

Designing a Socio-Economic Assessment Method for Integrative Biomedical Research: The Osteoporotic Virtual Physiological Human Project

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Abstract. In integrative biomedical research, methods assessing the clinical or even socio-economic impact of more complex technologies such as Information and Communication Technology (ICT)-based tools for modelling and simulation of human physiology have rarely been applied. The EU funded *Osteoporotic Virtual Physiological Human* (VPHOP) research project, part of the Virtual Physiological Human (VPH) European initiative, will create a patient-specific hypermodel to predict the absolute risk of bone fracture much more accurately than predictions based on current clinical practice. The project has developed an innovative, multilevel generic methodological framework to assess the clinical and socio-economic impact of biocomputational models. The assessment framework consists of three components: a socio-economic cost benefit analysis, health economic analysis of care pathways, and disease cost simulation models. Through its holistic perspective, the method provides a tool to appraise the overall value of biocomputational models for society.

Keywords. health technology assessment, multiscale modelling, cost benefit analysis, virtual physiological human, IT assessment

1. Introduction

The most significant clinical and societal impact of integrative biomedical research pertains to the objective of more precisely quantifying disease risks as well as identifying optimal pathways for treatment, thereby reducing both the burden caused by disease and from costs to healthcare systems. Against a paucity of meaningful data on the cost-benefit calculation of actual IT implementations [1], creating the business case for any health IT adoption becomes a challenge. Moreover, methods assessing the clinical and socio-economic impact are rarely applied to more complex technologies, such as patient-specific computer models for personalised and predictive healthcare and ICT-based tools for modelling and simulation of human physiology and disease-related

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processes. Health technology assessment (HTA) is a tool increasingly used to encourage an efficient use of health technologies [2]. Yet HTA is a mostly static, ex post methodology usually applied to medical devices, new clinical treatment methods etc., but not to ICT-based multiscale modelling technology and eHealth applications.

The EU funded VPHOP research project has recently been launched to create a patient-specific hypermodel that will predict the absolute risk of bone fracture more accurately than predictions based on current clinical practice. Its results will be validated not only technically, but also assessed in terms of their impact on organisational, economic and societal issues. VPHOP, similar to the vision behind the European initiative *Virtual Physiological Human* (VPH) as such, will impact on clinical practice by better tailoring patient-specific treatment plans, and by enhancing cooperation among various medical specializations [3].

The project has developed an innovative, multilevel generic methodological framework to assess the clinical and socio-economic impact of multiscale and predictive modelling technologies. This is a methodology paper: it introduces the concept, components and benefits of the VPHOP impact assessment methodology and highlights its value for a general transfer to evaluate biomedical integrative research.

2. Methods

Any assessment framework of predictive modelling is confronted with the problem of realistically addressing the inherent complexity without having to sacrifice parsimony. Assessing the impact of basic research and future technologies in their infancy (and being as multiscale and iterative as the VPHOP simulation models are) poses two methodological challenges. On the one hand, the impact assessment extends into the future – ex-post evaluation methods are insufficient and scenario developments are presupposed. On the other hand, the socio-economic assessment of the VPHOP technologies has to give answers to two analytically distinct objects of analysis: (1) the clinical management of the osteoporotic patient and, closely connected, the hospital change management; (2) the disease states and health of the patient (i.e. the expected consequences of fractures avoided).

3. Results

The framework of the new assessment method forms the content of this section. Quantifiable results of the actual assessment process of VPHOP will be available once the project has produced the first prototypes and has generated robust data.

3.1. Components of the Assessment Framework

Once clinically applied, the new technologies will first of all affect care provider and patient. In order to assess the technology's impact on the two stakeholders, two correspondingly different objects of analysis will need to be investigated – they present the constituting elements of the clinical impact:

1. the clinical management of the osteoporotic patient and, consequently, its change management;

2. the disease states and health of the patient (in other words, the expected consequences of fractures avoided)

For generating the financial and non-financial data necessary to conduct a cost benefit analysis, a method-mix has been designed. This mix serves as the tool-box for extracting, generating and interpolating data (clinical and non-clinical; tangible and non-tangible). The results that the tools are assumed to deliver will be embedded inside a broader CBA. The tools for feeding the CBA consist of two approaches:

- clinical pathway analysis deriving from clinical management and evidence-based medicine (cost-effectiveness of care paths);
- and disease modelling based on health economic evaluation methodologies.

Figure 1 depicts how the two tools are integrated and how the flow of work constitutes the overall assessment framework.

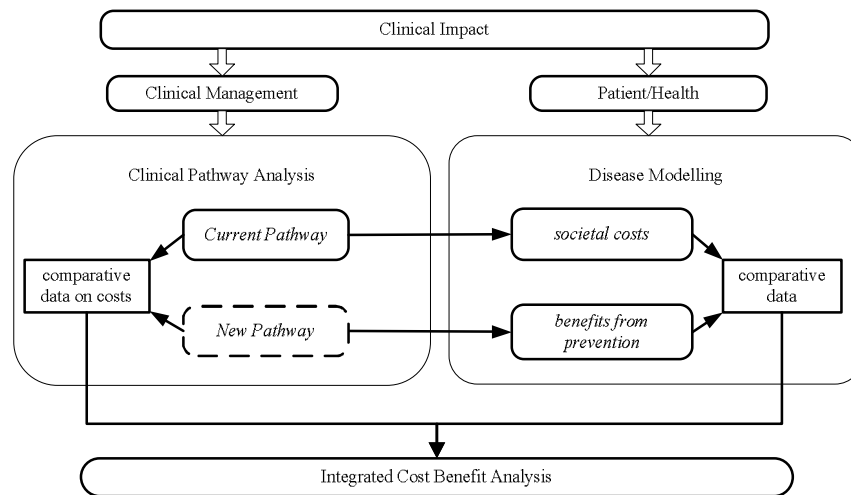


Figure 1. Configuration of the Assessment Framework

3.2. Working Step 1: Comparing Current and New Standard of Care

A commonly agreed clinical pathway reflecting the current standard of optimal care was supplemented by a benefit-cost dimension. The description and conceptualising of the clinical care pathway serves as a tool for collecting the required basic clinical, economic and organisational data. In practical terms, the current pathway, i.e. the current standard of care, was disaggregated into three levels: diagnosis; prognosis and pharmacological treatment; and interventional treatment planning. At each junction in the pathway tree, the human and instrumental resources involved, the duration, and the costs associated, will be attached. Additionally, as the modelling technologies strongly rely on imaging and radiographic devices, junctions involving radiation doses are recorded in order to reflect a risk category.

Once the new multiscale predictive technology has been validated in a clinical context, a new modified pathway will evolve. The comparison between the old and the new pathways represents the initial tool for estimating the expected overall impact of the new clinical technology for clinical management. At this stage, relevant factors specific to the clinical roll-out of the new technologies will be integrated.

3.3. Working Step 2: Disease Modelling to Assess Consequences of Fractures Avoided

Comprehensively identifying all relevant costs is a comparatively straight forward exercise in collecting data about direct and indirect costs of investment as well as the operating costs of the technology. However, assessing the impact of IT technology for the overall diagnosis and prognosis of diseases requires a different approach to categorising benefits. Here, a patient's life is at the heart of reaping the major benefits.

In a second step of the assessment process, the predicted, reduced societal costs of osteoporotic fractures avoided are measured. This can be achieved by translating expected changes in the patients' health states into estimates of socio-economic benefits and costs/ risks. Analytically, the increased clinical accuracy of the predictive technology leads to a second dimension in the assessment: benefits relating to the prevention of fractures. On the basis of transition probabilities between health states that are typical of osteoporosis, a decision-analytic simulation model [4,5] is conceptualised and integrated with the work flow in old and new clinical pathway.

The improved diagnostics and treatment plans of the new clinical pathway are integrated with the disease modelling tool. Those benefits are captured as more targeted prevention, and hence as the associated reduction in costs due to avoided fractures.

3.4. Working Step 3: Final Integration and Evaluation through Cost Benefit Analysis

For realistically assessing the potential and impact of the VPHOP technologies, CBA became the preferred economic concept for ex ante, long-term forecasting on which technologies will become successful clinical innovations. The VPHOP CBA methodology has already been tested and successfully applied to ex-post evaluations in other eHealth realms [6]. The design provides a scenario-oriented method covering timelines of up to ten years and, moreover, allows to aggregate results into a holistic analysis. Hence, the methodological consolidation and overall impact assessment is achieved by applying results and data from the clinical pathway analysis and its integrated disease modelling in a single CBA.

The comparability and a methodologically clean aggregation of the numerical data collected by the two tools from the previous working steps will be ensured by the following: all benefits will be assigned a monetary value, prices of intangible benefits will be inferred from commonly accepted estimation methods (e.g. willingness to pay), and optimism bias will be controlled for.

4. Discussion and Conclusion

The beneficial impact of the VPHOP predictive technology may involve, firstly, earlier and more focused interventions leading to a reduction of the individual and social costs of osteoporotic fractures (and to benefits like improved quality of life). Secondly, given

the reduced number of tests necessary and a much more accurate diagnosis and treatment planning, the simulation technologies as promulgated by VPHOP will reap large benefits such as time savings, increased quality of care, and more efficient use of healthcare personnel and medical devices. However, the financial and other costs associated with the improved clinical diagnosis, treatment and rehabilitation need to be assessed as well. For example, it can reasonably be expected that the introduction of simulation models to clinical routine will require extensive change management and investment costs to install the new technologies.

The aim of the socio-economic impact analysis is to dynamically translate the health states of patients, the clinical data and the running costs of the healthcare process into estimates of benefits, costs, and related risks, allowing for a balanced overall assessment. The developed innovative assessment method allows identifying relevant costs and benefits for all stakeholders, from patient over healthcare provider to policy decision-maker, and, thereby, provides a tool to appraise the overall value of multiscale modelling for society. Suitably refined, the VPHOP assessment methodology is an excellent basis for research, and, moreover, for an investment decision support methodology embracing this approach not only for hospitals and research centres, but also for ICT applications affecting any part of the health and healthcare value system.

Unlike most evaluated ICT applications in healthcare, the VPHOP model is more directly interrelated with improved clinical outcomes as well as the transformation of diagnosis and treatment of a chronic disease. Therefore, the concomitantly developed assessment method allows for deriving not only better tailored exploitation scenarios but also for business models with real industrial impact. Ultimately, its design has from the onset been configured to permit a general transfer of the evaluation methodology to a broader range of diverse future biomedical integrative research.

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