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ISPOR TASK FORCE REPORTS

Modeling Good Research Practices—Overview: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-1

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A B S T R A C T

Models—mathematical frameworks that facilitate estimation of the consequences of health care decisions—have become essential tools for health technology assessment. Evolution of the methods since the first ISPOR Modeling Task Force reported in 2003 has led to a new Task Force, jointly convened with the Society for Medical Decision Making, and this series of seven articles presents the updated recommendations for best practices in conceptualizing models; implementing state-transition approaches, discrete event simulations, or dynamic transmission models; and dealing with uncertainty and validating and reporting models transparently. This overview article introduces the work of the Task Force, provides all the recommendations, and discusses some quandaries that require further elucidation. The audience for these articles includes those who build models, stakeholders who utilize their results, and, indeed, anyone concerned with the use of models to support decision making.

Keywords: best practices, guidelines, methods, modeling.

Introduction

The use of models to support scientific endeavor is ubiquitous. Models are essentially communication tools that allow the complexity of a given system to be reduced to its essential elements. As such, models represent a simplification of reality and modeling is necessarily a reductionist methodology. This series of articles [1–6] relates to the application of modeling techniques to the area of health care decision making. This can include not only clinical decision models, designed to assist individual clinicians and their patients with decisions regarding their care, but also policy decision models, designed to more broadly evaluate whether particular health care technologies should be provided within the context of an organized health care system. These latter types of models are characterized by the need to explicitly include a budget constraint and therefore necessarily include both resource consequences and health outcomes in a health economic evaluation framework. Therefore, while these articles focus on modeling, drawing broadly on general methods, and apply beyond health economic assessment, the series necessarily touches on many aspects pertaining to economic evaluation.

Although the use of models to inform policy decision about the use of health technologies has been increasing [7], there remain strong concerns with their credibility [8,9]—a concern that is not unique to our field [10–12]. To help allay these concerns, several guidelines for good practices in modeling have been issued [13]. In 2000, the International Society for Pharmacoeconomics and Outcomes Research Task Force on Good Research Practices in Modeling Studies was created and after an extensive process of consultation, it issued its report in 2003. This report defined a model and its purpose, laid out the approach to evaluating a model, and described the Task Force's consensus regarding the attributes that characterize a good model, in terms of structure, data, and validation [14].

In the intervening years, the range of modeling techniques for medical and economic decision modeling has advanced substantially [15,16], as modelers in our discipline have become acquainted with more sophisticated modeling techniques. The relative simplicity of cohort-based models is still an attraction for many modelers

Conflict of Interest Statement: All members of the Task Force include modeling activities among their professional practices and in many cases these are funded by organizations with interest in the results. Some members of the Task Force own intellectual property relating to models. Many of the points made in these articles are supported by citations to articles authored by Task Force members. The Task Force took pains to avoid commercial considerations influencing the deliberations or the content of these articles.

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and decision makers. Nevertheless, there are situations when the decision problem demands taking extensive history into account and individual-level microsimulation methods are required [17]. One approach to implementing individual-level simulations is an adaptation of methods borrowed from engineering and operations research, which frames the problem in terms of the states individuals can be in and the events that can happen to them and their consequences [18,19]. These individual-level and stochastic techniques present additional challenges and require somewhat different approaches to modeling. Infectious disease modeling is a further approach that can handle interaction between individuals, and this dynamic form of modeling has also developed its own set of challenges and techniques [20]. The methods for simultaneously handling multiple parameters of a model and addressing uncertainty have also progressed significantly, and the approach to validation of models has received increasing attention.

Background to the Task Force

To ensure that the guidelines for good practices in modeling remain current, effective, and helpful, ISPOR judged it necessary to update them to accord with the newer methods being used in practice. As a result, a new Good Research Practices in Modeling Task Force was constituted to build on the excellent work done by the initial one from 2000 to 2003. To bring to bear the broadest expertise in this area, the Society for Medical Decision Making (SMDM) was invited to join the effort. The Task Force was asked to provide guidelines for designing the approach, selecting a technique, implementing and validating the model, parameterizing the inputs and assessing uncertainty, and using the resulting tool to inform decision making.

Early in 2010, the ISPOR and SMDM boards appointed the cochairs and consented to the proposed members of the Task Force. The Task Force convened expert developers and experienced users of models from academia, industry, and government, with representation from many countries. Given the breadth of the field at this point, a decision was made to divide the topic into six components and leads were appointed for each working group. Three of these topics covered the aspects felt to be general to all models in our field: conceptualization of a model, estimation of model parameters and handling of uncertainty, and validation of models and concerns for transparency. The other three dealt with specific techniques in common use: state-transition modeling, discrete event simulation, and dynamic transmission models. While there are undoubtedly topics of interest that are not addressed in these six articles, it was felt that these reports would cover the major areas that are at a stage of development appropriate for issuing guidelines.

The Task Force held its first meeting via teleconference on May 7, 2010, and hosted information sessions during 2010 at the ISPOR 15th Annual International Meeting in Atlanta, GA, at the 32nd Annual Meeting of the Society for Medical Decision Making in Toronto, ON, and at the ISPOR 13th Annual European Congress in Prague. Over numerous teleconferences, and occasional in-person meetings, the working groups produced draft reports for each section. Although the groups referred to the literature frequently, there was no systematic attempt to review it. Although substantiated as much as possible, the recommendations that emerged represent the opinions of the experts in the Task Force. These were not forced to consensus, and had substantial differences of opinion remained, they would have been documented as such. The draft recommendations were discussed by the Task Force as a whole in a meeting held in Boston in March 2011 and subsequently edited and circulated to the Task Force members in the form of a survey where each one was asked to agree or disagree with a recommendation, and if the latter, to provide the reason(s). Each group received the results of the survey and endeavored to address all rejections. In the end, there were no dissenting positions. The final drafts of the articles were posted on the ISPOR and SMDM Web sites for comment by the general membership of the societies.

A second group of experts—again, with broad representation of modelers and users of models—was invited to formally review the articles. Their comments were addressed by each working group, and revised drafts of each article were circulated to the Task Force as a whole. After receiving any additional comments and considering any further revisions, the final version of each article was prepared. (A copy of the original draft of this article, as well as the reviewer comments and author responses, is available at the ISPOR Web site: http://www.ispor.org/workpaper/Modeling-Good-Research-Practices-Overview.asp.) A summary of these articles was presented at a plenary session at the ISPOR 16th Annual International Meeting in Baltimore, MD, in May 2011, and again at the 33rd Annual Meeting of the Society for Medical Decision Making in Chicago, IL, in October 2011. These articles are jointly published in the Societies' respective journals, *Value in Health* and *Medical Decision Making*.

The audience for this set of articles encompasses both the researchers who develop models and those who use models to inform decisions. Investigators charged with reviewing others' models should find the guidelines helpful in their assessments. Even those affected by the decisions informed by models and those who report on the results of modeling analyses should find these recommendations useful.

It is important to note, however, that these articles are not intended as primers on their subjects. General textbooks and tutorial articles covering these techniques exist [21–25], and specific publications that address the methods are cited throughout. By the same token, these articles are not methodological treatises that address every aspect of a particular topic. Instead, they propose a set of best practices for modeling. They focus on the types of models and approaches taken today, not on nascent ones or even on those whose use is currently being debated (e.g., model averaging [26]). Further development of the methods will require that these guidelines be updated in due course.

Although it may not be possible to follow the entire set of recommendations in every modeling exercise, these do represent what the Task Force felt to be the best practices for modeling today and each recommendation should be given serious consideration. Nevertheless, the guidelines are not intended for use as a checklist to be followed unthinkingly. We encourage modelers who believe that they should not, or cannot, follow a particular recommendation to document this divergence, its rationale and likely consequences for their model, and its results and the inferences that will guide decision makers.

This overview article presents the process and methods of the Task Force and gives the reader an orientation to the contents of each of the detailed articles. It also provides all the recommendations of the Task Force, but without their detailed rationales and caveats. General quandaries and gaps in knowledge not covered in the other articles are addressed in the final section, along with some thoughts on developments in this area.