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Eight human factors and ergonomics principles for healthcare artificial intelligence

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INTRODUCTION

The COVID-19 pandemic dramatically accelerated the digital transformation of many health systems in order to protect patients and healthcare workers by minimising the need for physical contact.[1] A key part of healthcare digital transformation is the development and adoption of artificial intelligence (AI) technologies, which are regarded a priority in national health policies.[2 3] Since 2015, there has been an exponential growth in the number of regulatory approvals for medical devices that use machine learning,[4] with British standards currently under development in conjunction with international standards. In addition, there are an even larger number of healthcare AI technologies that do not require such approvals, because they fall outside of the narrow definition of medical devices.

The scope of healthcare AI appears seemingly boundless, with promising results being reported across a range of domains, including imaging and diagnostics,[5] prehospital triage,[6] care management[7] and mental health.[8] However, caution is required when interpreting the claims made in such studies. For example, the evidence base for the effectiveness of deep learning algorithms remains weak and is at high risk of bias, because there are few independent prospective evaluations.[9] This is particularly problematic, because the performance, usability and safety of these technologies can only be reliably assessed in real-world settings, where teams of healthcare workers and AI technologies co-operate and collaborate to provide a meaningful service.[10] To date, however, there have been few human factors and ergonomics (HFE) studies of healthcare AI.[11] There is a need for AI designs and prospective evaluation studies that consider the performance of the overall sociotechnical system, with evidence requirements proportionate to the level of risk.[12] Reporting guidelines have been developed both for small-scale early clinical intervention trials (DECIDE-AI)[13] as well as for large-scale clinical trials evaluating AI (SPIRIT-AI)[14] to enhance the quality and transparency of the evidence.

In order to support developers, regulators and users of healthcare AI, the Chartered Institute of Ergonomics and Human Factors (CIEHF) developed a white paper that sets out an HFE vision and principles for the design and use of healthcare AI.[15] Development of the white paper was an international effort bringing together over 30 contributors from different disciplines and was supported by a number of partner organisations including British Standards Institution, the Australian Alliance for AI in Healthcare, the South American Ergonomics Network (RELAESA), US-based Society for Healthcare Innovation, the UK charity Patient Safety Learning, Assuring Autonomy International Programme hosted by the University of York, Human Factors Everywhere and the Irish Human Factors & Ergonomics Society.

HFE PRINCIPLES

HFE as a discipline is concerned with the study of human work and work systems. It is a design-oriented science and field of practice that seeks to improve system performance and human well-being by understanding and optimising the interactions between people and the other elements of the work system, for example, technologies, tasks, other people, the physical work environment, the organisational structures and the external professional, political and societal environment.[16]

Current implementations of healthcare AI typically adopt a technology-centric focus, expecting healthcare systems (including staff and patients) to adapt to the technology. In this technology-centric focus, the function,

Table 1 Eight human factors and ergonomics principles for healthcare AI

Situation awareness	Design options need to consider how AI can support, rather than erode, people's situation awareness.
Workload	The impact of AI on workload needs to be assessed because AI can both reduce as well as increase workload in certain situations.
Automation bias	Strategies need to be considered to guard against people relying uncritically on the AI, for example, the use of explanation and training.
Explanation and trust	AI applications should explain their behaviour and allow users to query it in order to reduce automation bias and to support trust.
Human–AI teaming	AI applications should be capable of good teamworking behaviours to support shared mental models and situation awareness.
Training	People require opportunities to practise and retain their skill sets when AI is introduced, and they need to have a baseline understanding of how the AI works. Attention needs to be given to the design of effective training that is accessible and flexible. Staff should be provided with protected time to undertake training during their work hours.
Relationships between people	The impact on relationships needs to be considered, for example, whether staff will be working away from the patient as more and more AI is introduced.
Ethical issues	AI in healthcare raises ethical challenges including fairness and bias in AI models, protection of privacy, respect for autonomy, realisation of benefits and minimisation of harm.

AI, artificial intelligence.

performance and accuracy of AI are optimised, but these aspects are considered in isolation. This perspective raises various critical considerations that are often overlooked in the design and implementation of advanced technologies, sometimes with catastrophic consequences. From an HFE point of view, the design of healthcare AI needs to transition from the technology-centric focus towards a systems perspective. Applying a systems focus, AI should be designed and integrated into clinical processes and healthcare systems meaningfully and safely, with a view to optimising overall system performance and people's well-being. Understanding how a sociotechnical system works comes from taking time to look at the elements of the system and how they interact with each other. HFE provides several frameworks and methods to achieve this, including Systems Engineering Initiative for Patient Safety[17] and Cognitive Work Analysis.[18] These frameworks usually involve the use of observation or ethnography for data collection in order to provide a rich contextual description of how work is carried out ('work-as-done'[19]) and of people's needs.

The CIEHF white paper identifies eight core HFE principles, see table 1. Some of these are very familiar from the wider literature on automation and date back to the 1970s and 1980s but retain their importance in the novel context of healthcare AI. For example, the potentially adverse impact of highly automated systems on user situation awareness and workload, along with the potential for over-reliance and automation bias, became apparent decades ago in a series of transportation accidents and incidents.[20 21] These 'ironies of automation'[22] can arise when technology is designed and implemented without due consideration of the impact on human roles or the interaction between people and the technology, which can result in inadequate demands on the human, such as lengthy periods of passive monitoring, the need to respond to abnormal situations under time pressure and difficulties in understanding what the technology is doing and why. Alarm fatigue, that is, the delayed response or reduced response frequency to alarms, is another phenomenon associated with automated systems that has been identified from major industrial accidents, such as the 1994 explosion and fires at the Texaco Milford Haven refinery. In intensive care, it has been suggested that a healthcare professional can be exposed to over 1000 alarms per shift, contributing to alarm fatigue, disruption of care processes and noise pollution, with potentially adverse effects on patient safety.[23] Developers of AI need to be mindful of these phenomena and not create technologies that add additional burden to healthcare professionals.

However, the use of more advanced and increasingly autonomous AI technologies also presents novel challenges that require further study and research. AI technologies can augment what people do in ways that were not possible when machines simply replaced physical work, but in order to do this effectively the AI needs to able to communicate and explain to people its decision-making. This can be very challenging when using machine learning algorithms that produce complex and inscrutable models. Many approaches to explainable AI simply focus on providing detailed accounts of how an algorithm operates, but for explanations to be useful they need to be able to accommodate and be responsive to the needs of different users across a range of situations, for example, a patient might benefit from a different type of explanation compared with a healthcare professional. In this sense, rather than providing a description of a specific decision, explanation might be better regarded as a social process and a dialogue that allows the user to explore AI decision-making by interacting with the AI and by interrogating AI decisions.[24]

It is also important to build trust among staff to report any safety concerns with the AI. Many safety incidents are not currently reported and recorded in incident reporting systems.[25] While an AI system can potentially log every piece of data and every one of its actions to provide an auditable history, healthcare professionals require assurance and reassurance of how these data would be used during a safety investigation. If clinicians are held accountable for incidents involving AI unless they can prove otherwise, then this might reduce their willingness to trust and accept AI systems.

Many applications of healthcare AI will be used within teams of healthcare workers and other professionals, as well as patients. The computational capabilities of AI technologies mean that AI applications will have a much more active and dynamic role within teams than previous IT systems and automation, in effect potentially becoming more like a new team member than just a new tool. Effective human–AI teaming will become increasingly critical when designing and implementing AI to ensure that AI capabilities and human expertise, intuition and creativity are fully exploited.[26]

Part of effective human–AI teaming is handover from the AI to the healthcare professional when it becomes necessary.[10] To achieve this, the AI needs to recognise the need for handover and then execute the handover effectively. Handover between healthcare professionals is a recognised safety-critical task that remains surprisingly challenging and error prone in practice.[27] The use of structured communication protocols (eg, age–time–mechanism–injuries–signs–treatments) could improve the quality of handover even if challenges remain in their practical application.[28] Consideration should be given to the development of comparable approaches for the structured handover between AI and healthcare professionals.

While the intention of designers is to use AI to improve efficiency of workflows by taking over tasks from healthcare professionals, there is a danger that staff might get pulled into other activities instead or that the healthcare professional spends more time interacting with the AI. Lessons should be learnt from the introduction of other digital technologies, such as electronic health records, where it has been suggested that, for example, in emergency care physicians spend more time on data entry than on patient contact.[29] The impact of integrating AI into an already computer-focused patient encounter needs to be carefully considered.

The use of healthcare AI also raises significant ethical issues. Technical challenges, including the potential for bias in data, have been highlighted, and have been incorporated into international guidelines and reporting standards.[30] However, it is also important to address wider issues around fairness and impact on different stakeholder groups.[31] At European level, the High-Level Expert Group on AI published 'Ethics Guidelines for Trustworthy AI'.[32] The guidelines are based on a fundamental rights impact assessment and operationalise ethical principles through seven key requirements: human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability. HFE approaches can support addressing these ethical requirements through understanding stakeholders and their diverse needs and expectations.

BUILDING HFE CAPACITY

The systems perspective on healthcare AI set out in the CIEHF white paper is going to be instrumental in realising national AI strategies and delivering the benefits for patients and health systems. The digital transformation needs to be underpinned by HFE capacity within the health sector. Until very recently, there was no formal career structure for healthcare professionals with an interest in HFE. In the UK, this is changing with the recent introduction of both academic and learning-at-work routes towards accredited status of technical specialist or TechCIEHF (healthcare).[33] Enhancing the professionalisation of HFE knowledge among those with responsibility for quality improvement, patient safety and digital transformation can support healthcare organisations in making better informed AI adoption and implementation decisions.

There is also a need for funding bodies and regulators to require evidence that suitable HFE expertise is included in the design and evaluation of healthcare AI. Funding specifications frequently reflect only the technology-centric perspective of AI rather than reinforcing a systems approach. While inclusion of qualitative research to support scaling of healthcare AI from the lab to clinical environments is useful, it cannot replace the benefits of early inclusion of HFE expertise already during the design stage of AI technologies. Human behaviour is highly context dependent and adaptive as people navigate complexity and uncertainty and this needs to inform the design of AI to ensure that the use of AI in health and care systems is meaningful and safe. Regulators are trying to catch up on the technical AI expertise required, but the effective regulation of these technologies should also be supported through the recruitment of suitably qualified HFE professionals to establish appropriate interdisciplinary expertise in the advancement of AI technologies in healthcare.

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Developing, implementing and governing artificial intelligence in medicine: a step-by-step approach to prevent an artificial intelligence winter

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SUMMARY

Objective Although the role of artificial intelligence (AI) in medicine is increasingly studied, most patients do not benefit because the majority of AI models remain in the testing and prototyping environment. The development and implementation trajectory of clinical AI models are complex and a structured overview is missing. We therefore propose a step-by-step overview to enhance clinicians' understanding and to promote quality of medical AI research.

Methods We summarised key elements (such as current guidelines, challenges, regulatory documents and good practices) that are needed to develop and safely implement AI in medicine.

Conclusion This overview complements other frameworks in a way that it is accessible to stakeholders without prior AI knowledge and as such provides a step-by-step approach incorporating all the key elements and current guidelines that are essential for implementation, and can thereby help to move AI from bytes to bedside.

INTRODUCTION

Over the past few years, the number of medical artificial intelligence (AI) studies has grown at an unprecedented rate (figure 1). AI-related technology has the potential to transform and improve healthcare delivery on multiple aspects, for example, by predicting optimal treatment strategies, optimising care processes or making risk predictions.[1 2] Nonetheless, studies in the intensive care unit (ICU) and radiology demonstrated that 90%–94% of the published AI studies remain within the testing and prototyping environment and have poor study quality.[3 4] Also in other specialties, clinical benefits fall short of the high set expectations.[2 5] This lack of clinical AI penetration is daunting and increases the risk of a period in which the AI hype will be tempered and reach a point of disillusionment expectations, that is, an 'AI winter'.[6]

To prevent such a winter, new initiatives must successfully mitigate AI-related risks on multiple levels (eg, data, technology, process and people) that impede development and might threaten safe clinical implementation.[2 3 7 8] This is especially important since the development and implementation of new technologies in medicine, and in particular AI, is complex and requires an interdisciplinary approach to engagement of multiple stakeholders.[9] A parallel can be drawn between the development of new drugs for which the US Food and Drug Administration (FDA) developed a specific mandatory process before clinical application.[10–12] Because the delivery of AI to patients is in need of a similar structured approach to ensure safe clinical application, the FDA proposed a regulatory framework for (medical) AI.[13–16] In addition, the European Commission proposed a similar framework but does not provide details concerning medical AI.[17] Besides regulatory progress, guidelines have emerged to promote quality and replicability of clinical AI research.[18]

Despite the increasing availability of such guidelines, expert knowledge, good practices, position papers and regulatory documents, the medical AI landscape is still fragmented and a step-by-step overview incorporating all the key elements for implementation is lacking. We have therefore summarised several steps and elements (figure 2) that are required to structurally develop and implement AI in medicine (table 1). We hope that our step-by-step approach improves quality, safety and transparency of AI research, helps to increase clinicians' understanding of these technologies, and improves clinical implementation and usability.

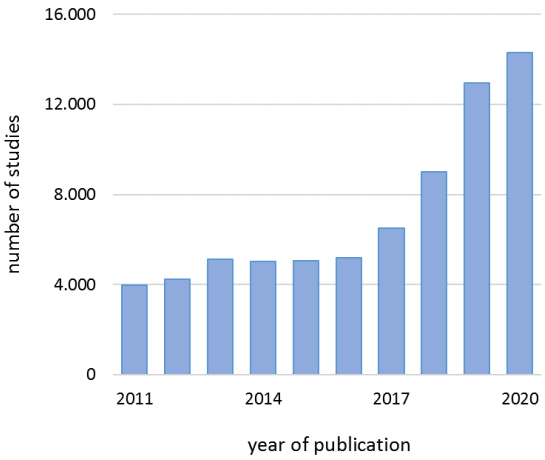

Figure 1 Global evolution of research in artificial intelligence in medicine. The number of AI papers in humans on PubMed.com was arranged by year, 2011–2020. The blue bars represent the number of studies. The following search was performed: ("artificial intelligence"[MeSH Terms] OR ("artificial"[All Fields) and "intelligence"[All Fields]) OR "artificial intelligence"[All Fields]) OR ("machine learning"[MeSH Terms] OR ("machine"[All Fields] AND "learning"[All Fields]) OR "machine learning"[All Fields]) OR ("deep learning"[MeSH Terms] OR ("deep"[All Fields] AND "learning"[All Fields]) OR "deep learning"[All Fields]).

IDENTIFYING KEY DOCUMENTS IN THE AI LITERATURE

Publications were identified through a literature search of PubMed, Embase and Google Scholar from January 2010 to June 2021. The following terms were used as index terms or free-text words: "artificial intelligence", "deep learning", "machine learning " in combination with "regulations", "framework", "review", and "guidelines" to identify eligible studies. Articles were also identified through searches of the authors' own files. Only papers published in English were reviewed. Regulatory documents were identified by searching the official web pages of the FDA, European Medicines Agency, European Commission and International Medical Device Regulators Forum (IMDRF). Since it was beyond our scope to provide a systematic overview of the AI literature, no quantitative synthesis was conducted.

PHASE 0: PREPARATIONS PRIOR TO AI MODEL DEVELOPMENT

Define the clinical problem and engage stakeholders

AI models should improve care and address clinically relevant problems. Not only should they be developed to predict illnesses, such as sepsis, but they also should produce actionable output directly or indirectly linked to clinical decision-making.[19] Defining the clinical problem and its relevance before initiating model development is therefore important.[20]

Varying skills and expertise are required to develop and implement an AI model, and formation of an interdisciplinary team is key. The core team should at least consist of knowledge experts, decision-makers and even users (figure 2).[9] While each of them are essential to make the initiative succeed, depending on the required skills

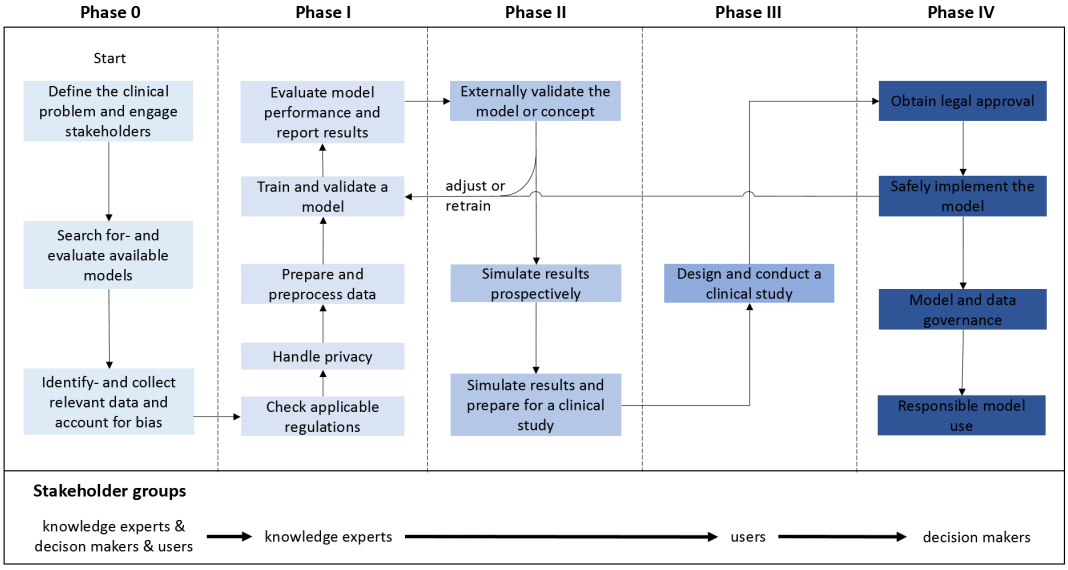

Figure 2 Structured overview of the clinical AI development and implementation trajectory. Crucial steps within the five phases are presented along with stakeholder groups at the bottom that need to be engaged: knowledge experts (eg, clinical experts, data scientists and information technology experts), decision-makers (eg, hospital board members) and users (eg, physicians, nurses and patients). Each of the steps should be successfully addressed before proceeding to the next phase. The colour gradient from light blue to dark blue indicates AI model maturity, from concept to clinical implementation. The development of clinical AI models is an iterative process that may need to be (partially) repeated before successful implementation is achieved. Therefore, a model could be adjusted or retrained (ie, return to phase I) at several moments during the process (eg, after external validation or after implementation). AI, artificial intelligence.

Table 1 Crucial steps and key documents per phase throughout the trajectory

Phase	Guidelines, position papers and regulatory documents
0: preparations prior to AI model development	
1. Define the clinical problem and engage stakeholders.	Wiens *et al*[9]
2. Search for and evaluate available models.	Benjamens *et al*,[21] ECLAIR[22]
3. Identify and collect relevant data and account for bias.	FHIR,[26] FAIR,[28] Riley *et al*[23] Wolff *et al*[25]
4. Handle privacy.	HIPAA[30] and GDPR[31]
I: AI model development	
5. Check applicable regulations.	'Proposed regulatory framework' (FDA),[13] 'Harmonised rules on AI' (EU)[17]
6. Prepare and preprocess the data.	Ferrão *et al*[40]
7. Train and validate a model.	Juarez-Orozco *et al*[42]
8. Evaluate model performance and report results.	Park and Han,[50] TRIPOD,[51] TRIPOD-ML* [52]
II: assessment of AI performance and reliability	
9. Externally validate the model or concept.	Ramspek *et al*,[53] Riley *et al*,[54] Futoma *et al*[55]
10. Simulate results and prepare for a clinical study.	DECIDE-AI* [59]
III: clinically testing AI	
11. Design and conduct a clinical study.	SPIRIT-AI,[63] Barda *et al*,[65] CONSORT-AI[66]
IV: implementing and governing AI	
12. Obtain legal approval.	Muehlematter *et al*[35]
13. Safely implement the model.	TAM,[70] Sendak *et al*[72]
14. Model and data governance.	FAIR,[28] 'SaMD: clinical evaluation' (FDA),[79] 'Application of Quality Management System'(IMDRF)[78]
15. Responsible model use.	Martinez-Martin *et al*[19]

Based on emerging themes in medical AI literature, important steps have been highlighted and categorised in five phases analogous to the phases of drug research. For each phase, the crucial steps are noted on the left and the corresponding key documents are noted on the right.
Standard protocol items: recommendations for interventional trials.
*Guidelines are currently under construction.
AI, artificial intelligence; CONSORT-AI, Consolidated Standards of Reporting Trials–Artificial Intelligence; DECIDE-AI, Developmental and Exploratory Clinical Investigation of Decision-Support Systems Driven by Artificial Intelligence; ECLAIR, Evaluating Commercial AI Solutions in Radiology; EU, European Union; FAIR, Findable, Accessible, Interoperable and Reusable; FDA, Food and Drug Administration; FHIR, Fast Healthcare Interoperability Resources; GDPR, General Data Protection Regulation; HIPAA, Health Insurance Portability and Accountability Act; IMDRF, International Medical Device Regulators Forum; ML, machine learning; SaMD, software as a medical device; SPIRIT-AI, Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence; TAM, technology acceptance model; TRIPOD, transparent reporting of a multivariable prediction model for individual prognosis or diagnosis.

for each step, some will play a more important role than others.

Search for and evaluate available models

Numerous AI models have already been published, so it is knowledgeable to search for readily available models when encountering a clinical problem (https://medical-futurist.com/fda-approved-ai-based-algorithms/)[21] and to evaluate such models using the 'Evaluating Commercial AI Solutions in Radiology' guideline.[22] Although the latter guideline was developed for radiology purposes, it can be extrapolated to other specialties.

Identify and collect relevant data and account for bias

Adequate datasets are required to train AI models. These datasets need to be of sufficient quality and quantity to achieve high model performance; Riley *et al*[23] therefore proposed a method to calculate a required sample size similar to traditional studies. Information on the outcome of interest (model output) as well as potential predictor variables (model input) need to be collected while accounting for potential bias. Unlike bias in traditional studies (eg, selection bias), bias in AI models can additionally be categorised in algorithmic and social bias which can arise from factors such as gender, race or measurement errors, leading to suboptimal outcomes for particular groups.[24] In order to mitigate the risk of bias and to collect representative training data, tools such as the Prediction Model Risk of Bias Assessment Tool can be of help.[24 25] Nonetheless, these clinical data are often underused since they are siloed in a multitude of medical information systems complicating fast and uniform extraction, emphasising the importance of adopting unified data formats such as the Fast Healthcare Interoperability Resources.[26 27] To enhance usability and sharing of such data, it must be findable, accessible, interoperable and reusable as described in the Findable, Accessible, Interoperable and Reusable (FAIR) guideline.[28] In this phase, developers should also look beyond interoperability of resources within institutions; namely, if AI models are to be used at scale, compatibility between hospitals' information systems may be challenging as well.[29]

Handle privacy

Regarding privacy, special care should be taken when handling such patient data (particularly when sharing data between institutions to combine datasets). A risk-based iterative data deidentification strategy for the purposes of the US Health Insurance Portability and Accountability Act as well as the European General Data Protection Regulation should therefore be taken into account. Such a strategy was recently applied to an openly available ICU database in the Netherlands.[30–32]

PHASE I: AI MODEL DEVELOPMENT

Check applicable regulations

Although medical device regulations are important in effectively implementing and scaling up newly developed models (phase IV), developers should be aware of it early on. AI models are qualified as a 'software as a medical device' (SaMD), when intended to diagnose, treat or prevent health problems (eg, decision support software that can automatically interpret electrocardiograms or advise sepsis treatment).[33] These devices should be scrutinised to avoid unintended (harmful) consequences, and as such, the FDA and the European Commission have been working on regulatory frameworks.[2 13 17] The IMDRF uses a risk-based approach to categorise these SaMDs into different categories reflecting the risk associated with the clinical situation and device use.[34] In general, the higher the risk, the higher the requirements to obtain legal approval. A recent review by Muehlematter *et al*[35] summarises the applicable regulating pathways for the USA and Europe.

Prepare and preprocess the data

Raw data extracted directly from hospital information systems are prone to measurement/sensing errors, particularly monitoring data, which increases the risk of bias.[36 37] Therefore, these data must be prepared and preprocessed prior to AI model development.[38 39] Data preparation consists of steps such as joining data from separate files, labelling the outcome of interest for supervised learning approaches (eg, sepsis and mortality), filtering inaccurate data and calculating additional variables. On the other hand, data preprocessing consists of more analytical data manipulations (specifically used for model training) such as smart imputations of missing values (eg, multiple imputation), variable selection (ie, selecting those highly predictive variables) and others to create a so called 'data preprocessing pipeline'. An example of such a data preprocessing framework has been described in more detail by Ferrão *et al*.[40]

Train and validate a model

To address the clinical problem, different AI models can be used. Herein, a distinction can be made between traditional statistical models such as logistic regression and AI models such as neural networks.[41] In a thoughtful review, Juarez-Orozco *et al*[42] provided an overview of advantages and disadvantages of multiple AI models and categorised them according to their learning type (broadly categorised as supervised, unsupervised and reinforcement learning) and purpose (eg, classification and regression). When selecting a model, trade-offs exist between model sophistication and AI explainability; the latter refers to the degree AI models can be interpreted and should not be overlooked.[43]

To determine whether AI models are reliable on unseen data, they are usually validated on a so-called 'test dataset' (ie, internal validation). Several internal validation methods can be used. For example, by randomly splitting the total dataset into subsets (train, validation and test dataset) either once or multiple times (which is known in literature as k-fold cross-validation) in order to evaluate model performance on the test dataset such as that demonstrated by Steyerberg *et al*.[44]

Evaluate model performance and report results

Clinical implementation of inaccurate or poorly calibrated AI models can lead to unsafe situations.[45] As no single performance metric captures all desirable model properties, multiple metrics such as area under the receiver operating characteristics, accuracy, sensitivity, specificity, positive predictive value, negative predictive value and calibration should be evaluated.[41 46–49] A guideline by Park and Han[50] can assist model performance evaluation. Afterwards, study results should be reported transparently, following transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD).[51] Since the TRIPOD statement was intended for conventional prediction models, a specific machine learning extension has recently been announced.[52]

PHASE II: ASSESSMENT OF AI PERFORMANCE AND RELIABILITY

Externally validate the model or concept

Unlike medical devices, such as mechanical ventilators, AI models do not operate based on a universal set of preprogrammed rules but instead provide patient-specific predictions. They might work perfectly in one setting and terribly in others. After local model development, AI models should undergo external validation to determine their generalisability and safety.[53 54] However, it is commonly accepted that poor generalisability should be avoided prior to implementation; it is argued that broad generalisability is probably impossible since 'practice-specific information is often highly predictive' and models should thus be locally trained whenever possible, that is, site-specific training.[55] Therefore, the AI concept (ie, the concept based on the specific variables and outcomes) may need to be validated rather than the exact model. Whether validating the exact model or concept, it is always important to evaluate whether the training and validation population are comparable in order to compare results appropriately. In case external validation demonstrates

inconsistencies with previous results, the model may need to be adjusted or retrained.[56]

Simulate results and prepare for a clinical study

In order to safely test an AI model at bedside, potential pitfalls should be timely identified. It has been suggested that model predictions can be generated prospectively without exposing the clinical staff to the results, that is, temporal validation.[57] Such a step is pivotal to evaluate model performance on real-world clinical data and is used to ensure availability of all required data (ie, data required to generate model predictions) for which a real-time data infrastructure should be established.[58] Because variation across local practices and subpopulations exists and clinical trials can be expensive, the Developmental and Exploratory Clinical Investigation of Decision-Support Systems Driven by Artificial Intelligence is being developed to decrease the gap to clinical testing.[59]

PHASE III: CLINICALLY TESTING AI

Design and conduct a clinical study

To date, only 2% of AI studies in the ICU were clinically tested while it is an important step to determine clinical utility and usability.[3] Clinical AI studies preferably need to be carried out in a randomised setting where steps are described in detail to enhance replication by others.[60–62] Such studies can have different designs similar to traditional studies, and the same considerations need to be made (eg, randomised versus non-randomised, monocentric versus multicentric, blinded versus non-blinded). At all times, the Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence guideline should be followed.[63] Since AI models are primarily developed to improve care by providing actionable output, it is important that the output is appropriately conveyed to the end users; that is, output should be both useful and actionable. For example, Wijnberge *et al*[64] clinically tested a hypotension prediction model during surgery and provided the clinicians the output via a specific display. A recent framework can help to design such user-centred AI displays, and reporting via the Consolidated Standards of Reporting Rrials–Artificial Intelligence guideline can promote quality, transparency and completeness of study results.[65 66]

PHASE IV: IMPLEMENTING AND GOVERNING OF AI

Obtain legal approval

Regulatory aspects (as described in phase I), data governance and model governance play an important role in the clinical implementation and should be addressed appropriately. Before widespread clinical implementation is possible, AI models must be submitted to the FDA in the USA and in Europe, they need to obtain a Conformité Européenne (CE) mark from accredited companies (these can be found on https://ec.europa.eu/growth/tools-databases/nando/), unless exempted by the pathway for health institutions.[67 68] Nowadays, some models already received a CE mark[35] or FDA approval.[21]

Safely implement the model

If an AI model is not accepted by the users, it will not influence clinical decision-making.[69] Factors such as usefulness and ease of use, which are described in the technology acceptance model, are demonstrated to improve the likelihood of successful implementation and should therefore be taken into account.[70 71] Furthermore, implementation efforts should be accompanied by clear and standardised communication of AI model information towards end users to promote transparency and trust, for example, by providing an 'AI model facts label'.[72] To ensure that AI models will be safely used once they are implemented, users (eg, physicians, nurses and patients) should be properly educated, particularly on how to use them without jeopardising the clinician–patient relationship.[19 73 74] Specific AI education programmes can help and have already been introduced.[75 76]

Model and data governance

After implementation, hospitals should implement a dedicated quality management system and monitor AI model performance during the entire life span, enabling timely identification of worsening model performance, and react whenever necessary (eg, retire, retrain, adjust or switch to an alternative model).[49 77–79] Governance of the required data and AI model deserves special consideration. Data governance covers items such as data security, data quality, data access and overall data accountability (see also the FAIR guideline).[19 28] On the other hand, model governance covers aspects such as model adjustability, model version control and model accountability. Besides timely identifying declining model performance, governing AI models is also vital to gain patients' trust.[80] Once a model is retired, the corresponding assets such as documentation and results should be stored for 15 years (although no consensus on terms has been reached yet), similar to clinical trials.[81]

Responsible model use

Importantly, one must be aware that AI models can be used in biased ways when real-world data do not resemble the training data due to changing care/illness specific paradigms (ie, data shift).[19 62 82–84] Clinicians always need to determine how much weight they give to AI models' output in clinical decision-making in order to safely use these technologies.[82 85]

DISCUSSION

We believe that this review complements other referenced frameworks by providing a complete overview of this complex trajectory. Also, stakeholders without prior AI knowledge should now better grasp what is needed from AI model development to implementation.

The importance of such a framework to transparently develop and implement clinical AI models has been highlighted by a study of Wong *et al*[86]; they externally validated a proprietary sepsis prediction model which has already been widely implemented by hundreds of hospitals in the USA despite no independent validations having been published yet. The authors found that the prediction model missed two-thirds of the patients with sepsis (ie, low sensitivity), while clinicians had to evaluate eight patients to identify a patient with sepsis (ie, high false alarm rate).[86] It is important to question why such prediction models can be widely implemented while they may be harmful to patients and may negatively affect the clinical workflow; they may, for example, lead to overtreatment (eg, antibiotics) of false-positive patients, undertreatment of false-negative patients and alarm fatigue among clinicians.

The main challenges to deliver impact with clinical AI models are interdisciplinary and include challenges that are intrinsic to the fields of data science, implementation science and health research, which we have addressed throughout the different phases in this review. Although it was outside the scope of this review to provide a comprehensive overview of the ethical issues related to clinical AI, they are of major concern to the development as well as clinical implementation and hence are an important topic on the AI research agenda.[87] Some examples are protecting human autonomy, ensuring transparency and explainability, ensuring inclusiveness, and equity, which are described in a recent guidance document on AI ethics by the WHO.[88]

In an attempt to prevent an AI winter, we invite other researchers, stakeholders and policy makers to comment on the current approach and to openly discuss how to safely develop and implement AI in medicine. By combining our visions and thoughts, we may be able to propel the field of medical AI forward, step-by-step.

CONCLUSION

This review is a result of an interdisciplinary collaboration (clinical experts, information technology experts, data scientists and regulations experts) and contributes to the current medical AI literature by unifying current guidelines, challenges, regulatory documents and good practices that are essential to medical AI development. Additionally, we propose a structured step-by-step approach to promote AI development and to guide the road towards safe clinical implementation. Importantly, the interdisciplinary research teams should carry out these consecutive steps in compliance with applicable regulations and publish their findings transparently, whereby the referenced guidelines and good practices can help.

Still, future discussions are needed to answer several questions such as the following: what is considered as adequate clinical model performance? how do we know whether predictions remain reliable over time? who is responsible in case of AI model failure? and how long must model data be stored for auditing purposes?

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Use of a community advisory board to build equitable algorithms for participation in clinical trials: a protocol paper for HoPeNET

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ABSTRACT

Introduction Participation from racial and ethnic minorities in clinical trials has been burdened by issues surrounding mistrust and access to healthcare. There is emerging use of machine learning (ML) in clinical trial recruitment and evaluation. However, for individuals from groups who are recipients of societal biases, utilisation of ML can lead to the creation and use of biased algorithms. To minimise bias, the design of equitable ML tools that advance health equity could be guided by community engagement processes. The Howard University Partnership with the National Institutes of Health for Equitable Clinical Trial Participation for Racial/Ethnic Communities Underrepresented in Research (HoPeNET) seeks to create an ML-based infrastructure from community advisory board (CAB) experiences to enhance participation of African-Americans/Blacks in clinical trials.

Methods and analysis This triphased cross-sectional study (24 months, n=56) will create a CAB of community members and research investigators. The three phases of the study include: (1) identification of perceived barriers/facilitators to clinical trial engagement through qualitative/quantitative methods and systems-based model building participation; (2) operation of CAB meetings and (3) development of a predictive ML tool and outcome evaluation. Identified predictors from the participant-derived systems-based map will be used for the ML tool development.

Ethics and dissemination We anticipate minimum risk for participants. Institutional review board approval and informed consent has been obtained and patient confidentiality ensured.

INTRODUCTION

Machine learning (ML) can identify statistical patterns from generated data to train computers to perform tasks intended to aid in human decision making.[1] Emerging use of ML is occurring in clinical trial evaluation and clinical trial recruitment,[2–4] a field in which improvement in reaching and recruiting racial and ethnic minorities is increasingly essential. For individuals from groups who are recipients of societal biases, utilisation of ML can lead to the creation and use of biased algorithms.[5 6] The design of equitable ML tools that advance health equity could be guided by community engagement processes which leverage collective knowledge and experience to inform clinical trial development and design.

Participation from racial and ethnic minorities in clinical trials has been burdened by issues surrounding mistrust and access to healthcare, both of which ultimately impact referral to clinical trials.[7 8] Furthermore, participation barriers may extend beyond these recognised factors. To address barriers, community-based participatory research (CBPR) has emerged to involve communities at all stages of a research study life cycle from study design through dissemination of results. A component of CBPR research is the formation of a community advisory board (CAB) to advise and direct research questions, recruitment plans and evaluate disseminated results of the study.[9 10] Although considered central in securing participation from under-represented communities, utilisation of the CAB's experience more broadly in therapeutic clinical trials has been limited. To date, the utilisation of the CAB experience to generate data has not been used to develop ML algorithms. We, therefore, seek to conduct a study in which CAB input is utilised for ML development through capturing 'lived experience-based knowledge' generated during a 12-month CAB participation study. We will achieve this goal by addressing three specific aims: (1) measure perceived barriers/facilitators to clinical trial engagement among African-Americans using qualitative and quantitative approaches; (2) use group-based model building as a systems

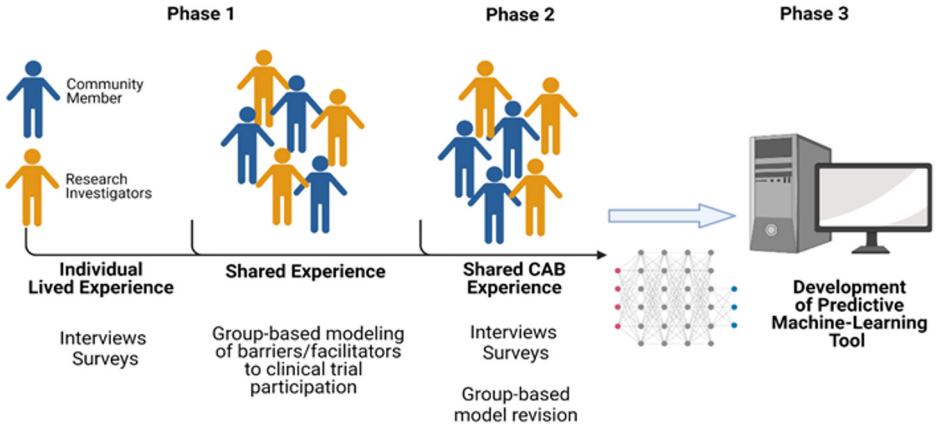

Figure 1 Graphical abstract of HoPeNET protocol: a community advisory board (CAB)-based protocol to evaluate lived experiences from multiple stakeholders, to create systems-based understanding of barriers and facilitators to clinical trial participation. HoPeNET will aid in creating a predictive algorithmic tool to help increase African-American clinical trial participation. Figure created by coauthors (NF, FOB and EO-C).

science approach to identify key activities to improve community trust and engagement and (3) develop an ML-based tool for predicting community engagement in clinical trials using data from the group-based model building. Figure 1 is a graphical representation of the three phases of the study.

METHODS

Recruitment and characterisation of study participants

This is a multisite 24-month, triphased study of 56 participants. The two sites for the study are Howard University (HU) and the Intramural Research Programme (IRP) of the National Institutes of Health (NIH). Both sites are located within the metropolitan Washington, D.C. area.

During phase 1 (figure 2), formation of a 50-member HoPeNET CAB will occur through the recruitment of two groups: 25 community partners and 25 investigators. Recruitment of participants will occur through multiple channels including emails to our current CAB on cardiovascular disease and obesity, the Washington D.C. Cardiovascular Health and Obesity Collaborative (D.C. CHOC)[11]; flyer distribution targeting members of community-serving non-profit organisations, through institutional communications and snowball recruitment for HU and the NIH IRP investigators. Inclusion and exclusion criteria for each group of HoPeNET CAB members are provided in figure 2.

A preparticipation survey and one-on-one interviews will be used to capture demographics, knowledge of CBPR principles, perceptions and beliefs surrounding clinical trial participation, and the role of social determinants and implicit bias on research outcomes (table 1). The preparticipation survey and interview guide will be pilot tested prior to administration.

Focus groups/workshops: group model building

Three focus groups/workshops with (1) community members, (2) investigators and (3) both groups combined will be conducted using a group model building (GMB) activity methodology[12] (figure 2). GMB is a powerful participatory method for actively engaging stakeholders or communities to provide perspective on a complex problem, structure, or dynamic process as well as the results and solutions.[12 13] To facilitate knowledge sharing, discussion and consensus on the issue, participants will be engaged in a number of activities (scripts). The objective of the first two sessions is to elicit discussion on factors contributing to a lack of African-American clinical trial participation by creating a systems-based map or causal

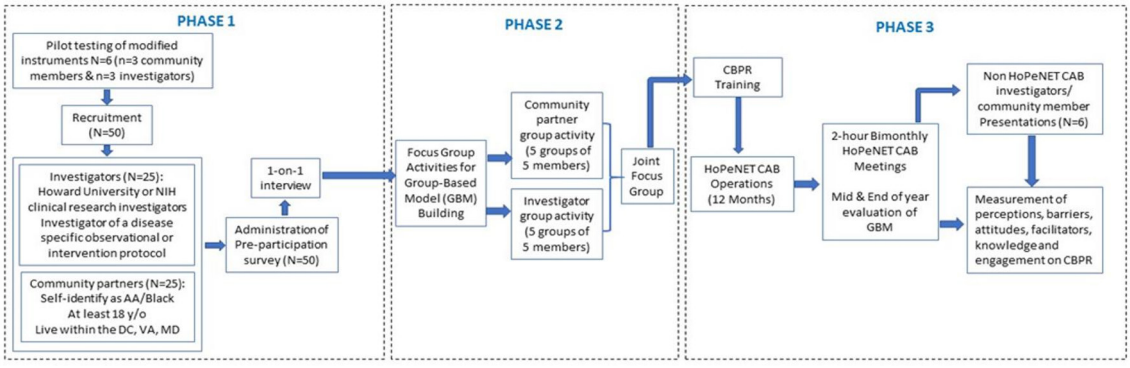

Figure 2 Study procedures. Figure created by coauthors (NF, FOB and EO-C). CAB, community advisory board; CBPR, community-based participatory research.

Table 1 Assessment data and measurement tools

Assessment of recruited participants Phase 1	Assessment of CAB members Phase 2	CBPR measurements Phase 3
► Engagement ► Self-efficacy scales ► Resilience measures ► Transcribed attitudes interviews	► Transcribed identified barriers/motivators for CAB participation ► Identification of latent factors affecting CAB members: ► RACE scale ► Discrimination	► Perception/barriers ► Attitudes ► Knowledge/engagement ► Mid and end of year evaluation of group-based modelling

CAB, community advisory board ; CBPR, community-based participatory research; RACE, Race Attributes in Clinical Evaluation.

loop diagrams (CLDs). Our rationale for conducting separate workshops prior to the combined sessions is to develop a richer understanding of participants' unbiased perceptions surrounding clinical trial participation. Additionally, this strategy improves stakeholders' engagement and participation in group activities that may suffer due to power imbalances. The research team will work offline between sessions to refine and synthesise the CLDs or informal causal maps, created during sessions 1 and 2 by participants. During the third combined session, participants will evaluate the synthesised map. This is necessary to ensure that the model reflects the insights and stories shared by participants. In addition, this allows for participants to identify potential areas in the system where they believe change is needed. Following the iterative process, all participants will be provided copies of the combined systems map to provide final feedback to the research team.

CAB intervention

In phase 2 (figure 2), the HoPeNET CAB experience will commence. Prior to the start of bimonthly meetings, the CAB participants will receive asynchronous training on CBPR principles, code of practices, and confidentiality procedures. Training will be provided by NIH site team members (TP-W, GRW, NF and VMM) and current members of the D.C. CHOC CAB. To ensure equitable discussions during meetings, 'Ambassadors' from each stakeholder group will be trained to lead CAB meetings.

The CAB will meet bimonthly for 2 hours over a 12-month period. During the meetings, non-CAB members (n=6) consisting of investigators and community members will be invited to present on specific disease areas from ongoing protocols or community health projects. Inclusion criteria for the HoPeNET presenters are based on criteria for the HoPeNET CAB members (see figure 2), except presenters do not have to self-identify as African-American. Exclusion criteria are that presenters cannot participate as CAB members or focus group facilitators. After the presentations, the HoPeNET CAB will evaluate the studies and provide feedback on ways to engage African-Americans in their protocols/programmes or to engage researchers in the community projects. All HoPeNET CAB meetings will be audio recorded for anonymised transcription. To continue the iterative process of the system-based map, at the mid-year time point, the HoPeNET CAB will reevaluate the systems-based model of facilitators and barriers to clinical trial participation. All revisions of the model will be provided to research staff for analysis. Participant engagement at the mid-year and end-of-year time points will also occur using a validated standardised metric.[13]

ML tool development

Phase 3 will occur over a 6-month period and will focus on the implementation of data results from phases 1 and 2 for the development of the ML-based tool and outcome evaluation. The primary input data for the ML algorithm will be the results of the facilitators and barriers model (table 2) created from the group-based model activity and analysis of collected qualitative and survey data. Initial survey responses will be aggregated thematically across multiple responses and Likert scales to create ordinal scales to use supervised ML approaches. This will include regression models and decision trees to identify patterns in the data. Supervised ML approaches are useful in identifying patterns where we have labelled and structured data. Meanwhile, coded responses from free form assessments such as focus groups will be analysed using unsupervised ML approaches such as hierarchical and non-hierarchical clustering of responses/participants. Unsupervised approaches can highlight and detect previously undetected patterns in data that provide insights into the perspectives of study participants. For example, each model will have an identified central latent variable that is directly and indirectly related to measurable or observable factors (second level or third level variables) for a clinical trial.

Outcomes and evaluation

Aligned with our goal to develop an ML predictive tool based on the lived experience of stakeholders, evaluation of the HoPeNET CAB study will be guided by an adaptation of the conceptual logic model of CBPR[14 15] (online supplemental figure 1). The evaluation approach includes careful consideration of community context and understanding group dynamics to build an equitable partnership that explicitly values reciprocal learning as illustrated in the model.

In addition to developing an ML tool, we anticipate that the HoPeNET CAB experience will influence investigators' behaviours and perceptions. To assess this, we will

Table 2 Analytical approaches used in HoPeNET machine learning algorithm development

Product/goal: **creation of data-trained predictive tool for examining barriers in future trials that will inform changes in recruitment, screening and enrollment of AA/Black participants**	
Analysis	**Data/tools**
Correlation analysis (Corrplot)	Self-reported self-efficacy/engagement between initial/terminal time points with CAB outcome assessments
t-distributed stochastic neighbour embedding	Initial and final participant self-efficacy, knowledge, engagement, barriers and attitudes
Natural language processing	Transcribed community and investigator focus group data to identify within and between group differences and similarities in attitudes, knowledge, perceptions of bias, etc.
Structural equation modelling (SEM-LAVAAN) and group-based modelling (GBM-CrimCV)	Phase 2 focus group attitudes to clinical trial participation among community and investigator group models.
Path analysis	Path analysis of phase 3 changes in perceptions on group-based model.

AA, African-American; CAB, community advisory board.

conduct post-CAB surveys and interviews. Engagement and reach in the community will be assessed using the following metrics from studies presented at CAB meetings: (1) number of participants screened who are directly from the community and (2) volume of requested recruitment materials from members of the community.

Ethics and dissemination

Participant confidentiality and privacy will be strictly maintained and held in trust by the participating investigators, and their staff. No information concerning the study, or the data will be released to any unauthorised third party without prior written approval of the Principal Investigator. The study data entry and study management systems used by research staff will be secured and password protected. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing institutional review board, institutional policies or sponsor requirements. We anticipate minimal risk for this study. However, we will ask participants to express their perceptions surrounding barriers and facilitators of clinical trial participation during the one-on-one interviews and focus group activities. We recognise that this activity may elicit emotional distress. Study participation will be voluntary and interviews can be stopped at any time. To be consistent with CBPR principles and to the stated programme evaluation, study findings will be disseminated to the HoPeNET CAB, presented at departmental and institutional levels at HU and the NIH IRP. We will also present our findings at national and international conferences, and peer-reviewed manuscripts from our project will also be submitted for publication.

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Machine learning in medical education: a survey of the experiences and opinions of medical students in Ireland

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INTRODUCTION

Leading figures in biomedical informatics advocate education in digital health for the healthcare workforce.[1 2] In healthcare, artificial intelligence/machine learning (AI/ML)-enabled tools increasingly play a role by informing patient triage decisions, clinical decision support systems, and healthcare resource management[3] – advances that are undoubtedly set to grow.[4] Tens of thousands of healthcare apps are available for download by consumers, promising a range of services, from symptom tracking to diagnostic and treatment advice.

To date, surveys of medical professionals reveal divergent views about the value and impact of AI/ML on their job with many physicians sceptical about the potential scope for technological innovations on medical tasks.[5–7] Furthermore, surveys consistently find limited evidence of formal teaching in medical education about AI/ML. Only a few studies – conducted in Europe, the US and South Korea – have explored the formal education and familiarity of medical or healthcare students with respect to digital advances in healthcare, and much of this work consists of single site studies.[8–14] To better understand and engage with discussion about the benefits, limitations, and ethical dilemmas presented by these tools, today's medical students will need to become more digitally savvy. Equally, as patients make increasing use of healthcare and well-being algorithms, medical students will need to become better prepared to offer patients advice, and to have knowledge about, the robustness of these tools including when algorithms are safe to use.

In the present study, we built on this research by assessing the experiences and opinions of final year medical students throughout Ireland about their exposure to AI/ML during their entire degree programme.

METHODS

A paper-based, cross-sectional survey was administered to final year medical students at four of Ireland's seven medical schools. Institutions were selected in each of the country's four geographical provinces. The study team devised an original survey instrument to investigate the familiarity, formal exposure to, and opinions of medical students about ML/AI in medicine. We developed the survey instrument in consultation with Irish, British, and American physicians and piloted the survey with physicians in Ireland and the UK (n=6) and final year medical students in the UK (n=5) to ensure face validity. The survey explored students' experiences and opinions about the teaching of AI/ML in their medical degree programme to date (see Section E of online supplemental appendix 1, and table 1 for survey items). Using 'yes' or 'no' responses, the survey asked whether students had heard of the term 'machine learning', were familiar with "big data analytics", and whether they had read any academic articles on AI/ML in medicine. Students were requested to estimate both how many hours their instructors or lecturers had spent, and will spend, discussing AI/ML during their degree. In addition, selecting from 'yes', 'no' or 'maybe' responses, the survey inquired whether students planned to learn about how AI/ML as it pertains to medicine. Finally, using a 6-point Likert scale, students were requested to rate their level of agreement with the statement 'Discussion about AI/ML should be part of medical training.'

The institutional review boards at University College Cork [protocol # 2018–188], National University of Ireland Galway [protocol # 19-Dec-15], Queen's University Belfast [protocol # 19.28], and University College Dublin [protocol # LS-19–89] approved the

Table 1 Familiarity and opinions of medical students about Artificial Intelligence/Machine learning in their medical degree

Survey item	Value	95% CI	Total *N*
Have you heard of machine learning? *n* (%)	–	–	242
Yes	137 (56.6%)	50.4 to 62.9	
No	105 (43.4%)	37.1 to 49.6	
Are you familiar with big data analytics? n (%)	–	–	242
Yes	101 (41.7%)	35.5 to 48.0	
No	141 (58.3%)	52.1 to 64.5	
Have you read any academic journal articles about artificial intelligence/ machine learning in medicine? n (%)	–	–	242
Yes	47 (19.4%)	14.4 to 24.4	
No	195 (80.6%)	75.6 to 85.6	
Please estimate how many hours your instructors/lecturers *have spent* discussing artificial intelligence/machine learning during your medical degree so far. median	-	–	221
0 hours	147 (66.5%)	–	
30 min to 1 hour	38 (17.1%)	–	
1 hour 30 min +	36 (16.3%)	–	
Please estimate how many hours your instructors/lecturers *will spend* discussing artificial intelligence/machine learning during your medical degree so far. media-n	-	–	
0 hours	133 (62.4%)		
30 min to 1 hour	19 (8.9%)		
1 hour 30 min +	61 (28.6%)		
Do you plan to learn about artificial intelligence/machine learning as they pertain to medicine? n (%)	–	–	241
Yes	99 (41.1%)	34.9 to 47.3	
No	29 (12.0%)	7.9 to 16.1	
Maybe	112 (46.5%)	40.2 to 52.8	
Discussion about artificial intelligence/machine learning should be part of medical training.	–	–	242
Strongly disagree	8 (3.3%)	1.1 to 5.6	
Moderately disagree	18 (7.4%)	4.1 to 10.7	
Somewhat disagree	26 (10.7%)	6.8 to 14.7	
Somewhat agree	117 (48.4%)	42.1 to 54.6	
Moderately agree	45 (18.6%)	13.7 to 23.5	
Strongly agree	28 (11.6%)	7.5 to 15.6	

study protocol at their respective sites. Between April 2019 and March 2020, the anonymous survey was distributed by lecturers after compulsory final year classes at each institution to increase responses. Participation was voluntary and all students who decided to participate provided written consent. After survey collection, responses were entered into Excel, and descriptive statistics and analysis were carried out using JASP (0.9.2) and SPSS v 27.

RESULTS

A total of 252 of 585 (43%) of final year students across three medical schools responded. Data collection at one medical school (University College Dublin) was terminated in March 2020 because of teaching disruption due COVID-19, and survey data from this site was excluded from the analysis. Of all respondents, 157 of 251 (62.6%) were female, and 223 of 246 (90.7%) were born in 1992 or later. Among respondents, 66.5% reported zero hours of teaching on AI/ML during their degree with 62.4% anticipating zero hours during the remainder of the degree programme, 43.4% (95% CI, 37.1% to 49.6%) had not heard of the term 'machine learning', and 80.6% (95% CI, 75.6% to 85.6%) had not read any academic journal articles on AI/ML. Asked about whether they intended to learn about AI/ML in medicine 41.1% (95% CI, 34.9% to 47.3%) reported 'yes' and 46.5% (95% CI, 40.2% to 52.8%) responded 'maybe.' However, 78.6% agreed that discussion about AI/ML should form part of their training. Results are reported in table 1.

Descriptive data were analysed for differences according to gender and birth year. Male respondents were more likely than females to report having heard about ML (69.7% v. 48.7%), $\chi^2(1)=10.05$, p=0.002. Participants who heard about ML, on average, had an earlier birth year than those who had not, t(234)=2.193, p=0.029. Willingness to learn about AI/ML was recoded to reflect the

ordinal nature of the data (yes=1, maybe=2, and no=3) so that inferential statistics could be run. There was a trend towards younger participants being less likely to plan to learn about AI/ML, rho=-.109, p=0.095. Based on the results of a Mann-Whitney U test, male respondents were more likely to plan to learn about AI/ML than female participants, Z=2.25, p=0.025.

DISCUSSION

This is the first study to explore the experiences and opinions of Irish medical students about AI/ML in their medical degree programme. Medical students reported limited awareness and education on AI/ML. Notably, around four in ten of survey respondents had not heard of the term 'machine learning'. Around two in three respondents reported no time spent learning about AI/ML during their whole medical degree. Although a minority of students did report some formal teaching on AI/ML, it is unclear whether this was part of their compulsory medical curriculum or (for example) via elective medical courses or guest lectures. Perhaps reflecting training gaps or lack of confidence on the topic, few students reported reading any academic articles on AI/ML in medicine. Relatedly, students were divided about their plans to fill educational gaps, with almost half of students reporting some uncertainty about whether they would undertake additional learning on these topics. Contrary to our expectations, younger participants were less likely to have heard of ML; however, the majority of participants were typically young adults: 91% had a birth year between 1992–1999. Conceivably, with greater variance in ages of participants we might have observed different findings. Finally, while the majority of students reported a lack of formal instruction on AI/ML in medicine, considerably fewer students seemed to approve of the status quo. In common with other surveys,[8 9 12–14] the majority of medical students considered learning about AI/ML should form part of their formal medical degree.

To help address education deficits, we suggest medical schools consider developing short, cross-disciplinary courses in digital health, including an understanding of augmented intelligence, to empower students to keep abreast of technological advances. Indeed, the need for further education on these topics may also apply to allied health professional training including nursing, pharmacy, clinical psychology, and physiotherapy. Because technology changes rapidly, we recommend that training and education encompass critical thinking skills so that students are well equipped to appraise new technologies. For example, courses in evidence-based medicine might incorporate discussion about evaluation of clinical decision support systems, the potential for algorithmic biases in data sets, and challenges associated with the explainability of AI/ML decisions. Medical ethics courses might usefully incorporate topics related to patient privacy with the use of digital devices and apps, and the potential for AI/ML-tools to mitigate or exacerbate digital divides in healthcare. Finally, we caution that without solid curricular advances, medical students and health professionals may rely too heavily on hype or inflated media reportage to inform their views, leading to negative consequences for healthcare. For example, surveys in Canada and the UK suggest that, under the misguided view that radiology will be imminently replaced as a field by AI/ML, students are more likely to rule out this specialty as a career choice.[12 15]

This study has some strengths and limitations. A strength was soliciting the views of students from institutions in geographically distinctive regions of the country. However, the moderate response rate (43%) raises questions about representativeness. Response biases could also have influenced our findings depending on whether students most enthusiastic or those inclined to view AI/ML negatively answered the survey. While our aim was to gauge the general awareness of medical students about these topics, some survey items, such as 'familiarity with big data analytics' might be challenged as vague and open to interpretation. We recommend that qualitative research methods might provide more nuanced findings on students' opinions and awareness about AI/ML in medicine. In addition, we suggest future studies might usefully explore the opinions and familiarity of medical faculty about AI/ML in medical education, and/or evaluate medical curricula course content to assess where, if at all, students acquire learning on these topics. Finally, the survey was administered prior to the COVID-19 pandemic which has overseen considerable developments and attention given to the role of AI/ML-enabled tools including in digital epidemiology and public health. Conceivably, as a result, had the survey been undertaken today we might have found increased awareness or familiarity about these topics among medical students. However, we emphasise it remains to be seen whether this heighted attention translates into tangible curricular developments. Furthermore, no surveyed medical school has since modified their curriculum to include education about AI/ML.

We close by noting, in recent years Ireland has gained recognition as a global technology hub with the fastest growing tech workforce in Europe.[16] Despite these advances, we cannot help but observe the risk of digital education in healthcare lagging behind. Improvements in digital education will help prepare tomorrow's doctors to lead policy and practice advances on the role of AI/ML-enabled tools in the health professions and in patientcare.

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Findability of UK health datasets available for research: a mixed methods study

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ABSTRACT

Objective How health researchers find secondary data to analyse is unclear. We sought to describe the approaches that UK organisations take to help researchers find data and to assess the findability of health data that are available for research.

Methods We surveyed established organisations about how they make data findable. We derived measures of findability based on the first element of the FAIR principles (Findable, Accessible, Interoperable, Reproducible). We applied these to 13 UK health datasets and measured their findability via two major internet search engines in 2018 and repeated in 2021.

Results Among 12 survey respondents, 11 indicated that they made metadata publicly available. Respondents said internet presence was important for findability, but that this needed improvement. In 2018, 8 out of 13 datasets were listed in the top 100 search results of 10 searches repeated on both search engines, while the remaining 5 were found one click away from those search results. In 2021, this had reduced to seven datasets directly listed and one dataset one click away. In 2021, Google Dataset Search had become available, which listed 3 of the 13 datasets within the top 100 search results.

Discussion Measuring findability via online search engines is one method for evaluating efforts to improve findability. Findability could perhaps be improved with catalogues that have greater inclusion of datasets, field-level metadata and persistent identifiers.

Conclusion UK organisations recognised the importance of the internet for finding data for research. However, health datasets available for research were no more findable in 2021 than in 2018.

Summary

What is already known?

- Science benefits hugely from the sharing and reuse of datasets.
- There are many barriers to reuse, one of which is researchers not knowing what datasets already exist that may be relevant to their analysis.

What does this paper add?

- Organisations say that they want to make datasets more findable online, but that the time and personnel to achieve this is often lacking.
- We assess findability of UK health datasets in online searches.
- We found that this aspect of findability is no better in 2021 than it was in 2018.
- Online catalogues of health data rarely include identifiers that would enable proper referencing or field level metadata to indicate suitability for reanalysis.

INTRODUCTION

With 65 million people, a single payer health system, a unique identifier for its citizens' health data, and long-standing population-wide electronic health records (EHRs), the UK is uniquely placed to harness insights from routinely collected health data. UK primary care has been an early adopter of information technology, with most practices computerising prescribing and clinical record keeping over the past 20 years.

EHRs are collected routinely as part of direct care in the National Health Service (NHS), with tens of millions of records in existing 'e-cohorts' based on geography or diagnosis.[1–4] An e-cohort can enable researchers to 'investigate the broadest possible range of social and environmental determinants of health and social outcomes by exploiting the potential of routinely collected datasets'.[5] Some e-cohorts thus include other detailed data, for example, the Wales E-Cohort for Children includes educational attainment.[6] There is an ambition to sequence 5 million NHS patients' genomes.[7] Reuse of such data is advancing research, from disease aetiology to drug discovery, translational research and public health. There is a drive across many fields towards the sharing and reuse of health data.[8 9]

Apart from several long-standing and widely used national e-cohorts, for example, the Clinical Practice Research Datalink (CPRD),[10 11] there exist regional e-cohorts[12–14] that are known anecdotally to

researchers connected to data providers, but are less well known by the wider research community. Lack of familiarity with existing e-cohorts may reduce their utilisation for research, weaken transparency and replicability of research and lead to duplication of effort in generating new equivalent datasets.[8 15]

The FAIR principles[16] were developed to guide sharing of scientific data and maximise the discovery, evaluation and reuse of such data. These four principles state that published data should be findable, accessible, interoperable and reusable. This article focuses on the principle of findability. The FAIR principle of findability recommends that data (or metadata) should be:

- Assigned a unique and persistent identifier.
- Described by rich metadata which links explicitly to the data described.
- Indexed in a searchable resource.

This project aimed to describe the current findability of routinely collected e-cohorts from the UK to a person (a researcher or interested citizen) using internet search engines. Specific objectives were: (1) to identify current approaches and potential barriers to increasing findability by surveying established organisations that facilitate access to health data (including e-cohorts) for research, and (2) to assess the findability of a target list of e-cohorts directly through internet searches and indirectly via online health data catalogues and see how findability changed between 2018 and 2021.

METHODS

Assessing approaches to findability at UK organisations supplying data to researchers

One route of access to routinely collected data for research is via organisations acting as data curators, providers, safe havens or research services. We wanted to understand what these organisations do to make their datasets findable and what obstacles they face in doing so. The datasets available may extend beyond health, but all are confidential datasets based in UK public sector organisations so findability practices should be transferable.

We conducted telephone surveys with staff from such organisations. We contacted the organisations with a participant information sheet via email, using publicly available contact information. These organisations were those of which the authors were aware, through their prior research or through participation in national initiatives such as the Farr Institute[17] or Safe Data Access Professionals.[18] As well as organisations specialising in health research, we included five that host other types of confidential data to understand their practices (eg, Her Majesty's Revenue and Customs (HMRC) Data Lab; see

Table 1 List of public sector organisations that took part in the surveys

Repository	Description	URL
Health Data Finder for Research	Health data finder is a metadata catalogue aiming to inform potential users about health datasets that are available for use in research	www.hdf.nihr.ac.uk
UK Data Service*	The UK Data Service enables access to a range of datasets, primarily in the field of social and economic research; funded by the Economic and Social Research Council (ESRC)	https://www.ukdataservice.ac.uk/
Consumer Data Research Centre (CDRC)*	The CDRC enables access to routinely collected consumer data; funded by the ESRC	https://www.cdrc.ac.uk
Urban Big Data Centre (UBDC)*	The UBDC enables access to urban-related data; funded by the ESRC	https://www.ubdc.ac.uk
Administrative Data Research Network (ADRN)*	The ADRN was a service funded by the ESRC to enable secure access to datasets	https://adrn.ac.uk
Electronic Data Research and Innovation Service (eDRIS)	eDRIS is a service coordinating access to the national Scottish health datasets	https://www.isdscotland.org/Products-and-Services/eDRIS
Health Informatics Centre—Trusted Research Environment (University of Dundee)	A data safe haven run as part of the University of Dundee, affiliated with National Health Service (NHS) Tayside and NHS Fife; the service coordinates access to local health datasets	https://www.dundee.ac.uk/hic/hicsafehaven
NHS Greater Glasgow and Clyde Safe Haven	A data safe haven and data service coordinating access to local health datasets	https://www.nhsggc.org.uk/about-us/professional-support-sites/nhsggc-safe-haven
CALIBER (University College London)	A platform for sharing data and methodologies; linked primary care, secondary care (hospital admissions), mortality and cancer registry data	https://www.ucl.ac.uk/health-informatics/caliber
Her Majesty's Revenue and Customs (HMRC) Data Lab*	A service providing secure access to deidentified HMRC data	https://www.gov.uk/government/organisations/hm-revenue-customs/about/research#the-hmrc-datalab
Connected Health Cities (CHC) North East and North Cumbria	CHC is a programme in the North of England which aims to use local health data and technology to improve health services; North East and North Cumbria are developing infrastructure to connect local hospitals with their trustworthy research environment—this will include development of a metadata catalogue	https://www.connectedhealthcities.org/connected-health-cities/cumbria-and-north-east-england
CHC Connected Yorkshire	Connected Yorkshire is based across Leeds, Sheffield and Bradford and works with the established Born in Bradford cohort; the dataset information described in this paper relates to the Born in Bradford study	https://www.connectedhealthcities.org/connected-health-cities/yorkshire-humber

*Not primarily health organisations.

asterisks in table 1). Up to two follow-up emails were sent to centres that did not initially respond.

Semistructured telephone surveys were conducted by RMJ and EG in April and May 2018 and focused on how organisations currently make their data findable, future plans to increase findability and any barriers to making data more findable. The HMRC Data Lab responded via email. An interview data collection sheet was developed from discussion among coauthors based on a preliminary interview with Electronic Data Research and Innovation Service conducted jointly by RMJ and EG. Notes were taken by RMJ or EG during each survey. Results were compiled by summarising and counting responses.

Assessing findability of e-cohorts for health research

We used several approaches to explore findability of e-cohorts from the perspective of health researchers. First, we quantified how frequently e-cohorts appeared in a series of internet searches. Second, we searched the health data catalogues for the prespecified e-cohorts, and for those e-cohorts that were present in the health data catalogues, we assessed whether the e-cohorts met the FAIR criteria of having rich metadata and a persistent identifier.

We aimed to replicate searches that might be carried out by a researcher trying to find data for their research or a member of the public curious about routine health information that is used in research. The study team, which has significant experience of research with health data and was involved in national initiatives such as the Farr Institute[17] and Health Data Research UK,[19] compiled a list of UK health-related e-cohorts known to them, without consulting the internet. This list served as targets for our searches (table 2), including well-known national datasets (eg, CPRD) and smaller, regional datasets of which the team had prior knowledge. The list also contained a number of data organisations, which provide access to e-cohorts.[20] Two kinds of search were performed to try to find these datasets.

Search using general internet searches

Search engines Google and Bing were searched separately in March 2018 (by EG and RMJ) and May 2021 (by EG and GT) using each of the following terms: health data research; acute care research datasets; community care research datasets; electronic health records; health datasets; health records research; hospital research datasets; primary care research datasets; secondary care research datasets and tertiary care research datasets (figure 1).

We used plain text search terms (no wildcards) to replicate simple searches the way someone might initially explore the public internet for relevant websites. We avoided terms such as ‘case control study’ or ‘clinical cohort’ as these relate to particular study designs, whereas we wanted to find routinely collected datasets. We wanted to replicate a well-motivated search and give a good chance of finding relevant results so we reviewed multiple pages of search results up to the hundredth listing. Search results were screened for reference to the target datasets (figure 1, step 1b). These references were either direct (the search result was itself the target’s website) or indirect (a link in the search result led to the target).

Search using research data catalogues

To identify existing catalogues of UK health data, Google was searched using the terms ‘health data catalogue’ or ‘research data catalogue’ (omitting the quotation marks). The first 100 search results were screened for our targets (figure 1, step 2b).

Search using Google dataset search engine

After our 2018 searches were conducted, a new search engine was available from Google dedicated to finding datasets. In 2021, two authors (GT and EG) each searched for our 10 search terms in Google Dataset Search and reviewed the top 100 search results for our 13 target datasets.

Findability was assessed according to the following criteria:

1. Was a direct link found from Google or Bing searches?
2. Was there any indirect link to the e-cohort from the Google/Bing search results which might prompt a researcher to investigate further?
3. Was the e-cohort listed in one of the catalogues that were found by searching the internet for health data catalogues? If so, as defined by the FAIR principles, what depth of metadata were available and was there a persistent identifier?[20]

Data sharing

We have made data freely available online on Mendeley and Figshare including survey participant information sheet and summary notes (https://data.mendeley.com/datasets/j49bgj7nmn/1), 2018 internet search results (https://data.mendeley.com/datasets/fp9mpj3t9r/1) and 2021 search results and protocol (https://doi.org/10.48420/14791590). Original survey notes have not been shared to protect respondent confidentiality.

RESULTS

Survey findings: current practice as reported by established organisations

Of the 18 centres contacted, 12 agreed to be surveyed (table 1) and 6 did not respond. Of the 12 organisations that responded to the survey, 11 reported to share public-facing information about the available datasets (for Connected Health Cities North East and North Cumbria, a catalogue was under development at the time of the interview, now available at https://github.com/connectedhealthcities/nenc-chc). Some had different levels of access where more sensitive information was restricted to an approved audience. Metadata were provided in various ways, including through interactive catalogues (based on a number of software packages), static websites, PDFs and Excel files. The UK Data Service, Consumer Data Research Centre and Administrative Data Research Network used the DDI (Data Documentation Initiative) metadata standard[21] to describe the datasets. The other

Table 2 Description of target UK e-cohorts assessed for findability in direct and indirect searches

E-cohort	URL	Responsible organisation	Description	Number of 2018 search results: direct (indirect)	Number of 2021 search results: direct (indirect)
Clinical Practice Research Datalink	https://www.cprd.com/	MHRA (Medicines and Healthcare Regulatory Agency)/National Institute for Health Research	Primary care research dataset with linkage to additional datasets	Bing 9 (1) Google 1 (3)	Bing 14 (8) Google 13 (33)
The Health Improvement Network	https://www.cegedim-health-data.com/cegedim-health-data/thin-the-health-improvement-network	Cegedim*	Primary care research dataset	Bing 3 (0) Google 0 (4)	Bing 1 (2) Google 1 (13)
QResearch	https://www.qresearch.org/	The University of Oxford; EMIS (Egton Medical Information Systems)*	Primary care research dataset	Bing 5 (0) Google 1 (4)	Bing 0 (3) Google 2 (15)
ResearchOne	http://www.researchone.org/	TPP SystmOne*	Primary care research dataset	Bing 4 (0) Google 1 (1)	Bing 0 (1) Google 4 (6)
Consultations in Primary Care Archive	https://www.keele.ac.uk/mrr/cipcadatabase/	Keele University	Primary care research dataset	Bing 0 (1) Google 0 (1)	Bing 0 (0) Google 0 (0)
Hospital Episode Statistics	https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics	National Health Service (NHS) Digital	Secondary care dataset	Bing 7 (3) Google 0 (4)	Bing 6 (3) Google 1 (8)
Salford Integrated Record	http://www.salfordccg.nhs.uk/download.cfm?doc=docm93jijm4n524.pdf&ver=680	Salford Royal NHS Foundation Trust	Integrated primary and secondary care dataset	Bing 0 (0) Google 0 (1)	Bing 0 (0) Google 0 (0)
Prescribing Information System	https://www.ndc.scot.nhs.uk/National-Datasets/data.asp?SubID=102	NHS Scotland	National prescribing dataset	Bing 0 (1) Google 0 (1)	Bing 0 (1) Google 0 (0)
SAIL databank	https://saildatabank.com	Swansea University; NHS Wales; Health and Care Research Wales	Linked health and other routinely collected datasets	Bing 4 (0) Google 1 (6)	Bing 1 (6) Google 3 (11)
NHS Lothian Research Safe Haven/The University of Edinburgh	https://www.accord.scot/researcher-access-research-data-nrs-safe-haven/safe-haven-network	NHS Lothian, University of Edinburgh, Edinburgh Napier University, Queen Margaret University	Service coordinating access to linked health datasets across the Lothian region, Scotland	Bing 0 (2) Google 1 (1)	Bing 0 (0) Google 0 (0)
Grampian Data Safe Haven	https://www.abdn.ac.uk/iahs/facilities/grampian-data-safe-haven.php	NHS Grampian and the University of Aberdeen	Service coordinating access to linked health datasets across the Grampian region, Scotland	Bing 0 (1) Google 1 (2)	Bing 0 (0) Google 0 (0)
Health Informatics Centre—Trusted Research Environment (University of Dundee)	https://www.dundee.ac.uk/hic/hicsafehaven	University of Dundee	Service coordinating access to linked health datasets across the Tayside region, Scotland	Bing 2 (1) Google 2 (1)	Bing 1 (0) Google 0 (0)
NHS Greater Glasgow and Clyde Safe Haven	https://www.nhsggc.org.uk/about-us/professional-support-sites/nhsggc-safe-haven	NHS Greater Glasgow and Clyde and the Robertson Centre for Biostatistics, University of Glasgow	Service coordinating access to linked health datasets across the Greater Glasgow and Clyde region, Scotland	Bing 2 (2) Google 1 (1)	Bing 0 (0) Google 0 (0)

Most of the organisations are public sector.
*Commercial organisations.

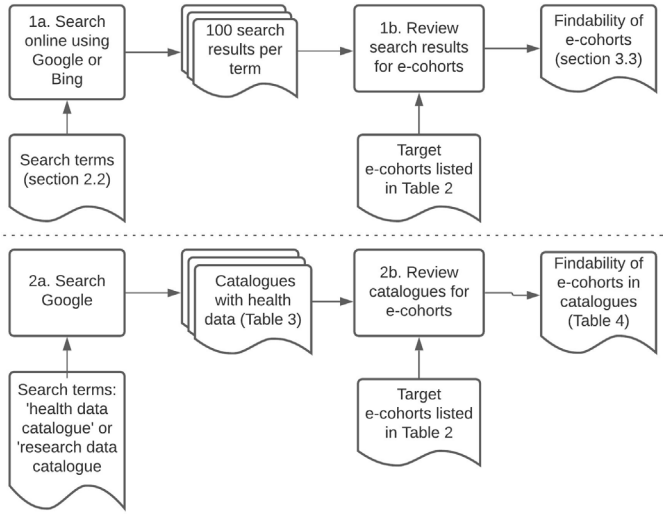

Figure 1 Internet search process—looking for health datasets via two popular, general search engines (1) and via catalogues (2).

nine organisations did not use a standard metadata schema.

Respondents talked about many other means of increasing findability, including using social media, newsletters, scientific articles and conference presentations to publicise their datasets. They were also interested in finding out what researchers wanted; three used Google Analytics to understand what people were looking for and others described discussions with researchers to better understand their needs. One organisation described a more proactive approach, using calls for expressions of interest to find and support researchers interested in using their data. For further details on approaches to findability, see the supplementary files available on Mendeley Data (https://doi.org/10.17632/j49bgj7nmn.1).

Perceived challenges to findability according to established organisations

Respondents were also asked for perceived barriers to data findability. This prompted a broad range of responses, which are summarised below and detailed in the supplementary files available on Mendeley Data (https://doi.org/10.17632/j49bgj7nmn.1). Issues include: datasets submitted with poor quality metadata, no widely adopted metadata standards or cataloguing technologies. Shortages in expertise and time were also cited, as was the view that data providers and funders did not prioritise curation of metadata and that the role of data curators is underappreciated. Many respondents recognised that more support was needed to curate good quality metadata. The challenges of dealing with the inherent variability of routinely collected health data for both curators and researchers and lack of appropriate metadata standards for health data were also raised.

When asked about plans to improve findability, respondents covered topics as diverse as making better use of existing web tools (cited most often), improving metadata quality, offering more support to research users and overlapping with other developments in the repository operations such as data linkage or migration (cited least often). Some organisations reported actively exploring new tools to replace their existing catalogues. Respondents highlighted that a good catalogue needs to contain entries for a wide range of datasets and have a usable search tool, developed with an understanding of researchers' needs.

Findability of target e-cohorts and data organisations using general internet search engines

Internet searches in 2018 found direct links to the websites of 8 of the 13 target e-cohorts listed in table 2. When clicking on links within each search result, all 13 targets were indirectly findable. For further details see the supplementary files available on Mendeley Data (https://doi.org/10.17632/fp9mpj3t9r.1).

In 2021, there were direct links to 7 of the 13 target e-cohorts listed in table 2, but when clicking on links within each search result 8 were indirectly findable. See supplementary files available on Figshare (https://doi.org/10.48420/14791590).

Findability of target e-cohorts and data organisations using health data catalogues

In 2018 we identified nine catalogues of UK-based e-cohorts through internet searches (table 3). Six catalogues referred to 1 or more of the 13 target e-cohorts listed in table 2, while 3 catalogues did not reference any of the targets. In 2021 two of those nine catalogues were inaccessible, and, among the remaining seven catalogues, one listed more target e-cohorts (from one in 2018 to four in 2021).

In 2018 all the catalogues included dataset-level metadata (descriptive, structural or administrative metadata about the dataset). The Health Data Finder, particular entries in the NHS England Data Catalogue, the Perinatal Mental Health (published by Public Health England) and Social Services Improvement Agency Data Catalogue had field-level metadata (descriptive, structural or administrative metadata held at the level of individual fields). None of the catalogues attached DOIs to their entries. The results are summarised in table 4. In 2021, among the seven catalogues still accessible, their findability in terms of metadata detail and identifiers was unchanged. Nine additional catalogues were found in the searches in 2021, seven of which included persistent identifiers but not always field level metadata and only two included target e-cohorts.

Findability of target e-cohorts and data organisations in 2021 using Google dataset search

Using the Google dataset search, all but 1 of our 10 searches produced over 100 results (searching for 'tertiary care research datasets' only produced 30 results). Among all available search results up to 100, 3 of the 13 target datasets were found once (HES, CPRD and SAIL).

Table 3 Catalogues of UK-based e-cohorts found through general internet search engines in 2018 and the number of target e-cohorts within them in 2018 and 2021

Catalogue	Web link (correct in March 2018 at the time of searching)	Number of targets found (2018)	Number of targets found (2021)
Health Data Finder for Research	http://www.hdf.nihr.ac.uk/	2	NA
Children and young people's health data catalogue 2009	http://www.childhealthresearch.eu/research/add-knowledge/Health/Data/Catalogue__2.pdf/at_download/file	0	NA
NHS Digital: Data and information	https://digital.nhs.uk/data-and-information/	1	1
Perinatal mental health: national datasets	https://www.gov.uk/government/publications/perinatal-mental-health-national-datasets (also linked to https://fingertips.phe.org.uk/profile-group/mental-health/profile/perinatal-mental-health)	1	1
NHS England Data Catalogue	https://data.england.nhs.uk/dataset	1	1
National Data Catalogue Scotland	http://www.ndc.scot.nhs.uk/	1	1
Asthma UK Data Catalogue	https://www.aukcar.ac.uk/asthma-observatory/data-catalogue	1	5
Urban Big Data Centre Health and social care data	http://ubdc.ac.uk/data-services/data-catalogue/health-and-social-care-data/	0	0
Social Services Improvement Agency Data Catalogue	http://www.dataunitwales.gov.uk/SharedFiles/Download.aspx?pageid=30&mid=64&fileid=22	0	0

Catalogues no longer accessible in 2021 are marked as NA.

DISCUSSION

We sought to understand how easily a person could discover e-cohorts from the UK via internet search engines. We used a telephone survey to understand how organisations try to make data findable and measured how findable e-cohorts were across two internet search engines. In our survey, findability was recognised as valuable, however those managing e-cohorts were still exploring how to harness the power of the internet to improve findability. Using internet search engines, we found a wide range of e-cohorts and catalogues, but between 2018 and 2021 neither the findability of target e-cohorts in the top 100 results nor in catalogues had improved. If anything, findability had decreased slightly. Target e-cohorts were less findable using a new, dedicated dataset search than a general internet search engine. While established national e-cohorts were found directly through search engines, several catalogues and smaller, local or specialist e-cohorts were only found indirectly through other webpages. A crucial factor appears to be the coverage of e-cohorts listed in catalogues or specialist search tools.

Many authors have argued for improved findability, but empirical studies to assess findability have been rare and have not previously been done for UK health data. In the FAIR principles,[16] findability requires that datasets have a globally unique and persistent identifier, are described with rich metadata which explicitly include that identifier and are registered or indexed in a searchable web catalogue. In the UK, there have been government-commissioned reports into how FAIR research information is, which recognised the importance of a sector-specific approach but said little about health and did not measure findability.[22] Wilkinson *et al* proposed a set of metrics and a design framework for a FAIRness assessment[23] and this framework has been applied to omics data.[24] That assessment takes a machine-led approach, that is, whether a dataset is findable, accessible, interoperable and reusable without human intervention. We took an alternative starting point, assessing findability using the searches that might be carried out by a person trying to find e-cohorts. The importance of the public internet in providing search engines that index metadata to make data findable has been recognised,[25] although others have highlighted challenges to implementing the FAIR principles for online searches.[26] Such publications describe and debate what findability is or should be, but they do not offer an empirical assessment of findability and their claims that improving findability for machines will improve findability for humans are untested. A toolkit was published in 2019[27] that includes at least three metrics of whether or how easily datasets and other resources can be found using internet searches[28]; our methods fall in this vein. Looking back to just before our first online searches, a

Table 4 Assessment of findability within catalogues, including whether the catalogue listed target e-cohorts from table 2 (see figure 1)

	Catalogue name	Target e-cohorts listed	Searchability	Metadata	Unique and persistent identifier
Found in 2018 but not in 2021	Health Data Finder for Research	Clinical Practice Research Datalink (CPRD) Hospital Episode Statistics (HES)	Can filter	Dataset and field level	No
	Children and young people's health data catalogue 2009	–	Downloadable file	Dataset level	No
Found in 2018 and 2021	NHS Digital: Data and information	HES	Search bar; Can filter	Dataset level	No
	NHS England Data Catalogue	HES	Search bar; Can filter	Dataset and field level	No
	Perinatal mental health: national datasets	HES	Downloadable file	Dataset and field level	No
	Asthma UK Data Catalogue	HES In addition in 2021: SAIL QResearch Clinical Practice Research Datalink (CPRD) PIS	Search bar; Dropdown list	Dataset level	No
	Urban Big Data Centre Health and social care data	–	Dropdown list	Dataset level	No
	Social Services Improvement Agency Data Catalogue	–	Downloadable file	Dataset and field level	No
	National Data Catalogue Scotland	PIS	a-z listing	Dataset level	No
Not found in 2018, found in 2021	DataCat (University of Liverpool)	–	Search bar; Can filter	Dataset level	Yes
	ORDA (University of Sheffield)	–	Search bar; Can filter	Dataset level	Yes
	UK Data Archive	–	Search bar; Can filter	Dataset level	Yes
	University of Lancaster	–	Search bar; Can filter	Dataset level	Yes
	Mauro Data Mapper/ Oxford Metadata Catalogue	–	Dropdown list	Dataset and field level	Yes
	Zenodo	–	Search bar; Can filter	Dataset level	Yes
	Health Innovation Gateway	CPRD PIS SAIL HES Grampian	Search bar; Can filter; Dropdowns; Highlight new datasets	Dataset level	Yes
	Social Care Wales	–	Search bar; filter; show all	Dataset level	No
	ONS Secure Research Service	HES	Spreadsheet	Dataset level	No

For catalogues found in 2018, these were revisited in 2021; two were inaccessible, the other eight were unchanged in terms of metadata detail and presence of identifiers.

paper from 2016 envisaged a community to advance the FAIR principles (including searchability) in the life sciences,[29] and in 2017 researchers highlighted the need for better web-based identifiers for life sciences datasets[30] and for improved online discoverability and standardisation for UK health data.[31] Our 2021 results show many of those lessons still need to be heeded.

Our finding that some regional e-cohorts had by 2021 become less findable than national counterparts and that some catalogues had become inaccessible has implications for those working to increase data findability. Community efforts and standardisation have been advocated by researchers as the best way to implement the FAIR principles.[32] One approach has been to collate metadata centrally, as was done recently for opthalmology.[33] Centralised repositories and dedicated data search tools may be increasingly important for fostering findability as more and more datasets are described online, however

we found that not all available datasets are currently listed. Search engines, which are increasingly embedded into catalogues as well as being available for the general internet searches we conducted, enhance the findability of some datasets more than others. For example, CPRD was the most findable of our target e-cohorts in 2018 and 2021 and even increased its presence in search results, while some other target e-cohorts became less findable. As well as creating hubs, we suggest that the health data community also discusses variability in the findability of datasets and use benchmarks for online findability to assess progress.

A large effort as a result of the COVID-19 pandemic has given momentum to new findability tools, such as Health Data Research UK with their new catalogue: the Innovation Gateway.[34] COVID-19 data were listed in the catalogue and already found in our 2021 searches. The pace and scale of these developments, which are already producing research insights, are impressive. This may be helped by a more coordinated effort in the NHS under the UK government's data strategy.[35] Such efforts need continued support to enhance coverage, for example, to include more of our target e-cohorts or newer e-cohorts such as OpenSAFELY[4] and to boost metadata quality and accessibility.

Our work has some limitations. First, although we tried to contact as many organisations as possible across the UK, not all the ones we contacted were able to participate, and we may have missed some others. We can only speculate on how this has affected our results; it is possible that organisations that did not respond are stretched and chose to prioritise other work over our survey into findability. Second, our prior knowledge of the target e-cohorts probably made it easier for us to find them. Third, when screening search results, we reviewed 100 results per search (approximately 10 pages), two or three pages might be more realistic. We may therefore have overestimated the findability of UK e-cohorts. Fourth, the proprietary nature of search engines makes their operations unclear, for example, the consistency of the search rankings among different users[36] or how algorithms may have altered findability between 2018 and 2021. Google and Bing limit automated processing of their search tool[26] and manually checking 100 results per search was time intensive.

There are opportunities to extend our approach in further research. It would be useful to study how researchers find and access e-cohorts in practice. The use of wildcards to make searches more flexible, analysis of rankings and use of other search engines could be adopted in future. Comparison across organisations of the investment (time, money) and competencies of personnel working to make e-cohorts findable and accessible could reveal the most efficient methods to inform successful strategies for improving findability.

Based on our findings, we recommend that UK e-cohorts implement the following features to improve their findability: create a unique and persistent identifier, have richer metadata descriptions and ensure they are indexed in a searchable resource either through search engine optimisation of their own website or through catalogues that are highly ranked by search engines.

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