Virtual Journal club

The promise of artificial intelligence (AI) and machine learning (ML) for improving clinical outcomes

Thursday, February 15, 2024 11:00am ET
But first, housekeeping

• Please note today’s session is being recorded
• To ask a question for discussion during Q&A, please:
  • Either ‘raise your hand’ in the participant window and moderator will unmute you to ask your question live, or
  • Type your question into the chat box
• Slides and recording will be available after today’s session
The promise of artificial intelligence (AI) and machine learning (ML) for improving clinical outcomes

Thursday, February 15, 2024 11:00am ET
Resolving the Credibility Crisis: Recommendations for Improving Predictive Algorithms for Clinical Utility

Stephen Ruberg, Sandeep Menon, Charmaine Demanuele

Harvard Data Science Review
Fall 2023
https://doi.org/10.1162/99608f92.c1292c54
What’s the Problem?

Large errors in flu predictions were largely avoidable, which offers lessons for the use of big data.

Conclusions — Few prospective deep learning studies and randomised trials exist in medical imaging. Most non-randomised trials are not prospective, are at high risk of bias, and deviate from existing reporting standards.
What’s the Problem?

THE LANCET

EDITORIAL | VOLUME 392, ISSUE 10142, P 95, JULY 14, 2018

Is digital medicine different?

The Lancet

Published: July 14, 2018  •  DOI: https://doi.org/10.1016/S0140-6736(18)31562-9  •  Check for updates

The risks of digital medicine, particularly use of AI in health interventions, are concerning. Continuing to argue for digital exceptionalism and failing to robustly evaluate digital health interventions presents the greatest risk for patients and health systems."
What’s the Solution? A Framework

Maximize $\text{Total Value} = PPV \cdot V_{TP} + (1-PPV) \cdot V_{FP} + NPV \cdot V_{TN} + (1-NPV) \cdot V_{FN}$
### What's the Solution? A Framework

<table>
<thead>
<tr>
<th>Identification Phase 0</th>
<th>Development Phase 1</th>
<th>Feasibility Phase 2</th>
<th>Evaluation Phase 3</th>
<th>Implementation Phase 4</th>
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</thead>
<tbody>
<tr>
<td>Identify diagnostic/prognostic need</td>
<td>Select databases and modeling approaches</td>
<td>Conduct multicenter CRTs* in patient care, including clinical workflow</td>
<td>Conduct prospective, broad CRTs with clear protocol (workflow) &amp; SAP</td>
<td>Embed CPA in EHS for appropriate setting(s)</td>
</tr>
<tr>
<td>Identify appropriate data sources</td>
<td>Develop model on retrospective database</td>
<td>Define protocol &amp; SAP** with surrogate or clinical outcomes</td>
<td>Account for local prevalence</td>
<td>Monitor clinical outcomes from implementation of CPA</td>
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<tr>
<td>Identify modeling approaches</td>
<td>Test algorithm in healthcare setting outside patient care</td>
<td>Estimate TV given prevalence by varying cut-off C</td>
<td>Pre-specify appropriate clinical outcomes (e.g., survival, AEs), benefit-risk and TV</td>
<td>Conduct studies for utility/TV in other populations or settings</td>
</tr>
<tr>
<td>Identify clinical workflows</td>
<td>Explore cut-off (C); estimate AUC; identify safety concerns</td>
<td>Fine-tune algorithm for Evaluation phase; Draft Model Facts Sheet</td>
<td>Perform comparative algorithm research using the TV metric</td>
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*CRT = Cluster Randomized Trials
**SAP = Statistical Analysis Plan
Historical Context (1)

Pre-1962
No statutory requirements for proving safe and effective treatments

1962 - …
“… substantial evidence from adequate and well-controlled investigations …”

Kefauver-Harris Amendment

“The anarchy of guess and intuition [in the design and analysis of clinical trials] has given way to a benevolent tyranny of statisticians.”

Donald S. Frederickson
Director of the National Heart Institute
1968

1980-2000

“Isolated laboratory investigators received convenient specimens from their clinical collaborators and applied their favorite technology to search for biomarkers. Non-reproducible but highly acclaimed findings were rampant, but few successful translational products made it to clinical use.”

Clinical Predictive Algorithms

Statistical Principles?
Systematic Development?
Learn from History

“We shall not cease from exploration, and the end of all our exploring will be to arrive where we started and know the place for the first time.”

T.S. Eliot
V3+: An extension to the V3 framework to ensure user-centricity and scalability of sensor-based digital health technologies

**DATAcc**

Digital Health Measurement Collaborative Community

**Tuesday, February 27**

11 am - 12 pm ET

**Bryan Cobb**  
*Pr. Medical Science Director*  
Genentech

**Kim Kontson**  
*Biomedical Engineer*  
Center for Devices and Radiological Health, U.S. FDA

**Elizabeth Kunkoski**  
*Health Science Policy Analyst*  
Center for Drug Evaluation and Research, U.S. FDA

**Stéphane Motola**  
*Strategic Partnership Project Manager*  
SYSNAV

**Oana Paun**  
*QA Manager*  
Aardex Group

**Benjamin Vandendriessche**  
*VP, Science*  
Digital Medicine Society (DiMe)
Virtual Journal Club

Defining the Dimensions of Diversity to Promote Inclusion in the Digital Era of Healthcare

March 27, 2023 | 11 am ET
THANK YOU