Evidence-based decision making in the assessment of public health interventions: How can we evaluate the return on investment figures of smoking cessation interventions?

Ph.D. Thesis Outlines

Bertalan Németh

Semmelweis University
Pharmaceutical Sciences School of Ph.D. Studies

Supervisors: Dr. Balázs Hankó, Ph.D.
Dr. Zoltán Kaló, Ph.D.

Official reviewers: Dr. Veronika Müller, DSc.
Péter Rózsa, Ph.D.

Head of the Complex Examination Committee:
Dr. István Antal, Ph.D.
Members of the Complex Examination Committee:
Dr. Sándor Kerpel-Fronius, DSc.
Dr. András Fittler, Ph.D.

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1. Introduction

The adverse effects of smoking have been known for decades, and the role of smoking in the development of several diseases has also been proven. Hundreds of thousands of lives are lost due to smoking-related illnesses every year in Europe alone, and smoking puts a substantial health-related and economic burden on the Hungarian society as well.

Though health technology assessment has been a part of the Hungarian decision making processes in various fields, in the case of public health interventions we still lack an adequate, comprehensive and consistent analytical methodology that can support evidence-based decision making.

The European-study on Quantifying Utility Investment in Protection from Tobacco (EQUIPT) project aimed to further develop a model, that was capable of calculating return on investment (ROI) figures of smoking cessation interventions, and to oversee its application in several European Union member states.

2. Objectives

My research aimed at describing a complex analytical methodology, that covered the development of the ROI calculation model of the EQUIPT project and its applications, based on international experiences. An additional aim of the research was the assessment of the practical use of the model in evidence-based macro-level decision making, taking into account the local settings and the selection and reach of the planned interventions. The four research hypotheses were the following:

- **First hypothesis:** Is it possible to support the resource allocation decisions of public health interventions in European countries and Hungary in particular, with a methodology similar to the evidence-based health economic analyses that is being used in the field of medicines?
- **Second hypothesis:** If a modelling methodology is developed for the field of smoking cessation interventions, will it be transferable across countries and regions?
- **Third hypothesis:** Is it feasible to use the ROI estimation model developed for smoking cessation

interventions with a limited set of input data – selected based on the sensitivity of input parameters – in countries where data collection is difficult or comes with a high cost?

- **Fourth hypothesis:** Based on the ROI estimation model developed for smoking cessation interventions, can the following packages – selected by local clinical experts – be suggested for implementation in Hungary?
    - Country-wide social marketing campaign
    - Doubling the utilization of group-based supportive therapy and proactive telephone support
    - The first two packages combined

3. Methods

The analysis of the first hypothesis was based on the development of the model and the establishment of the suggested decision making methodology. The model is able to assess societal interventions, medicine-based and non-medicine-based interventions as well. Assessment of all interventions require the determination of the price, the utilization, and the relative effectiveness. The model follows a cohort of smokers, who can stay smokers, can quit smoking, can start smoking again, and can pass away as well during the modelled time horizon. The model is flexible regarding time horizons and perspectives, it takes into account passive smoking and productivity losses as well. In the model the risk of diseases is tied to the smoking status. A total of 18 ROI outputs are being calculated by the model.

Firstly, we took the averages of the cost data, utilities and life expectancy figures from the five countries involved in the EQUIPT project, and assessed the implementation of three hypothetical interventions on a hypothetical cohort. The first of these interventions increases the number of quit attempts during the next 12 months by 25%, the second one increases the success rate of quit attempts by 25%, while the third hypothetical intervention doubles the utilization of the second intervention.

The second hypothesis covered the local adaptations of the EQUIPT model in various countries. This process always started with the collection and analysis of country-specific input data, and the determination of the intervention package. Based on consultations with local experts, we established the potential new intervention packages, we conducted the analyses, the results of which were tested with sensitivity analyses, and finally we conducted the evaluation of the results. In the second hypothesis, I focused on the German and the Spanish model adaptations.

The first intervention package suggested for Germany included the increase of the utilization of group-based therapy to 1.9%, the positive financial incentive programme to 1.0%, and varenicline to 1.7% of all quit attempts. The second intervention package suggested for Germany included the increase of the utilization of group-based therapy and the financial incentive programme to

2.9%, while the utilization of varenicline was increased to 14.49% of all quit attempts.

The first intervention package suggested for Spain included the introduction of the proactive telephone support, on top of the current intervention package. The second, third, and fourth intervention packages included nicotine replacement monotherapy and combination therapy, varenicline, and buproprion respectively, as additions to the current intervention package.

The analysis of the third hypothesis covered the assessment of the changes in seven ROI outputs. Collection of those input parameters, that have a great influence on the end results can be strongly suggested. One by one we changed the values of input parameters from the average values to the country-specific ones, by conducting a series of one-way deterministic sensitivity analyses. The final shortlist included those key input parameters that caused a change greater than 10% in the value of at least four out of the seven ROI outputs.

Analysis of the fourth hypothesis started with the determination of the intervention package that was in use in Hungary at the time of the analysis (2015). This package included the ban of indoor smoking in public places, taxation of tobacco products, brief physician advice, single form nicotine replacement therapy (NRT), standard duration varenicline therapy, one-to-one and group-based specialist behavioural support therapies and the use of printed self-help materials.

The determination of the suggested intervention packages was based on consultations with clinical experts. The first package included a country-wide social marketing campaign on top of the current intervention package, aiming to reach the entire population. The second package included maintaining the unit costs and doubling the utilization of group-based supportive therapy and proactive telephone support, which were reaching only a small fraction of smokers at the time of the analysis. Finally, the third package included the combination of the first two packages.

4. Results

The result of the assessment of the first hypothesis was the further development of an economic model, and based on the calculations with the three hypothetical interventions in a theoretical example, it was able to support decision making in the hypothetical scenario as well, which paved the way for the local adaptations.

The EQUIPT model allows the analyses of smoking cessation interventions to be used within various decision making frameworks through its 18 ROI outputs. One possible decision rule is to compare the incremental cost-effectiveness ratio (ICER) – based on quality-adjusted life years (QALYs) – with the threshold that is currently being used in the assessment of pharmaceuticals. Secondly, some model outputs can be used according to the methodology of cost-benefit analyses to calculate the returns on investment. The third possible decision rule is to develop a so-called investment threshold, based on the number of quitters needed to positive return on investment in public health programmes. Finally, the outputs calculated by the EQUIPT model can be utilised in a multicriteria decision analysis (MCDA) framework.

The results related to the assessment of the second hypothesis indicated that the first intervention package suggested for Germany was dominant compared to the current package, as it provided an additional 15 034 QALYs for the German society, while saving 27 Million Euros overall. The second intervention package suggested for Germany resulted in 83 370 incremental QALYs, while saving a total of 86 Million Euros. According to the model results, introduction of proactive telephone support would have resulted in 12.6 Million Euros of additional costs, but it would have also resulted in 1053 successful quit attempts. One monetary unit invested into this package would result in a return rate of 1.9. Introduction of nicotine replacement therapies would result in 6 905 successful quit attempts and 260 Million Euros of additional costs. The return on every invested currency unit was 1.2 in this case, while in the case of varenicline and buproprion it was 2.4 and 2.2, respectively.

The outcome of the assessment of the third hypothesis was that changes in fifteen input parameters resulted in significant sensitivity in case of at least four of the seven ROI outputs: Background quit rate, Quit rate in those smoking 10+ cigarettes per day, Proportion of those who smoke 10+ cigarettes per day, Unassisted quit rate. Chronic obstructive pulmonary disease (COPD) prevalence, Coronary heart disease (CHD) prevalence, Cost of COPD, Outcome discount rate, Smoking status by sex and age, Cost of discount rate, Cost of CHD, Cost of lung cancer, Cost of stroke, Lung cancer prevalence and Stroke prevalence.

Three additional input parameters (Population aged 16 years or older, Smoking prevalence, Threshold value) were considered to be essential for the calculation of certain ROI outputs, therefore these were added to the list of key parameters as well. Five additional input parameters (Intervention uptake, Intervention unit cost, Inflation adjustment, Average hourly wage, Passive smoking costs) were considered to be essential for running the model, therefore the final list of key parameters included 23 items.

The result of the assessment of the fourth hypothesis was that all three intervention packages suggested for Hungary were dominant compared to the package that was in place at the time of the analysis, as they all resulted in lower costs overall, while producing more health gains. Every currency unit spent on the first suggested intervention package can provide a return rate of 20.8 on a lifetime horizon, if health gains are monetized. The same figure was 33.8 in case of the second intervention package, and 22,6 in case of the third intervention package. In line with prior expectations, the third intervention package would result in the highest number of quitters, and the greatest amount of monetary savings and health gains as well.

5. Conclusions

Resource allocation decisions of public health programmes should be supported by scientific evidence, and in case of priority areas, with full economic evaluation. The feasibility of this is substantiated by the creation and the local adaptations of the EQUIPT model. For this kind of decision making it is necessary to establish an objective and transparent decision making system, that takes into account the results of these calculations in an explicit way. According to my original research, this can be conducted based on the thresholds used in cost-utility analyses, based on the general cost-benefit analysis methodology, though we can also define a threshold based on natural output parameters (i.e. the 'number needed to benefit' for a positive return), or we can construct an MCDA framework as well. The outputs provided by the EQUIPT model can be used in all four of these decision making systems.

The modelling methodology described above is transferable across different countries and regions. The local adaptations of the model, conducted in accordance with the principles of transferability, can provide information for decision support in various jurisdictions. This was proven through the local adaptations of the EQUIPT model, as a joint work of the international group of scientists of the project, where I was leading the Hungarian adaptation process.

According to my original research, local adaptation of the EQUIPT model can be conducted with limited data as well. This is especially important in countries where data collection is complex or requires a significant amount of costs. Key input parameters of the EQUIPT model were selected based their sensitivity, and the collection of these is strongly advised.

According to my original research, based on the ROI outcomes of the EQUIPT model, the following packages of smoking cessation interventions can be suggested for implementation in Hungary:

- National social marketing campaign
- Doubling the utilization of group-based supportive therapy and proactive telephone support
- The first two packages combined

These packages were selected by local clinical experts, based on their expert opinions, the implementation of these is both feasible and advisable from a medical point of view. Based on the ROI outcomes calculated by the model, the implementation of these packages can be suggested according to all investigated considerations.

6. Publications by the Ph.D candidate

Publications related to the thesis

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