Algorithm for the estimation of the fiscal impact of new technologies

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Executive summary

This report constitutes deliverable D9.1 of WP9 of the IMPACT HTA project.

Work Package 9 (WP9) has focused on an area where use of economic evaluation for HTA is not used and valued, as we focus a lot on choices based on expense items or at most indirect costs. The overarching objective of this WP is to define a consistent methodology to incorporate fiscal impact in economic evaluations, focusing on productivity gains, consumption increases and potential tax revenues, deriving from health gains of new healthcare interventions.

The ambition of WP9 is to establish a standardized method to assess the fiscal impact deriving from health gains (i.e. consumption increases, productivity gains) in order to support decision-making for pricing and reimbursement of new drugs, vaccines, and other health technologies by providing an integrated view of the economic and social impact of new healthcare interventions. In doing so, it will take a public decision maker perspective into account when assessing new technologies. While some evidence exists in this field, this remains sporadic and heterogeneous. The WP will propose and validate a replicable methodology, coupled with an algorithm and simple software that can be used immediately by decision-makers in Europe and beyond.

We built an algorithm for the estimation of the fiscal impact of new technologies. The development of the algorithm is based on results from a systematic literature reviews, multiple interviews and case studies.

Introduction

The deliverable D9.1 presents a replicable methodology, coupled with an algorithm and simple software that can be used immediately by decision-makers in Europe and beyond.

The algorithm developed during the project, being shared and standardized, could become integral part of HTA when this is relevant in relation to the type of technology evaluated. Additionally, the availability of validated tools and data sources for this kind of analysis could facilitate its usage as a criterion to be taken into account when performing decision analysis, for instance in the context of multi-criteria decision analysis.

We used the algorithm for the estimation of the fiscal impact (algorithm) for medical technologies involving in different diseases / therapeutic areas. Setting / Area:

- Patients with Type 2 Diabetes in Italy;
- Ostomy and continence care in Italy.

Methods

A range of qualitative, quantitative and action-oriented research methods were used by the research team. Questionnaires and templates were built to HTA experts in Italy to document processes and compare case studies. Systematic literatures searches were undertaken to explore assessment methods associated with fiscal impact, in particular we used a model developed and published (Ruggeri M, Di Brino E, Cicchetti A. Estimating the fiscal impact of three vaccination strategies in Italy. Int J Technol Assess Health Care. 2020. Apr;36(2):133-138).

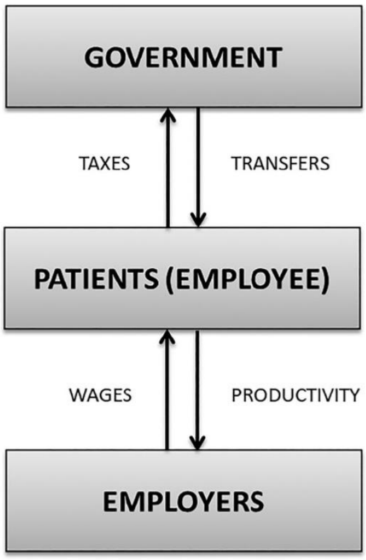
One of the most used methods to estimate productivity losses is the human capital approach (Drummond MF, 2005; Johannesson M, 1996). The human capital approach can be used to extend the societal perspective beyond the effect of the productivity losses on individuals, social insurances or employers. Fiscal impact estimate: decrease of income tax revenues caused from lower pays after a sickness status. The sustainability of national health services depends on their capability to ensure high levels of productivity through maintenance or improvement in health.

This process can be simplified to the following cause–effect formalization (Ruggeri M et al., 2020):

$$+H \xrightarrow{yields} +y \xrightarrow{yields} +W \xrightarrow{yields} +T \xrightarrow{yields} +G,$$

where H represents the number of healthy individuals, y represents employers' productivity, W represents employee income, T represents total fiscal revenues, and G represents public expenditure for health.

Fig. 1 – Fiscal Impact Model (Ruggeri M, Di Brino E, Cicchetti A, 2020)



The accumulation of human capital and the increase of population's health are the key-drivers for economic growth and the result of an endogenous process. Therefore, governments should invest in new medical technologies to increase population's health thus enhancing productivity growth. Increases in productivity would increase income and therefore consumption and tax revenues that would be used to increase investment in health.

We considered that, as empirical evidence shows, social insurances do not cover the full wage of workers. We considered a 33% decrease in the gross daily salary which accounts for items not being remunerated by the social insurance (i.e. shift, benefits, work during bank holidays etc...). We applied income tax rates according to the Italian taxation scheme (IRPEF) to estimate the fiscal impact resulting from experiencing productivity losses due to a specific condition.

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We are assuming the implementation of a specific home telehealth programme able to increase the adherence to the treatments in the target population, reducing the incidence of the hospitalizations (-18%).

We are assuming a different percentage in the distribution methods of ostomy and incontinence devices in the Italian clinical setting. In particular, we are assuming an annual increase in the 5% of the home distribution (*hypothesis*) which affect the indirect costs in the target population.

The WP will propose and validate a replicable methodology, coupled with an algorithm and simple software that can be used immediately by decision-makers in Europe and beyond.

Background

The conventional economic framework for evaluating the effects of suboptimal health conditions, as well as treatments aimed at their improvement, is mainly oriented to the investigation of the direct costs of health care. In this way, however, there is the risk of neglecting some effects (direct and indirect) that fall on the public sector but beyond the health system, even when health programs are ultimately financed with public resources.

If we look at the effects of health from the perspective of the public decision-maker, it is possible to quantify the extent to which the suboptimal state of health that affects some individuals affects the entire public sector not only through the consumption of health services, but also through the expenditure linked to the compensation of disability and the provision of social services, as well as the loss of productivity of individuals of working age which negatively impacts tax revenues in a more or mediated way by consumption.

Technological innovations in the health sector have in fact economic implications that go far beyond the impact generated on health expenditure (in a positive or negative sense). The impact expands in the other chapters of the state budget (e.g., social security system).

In an even broader way, innovation can impact on the production of wealth by workers and businesses (and on costs) and this, in turn, affects tax revenues. Ultimately, the presence of chronic diseases tends to reduce the propensity to consume and changes the allocation of consumption between the different sectors.

Allocative decisions in the health system are rarely supported by an analysis that combines the health effects of innovations and all the consequences this brings to the economic system.

The economic evaluation of large public health programs, or in any case of health policies capable of impacting the health of adults of working age, passes through the analysis of the relationship between investments in health and the effect of the consequent variations in morbidity and mortality on public accounts. It is a question of determining the return on investment in terms of discounted future net tax revenues, according to the perspective of the public decision-maker following the implementation of wide-ranging health programs.

Considering the dynamics of the demographic context, the management of patients with one or more chronic diseases represents the real challenge for the National Health Services in the coming decades. They are now struggling with methods and approaches that are significantly different from each other. These different methods are based on heterogeneous combinations of new technologies and new drugs, of professional skills, thus restoring the most diverse organizational and operational models.

Similarly, the National Drug Agencies, in this phase, have involved industrial companies in defining a new drug governance model in the context of the management of chronic diseases.

The understanding of the "value" associated with these different forms of governance of chronic diseases can only take place by adopting a "broad" perspective of fiscal impact that has been outlined above in the general features.

The basic methodological approach is the one already tested in the previous project on the fiscal impact of vaccinations (Ruggeri M, Di Brino E, Cicchetti A, 2020) and is being refined as part of the Horizon 2020 project (IMPACT HTA).

The perspective of the analysis is that of the public decision maker. Costs and benefits of chronicity management programs will be expressed in monetary terms. Overall, the study will therefore be configured as a cost-benefit analysis (Drummond MF, 2005).

The analysis tool will be a projection model that will allow to estimate the dual impact of diabetic patient management programs on transfers from the state to people (health care, pensions) and from people to the state (income tax, value added tax).

The basic information was collected through the literature review, and this allowed the definition of the reference model for the implementation of the data collection and analysis protocol.

A data collection protocol has been implemented which is useful for incorporating in the model the productivity gains resulting from the adoption of specific management models for chronic patients, the variations in the distribution of consumption by the different groups of the population concerned (e.g., between healthcare consumptions and non-health care) and on this basis estimates of the change in tax revenue can be made.

Moreover, a “Discrete Choice Experiment” (DCE) allowed the analysis of changes in consumption patterns in the event of ill health and will form the basis for the study of changes in tax revenues resulting from indirect taxation (YHEC, 2016).

Thus, a decision-making model was then created to incorporate productivity gains and potential tax revenues into economic assessments.

The fiscal impact analytical framework

In a market economy, the interventions of policy makers have only a guiding function since the economic phenomena that occur are due to the arbitrary behaviour of individuals, which cannot be changed by direct effect.

Therefore, the decision-makers will only have the possibility of influencing these behaviours through indirect tools, that is, influencing the subjects without affecting the free choice of the latter.

When it comes to the objectives of political decision makers, as indeed in the economy in general, the latter must be distinguished based on the time horizon on which they are made.

On the one hand, it is possible to highlight the short-term objectives that can be reached in months or a few years. For example, it could consist in the policy implemented to contain the growth of inflation prices; while, on the other hand, there will be long-term objectives, which can be pursued over a longer period, which occur, for example, with policies for economic development and which require more time to achieve the objectives set.

With reference to the instruments available, the main ones generally consist of fiscal policy and monetary policy interventions.

While the first concerns the intervention options on public spending and the fiscal levy to pursue economic growth, monetary policy consists in the evaluation of economic interventions with a view to an efficient use of money through factors such as monetary leverage, the supply of money, liquidity, credit, and the level of prices in the sector: in fact, it is used by the Central Bank to seek economic stability.

In the model that we find illustrated at the beginning of the chapter and on which we are based to develop this work, the central role of the State in the economic sector of the country and the need for a real "network of relations" between it and the other actors is evident. of the sector.

In fact, if on the one hand the State must incentivize companies present in the territory that produce positive externalities through in-kind or monetary instruments, on the other hand it must discourage the behaviour of those companies that instead involve negative externalities (e.g., pollution and damaging behaviour).

Again, another direction of the state's network of relations consists in the relationship that is established between it and individuals. To give an example, state intervention plays a fundamental role in protecting the latter in the event of information asymmetries between producers and consumers: in a totally private health sector, for example, one could find oneself in a situation of surplus. benefits as service providers could take advantage of the information asymme try and make patients purchase services more than what is really needed.

These are the relationships that a state normally establishes with the other players in the system. In other words, the fundamental component of this model concerns purely the transfe rs that take place between the State, individuals, and businesses, as well as the deeds of payment and payment of taxes and contributions made by citizens and businesses (against) as consideration for the transfers received.

To be able to estimate the economic impact that a given pathology has in terms of reducing tax revenue, the first thing to analyze is the taxes that affect individuals and companies and how, so as to be able to detect the influence that these have on the behaviour of them.

First of all, for the purposes of the analysis, it is necessary to clarify what taxes are; as already mentioned, the latter are part of a larger set which is that of taxes which are classified into: taxes, fees and contributions and, while the last two consist of compu lsory or non-compulsory fees that give the right to a public service, In any case, taxes will consist of a compulsory levy based on the income or part of the household assets, or on consumption and production activities, aimed at obtaining the resources necessary to provide public services that are indivisible for the community.

In this regard, we will talk about direct taxes and indirect taxes: the former affect wealth when it is produced, that is income, and the latter affect wealth when it is spent as in the case of transfers and purchases.

In this study, only the first, that is direct taxes, are taken into consideration because they are necessary for the purposes of the economic evaluation.

These, since, as mentioned, concern wealth when it is produced, they are excellent indicators that allow us to observe the variations of this, or when and by how much the wealth produced by the subject increases / decreases: in fact, the latter, when he is absent from work for the period necessary for his convalescence, for example, he will perceive a lower wealth which will therefore correspond to a lower taxable income. The most relevant, in Italy, are IRAP (Regional Tax on Productive Activities), IRES (Corporate Income Tax) and IRPEF (Personal Income Tax) (MEF, 2018).

Specifically, the tax that is analyzed for the purposes of the study is IRPEF (Personal Income Tax). The latter is of a personal and progressive nature and affects the overall income produced by individuals residing in Italy and the income produced in Italy by non-resident individuals (MEF, 2018). This tax is determined on the basis of progressive rates: it is, in fact, a progressivity by brackets, in this way the income produced by individuals is divided into fractions and each fraction is assigned a rate that will correspond to a certain level of taxable income. The correct classification of the activity carried out is therefore essential for the purposes of calculating the tax impact. In fact, personal income tax is the main source of revenue for the state.

As the declared income increases, the personal income tax rate gradually rises in order to respect the logic according to which to make those who receive a higher income pay more: (EUR 0–15,000, 23 percent; EUR 15,001– 28,000, 27 percent + EUR 3,450; EUR 28,001– 55,000, 38 percent + EUR 6,960; EUR 55,001–75,000, 41 percent + EUR 17,220; EUR > 75,001, 43 percent + EUR 25,420) (MEF, 2018).

The diagram shows how for incomes up to 15 thousand euros the personal income tax levy is 23% and then increases, moving to the next income bracket which will range from 15 thousand to 28 thousand euros with a corresponding rate of 27%. Beyond this threshold, the tax gradually increases until it reaches the last bracket corresponding to the maximum income bracket and set above 75 thousand euros which will be subject to taxation of 43% (MEF, 2018).

Although, in fact, initially the basic ratio of IRPEF consisted in creating a tax that represented an all-encompassing levy to include all types of taxpayer earnings; in reality, the IRPEF mainly affects income from retirement and work (especially employees) which, in fact, make up 78% of the total tax through with holdings in pay checks or INPS checks (INPS, 2019).

Precisely this peculiarity makes this tax particularly suitable for defining the impact of the pathologies dealt with in the study in question regarding the impact on tax revenues: it is, in fact, a tax paid above all by those who work, or who have worked in any case, and that does not take into consideration the so-called rentiers, or those individuals whose wealth produced does not depend on the work done, but on income unrelated to work activities, except to a marginal extent. For the pathologies under study, a gross hourly wage of 18 euros was considered, based on the ISTAT average (ISTAT, 2017).

In the two scenarios constructed, therefore, in addition to the variables about the incidence of the disease and the average working days, it was also necessary to define the other key and significant parameters for the model.

As regards the estimate of the cost incurred for social security, this was assumed to be equal to the percentage due by INPS deriving from the gross hourly wage - based on an ISTAT average - equal to 18 euros in total and as follows: 15 euros for fixed part (RAL) and 3 euros for the variable part.

The total cost of the productivity loss was estimated according to the Italian cost-sharing rule, which charges reimbursement for the first 3 days of missed work to employers and the remainder to the INPS (INPS, 2019). Furthermore, we considered an average of 36 hours of work per week and a total of 48 working weeks per year (considering 4 weeks of vacation).

Algorithm for the estimation of the fiscal impact of new technologies

This technical report describes the development of the fiscal impact model: a compartmental (mathematical) multi-state disease transmission model to quantify relevant measures of value to patients and populations from both a health service provider and policy maker perspective.

The fiscal impact model is a compartmental (mathematical) multi-state disease transmission model designed to quantify relevant measures of value to patients and populations from a health service provider and policy maker perspective by modelling the relationship between a specific disease and treatment options or a specific setting of care, clinical and economic outcomes.

The model has been developed in Microsoft Excel for Windows and is compatible with Excel 2007 or later. The model's core calculations are undertaken within Visual Basic for Applications (VBA). Excel's built-in solver module must be available to use the optimization module.

Figure 2 – The fiscal impact model:

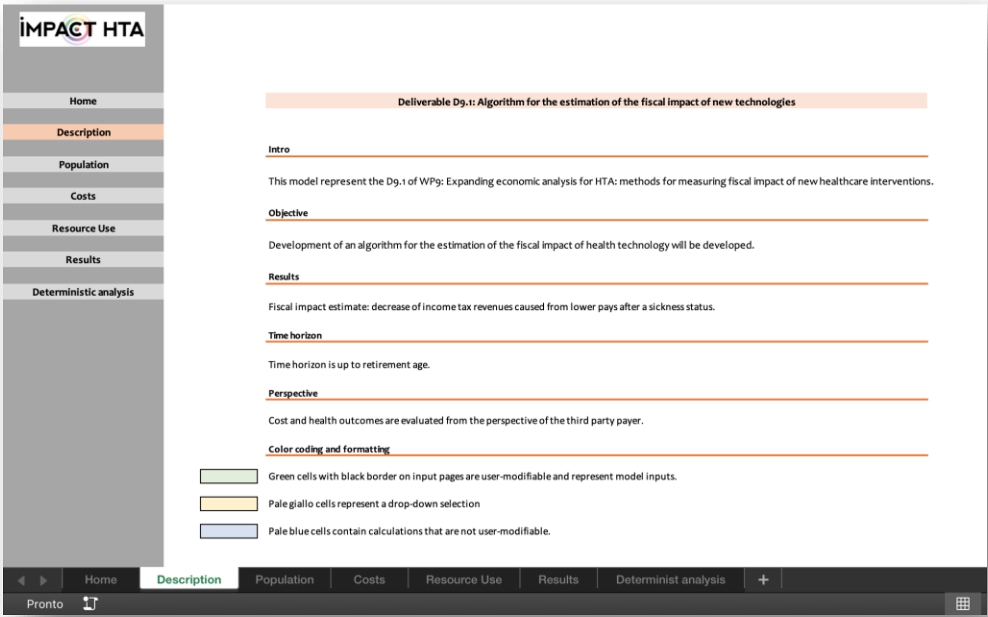
The model is primarily operated via a single worksheet (Model Control) from which the user may run a mean value analysis, where a cohort of patients is simulated using a single set of model inputs.

When simulations are run from the Model Control, model input values and settings used in model analyses are automatically loaded based on pre-defined profiles as selected by the user.

The modelled population includes all adult patients (16-65 age) within a hypothetical disease.

The model considers a starting scenario in which applying a specific policy (for example, introduction or extension of telemedicine, introduction or change in the model of care, introduction or change in the model of care, introduction or change of the setting in which it is treated a patient, ...) we analyze the impact in terms of reduction of productivity losses and the increase in tax revenue given by the fewer days of work lost.

Figure 3 – The technical input



The model has been populated with data for the Italy setting and adopts an Italy payer perspective, considering direct costs and health effects. In line with ISPOR and AIES guidelines costs and health effects are discounted at an annual rate of 3%.

The fiscal impact model is a cost-benefit and fiscal model and was predominantly based on the recommendations made in the ISPOR modelling good research practices.

The model can evaluate two strategies or scenarios and is comprised of three core components. These three core components are:

1. **Epidemiology data:** to estimate the incidence and prevalence of a given population with a specific disease to calculate the eligible population.
2. **Tax and cost data:** parameters allow to present an algorithm to analyze the productivity losses, the annual gross income and therefore the fiscal impact subject to the variability of information included in the survey. Human capital approach (estimate of the number of days lost). Estimate of the cost of social security. Estimation of the reduction of taxable income by workers by applying IRPEF brackets to the average gross salary in Italy.
3. **Optimization module:** allows users to use an optimization algorithm that modifies inputs (within specified limits) to minimize or maximize specific results.

The treatment pathway component of the model allows for flexible, user-defined treatment algorithms; as such the model can assess the impact of differing policy efficacy, but also the impact of different stewardship strategies. The probability of successful treatment is determined by the efficacy of the policy applied.

The fiscal impact model is also capable of extrapolating the results of hospital-based analyses to estimate the impact of different treatment strategies at a national or sub-national level.

The fiscal impact model utilizes a variable time horizon with an annually cycle. Due to the annually cycle length the policy impact is assumed to be resolved within the incident cycle.

The model does not consider mortality but is based on a hypothesis in which a given cohort of patients is analyzed from the point of view of the impact of the policy on taxation up to retirement age.

An Excel simulation was therefore constructed to be able to observe the variation in the estimates at the current complication rates or other parameters and clinical incidence as the key and sensitive variables for our model vary. Through this analysis, therefore, it was possible to detect the extent of the consequent changes when the value relating to one or more sensitive parameters was changed.

To investigate the impact of the extension of adult vaccination on the increase in tax revenues in Italy, a multivariate sensitivity analysis was performed with the variables of epidemiology, number of days of absence from work, hourly wages, and vaccination coverage included in the models. Disease incidences were fitted using a beta random variable, and the number of days of absence from work and hourly wages were associated with a gamma random variable. A multi-way bootstrap analysis is conducted to investigate the variability and the generalizability of the results. One-way bootstraps are performed to observe the elasticity of the fiscal impact estimation according to the variation of age and number of episodes. In all bootstrap simulations 10th, 25th, 50th, 75th and 90th percentiles are presented in tabular format.

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