Chapter 4 The Role of Pharmacoinformatics in Enhancing the Pharmacoeconomics Context of Decision Making

Maarten J. Postma University of Groningen, The Netherlands

Gijs A. A. Hubben University of Groningen, The Netherlands

ABSTRACT

This chapter addresses the increasing role of pharmacoinformatics in enhancing the pharmacoeconomics context of decision-making. Notably, the role of pharmacoeconomics—i.e. cost per QALY calculations— is growing rapidly for decisions on reimbursement of new drugs. These pharmacoeconomic analyses often involve complex mathematical computer models requiring specific informatics techniques such as probabilistic simulations, bootstrapping, and discrete-event approaches. Transparancy of these complex models is crucial for decision makers to accept the model and its results. The authors argue that Web technology, Web-based access to models, international transferability of analyses, and decision-support systems may help in this respect. In particular, to allow decision makers and researchers to directly interact with transferable economic models and adapt a model to their region, efficient solutions have to be found to disseminate technically complex models to decision makers and researchers outside of the original setting. One such solution is through the use of Web technology and other pharmacoinformatics' techniques as explored in this chapter.

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INTRODUCTION

Pharmacoeconomics concerns cost-effectiveness analysis, generally of new drugs. Next to pharmaceutical, mathematical, and economical inputs, this is a complex endeavor often requiring extensive computer modeling and informatics science. Also, often the issue on cost-effectiveness of specific drugs-often in relation to reimbursement decisions-is eminent is various countries at the same time, similar to registration of new drugs. This enhances the usefulness of generalisable, transferable, and accessible computer models on these drugs using state-of-the-art informatics techniques with user-friendly interfaces, global web-based access and concise and explicit user guides for these models. In this respect, informatics technology can greatly help the dissemination and understanding of such pharmaceutical models. These specific aspects of these pharmaceutical models and the corresponding needs could be seen as being part of the pharmacoinformatics science, where pharmacy and informatics (and economics in this case) meet. The application of pharmacoinformatics is still in its infancy in the area of pharmacoeconomics; yet huge potentials exist.

In many countries (in the Netherlands since 2005), pharmaceutical companies have to show favorable cost-effectiveness for new innovative drugs using reliable and valid modeling techniques, next to evidence on quality, safety and efficacy of these products (www.ispor.org). In other words: does the new drug (or any other health technology actually) provide sufficient "health gains" for the (often relatively high) price that has to be paid, i.e. do we get enough "bang for the buck"? As such, cost-effectiveness has becomes the fourth hurdle in practice for new health-care technologies, including tests, vaccines and drugs. In this respect, showing that the development and production processes of a new drug are qualitatively according to the highest standards is considered as the 1st hurdle, inclusive aspects such as Good Manufacturing and Good Laboratory Practices (GMP & GLP). The second and third hurdle refer to efficacy and safety, respectively.

Do note that the fourth hurdle of cost-effectiveness regards reimbursement in particular, rather than registration issues concerning new drugs. One effectiveness outcome relates to life years gained, if the investigated drug is indeed a life-saving one. If quality of life gains are significant, health gains are often expressed in "Quality-Adjusted Life Years" (QALYs): a measure valuing health between 0 (death) and 1 (perfect health) using standardized questionnaires, such as the EQ5D (www.euroqol.org). Obviously, next to quality of life, the QALY-concept includes life-year gained additionally (corrected for quality if needed). For this purpose, the pharma company often hires a consultancy bureau to design, implement, and perform these cost-effectiveness models and analyses. Various companies are active worldwide including Mapi Values (UK/Netherlands), PharMerit (USA/Netherlands), BaseCase (Germany), and 13 Innovus (UK), all performing analyses in the area of pharmacoeconomics/health economics. Rather than for registration purposes these costeffectiveness analyses are primarily performed for underpinning reimbursement decisions, formulary inclusions and treatment guidelines/ recommendations. Frameworks in which these cost-effectiveness analyses are considered are, for example, the National Institute of Clinical Excellence (NICE) and the Scottish Medicines Consortium in the United Kingdom and the Foundation for Health Care Insurance in the Netherlands. The latter institute advises on the inclusion of new drugs in the Dutch reference pricing system ("Geneesmiddel Vergoedings Systeem"). In such committees often various disciplines are involved. illustrating the multidisciplinary character of pharmacoeconomics: clinicians, pharmacists, statisticians, economists, econometricians, and modelers (often mathematicians).

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