MEETING FOCUS: Discussion of the draft NAM Special Publication on Artificial Intelligence (AI) and Machine Learning (ML) describing the promise, development, and deployment of AI/ML models to improve health.

Motivating Questions: For each chapter in the NAM Special Publication, participants were asked to consider the following:
1. **Key Issues**: Does the chapter address the most significant issues facing the development, deployment, or use of AI/ML in health care?
2. **Solutions**: Do the solutions proposed in the chapter adequately balance the key consideration and issues discussed? Do they provide fair and balanced guidance to those interested in developing and deploying AI/ML models in health care settings?
3. **Improvements**: Are there recommendations regarding ways the chapter content could be improved to increase its usefulness to field?

Expected outcome: Refinement of the draft NAM Special Publication so that it is effective at accelerating the appropriate development, adoption, and use of valid, reliable, sustainable AI and ML models for transformative progress in health and health care.

REPRESENTATIVE OBSERVATIONS/RECOMMENDATIONS
- **Global Comments**: The goal of this publication is to explore the realistic promise and potential of AI while surfacing and addressing the unintended consequences. Therefore, this publication should walk a balance between exuberance and nihilism, carefully maintaining an equilibrium that prevents over-promise and under-delivery.
- Since most readers will selectively focus on the chapters that relate to their areas of expertise, each chapter should summarize the broader points in bullet form at the end for easy perusal. Priorities identified in each chapter, especially those regarding education, need to be concrete, actionable, poignant, and should have consistent formatting.
- To increase the accessibility of the publication, meeting participants suggested turning the chapters into digestible podcasts.
- **Chapter 1**: In the introductory chapter key terms such as learning health system, AI, ML, augmented intelligence, continuous vs static systems, open vs closed, and rules-based vs expert-driven systems should be defined.
- In addressing the “why AI now” question, there is an opportunity to provide a brief overview of the deficiencies of current EHR systems and how AI might be useful in filling the gaps.
- Considering that a multitude of factors that influence health occur outside of the traditional clinical care setting, Chapter 2 should include a discussion of Internet of Things (IoT), how it impacts data collection with particular reference to patient generated data in public devices, and how AI is deployed in such an environment.
- Key stakeholders should be expanded to civil society organizations such as HLU, standard setting bodies such as IEEE, and end users such as patients and consumers.
- **Chapter 3**: Applications could be delineated by use case, eventual impact, level of risk, cost, level of regulation, fixed vs continuous system, cottage developed vs commercial AI, and whether the intention is to advance the science of medicine or the science of improving health.
- Instead of being comprehensive, Chapter 3 and 4 should synchronize on a limited set of examples to present both the opportunities and potential of an application as well as the pragmatic considerations and challenges.
- Regarding robust evaluation of performance, Chapter 4 should perhaps undertake an exploration of rules-based and/or logic-based AI systems that are more transparent, explainable and less prone to vulnerabilities.
- Chapter 4 should also underscore the need for continuous learning and vigilance as algorithms generated in one hospital may function improperly at another setting. Furthermore, since EHRs are not static, algorithms deployed in a constantly changing system require continual review and calibration.
- As a central theme of Chapter 4, the issue of data bias needs to be separated from data accuracy which is the result of how data is inputted based on the design of the information system.
- Efforts to minimize bias in training data sets prior to their use in model development and the use of synthetic data could fit into Chapter 5.
- Chapters 5 and 6 should work in tandem to highlight the importance of embedding clinical utility into the data validation process.
- Health care systems need a mechanism to evaluate the risk and ROI of AI models.
- Critical to Chapter 6 is the need for internal and external validation. When assessing the performance of an AI solution, health systems need to benchmark against existing processes and evaluate the impact on health care culture and workflow.
- A portion of Chapter 6 could also be devoted to the development of certification and governance structures outside of FDA, such as consumer agencies, to promote the safe, effective, and ethical deployment of AI where regulations are not currently providing sufficient protection to users.
- **Chapter 7** should consider making concrete recommendations on where additional legislation and regulation is imperative and where it could be disadvantageous to over-regulate.
- The overriding challenge with Chapter 7 is controlling the scope and length while touching on the myriad issues brought up by the group: informed consent, patient data privacy issues, data as a public good versus patient data ownership, and data aggregation.

COLLABORATIVE ACTIVITIES FOR CONSIDERATION
Members of the writing group will reflect on the content of this meeting and determine collectively which topics to include in the final iteration of the publication.
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DIGITAL LEARNING COLLABORATIVE
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