Imperial College London

FAIHealth camo centre for antimicrobial optimisation

Designing, evaluating and integrating AI decision support systems in healthcare

William Bolton

CAMO-Net UK Workshop

21st June 2024

Objective, agenda and outcomes

Ideate and discuss how to best design clinical decision support systems, evaluate them with clinical studies and set up infrastructure for integration

Agenda

1. Introduction and background
2. Online Q&A – mentimeter
3. Interactive Breakout Session
4. Set goals and conclude

Outcomes

- Clustered opinions
- User statements on design, evaluation and integration
- SMART goals to work towards in the future
- Education, collaboration and fun!

Artificial intelligence for optimised antibiotic decision making.

STAGES OF ANTIBIOTIC DECISION MAKING

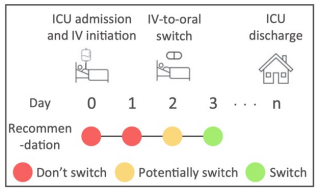
Hospital admission

Antimicrobial stewardship

Hospital discharge

0 — 1 — 2 — 3

IV-to-oral switch



Antibiotic readmission

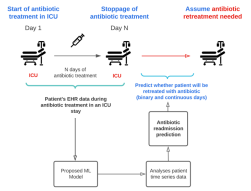


Figure 1.2: Proposed ML-based decision support model

Side effects

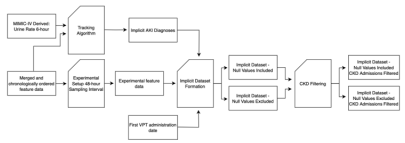
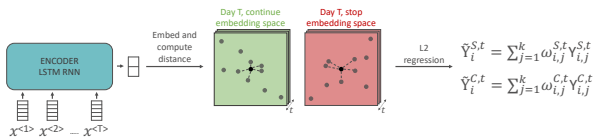
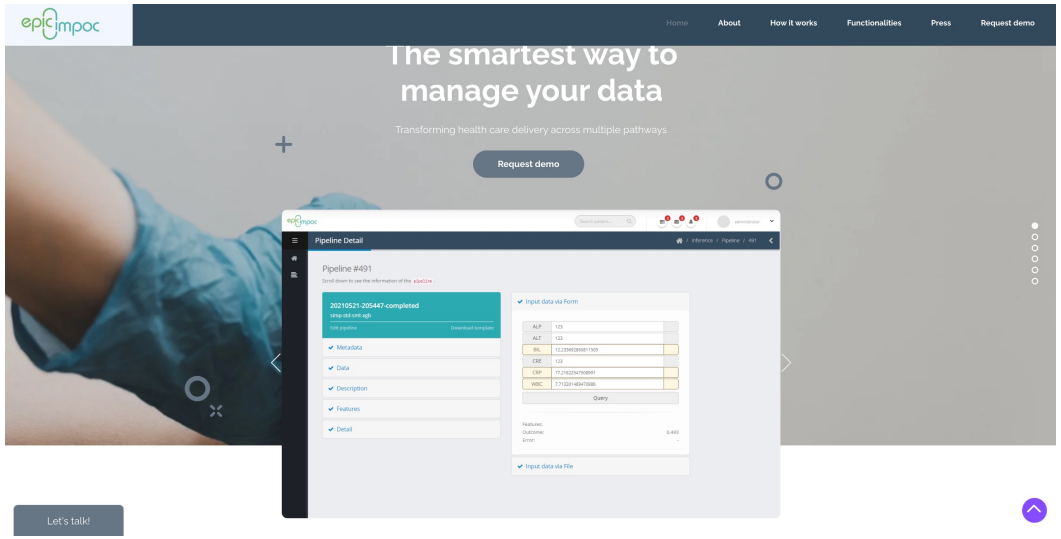


Figure 13: Implicit dataset formation workflow.

Antibiotic cessation



Demo of current decision support systems: EPIC-IMPOC



Geoloaction

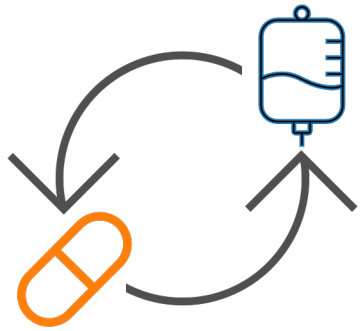
Microbiology

Management

2D Latent Space

Demo of current decision support systems: AI-IVOS

make the switch
FROM IV TO ORAL ANTIBIOTICS



Demo

Participate in our study:

william.bolton@imperial.ac.uk

If you are a clinician and would like to participate in a research study investigating how a novel AI clinical decision support system can support intravenous to oral antibiotic switch decision making, please email us ☺

We are particularly interested in recruiting those who are more **junior and generalist**

Can we create a roadmap for responsibly designing, evaluating and integrating AI in healthcare

nature medicine

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nature › nature medicine › perspectives › article

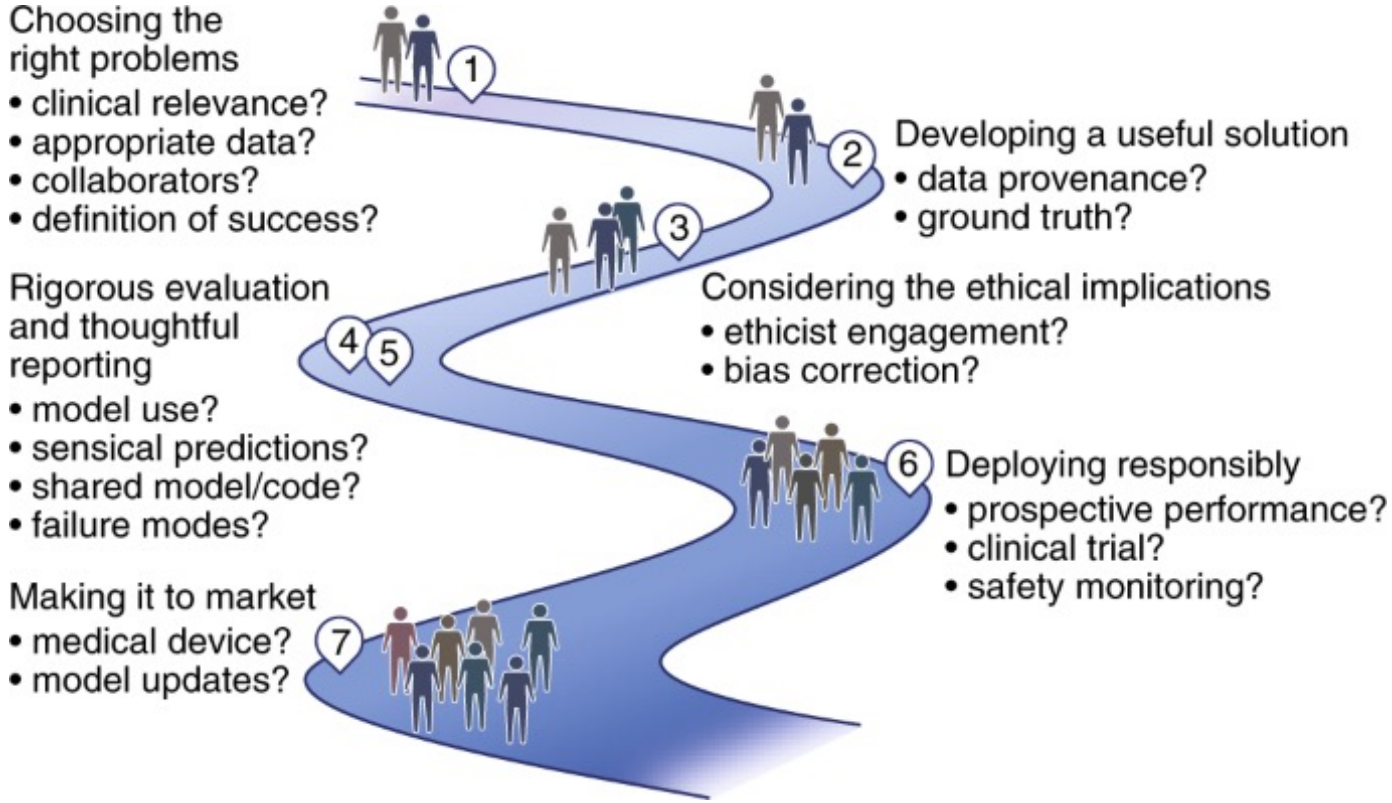
Perspective | Published: 19 August 2019

Do no harm: a roadmap for responsible machine learning for health care

Jenna Wiens ✉, Suchi Saria, Mark Sendak, Marzyeh Ghassemi, Vincent X. Liu, Finale Doshi-Velez, Kenneth Jung, Katherine Heller, David Kale, Mohammed Saeed, Pilar N. Ossorio, Sonoo Thadaney-Israni & Anna Goldenberg ✉

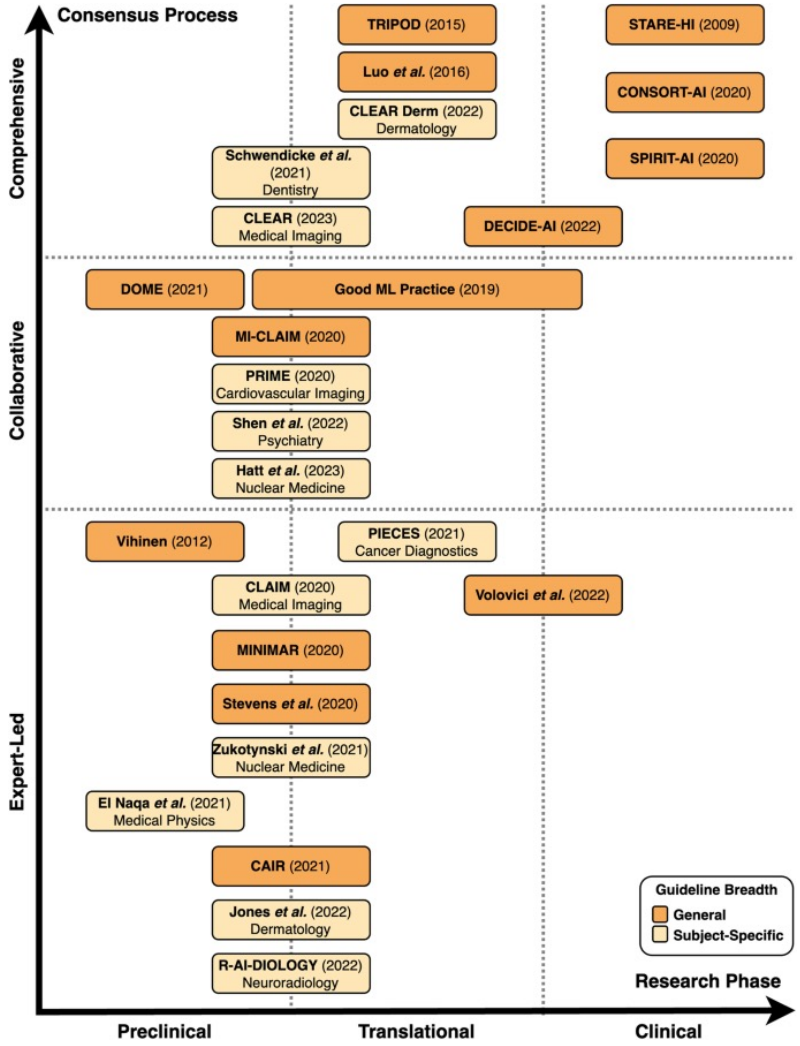
Nature Medicine **25**, 1337–1340 (2019) | Cite this article

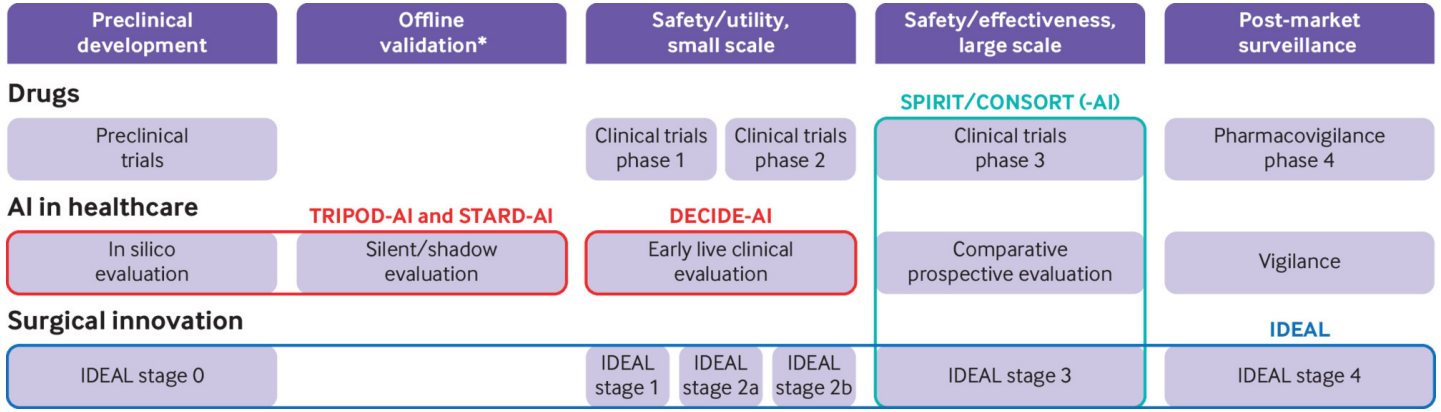
33k Accesses | **409** Citations | **704** Altmetric | Metrics



Wiens, J., Saria, S., Sendak, M. *et al.* Do no harm: a roadmap for responsible machine learning for health care. *Nat Med* **25**, 1337–1340 (2019). https://doi.org/10.1038/s41591-019-0548-6

Many guidelines exist for reporting AI in medicine





Box 2: Noteworthy changes and additions to TRIPOD 2015

- New checklist of reporting recommendations to cover prediction model studies using any regression or machine learning method (eg, random forests, deep learning), and harmonise nomenclature between regression and machine learning communities
- New TRIPOD+AI checklist supersedes the TRIPOD 2015 checklist, which should no longer be used
- Particular emphasis on fairness (box 1) to raise awareness and ensure that reports mention whether specific methods were used to deal with fairness. Aspects of fairness are embedded throughout the checklist
- Inclusion of TRIPOD+AI for Abstracts for guidance on reporting abstracts
- Modification of the model performance item recommending that authors evaluate model performance in key subgroups (eg, sociodemographic)
- Inclusion of a new item on patient and public involvement to raise awareness and prompt authors to provide details on any patient and public involvement during the design, conduct, reporting (and interpretation), and dissemination of the study
- Inclusion of an open science section with subitems on study protocols, registration, data sharing and code sharing

TRIPOD=Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis; AI=artificial intelligence.

Medicines & Healthcare products Regulatory Agency

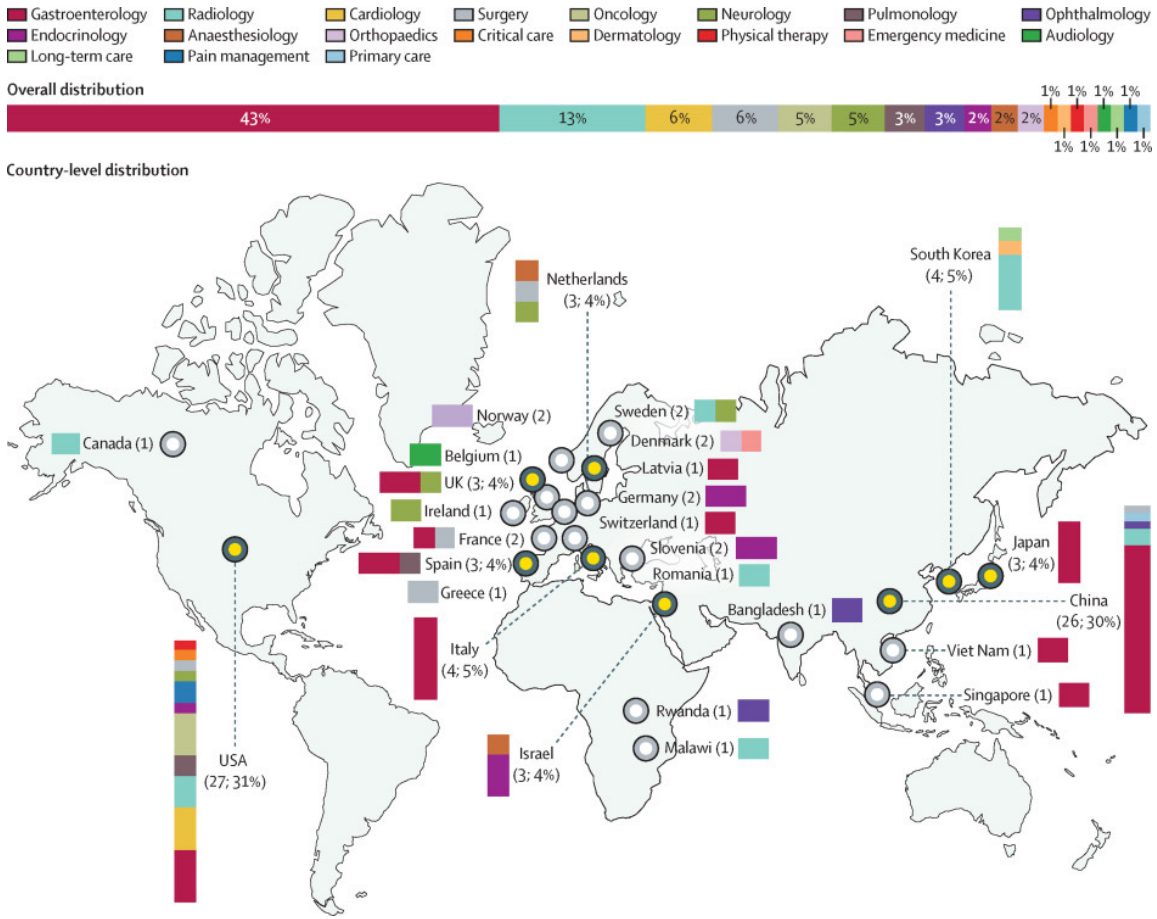
Guidance

Good Machine Learning Practice for Medical Device Development: Guiding Principles

Published 27 October 2021

Kolbinger, F.R., Veldhuizen, G.P., Zhu, J. *et al.* Reporting guidelines in medical artificial intelligence: a systematic review and meta-analysis. *Commun Med* **4**, 71 (2024). https://doi.org/10.1038/s43856-024-00492-0
Vasey B, Nagendran M, Campbell B, Clifton D A, Collins G S, Denaxas S et al. Reporting guideline for the early stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI BMJ 2022; 377 :e070904 doi:10.1136/bmj-2022-070904
Collins G S, Moons K G M, Dhiman P, Riley R D, Beam A L, Van Calster B et al. TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods BMJ 2024; 385 :e078378 doi:10.1136/bmj-2023-078378

Few clinical trials of AI in real clinical practice exist - especially in infectious diseases.



nature medicine

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Article | Published: 21 July 2022

Prospective, multi-site study of patient outcomes after implementation of the TREWS machine learning-based early warning system for sepsis

Roy Adams, Katharine E. Henry, Anirudh Sridharan, Hossein Soleimani, Andong Zhan, Nishi Rawat, Lauren Johnson, David N. Hager, Sara E. Cosgrove, Andrew Markowski, Eili Y. Klein, Edward S. Chen, Mustapha O. Saheed, Maureen Henley, Sheila Miranda, Katrina Houston, Robert C. Linton, Anushree R. Ahluwalia, Albert W. Wu ✉ & Suchi Saria ✉

Nature Medicine **28**, 1455–1460 (2022) | Cite this article

32k Accesses | **73** Citations | **496** Altmetric | Metrics

Han R, Acosta JN, Shakeri Z, Ioannidis JP, Topol EJ, Rajpurkar P. Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review. The Lancet Digital Health. 2024 May 1;6(5):e367-73.
Adams, R., Henry, K.E., Sridharan, A. et al. Prospective, multi-site study of patient outcomes after implementation of the TREWS machine learning-based early warning system for sepsis. Nat Med 28, 1455–1460 (2022). https://doi.org/10.1038/s41591-022-01894-0

AI clinical decision support systems are regulated at a minimum as Class II software as a medical device in the UK.

The Journey

Pre-Market

1 **Intended Use**
The critical first step in the development of AI and health tech products. A clear intended use prioritises safety, effectiveness and gives clarity on how to position your SaMD for success.
READ MORE →

2 **Risk Classification**
The risk level of a medical device or AI product determines the required clinical evidence and regulatory oversight. Read on to learn more!
READ MORE →

3 **Notified / Approved Body Engagement**
To launch a product in the UK or EU, an independent notified body or approved body must review and comply with European legislation, granting UKCA marks.
READ MORE →

4 **Quality Management Systems (ISO 13485)**
Elevate compliance in medical device manufacturing with our QMS. We cover design, supply, risk management, and CAPAs for a solid regulatory strategy. Read more!
READ MORE →

5 **Medical Device File Design**
Your MDF provides evidence to demonstrate compliance of the device to all the applicable regulations. Its structure and design is key.
READ MORE →

6 **MDSAP**
The Medical Device Single Audit Programme (MDSAP) streamlines quality management systems by enabling compliance proof through a single audit for five markets.
READ MORE →

7 **Clinical Evaluation Plan**
The Clinical Evaluation Plan (CEP) is a vital tool in product development, guiding device clinical evaluation through the Valid Clinical Association. Read more!
READ MORE →

8 **QMS Deployment & Training**
Hardian is an AI-based SaMD company that offers training and guidance to help clients meet international standards for quality management system implementation.
READ MORE →

9 **Software Verification & Validation**
The process of the software development lifecycle is essential to ensure all requirements are met before testing the product in the real world. Read more!
READ MORE →

10 **Clinical Evaluation Report**
The Clinical Evaluation Report (CER) is a crucial document in clinical evaluation, containing development activities and clinical evidence for device marketing.
READ MORE →

11 **Responsible Person (PRRC and UKRP)**
Depending on your jurisdiction of deployment, you may need to appoint responsible persons across these jurisdictions.
READ MORE →

12 **Product Registration**
Now the hard work is done, registering your product on the relevant regulatory databases is the final step to legally place your product on the market.
READ MORE →

Medicines & Healthcare products Regulatory Agency

Guidance
Software and artificial intelligence (AI) as a medical device
Updated 13 June 2024

https://www.england.nhs.uk/long-read/artificial-intelligence-ai-and-machine-learning/
https://www.hardianhealth.com/regulatory
https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device

Usability is also essential for trust and adoption

ELSEVIER
Journal of Systems and Software
Volume 208, February 2024, 111881

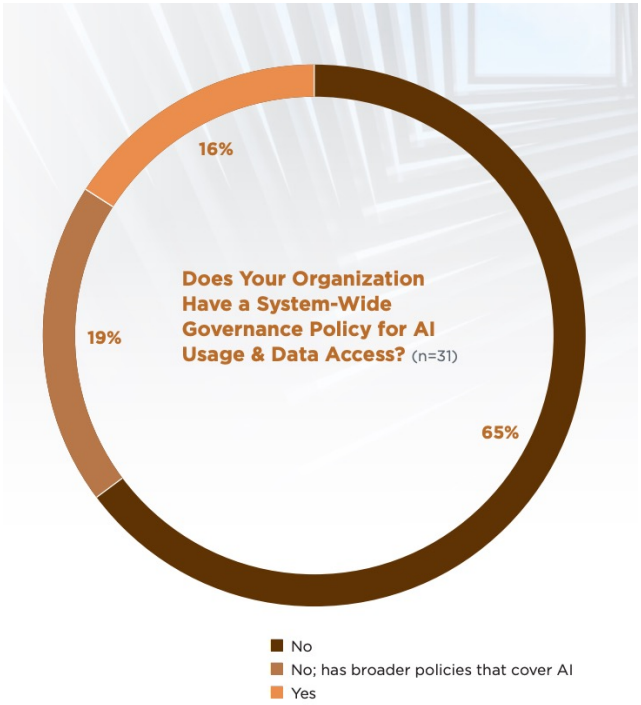
Potential effectiveness and efficiency issues in usability evaluation within digital health: A systematic literature review ☆

Bilal Maqbool, Sebastian Herold

https://www.mgma.com/mgma-stat/ehr-usability-patient-communications-billing-outrank-ai-as-top-tech-priorities

Maqbool, B. and Herold, S., 2023. Potential effectiveness and efficiency issues in usability evaluation within digital health: A systematic literature review. Journal of Systems and Software, p.111881.

Are hospitals ready for AI?

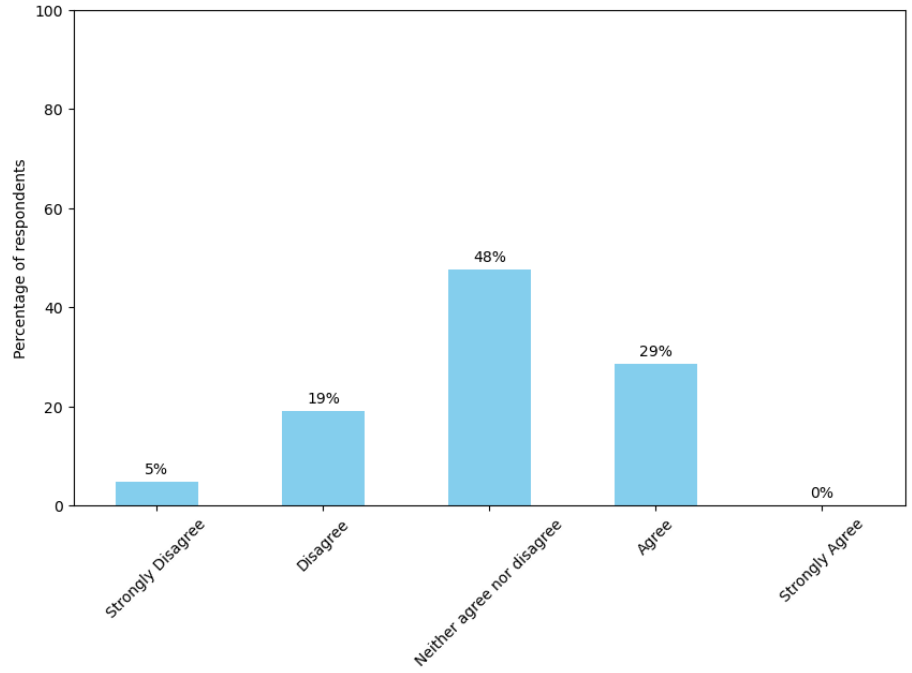


Survey respondents identified a host of challenges to executing digital and AI transformation in the next two years.

Challenges ranked in top 3, number of respondents[1]

Challenge	Ranked No. 1	Ranked No. 2	Ranked No. 3	
Legacy systems are difficult to upgrade; the digital switch is too challenging	33	47	29	109
Budget or capital limitations	50	25	27	102
Workforce not ready to implement new technology	20	24	24	68
Poor data quality prevents use of new tech	28	16	23	67

I think my healthcare institution has the necessary infrastructure to support this AI CDSS*



https://info.connectedmed.com/l/689353/2024-02-09/2lvknc/689353/1707510824kuJAqb0f/How_Health_Systems_Are_Navigating_The_Complexities_Of_AI_CCM_Reports.pdf?
https://www.mckinsey.com/industries/healthcare/our-insights/digital-transformation-health-systems-investment-priorities?utm_source=substack&utm_medium=email
*Unpublished research – n = 21

Any thoughts or questions?

Q&A

Quick fire Q&A

Be as creative as possible!

You can submit multiple responses

Join at menti.com | use code 8100 8519

Interactive Breakout Session!

1. Split yourself into groups of 4-6
   - Try to ensure an even split of skills
   - Work with those you don’t normally collaborate with
   - Nominate a leader to speak

2. Each group will be assigned a topic:
   - **Design / usability**
   - **Clinical evaluation**
   - **Integration**

3. You will have 8 minutes to to discuss and come up with **5 statements** of the form: **User – Need/Goal – Benefit/Insight/Opinion**
   - E.g., "As a doctor, I want the AI system to automatically integrate with our EHR, to enable real-time decision support as I don't have time to manually enter patient data."

4. Each group has **2 minutes to present** their statements to the rest of the group

5. Each group will **rotate topic** and try to **build of the previous group's ideas**

6. **Repeat** unit every group has covered every topic

Finally let's set some future goals

S	**Specific**	Make your goal specific and narrow for more effective planning	
M	**Measurable**	Make sure your goal and progress are measurable	
A	**Achievable**	Make sure you can reasonably accomplish your goal within a certain time frame	
R	**Relevant**	Your goal should align with your values and long-term objectives	
T	**Time-based**	Set a realistic but ambitious end date to clarify task prioritization and increase motivation	

Design / usability

Clinical evaluation

Integration

E.g., By the end of the year, develop and implement a streamlined method for checking projects against current reporting guidelines and regulatory requirements. This method will include a checklist and automated reminders to ensure no critical aspects are missed. Progress will be reviewed and measured during monthly catch-up meetings to ensure continuous improvement and compliance.

Designing, evaluating and integrating AI decision support systems in healthcare .

Conclusion

- **Design, evaluation and integration** are critical components towards AI clinical decision support systems for antibiotic optimisation becoming a reality in real clinical practice
- Reviewed the current **literature** on these topics
- Came up with innovative responses to **'How might we' questions**
- **Ideated and discussed** how to best design clinical decision support systems, evaluate them with clinical studies and set up infrastructure for integration
- Developed **goals** to work towards in the future

Imperial College London

I would like to acknowledge the contribution of the following individuals.

Dr Tim Rawson

Professor Pantelis Georgiou

Professor Alison Holmes

Dr Bernard Hernandez Perez

Mr Richard Wilson

Dr Mark Gilchrist

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Thank you!

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CAMO-Net UK Workshop

21st June 2024

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