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COMMITTEE ON CREDIBLE PRACTICE OF MODELING & SIMULATION IN HEALTHCARE

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INTRODUCTION

Leading health institutions, government agencies, education and research institutions, as well as medical product developers around the world have recognized the substantial potential of computational modeling and simulation (M&S) to support clinical research and decision making in healthcare, e.g., [1]. Consequently, research activities in computational medicine are growing at a significant rate and notable discoveries are being made [2]. However, the mechanisms or processes necessary to appropriately translate these research activities and discoveries in computational methods to clinical practice are lacking. Moreover, there is substantial research diversity in the field such that subject matter experts within and across mathematical and biological disciplines tend to have their own interpretation of credible practice in M&S [3-5]. Additionally, tools and good practice guidelines established by individual disciplines or research areas do not readily transfer across other disciplines or are not adopted by different fields.

To help fill these critical gaps, the "Committee on Credible Practice of Modeling & Simulation in Healthcare" was established (see Box 1 for definitions). The activity was an initiative of the Interagency Modeling and Analysis Group (IMAG) and the Multiscale Modeling (MSM) Consortium. The IMAG and MSM are organized by the National Institutes of Health (NIH) in collaboration with other government agencies and academic researchers to promote the advancement of computational medicine [6]. The Committee on Credible Practice of Modeling & Simulation in Healthcare (hereafter the Committee) aims to lead the establishment of acceptable practice guidelines, as well as identifying new areas of research, for development and implementation of credible computational models and simulations for healthcare research and intervention. The purpose of this document is to provide a

detailed overview of the Committee's goals, organization, and activities.

BOX 1. Tentative definitions relevant to the activities of the Committee on Credible Practice of Modeling & Simulation in Healthcare.

credible

dependable with a desired certainty level to guide research or support decision making within a prescribed application domain and intended use; establishing reproducibility & accountability

practice

any activity involving development, solution, interpretation and application of computational representation of biological, environmental and man-made systems and their interaction thereof

modeling

specifically computational modeling; virtual representation of system(s) of interest in a usable form in order to provide descriptive and predictive metrics for timely and systematic exploration of the system(s)

simulation

computational solution of models to quantify descriptive and predictive metrics of system(s) of interest; including related post-processing efforts to calculate these metrics from raw analysis results

healthcare

any activity involving development, maintenance, advancement, or administration of medical care; including research, diagnosis, risk assessment, prevention, therapy, rehabilitation, surgery, intervention design, and regulation

COMMITTEE CHARGE

The goals of the Committee has been defined as:

1. To adopt consistent terminology in computational medicine in order to unify the use of M&S vocabulary to ensure clear communication across a variety of disciplines and stakeholders in the field.
2. To propose guidelines and procedures for credible practice in computational medicine by leveraging readily available techniques to increase M&S credibility, and to define novel translational workflows to enhance credibility of M&S processes.
3. To demonstrate workflows for credible practice by identifying state-of-the-art workflows in credibility assessment procedures, by conducting studies for the implementation of novel credibility assessment procedures, and by disseminating examples of credibility assessment via a repository of case studies that illustrate the implementation of proposed guidelines and procedures for different types of M&S.
4. To promote good practice by bridging synergistic activities of establishing confidence in simulation-based medicine conducted by M&S communities, as well as conducting outreach activities to advocate credible practice through increased awareness and training, e.g., by providing webinars and lectures.

ORGANIZATION

To realize the objectives, the Committee was organized in two groups; one to carry-out day-to-day operations and active tasks to realize the charges of the committee, the other to review and provide feedback on the activities (Figure 1). The former group, the Executive Committee, consists of ten Committee Members including two co-chairs, who are held accountable for carrying out the charge of the Committee. The latter group, the Advisory Council, has been put in place to assist the Executive Committee with document reviews and providing guidance on various subject matters. Furthermore, given the wide range of stakeholders in the field, both the Committee Members and Advisory Council roster are aimed to be inclusive of prominent experts from many disciplines, governing bodies and commercial entities. This includes medical practitioners, mathematicians, biologists, engineers, computer scientists, product developers and federal regulatory bodies to name a few. At the time of preparation of this document, the Committee was at the initial stages of member recruitment; the Executive Committee consisted of 7 members (including co-chairs) and the Advisory Council included 10 members.

To ensure the Committee is effective in meeting its objectives and tangible deliverables, all Committee Members and the members of the Advisory Council are held accountable to fulfill their specific roles, responsibilities and scheduled deliverables. Committee Co-Chairs are tasked to distribute the workload to Executive Committee members, who will meet online in a biweekly manner. Quarterly reviews will be carried out by the Advisory Council to ensure Committee's success. All

members are also encouraged to carry out unstructured public discussions through the web-based infrastructure to inform ongoing and prospective activities of the Committee and to promote outreach.

INFRASTRUCTURE

The operations of the Committee are conducted publicly and are supported by the online infrastructure of Simbios, NIH Center for Biomedical Computing at Stanford [7]. The Committee website (<https://simtk.org/home/cpms>) includes a version control system to keep materials relevant to the activities; public forums for discussions; tools to conduct surveys; and various sections for downloads and documents for outreach. The activities are supported by web conferencing tools to allow online meetings among members.

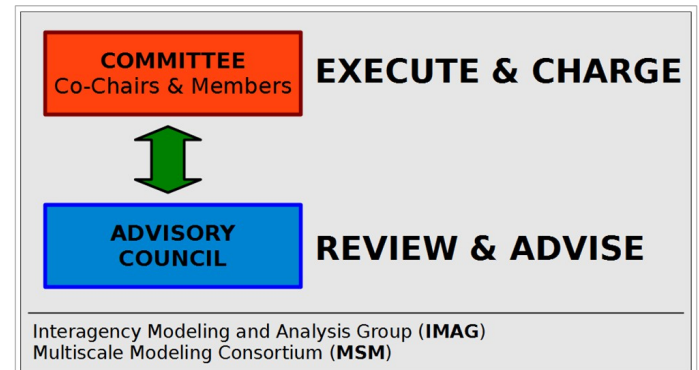


FIGURE 1. Operational organization of the Committee on Credible Practice of Modeling & Simulation in Healthcare.

PLANNED ACTIVITIES

The first two-year term of the Committee started in Spring 2013. In line with the Committee's charge, the Co-Chairs vision for the first-term includes the development of a guidance document on establishing credible practice of M&S in healthcare, and drafting of a proposal for model certification process. Anyone who may have a stake or an interest in M&S are invited in discussions to establish adaptive workflows, which will likely increase confidence in the use of M&S for healthcare, and that can be utilized broadly.

ACKNOWLEDGMENTS

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