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Conceptualizing a Model: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-2

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ABSTRACT

The appropriate development of a model begins with understanding the problem that is being represented. The aim of this article was to provide a series of consensus-based best practices regarding the process of model conceptualization. For the purpose of this series of articles, we consider the development of models whose purpose is to inform medical decisions and health-related resource allocation questions. We specifically divide the conceptualization process into two distinct components: the conceptualization of the problem, which converts knowledge of the health care process or decision into a representation of the problem, followed by the conceptualization of the model itself, which matches the attributes and characteristics of a particular modeling type with the needs of the problem being represented. Recommendations are made regarding the structure of the modeling team, agreement on the statement of the problem, the structure, perspective, and target population of the model, and the interventions and outcomes represented. Best practices relating to the specific characteristics of model structure and which characteristics of the problem might be most easily represented in a specific modeling method are presented. Each section contains a number of recommendations that were iterated among the authors, as well as among the wider modeling taskforce, jointly set up by the International Society for Pharmacoeconomics and Outcomes Research and the Society for Medical Decision Making.

Keywords: conceptualization, best practices, methods, modeling.

Background to the Task Force

A new Good Research Practices in Modeling Task Force was approved by the ISPOR Board of Directors in 2010, and the Society for Medical Decision Making was invited to join the effort. The Task Force cochairs and members are expert developers and experienced model users from academia, industry, and government, with representation from many countries. Several teleconferences and hosted information sessions during scientific meetings of the Societies culminated in an in-person meeting of the Task Force as a whole, held in Boston in March 2011. Draft recommendations were discussed 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 each recommendation, and if the latter, to provide the reasons. Each group received the results of the survey and endeavored to address all issues. The final drafts of the seven articles were available on the ISPOR and Society for Medical Decision Making Web sites for general comment. A second group of experts was invited to formally review the articles. The comments received were addressed, and the final version of each article was prepared. (A copy of the original draft article, as well as the reviewer comments and author responses, is available at the ISPOR Web site: http://www.ispor.org/workpaper/Conceptualizing-A-Model.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*. Other articles in this series [1–6] describe best practices for building and applying particular types of models, addressing uncertainty, and ensuring transparency and validity. This article addresses best practices for conceptualizing models. Examples are cited throughout, without implying endorsement or preeminence of the articles referenced, and an appendix in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2012.06.016 provides a detailed example.

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Introduction

Perhaps no other word in the policy analyst's lexicon inspires greater confusion among lay observers than the word "model." Most would agree that a model is a simplified representation of reality. Beyond that description, the term may lead in various directions. The Task Force has agreed that for its context, a model's purpose is to inform medical decisions and health-related resource allocation questions. Thus, this article is restricted to models as normative decision-making aids, and recommendations apply most directly to models that structure evidence on clinical and economic outcomes in a form that helps decision makers choose from among competing courses of action and allocate limited resources. It excludes from consideration several useful, scientifically sound modeling forms. For example, regression models lie outside the scope of this report. While regression is of critical importance in generating inputs for models, it is a descriptive method that explains and predicts the relationship between inputs and outputs. A regression model, however, cannot give normative direction regarding policy options. An infectious disease transmission model is beyond this report's scope if it is about what epidemics do but is within scope if it uses that information to evaluate what can be done to affect epidemics.

This article describes two distinct components of the modeling process (Fig. 1): the problem conceptualization, which converts knowledge of the health care process or decision into a representation of the problem, followed by model conceptualization, in which the components of the problem are represented by using a particular analytic method (1 in figure). The model's conceptual representation will usually direct the decision as to which modeling technique to use (2, 3, and 4 in figure). This article covers the process up to technique selection.

Conceptualizing the Problem

Statement of problem and objectives

Before constructing a model, it is important to be clear about the nature of the problem under consideration and the project objectives, which will usually fall in one of several categories:

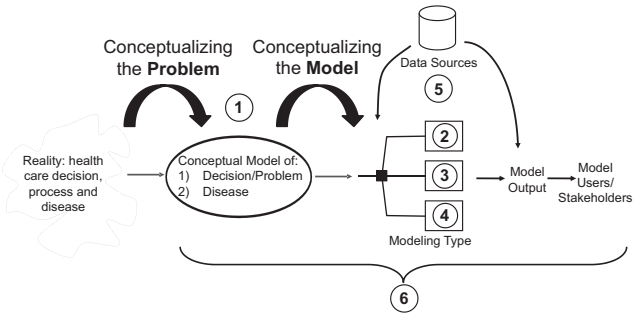

Fig. 1 – Development and construction of a model. The numbers in the figure represent the methods papers in this series: 1) the conceptualization paper, which describes the conceptualization of both the problem and the model; 2), 3) and 4) which describe the three main kinds of modeling methods addressed, including state transition model, discrete event and agent based models and dynamic transmission models; 5) parameter estimation used to calibrate the models, and 6) the transparency and validation of a model. See text for details.

- **Guide clinical practice**

A study involving 6 models designed to support the recommendations of the US Preventive Health Services Task Force (USPSTF) on mammography screening [7] will be used as an ongoing example for how the objectives, scope, and policy context of a modeling exercise are described (see Box).

- **Inform a funding decision or reimbursement rate for a new intervention**

For example, the cost-effectiveness of multidisciplinary heart failure clinics was evaluated to guide the Ontario Health Technology Advisory Committee's decision regarding their widespread diffusion [8].

- **Optimize use of scarce resources**

For example, a model of the US organ allocation system was developed to guide policy around the use of livers for transplantation [9].

- **Guide public health practice**

For example, a model was developed to assess the cost-effectiveness of universal vaccination for epidemic influenza [10].

The problem's nature will have important implications for model structure, data requirements, analytic strategy, and reporting. Components of the problem, including factors such as disease or condition, patient populations, diagnostic or therapeutic actions and interventions, and outcomes, will be addressed below.

Although the problem's general nature may seem clear, there is often some ambiguity leading to variation in understanding of the problem by stakeholders. For example, while it seems clear that a model of a genetic test aiding patient selection for adjuvant breast cancer therapy [11] was developed to inform the decision whether to cover it, it subsequently became apparent that the problem could be understood in several ways. One was to ask what the consequences of a positive decision were likely to be in practice regarding health outcomes and costs. A model answering this question would represent practice regarding clinical risk stratification, the new test's use, and chemotherapy use conditional on test results. The potential benefits of testing are then compared with current practice. A second way is to ask about the optimal circumstances of test use to maximize patient outcomes. A model answering this question must explore benefits of testing in a wide variety of risk groups and treatment options conditional on test results, irrespective of how the test is currently used.

Early specification of the decision problem and modeling objectives will improve model building efficiency. Defining the modeling objective is an iterative process, and specific objectives may change as understanding of the problem deepens.

Best practices

II-1 The modeling team should consult widely with subject experts and stakeholders to assure that the model represents disease processes appropriately and adequately addresses the decision problem.

It is important to read and consult widely and refine the problem definition early in model development. Existing models addressing related problems should be reviewed. The clinical and policy literature describing the problem should be understood by the modeling team. Experts, including clinical, epidemiologic, policy, and methodological, should be consulted. Clinical experts are central in developing a representation of clinical practice. Policy