

**FORUM**

**SMDM**  
Society for Medical Decision Making

**MODELING GOOD RESEARCH PRACTICES  
(THE GOOD, THE BAD, AND THE AMBIGUOUS)**



**ISPOR TASK FORCES**

**ISPOR**  
INTERNATIONAL SOCIETY FOR PHARMACEUTICAL OUTCOMES RESEARCH

**ISPOR-SMDM Joint Modeling Good Research Practices Task Force**  
**Tuesday, 9 November 2010 8:30-9:30 AM**

**SMDM**  
Society for Medical Decision Making

**ISPOR-SMDM Joint Task Force**  
**Good Modeling Research Practices**

**J. Jaime Caro MDCM, FRCPC, FACP**  
Chair, ISPOR-SMDM Modeling Good Research Practices Task Force  
Senior Vice President, Health Economics, United BioSource Corporation  
Lexington, MA, USA

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INTERNATIONAL SOCIETY FOR PHARMACEUTICAL OUTCOMES RESEARCH

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**Moderator & Speaker**



**J. Jaime Caro MDCM, FRCPC, FACP**  
Chair, ISPOR-SMDM Modeling Good Research Practices Task Force  
Senior Vice President, Health Economics, United BioSource Corporation  
Lexington, MA, USA

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**Task Force Co-Chairs**

 **Karen Kuntz ScD, SMDM Issues in Methodology Working Group Chair, and Professor, University of Minnesota School of Public Health, Minneapolis, MN USA**

 **Andrew Briggs DPhil, Lindsay Chair in Health Policy & Economic Evaluation, Public Health & Health Policy, University of Glasgow, Glasgow, Scotland UK**

 **Uwe Siebert MD, MPH, MSc, ScD, SMDM Board representative-Issues in Methodology Working Group Co-Chair, Professor of Public Health, UMIT – Univ. of Health Sciences, Medical Informatics & Technology, Hall i.T, Austria**

 **J. Jaime Caro MDCM, FRCPC, FACP, Adjunct Professor Medicine & Epidemiology & Biostatistics, McGill University, Montreal, Quebec, Senior Vice President, Health Economics, UBC, Lexington, MA, USA**

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**Establishment**

- January 2003: ISPOR Modeling Good Research Practices Task Force Report published in *Value in Health*
- 2008: ISPOR Health Science Policy Council recommends an update of the 2003 Modeling Task Force Report .
- November 2009: Jaime Caro agrees to submit a Modeling Good Research Practices proposal to ISPOR Board of Directors
- March 25, 2010: Modeling Task Force approved by ISPOR board
- May 1, 2010: Joint ISPOR-SMDM Modeling Task Force approved by SMDM board
- May 18, 2010: 1<sup>st</sup> Task Force meeting at ISPOR, Atlanta
- May 24, 2010: 1<sup>st</sup> Task Force Working Group Chair Teleconference
- June 2010-present: Six Task Force Working groups formed and developing guidelines.


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**Timeline**



Activity:	Deadline:
Define papers to be included in this Task Force Report, lead authors, and additional members	May 6, 2010
Identify authors for each paper included in the Task Force Report	May 15, 2010
Develop consensus on the content of each paper & draft detailed outline of each paper	August 1
Finalize detailed outline of each paper & assign sections of each paper to Task Force members	September 15
First draft of each paper completed	October 15
Overview of papers presented at SMDM, ISPOR Congresses	October-November
Second draft of papers prepared and face-to-face meeting to discuss contentious issues	March 2011
Draft papers submitted to Reviewer Group and ISPOR membership for comments	April 15, 2011
Draft papers presented at ISPOR Forum at 16th Annual International Meeting (Baltimore) for comment	May 23, 2011
Draft papers revised based on comments	June 2011
Papers submitted to <i>Value in Health</i> and <i>MDM</i>	July 2011

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## Seven Papers

1. Modeling Good Research Practices Task Force Overview, Issues, and Preferred Practices
2. Conceptual Modeling
3. Discrete Event Simulation
4. State-Transition Modeling
5. Dynamic Transmission Modeling
6. Parameter Estimation & Uncertainty in Models
7. Transparency and Validation of Models.

## Review Process

- Peer review group will be constituted
  - Broad representation
  - Reviewed/approved by journal editors
  - Peer review comments documented as well as responses
- Societies' members review & comment
- Editors review.



## Working Groups & Status




## 2. Conceptual Modeling




**Chair**  
**Mark Roberts MD**, Professor and Chair, Department of Health Policy & Management, University of Pittsburgh, Pittsburgh, PA, USA

**Group Members**  
**Murray Krahn MD, MSc**, Professor, Medicine, University of Toronto, Toronto, Ontario, Canada  
**A. David Paltiel PhD**, Professor and Acting Division Head, Yale University, Yale School of Public Health, New Haven, CT, USA  
**Michael Chambers MSc, MA**, Health Economics, GlaxoSmithKline, Uxbridge, England, United Kingdom  
**Phil McEwan PhD**, Managing Director, CRC, Cardiff, England, United Kingdom  
**Louise Russell PhD**, Chair, Division on Health Policy and Professor, Department of Economics, Institute for Health, Health Care Policy and Aging Research, Rutgers University, New Brunswick, NJ USA

## 2. Conceptual Modeling

- **Current Status**
  - Two TCs
  - Basing paper on case(s): HIV, Cancer
  - TCs scheduled q3wks
- **Issues**
  - Start with data vs. start with disease concept
  - Must be fit for purpose: address specific question vs. general model
    - about models built for the purpose of making a policy decision
  - Matrix of types of questions & modeling techniques
  - How do data affect the design?
- **Detailed Outline Next**




## 3. Discrete Event Simulation




**Chairs**  
**James Stahl MD, CM, MPH**, Senior Scientist MGH Institute for Technology Assessment & Assistant Professor of Medicine, Harvard Medical School, Boston, MA, USA




**Jonathon Karnon PhD**, Professor in Health Economics, University of Adelaide, Adelaide, South Australia

**Group Members**  
**Jürgen Möller MSc**, Vice President, Modeling, United BioSource Corporation, Eslov, Sweden  
**Javier Mar MD**, Clinical Management Unit, Hospital Alto Deba, Mondragon, Spain  
**Alan Brennan PhD**, Section Director, University of Sheffield, Sheffield, England, United Kingdom



 **3. Discrete Event Simulation**

- **Current Status**
  - Two TC s
  - Detailed outline complete
  - Draft sections in review
- **Issues**
  - For what problems is DES best?
  - Disease course vs. constrained resource models
  - Data issues specific to DES
  - Terminating & non-terminating analyses
  - Variance reduction techniques
  - Implementation & software
  - Presentation of DES
  - Common traps & errors
- **Full first draft Next**




 **4. State-Transition Modeling**

 **Chairs**  
**Karen Kuntz ScD**, Task Force Co-Chair, Professor, University of Minnesota School of Public Health, Minneapolis, MN USA


 **Uwe Siebert MD, MPH, MSc, ScD**, Task Force Co-Chair, Professor of Public Health, UMIT – Univ. of Health Sciences, Medical Informatics & Technology, Hall i.T, Austria


**Group Members**  
**Oguzhan Alagoz PhD, MS**, Assistant Professor, University of Wisconsin-Madison, College of Engineering, Department of Industrial & Systems Engineering, Madison, WI USA  
**Doug Owens MD, MS**, Professor of Medicine, CHP/PCOR, Stanford University, Stanford, CA USA  
**David Cohen MD**, Director of Cardiovascular Research, Saint Luke's Mid America Health Institute, Kansas City, MO USA  
**Beate Jahn PhD**, Researcher, UMIT – Univ. of Health Sciences, Medical Informatics & Technology, Hall, i.T, Austria  
**Ahmed Bayoumi MD, MSc**, Scientist, Centre for Research on Inner City Health, St. Michael's Hospital, Toronto, Canada




 **4. State-Transition Modeling**


- **Current Status**
  - Two TC s
  - Detailed outline complete
- **Issues**
  - For what problems is state-transition approach best?
  - Cohort vs. individual implementation
  - Data issues specific to state-transition
  - Structural aspects specific to state-transition
  - Presentation of state-transition models
  - Technical issues (efficiency, reduction of "noise"/variance)
- **First drafts of text Next**




 **5. Dynamic Transmission Modeling**


 **Chair**  
**John Edmunds PhD, MSc**, Professor of Infectious Disease Modelling, London School of Hygiene and Tropical Medicine, London, England, United Kingdom

**Group Members**  
**Richard Pitman PhD**, Senior Health Economist, Oxford Outcomes, Ltd., Oxford, England, United Kingdom  
**Maarten Jacobus Postma PhD**, Professor in Pharmacoeconomics, Groningen University Institute for Drug Exploration, Groningen, Netherlands



 **5. Dynamic Transmission Modeling**

- **Current Status**
  - One TC
- **Issues**
  - For what problems is dynamic transmission approach best?
  - Focus on infectious diseases
  - Features specific to dynamic transmission
    - Mixing matrix
    - Calibration of equations
  - Presentation of dynamic transmission models
- **Detailed outline Next**




 **6. Parameter Estimation & Uncertainty**


 **Chair**  
**Andrew Briggs DPhil**, Lindsay Chair in Health Policy & Economic Evaluation, Public Health & Health Policy, University of Glasgow, Glasgow, Scotland UK


**Group Members**  
**Milton Weinstein PhD**, Professor Health Policy & Management, Harvard School of Public Health, Boston, MA USA  
**Mark Sculpher PhD, MSc**, Professor, University of York, Heslington, York, England, United Kingdom  
**Elizabeth Fenwick PhD, MSc**, Lecturer in Health Economics, University of Glasgow, Glasgow, Scotland, United Kingdom  
**Jonathon Karnon PhD**, Professor in Health Economics, University of Adelaide, Adelaide, South Australia  
**A. David Paltiel PhD**, Professor and Acting Division Head, Yale University, Yale School of Public Health, New Haven, CT, USA






 **6. Parameter Estimation & Uncertainty**

- **Current Status**
  - Three TC s
  - Detailed outline complete
  - Draft sections in review
- **Issues**
  - Why does uncertainty matter?
  - Types of uncertainty
  - Role of the decision maker
  - Role of PSA and traditional SA
  - Estimation and Choice of distribution for PSA
  - When can structural uncertainty be parameterised?
  - Correlating parameters and calibration
  - Decision uncertainty & reporting
- **Full first draft Next**





 **7. Model Transparency and Validation**


**Chair**  
**John Wong** MD, Chief, Division of Clinical Decision Making, Informatics and Telemedicine; GMA Physician and Professor, Tufts University School of Medicine, Boston, MA, USA  
**David Eddy** PhD, MD, Founder and Medical Director, Archimedes, Inc., San Francisco, CA USA

● **Team**  
**Joel Tsevat** MD, MPH Professor of Medicine and Associate Dean for Clinical and Translational Research, University of Cincinnati, College of Medicine, Cincinnati, OH USA  
**William Hollingworth** PhD, Reader in Health Economics, University of Bristol, Bristol, UK  
**Kathy McDonald** MM, Executive Director, Senior Research Scholar, Center for Health Policy / Center for Primary Care and Outcomes Research, Stanford, CA USA



 **7. Model Transparency and Validation**

- **Current Status**
  - Two TC s
  - Very detailed outline complete
- **Issues**
  - Why is validation important?
  - Must do vs. desirable to do
  - General vs. specific validation
  - Face validity: necessary? Sufficient?
  - Role of peer review
  - Internal validity: use quality assurance/control methods?
  - External validation
  - Predictive ability
- **First drafts of text Next**



Review Process