

Credible Practice of Modeling and Simulation in Healthcare

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INTRODUCTION

Leading government, health, academic and private institutions around the world recognize that computational methods have tremendous potential to support clinical research and decision making in healthcare [1-5]. To realize these goals, it is imperative to establish guidance and standards that can enable reliable use of computational modeling in the practice of healthcare and translational research [6,7]. To this end, we formed the Committee on Credible Practice of Modeling & Simulation in Healthcare (hereafter referred to as the Committee) to begin addressing these issues. The Committee is part of the Interagency Modeling and Analysis Group (IMAG) and the Multiscale Modeling (MSM) Consortium [8]. The IMAG and MSM are organized by the National Institutes of Health (NIH) in collaboration with ten other government agencies and many academic researchers to promote the advancement of computational methods in healthcare practice and translational research. This presentation will discuss the Committee's efforts to advance in silico methods in healthcare.

Repeatability

Inclusive of a variety of procedures

Glossary of Terms

Mission: To establish credible practice guidelines, consistent terminology and a model certification process as well as to demonstrate workflows and identify new areas of research for reliable development and application of M&S in healthcare practice and research.

ABOUT THE COMMITTEE

& Multiscale Modeling (MSM) Consortium NIH FIDA WASA CO USDA NITACS LA R P A NITACS

Stakeholders

Primarily driven by research initiatives under the

IMAG and MSM

The Committee strives for balanced representation of interests and perspectives of different stakeholders, such as clinicians and experts in modeling, simulation, development and evaluation of medical products, and biomedical engineering.

Engaging diverse organizations Integration of multiple disciplines **Mathematics** Government Life sciences Academia Engineering Hospitals Computing Medicine Diagnosis Reporting Clinical research Standards Validation Disease pathway Verification Drug development

Multi-faceted Approach



Committee Structure

END PRODUCTS

Primary Deliverables

- Guidelines for Credible Practice of M&S in Healthcare
- Proposed model certification process
- Identify new areas of research to advance I & II

Synergistic Initiatives

Application across many areas

Promoting Good Practice

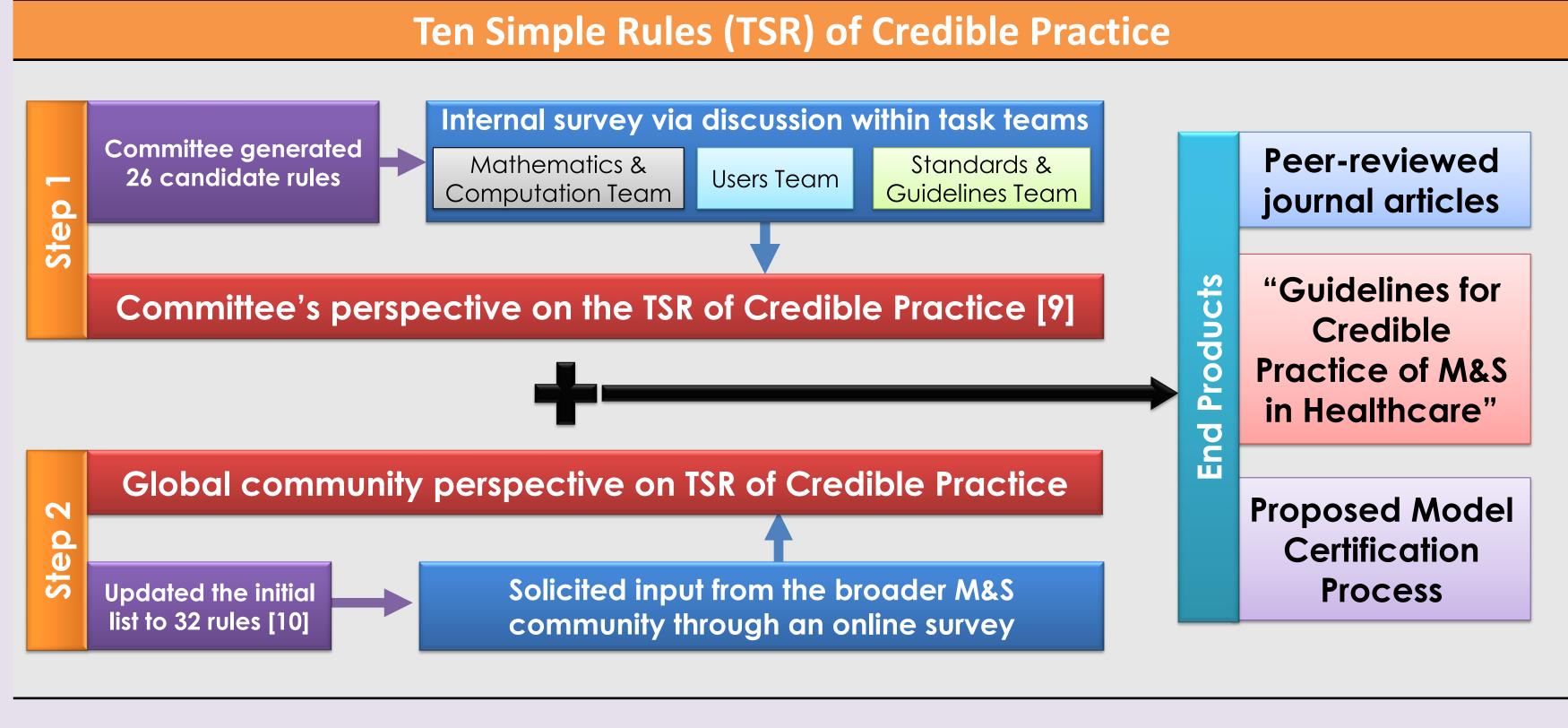
Develop consistent terminology among stakeholders

Promote good practice through webinars, presentations and professional engagements

Demonstrate Workflows

Document different strategies to achieve credible practice throughout the entire M&S life-cycle - concept, coding to the numerical implementation

METHODS



Implementation of Synergistic Initiatives

Glossary of Terms - Curation of definitions of various M&S terms on the Committee's wiki page [11] based on dictionary definition, committee definition, domain-specific usage, as well as members' notes and discussions. sensitivity

Promote Good Practice - Committee members constantly serve as stewards of promoting the good practice through various professional engagements and public presentations.

Demonstrate Workflows - Engaged the community via public forum discussions [12] and webinars [13] to share examples and unique ideas to demonstrate workflows of credible practice of M&S in healthcare.

Current status: Analysis of the global survey data and consolidation with the Committee's perspective results are still in progress. However, the following four high priority rules have been identified by both the Committee and broader M&S stakeholder community.

RESULTS AND **FORWARD** WORK

Rule Description **Define context clearly** Develop and document the subject, purpose, and intended use(s) of the model or simulation. Employ relevant and traceable information in the development or operation of a model or Use appropriate data simulation. **Evaluate within** Verification, validation, uncertainty quantification, and sensitivity analysis of the model or simulation are accomplished with respect to the reality of interest and intended use(s) of the context

Restrictions, constraints, or qualifications for or on the use of the model or simulation are

available for consideration by the users or customers of a model or simulation.

The Committee's activities to establish broadly applicable strategies for credible modeling and simulation have also informed funding programs focusing on multiscale modeling and simulation in healthcare [14].

A projected outcome of the glossary initiative is a peerreviewed manuscript and contribute to the Medical Dictionary maintained by the National Library of Medicine. The result of the other two synergistic initiatives will augment the guideline and certification process.

References:

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model or simulation.

2. Avicenna Alliance, <u>In Silico Roadmap for Clinical Trials</u>, 2015.

List limitations

explicitly

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- 4. FDA's Advancing Regulatory Science Report, 2011.
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- 14. PAR-15-085 (NIH U01), http://grants.nih.gov/grants/guide/pa-files/PAR-15-085.html, May 22, 2016.