Quality of Life through Quality of Information
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Conceptual Modeling for Prospective Health Technology Assessment

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Abstract. Prospective Health Technology Assessment (ProHTA) is a new and innovative approach to analyze and assess new technologies, methods and procedures in health care. Simulation processes are used to model innovations before the cost-intensive design and development phase. Thus effects on patient care, the health care system as well as health economics aspects can be estimated. To generate simulation models a valid information base is necessary and therefore conceptual modeling is most suitable. Project-specifically improved methods and characteristics of simulation modeling are combined in the ProHTA Conceptual Modeling Process and initially implemented for acute ischemic stroke treatment in Germany. Additionally the project aims at simulation of other diseases and health care systems as well. ProHTA is an interdisciplinary research project within the Cluster of Excellence for Medical Technology - Medical Valley European Metropolitan Region Nuremberg (EMN), which is funded by the German Federal Ministry of Education and Research (BMBF), project grant No. 01EX1013B.

Keywords. conceptual modeling, conceptual model, prospective health technology assessment, simulation, health care, health economics, ischemic stroke treatment

Introduction

Health technology is fundamentally important for prevention, diagnosis and treatment of diseases and therefore contributes extensively to improve patients' quality of life. But financing health technology involves enormous investment costs for companies as well as for government and patients, all belonging to the health care system. And still there is no proven evidence for the medical and economic benefit of a new technology when introducing it to the system.

Due to the fast development cycles for new health technologies, methods, procedures and pharmaceutical products independent research and evaluation processes have been established worldwide to provide information on effectiveness, costs and broader impact. So far three different approaches exist to assess health technology:

- Health Technology Assessment
- Early Health Technology Assessment

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- Horizon Scanning

Health Technology Assessment (HTA) describes an evaluation process regarding procedures and technologies relevant for people's health and health care provision. Integrated in the evaluation process are the following aspects: efficacy, effectiveness, comparative effectiveness, efficiency, ethics and social aspects [1]. HTA is usually conducted after the market launch when appropriate data is available in studies or trials.

Early HTA aims to support investment and design decisions at an early development phase which means at the time when major financial and strategy decisions are made [2].

Horizon Scanning evaluates either potential impact or clinical and cost effectiveness of emerging and new technologies (technologies that are not yet adopted or just in the phase of adoption and only available for clinical use for a short time) and prioritizes those technologies most likely to have a significant future impact [3].

Still, even with Horizon Scanning and Early HTA the cost-intensive design and development phase is mostly finished as market access is prepared or even already performed. This is where Prospective Health Technology Assessment (ProHTA) differs from the existing approaches in understanding the impact of products and solutions on medical and organizational processes already at the beginning of the concept phase. Thereby these processes can be prospectively optimized with the health technologies' innovative possibilities.

ProHTA integrates knowledge on processes and technology in simulated scenarios in order to derive and analyze impacts on health care players on a cost-efficiency basis. Processes are optimized towards the launch of an innovation, which also means that innovations are assessed before major financial investments and design decisions. Simulation models should be able to describe and evaluate health care innovations with respect to quality, efficiency, effectiveness and acceptance by patients. Hence the health care system is examined as a whole. Furthermore ProHTA provides a possibility to detect potentials for efficiency enhancements in health care provision by simulating the system and thereby extracting bottlenecks and weaknesses.

The overall goal of the project ProHTA is the implementation of a platform for scientific services accumulating knowledge and technical tools to mainly answer two questions:

- What are the changes that result from the launch of a new technology?
- What does a technology need to be like in order to have a specific effect?

In order to establish an executable simulation, the ProHTA project teams' objective was first of all to develop an overview of structures for the German health system and health services delivery as well as analyzing and formalizing the knowledge and requirements for the simulation and a knowledge management system. Therefore the objective formed towards an own Conceptual Modeling Process together with an own Conceptual Model. The ProHTA Conceptual Model should encompass the domain experts' knowledge on health system and health services combined with the technical experts´ requirements for simulation and knowledge management and thus forming the base line of the scientific services platform.

1. Methods

The *ProHTA Conceptual Modeling Process* (see Figure 1) was developed by partially adopting project specific improved methods and characteristics of scientific research on

simulation modeling [4]. The process encompasses two different views: *Domain World* (reality) and *Model World* (abstraction) and includes steps for knowledge collection, acquisition and processing leading through formalization to the *ProHTA Conceptual Model*. The Conceptual Model is the basic component of the Conceptual Modeling Process and made up of the *Conceptual Domain Model* together with the *Formal Conceptual Model*. Based on the Conceptual Model, the implementation of the *Simulation Model* and *Knowledge Base* can be derived.

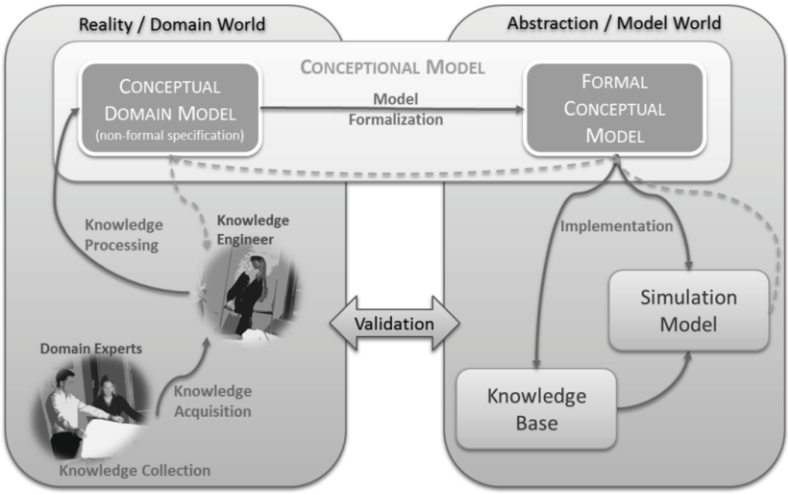

Figure 1. Overview of the iterative ProHTA Conceptual Modeling Process

Performing the ProHTA Conceptual Modeling Process, first of all the *Domain Experts* identified relevant data sources and a literature research was executed (*Knowledge Collection*). Afterwards, the *Knowledge Engineer* gathered the Domain Experts' knowledge and data by interviews, workshops and document reviews (*Knowledge Acquisition*) and subsequently all input was consolidated into the Conceptual Domain Model in a non-formal way (*Knowledge Processing*). This model was then thoroughly reviewed and checked in order to be correct and comprehensible from the Domain Experts view to ensure validity, credibility and utility. Thereafter it served as inevitable basis for the Model World.

The transition from Domain to Model World was then taken by formalizing the Conceptual Domain Model into the so-called *Formal Conceptual Model*. Therefore the Knowledge Engineer presented the model together with all collected information to simulation and data management experts (*Technical Experts*). Together they created a first draft of the Formal Conceptual Model. Later on the Technical Experts finished the *Model Formalization* by applying technical standards to the model. Concluding with a successful check on utility and feasibility, the model was finally used to implement executable Simulation Models.

Both the Conceptual Domain Model and the Formal Conceptual Model are modularized for reuse and to master complexity. Therefore different aspects of health care, health care financing, population, disease and treatment were configured into models and sub-models in order to reduce complexity and enable a generic and transferable approach.

The Conceptual Modeling Process was developed on the basis of acute ischemic stroke treatment in Germany using knowledge and data from the stroke-registry

Erlangen ("Erlanger Schlaganfallregister"). The modular and partially generic design should allow for future extension to implement executable simulations also for other diseases and health care systems.

2. Results

An overview of the ProHTA Conceptual Model is given in Figure 2. The Comprehensive Model is one of five generic models together with Population Dynamics, Disease Dynamics, Health Care and Health Care Financing.

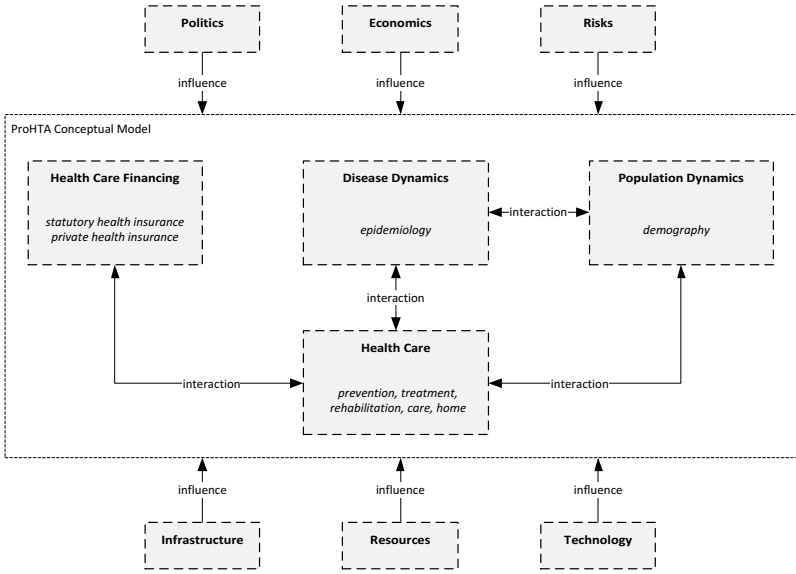

Figure 2. Comprehensive Model of the ProHTA Conceptual Model

Population Dynamics represents dynamics in demography, referring to the statistical study of human populations. Demography mainly contains the four indicators birth rate, death rate (mortality), immigration rate and emigration rate. Disease Dynamics represents epidemiology meaning the study of health-related topics and events within a population. Epidemiology mainly contains five indicators: incidence, prevalence, case fatality rate (lethality), remission and recurrence (relapse). Health Care represents a generic view of the health care system together with primary public health care, referring to the structures in Germany. Health Care is split up into four parts: prevention, pre-treatment, treatment and post-treatment. Health Care Financing represents health insurance coverage and health care costs. Different cash flows between population, health care provider, payer and general government are shown.

Politics, Economics, Risks, Infrastructure, Resources and Technology are considered for later development stages in order to provide best reusability and applicability for enlarging the project scope.

Additionally to the generic models, eight specialized models were developed, extending the Health Care and Health Care Financing model. Six out of the eight specialized models relate to ischemic stroke treatment within German health care delivery. Those characterize primary, secondary and tertiary prevention, pre-treatment

by general practitioner as well as rescue service, inpatient treatment and post-treatment containing rehabilitation and care. Another two models refer to the German health insurance system illustrating statutory health insurance and private health insurance.

3. Discussion

So far the ProHTA Conceptual Modeling Process together with its Conceptual Model is highly developed for the use case stroke. Referring to Robinson, the main requirements for a conceptual model [5] have been successfully achieved and serve as ideal basis for an executable simulation.

Compared to other scientific research for health care modeling and simulation, the Conceptual Modeling Process as well as Prospective Health Technology Assessment is quite unique and innovative. Current academic literature mostly presents tool-based modeling and simulation whereas no real distinction between a conceptual and a simulation model is drawn [6, 7]. Conceptual modeling and conceptual models are more common in software and knowledge engineering and similarities can be found [8]. Nevertheless there is a significant difference between engineering and simulation.

Conceptual modeling for simulation is looking back at approximately one decade and yet emerging. Thorough research and development is still underway and can be supported by ProHTA. Recently an international group of scientists discussed the education on conceptual modeling especially for simulation, demanding a clear definition, well-defined standards and good modeling principles [9]. The ProHTA Conceptual Modeling Process is our response.

After completing the conceptual model for the stroke use-case, the next use-case will be established: personalized medicine in oncology. Thereby the Conceptual Modeling Process will be tested and validated. In parallel an executable simulation to evaluate the impact of digital imaging technology within ambulance vehicles (Mobile Stroke Units) on diagnostics, therapy, outcome and costs of ischemic stroke patients and treatment will be developed.

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