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Development and Validation of a Microsimulation Economic Model to Evaluate the Disease Burden Associated with Smoking and the Cost-Effectiveness of Tobacco Control Interventions in Latin America

Andres Pichon-Riviere, MD, MSc, PhD[1,2,], Federico Augustovski, MD, MSc[1,2], Ariel Bardach, MD, MSc[1], Lisandro Colantonio, MD, MSc[1], for the Latinclen Tobacco Research Group[3]*

[1]*Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina;* [2]*School of Public Health, University of Buenos Aires, Buenos Aires, Argentina;* [3]*LatinCLEN Tobacco Research Group: Argentina (Institute for Clinical Effectiveness and Health Policy): Andres Pichon-Riviere, MD, MSc, PhD, Adolfo Rubinstein, MD, MSc, PhD, Federico Augustovski, MD, MSc, Ariel Bardach, MD, MSc, Lisandro Colantonio, MD, Andrea Alcaraz, MD, Sebastian Garcia-Marti, MD, Luz Gibbons, MSc; Argentina (Clinical Epidemiology Unit–University of Tucuman): Evelina Chapman, MD, MSc, Ramon Gonzalez, MD, Sara Aulet, MD; Bolivia (Clinical Epidemiology Unit–San Andres University): Maria del Pilar Navia Bueno, MD, MSc, Lijia Elizabeth Avilés Loayza, MD, MSc; Brazil (Universidade Federal do Rio de Janeiro): Antonio Jose Ledo Alves da Cunha, MD, MPH, PhD, Alberto José de Araujo, MD, MSc; Chile (Research and Training Center in Clinical Epidemiology–Frontera University): Sergio Muñoz, MS, PHD, Carlos Vallejos, MD, MS; Colombia (Clinical Epidemiology & Biostatistics Unit–Pontificia Universidad Javeriana): Juan Manuel Lozano Leon, MD, MSc, Esperanza Peña Torres, RN, MSc; Mexico (Clinical Epidemiology Unit–Instituto Mexicano del Seguro Social–Faculty of Medicine): Fernando Carlos Rivera, MSc, Araceli Camacho Chairez, MSc, Araceli Aguirre Granados, Patricia Clark Peralta, MD, MSc, PhD; Peru (Clinical Epidemiology Unit–Universidad Peruana Cayetano Heredia): Leandro Huayanay Falconi, MD, MSc, Cezar Loza Munárriz, MD*

A B S T R A C T

Objective: To describe the development and validation of a health economic model (HEM) to address the tobacco disease burden and the cost-effectiveness of smoking cessation interventions (SCI) in seven Latin American countries. **Methods:** The preparatory stage included the organization of the research network, analysis of availability of epidemiologic data, and a survey to health decision makers to explore country-specific information needs. The development stage involved the harmonization of a methodology to retrieve local relevant parameters and develop the model structure. Calibration and validation was performed using a selected country dataset (Argentina 2005). Predicted event rates were compared to the published rates used as model inputs. External validation was undertaken against epidemiologic studies that were not used to provide input data. **Results:** Sixty-eight decision makers were surveyed. A microsimulation HEM was built considering the availability and quality of epidemiologic data and relevant outcomes conceived to suit the identified information needs of decision makers. It considers all tobacco-related diseases (i.e., heart, cerebrovascular and chronic obstructive pulmonary disease, pneumonia/influenza, lung cancer, and nine other neoplasms) and can incorporate individual- and population-level interventions. The calibrated model showed all simulated event rates falling within ± 10% of the sources (-9%–+5%). External validation showed a high correlation between published data and model results. **Conclusions:** This evidence-based, internally and externally valid HEM for the assessment of the effects of smoking and SCIs incorporates a broad spectrum of tobacco related diseases, SCI, and benefit measures. It could be a useful policy-making tool to estimate tobacco burden and cost-effectiveness of SCI.

Keywords: cost-effectiveness, cost-utility, disease burden, economic model, Latin America, Monte Carlo microsimulation, smoking cessation interventions, tobacco, validation.

Introduction

Smoking is the single most preventable cause of disease and death worldwide, and this burden is increasingly shifting from upper to lower and middle-income countries. In the year 2000 there were 4.83 million premature tobacco-related deaths [1], and this number is expected to grow to 10 million per year by 2030 [2,3]. Currently half of the current tobacco-attributable deaths occur in high-income countries [1,3]; however, by the year 2030 7 out of 10 of these deaths are expected to occur in developing countries. This represents one out of six of all the deaths around the world [3].

Although the Framework Convention Tobacco Control from World Health Organization has been signed by almost every country in the Latin American region [4], tobacco control policies are still scarce in these countries.

The lack of quality information related to the health and economic consequences of tobacco use in our region is an important barrier for the implementation of evidence-based tobacco control policies. This has led to a biased assessment by policy makers, resulting in a distorted prioritization of health policies where tobacco control interventions are considered less urgent than action on other diseases [5].

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

* *Address correspondence to:* Andres Pichon-Riviere, Institute for Clinical Effectiveness and Health Policy, University of Buenos Aires, Arevalo, 1457 (1414), Buenos Aires, Argentina.

E-mail address: pichon-riviere@post.harvard.edu.

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Model-based health economic evaluations (HEEs) are widely accepted as decision-making tools [6] that can provide valuable information for the optimization of health resource allocation [7]. Although in many developed countries this "fourth hurdle" based on health economic evidence is required to shape health policies [8], there is still little experience in Latin America [9]. This project constitutes a collaboration among seven Latin American countries that aims to provide relevant evidence to inform tobacco control policies.

The LatinCLEN Tobacco Research Group, an international and interdisciplinary network, is composed of eight research units from the Latin American chapter of the International Clinical Epidemiology Network in Argentina, Bolivia, Brazil, Chile, Colombia, Mexico, and Peru. The specific aims for this project were to select and develop the most suitable methodologic framework, as well as to elaborate a common health economic model to estimate the smoking-related disease burden and the cost-effectiveness of smoking cessation interventions (SCIs). In this article we present the details of the model's development, structure, and validation using data inputs from one of the participating countries.

Material and Methods

The final model structure and its inputs were agreed after two stages; the preparatory stage and the development stage.

Preparatory stage

Organization of a research network to monitor the model building process and to ensure the generalizability to all participant countries. The LatinCLEN Tobacco Research Group was formed in 2004. The group designed two surveys that were completed in each country to 1) evaluate the availability, cost, and current coverage policies of SCIs; and 2) assess the availability and the quality of relevant information to be incorporated in each country-specific analysis (e.g., local epidemiology and cost of smoking-related diseases).

Performance of a rapid systematic review of existing health economic evaluations regarding tobacco cessation strategies. Forty-four individual studies and seven reviews published between 1984 and 2003 (search data up to November 2004) were critically assessed.

Design and administration of a survey to health decision makers to explore country-specific information needs when deciding on the implementation and coverage of SCIs. As future users of the HEE, relevant decision makers from the different health sectors in the seven participant countries defined the key aspects to be considered (e.g., relevant time horizon and relevant perspective) and the outcomes to be reported (e.g., the number of cases prevented, life years gained, or quality-adjusted life years [QALYs]) in the HEE.

Development stage

This stage involved the following tasks: 1) definition of the methodology for the information source selection and parameter incorporation; 2) development of the model structure; and 3) calibration and validation of the model.

The research group used Email and a Web-based platform to exchange documents, outlines, and ideas. The development of the model was completed in three phases: 1) based on information obtained in the preparatory stage, a first draft of the health economic model was sent to the participating countries for feedback, including the basic structure, disease states to be incorporated, and main assumptions; 2) three consultation rounds for refining the model description and structure; and 3) a face-to-face research meeting carried out in Buenos Aires, Argentina, during November 2006 where participants agreed on the final version of the HEE.

Excel (Professional Edition 2003, then updated to version 2007, Microsoft Corp., Redmond, WA) with Visual Basic Macros (version 6.3, Microsoft Corp., Redmond, WA) was selected as the model platform to easily share the information. A software package was installed to improve the original Excel's random number generator function [10,11].

Results

Preparatory stage

The surveys and data retrieved in each country showed that implementation of tobacco control interventions was a relevant issue in the region. Sixty-eight decision makers (9–10 from each of the participating countries) completed the survey. The majority of decision makers belonged to the public (56%) or the social security (25%) health care sector and 80% considered that the lack of coverage for SCI adversely affected the prevalence of smoking in their institutions and countries. Ninety-three percent considered that this level of coverage should be increased and 83.3% believed that SCI should be included in the national lists or basket of mandatory coverage in their countries. When asked about what would be the most relevant information on the interventions needed when having to decide their incorporation into the health system, most of the decision makers identified the cost per QALY, cost per life-year saved, and budget impact information. The decision makers also mentioned a wide range of interventions that they considered should be evaluated for coverage, from population-wide interventions to pharmacological treatments, so the HEE had to be able to include all these aspects. On the other hand, the survey of epidemiologic data showed that the availability and quality of information in the region was very heterogeneous and poor, especially with regard to the incidence of events, thus making it necessary to design and harmonize a methodology to estimate locally relevant information in each country. All the results obtained during this first stage strongly influenced many of the decisions made later and shaped the type and structure of the model to be developed.

Development stage

Information source selection and parameter incorporation. We defined a decision rule that would establish a priority order among the possible data sources to populate the model: 1) use good quality local (country-specific) sources when available [12-14]; 2) use international sources when local data were unavailable or poor and when the parameter was considered transferable from other settings; or 3) derive or estimate the parameter from the best available local data when international sources were considered nontransferable.

Special attention was paid to the estimation of baseline disease event incidence in nonsmokers because these data are keys to the generalizability of the model. Given the low availability of information encountered in the region, we defined a common methodology, anchored on national health statistics, to derive these parameters from mortality data. This methodologic assumption linking mortality to incidence data is a widely used assumption in epidemiologic and health economic models, used by the World Health Organization in tools such as DisModII or the WHO-