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Economic Evaluation of Health IT

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Abstract. Economic evaluation in health care supports decision makers in prioritizing interventions and maximizing the available limited resources for social benefits. Health Information Technology (health IT) constitutes a promising strategy to improve the quality and delivery of health care. However, to determine whether the appropriate health IT solution has been selected in a specific health context, its impact on the clinical and organizational process, on costs, on user satisfaction as well as on patient outcomes, a rigorous and multidimensional evaluation analysis is necessary. Starting from the principles of evaluation introduced since the mid-1980s within the Health Technology Assessment (HTA) guidelines, this contribution provides an overview of the main challenging issues related to the complex task of performing an economic evaluation of health IT. A set of necessary key principles to deliver a proper design and implementation of a multidimensional economic evaluation study is described, focusing in particular on the classification of costs and outcomes as well as on the type of economic analysis to be performed. A case study is eventually described to show how the key principles introduced are applied.

Keywords. Health information technology, technology assessment, economic evaluation.

1. Introduction

The successful application and the consequent systematic adoption of a Health Information Technology (health IT) are broadly considered a promising strategy to improve the quality and delivery of health care. However, to determine whether the appropriate health IT solution has been selected in a specific health context, its impact on the clinical and organizational process, on costs, on user satisfaction as well as on patient outcomes, a rigorous and multidimensional evaluation analysis is necessary.

Since the mid-1990s an increasing number of studies have addressed this issue, and some of them also include an economic evaluation with the aim of providing decision makers with a set of analyses that can support them in prioritizing interventions and maximizing the available limited resources for social benefits [1-2]. Being the "study of choice" [3], health economic evaluation is defined as the *"comparative analysis of alternative courses of action in terms of both their costs and*

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consequences. Therefore, the basic task of any economic evaluation is to identify, measure, value and compare the costs and consequences of alternatives being considered" [4].

Health IT has a supporting role both in the care process (diagnostic, treatment/therapy and nursing) and in the auxiliary process (for instance, appointing making, image archiving and documentation) [5]. Therefore, a causal relation [6] between the improvement of the efficacy and effectiveness of both care and auxiliary processes is usually very difficult to determine and measure. This makes the economic assessment of the health IT value – preferably in monetary terms – a challenging task, for a number of reasons e.g. the difficult identification of costs given, among other problems, the incremental development of many health IT solutions and their often locally adjusted implementation; the measurement of benefits that generally also depend on how systems are used, the organization and medical context in which they are embedded, and even on the national health system in place.

As health IT does not directly alter the states of health or disease [7], compared to other types of technologies such as drugs or medical devices, benefits have to be measured in terms of changes in the health care and management processes, for instance improvements resulting from a better sharing of patients' information, better resource allocation, or workload definition and deployment. This also implies that the economic evaluation has to combine or privilege different methods – qualitative and quantitative – that have to be coherently selected according to the objectives and perspective driving the assessment. Moreover, the difficulty in isolating the impact of health IT may be partially solved by distinguishing the main functionalities in: 1) capturing, storing, managing and sharing data; 2) informing and supporting clinical decision-making; 3) delivering expert professional and or consumer care remotely [8].

Economic evaluation of health IT is still a research area. There are no common agreed and fixed standards that guide the performance of health economic analysis [9] considering the multiple dimensions on which health IT may have an impact. For these reasons systematic reviews generally reveal a limited number of economic evaluation compared to other types of analysis [10-11], poor use of analytical technique and documentation, partial identification of costs and benefits, or use of predictive analysis on assumptions based on limited empirical data. Moreover, although different evaluation frameworks and guidelines have been proposed (none of them specifically focused on economic evaluation of health IT), there is no uniform reporting of results, thus limiting the comparison across institutions.

This contribution intends to contribute to the discussion on the methods and approaches supporting the assessment of health IT solutions by providing key features that support a scientifically sound economic evaluation. Section 2 provides a brief overview of the economic evaluation within the health technology assessment (HTA) framework as well as in a selected number of widely diffused health IT evaluation models. Section 3 summarizes some key principles that guide to a proper design and implementation of an economic evaluation of health IT, focusing in particular on the classification of costs and outcomes as well as on the main criteria used to choose the type of analysis. These principles are applied in a case study described in section 4.

2. The framework of the economic evaluation development

Economic evaluation was the major focus of the first governmental national agencies that were constituted to develop Health Technology Assessment (HTA) round the mid 1970s. The main concern was the rising expenditure for health care, the rapid change of health technology generally associated with the ageing of population and increased population health care service demand. The establishment of the US Office of Technology Assessment (OTA) – replaced by the Agency for Health Care Policy and Research which in turn became the Agency for Health Research and Quality (AHRQ) – clearly identified its scope as provider of analyses to support decision makers in "formulating policies to ensure that research-and–development funds are invested wisely" [12].

The subsequent development of similar national agencies in Europe, even if generally motivated by rationalising health care expenditure and by cost containments, soon addressed issues more closely related to quality and safety of care as well as social and ethical implications [13]. This has led to the adoption of a more comprehensive approach to technology assessment that considers economic evaluation as part of a more complex framework of analysis that includes – at least at the level of HTA scope statements [14] – the technological, patient and organisational dimensions.[2] Moreover, other evaluation approaches developed within the Cochrane Collaboration and the evidence-based medicine (EBM) movement[3] contributed to the consideration of economic evaluation as a specific phase of the assessment process, generally performed after safety, efficacy and effectiveness of interventions have been analysed [15].

The application of HTA differs from country to country, being influenced by the national health care system in place, and by the aim and mandate of the agencies performing the assessment. This pertains also to the economic evaluation that depending on the national agency tends to privilege certain types of analysis (for instance cost-utility instead of cost-effectiveness) and/or prefers to consider certain types of cost and/or benefit [16]. Moreover, even if most HTAs have broadened the range of technology to include drugs, medical device, procedures and organisational and support system for care provision, the majority of analysis are generally focused on pharmaceutical products. This has the consequence that traditionally applied methods to verify safety and efficacy of drugs such as RCT (Randomized Clinical Trials) have been privileged making the evaluation of the impact of health IT limited to certain aspects, such as system performance or particular changes in clinical practices that may affect patient care [17, 18].[4]

Despite differences and specificities, HTA has had the merit of providing a set of principles for the conduct of a sound evaluation defining the main steps and contents of the study design, providing guidance on types of economic analysis to be performed, on criteria and methods to be followed in the collections and analysis of data as well as in the reporting of evaluation results.

However, the need to specifically address the evaluation of health IT has led to the development of further frameworks, differently connected with HTA, that are

[2] See also: P. Doupi, Evolving Health IT systems evaluation: the convergence of health informatics and HTA, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[3] See also: C. Urquhart et al., Systematic reviews and meta-analysis of health IT, in: ibid

[4] See also: C.R. Weir, Ensuring the quality of evidence: Using the best design to answer health IT questions, in: ibid.

conventionally classified as subjectivist approaches [17, 18]. These frameworks complement each other [19], as they each tend to privilege a specific perspective of the health IT evaluation, focusing on user behaviour and perception, or emphasising social/organizational relationships or software lifecycle. They are generally based on qualitative approaches that use among other methods interviews, questionnaires, or focus groups to perform their analysis (see reviews [20, 21] that use this classification of frameworks). Moreover, comprehensive and multi-dimensional frameworks have been developed to include the different aspects that influence health IT adoption and applying matrix and/or taxonomy to identify the main components to be taken into account in the evaluation.

Worth mentioning is the Information System Success model proposed by DeLone and McLean [6, 22], which provides a framework of interconnected aspects that should be considered also when performing an economic evaluation. The model is based on a taxonomy of six interrelated dimensions that measure the *system quality* (e.g. system performance and use), *information quality* (e.g. accuracy, reliability, etc.), *service quality* (e.g. the overall support delivered by the service provider), *system use* (e.g. human acceptance or resistance toward the system), *user satisfaction* (e.g. positive experiences in using the system) and *net benefit* (e.g. the combination of individual and organizational impact). The first three dimensions are to be measured singularly or jointly to evaluate how they affect the two closely interrelated variables of *system use* and *user satisfaction* so to ascertain the *net benefit*, which in the DeLone and McLean previous version of the model [6] were described as the individual and organisational impact. *Net benefit* thus summarises the outcomes of this complex interaction providing a value – a positive or negative association in DeLone and McLean terms – that can be transformed into an economic evaluation.

Further developments [23, 24] of the Information System Success model have given in more recent times a major focus on the organisational component and identify a more complex set of interactions among the dimensions identified by DeLone and McLean. The category of net benefits, common to these frameworks, helps in the identification of outcomes derived by the interaction of these dimensions and provides the basis for both qualitative and quantitative analyses on which to derive for instance cost reduction resulting from productivity and/or reduced time in performing specific tasks, error decline in terms of adverse events as well as impact on patient care and access to information.

3. Principles of economic evaluation of health IT

Guidelines on evaluation agree on the importance of the identification of a specific and clear research question that details the purpose of the analysis.[5] The scope of the economic evaluation also defines the perspective of the analysis that has to match the need of the commissioning body that generally poses the study question. The scope and perspective of the research question determine the type of study design as well as the appropriate approach to analyse data collected during the evaluation framework. The key elements of the economic evaluation framework are shown in Figure 1 and

[5] See also: P. Nykänen et al., Quality of health IT evaluations, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

described in the following paragraphs. They are based on the criteria described in selected HTA guidelines containing a specific part on economic analysis [1, 25-27].

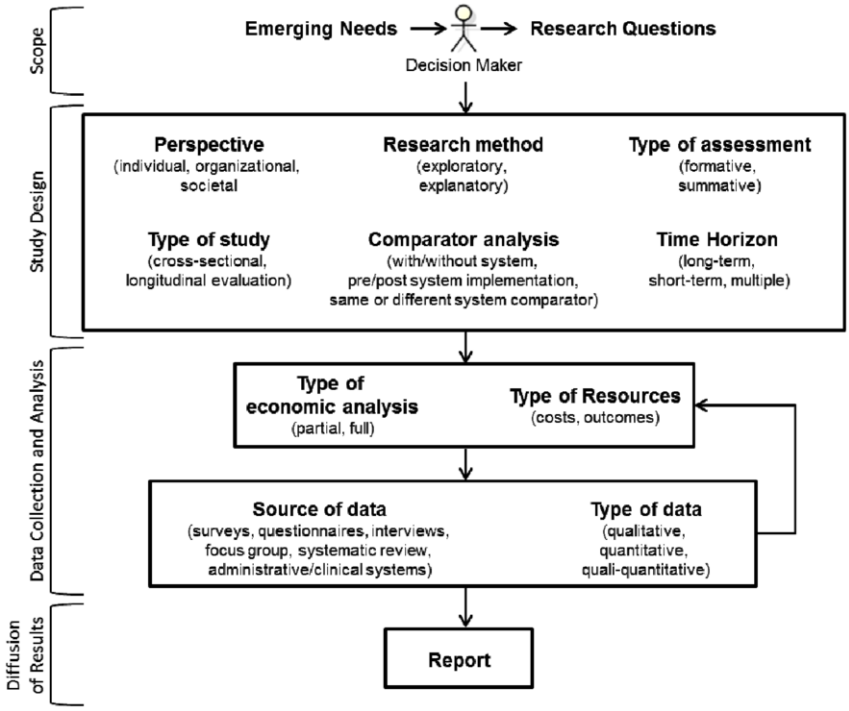


Figure 1. Principles of the economic evaluation of health IT.

3.1. Study design

Depending on the research question, the study design has to consider the key principles listed below and choose for each one the appropriate approach.[6]

The *perspective* represents the point of view from which the study is conducted (individual, organizational, societal). Clearly establishing the perspective of the economic evaluation is particularly important for the identification of costs, resources and consequences to be examined. This also ensures comparability of different analyses. The perspective can be limited to the primary stakeholders of the health care system (e.g. physicians), or it can consider impact on the organization or even on the welfare system. In the latter case, a wider range of relevant costs and consequences are considered including those that are related to other public sector agencies, patients or their carers.

The identification of the *research method* [28] is mainly based on the knowledge about the problem to be analysed. When the problem is not well defined the study is conducted using an exploratory research, for example using a case study to generate a hypothesis and find the relationships between the introduction of a new technology and

[6] See also: C.R. Weir, Ensuring the quality of evidence: Using the best design to answer health IT questions, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

its effect on the context where it is deployed. In this approach data are collected from literature reviews, databases and/or from relevant stakeholders (e.g. physicians, patients) using techniques such as informal discussions, in-depth interviews, or focus groups. Conversely, an explanatory research is adopted when the investigation is conducted analysing the relation between the cause (e.g. technology to be adopted) and the effect (e.g. costs and outcomes) derived from the introduction of the health IT. This relationship is explored using two main research methods: experimentation (e.g. randomized clinical trial performed in a hospital), and statistical research (e.g. multiple regression techniques). A clear identification of the research method is helpful to determine the best research design and data collection method as well as the selection of the target population.

The *type of assessment* indicates in which phase of the development lifecycle the health IT is analysed. Substantially, a technology can be evaluated throughout the whole development lifecycle using a formative approach, providing information on the system under development that may also lead to improvement or modifications. Once the system has been implemented, assessment of the effect/outcome is performed using a summative evaluation.

The *type of study* determines whether the relationship between costs and outcomes deriving from the introduction of a new technology is analysed at one particular time during the system deployment (i.e. cross-sectional study) or repeatedly observed over time with continuous monitoring (i.e. longitudinal study). Type of study also includes the identification of inclusion and exclusion criteria of the target population.

The identification of the *comparator* is one of the most significant activities of the economic evaluation framework. The new technology can be introduced as an improvement of existing, generally paper-based, routine care system (i.e. pre/post system implementation). In this case one or more relevant alternatives of the health IT under evaluation could be taken into account (same or different system comparator). These circumstances can involve either information systems that are classified in the same group of health IT or systems that share only a small set of functionalities. Moreover, it is also possible to evaluate a new process implemented by means of a health IT (i.e. with/without system comparison) to verify costs and benefits of the chosen solution.

The appropriate *time horizon* of the evaluation specifies the period during which all the costs and outcomes are captured (short or long-term). It strictly depends on the research questions and can vary from a few days to several years capturing changes in the patient's health status and/or impact of health IT over an expected time period. This implies the identification of outcomes and costs of alternative options measured in the specified period. It is also possible to explore multiple time horizons to verify the cost effectiveness of a health IT based on alternative scenarios.

Once the scope has been identified and the study design determined, data collection and analysis can be performed. This implies on the one hand the choice of the most fitting *type of economic analysis* (to be identified within the full and partial analysis frameworks) and the selection of related *type of resources* (in terms of both costs and outcomes). On the other hand, it implies the identification of the *types of data* (e.g. qualitative and/or quantitative) as well as the *source of data* (e.g. systematic reviews, surveys, clinical information systems already deployed). The backwards arrow in Figure 1 sets forth the mutual influence between the data and the analysis domains: the decision towards the use of a given economic analysis somehow conditions the data retrieval; conversely, the deployment of a specific type of analysis might depend on the

purpose of the economic evaluation as well as on the availability of suitable data. It should also be noted that a combination of more than one type of analysis could be useful. The next sections describe in detail the classification of costs and outcomes and the different types of methods included within the framework of full and partial economic analysis.

A structured *report of results* of the economic evaluation ensures eventually that the performed study is thoroughly presented and organized consistently to facilitate review and comparison by decision makers [29].[7] The report has to be presented in a clear and transparent manner with enough information provided according to a consolidated schedule [30]. The Executive Summary and Conclusions should be written so that they can be understood by a non-technical reader, in order to enable the audience to critically evaluate the validity of the analysis. It is essential to explain and justify the choice of variables and methods, mention the reasons why certain data were excluded and last but not least describe in detail the organisational characteristics that may hinder or facilitate a health IT introduction or maintenance. However, it is likely that the results may not be (totally or in part) generalizable, as the key principles may differ significantly, e.g. between different jurisdictions or time periods.

3.2. Classification of costs and outcomes

The economic evaluation of health IT includes the identifications of costs to be quantified in monetary terms generally related to infrastructure (e.g. hardware, software, network), personnel (e.g. time spent for users' training), facility (e.g. space necessary to store the technology) and other materials (e.g. consumable, paper) [e.g. 31, 32]. Table 1 summarizes the different classes of costs as reported by referenced relevant literature.

Table 1. Classification of costs.

Description of costs categories (with references)	**Example of costs**
Tangible and intangible [e.g. 33] (level of measurability of the cost)	Tangible: tablets Intangible: stress caused to a patient due to the health IT
Direct and indirect [e.g. 34] (impact of the health IT)	Direct: information system implementation Indirect: loss of productivity
Health and non-health [e.g. 35] (cost related or not to the health sector)	Health: outpatient visits Non-health: private travel costs
One time and ongoing [e.g. 36] (cost is considered once or repeatedly)	One time: local area network installed in the health facility Ongoing: software maintenance
Average and marginal [e.g. 37] (cost is considered as a total amount or as a price per unit)	Average: software implementation Marginal: personal computers
Fixed and variable [e.g. 38] (cost remains constant or vary in proportion of the activities performed)	Fixed: initial user training Variable: telephone bills

Easily identifiable costs are generally related to the health IT implementation and maintenance as well as to the infrastructure supporting its deployment (e.g. PCs, network, printers). However, given that the introduction of a new technology impacts

[7] See also: E. Ammenwerth et al., Publishing health IT evaluation studies, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

on the core organizational and clinical processes, identification of indirect costs such as time spent for training and/or for modifying use of the technology (loss of productivity) are difficult to measure and therefore frequently overlooked and/or subjectively attributed to different classes [36].

Similarly to costs, also outcomes can be classified as direct (e.g. investment reduction of personnel wages) and indirect (e.g. savings resulted from the decrease of adverse events) depending on whether the monetary savings are strictly related or induced by the introduction of the health IT. Moreover, outcomes can be related with the health of the patient (e.g. the reduction of medical errors) or not (e.g. time and money saved due to the reduction of patient transportation in a telemedicine program) [39]. However, the identification and classification of outcomes are even a more challenging task if compared with costs, as outputs are generally intangible and indirect measures related to the improvement of the patient's health status as well as of the organizational process. This issue is also crucial considering that a parameter can describe more than one category of benefits implying an overestimation of outcomes. For instance adverse event prevention can be measured as an improvement of both quality of care and patient safety.[8]

Many studies classify the same parameter either as a cost or an outcome of the health IT deployment. For instance, patient's length of stay can be considered either as a cost [40, 41] or as a consequence of the intervention [42, 43] depending on the point of view of the analysis. It is therefore essential that authors give in the first place, to the greatest extent possible, a clear indication of the nature (costs or benefits) of the parameters used to perform the evaluation, in order to justify the results of the evaluation as well as allow its comparison with similar studies.

Outcomes are not only a measure of the increase of revenues but also an assessment of the costs averted as a consequence of the introduction of the health IT. Their measurement implies a careful analysis as some costs may not be simply eliminated, but shifted to other hospital services or even to different components of the health care system [44]. This makes it also challenging to transform outcomes into a monetary value that is a necessary activity when the economic evaluation is performed using a Cost Benefit Analysis. For this reason analysts have often chosen other types of analysis that do not imply this conversion, such as Cost Analysis, or Cost Effectiveness Analysis [45].

The difficulty in the identification and classification of outcomes has led different authors to adopt customized classifications considering, for instance, the impact of the Electronic Health Record [46, 47] that can result in outcomes about the patient flow (e.g. reduction of patient cycle time and increasing patient capacity), resource allocation (e.g. transcription, chart management and paper consumption), coding and billing (e.g. reduced billing errors), patient safety (e.g. decrease in infection rate), caring process (e.g. high quality of care) and staff compliance (e.g. reducing the redundancy of laboratory tests). Finally, the evaluation toolkit provided by the AHRQ [48] classifies the different measures that can be used to assess a health IT project in the following categories: patient safety (e.g. hospital complication rates), effectiveness (e.g. mortality), quality of care (e.g. documentation of key clinical data elements), efficiency (e.g. length of stay), and patient centeredness (e.g. patient knowledge). The

[8] See also: F. Magrabi et al., Health IT for patient safety and improving the safety of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

assessment of costs and outcomes included in the economic evaluation should take into account that the technology can lose its validity in a relatively short period of time. This is particularly true considering that health IT may become obsolete quite quickly, making it necessary to quantify costs to be invested to replace the technology after its use life as well as to consider the fast decline of prices (e.g. devaluation) of the technology that can be also caused by an increased value of production and a recovery of development charges. Moreover, an important aspect to be taken into account when performing an economic analysis is that the impact of a health IT often considers a broad period of time (for instance, Cost Benefit Analysis conducted on a 5-years period) that requires the correction of costs and outcomes for the effects of inflation to provide realistic resource costs.

3.3. Type of economic analysis

A health economic analysis aims to identify criteria to support decision makers in choosing between competitive alternatives the one which is most efficient and cost-effective in an environment with limited resources [4, 10, 32, 33, 48]. This comprehensive analysis is achieved within the framework of a full economic evaluation when both costs and consequences of alternative interventions (e.g. intervention X versus comparator Y) are compared to assess their efficiency. A partial economic evaluation occurs instead when costs and outcomes are separately analysed (cost analysis/cost description; efficacy or effectiveness evaluation/outcome description) and/or alternative solutions are not considered (cost outcome description). Systematic reviews [34] indicate that the majority of economic evaluation studies generally perform cost analyses that focus on cost saving of two or more alternatives.

Full economic evaluation represents a framework composed of different types of analysis, which are applied depending on the research questions, the viewpoint of the decision maker as well as data availability. Table 2 reports the most frequently adopted types of analysis giving a general description, the main objective as well as criteria that have to be fulfilled when choosing the appropriate method. What differentiates these analyses is the metric used as well as the number of parameters considered to evaluate the outcomes of the different interventions. The Cost Effectiveness Analysis (CEA) measures the health effects using a single outcome, such as the life years gained, while the Cost Utility Analysis (CUA) considers one or more outcomes aggregated in a global measure of health outcome, such as the QALY (Quality-Adjusted Life Years) or DALY (Disability Adjusted Life Years). CEA and CUA may use an incremental ratio – respectively, incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) – that allows comparison of the effectiveness of the intervention against an alternative solution given a fixed budget. When outcomes can be transformed in a monetary term a Cost Benefit Analysis (CBA) can be applied. However, even if this method can provide a useful indication for the right allocation of resources measuring whether gains overweight costs, its application has to face ethical issues as it means placing a value on the cost of human life.

Table 2. Types of full economic analysis.

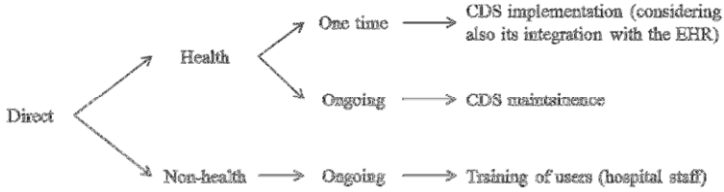
Methodology	Description	Objective	Application Criteria
Cost Effectiveness Analysis (CEA)	Consequences of different health interventions are measured in natural units using a single outcome related to the objective of the program (e.g. life-years gained, adverse events avoided).	To establish whether differences in expected costs between interventions can be justified in terms of changes in expected health effects.	• Different interventions have to be compared using an uniform measurement of a single outcome • Outcomes cannot be expressed in monetary terms
Cost Utility Analysis (CUA)	As an extension of the CEA, it measures the strength of preference for a particular clinical outcome state. Outcomes are measured using QALY or DALY gained.	To compare the value of interventions for different health problems, in order to facilitate the allocation of resources to maximize health gains.	• Meaningful differences in the combination of the duration of life and health-related quality of life (HRQoL) between the interventions have to be demonstrated • Outcomes are not expressed in monetary terms
Cost Benefit Analysis (CBA)	It measures and values in monetary terms the benefits and costs of outcomes achieved from different programs or interventions.	To address the efficiency in allocating resources between sectors	• Outcomes have to be expressed in monetary terms

Moreover, there are two additional types of analysis that are not reported in the Table 2 as they represent two specific forms of CEA: Cost Minimization Analysis (CMA) and Cost Consequence Analysis (CCA). In the CMA outcomes of alternative interventions have been proven to be identical and therefore only the least expensive option has to be determined. In the CCA multiple outcomes are analysed separately and compared with the relevant costs. This has the advantage of considering the full range of health and organisational effects of an intervention or when it is difficult or misleading to combine multiple outcomes from an intervention in a QALY for a CUA.

4. Case study

In this section we model a timely implementation of economic evaluation for health IT providing a case study based on the key principles described in section 3. Characteristics of the environment are: a mid-sized hospital (300 beds and 145 care professionals) that comprises Intensive Care Units (ICUs) hosting patients with comorbidities treated with multiple drugs. The hospital is already equipped with an Electronic Health Record (EHR) system that manages clinical and administrative patient data. The General Directorate intends to integrate the existing EHR with a Clinical Decision Support (CDS) module to overcome the current paper-based prescription procedures. The main scope is to support physicians in the choice of the appropriate medical treatment (drugs type and dosage), taking also into account the interaction with other drugs. Table 3 summarizes the key principles of the economic evaluation.

Table 3. Key principles of economic evaluation of the integration of a CDS module within an EHR system.

Principle	Description
	Scope of the economic analysis
Decision maker	General Directorate of the hospital
Emerging Needs	Reduction of Adverse Drug Events (ADEs) caused by prescription errors that derive from: • interaction with other therapies (drug-drug interaction, DDI); • dosage and/or length of the therapy; • type of medicine prescribed.
Research questions	• Will the integration of the existing EHR with a CDS module improve the quality of care compared with the actual paper-based prescription procedure? • Is there particular evidence that the adoption of CDS modules reduce ADEs? • Will outcomes derived from the CDS balance the implementation and adoption cost?
	Study design
Perspective	Organizational: integration of the already deployed EHR system with a CDS module to improve the quality of treatment via the implementation of e-prescription procedures.
Research methods	A literature review is carried out to collect and analyse evidence on outcomes derived by the adoption of CDS module in other contexts (e.g. PubMed, Cochrane, AHRQ, York).
Type of study	Cross-sectional: the evaluation is conducted considering the number of ADEs occurred in a year. in a hospital with similar environmental characteristics.
Time horizon	The evaluation considers the costs and outcomes over a 5-years period.
Comparator analysis	Pre-post ADE alert system implementation: manual data entry of drug prescription procedures into EHR system versus EHR system integrated with a CDS module.
Type of assessment	Formative: the CDS module is assessed prior to its implementation.
	Data collection and analysis
Type of economic analysis	Incremental Cost Effectiveness Analysis
Source of data	Literature review; Open databank provided by the Ministry of Health; Budget proposal by vendors
Type of data	Quantitative
Costs	 Productivity loss and hardware costs are not included considering that users are already confident with the use of health IT and the hospital is already equipped with PCs and printers. Costs of process changes have not been considered as CDS module effects only a limited part of the process.
Outcome	The number of ADEs that could be averted has been included as a unique indirect outcome

The result of the Cost Effectiveness Analysis is reported in Table 4 highlighting costs to implement and maintain the CDS module as well as to train the physicians in its use. Costs have been measured based on the budget proposed by selected vendors and represented in US Dollars in order to pursue an as broad as possible visibility and data usability. The number of ADEs that could occur in a year have been captured from

an open data source released by the Italian Ministry of Health[9] considering a health structure with the same environmental characteristics of the one under investigation; while the expected reduction of ADEs has been obtained from a literature review where different studies [32, 48-51] have reported that the introduction of a CDS module can reduce the number of adverse events by 40% to 80% each year. This wide range of percentage reduction makes it also necessary to perform a sensitivity analysis. Starting from the total costs and outcomes, the Incremental Cost Effectiveness Ratio (ICER) has subsequently been computed to determine the US dollars spent per ADE averted.

Table 4. Results of the cost effectiveness analysis (in US Dollars).

	0-year	1-year	2-year	3-year	4-year	5-year	Total
Costs (expressed in US Dollars)							
CDS implementation	500.000						500.000
CDS maintenance		50.000	50.000	50.000	50.000	50.000	250.000
User training (per user)	*200*	*150*					
User training (total) for 145 physicians	29.000	21.750					50.750
Total costs	*529.000*	*71.750*	*50.000*	*50.000*	*50.000*	*50.000*	*800.750*
Outcomes (based on initial 183 ADEs)							
# of ADEs (60% of ADEs averted)		*110*	*110*	*110*	*110*	*110*	*550*
# of ADEs (40% of ADEs averted)		*73*	*73*	*73*	*73*	*73*	*365*
# of ADEs (80% of ADEs averted)		*146*	*146*	*146*	*146*	*146*	*725*
Cost-effectiveness analysis (Total expressed in US Dollar spent per ADE averted)							
ICER (60% of ADEs reduced)							1455.9
ICER (40% of ADEs reduced)							2193.8
ICER (80% of ADEs reduced)							1104.5

Limitations of the study: The literature review to assess the percentage on ADEs reduced by the introduction of a CDS is based on heterogeneous studies considering specific functionalities implemented, population involved as well as the study design adopted. Moreover, ADEs are measured using different methodologies that often do not take into account non-intercepted ADEs (e.g. ADE occurred after the discharge). Another important aspect to be considered in this study is that ADEs are surrogate measures not necessarily directly related to changes in the patient-relevant medical outcomes. Moreover, the number of ADEs considered does not take into account the degree of severity of the adverse events.

Note that the proposed simplified case study has to be considered as an educational example of the application of the principles of economic evaluation of health IT described in the previous section. When the evaluation analyses the replacement of a paper-based procedure, it is necessary to assess process changes that introduce a set of specific dimensions such as savings of ceasing old processes as well as costs of new processes, equipment costs, loss of production due to the introduction of a health IT.

[9] http://www.salute.gov.it/portale/documentazione/p6_2_8_1_1.jsp?id=6

5. Conclusions

The rapidly changing technology as well as its adoption in increasing health-related environments (suffice it to think of m-Health applications) requires the economic evaluation to become an on-going assessment that includes a multidisciplinary team of experts to comprehensively consider the benefits of health IT introduction and use.

The present contribution aimed to enrich the line of inquiry into economic evaluation approaches for the adoption and implementation of health IT, as a means to support decision makers in prioritizing interventions and maximizing the available limited resources for social benefits. The vast literature analysis conducted made clear that, though it is not possible to diverge from the principles of HTA, a sort of new interpretation (far from an adjustment) is necessary when applying the economic evaluation on health IT. This is a challenging task, as no consensus exists regarding the multiple dimensions to be considered when evaluating the indirect effects on patients' health status as well as the impact on both health care and managerial processes. To this purpose, the authors' main effort was to outline a set of guiding principles to conduct an appropriate analysis of costs and outcomes as well as to choose the proper type of economic evaluation. The case study has then applied the set of criteria emerging from the mentioned principles that can lead to a timely and consistent evaluation.

Recommended further readings

1. M.F. Drummond, M.J. Sculpher, G.W Torrance, B.J. O'Brien, G.L. Stoddart, *Methods for the economic evaluation of health care programmes*, Oxford University Press, 2005.
2. J. Car, A. Black, C. Anandan, K. Cresswell, C. Pagliari, *The Impact of eHealth on the Quality & Safety of Healthcare. A Systematic Overview & Synthesis of the Literature*, Report for the NHS Connecting for Health Evaluation Programme March 2008. https://www1.imperial.ac.uk/resources/32956FFC-BD76-47B7-94D2-FFAC56979B74, last access 11 February 2016.
3. CP Friedman, J C Wyatt, *Evaluation Methods in Biomedical Informatics*, 2nd edition, Springer, New York, 2006.
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Food for thought

1. Which are pros and cons of a quantitative, objectivist research method?
2. What are the advantages and issues related to the performance of a formative economic evaluation compared to a summative one?

3. What are the criteria to be considered when choosing the type of economic analysis?
4. Think of some examples that describe the mutual relationship between the type of resources (costs and outcomes) and the availability of data to perform an economic analysis!
5. When health IT replaces a paper-based procedure, which are the difficulties in the classification of costs and benefits? Make some examples.

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