

Progress Update for Advisory Council Meeting

Committee on Credible Practice of Modeling & Simulation in Healthcare

prepared for July 06, 2016 meeting of the Advisory Council

REVIEW OF GOALS

Committee Charge

1. Adopt a consistent terminology
2. Propose guidelines and procedures for credible practice
3. Demonstrate workflows for credible practice
4. Promote good practice

Second Term (2015-2017) Goals

1. Develop a guidance document on establishing credible practice of modeling and simulation in healthcare *(In Progress)*
2. Draft a proposed model certification process
3. Establish a mechanism to tie the Committee's activity to the future IMAG MSM solicitation to bolster the credibility portion of the solicitation by:
 1. Proactively engaging the investigators to share with us their proposed credibility plan and how we might be able to incorporate that into our overarching work
 2. Use the pool of funded investigators may also be a great source to find future members and co-chairs

Current Membership

Executive Committee Members

Gary An
Ahmet Erdemir (Co-Chair)
Marc Horner (New & Prospective Vice Co-Chair)
Joy Ku
William Lytton
Tina Morrison
Jerry Myers
Lealem Mulugeta (Co-Chair)
Lu Tian

Vacancies: 1

Advisory Council Roster

Jeff Bischoff
David Eckmann
Tony Hunt
Donna Lochner
Vasilis Marmarelis
Alison Marsden (New)
Pras Pathmanathan
Gaurav "Gary" N. Pradhan (New)
Grace Peng
Martin Steele
Marlei Walton

Past Members

Wing Kam Liu
Jim Thomas

Vacancies: 1

See http://wiki.simtk.org/cpms/CPMS_Members for more details.

Infrastructure Update

1. The SimTK website was recently updated to include some new features.

2. Due to the updates to the SimTK sites, data in the subversion repository can be a bit more challenging to get to via the website. So we encourage all members to install and use a local subversion host using the instructions posted on the CPMS project page:
https://simtk.org/websvn/wsvn/cpms/doc/help/version_control.pdf
3. All of our publications are now listed on the SimTK site:
<https://simtk.org/plugins/publications/index.php?type=group&id=848&pluginname=publications>
4. Additional directory has been added to the subversion repository to maintain all data from the Ten Simple Rules public survey - <https://simtk.org/websvn/wsvn/cpms/dat/>

Current Tasks

- I. **Task: Ten Simple Rules:** To establish the foundations of a guidance document, the Committee started an activity to identify Ten Simple Rules to guide credible practice in modeling and simulation in healthcare. The activity is aimed towards a publication, similar to articles in PLoS Computational Biology: Ten Simple Rules Collection. In pursuit of this objective, we have two parallel activities:
 - Based on the internal survey the committee conducted, a decision was made with majority vote to publish a precursor paper titled, “*Ten “Not So” Simple Rules for Credible Practice of Modeling and Simulation in Healthcare: Perspectives from a Multidisciplinary Committee*”.
 Current draft can be accessed from: <https://simtk.org/websvn/wsvn/cpms/doc/articles/tsr-committee.odt>
 - The public survey was launched on August 15th, 2014 with IRB exceptions from Cleveland Clinic and Stanford University. The survey was closed on April 15th.
 - Significant refinements have been made to the analysis approach since the previous Advisory Council meeting, and the Data Analysis Team is still analyzing the data. For details, please refer to the Data Analysis Team Meeting Minutes:
January 13, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/dag_20160113.pdf
February 3, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/dag_20160203.pdf
April 27, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/dag_20160427.pdf
June 29, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/dag_20160629.pdf
 - Preliminary findings of the data analysis are summarized below:

Summary of survey results – 148 valid responses

Region	Background	Profession	Education
Asia - 5	Computer Science - 7	<i>Academia - 79</i>	Bachelor - 7
Europe - 34	<i>Engineering - 68</i>	Government - 24	<i>Doctorate - 101</i>
<i>North America - 102</i>	Formal Science - 5	Healthcare - 8	Masters - 26
Oceania - 5	Healthcare - 11	Industry - 16	Medical & Doctorate - 14
No Response - 2	Life Sciences - 23	Research - 17	
	Physical Sciences - 19	Other - 1	
	Scientific Computing - 5	No Response - 3	
	Social Sciences - 2		
	Other - 8		

Motivation	Experience with M&S
Not using nor interested in M&S - 1	Familiar without direct experience with M&S - 13
To support clinical decision making - 20	< 5 years of experience in developing and/or using M&S - 26
To support clinical research - 11	<i>> 5 years of experience in developing and/or using M&S - 107</i>
To support medical training - 3	Not familiar at all - 1
To support product development - 15	No Response - 1
To support regulatory approval - 10	
<i>To support scientific research - 78</i>	
Other - 10	

Analysis of the rule rankings suggests that the global community agree that the top 4 rules listed in the Committee's perspective on the Ten Simple Rules of Credible Practice should be among the high priority rules of credible practice (see image below). Additionally, closer assessment of the 32 rules suggests it may be possible to consolidate some of the rules into higher order rules. For example, there are several rules that may fall under the category of "Documentation" activities.

Rule	Description
1. <i>Define context clearly</i>	Develop and document the subject, purpose, and intended use(s) of the model or simulation.
2. <i>Use appropriate data</i>	Employ relevant and traceable information in the development or operation of a model or simulation.
3. <i>Evaluate within context</i>	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.
4. <i>List limitations explicitly</i>	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.
5. <i>Use version control</i>	Implement a system to trace the time history of M&S activities including delineation of contributors' efforts.
6. <i>Document adequately</i>	Maintain up-to-date informative records of all M&S activities, including simulation code, model mark-up, scope and intended use of M&S activities, as well as users' and developers' guides.
7. <i>Disseminate broadly</i>	Publish all components of M&S activities, including simulation software, models, simulation scenarios and results.
8. <i>Get independent reviews</i>	Have the M&S activity reviewed by nonpartisan third-party users and developers.
9. <i>Test competing implementations</i>	Use contrasting M&S execution strategies to check the conclusions of the different execution strategies against each other.
10. <i>Conform to standards</i>	Adopt and promote generally applicable and discipline specific operating procedures, guidelines, and regulations accepted as best practices.

- The raw data and processed data are available at: <https://simtk.org/scm/viewvc.php/dat/Survey/?root=cpms>
- Advisory Council members are invited to participate in the processing and interpretation of the data. A forum discussion thread has been initiated to facilitate this: <https://simtk.org/plugins/phpBB/viewtopicPhpbb.php?f=848&t=5616&sid=fdcab3f040d5c52b8667a0b0812d2e2b>
- The Committee's activities to establish broadly applicable strategies for credible modeling and simulation have been formally incorporated into the IMAG/MSM Predictive Multiscale Models for Biomedical, Biological, Behavioral, Environmental and Clinical Research (U01) funding opportunity. Researchers responding to this call have also contacted members of the Executive Committee requesting copies of the Committee's perspective on the Ten Simple Rules of Credible Practice to develop their model credibility plan.
- We also plan to have funded investigators to be more directly involved in sharing their model credibility plan to bolster the credibility guidelines the Committee is developing.

1. Past Advisory Council meeting progress reports and minutes are available at
May 29, 2015 (progress report). https://simtk.org/websvn/wsvn/cpms/doc/minutes/ac_20150529-pu.pdf
May 29, 2015 (minutes). https://simtk.org/websvn/wsvn/cpms/doc/minutes/ac_20150529-minutes.pdf
2. Past Executive Committee meeting minutes are available at
June 25, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20150625.pdf
August 10, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20150810.pdf
October 8, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20151008.pdf
November 5, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20151105.pdf
December 10, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20151210.pdf
January 22, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160122.pdf
February 18, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160218.pdf
March 10, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160310.pdf

April 7, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160407.pdf

May 5, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160505.pdf

June 9, 2016: https://simtk.org/websvn/wsvn/cpms/doc/minutes/cm_20160609.pdf

3. Past Community Meeting minutes are available at

September 9, 2015: https://simtk.org/websvn/wsvn/cpms/doc/minutes/msm_20150908.pdf

II. Task: Visibility & Outreach:

• *Posters & Presentations.*

1. “Towards the Establishment of Guidelines for the Credible Practice of Modeling and Simulation in Healthcare”, *Latsis Symposium ETH Zurich on Personalized Medicine*, 2016, 27-29 June 2016, Zurich, Switzerland.

https://simtk.org/websvn/wsvn/cpms/doc/posters/Poster_LATSIS2016_CPMS.pdf

2. “A Comparison of Community-Based Guidelines and Standards for the Credible Use of Computational Methods in Healthcare”, *2016 BMES/FDA Frontiers in Medical Devices*, Washington, DC.

https://simtk.org/websvn/wsvn/cpms/doc/posters/BMESFDA_FMD_2016_CPMS.pdf

3. “Credibility of Computational Methods in Healthcare: A Comparison of Community-based Standards and Guidelines”, *2016 ASME V&V Symposium*, Las Vegas Neva.

https://simtk.org/websvn/wsvn/cpms/doc/presentations/ASME_VV_Symposium_2016.pdf

4. “Developing Credible Practice Guidelines for Modeling and Simulation in Healthcare: A Multifaceted Approach”, *38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, 16-20 August 2016, Orlando, FL. [Abstract Accepted]

https://simtk.org/websvn/wsvn/cpms/doc/abstracts/EMBC_2016.pdf

5. “Credible Practice of Modeling and Simulation in Healthcare”, *Virtual Physiological Human Conference*, 2016, 26-28 September 2016, Amsterdam, Netherlands. [Abstract submitted]

<https://simtk.org/websvn/wsvn/cpms/doc/abstracts/VPH2016.pdf>

• *Webinars*

1. We plan to host more webinars in the near future, and suggestions are welcome for possible topics. Prospective presenters include:

- *FEOps* - <http://feops.com/>
- *EndoSize* - <https://www.endosize.com/>
- *BraceSim* - <http://www.bracesim.com/>
- *BioGears* - <https://www.biogearsengine.com/>
- *Medtronic* - <http://www.medtronic.com/>

• *Other*

1. Executive and Advisory Council Members highlighted the Committee's efforts through various presentations and interactions regarding biomedical/healthcare computational M&S at the following events:

- a) Grace Peng at the *Modeling Science, Technology & Innovation Conference*, Washington, DC, May 17-18, 2016 (Grace Peng)
- b) Tony Hunt at the, *Spring Simulation Multi-Conference (SpringSim'16)*, Pasadena, CA, April 3 - 6, 2016
- c) Marlei Walton at *NASA's Human Research Program (HRP) Investigators' Workshop (IWS)*, February 8, 2016

2. The Committee was mentioned in the Avicenna roadmap: <http://avicenna-isct.org/roadmap/>

- Page 69 - Footnote 86
- Page 70 - Footnote 87

III. Task: Literature Survey: The Committee has been heavily focused on the Ten Simple Rules task, so there has been no progress on this. For more details, see the literature database at <https://www.zotero.org/groups/167342>.

IV. Task: Definitions: This task has lost some momentum due to greater focus being placed on the Ten Simple Rules task. However, there was significant discussion at the 2015 MSM Consortium meeting to expand this work and publish it in a formalized manner as a journal article and/or contribution to the Medical Dictionary: <https://www.nlm.nih.gov/medlineplus/mplusdictionary.html>

- All Committee members are encouraged to contribute and invite others to do the same.
- For more details, please refer to http://wiki.simtk.org/cpms/Glossary_and_Definitions.
- Video tutorial for contributing to glossary: https://www.youtube.com/watch?v=n2c_9QEOO5c

V. Task: Workflows for Credible Practice: Several Committee members have been leading a discussion among the M&S community regarding broadly applicable workflows for credible practice of M&S in healthcare. Much of these discussions have been via the CPMS forum: <https://simtk.org/plugins/phpBB/viewtopicPhpbb.php?f=848&t=6044&p=0&start=0&view=>

Membership

1. The Committee has approximately one year left before completing our second two year term. So we need to start thinking about how we are going to move forward with transitioning new leadership and members into the committee. Particularly considering the fact many of the current members are becoming over tasked and they will have served four years on the Committee, it is imperative that we consider bringing new and energetic members on board to ensure steady progress to our end goal.

Current proposed strategies to achieve this goal include:

1. Establishing vice Co-Chairs to take over for the current Co-chairs in the coming term. Marc Horner has tentatively agreed to take on this role, and has been shadowing the current Co-chairs to learn about the Committee. We are actively looking for a second Vice Co-chair.
2. The current Co-chairs will take on Advisory Member or Past Chairs as resources to the new Co-chairs.
3. In-coming Co-chairs should be well-balanced in their perspective to ensure that the diverse interests of the research (particularly IMAG/MSM) and clinical community are represented
4. It may be ideal to recruit young investigators funded under the MSM U01.

Plans until Next Advisory Council Meeting

Committee will continue putting effort in the tasks that already started. Ongoing progress will be documented. Task specific goals aimed for completion are

- **Task: Visibility & Outreach.**
 - VPH Conference presentations
 - Developing a three-way folding pamphlet to distribute to interested parties during special events or meetings (e.g. conferences, seminars, etc)
 - Seeking to host at least one webinar from one of the prospective candidates
- **Task: Definitions.**
 - We need contribution from the Advisory Council to help us complete the definitions list, and to invite contribution from the broader community
 - Provide definitions of terms (a few per Executive Committee member) before each biweekly meeting of the Executive Committee.
- **Task: Ten Simple Rules.**
 - Complete public survey data analysis to develop the Ten Simple Rules master document that will set the foundation for the “*Guidelines for Credible Practice of Modeling and Simulation in Healthcare*”

- *Data analysis team: Lu Tian, Lealem Mulugeta, Tina Morrison and Martin Steele*
- **Task: Workflows for Credible Practice**
 - We will continue to reach out to the research and clinical communities for contributions to credible practice workflows we can learn from

Goals for 2016-2017:

- PLOS article on the Committee's perspective on the Ten Simple Rules (PLOS), 'Ten “Not So” Simple Rules for Credible Practice of Modeling and Simulation in Healthcare Perspectives from a Multidisciplinary Committee'
- Journal publication on the Ten Simple Rules of Credible Practice of M&S in Healthcare based on the public survey results and Committee's perspective
- Draft the first version of the “Guidelines for Credible Practice of Modeling and Simulation in Healthcare” based on the the results of the outcome of the Ten Simple Rules task
- Draft a proposed model certification process for the third term CPMS to advance
- Develop Committee Charter to define ground rules, roles and responsibilities of all members
- Establish a mechanism to tie the Committee's activity to the future IMAG MSM solicitation to bolster the credibility portion of the solicitation by:
 - Proactively engaging the investigators to share with us their proposed credibility plan and how we might be able to incorporate that into our overarching work
 - Use the pool of funded investigators may also be a great source to find future members and co-chairs