A Comparison of Community-Based Guidelines and Standards for the Credible Use of Computational Methods in Healthcare

M. Horner[1,2], L. Mulugeta[1,2], A. Erdemir[1], G. An[1], D.M. Eckmann[1], J.E. Bischoff[1,2], C.A. Hunt[1], J. Ku[1], D. Lochner[1], W.W. Lytton[1], V. Marmarelis[1], J.G. Myers[1], G. Peng[1], M. Steele[1] and M. Walton[1]

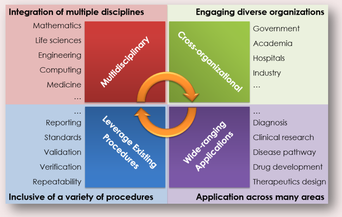
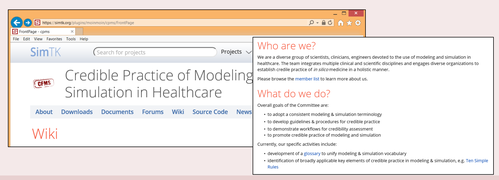
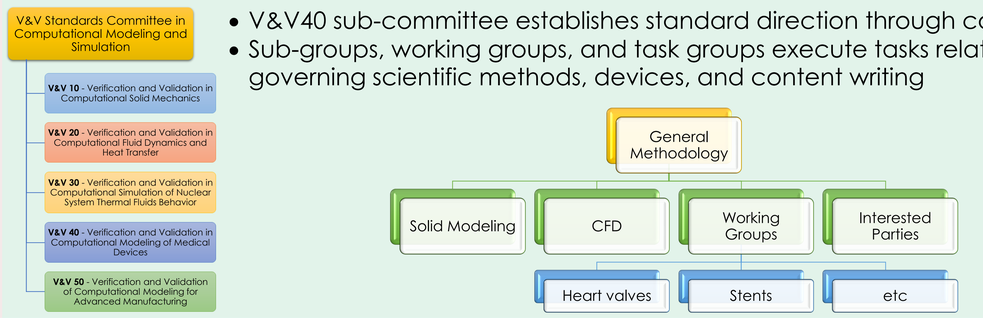
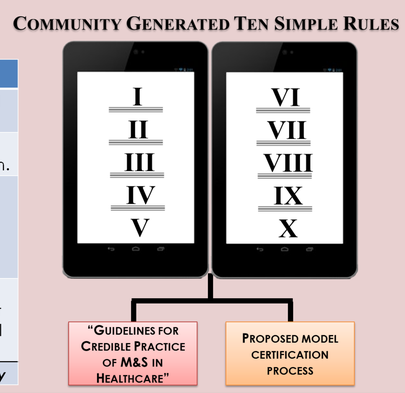
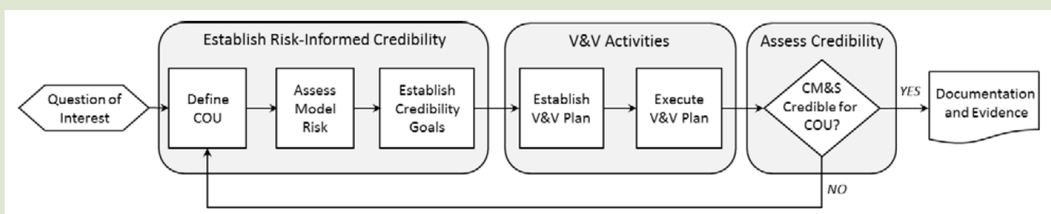
[1]Committee on Credible Practice of Modeling & Simulation in Healthcare - http://wiki.simtk.org/cpms/

[2]V&V40 Sub-Committee under the ASME Standards Committee on Verification and Validation in Computational Modeling and Simulation

Committee on Credible Practice of Modeling & Simulation in Healthcare
Web: https://simtk.org/home/cpms
e-mail: cpmsinhealthcare@gmail.com

INTRODUCTION

The role of computational modeling and simulation (M&S) in the development and delivery of healthcare continues to grow at a rapid pace. Consequently, there is a demand within the healthcare community to establish standards and guidelines to ensure M&S will be developed and applied reliably in healthcare practice and research. However, the multidisciplinary nature of healthcare practice and biomedical research, combined with the multi-contextual use and highly diverse maturity levels of biomedical M&S, present significant challenges for establishing unified M&S credible practice standards and guidelines. This presentation will compare and discuss the synergistic efforts of two cross-disciplinary initiatives to identify overlaps and differences in the context of M&S credibility. The specific initiatives are the Committee on Credible Practice of Modeling & Simulation in Healthcare (CPMS hereafter) and the American Society of Mechanical Engineers (ASME) V&V 40 Sub-Committee (V&V 40 hereafter).

	CPMS	V&V 40
Mission Statement	"To establish credible practice guidelines, consistent terminology and a model certification process (proposed), 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."	"Provide procedures to standardize verification and validation for computational modeling of medical devices." -- ASME V&V 40 charter, approved 2011
Primary Stakeholders	Computational M&S in healthcare as a whole – mainly driven by research initiatives under the IMAG Multi-scale Modeling Consortium IMAG & Multiscale Modeling (MSM) Consortium 	Biomedical device industry, industry service providers, and regulatory and standards bodies such as the US Food and Drug Administration (FDA) and ASME
End-products	I. "Guidelines for Credible Practice of M&S in Healthcare" II. Proposed model certification process III. Identify new areas of research to advance I & II	I. A standard (or guide) for, "Assessing Credibility of Computational Modeling & Simulation Through Verification & Validation: Application to Medical Devices" II. Series of examples that demonstrate application of one or more components of the standard
Approach to Developing End-products	• Executive Committee (EC) executes mission • Advisory Council provides guidance to EC • Extensive use of crowd-sourcing of the healthcare and M&S community through surveys, wiki contributions and forum discussions  	• V&V40 sub-committee establishes standard direction through consensus • Sub-groups, working groups, and task groups execute tasks related to governing scientific methods, devices, and content writing 
General Credibility Workflow	• Apply the Ten Simple Rules of Credible Practice with appropriate intensity for given context of use (iterative). 	• The V&V40 guide outlines a process for making risk-informed determinations as to whether CM&S is credible for decision-making for a specified context of use. 

Simple Rule	Description
Define context clearly	Develop and document the subject, purpose, and intended use(s) of the model or simulation
Use appropriate data	Employ relevant and traceable information in the development or operation of a model or simulation.
Evaluate within context	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 model or simulation.
List limitations explicitly	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.

Four high priority credibility rules identified by the Committee & broader Community

CONCLUSIONS

The CPMS and V&V 40 groups have similar goals with respect to their pursuit to establish procedures for credible application of M&S in medicine. However, they differ significantly with respect to their approach, end-products and target audience. The CPMS aims to establish guidelines, consistent terminology, and a model certification process that are broadly applicable to M&S in healthcare practice and research. Moreover, their work is largely driven by the research community. The work of V&V40, on the other hand, is dedicated to developing procedures to standardize verification and validation for M&S of medical devices for medical device development and in regulatory applications. Consequently, the V&V 40 initiative is largely driven by the medical device industry, and regulatory and standard bodies such as FDA and ASME.