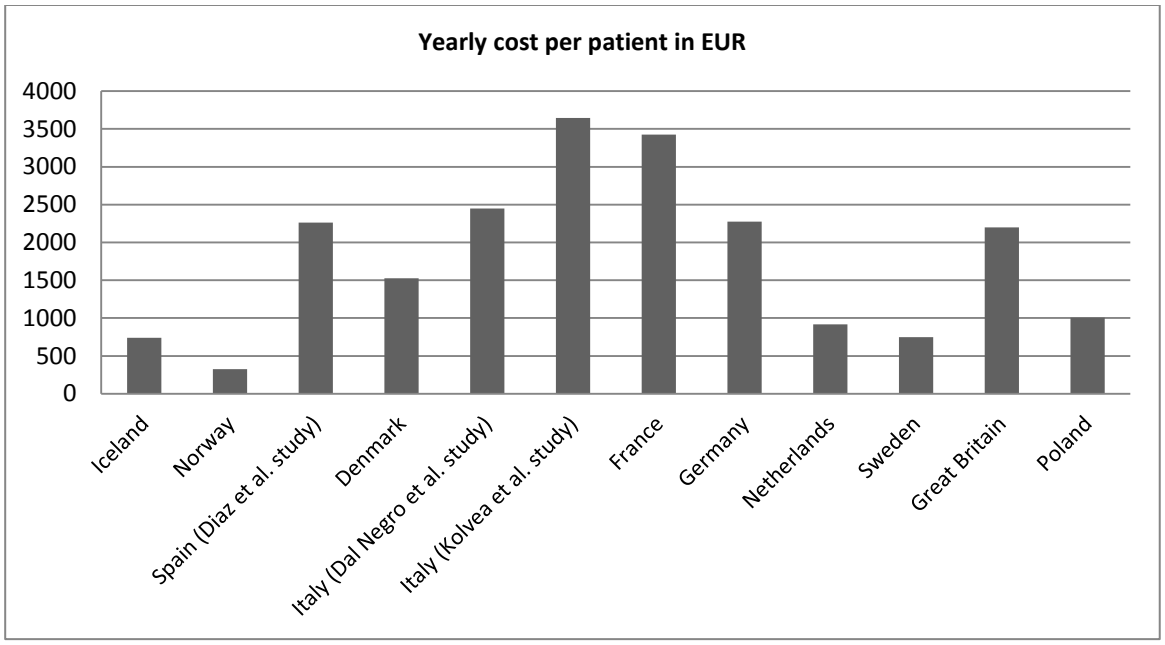

Figure 5.2 Direct medical costs of COPD in Europe in 2011 or closest year with available full data (Hoogendoorn, 2011)

Numerous studies have shown that the majority of direct medical costs for exacerbations are due to hospitalization (Jahnz-Różyk, Targowski & From, 2008). It has been estimated that hospitalizations account for around 40.4% of direct medical costs in moderate COPD and for 62.6% in severe COPD (Hilleman et al., 2000). In some cases, costs of hospitalizations can account for up to 75% of direct medical costs (Celli & MacNee, 2004). Another piece of information that played an important role in initiating the implementation of PMIC was the very high risk of re-hospitalization due to exacerbations. According to the published data, 67% of patients have a secondary exacerbation requiring hospitalization within one year of their first exacerbation (NICE, 2004). Also alarming was the death rate among patients who were admitted to hospitals due to exacerbation of COPD. According to Polish data from 2001 this rate around 20% (Zieliński, 2001). Specific information on exacerbations is presented in Appendix section 5.7.3.

In 2007-2008 a first attempt was made to estimate the level of direct medical costs of exacerbations treated in hospitals and by outpatient care providers in Poland. In a multicenter study, Polish patients had on average 1.27 exacerbations per year requiring only outpatient treatment and 0.24 exacerbations requiring hospitalization. The average cost of hospital treatment of COPD exacerbation was 5,548 PLN (4,543 PLN-6,502.3 PLN). The cost of outpatient care for COPD exacerbations was ten times less costly, at an average of 524 PLN (434 PLN-614 PLN) (Jahnz-Różyk, Targowski & From, 2008).

In the context of the estimated direct medical costs and the fact that the costs of hospital treatment are significantly higher than the costs of outpatient treatment, it could be considered justifiable from an economic perspective to implement PMIC, with the aim of limiting exacerbations requiring hospitalization, which could in turn lead a reduction of hospitalization costs. However, at the time of planning, no specific calculations were done and only published evidence was considered. The

assumptions were based on clinical knowledge of specialists engaged in the PMIC. At the time of writing, a full economic analysis is being undertaken.

Establishment of a COPD disease registry and coordination center

Simultaneously with the consultations with local government, an Allergology and Pneumonology Clinic in Gdansk started to coordinate PMIC**.** This work included development of a digital tool to help coordinate different aspects of patient care, the Register of Patients with Severe COPD in Pomerania Voivodeship.

After giving informed consent to join the PMIC, patients were introduced into the register which is hosted at the internet portal SPIRO[14]. The general role of the register is to collect data on incidence, prevalence and course of disease. The data is used to: assess the prevalence of severe COPD, determine the number of exacerbations (including those requiring hospital treatment) in this group of patients, supervise treatment and set up appointments.

The register improves integration of medical and non-medical activities undertaken to help patients with severe COPD. At time of writing there are 200 patients in the register. Out of this group, 60 patients are enrolled in PMIC.

5.4 Discussion and lessons

The structure of PMIC is coherent with other interventions of this type, which are currently implemented in many countries. At present, the most important successes achieved through PMIC have been:

- The set-up of the Register of Patients with Severe COPD in Pomerania Voivodeship as a tool for the collection and exchange of information among care providers
- The establishment of cooperation with the public-payer National Health Fund, which was an achievement with externalities on a national scale
- The establishment of integrated care teams, including both medical and non-medical specialists
- The cooperation between centers of social services in the Pomeranian Voivodeship, and the realization of training for social service workers and caregivers on the medical and non-medical needs of patients with severe COPD
- The initiation of a well-organized and active group of volunteers
- The development of potential opportunities for public cost savings, supported by the first results of cost analysis produced at the time of writing the study considering the group of patients included into home support

[14] http://pochp.eu/

Challenges the program is expected to face in the future:

- Organizational and financial issues: although PMIC initially resulted in improvement on many indicators analyzed within the study, the creators of the program are having difficulties obtaining funds for current expenses such as salaries for medical caregivers and patients' assistants. In the previous years those salaries have been financed with regional resources (provided by the local government) in a non-competitive procedure, but currently there is no certainty that this type of financing is sustainable.[15]
- Personnel difficulties: problems finding competent individuals who could work as medical caregivers and be volunteers
- Cooperation: maintaining cooperation with centers of social services, an integral non-medical element of the integrated care team, and with National Health Fund through changing organizational and political conditions
- establishment of the integrated care model as an element of evaluation during the procedure of contracting with public health system payer

In Poland, the use of health-economic evidence is a relatively new procedure. The Health Technology Assessment authority in Poland, Agency for health Technology Assessment (AHTAPol), was established in 2005. AHTAPol uses a three stage process of medical, economic and financial evaluation to assess the effectiveness of an intervention and recommend whether it should financed with public money. AHTAPol does not currently evaluate programs like PMIC, and has had no role in the assessment of PMIC. At the moment there is no legal obligation to include AHTAPol in such processes and no custom to do so.

Currently, the most pressing issues with respect to carrying out a formal economic evaluation of PMIC are an incomplete database of direct medical costs, a lack of epidemiological data (e.g. incomplete data on incidence, prevalence of COPD in Pomeranian Voivodeship), and only partial data on indirect non-medical costs.

Furthermore, an increase in the number of patients enrolled in PMIC would be needed to get more accurate results. Lengthening the time of observation from 6 months to one year would also enable the collection of more accurate data, including how the time of year affects the course of the disease and risk of exacerbations.

5.5 Conclusions

PMIC was based not only on evidence of medical effectiveness but also on economic evidence, which previously was not common practice in Poland. The results of the pilot study in Chojnice indicated high level of acceptance of integrated care by patients and an urgent need to introduce this type of support more broadly due to improper use of drugs by patients (especially inhaled), unbalanced diet, lack of

[15] At the moment of writing it is known that the additional costs resulting from running PMIC are lower that the savings resulting from decrease number of medical services realized for patients

rehabilitation in outpatient care and limited access to rehabilitation in stationary care**.** The data identified at the inception of PMIC suggests integrated care could lead to both clinical and economic benefit, however no formal economic evaluation was carried out, and both economic and epidemiological data was severely limited. As more data becomes available from the ongoing program, the authors plan to carry out a more detailed assessment using costs and outcomes observed following the implementation of PMIC. There is currently no institutional support to conduct economic evaluations of integrated care programmes in Poland. For the present case study, clinical and economic expertise was brought together from Polish universities and hospitals.

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5.7 Appendices

5.7.1 Data on COPD incidence in Pomeranian Voivodeship

The data obtained from the public health system payer, National Health Fund (NHF), during preparation of the *Health for Pomeranians Program,* indicated that in 2009 36,363 people in outpatient specialist care in the Pomeranian Voivodeship had a diagnosis that could be COPD. COPD cases could not be differentiated because the diagnosis of airway obstruction includes all diseases of this type. It can be assumed that patients with severe forms of disease or patients whose symptoms have not been adequately controlled are the ones who present at outpatient care. According to data provided by the National Health Fund, between January 2009 and June 2011, 219,110 specialist consultations were provided for 101,440 patients with obstructive disease of the bronchi. Additional pieces of data that were used in the initial estimation of the number of patients who might benefit from inclusion in integrated care in Pomerania, were those reported by hospitals, outpatient care providers and other health care providers. The data came from reports by hospitals and other institutions, which were sent to the National Health Fund for reimbursement of benefits realized. The data is presented in the Table 5A.

Table 5A. Hospital wards of lung's diseases and tuberculosis in Pomeranian Voivodeship (Jassem & et al, 2011)

Health care provider	Ward's name	Numer of beds - status at 31/12/2011	Number of patients	Number of person per day *	Use of hospital beds in %	Mean lenght of hospitalization
Pomeranian Center for Infectious Diseases and Tuberculosis	Pulmunology Ward	20	672	4091	56	6,1
	Tuberculosis Ward	48	351	14717	84	41,9
University Clinical Center in Gdansk	Pneumonology Ward of the Allergology and Pnemumonol	20	891	6605	90,5	7,4
J.K. Łukowicz Specialist hospital in	Pulmunology Ward	33	1148	9918	82,3	8,6
Specialist hospital in Prabuty	Pulmunology Ward	30	1551	6361	58,1	4,1
	Tuberculosis and Lung's Diseases Ward	70	1659	17501	68,5	10,5
F. Ceynowa Specialist Hospital in Wejherowo	Tuberculosis and Lung's Diseases Ward	45	747	12894	78,5	17,3

*- person per day= number of days spent in hospital by all the patients hospitalized in the discussed period of time.

Standard reporting procedure in the Polish health system requires outpatient care providers to produce proper reporting about number of patients and services provided. According to the data coming from annual reports made by the Pomeranian Voivodeship outpatient providers, in 2011 there have been 32 292 patients with COPD registered (Jassem & et al, 2012).

Table 5B. Number of patients in outpatient care providers dealing with lung's diseases and tuberculosis in 2011 in Pomeranian Voivodeship (Jassem & et al, 2011)

Disease	Patients registered - information form 31st of December of the previous year	Patients registered during the year reporting year	Patients erased from the list in the year of the report		Patients registered - information from 31st of December of the reporting year
			together	including deaths	
COPD	25834	8626	2168	x	32292

5.7.2 Schedule of the consultation meetings leading up to the establishment of the PMIC programme

These meetings were used to clarify the clinical need for an integrated COPD programme

With representatives of local government:

- Town council- May 12th, 2011
- Town council – November, 28th 2011

With coordinators of social services offices in four selected cities:

- Starogard Gdanski - September 22nd, 2011
- Słupsk – October 10th, 2011
- Chojnice – October 25th, 2011
- Gdansk – November 16th, 2011

With doctors and nurses to present concepts of Pomeranian Programme of Integrated Care for Patients with Severe COPD was

- Starogard Gdański – January 14th, 2011
- Meeting of Polish Society for Lung Disease – June 16th, 2011

- Gdansk – meeting with family doctors „Sekstans"– October 22nd, 2011
- Town Council of Gdansk – meeting with nurses to start training of coordinating nurses – December 16th, 2011

5.7.3 Exacerbations in COPD

Preventing exacerbations, especially severe cases requiring hospitalizations, is very important from both a medical and economic point of view. Severe exacerbation is a negative prognostic factor associated with a high risk of further exacerbation and a high mortality rate. Groups of patients suffering from frequent exacerbations are observed to have the highest mortality rates among all COPD patients, 4.3 times higher than patients who do not require hospitalization (Connors et al., 1996). Some studies have presented mortality rates after severe exacerbation. The data found by coordinators of PMIC are presented in Figure 5C.

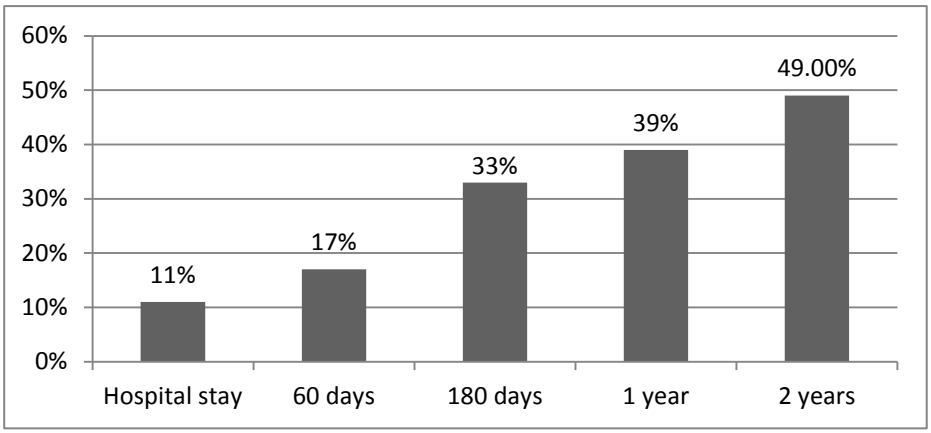

Figure 5C. Mortality (in %) after severe exacerbation of COPD during hospitalization, after 60 days, 180 days, 1 year, 2 years observed in Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) in USA (Connors et al., 1996)

According to European data, patients with severe COPD (GOLD III or IV) suffer from 3.43 exacerbations per year. Patients with moderate type of disease (GOLD II) have exacerbations less often - the mean number of exacerbations is 2.68 per year (Donaldson et al., 2003).

According to results of the ISOLDE (Inhaled Steroids in Obstructive Lung Disease in Europe) study, which measured mean incidence of exacerbations per year related to forced expiratory volume in one second (FEV1L), patients with FEV1L <1.25 had average number of exacerbations 2.5 per year, patients with FEV1L between range 1.25-1.54 had 1.75 exacerbation/year, and patients with FEV1L over 1.54 had around 1.2 exacerbation/year.

Another study, European Respiratory Society Study on Chronic Obstructive Pulmonary Disease, revealed that average number of exacerbations in patients with FEV1L at level 2.40 is less than 0.5 per year

(Burge & Wedzicha, 2003a). According to Copenhagen City Lung Study, as FEV1L approaches 2.5, exacerbations are very rare (Burge & Wedzicha, 2003b).

Data from Poland corresponds to the European data. In a domestic questionnaire conducted in 2008-2009, which included nearly 9000 patients with COPD at different stages, it was found that the average number of hospitalizations due to exacerbation of COPD ranges from 1.53 hospitalizations/year for mild COPD to 2.5 hospitalizations/year for advanced COPD. Similar ratios were observed between demand for unplanned medical consultations and stage of COPD. The more severe the disease, the more often patients needed unplanned medical help. Mild COPD cases required around 2 unplanned visits per year, while this number was up to 4 visits per year for severe cases (Boros & Lubiński, 2012).

6 The NHS Health Check

Fiona Thom[*]

[*]*Health Improvement Analysis Team, Department of Health, United Kingdom*

6.1 Introduction

Changing demographic and epidemiological patterns in the developed world over recent years have led to an increased focus on non-communicable diseases; coupled with growing constraints on nations' finances following the 2008 global recession. This has, in turn, led to a focus on preventing non-communicable diseases (NCDs)[16], particularly cardiovascular diseases (CVDs) and cancer. The WHO Global Burden of Disease report (WHO, 2008b) highlighted the need to reverse the growing trend in the number of people dying prematurely and living years of life in less than full health as a result of non-communicable diseases. In addition, these diseases place significant demands on the consumption of social welfare and healthcare resources, cause decreased productivity in the workplace, diminished resources and ultimately impact on economic growth. NCDs were responsible for 68% (38 million) of all global deaths in 2012, up from 60% (31 million) in 2000. Cardiovascular diseases killed 2.6 million more people in 2012 than in 2000 (WEF/HSPH, 2011). Epidemiological studies show that there are a number of well-known proximal risk factors which contribute to much of the population attributable risk for CVD: poor diet, smoking, high blood pressure, obesity, physical inactivity, alcohol use and high cholesterol (Murray et al., 2013). Since the 1990s, the number of people globally dying from ischemic heart disease and type 2 diabetes has risen by 30%, whilst high body mass index has been attributed as a key cause of premature mortality and disability (WHO, 2008b). This trend has been apparent in the UK, leading to pressure on limited National Health and Social Care (NHS) resources. A recent report showed that whilst mortality rates and years of life lost have decreased substantially in the UK over the last 20 years, the increased years of life are more likely to be spent in poor health (WEF/HSPH, 2011). The Office of National Statistics (ONS) projected that between 2010 and 2022 the number of people aged 65 or over in the UK will rise by 27% (ONS, 2014). Additionally, currently 60% of the UK population are overweight, with one quarter who are obese (HSCIC, 2014).

Many NCDs can be prevented through early detection and primary prevention, such as lifestyle changes and interventions. Economic analysis and evidence plays a key role in determining cost effective interventions and recommendations about policies which represent good value for money.

In 2009, the Department of Health (DH), which is responsible for health and social care services in England[17], implemented a preventative public health policy of 'vascular checks' as part of the "Putting Prevention First" strategy. This was aimed at identifying risk factors for vascular disease and preventing

16 NCDS are defined as diseases of long duration, generally slow progression and they are the major cause of adult mortality and morbidity worldwide. Four main diseases are generally considered to be dominant in NCD mortality and morbidity: cardiovascular diseases (including heart disease and stroke), diabetes, cancer and chronic respiratory diseases (including chronic obstructive pulmonary disease and asthma)

17 Health and social care are devolved policies in the UK. The Department of Health is responsible for health and social care for England only.

development of these diseases. The 'vascular checks' programme was later renamed as the "NHS Health Check programme".[18] NHS Health Checks are designed to target, through a national integrated risk assessment, individuals aged between 40 and 74 years old who are at higher risk of developing vascular disease and are not being treated for an existing health condition. NHS Health Checks are commissioned by Local Authorities (LAs),[19] and usually provided in primary care settings, with relevant individuals invited for a Check on a 5 year cycle. These were made mandatory for LAs to offer patients in 2013, whilst the Health Check itself is voluntary for an individual to attend. As many NCDs share common risk factors, the Health Check aims to identify risks and offer appropriate preventative interventions which can target conditions before they require more significant treatment. There is a strong consensus from existing evidence that finding and managing those at high risk of vascular disease is likely to be clinically and cost effective, particularly in comparison with treatment of the disease itself (PHE, 2013). This type of national preventative risk assessment programme was not being offered in other countries at the time, however Japan began a national health screening programme in 2009 (Kohro et al., 2008).

The economic modelling was integral to the implementation of the NHS Health Check programme. This provided final recommendations for the optimal age group and recall frequency for Health Checks; the interventions which should be included and the cost effectiveness of such a programme. The modelling provided a strong initial evidence base and suggested the programme was very cost effective. DH followed a specific internal process for assuring the analytical work to ensure transparency and that objective advice and evidence was provided.

This case study will outline the methods used to gather information for the economic modelling and the evidence developed for the options appraisal; outline the process and structure of decision making in DH; present an overview of the results of the options analysis; identify any barriers which were experienced in the development of the analysis and provide context on the current Health Check programme after 5 years of implementation.

6.2 Methodology

Review of evidence and analysis for the case study

The initial step for this case study was to gather the relevant information and economic evidence used in the modelling and option analysis for the Health Check Programme. This was conducted via the central UK Government website which stores documents, statistics and consultations conducted across government[20]. This search provided the key documents that had been published about the programme, notably the technical consultation (DoH, 2008a) and final impact assessment (DoH, 2008b). A literature and news review was also conducted covering the terms 'NHS health check', 'vascular check' and 'England' which identified articles, comments and local evaluations of the programme which have been carried out to date, as well as the work published by Public Health England (PHE).

18 The NHS Health Check programme name will be used in this case study
19 There are 152 local authorities in England
20 http://www.gov.uk – website holding documents for all 24 ministerial departments and 331 agencies and public bodies

A request for information about the analysis on the Health Check programme was raised within the DH analytical community. This resulted in the identification of individuals who could provide further information and conduct an interview where relevant. A review of the economic analysis was conducted and a detailed list of interview questions was developed for the analysts and policy leads in the modelling and policy.

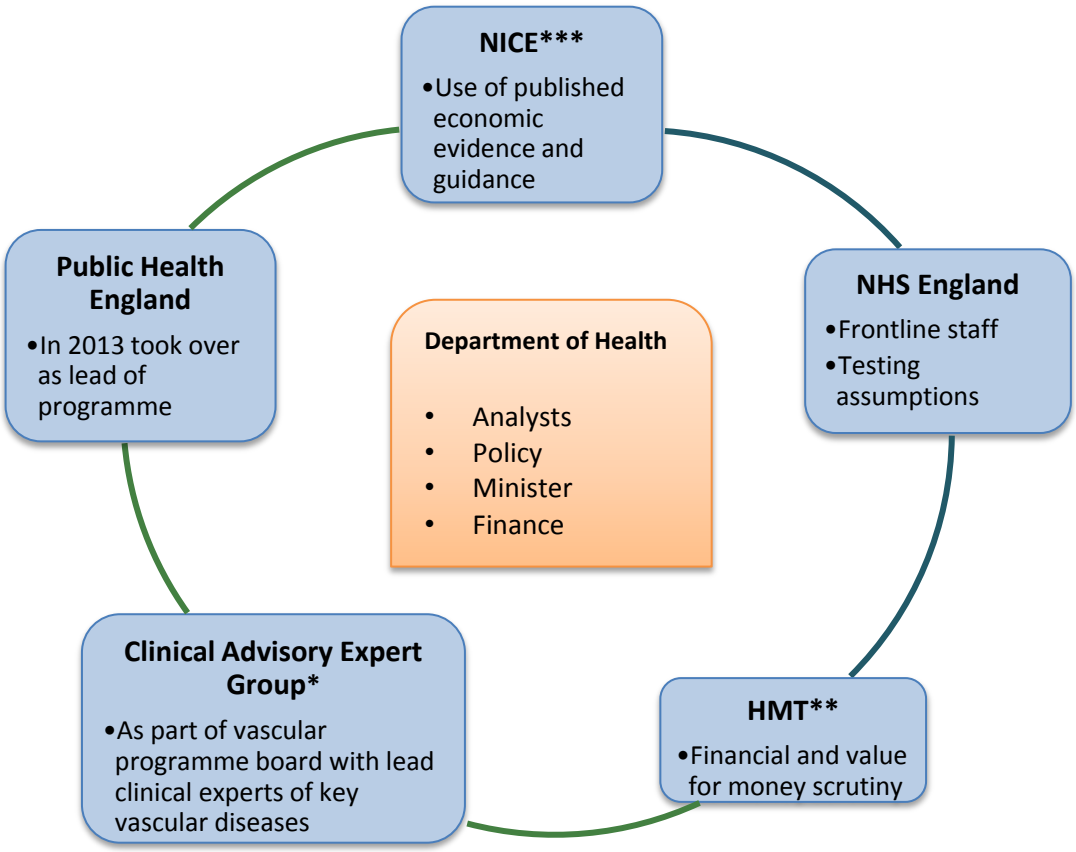

Figure 6.1 Stakeholder map

**The vascular programme board was set up in 2008 to bring together experts from the main vascular diseases to discuss the evidence and cost effectiveness results and to ensure that all relevant health conditions were considered as the Health Check programme progressed. **HMT – Her Majesty's Treasury ***NICE – National Institute for Clinical Excellence*

Stakeholder Review

The development of the Health Check programme involved a wide range of stakeholders, both within and external to the Department, which included clinicians. It was therefore important for this case study to identify all those who played a key role in the evidence development, analysis and final implementation. In April 2013 the ownership of the programme was transferred from DH to Public Health England (PHE, 2015), a new independent agency set up to run public health policies at a national and a regional level in England. Figure 6.1 provides a map of the key stakeholders that have been involved in this policy since 2008. This information was sourced through dialogue with DH and PHE colleagues.

Interviews

Interviews were held with policy advisers and analysts from DH who provided key inputs to the analysis and policy implementation and PHE policy advisers who now lead the programme. A detailed interview was held with the analyst who conducted the economic modelling in 2008. Throughout the development of the case study there has been communication with the DH and PHE programme leads.

6.3 Results

DH decision making process

Figure 6.2 outlines the timeline and departmental process that the NHS Health Check programme followed, from implementation to current day. The initial stages, prior to implementation, are adhered to for many new government policies.

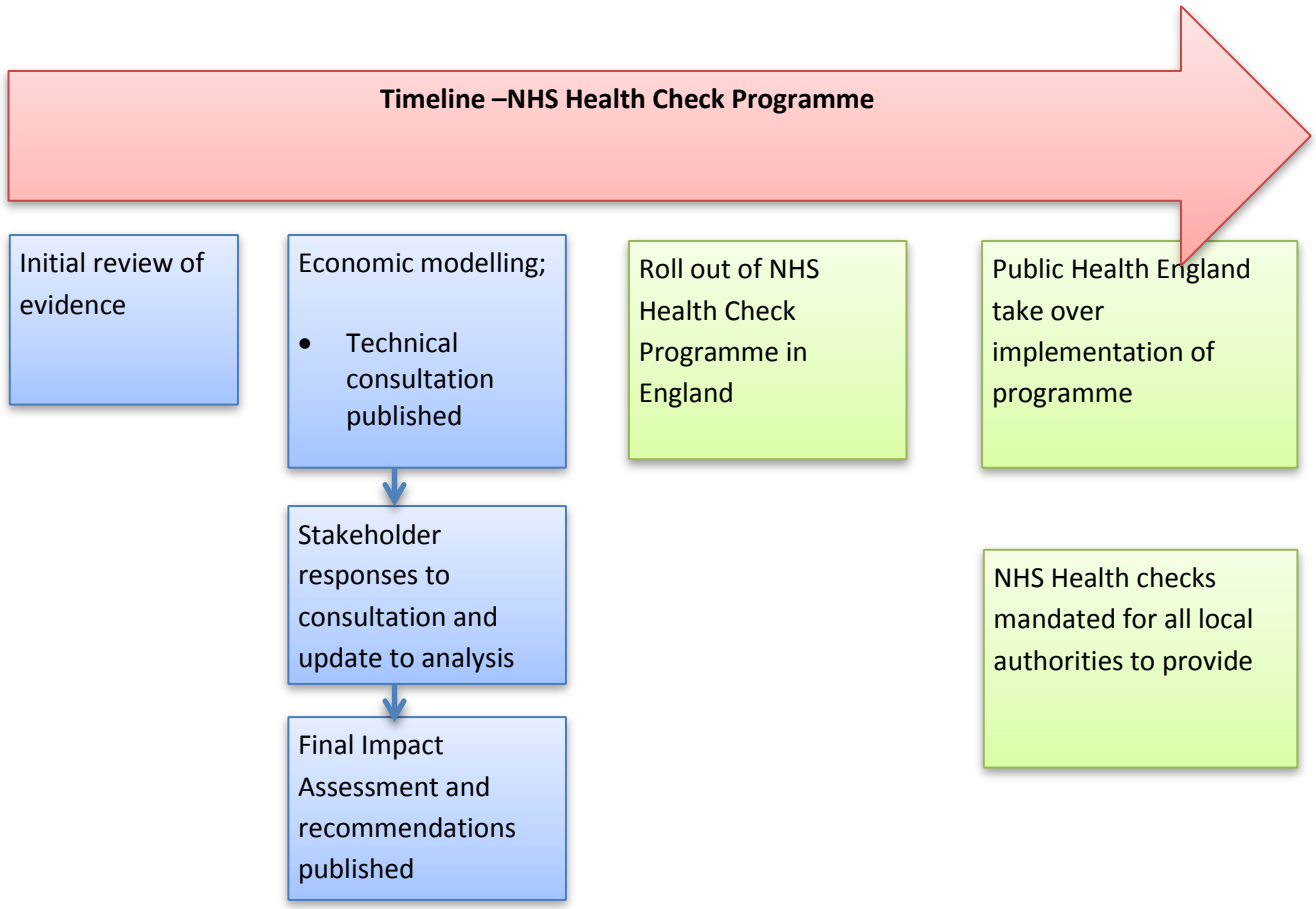

Figure 6.2 Timeline and process of NHS Health Check analysis and implementation

Prior to the modelling, a literature review of clinical and cost-effectiveness studies was conducted, including National Institute for Clinical Excellence (NICE)[21] guidance and published academic research. A 'Vascular Programme Board' of clinical experts from the main vascular diseases was set up and consulted throughout the process[22]. These have been outlined in Figure 6.1.

The aim of a technical consultation is to enable stakeholders and the public to comment on proposed policy options (in this case for a national Health Check programme). To ensure transparency individuals can review the analysis and assumptions used to estimate the costs, benefits and cost effectiveness of different options. This was published in 2008 providing cost and benefit estimates for the different options and an overall recommendation. The document requested input and comments from experts and stakeholders about the assumptions made; further evidence which could be included and areas where the modelling could be improved to generate more robust results. Comments received were reviewed and where relevant updated in the analysis before a final impact assessment was published outlining the final recommendation and estimates.

The final impact assessment included specific impact tests which outlined and identified any groups in society who could disproportionally be affected by the policy. These included: a 'Health Impact Assessment'(DoH, 2008b, Annex 6) which considered any specific benefits and costs on an individual's health and wellbeing as a result of the policy and an 'Equality Impact Assessment' (DoH, 2008b, Annex 7) which determined any potential effects on particular populations and also ensured that the policy was being designed to increase the probability of equitable outcomes, including matters relating to race, gender, human rights and disability.

The economic appraisal and cost effectiveness results are key inputs to the decision of whether to implement a policy; however, the government must have the finances to cover any costs. Therefore, the financial scrutiny from DH and the UK Treasury (HMT) are integral elements in the overall decision of whether a policy can and should be funded. This is particularly relevant in the current economic climate with spending cuts and limited resources available. HMT require a strong assessment of the evidence and any costs and benefits to ensure that taxpayers money provides value for money.

<u>Health Economic Evidence and modelling</u>

There were three key aspects that the economic evidence and modelling was required to answer:

- **a)** What interventions should be offered in terms of cost effectiveness (for the relevant high risk individuals)?
- **b)** What was the optimal age bracket and recall frequency for this programme?
- **c)** What were the cost estimates and benefits of the policy under different scenarios?

21 NICE is a body which was set up in 1999 as a special health authority, to reduce variation in the availability and quality of NHS treatments and care and to develop public health guidance to help prevent ill health and promote healthier lifestyles. https://www.nice.org.uk/

[22] This board has been outlined in Diagram 1

Evidence

The evidence and data gathered as part of the literature review were used as the main inputs of the simulation model to:

- Identify the tests and interventions that should be included in the NHS Health Check package. Tests were only included if there was cost effectiveness evidence to support their inclusion. Much of this evidence was sourced from published NICE guidance.[23]
- Build assumptions on the probability of take up of interventions by those individuals offered. This was based on data sources and academic literature such as the Health Survey for England (HSE), NICE guidance, Diabetes Prevention Programmes, Foresight obesity report.[24]
- Model changes over time (the analysis was over a 20 year time period) and changes in risk factors for individuals. This included the impact of age on blood pressure and obesity changes over time considering average obesity percentage rate changes by age group per year. The HSE, Foresight Tackling Obesity Report (GOS, 2015) are examples of evidence and data used.
- Determine costs and benefits of interventions, for example using the estimated cost of smoking cessation services (NICE) and QALY benefits for smoking cessation.

Modelling

The modelling was based on a discrete event simulation approach[25] using a population database derived from GP data and sampled for each run of the model to provide characteristics of individuals receiving vascular checks. The model simulated: individual patients being invited for checks; their attendance and participation in any intervention; and their health outcomes over time, including the incidence of vascular disease. This was combined with cost effectiveness analysis and net present values to provide recommendations and estimates for the questions outlined above. The comparator of the analysis was "do nothing", and maintain the current situation. NICE did not contribute to the actual model but a significant element of the inputs were derived from NICE evidence.

A number of options were considered for the optimal age bracket, the frequency of the check and the interventions that should be included. The costs and benefits were modelled over a 20 year time period and a discount rate of 3.5% was used for costs and 1.5% for QALY benefits.[26]

These were:

[23] Some of the evidence about tests and interventions were sourced from other academic and published literature such as blood glucose testing and kidney function testing.

[24] See (DoH, 2008a, Appendix B) for full details of sources used to determine assumptions

25 SIMUL8 model used
26 This follows UK government procedure for discounting (HMT Green Book)

a) Three starting ages: 40, 45 and 50 years old[27] and assumed people would be eligible up to the age of 75.[28]
b) Recall frequency of checks: every 5 or 10 years, or by invitation only for high risk individuals.

The cost estimates included two elements: the cost of the actual assessment plus any follow on tests or monitoring required in terms of staff time and laboratory costs; and the cost impact of the actual interventions which would be provided as part of the Health Checks. Net costs to the NHS were calculated, net of any savings in treatment costs that would occur as a result of the intervention.

Quality Adjusted Life Years (QALYs) were used to estimate the benefits. This enabled a range of different health benefits and interventions to be compared against one another. The QALY measure combines life years gained as a result of a health intervention with a judgment of the quality of life over these years. The total benefits were calculated by estimating the QALY gain for the number of individuals who would take up an intervention and would gain in terms of their health. The model aimed to capture only the additional gain for those individuals who would not have received an intervention without having had the Health Check. The results also estimated the total number of corresponding QALYs which could be achieved for each option. The QALYs were monetised at £50,000 per QALY estimate which represents the social value of an additional life year in the UK.[29]

The model provided an estimate of how many individuals were expected to take up and complete each intervention. As the Health Check is completely voluntary for an individual to attend, assumptions had to be made about the proposed take up (central assumption of 75%). This was multiplied by the costs of additional interventions and benefits in terms of QALY gain to give an overall cost per QALY over the first 20 years for each scenario. The first test of cost effectiveness was to compare the results against the NICE cost effectiveness threshold of £20,000 per QALY. This is used in England as the threshold of acceptability for a new healthcare intervention. All of the scenarios modelled were found to be very cost effective following this test (see Table 6.1). A second test of cost effectiveness was used to determine which would generate the largest net present value (NPV) and provide the best value for money. Option i) estimated a cost per QALY below £20,000 and had the highest NPV.

Results of analysis

The analysis established that the NHS Health Check policy was likely to be very cost effective. This provided an evidence base to implement and build the NHS Health Check programme. The final results are summarised in Table 6.2. Table 6.3 outlines the headline results from the analysis. The costs and benefits are in present value terms (PV) over a time period of 20 years.

27 The reason for the starting ages not going below 40 is that cardiovascular risk algorithms tend not to work below this age and the evidence for many of the interventions do not cover people below 40.
28 It was assumed as the majority of those over 75 have regular contact with GPs and also CVD risk algorithms are poor in identifying risk in this age group.
29 This was the value used to quantify the societal value places on an additional life year in the UK. This is now 60,000GBP per additional life year.

Table 6.1 Cost per QALY (Incremental Cost-Effectiveness Ratio) for each scenario and NPV. Final impact assessment analysis

Option *Age* *Frequency recall*	Cost per QALY (ICER) *(1st CE test)*	NPV *(2nd CE test)*
i. 40-74 Every 5 years	£3,505	£55,304
ii. 40-74 Every 10 years	£3,583	£38,388
iii. 45-74 Every 5 years	£3,580	£48,044
iv. 45-74 Every 10 years	£3,390	£36,544
v. 50-74 Every 5 years	£3,746	£37,580
vi. 50-74 Every 10 years	£3,701	£27,287
vii. 40-74 High risk individuals only	£6,241	£26,087

Table 6.2 Final Recommendation for the NHS Health Check

Final Recommendation	Detail
Tests	· General medical questions;[30] body mass index; · cholesterol; · blood pressure; · FINDRISC[31] score
Interventions *(dependent on the risk assessment score of an individual)*	· Statins; · anti-hypertensive drugs; · exercise and weight interventions; · lifestyle management and advice; · smoking cessation services; · glucose monitoring tests. *(In 2013, other interventions relating to alcohol use and to diabetes were included in the NHS Health Check, after consideration of their clinical and cost-effectiveness)*
Age range	40 to 74 years old
Recall frequency	Every 5 years *In 2008 this represented approximately 15 million people. At a 5 year frequency rate, on average in any one year 20% of the eligible population (3 million people) could be invited for an appointment (although how much of the eligible population was offered a Health Check in any one year was left to local discretion of commissioners).*

Table 6.3 Overall results

Total Benefits (QALYs)	**1,286,309**
Net Present Value (NPV)	**£55,304m**
Cost per QALY (ICER)	**£3,505**

[30] For example, age, gender, family background, smoking, alcohol

31 FINDRISC is a score that indicates risk of diabetes designed in Finland.

It was estimated that the programme could prevent: 1,600 heart attacks and strokes; at least 650 premature deaths and over 4,000 new cases of Type 2 diabetes each year. Also at least 20,000 cases of diabetes or kidney disease could be detected earlier.

A sensitivity analysis was conducted to identify which variables and assumptions were the main drivers of the estimates. The parameter of the proportion of individuals who accept an appointment when offered was set at 75% in the base model. This was varied from 65% to 85% in the sensitivity analysis. Further sensitivity analysis was carried out on the assumptions about QALY gains from the interventions in the programme and the costs relating to the risk assessment and interventions.[32] The sensitivity analysis predicted there could be different rates of prescribing and take up of different interventions which would cancel each other out; and at a 10% less QALY gain, the programme would still be highly cost-effective. The dominant variable in the modelling was the proportion of the population already receiving assessments in the do nothing scenario.

Implementation

Following the process outlined in Figure 6.2, the recommendations were signed off by the Chief Analyst, Minister of State for Public Health and HMT and a phased implementation began in 2009. The NHS Health Check programme became mandatory for all Local Authorities to commission as part of the public health mandate[33] in April 2013, under PHE's responsibility.

6.4 Discussion

Challenges and barriers in the modelling

The main challenges outlined by the analysts who conducted the modelling were the lack of evidence on similar programmes which had been implemented, either domestically or internationally. This was one of the reasons behind using only a simulation modelling approach for this analysis. In addition, the cost effectiveness evidence for some of the interventions was stronger than others; for example blood glucose monitoring and kidney function testing evidence was weaker and at that time not covered in NICE guidance.

At the modelling stage, considerations had to be made to ensure that the differences in risk factors over an individual's lifetime were represented. Additionally, assumptions were made to ensure that any deadweight loss of the policy was accounted for i.e. the additional benefits were only captured for individuals who took up an intervention because of the policy.

Outside the modelling, the challenge was to work together with the clinical experts to collectively develop and agree the best use of evidence, data and the approach for the implementation of the programme with the aim of targeting a combination of diseases.

[32] Sensitivity analysis included: alternative datasetof patient records; different algorithm; take up assumpations; assumpatino of QALY gain

33 The NHS Mandate between the government and NHS England sets out the ambitions for the health service.

Current Implementation

The most recent data suggests that in Q4 14/15, 4.9% of the eligible population were offered a Health Check. This translates into 98% of eligible population if spread evenly over the 5 year cycle, where almost everyone in the eligible population would receive an offer over the cycle. However, the actual take-up of the programme after 5 years (two years of full mandatory implementation) remains lower than the model originally estimated. The central assumptions in the model were set at a 75% take up rate, versus the 50% current take up rate (NHS, 2015). Subsequently the estimated benefits have not been fully realised. In 2012/13 the first full year of the programme, there were 2.7 million offers made and 1.3 million NHS Health Check appointments received.

There are also regional disparities in the take up of the Health Check, with some areas in reporting less than 25% take up[34], whilst other areas have achieved almost 100% take up of Health Check offers. Consequently, there is work to be done by PHE and local authorities on addressing this gap and sharing best practice across local services.

Criticisms and next steps

There have been concerns raised from health bodies and academics about the lower take-up rate than the original estimate. It has been highlighted that there is need for further evaluation and research into the NHS Health Check programme in order to improve its effectiveness, including possibility of randomised control trials to determine whether this is still a cost effective policy and has the overall health benefit.

PHE are leading a programme of work in collaboration with local authorities to improve and support the take-up rate over the coming years. A number of 'tools' have been published for local authorities, including a local Health Check online evaluation tool which outlines the potential benefits a specific area could receive and best practice guidelines. The Behavioural Insight Team in DH has recently conducted a randomised control trial which tested different types of health check invitation letters sent to individuals to determine, using behavioural economics approaches, if there is a difference in take-up rates depending on the style and format of letter received.

PHE are also working with NICE on guidance that will further support elements of the NHS Health Check programme. This includes the establishment of an expert clinical and scientific advisory panel that will be responsible for reviewing emerging evidence and research needs and promoting future research and evaluation of the programme. Further intelligence can be gained from the mandated information that is now submitted quarterly by Local Authorities (since 2013). With this information PHE are conducting a review of the original economic modelling based on actual data. There is a national evaluation of the NHS Health Check programme currently in the field which is due to report in autumn 2015.

34 6 areas reported less than 25% and 7 have reported approximately 100% in 14/15 Q1.

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7 Barriers to successful implementation of HTA recommendations in Belgium

*Allira Attwill**
** Consultant, World Health Organization, Brussels*

7.1 Introduction

Rotaviruses are the most common cause of severe diarrhoeal disease in young children throughout the world. Rotavirus results in significant costs to society and health systems in terms of human life; lost productivity while parents stay home and care for their sick child; and health system expenditure (Rheingans et al., 2009)

Belgium was the first country in the European Union (EU) to introduce a universal rotavirus vaccination programme. This programme partly subsidizes the available vaccines (Rotarix and RotaTeq) though still requires an out of pocket payment of €11.60 per dose (KCE, 2007a).

The Belgian Healthcare Knowledge Centre (KCE), conducted a Health Technology Assessment (HTA) to determine the cost-effectiveness of the current subsidized programme compared to a fully funded universal vaccination programme. The HTA found that partial reimbursement is less cost-effective than fully funded universal vaccination (KCE, 2007a).

The logical policy response from a societal perspective may seem clear: introduce fully funded universal rotavirus vaccination. However, the KCE findings were not implemented in Belgium. Using the Belgian experience as a case study, this article seeks to explore barriers to uptake and implementation of HTA recommendations.

Rotavirus vaccination

Rotaviruses are the most common cause of severe diarrhoeal disease in young children throughout the world. According to WHO 2004 estimates, 527 000 children aged <5 years die each year from vaccine-preventable rotavirus infections; most of these children live in low-income countries (World Health Organisation, 2010).

Two oral, live, attenuated rotavirus vaccines, Rotarix and RotaTeq, are available internationally: Rotarix requires two doses, and RotaTeq requires three doses. Both vaccines are considered safe and effective in preventing gastrointestinal disease (World Health Organisation, 2010).

WHO recommends that rotavirus vaccine for infants should be included in all national immunization programmes. In countries where diarrhoeal deaths account for ≥10% of mortality among children aged <5 years, the introduction of the vaccine is strongly recommended (World Health Organisation, 2010). WHO recommends that the first dose of either RotaTeq or Rotarix be administered at age 6–15 weeks. The maximum age for administering the last dose of either vaccine should be 32 weeks (World Health

Organisation, 2010). WHO explicates that rotavirus vaccines are an important measure that can be used to reduce severe rotavirus-associated diarrhoea and child mortality.

The Gasthuisberg University Hospital has monitored the incidence of rotavirus gastroenteritis since 1986 (Zeller et al., 2010). The average percentage of rotavirus positive cases out of all hospitalized gastro-enteritis cases tested (>95% of these cases are younger than 5 years old) at the GUH between 1986 and 2006 was 19.0%. This percentage dropped to 12.4%, 9.6% and 6.4% in the three seasons post vaccine introduction (2006–2009), which is a decline of 34.7%, 49.4% and 66.3% respectively. In addition the rotavirus season was found to be shortened and delayed (Zeller et al., 2010).

Belgium was the first country in the European Union (EU) to introduce a universal rotavirus vaccine programme. Access to the partially reimbursed vaccine requires an out of pocket payment of €11.60 per prescribed dose, with the remainder (€59.60 and €40.10 for Rotarix and RotaTeq respectively) being paid by National Health Insurance.

Healthcare decision-making in the Belgian health system is complex due to its decentralised nature and consequent number of stakeholders. The federal level is responsible for health insurance and the public health budget. Responsibilities for health policy are divided between the federal level and the federated entities (regions and communities). The federal level is responsible for regulating and financing compulsory health insurance; accreditation and minimum standards; the financing of hospital budgets and market access, pricing and reimbursement of pharmaceuticals (Gerkens & Merkur, 2010).

Federated entities (regions and communities), have responsibility for health promotion and prevention; maternity and child health services; different aspects of elderly care; the implementation of accreditation standards; and the financing of hospital investment (Gerkens & Merkur, 2010).

The cost-effectiveness of rotavirus vaccination depends largely on the value policy makers place on the prevention of mild disease and their willingness to pay (KCE, 2007a). In Belgium, rotavirus vaccination would prevent short-lived mild disease in virtually all children, and thus represent a potential saving to society and healthcare payers. The majority of these savings are in the form of QALYs and indirect cost savings, largely attributable to lost productivity averted due to parents staying home (KCE, 2007a).

7.2 Methods

All information and data were accessed from public sources. The KCE website was used to access the HTA report (KCE, 2007a). PubMed database was searched for relevant articles using the following search term:

((("rotavirus"[MeSH Terms] OR "rotavirus"[All Fields]) AND ("vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields])) AND (("economics"[Subheading] OR "economics"[All Fields] OR "cost"[All Fields] OR "costs and cost analysis"[MeSH Terms] OR ("costs"[All Fields] AND "cost"[All Fields] AND "analysis"[All Fields]) OR "costs and cost analysis"[All Fields]) AND effective[All Fields])) AND ("belgium"[MeSH Terms] OR "belgium"[All Fields]).

7.3 Results

Findings of the HTA report

KCE considered three options in their analysis:

- Option 1: no vaccination.
- Option 2: private vaccination (current situation with partial reimbursement), i.e. Rotarix vaccination using a 2-dose schedule with vaccine administration at 2 and 3 months of age.
- Option 3: fully funded universal vaccination

As illustrated in Table 7.1, KCE's HTA report expressed findings from both a healthcare payer perspective and a societal perspective. Both perspectives found that fully funded universal vaccination is more cost-effective than the present system of partial reimbursement on a case-by-case basis; and, that fully funded universal vaccination is more cost-effective with Rotarix than with RotaTeq (KCE, 2007a). Specifically:

- From a healthcare payer's perspective, the current approach (partial reimbursement) costs, on average[35] €80,709/QALY, compared to no vaccination.
- From a healthcare payer's perspective, fully funded universal rotavirus vaccination would cost €50,024 (95% range: €25,374 - €99,730) per QALY gained with Rotarix®, and €68,321 (95% range: €35,982 - €132,635) per QALY gained with RotaTeq® (Belgian Healthcare Knowledge Centre, 2007), compared with no vaccination.
- From a societal perspective, fully funded universal rotavirus vaccination would be slightly cost-saving with Rotarix® (95% range: cost-saving to €128,662), and would cost €29,618 (95% range: cost-saving to €183,164) per QALY gained with RotaTeq® (Belgian Healthcare Knowledge Centre, 2007), compared with no vaccination.

[35] The 'average' pertains to the average cost of both available vaccines.

Table 7.1 Summary of the KCE Health Technology Assessment findings

	Vaccine	Present situation v no vaccination (HC perspective)	Fully funded universal vaccination v no vaccination (HC perspective)	Fully funded universal vaccination v no vaccination (Societal perspective)
ICER	Rotarix®	Average cost of both vaccines = €80,709/QALY	€50,024/QALY	Cost-saving
	RotaTeq®		€68,321/QALY	€29,618/QALY
Overall budget impact	Rotarix®	€11,694,633	€14.0 million	-
	RotaTeq®	€15,592,844	€14.6 million	-

Notes: HC = Healthcare perspective; QALY = Quality Adjusted Life Years

Given the present situation results in an average cost of €80,709 per QALY gained compared to no vaccination, it is dominated (i.e. less effective and more costly) by fully funded universal vaccination, regardless of the perspective taken (with Rotarix as well as RotaTeq) (KCE, 2007a; Bilcke, Van Damme & Beutels, 2009). The KCE report also found that fully funded universal vaccination is more cost-effective with Rotarix® (€50,024/QALY) than with RotaTeq® (€68,321/QALY), and that the same probably applies for private vaccination.

In terms of budget impact, the KCE report explicates that universal vaccination (>97% uptake) is estimated to cost between €14.0 million (with Rotarix®) to €14.6 million (with RotaTeq®) per vaccinated cohort per annum. This is compared to the present situation, where at just 60% to 80% uptake, the annual cost of the programme is already between €11.7 to €15.6 million, yet without the full benefits of herd immunity, and without considering the full impact that bulk-purchasing may have on cost-effectiveness (KCE, 2007a).

Multivariate sensitivity analysis showed cost-effectiveness varied according to the perspective taken. Cost-effectiveness depended mainly on the uncertainty of estimates for waning efficacy and number of RV related deaths; and on the uncertainty around the number of days away from work to care for a child with rotavirus, when taking a healthcare payer or societal perspective, respectively (KCE, 2007a).

KCE also communicated the HTA findings via a press release on 26/07/2007. The press release included a detailed but clear discussion of why the vaccine is not included in the calendar of free vaccines. The press release includes a discussion of costs included in the CEA (hospitalizations and consultations, salaries, vaccine costs and gain in QoL) and uses terms such as ‘cost per QALY’, and ‘cost-benefit ratio’. The press release also used the pneumococcal vaccine as a reference point to highlight the difference in cost-effectiveness between the pneumococcal vaccine (€10,000 per QALY) - the most recent vaccine to be accepted onto the calendar of free vaccines - and the rotavirus vaccines (~ €50,000 and €68,000 per QALY).

HTA Conclusions

The KCE report concluded that the current situation in Belgium is clearly less preferable than fully funded universal vaccination. Private purchasing attracts a higher price per unit than fully funded universal coverage would (as bulk buying discounts and a tendering process are forfeited), and copayments may discourage some Belgian citizens from vaccinating their children. Overall, this system is more expensive per vaccinated person; less effective (due to lower uptake); less equitable (due to co-payments), and, at best, equally efficacious per vaccinated person (KCE, 2007a).

Complexities and political implications

Health policy decision-making in Belgium is complex due to the division of power and responsibility between the Federal level and the Federated entities. Figure 7.1 below shows that the Federated entities are financially accountable for health promotion, prevention and education, which includes vaccines listed on the national calendar of free vaccines (but not those that are privately purchased) (Gerkens & Merkur, 2010).

Currently, the Federal level subsidises/reimburses privately purchased vaccines on a case-by-case basis. However, as illustrated in Figure 7.1, if the rotavirus vaccine was added to the national calendar of free vaccines, the federated entities would be required to partly subsidise the fully-funded universal vaccination programme (Gerkens & Merkur, 2010).

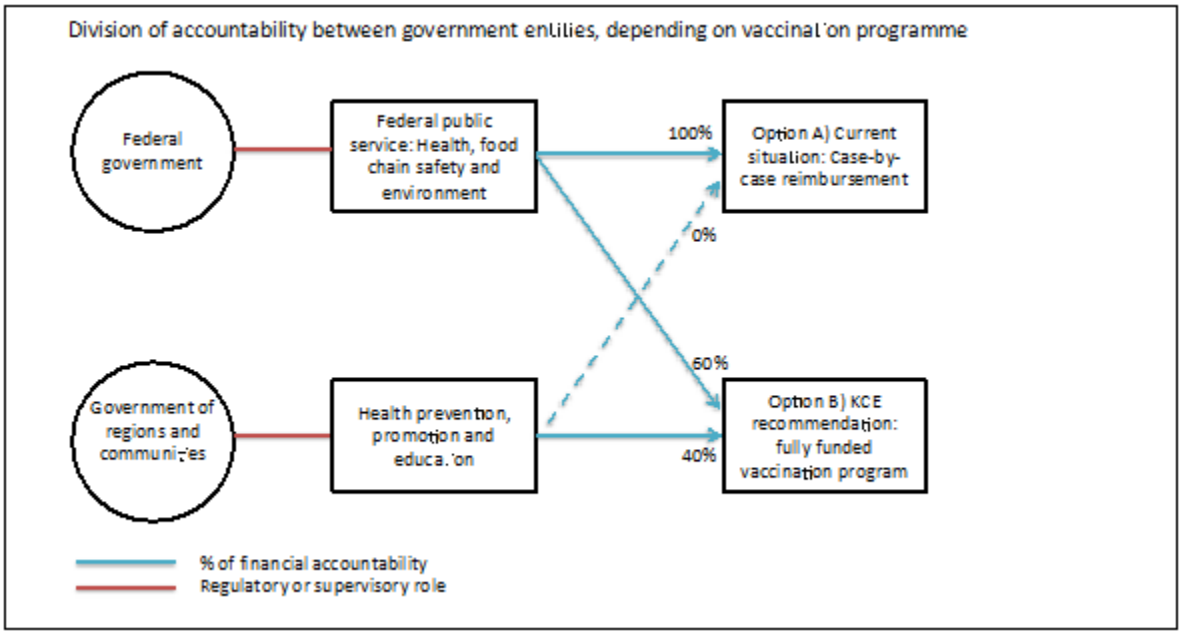

Figure 7.1 Overview of the funding flows of the Belgian healthcare system according to the scenarios considered

The federated entities would not, however be liable for the full cost of treatment. If the fully funded universal vaccination programme was implemented, the federal level would remain accountable for 60% of the costs, leaving the federated entities responsible for only 40%. Furthermore, the unit price would reduce significantly under the fully funded programme as vaccines purchased in bulk quantities attract a

considerable discount and may be purchased via a tendering process. Such a price drop was observed when HPV vaccines fell from €120 to a fraction of this per dose, after being accepted onto the national calendar of vaccines (KCE, 2007b). Nevertheless, if the fully funded universal rotavirus vaccine programme was introduced, the federated entities would be accountable for an expense they previously were not liable for. Although the exact reasons for not adopting the KCE guidance are unknown, it is likely that the potential added cost evoked significant opposition from the federated entities.

7.4 Conclusions

This case study highlights that even when robust HTAs produce recommendations offering potential savings to tax payers and healthcare budgets, the intricacies of individual healthcare systems can influence the successful uptake of these recommendations. The present case highlights the importance of considering costs not only from the healthcare payer's perspective, but from *all* healthcare payer's perspectives when federal and state/regional budgets exist, or when there are other budgetary silos that may affect the final decision.

HTAs represent a useful tool for determining the cost-effectiveness of healthcare interventions. However, this case study highlights that even when an intervention is recognized as being a) cost-effective; b) the best strategy for insuring maximum coverage, especially amongst underprivileged populations, and; c) less expensive when purchased in bulk, recommendations may still not translate into an economically optimal policy response.

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8 Discussion and conclusions

These case studies from a variety of settings and interventions provide a number of insights into the use of economic evidence in practice. It appears that a more institutionalized setting, where economic evaluation is part of the formal policy cycle, is a key enabling factor (England, Belgium), although the results of economic evaluation are not necessarily taken into account if there are other interests at stake, such as budgetary conflicts between different levels of government (Belgium). In Belgium, the more cost-effective option revealed by the economic analysis was not adopted due to increased costs befalling regional authorities which were not previously liable for expenses in the area. In England, the modelling team found no economic evidence on similar programmes elsewhere, and the published cost-effectiveness evidence was weaker for certain interventions such as blood glucose monitoring and kidney function testing, underlining weaknesses in the use of published evidence and a need for custom modelling.

The presence of centrally institutionalized economic evaluation does not necessarily improve or promote the use of economic evidence at a regional level. The AHTAPol HTA agency in Poland deals with economic assessment of pharmaceuticals, devices and medical procedures prior to reimbursement, but economic analysis of the Pomeranian model of integrated COPD care was not performed with support from AHTAPol. Since economic evaluation was not required for the establishment of the programme at the regional level, there was little impetus for a formal evaluation. This is in contrast to the Slovenian case study, where a legal requirement exists for an assessment, including economic evaluation, of e.g. nationally organized screening services, despite the absence of a formal HTA agency in the country. In this case, economic evaluation was carried out by economic experts from the Health Insurance Institute.

Economic evaluation and modelling was thoroughly performed prior to implementation of the health checks in England, including a literature review and custom cost-effectiveness model. The modelling exercise also provided insight into key parameters of the health intervention, such as age range and frequency of recall. Apart from informing whether the intervention was good value for money, the economic evaluation was also instrumental in securing funding for the programme from the Ministry of Finance.

Although all four countries reviewed existing literature as part of the economic assessment, the majority (except Poland) performed additional, custom analysis for the particular decision problem.

In summary, the following conclusions are tentatively drawn from the case studies:

- Use of health economic evaluation was associated with formal requirements and processes in the policy cycle for such evidence
- Published, peer-reviewed evidence was generally not considered sufficient to inform policy, and custom analysis was undertaken in three out of four case studies.
- The presence of budgetary silos and political realities which were not reflected in the economic analysis could be a barrier to implementation