TEN "NOT SO SIMPLE" RULES FOR CREDIBLE PRACTICE OF MODELING & SIMULATION IN HEALTHCARE
A Multidisciplinary Committee Perspective

2013 BMES/FDA Frontiers in Medical Devices
May 18-20, 2013 Washington, DC

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with contributions from members of the Committee on Credible Practice of Modeling & Simulation in Healthcare

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 decision-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.
- To synthesize 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.

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
- EXECUTE & CHARGE
  - EXECUTIVE COMMITTEE
    - 2 co-chairs
    - 6 current members including co-chairs
    - 2 paid members
- REVIEW & ADVISE
  - ADVISORY COUNCIL
    - 12 current members

INITIAL SET OF RULES

<table>
<thead>
<tr>
<th>Rule number</th>
<th>Rule content</th>
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| 1 | Define context clearly.
| 2 | Use appropriate data.
| 3 | Evaluate within context.
| 4 | List limitations explicitly.
| 5 | Use version control.
| 6 | Document adequately.
| 7 | Disseminate broadly.
| 8 | Get independent reviews.
| 9 | Test competing implementations.
| 10 | Conform to standards.

Mathematics & Computation Team
- Interest in development of models and simulation approaches
- 7 participants
  - 1 - Executive Committee
  - 1 - Advisory Council
  - 5 - CoE Members
- Scientists
  - engineers
  - academia
  - industry
  - government

Users Team
- Interest in application of models for clinical research and practice
- 7 participants
  - 1 - Executive Committee
  - 1 - Advisory Council
  - 5 - CoE Members
- Scientists
  - engineers
  - academia
  - industry
  - government

Standards & Guidelines Team
- Interest in evaluation of models and simulation approaches
- 7 participants
  - 1 - Executive Committee
  - 1 - Advisory Council
  - 5 - CoE Members
- Scientists
  - engineers
  - academia
  - industry
  - government

TASK TEAM RANKINGS
- 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.

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PROJECT SITE: https://simtk.org/home/cpms
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Committee’s activities are facilitated by the Interagency Modeling and Analysis Group and Multiscale Modeling Consortium.

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