

Minutes for Advisory Council Meeting

Committee on Credible Practice of Modeling & Simulation in Healthcare

Date: June 3, 2013
Time: 1:00 PM CDT

Means: Conference Call

Attendees: Jeff Bischoff
David Eckmann
Ahmet Erdemir
Tony Hunt
Wing Kam Liu
Donna Lochner
Vasilis Marmarelis
Lealem Mulugeta
Pras Pathmanathan
Grace Peng
Martin Steele
Jim Thomas

Not Available: Ron Germain
Marlei Walton

Agenda:

1. **Introductions** – 30 min - Each Advisory Council member will introduce him/herself and his/her interests in the Committee. Please keep it brief.
2. **Roles and expectations** - 10 min - Committee Co-Chairs will summarize what is expected from Advisory Council members.
3. **Feedback on current activities** - 20 min - Committee Co-Chairs will ask Advisory Council to provide feedback on current activities. Please check the attached document for a summary of progress (ac_20130603-pu.pdf).

Key Points:

See Notes for details.

1. **Potential groups to divide the AC to work on definition of terms and areas of focus for the first two year term, e.g.,**
 - Clinicians
 - Hardcore modelers
 - End users (clinicians, biologists, environmentalists, etc)
 - Standards

The groups should ultimately capture the various types of modeling and simulation categories within the Multiscale Modeling Consortium (biomedical, biological, behavioral scientists) since they are inclusive

of all the agencies involved in the Interagency Modeling and Analysis Group and are also representative of the wider healthcare related modeling and simulation community.

2. **Given that the committee was originally established for developing credible practice guidelines to help advance research models to clinical practice, we may want to think of models with respect to the following four questions:**
 - Which ones are already being used as clinical tools?
 - Which ones are on their way to becoming clinical tools?
 - Which ones are research tools?
 - Which ones are still in development to become research tools?
3. **The goal of the committee for the next two years is not to solve all problems related to credible practice of modeling and simulation in healthcare. The goal is to establish a good foundation from which we can continually build on and advance the state of the art in credible practice.**

Action Items

See Notes for details.

1. ***Co-chairs will work with the rest of the Committee Members to divide the Advisory Council into different groups based on similarities in their expertise and interests.*** The goal of these groups will be:
 - to help define key terminologies as it pertains to their areas of interests, and
 - to help define the key focus areas of the committee.The executive Committee Members will also be coordinated with these groups to ensure that everyone is in sync on the advancement of the Committee's objectives in a cohesive manner. Co-chairs will discuss this with the Executive Committee at the next Committee meeting.
2. ***Jim Thomas has been asked to provide his biosketch to Lealem.***
3. ***All Advisory Council members have been asked to review and provide feedback on the Committee's progress summary and the summary presentation*** (ac_20130603-pu.pdf and committee_summary.pdf).

Notes:

1. **Introductions - 30 min**
 - A quick overview of the current executive Committee Members was provided.

Committee Members

Gary An
Jacob Barhak
Ahmet Erdemir (Co-Chair)
Marc Garbey
Tina Morrison
Jerry Myers
Lealem Mulugeta (Co-Chair)

- Each Advisory Council member introduced themselves, and expressed their interest in the Committee (see notes below for details on each member). More extensive bio-sketches are available for all members.

Ahmet Erdemir (Co-Chair)

Co-chair of Committee and works at the Cleveland Clinic as researcher in multiscale modeling of joint, tissues, and cells to understand body movement and deformation. Also runs a computational modeling service facility at the Cleveland Clinic.

Lealem Mulugeta (Co-Chair)

Co-chair of Committee, works as Project/Lead Scientist with NASA Digital Astronaut Project to develop series of models to inform research and countermeasures development of astronaut health risks. Model verification and validation, and credibility assessment is an essential part of this work.

Advisory Council Roster**Jeff Bischoff, PhD**

Works for Zimmer in computational modeling and simulation for orthopaedic applications and joint reconstruction. He has also been involved in verification and validation standards development with the American Society of Mechanical Engineers for the past 2 years.

David Eckmann, MD, PhD

University of Pennsylvania, School of Medicine - computational methods, microvascular blood flow, cell signaling, mechanotransduction with an emphasis in cell targeting for nano carrier drug delivery.

Tony Hunt, PhD

Bioengineering at therapeutic sciences in University of California at San Francisco – models to improve the explanatory mechanistic insights.

Wing Kam Liu, PhD

Northwestern University – currently pursuing modeling and simulation in fluid-solid mechanics, multiphysics, biological flow, design sensors, drug delivery and related to uncertainty quantification via Bayesian probability analysis.

Donna Lochner

FDA - manages computational modeling programs and their implementation in regulatory process.

Vasilis Marmarelis, PhD

University of Southern California - professor of biomedical engineering, modeling of time series data following a nonlinear approach. Recently working on model based physio-markers to quantify physiological function for clinical utility and advancing diagnostics. Credible practice is an important aspect of this, which is why he is interested in participating.

Pras Pathmanathan, PhD

FDA, University of Oxford - modeling of cardiac activity, electrophysiology, electro mechanics. His current work is based on verification/validation and uncertainty quantification for cardiac models.

Grace Peng, PhD

Program Director at NIBIB/NIH – responsible for programs including modeling, analysis and simulation as well as next generation engineering systems for rehabilitation and surgical systems. Also the chair of Interagency Modeling and Analysis Group (IMAG), which is a group of federal agencies across the US and Canada who coordinate the Multiscale Modeling Consortium that has

over 80 projects now. Verification and validation, and uncertainty quantification in modeling and simulation are important elements of the areas she is focused in.

Martin Steele, PhD

NASA Kennedy Space Center – has been doing modeling and simulation for 13-14 years in the areas of process analysis. The last 8 years involved in NASA standards in models and simulations including credibility assessment mechanisms. Kicked off a handbook to accompany the NASA standard for models and simulation, which will be published in the next month or so.

Jim Thomas, MD

Cardiologist at the Cleveland Clinic - cardiovascular imaging, applied mathematics background, blood flow, mitral valve flow, regurgitative flow, as well as advanced FEA of the heart to understand stress-strain within the fibers of the heart walls. He is working with Peter Hunter from the University of Auckland in New Zealand.

Ron Germain, MD, PhD – Unable to attend

Marlei Walton, PhD – Unable to attend

2. Roles and expectations - 10 min

- Committee Co-Chairs summarized what is expected from Advisory Council members, Executive Committee and the Co-Chairs.
- Executive Committee – currently compiling information related to credible practice. Committee Members are expected to dedicate 8 hours of effort per months. Advisory Council is expected to provide consistent feedback to meet charges of the Committee.
- Advisory Council was selected to provide critical feedback, e.g., what we may be missing, keeping the Committee in check, relying on an accountability based system.
- Ahmet and Lealem described the infrastructure that the committee has been using to communicate, exchange ideas, share documents, version control of documents, and reference management (SimTk website, Forum, Subversion, Zotero, OpenMeetings, and Teleconference line). See document ac_20130603-pu.pdf for details.
- The Committee's charge was described to the Advisory Council, which led to extensive discussion on what the focus of the Committee should be. The topic we are attempting to tackle can be quite broad and is challenging.
- The Advisory Council was encouraged not to limit their interactions with the Co-Chairs and the other Advisory Council members. They should also engage the rest of the executive Committee Members, and the executive Committee Members will also engage with them to get feedback on various areas. When the Advisory Council is not able to provide direct feedback, the executive Committee will also request names of people that could possibility provide critical feedback.
- If the current structure does not work well, the Advisory Council is expected to let the executive Committee know so that appropriate adjustments can be made to improve communication and Committee end products.
- The Advisory Council was also encouraged to provide any unique ideas they may have. The goal is to be inclusive of all ideas so that we may arrive at a superior product in the end.

3. Feedback on current activities - 20 min

- Vasilis recommended that role of definition of various terms and phrases be shared with the Advisory Council and with the Executive Committee's leadership.

- It was suggested by Vasilis that validation and transparency are at the heart of the Committee's primary objectives. Therefore they should be highlighted and repeated. The reason being that validation is at the heart of the problem with regards to credible practice. Lealem and Ahmet agreed that validation is an important element, however depending on the type of modeling and simulation in consideration, validation may not be as important as other elements such as uncertainty quantification, data quality, etc. In general, depending on the use case of the model, the level of validity needed can differ substantially. It was also noted that validation is indeed a subset of Committee charge, though may not appear explicitly.
- During the above discussion it was acknowledged that the terminology can be tricky and that it was recommended that offline discussions among the Advisory Council and other Committee Members should be carried on so that we have more consistent way of using the terms. This aligns perfectly with the one of the current tasks that the Executive Committee, which is pursuing on establishing consistent terminology (Ahmet and Gary are leading). The Advisory Council was encouraged to engage in the online discussions that are currently taking place on the forum so that they can provide key terms and definitions. The forum thread on this topic can be accessed here: <https://simtk.org/forums/viewtopic.php?f=848&t=4159>
- To help provide a consistent vision and use of terminology, the Advisory Council was encouraged to provide feedback on the Committee summary presentation.
- Wing Liu – concurred that terms may mean completely different things to different people, depending on their backgrounds. Therefore, he suggested that that we divide the Advisory Council and executive Committee Members into different groups based on areas of expertise and interests. There should be two groups at a minimum, and instead of having a single source for the different definitions, we can have a push-pull relationship between the different groups and different applications to come up with terms and definitions that are more multidisciplinary. For example:
 - The individuals who have a modeling and simulation background generally have similar definitions for the different terms.
 - The clinicians may use the same terms in a completely different manner.
- Possible groups may include: clinicians, engineers, physicians, regulatory folks, etc. However, we should also be flexible to dynamically change the groups, depending on the feedback as we move forward.
- David Eckmann – possible organizational approach to think about models are with respect to their maturity:
 - clinical tools
 - established as clinical research tools
 - becoming research tools

Some of these borders may cross, but the idea would be to identify which models are established as clinical tools, and what we need to do to graduate the research and development models to become clinical tools. This is exactly what led us down the path of establishing the Committee.

- From a perspective of a person who sits in both camps, as a clinical practitioner and modeler, David Eckmann pointed out that he needs to think about what are the sophisticated tools that can be used to guide his practice. Some models are tightly integrated into devices he uses for interpreting clinical data. These models would be classified as very mature for clinical practice. There are other models on the other hand which are not as mature, but may still be used to inform clinical practice. The question becomes to what degree do they play a role in clinical practice and how might they influence the treatment? This could also give ties partly into visibility and outreach to help cultivate interest outside of the research community to promote how modeling and simulation can be useful for clinical practice. This is again in alignment with the intent of the Committee.
- Grace - David's comments regarding defining where a model's maturity level stands is in good correlation with current efforts of the Interagency Modeling and Analysis Group, e.g., to have an

index of models with appropriate categories to specify the maturity of the model and how they can be used.

- Vasilis – given that this is a very complex task we are trying to tackle, we need to scope the work to key principles and common areas to tackle in order to be effective in our ultimate contribution.
- Lealem - The goal of the committee for the next two years is not to solve all problems related to credible practice of modeling and simulation in healthcare. The goal is to establish a good foundation from which we can continually build on and advance the state of the art in credible practice.
- Co-Chairs agreed and suggested to establish and get feedback from different groups. Co-Chairs have accepted an action item to identify how to divide up the Advisory Council and the executive Committee Members so that they can help identify key areas of focus.
- Some suggestions is that we focus on areas which are more mature for the near term and identify longer term areas in parallel.