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Technology foresight for medical device development through hybrid simulation: The ProHTA Project

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ABSTRACT

"Prospective Health Technology Assessment" (ProHTA) aims to develop a platform targeting health care manufacturers and decision makers that facilitates the assessment of innovative health technologies prior to their launch. The simulation has been run for the first case study of Mobile Stroke Units (MSUs). In the highly time sensitive setting of acute stroke, MSUs are an innovative approach as they aim to reduce 'time-to-thrombolysis'.

The ProHTA approach focuses on interdisciplinary work related to forecasting with hybrid simulation consisting of system dynamics models for macro-simulation and agent-based models for micro-simulation.

Results of the simulation show that MSUs save up to 49 min of time between ambulance call and therapy decision. Whereas without MSUs, only 0.2% of patients fall in the group with the most favourable time interval between 0 and 90 min, up to 16.6% of patients treated in MSUs fall into this group of early onset times to thrombolysis. As a flexible and primarily quantitative decision-making tool for foresight, ProHTA adds value to existing methodologies for pre-assessing health technology at a very early stage of technology research and development. With its emphasis on strategic planning, ProHTA helps to improve the efficiency of health care delivery in different settings using hybrid simulation techniques.

1. Introduction

The global medical device market is estimated at $300 bn with a 4.6% annual growth rate in 2013 [1]. Key factors contributing to the growth of this industry are related to the growing demand for health care, due to increased life expectancy and active lifestyles of the ageing population, growing middle classes in emerging markets and the spread of Western lifestyles and nutrition preferences. In addition, patients' expectations of health care provision are also intensifying. The supply of new health technologies exploits advances in bioscience and widening technical possibilities for health product development. These growth opportunities need to be put into the context of increasing cost pressures, due to tightening health care budgets, and complex reimbursement systems [2]. Especially in the current climate of economic austerity, these pressures are increasingly impacting on health care systems [3]. In this regard, foresight

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methods are useful for predicting such health care relevant developments in the future.

1.1. Foresight approaches: general outlook, health specific methods and their use

Health foresight methods are wide ranging, but trend analysis including modeling and simulation and scenario planning are most widely used. In addition, the DELPHI method which focuses on the systematic iteration of expert panels is an established interactive forecasting method [4,5]. Concerning an extensive overview of forecasting methods and applications we refer to Armstrong [6] and Markridakis [7]. A useful overview of scenario analysis planning for strategic management to support decision making is provided by Postma et al. [8,9].

Forecasting requires accurate data gathering, along with combining economic and health information into predictive models [2]. Existing health forecasting methods are currently used increasingly in the context of global health and specifically infectious diseases [10], but there is great opportunity to learn from and customize foresight methods to improve the process of health technology innovations. The impact of Health Information Technology (HIT) in the area of health care is increasing as its use aims at reducing costs and improving patient experience and quality, for example through the application of Technology Forecasting and Technology Assessment [11]. The use of Technology Intelligence in research forecasting aims at improvements in policy planning and implementation [11]. Information (and Communication) Technology is used extensively within Foresight Support Systems (FSS), a concept which aims to reduce uncertainty [12,13]. According to Banuls et al., FSS in collaborative computer-based systems aims at supporting communication, decision modeling and rules of order in foresight processes. Scenarios and simulation are used as specific FSS modeling tools [14].

1.2. Health care innovations: industry perspective

Successfully launching innovations is time sensitive and requires strategic and future-oriented thinking. Health technology manufacturers often fail at this task and lose millions as existing methods of early detection and evaluation of all the aspects of a new technology have shortcomings. Bringing a new product successfully from 'bench to bedside' has become increasingly complex in recent years. The diffusion of innovation in the health care market is subject to multiple requirements of third parties, including regulators such as the "Food and Drug Administration" (FDA) in the USA and "European Medicines Agency" (EMA) in the European Union. Other actors include Health Technology Assessment agencies at the national level as well as payers. These strict regulatory requirements combined with the ever increasing importance of reimbursement decisions for successful health technology commercialization require careful planning [15]. The health care industry is unique in that there are large national differences which have to be considered for regulatory processes, HTA decision making and reimbursement requirements. Due to the composition of health systems, for example manufacturers need to consider disparities in terms of direct or indirect negotiations with health care payers and providers. Average life cycles of medical devices range from 18 to 24 months, and are thus much shorter than for drugs [16]. In addition, the differences between medical devices and pharmaceuticals are also characterised through the context of incremental technological innovation of medical devices [17]. Further differences between drugs and medical devices and their impact on assessment technologies are highlighted by Drummond et al. [18]. Long HTA processes have the effect that manufacturers share a larger risk that competing products access the markets in the meantime. In addition to assessing clinical outcomes, other aspects need to be considered, such as potentially, patient preferences and health economic impacts.

Assessing new innovations at an early stage is difficult as there is a lack of available evidence and current methodologies are limited in their reach. New methodological approaches are therefore necessary to estimate unmet needs within global health care systems and to assess the market potentials of emerging health technologies [19].

The objective of this work is to enrich current methodologies for technology assessment by the added value of starting the assessment at an earlier time.

1.3. Existing assessment methods for health technology

Established health technology assessments can only partially address these needs, as they strongly focus on an economic analysis of technology costs and on the benefits to the patient, based on technology-specific data, as soon as data is available [15]. Health technology assessment refers to a process of systematic assessment of new technologies, treatments and methods in health care. As the approach is based on the results of evidence-based studies, in general it is only possible to apply HTA after the development or launch of a new technology.

In addition, the terms Early Technology Assessment and Future-oriented Technology Assessment have emerged [20,21]. The relevant concepts estimate cost-effectiveness at an early stage of technology development, and re-iterate this evaluation as the development progresses [16]. Early and future-oriented health technology assessments, as well as Horizon Scanning, are steps in the right direction which have already been taken. We refer to Ijzerman and Steuten for a detailed literature review on methods for the early assessment of medical technologies [19]. The authors argue that in order to produce the right information to decision makers, no single solution has been found to be effective [19]. Hence it is important to combine methods according to their advantages and disadvantages.

2. Background

2.1. ProHTA—overview, goals, added value

A new approach, "Prospective Health Technology Assessment" (ProHTA) is proposed to address other methodologies' shortcomings and to provide added value to developing innovations in medical product development.

"Prospective Health Technology Assessment" (ProHTA) is a project within the National Cluster of Excellence "Medical Technology—Medical Valley EMN (European Metropolitan Region Nuremberg)", funded by the German Ministry of Education and Research. ProHTA aims to develop a scientific service platform targeting primarily health care manufacturers that facilitates the assessment of innovative health