TEN "NOT SO SIMPLE" RULES FOR CREDIBLE PRACTICE OF MODELING & SIMULATION IN HEALTHCARE

A Multidisciplinary Committee Perspective

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MOTIVATION

- Computational modeling and simulation (M&S) plays a growing role in the development and delivery of healthcare.
- Government agencies and industry are making substantial investments in simulation-based medicine and notable discoveries are being made.
- There is an emerging need to ensure credible decison-making with output from M&S, accommodating broad and multidisciplinary perspectives in healthcare.

***Common practice guidelines**, to ease communication among stakeholders and to allow a unified and appropriate approach **to establish credibility of M&S** in a multidisciplinary environment, **do not exist**.*

GOALS

To identify **broadly applicable common rules** for establishing **credibility in M&S** in healthcare

by

synthesizing discussions within a multidisciplinary Committee, the **Committee on Credible Practice for M&S in Healthcare**.

None of us are experts in everything. We need to learn from each other.

Credible practice of modeling and simulation in healthcare requires *ongoing* **inclusive communications** to establish adaptive **workflows** that can be utilized **broadly**.

COMMITTEE

EXECUTE & CHARGE — **EXECUTIVE COMMITTEE** — 2 co-chairs, 8 current members including co-chairs, 2 past members

COMMUNICATION ⇅ ACCOUNTABILITY

REVIEW & ADVISE — **ADVISORY COUNCIL** — 12 current members

Committee roster is targeted

- to establish a balanced representation of the interests and perspectives of the different stakeholders
- to bridge synergistic activities in simulation-based medicine throughout various M&S communities

integrating multiple disciplines
mathematics
life sciences
engineering
computing
medicine
...

engaging diverse organizations
government
academia
hospitals
industry
...

leveraging various procedures
reporting
standards
validation
verification
repeatability
...

applications in many areas
diagnosis
clinical research
disease pathway
drug development
therapeutics design
...

TASK TEAMS

Mathematics & Computation Team	Users Team	Standards & Guidelines Team
interest in development of models and simulation approaches	interest in application of models for clinical research and practice	interest in evaluation of models and simulation approaches
7 participants 3 - Executive Committee 4 - Advisory Council	7 participants 3 - Executive Committee 4 - Advisory Council	7 participants 3 - Executive Committee 4 - Advisory Council
scientists engineers	clinicians scientists engineers	scientists engineers directors managers
academia industry government independent	academia industry government healthcare organizations	industry government

initial set of rules → **discussions within task teams** → **individual task team rankings**

Task teams decided upon their own approach to identify top ten rules with or without ranking.
Task teams interpreted the rules in their own way and combined rules or added new ones.

INITIAL SET OF RULES

26 rules to start with

• use version control • use credible solvers • explicitly list your limitations •
• define the context the model is intended to be used for •
• define your evaluation metrics in advance •
• use appropriate data (input, validation, verification) •
• attempt validation within context • attempt verification within context •
• attempt uncertainty (error) estimation •
• perform appropriate level of sensitivity analysis within context of use •
• disseminate whenever possible (source code, test suite, data, etc) •
• report appropriately • use consistent terminology or define your terminology •
• get it reviewed by independent users/developers/members •
• learn from discipline-independent examples •
• be a discipline-independent/specific example • follow discipline-specific guidelines •
• conform to discipline-specific standards • document your code •
• develop with the end-user in mind •
• provide user instructions whenever possible and applicable •
• practice what you preach • make sure your results are reproducible •
• provide examples of use • use traceable data that can be traced back to the origin •
• use competition of multiple implementations to check and balance each other •

TASK TEAM RANKINGS

Mathematics & Computation Team	Users Team	Standards & Guidelines Team
4 responsive members forum discussion *alternatives, clusters, additions* individual member ranking *listing of 3 most important rules* group ranking *non-linearly weighted scoring* *first 10 shown*	4 responsive members e-mail response by individuals individual member response *clustering of rules in relation to each other* *listing ten important rules without ranking* group ranking *frequency of rules emerging in individual lists (separately or within a group)* *first 10 shown*	7 responsive members forum and e-mail discussions no explicit individual member ranking group ranking *synthesis into 10 general themes by consensus weighing based on majority feedback*
Use competition of multiple implementations to check and balance each other.	Define the context the model is intended to be used for.	Plan and develop the M&S with the intended purpose/context, as well as the end-user in mind.
Document your code and make your code readable.	Disseminate whenever possible (source code, test suite, data, etc).	Use appropriate data (input, validation, verification).
Explicitly identify experimental scenarios illustrating when, why, and how the model is false (alternative: Explicitly list your limitations).	Use appropriate data (input, validation, verification).	Test the M&S appropriately within context (verification & validation, uncertainty quantification, sensitivity analysis, test cases).
Make it easy for anyone to repeat and/or falsify your results (alternative: Make sure your results are reproducible).	Provide examples of use.	Document important elements of the M&S (domain of validity/invalidity, intended use, users' guide, code documentation, etc.).
Use traceable data that can be traced back to the origin.	Get it reviewed by independent users/developers/members.	Explicitly list your limitations.
Use version control.	Use version control.	Have the M&S reviewed by independent users/developers/members.
Define your evaluation metrics in advance.	Attempt uncertainty (error) estimation.	Use version control.
Practice verification / validation / uncertainty quantification (alternative: attempt verification within context).	Explicitly list your limitations.	Use appropriate discipline specific guidelines and standards.
Define the use context for which the model is intended.	Perform appropriate level of sensitivity analysis within context of use.	Use consistent terminology or define terminologies.
Develop with the end user in mind.	Attempt verification within context.	Dissemination of the M&S.

COMMITTEE RANKING

Consolidation ← commonality of a rule between task team lists; relative ranking of a rule in task team lists; grouping of rules based on similarities; grouping of rules that enhance each other

Rule 1 – ***Define context clearly.***
Plan and develop the M&S activity with clear definition of the intended purpose or context accommodating end-users needs.

Rule 2 – ***Use appropriate data.***
Use data relevant to the M&S activity, which can ideally be traced back to the source.

Rule 3 – ***Evaluate within context.***
Evaluate the M&S activity through verification & validation, uncertainty quantification, and sensitivity analysis faithful to the context/purpose/scope of the M&S efforts, with clear and a-priori definition of evaluation metrics and including test cases.

Rule 4 – ***List limitations explicitly.***
Provide an explicit disclaimer on the limitations of the M&S to indicate under what conditions or applications the M&S may or may not be relied on.

Rule 5 – ***Use version control.***
Implement a version control system to trace the time history of the M&S activities, including delineation of contributors' efforts.

Rule 6 – ***Document adequately.***
Document all M&S activities, including simulation code, model markup, scope and intended use of M&S activities, users' and developers' guides.

Rule 7 – ***Disseminate broadly.***
Disseminate appropriate components of M&S activities, including simulation software, models, simulation scenarios and results.

Rule 8 – ***Get independent reviews.***
Have the M&S activity reviewed by independent third-party users and developers, essentially by any interested member of the community.

Rule 9 – ***Test competing implementations.***
Use competition of multiple implementations to check the conclusions of different implementations of the M&S processes against each other.

Rule 10 – ***Conform to standards.***
Adopt and promote generally applicable and discipline specific operating procedures, guidelines, and standards accepted as best practices.

CONCLUSIONS

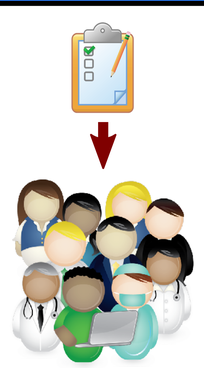
- It is possible to establish broadly applicable overlapping themes for credible practice of M&S in healthcare.

Nonetheless

- These rules are considered "***not so simple***" as their implied meanings may vary, indicating the need for clear and detailed descriptions during their application.
- Perception and relative importance of these rules are likely to be influenced by disciplinary, organizational, and context of use (purpose) factors.

FUTURE

- Gauging broader community's opinion
  Public online survey
  December 2014 - April 2015
  195 participants
- Preparation of a guidance document
  relying on Committee's perspective
  informed by community insight
- Development of a model certification process
  to facilitate systematic evaluation of credibility
- Support by
  establishing consistent terminology
  demonstration of workflows
  outreach



Committee's activities are facilitated by the Interagency Modeling and Analysis Group and Multiscale Modeling Consortium:

Project Site: *https://simtk.org/home/cpms*
Wiki Site: *http://wiki.simtk.org/cpms*
e-mail: *cpmsinhealthcare@gmail.com*