Credible Practice of Models and Simulations for Healthcare Presented by: Jerry Myers NASA - Glenn Research Center

On behalf of the Committee on Credible Practice of Modeling & Simulation in Healthcare

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NASA Export Control review (20205010469 : 11/2/2020) designates this presentation STI suitable for public presentation at IITSEC.



Obligatory images of astronauts doing stuff in microgravity



BACKGROUND

- Computational modeling and simulation (M&S) methods have substantial potential to support research and development, clinical decisions, and education in healthcare.
- Government agencies and industry are making substantial investments into R&D activities in simulation-supported medical research, and decision-making.



3

3





Space Safety Magazine - Winter 2013



Columbia Accident – Influence of Computational Models



- Debris Assessment Team (DAT) was restricted to using a mathematical modeling tool called *Crater* to predict the depth to which debris penetrated Thermal Protection System (TPS) tile.
- Crater was classified as a "conservative" tool due to historical use with predicting damage from ice impacts.
- Crater was validated as accurately predicting damaged for <u>small</u> <u>debris impacts</u>, on the order of 49cm³ - <u>estimated size of actual</u> <u>foam impact : 19665cm³</u>.
- DAT used a qualitative extrapolation of the test data and engineering judgment that a foam impact angle of up to 21° would not penetrate the shuttle.
- Crater, as the only predictive tool available, was correctly applied, but it was given weight in the decision making process far outside the boundaries of its Credibility.



8 Factors of Model Credibility



Factor

Score

4

3

2

1

0

5

NASA-STD-7009A – Credibility of Models and Simulation



CREDIBLE PRACTICES OF M&S IN HEALTHCARE

IMAG & Multiscale Modeling (MSM) Consortium



NIH) FDA 🍪 🚳 🕜 🕞

Committee on Credible Practice of Modeling & Simulation in Healthcare



Goal: Guide reliable application of M&S in healthcare practice and research

USDA

- Establish credible practice guidelines
- Consistent terminology
- Demonstrate workflows
- Extensible to new areas of research
- Generally promote good practice

Ten Rules from a Multidisciplinary Perspective

Rule		Description
1.	Define context clearly	Develop and document the subject, purpose, and intended use(s) of the model or simulation
2.	Use contextually appropriate data	Employ relevant and traceable information in the development or operation of a model or simulation
3.	Evaluate within context	Perform verification, validation, uncertainty quantification, and sensitivity analysis of the model or simulation with respect to the reality of interest and intended use(s) of the model or simulation
4.	List limitations explicitly	Provide restrictions, constraints, or qualifications for or on the use of the model or simulation for considera- tion by the users or customers of a model or simulation
5.	Use version control	Implement a system to trace the time history of modeling and simulation activities including delineation of each contributors' efforts
6.	Document appropriately	Maintain up-to-date informative records of all modeling and simulation activities, including simulation code, model mark-up, scope and intended use of modeling and simulation activities, as well as users' and developers' guides
7.	Disseminate broadly	Share all components of modeling and simulation activities, including simulation software, models, simula- tion scenarios and results
8.	Get independent reviews	Have the modeling and simulation activity reviewed by nonpartisan third-party users and developers
9.	Test competing implementations	Use contrasting modeling and simulation implementation strategies to check the conclusions of different strategies against each other
10.	Conform to standards	Adopt and promote generally applicable and discipline specific operating procedures, guidelines, and regu- lations accepted as best practices

Erdemir, A. et al. J. Transl. Med. 2020.



CPMS Credibility Ten Rules (TR)



Preliminary Conformance Rubric: Outreach

Outreach Capability	Outreach to application-domain experts who may not be M&S practitioners	Outreach to M&S practitioners who may not be application-domain experts	Outreach to application-domain specific M&S practitioners	Outreach to application-domain specific M&S practitioners	None or very limited	
Conformance	Comprehensive	rehensive Extensive Adequate		Partial	Insufficient	
Level	4	3	2	1	0	
Description Level	Can be understood by <u>non-M&S</u> <u>practitioners</u> familiar with the application domain and the intended context of use	Can be understood by M&S practitioners <u>not</u> familiar with the application domain and the intended context of use	Can be understood by M&S practitioners familiar with the application domain and the intended context of use	<u>Unclear</u> to the M&S practitioners familiar with the application domain and the intended context of use	Missing or grossly incomplete information to properly evaluate the conformance with the rule	



Application to Early Covid Model Assessment

CHIME Covid-19 Model TR Conformance Review Summary



April 2020

CHIME: U Penn – <u>https://penn-</u> <u>chime.phl.io/</u>

- Reviewer comments
 - Model "validated by epidemiologist" – no details provided on extent or when.
 - Prediction capacity compared to early versions of the Imperial College COVID-19 model.
 - Unclear uncertainty and robustness evaluation



Keep In mind...

TR describes evaluation of Credible Practice Activities

Decision makers should consider the credible practice factors in their unique decision making application

- Domain of Use
- Use Capacity
- Strength of Influence





1.5

1.0

0.5

0.0

FN side fall 0.00

TR Example: Predictive Bone Fracture **Risk Model for Astronauts**

https://imagwiki.nibib.nih.gov/resource_credibility_assessment/cpms-tsr-example-predictive-bone-fracture-risk-model-astronauts



Elderly

Young

(all) (all)



Submitted by JamyWyara on Max. 03(0):0000 - 12:33

Investigators.

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Contact info lemail)

jerty g inyers@mesa.gov

1. Define context(s)

Conformance Level

Extensive

Primary goal of the model/tool/database

Lacking phenomenological state on fracture risk in space, we have developed a predictive tool based on biomechanical and bone loading models at any gravitational level of interest. The tool is a statistical model

that forecasts fracture rais, locards the associated uncertainties, and performs sensitivity analysis. The model is intended to be extensible to all genilers, all races and all age groups applicable to antenaut dereographics. The model is intended to addresses, in Fight and post Eight risks based on assumptions regarding aptronaut mission and personal activities utilizing the litest auxiliable information for space flight induced bane loss, and return from flight recovery in tome gravity load bearing regions (hps. lumbar spine) and areas endangered from falls (what hips). To make the model tractable with summit space fight planning, the model uses a series of characteristic loading scientifics to characterize the risk. Objecterization of this risks allows for mission tracks with other medical conditions, as well as defining mission parameters and engineering requirements

Biological domain of the model



Structure(s) of interest in the model

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Form is free to use...

🦑 U.S. Department of Health & Human Services 🖉 🔊 National Institutes of Health 🔪 🔊 National Institute of Biomedical Imaging and Bioengineering



https://www.imagwiki.nibib.nih.gov/

10 Simple Rules for Credible Practice of Modeling

Access Rubric Here

Accessed by this button



Many Thanks From the CPMS Members



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REVIEW

Open Access

Credible practice of modeling and simulation in healthcare: ten rules from a multidisciplinary perspective

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Abstract

The complexities of modern biomedicine are rapidly increasing. Thus, modeling and simulation have become increasingly important as a strategy to understand and predict the trajectory of pathophysiology, disease genesis, and disease spread in support of clinical and policy decisions. In such cases, inappropriate or ill-placed trust in the model and simulation outcomes may result in negative outcomes, and hence illustrate the need to formalize the execution and communication of modeling and simulation practices. Although verification and validation have been generally accepted as significant components of a model's credibility, they cannot be assumed to equate to a holistic credible practice, which includes activities that can impact comprehension and in-depth examination inherent in the development and reuse of the models. For the past several years, the Committee on Credible Practice of Modeling and Simulation in Healthcare, an interdisciplinary group seeded from a U.S. Interagency initiative, has worked to codify best practices. Here, we provide Ten Rules for credible practice of modeling and simulation in healthcare developed from a comparative analysis by the Committee's multidisciplinary membership, followed by a large stakeholder community survey. These rules establish a unified conceptual framework for modeling and simulation design. Implementation, evaluation, dissemination and usage across the modeling and simulation life-cycle. While biomedical science and clinical care domains have somewhat different requirements and expectations for credible practice, our study converged on niles that would be useful across a broad swath of model types. In brief, the rules are (1) Define context clearly, (2) Use contextually appropriate data, (3) Evaluate within context, (4) List limitations explicitly, (5) Use version control. (6) Document appropriately. (7) Disseminate broadly. (8) Get Independent reviews. (9) Test competing Implementations. (10) Conform to standards. Although some of these are common sense guidelines, we have found that many are often missed or misconstrued, even by seasoned practitioners. Computational models are already widely used in basic science to generate new biomedical knowledge. As they penetrate clinical care and healthcare policy. contributing to personalized and precision medicine, clinical safety will require established quidelines for the credible practice of modeling and simulation in healthcare.

Keywords: Credibility, Simulation, Healthcare, Verification, Validation, Computational modeling, Computer modeling, Reliability, Reproducibility

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Background

Computational modeling and simulation has become increasingly popular in biomedical research and has found proven utility in healthcare. However, the





Backup



Rules Overview



Rule 1 – Define context clearly - document the subject, purpose, and intended use(s) of the model or simulation

- Domain of Use
- Use Capacity
- Strength of Influence

Rule 2 – Use contextually appropriate data - Employ relevant and traceable information

- Data used in development, operation, and evaluation of the M&S traceable to their original source
- Data's relevance to the stated COU is well articulated
- The Domain of Use SME understands which and how the data is applied
- Findable, Accessible, Interoperable, Reusable (FAIR)



Rule 3 – Evaluate within context - accomplished with respect to the reality of interest and intended use

- <u>Verification</u> determine computational M&S accurately represents the underlying mathematical model and its solution.
- <u>Validation</u> determine the degree to which the model is an accurate representation of the real world from the perspective of its COU
- <u>Uncertainty quantification</u> characterize the pertinent variability in the model and comparator and to quantify their effect on the simulation outcomes
- <u>Sensitivity analysis</u> establish the degree to which the uncertainty in the model output(s) can be attributed uncertainty in the model inputs



Rule 4 – List limitations explicitly - Restrictions, constraints, or qualifications

- Assumptions that are application-specific, limits generalizability
- Clearly identify the conditions under which their M&S cannot be relied upon

Rule 5 – Use version control - Implement a system to trace the time history of M&S activities

- Version control for all model, software, data, and documentation files
- Tracking changes between versions
- Associating specific modifications to the creator/developer
- Including annotations/comments/notes with each version



Rule 6 – Document appropriately - Maintain up-to-date informative records of all activities, including simulation code, model mark-up, scope and intended use, and users guide

- Providing the information needed for to assess the credibility of the M&S activity planned and probably COU's
- Providing the information needed to understand the nuances of reproducing and using/reusing the associated code and model.

Rule 7 – Disseminate broadly - Publish all components of M&S activities

- Sharing of knowledge via publications and the sharing of M&S assets
- Methods sections of scholarly publication is generally not sufficient to embed all the details needed to meet rule 6 and 7



Rule 8 – Get independent reviews - M&S activity reviewed by nonpartisan third-party users and developers

- Independent "third-party" reviews by end-users or peers evaluating the activity in its entirety - Evaluate rules 2-6, 9 & 10 wrt 1.
- Mechanism should be a thoughtful, impartial evaluation predicated on accepted guidelines and requirements
- Peer reviews of manuscripts should not be the sole form of third-party review

Rule 9 – Test competing implementations - Use contrasting M&S execution strategies to check conclusions

- Understanding of model behavior WRT familiar standards of performance
- Insight deriving from weighing the pros and cons of competing approaches



Rule 10 – Conform to standards - Adopt applicable procedures, guidelines, and regulations accepted as best practices within supporting disciplines

- When consistently applied, represent a means of providing requirements, specifications, and guidelines that establish that the M&S materials and products fit the intended purpose
- May vary depending on the institution or discipline
- Importance will vary with the development stage of the M&S application
- Improved insight into and adoption of M&S follows from adherence to standards which promote transparency



Summing it up...

- Biomedical sciences and clinical disciplines are diverse and multidisciplinary
- Intentions of M&S vary dramatically
- Are Credible Practices Being Implemented?

Ten Simple Rules represent a tightly linked cohort, in a customizable framework that can be tailored to the domain of application, state of development, and stakeholder community

- Most importantly viewed as a communications tool bridging the implemented and the expected practices to support M&S decision making.
- Many researchers and developers follow and communicate many aspects of these TSR
- Few demonstrate all aspects There is room for improvement!!!



What Constitutes Credible Practice?

- Started with 26 proposed rules of good practice from the Committee
- Committee estimated proximity to clinical applications:
 - mathematics and computation
 - vested interest in the end-use of M&S
 - standards, guidance, evaluation and regulation
- August 15, 2014 to April 15, 2015 An international public survey with spectrum of perspectives in healthcare M&S
- Ranking of committee and survey findings identified the top 10 "rules"
- Tested and refined these rules in the IMAG community and open access.
- Submitted for publication this year.



NASA Credibility Levels of Evidence



	M&S Development				M&S Use (Operations)	Supporting Evidence			
Level	l Data Pedigree Verification Valid		Validation	Input Pedigree Uncertainty		Results	M&S History	M&S Process /	
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						100000000000000000000000000000000000000		Management	
4	All data known &	Reliable practices	All M&S outputs	All input data	Statistical analysis of the	Sensitivities	Nearly identical	Controlled	
	traceable to RWS	applied to verify	agree with data	known & traceable	output uncertainty after	known for most	model and use.	processes are	
	with acceptable	the end-to-end	from the RWS	to RWS with	propagation of all known	parameters; most		applied;	
	accuracy, precision,	model; all model	over the full range	acceptable	sources of uncertainty.	key sensitivities		measurements	
	& uncertainty.	errors satisfy	of operation in its	accuracy, precision,		identified.		used for process	
		requirements.	real operating	& uncertainty.				improvement.	
			environment.						
3	All data known &	Formal practices	All key M&S	All input data	Uncertainty of results are	Sensitivities	At most minor	Controlled	
	traced to sufficient	applied to verify	outputs agree with	known & traced to	provided quantitatively	known for many	changes in model	processes are	
	referent. Significant	the end-to-end	data from the RWS	sufficient referent.	through propagation of	parameters	and at most minor	applied; process	
	data has acceptable	model; all	operating in a	Significant input	all known uncertainty.	including many	differences in model	compliance is	
	accuracy, precision,	important errors	representative	data has acceptable		of the key	use.	measured.	
	& uncertainty.	satisfy	environment.	accuracy, precision,		sensitivities.			
		requirements.		& uncertainty.					
2	Some data known	Documented	Key M&S outputs	Some input data	Most sources of	Sensitivities	At most moderate	Formal processes	
	& formally	practices applied	agree with data	known & formally	uncertainty identified,	known for a few	changes in model	are applied.	
	traceable with	to verify all model	from a sufficiently	traceable with	expressed quantitatively,	parameters. Few	and at most		
	estimated	features; most	similar referent	estimated	and correctly classified.	or no key	moderate differences		
	uncertainties.	important errors	system.	uncertainties.	Propagation of the	sensitivities	in model use.		
		satisfy			uncertainties is assessed.	identified.			
		requirements.							
1	Some data known	Informal practices	Conceptual model	Some input data	Sources of uncertainty	Qualitative	New model or major	Informal processes	
	and informally	applied to verify	addresses problem	known and	identified and	estimates only for	changes in model, or	are applied.	
	traceable.	some features of	statement and	informally	qualitatively assessed.	sensitivities in	major differences in		
		the model and	agrees with	traceable.		M&S.	model use; but,		
		assess errors.	available referents.				model/changes/uses		
							documented.		
0	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient evidence.	Insufficient	Insufficient	Insufficient	
	evidence	evidence	evidence	evidence		evidence	evidence	evidence	



Important Definitions

Credible: Dependable, with a desired certainty level to guide research or support decision-making within a prescribed application domain and intended use; establishing reproducibility and accountability.

Practice: Any activity involving the development, solution, interpretation and application of computational representations of biological, environmental and man-made systems and their interaction thereof.

Modeling: Virtual, in silico, representation of system(s) of interest in a usable form in order to provide descriptive and predictive metrics for timely and systematic exploration of said system(s).

Simulation: Computational solution of models that 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.