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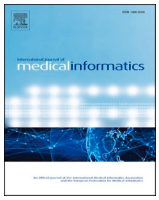

A multinational study on artificial intelligence adoption: Clinical implementers' perspectives

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ABSTRACT

Background: Despite substantial progress in AI research for healthcare, translating research achievements to AI systems in clinical settings is challenging and, in many cases, unsatisfactory. As a result, many AI investments have stalled at the prototype level, never reaching clinical settings.
Objective: To improve the chances of future AI implementation projects succeeding, we analyzed the experiences of clinical AI system implementers to better understand the challenges and success factors in their implementations.
Methods: Thirty-seven implementers of clinical AI from European and North and South American countries were interviewed. Semi-structured interviews were transcribed and analyzed qualitatively with the framework method, identifying the success factors and the reasons for challenges as well as documenting proposals from implementers to improve AI adoption in clinical settings.
Results: We gathered the implementers' requirements for facilitating AI adoption in the clinical setting. The main findings include 1) the lesser importance of AI explainability in favor of proper clinical validation studies, 2) the need to actively involve clinical practitioners, and not only clinical researchers, in the inception of AI research projects, 3) the need for better information structures and processes to manage data access and the ethical approval of AI projects, 4) the need for better support for regulatory compliance and avoidance of duplications in data management approval bodies, 5) the need to increase both clinicians' and citizens' literacy as respects the benefits and limitations of AI, and 6) the need for better funding schemes to support the implementation, embedding, and validation of AI in the clinical workflow, beyond pilots.
Conclusion: Participants in the interviews are positive about the future of AI in clinical settings. At the same time, they propose numerous measures to transfer research advances into implementations that will benefit healthcare personnel. Transferring AI research into benefits for healthcare workers and patients requires adjustments in regulations, data access procedures, education, funding schemes, and validation of AI systems.

1. Introduction

The widespread adoption of health information systems (HIS) in general, and electronic health records (EHRs) in particular, has increased the availability of a large volume of real-world data (RWD) to advance medical science. However, these data are often unstructured, heterogeneous, incomplete, and subject to the idiosyncrasies of the organization where they were initially produced. Artificial intelligence (AI) has been proposed to deal with large amounts of heterogenous RWD to develop diagnostic, predictive, and recommendation models to support healthcare professionals to work more effectively and alleviate the workloads arising from workforce shortages [1]. This potential to help healthcare workers deal with large amounts of heterogeneous data has led to renewed AI research investment and interest in AI data-driven methods, i.e., machine learning and computational statistics [2]. However, this new wave of AI enthusiasm has raised significant expectations

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about revolutionizing biomedical research and healthcare delivery, which are yet to be fully realized [3]. Recently, after several years of optimism from what has been known as "Big Data hubris", AI implementation experiences in the biomedical domain have had significant challenges. There are multiple examples of remarkable downturns of well-known initiatives that failed to deliver the expected results, despite proper planning and high expertise in AI [4–6]. These challenges are commonly attributed to the biomedical domain's complexity, difficulties in accessing data for training AI models, and the lack of transparency of some AI algorithms (e.g., deep learning) [7–9]. Moreover, beyond these challenges inherent to many AI implementations, medical informatics studies point to other causes related to healthcare professionals' requirements for AI adoption in healthcare settings [7,10–12].

1.1. What is already known

Undoubtedly, AI has the potential to help healthcare workers work more efficiently in most clinical domains by equipping them with tools to process the complex streams of information they manage [13–15]. Examples include screening radiological images to prioritize patients according to their risk, using Natural Language Processing (NLP) real-time analysis when prescribing new drugs to detect possible drug interactions by checking previously prescribed medications, or leveraging several variables from laboratory tests, medical devices, and clinical observations to warn about the risk of sepsis. However, the health informatics arena contains many studies reporting barriers to, and facilitators of, the use of AI [16]. Some studies have focused on reporting healthcare professionals' attitudes towards using AI [9,17]. These studies have pointed to limited satisfaction and disappointment among clinical users [17]. The limitation of studies about clinicians' perceptions of AI is that most of them are based on numeric scale surveys that do not allow for an understanding of the reasons for the provided results. Other studies have taken a qualitative approach to understanding AI implementations [8,10,18], but they relate to one specific clinical setting. In addition, many studies do not report on the implementation stage of the AI system. Literature reviews have helped to identify some common challenges and facilitators [7,19]. However, their main limitation arises from the indirect knowledge of each implementation, making it difficult to determine the AI systems' level of implementation.

Moreover, for many AI studies, it is difficult to determine the degree of adoption and maturity by differentiating academic research projects that overcame the piloting stage from the implementations fully deployed in the clinical setting that have been used to support healthcare tasks. That is, if the system has been deployed in the clinical workflow of a health organization or has only been piloted to publish the project results and then has been discontinued. These issues have raised concerns about biases and reproducibility of AI-related studies [11]. Gama et al. performed a literature review on implementation frameworks, reporting that the implementation of AI is still in the early stages, making it challenging to plan AI implementation projects correctly [20]. This was also confirmed by Sharma et al. [7] who reported the need to understand better the implementation stage of AI adoption with empirical research. This lack of precise reporting on the maturity and stage of implementation of AI projects has led to a sizeable gap in understanding of the success factors and barriers perceived by AI implementers first-hand [16,20].

1.2. What this paper adds

Implementing AI requires significant resources at all stages [7,16]. Large representative data sets are needed for model estimation, and extensive validation is required in the implementation stage in the clinical setting [16]. Additionally, AI must be embedded in the clinical workflow when deployed, without negatively impacting healthcare workers [7]. Hence, it is crucial to understand the factors that can challenge an AI implementation project and the factors that can facilitate and contribute to its positive effect on clinicians' work.

This paper aims to understand the barriers and facilitators in the AI implementation stage by gathering firsthand experiences from a multinational group of AI implementers. The study builds on previous research [7,16,20] to understand the AI implementation stage in healthcare organizations. To that end, the study focuses on the experiences of AI implementers who have participated in AI deployments in clinical settings that transcended the piloting stage and were implemented as integral parts of clinical workflows in health organizations. The analysis of their experiences seeks to understand the rationale behind the success and failures of AI projects from a self-perceived clinical efficiency point of view. Hence, we aim to understand better the AI implementation barriers, facilitators, and socio-technical relationships among clinical implementers, technical implementers, data scientists, and AI vendors. The paper looks at the implementation of AI from the implementation science perspective, defined as "…the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practices…" [21]. The AI field encompasses many subdomains, such as logic, expert systems, knowledge representation, and data-driven methods (e.g., machine learning). This paper uses AI as a synonym for the latter.

2. Methods

2.1. Setting

The study design is qualitative and explores the experiences of AI implementers who work directly in healthcare. The study presents the perceptions of a set of multinational implementers with the following roles: AI scientists, AI technical developers at hospitals, vendors commercializing AI, clinicians using AI, and clinical managers involved in the adoption of AI.

The research group is a multidisciplinary team of AI researchers, medical informaticians and sociologists. We performed semi-structured interviews and analyzed them with the framework method [22,23]. The framework method facilitates qualitative analysis performed by a multidisciplinary team of experts with varying degrees of experience in the qualitative analysis [23]. Our semi-structured interview guidelines were grounded on the results of a previous scoping review that helped us to narrow down the critical factors influencing AI implementations [16]. Additionally, we held two workshops with all the researchers involved. This extended the interview guidelines, adding more questions considered necessary based on the research team's experience and various national and international reports about AI implementation. Additional interview questions were also intended to encourage the participants to propose recommendations for building a more favorable context for AI implementation. For example, to propose actions expected from the government at a local, regional, and national level for improving AI adoption. Table 1 displays a summary of the interview guidelines, and the complete interview guide is available in Appendix A.

2.2. Sampling

To find relevant interviewees, we used the list of members of the Norwegian Network for AI in Healthcare (Kunstig intelligens i norsk helsetjeneste (KIN), in Norwegian), contacts from previous projects at the Norwegian Center for E-health Research, in addition to Google search results on "Artificial intelligence in healthcare". The interview participants were recruited by In the email, we explained the project goal and the interview process with the attached interview questions. Potential respondents interested in more details about the interview were contacted by phone.

Our inclusion criteria required participants to be directly involved in implementing an AI project in the clinical setting beyond the research stage. Participants without direct experience in the implementation of

Table 1
Excerpt of the interview guidelines.

1. In your experience, what is the status of AI implementation in general?
2. Did your organization have any experience in the adoption/implementation of AI systems?
3. Was it clear for you if the AI needs approval or certification? Do you perceive this procedure as a barrier that poses a risk for the success of the intervention?
4. Was the regulatory framework clear and did you feel knowledgeable about where to ask for support with regards to regulatory compliance?
5. Can you tell us about the organization of the project (planning, implementation, testing)? Who was championing and promoting the project (hospital management, research groups)?
6. What are the licensing structures, implementation and licensing costs, IP rights, and data ownership?
7. What sources of evidence are supported by your AI system?
8. Do you perform data quality pre-processing before applying AI? Can you explain the procedure you followed to improve the data quality?
9. Is the new AI system integrated into the clinical workflow? (e.g., embedded in the EHR)
10. How was the new system evaluated?
11. Do you think your AI system is generalizable to different populations? Can it be used by another organization/country?
12. Is there in-house support for the system or is it supported by an external vendor?
13. Currently, there is concern about algorithms discriminating against some population subgroups. Do you perceive a risk of discrimination arising from your AI system?
14. Did you detect barriers or challenges related to the lack of transparency of the AI model?
15. How was the education/training plan structured? Who received training?
16. Were financial resources sufficient for the implementation of the project?
17. Can you think of other areas that would benefit from AI that have not been considered so far (within healthcare)?
18. What was the perception of AI by clinicians? And by patients?
19. In your opinion, what are the important barriers and facilitators for successful AI implementation?
20. If you could choose 3 actions to be undertaken at a national, regional, or local level to facilitate the use of AI in healthcare, which would you choose?

AI systems deployed in clinical settings were excluded. For example, we did not consider AI developers who had developed Machine Learning (ML) models using clinical data but never implemented their models as running AI systems in the clinical setting. In this way, we focused on the barriers and facilitators that appeared when deploying AI systems running in real clinical settings. We excluded purely academic projects that did not reach the implementation stage. In total, we contacted seventy-four people.

We did not interview all the potentially valuable projects. Twenty-eight potential respondents from the following countries were not interviewed: Norway (7), Germany (6), the Netherlands (3), the USA (3), Sweden (2), Iceland (2), Austria (1), England (1), Denmark (1), France (1), and Spain (1). We had correspondence with fourteen of them (of which half did not agree to the interview and another half were last-minute drop-outs), and fourteen did not reply to the invitation.

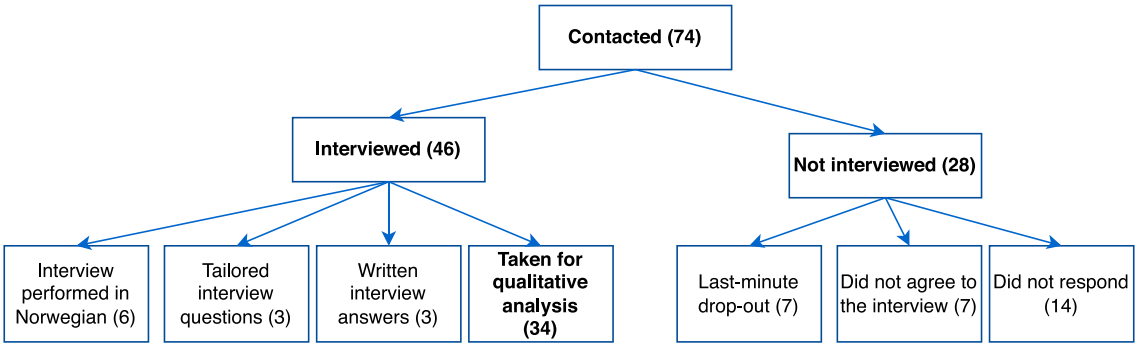
In total, we conducted forty-six interviews with representatives of private and public organizations, such as vendors for EHR and clinical systems, secondary healthcare providers, management of healthcare organizations, universities, technology transfer offices, a competence center, and national authorities from Norway (25), Sweden (5), the USA (3), England (3), Denmark (2), Finland (2), France (2), Estonia (1), Spain (1), the Netherlands (1), and Chile (1). To avoid bias, for further analysis we excluded the interviews performed in Norwegian (6), the interviews in which we had to tailor the interview questions (3), and written interviews (3). By profession, eleven participants were clinicians, nine were AI researchers, seven were vendor representatives, five were taking managerial roles, three represented Technology Transfer Offices (TTOs) related to hospitals, and two worked at Health Trusts coordinating AI implementations. Consequently, we finished up with thirty-four interviews (with 37 participants in total) suitable for qualitative analysis.

2.3. Data collection

TO was responsible for contacting the participants and explaining the interview procedure. Participants gave their permission to be recorded and confirmed their consent while being recorded. Interviews were performed remotely on Microsoft Teams by the research team (TO, LMR, MATH, MT, PN, AM). At least three research team members were present at each interview. We followed the semi-structured interview guidelines previously described, but participants were free to elaborate on each interview question as much as they wanted. At the end of the interview, participants were offered the option of commenting on any topic that they considered relevant regarding the barriers and facilitators of AI implementation. This helped us not only to identify barriers and success factors, but also to elucidate why barriers affect the implementations process, at what stage they influence it, and what should be done to alleviate them.

We collected data from 34 interviews with 37 participants. The duration of the interviews varied between 35 and 60 min. Interviews were video-recorded and transcribed by the research team. All research team members were involved in the transcription process, and AM was responsible for examining the transcripts to ensure comparable formatting and resolve any inconsistencies as described further on. All transcripts were checked for errors by listening back to the audio recording and reading the transcripts simultaneously. Each transcript was supplemented using notes taken during the interviews. Each interview transcript was edited, deleting repetitions, and correcting the grammar, thus following "naturalized" transcription (i.e., "intelligent verbatim''). This was a necessary step since all transcripts were sent to interviewees for their approval and further expansion on a topic if they wished to add more information. Interviewees were given a week to review the transcript, and several participants added new content. During this process, the interviewees accepted all the transcriptions, and no further revisions were needed.

Once participants approved the content of the interview transcript, interviews were coded by three independent reviewers using NVivo 12 (QRS International, Burlington, Massachusetts) and following the framework method [22,23].



2.4. Data analysis

Our coding strategy aimed to gain a detailed understanding of the barriers and facilitators by analyzing firsthand experiences about how implementers perceive these barriers and how they can be alleviated. Three reviewers (PN, MATH, LMR) read and coded the interview transcriptions separately. The initial thematic index used was the index produced in a previous scoping review [16]. Each interview was analyzed by at least 2 reviewers independently. Each reviewer freely elaborated on the initial index, adapting it to cover the study's main objective.

Initially, the three researchers that formed the analysis team (PN, LMR, and MATH) went through a familiarization stage by re-reading all the approved interviews. After familiarization, the analysis team coded a subsample of three interviews. This was used to identify the themes that reviewers interpreted in disparate ways and homogenize the coding style. After coding the interviews, the researchers gathered and agreed on the themes to be used and the specific way of coding sections to maximize coding consistency. Some themes were edited in the framework index to reflect the themes identified better. This procedure continued until thematic saturation was reached in the 10th interview, and no further modifications to the thematic index were needed. The framework index remained stable until finalizing the analysis of the remaining 34 interviews. This assured us as to the appropriate coverage of our thematic framework. Differences among participants regarding nationality, organization, and professional role were analyzed. The integrated agreement (Cohen's kappa) was 0.79, signifying substantial agreement.

3. Results

3.1. Status of AI

Respondents perceived the status of the implementation of AI as promising but immature. In addition, outside the medical imaging and NLP domains, respondents reported that commercial AI products were scarce. Respondents reported that most AI implementations were pilots from academic projects that were unlikely to become products fully embedded in the clinical setting. Respondents reported that many AI projects were funded and piloted, but had yet to go from the research stage to implementation in the clinical setting to prove their ability to translate AI knowledge into benefits for health organizations, professionals, and patients.

3.2. Adapting an AI system

Generalizability, understood as the ability of an AI system to preserve its performance when used in new populations and contexts, is an essential concern for the clinical implementers interviewed. Depending on the use of an AI system and its medical domain, the AI system may or may not be generalizable to other contexts and populations.

> *"But the big issue here is that even if we had a model that mathematically understood the clinical language that is used in [name of hospital], that Natural Language Processing model would differ in other hospitals because the clinical language is different from hospital to hospital. It should be re-trained."*

Respondents pointed out that the differences in protocols across healthcare organizations in the same country may affect the AI system's utility. Hence, they considered that careful local validation will always be required to account not only for the AI system performance but also for the effect on clinicians' workflows. In most cases, the implemented AI system had to be tested by the local implementation team (of clinicians and technicians) using local data to understand if its behavior was correct. This need for validation is also dependent on the medical context. For example, respondents explained that anatomical differences among ethnicities affect the performance of AI systems used for breast cancer screening, while other contexts are unaffected. All respondents agreed on the need for guidelines in the AI implementation process. In particular, national guidelines that unify the local validation of newly acquired AI systems. Testing and evaluation were named as the most crucial challenges due to the importance of having both general and local evidence of the benefits resulting from AI implementations. This evidence must be produced once the AI system is embedded into the clinical workflow to understand its impact and determine if the AI system, once embedded in a particular organization's clinical workflow, provides a cost-effective benefit. To that end, interview participants would like to have national standard evaluation guidelines that recommend the type of clinical trial to be conducted depending on the context (i.e., prospective, retrospective, Randomized Controlled Trial, etc.). In addition to validation, re-training the model with local data may also be needed depending on the discipline and usage of the AI. For example, one respondent mentioned that a colorectal polyp screening system might be effective but cause inefficiency if it recommended excessive biopsies of polyps, causing a bottleneck for pathologists. Evidence-based evaluation, where some patients go through the current workflow and others follow the alternative workflow with the AI, was recommended by one respondent for building evidence on how cost-effective the AI system is.

The respondent proposed *"before releasing new tools to the public, you can have a parallel system where both can be used (the new AI system and the current one). Then you can monitor the performance and see the changes, for example a fraction of the patients uses the old set up and the rest use the new set up. Then you can monitor and see how that changes the way doctors make decisions for a while and then evaluate the system before rolling it out. The way we do it now, just to test the system technically, but not really look at how it changes the way people work and the way it influences the patient consequently"*.

Beyond the AI system's effect and performance, other types of evaluation, including technology acceptance and usability, were recommended.

> *"At first, model evaluation was done retrospectively. Next, we performed a prospective evaluation of the system. In between - software testing. Also, we did usability testing where several clinicians were piloting the system before it was implemented. After implementation and evaluation, we received several feedback from the clinicians on how to improve the system."*

Respondents also pointed out the need for national and regional coordination in evaluation studies since multicenter studies were convenient for understanding the positive effect of AI systems independently from a specific organizational context. There is also a need to monitor AI implementation and detect if their performance is deteriorating in order to reassess them. Some areas are particularly complex for adapting and evaluating AI. Respondents reported that the lack of effective mechanisms to allow AI systems to use EHR data significantly affects these systems. NLP systems need re-training if they are deployed in a setting with a different language and among centers in the same country to account for differences in clinical jargon and terminology across healthcare organizations.

3.3. Regulatory framework

Most respondents agreed that their countries have the right competence for AI systems development (data scientists, digitalized healthcare organizations, etc.) and, at the same time, that regulatory changes are needed to facilitate AI implementation. The regulatory framework is perceived by respondents as complex and needs to be clarified. Respondents understood the difficulty of legislating in a dynamic area such as AI and healthcare given that legislation must focus on the safety of individuals. However, respondents perceived AI to have been rapidly evolving in recent years, while legislation has evolved slower, which has

caused inadequate support for AI implementers.

> "*They have changed a law a little bit which considers AI as an exception to access health data. But there are still a lot of legal issues in terms of how you interpret laws. Since you have different laws managed by separate entities, it is difficult to orient yourself and understand. It is not a clear pathway.*"
>
> "*You also need to monitor the performance according to the medical device regulation. Or the manufacturer has the responsibility to monitor the performance over the lifetime of their product because you might get a drift in the data. And then how do you make that data available to the manufacturer? How should you set up your contract with them? Should you let them into your infrastructure? Can they log on and access the data? Or should we pack it up in a USB stick and send it to them once a week? How do we solve those things in practice? I do not have a solution for that.*"

The most significant regulatory complexity mentioned by the participants was understanding and determining the applicable legislation in large cross-institutional data reuse projects. This included determining the bodies that have to approve each project. Respondents identified the overlap among different legislation and approval bodies as the primary regulatory barrier. Several respondents involved in implementing AI systems reported that a significant part of the budget went into figuring out which legislation was appropriate. Implementers considered a need for more knowledgeable professionals working at the approval bodies to provide guidance and answer inquiries promptly. It was also reported that, due to a project's complexity and legislation overlapping, one regulatory body had approved the use of data for the project, and at the same time another body had complained and threatened the implementers because the regulatory bodies disagreed on who was supposed to approve it.

Respondents reported that several countries have started initiatives to introduce legal and organizational changes concerning data access approval. Findata is a Finish organization aiming to centralize support, approval, and data access, establishing clear deadlines for answering data access and approval requests [24]. Respondents expected that centralizing approval in one single body would avoid having to figure out which regulatory body should be involved and asking whoever initially captured the data (e.g., a hospital department) for approval. This homogenization of approval and data access in one body should make data access comply better with Findability, Accessibility, Interoperability, and Reusability (FAIR) principles and be less prone to conflicts of interest. Respondents reported that harmonized data should ideally be kept in long-term storage controlled by the centralized data governance entity so that data cleaning and harmonization tasks do not have to be repeated for the same datasets in different projects.

> *"We tried to talk to [office of the ministry of health], the hospital's privacy officer, [the health trust], and [national data protection agency]. At that time, approval from [national data protection agency] was needed for implementing such systems. But we didn't get fulfilling answers from anyone."*

Respondents perceived AI as a tool to support clinicians rather than an automatic system that could make decisions without human supervision. In this regard, they reported that the responsibility for treatment errors would fall on the clinician as the ultimate decision maker. Contrary to what other publications suggest [9], respondents tolerated a lack of interpretability and accepted using AI systems with robust evidence of their validity. They mentioned the example of drugs whose pharmacokinetics and pharmacodynamics needed to be better understood, but that were backed by clinical studies regarding positive effects and safety for patients. Thus, from the clinical respondents' point of view, if proper clinical studies supported an AI implementation, there would be no concern about its transparency since trustworthy AI could be developed based on validation studies. Respondents reported the need for clinical studies that would show the positive and negative effects of the implementation when embedded in the clinical workflow (retrospective, prospective, and Randomized Controlled Trials) in addition to evaluating the performance of the AI model. More critical for respondents was the reproducibility of the AI system's results.

Respondents reported difficulties distinguishing between what could be considered AI and what could not. New European Union (EU) regulations may help with the recently introduced guidelines and regulations [25]. Another reported challenge was the Conformité Européenne (CE) marking process for AI products. They warned that sometimes AI systems acquirers misunderstood the meaning of CE marking. They clarified that the CE marking guaranteed compliance with health, safety and environmental regulations, but did not guarantee that the AI system positively affected clinicians' performance and patients' health. In other words, CE marking is necessary, but insufficient for deciding whether an AI system should be implemented in the clinical setting. In addition, respondents perceived CE marking as complex and time-consuming. One of the respondents reported stopping the use of a home-grown AI system which clinicians were satisfied with because they could not afford the CE marking process.

Respondents also reported that regulations should accommodate the dynamic nature of machine learning algorithms if implementations wish to directly learn from data in real time as it becomes available in the EHR. Currently, the AI models in the core of an AI system are encapsulated as medical software, and a "frozen" version or a snapshot of the model produced by machine learning techniques is used. However, respondents specified that if adaptive (i.e., continuously learning) AI models were accommodated, the legislation should reflect how to correctly use them so they can learn in (nearly) real-time while still preserving the safety of patients.

Respondents stated the need for unified national laws, organizations, and infrastructures to regulate and govern the secondary use of data. Several interviewees mentioned the progress of their countries in approving laws that centralize data governance and ethical approval. One of the countries working in this direction is France, with the promotion of the French Health Data Hub that will centralize data management for secondary uses [26]. As mentioned before, Finland is following this direction for data access approval. These countries have established unified legislation and data hubs that manage access approval to several datasets in a centralized manner to avoid conflicts of interest arising from the original data controllers.

The last regulatory challenge was related to the procurement of AI systems. Some interviewees working at AI companies stated that the implementation of AI systems follows an iterative process in which close collaboration with the clinical personnel of the hospital is required even before the project's inception. In some countries, procurement regulations excluded those companies from becoming the system implementers because they had been involved in defining the project. They suggested that regulations should be adapted to these cases since it is unrealistic for a second vendor to follow with the implementation while the first has done the detailed context-aware analysis.

3.4. Data availability

Respondents involved in the development of new AI models stated that data availability is among the most critical challenges for successfully implementing AI in healthcare. Machine learning algorithms learn from data. Thus, access to updated data is needed to keep them updated and monitor their performance (e.g., specificity and sensitivity). Only then can it be determined whether a specific algorithm remains valid over time with stable performance.

European participants looked at the US as more fertile soil for AI implementations in terms of data access and regulations. European clinical implementers believed they were not rewarded when a successful product was implemented, but could be punished if the implementation did not function appropriately.

"You are not rewarded if the things go well, but you get punished if the things go wrong."

Implementers reported significant delays when accessing data due to the time approval bodies took to evaluate their cases. Delays caused substantial losses for researchers regarding time, publications, and funding devoted to coordinating all the requests to these bodies. Respondents felt that regulators needed to understand better that for running data-driven algorithms, it is possible to let the algorithm explore the data without exposing it to anyone else. Respondents considered that more expertise is needed in regulatory and approval bodies to evaluate data access requests. They reported that the challenge lies not only in having more unified legislation, but mostly in facilitating the approval process and making it coherent without several approval bodies having an overlapping domain of responsibility. The data access approval flow in some countries is also exceptionally tedious. When data from several data registries were needed, implementers needed approval from the Ethical Review Board and the registry steering committee.

"There is something about the need to make organizational and regulatory arrangements so that specific types of data sources are available within specific purposes to benefit society. I think it is the organizational and regulatory that are the barriers. There have been challenges associated with defining 'what the actual development of AI is."

"The system was gathering the data and sending it along to the [national registry], for testing and evaluating the system, it took one and a half years since we could explain to the regional authority of [the health region] to be allowed to put this into the environment."

When it comes to the operational environment to enable secondary use of data, respondents reported challenges in implementing the infrastructure and finding out who was responsible for implementing it to export data into research clinical data warehouses. In their view, a broader planning that assigns roles and responsibilities for the secondary use infrastructure is needed, and funding must be allocated. In this regard, a data reuse pipeline with a test environment that involves all stakeholders throughout the entire process (approval, data cleaning, data export, data storage, and data access control) must be established.

Patient consent can become complex since AI requires large amounts of data, and getting patient consent for each data instance is not feasible. European respondents mentioned a need for methods to use large data sets without explicit patient consent from each patient.

3.5. Data quality and processing

Data quality is defined as "fit for [its] intended uses in operations, decision making and planning" [27]. In AI data quality refers not only to its syntactic and semantic dimensions (e.g., in structured annotated data), but also to the representativeness of a training data set regarding a population of interest. To that end, data must be accurate, reliable, complete, timely, and relevant [27]. Respondents agreed on the need to improve data quality to build a data set that could be used to train AI models. Hence, initiatives for improving data quality and standardization need to continue. Infrastructures for data cleaning and standardization are required to build cross-institutional data warehouses that provide access to anonymized data sets to train and validate AI models. The commitment to data quality will affect EHR implementations [28]. In many cases, the only way to achieve good quality is by structuring and coding clinical information at the point when it is produced (bedside).

Respondents considered that current infrastructure for data processing needs more computational power and secure mechanisms for storage while enabling research and interoperability across health institutions. Respondents desired better infrastructures for data reuse, but warned that big data processing infrastructures might not be worth building if local systems such as EHRs, often outdated and very slow, are not modernized to become more efficient and increase data quality. Respondents believed that regional or national infrastructures for AI models are more cost-effective and better than local ones since they can concentrate more computational power shared between various AI implementers. These infrastructures, allowing for data-sharing, are crucial to gathering and processing diverse data sets representing several populations, ethnicities, age groups, etc.

3.6. Data structures and interoperability

Respondents agreed on the need to continue and progress with large health information standardization programs, such as EHDS (European Health Data Space) in the EU [29] and Meaningful Use in the US [30], to improve data quality and interoperability. These programs should include the advances in adopting clinical information standards (e.g., Observational Medical Outcomes Partnership Common Data Model, HL7 FHIR, openEHR), terminologies, and common Application Programming Interfaces (APIs) for clinical data warehouses. Data standardization will make AI models more generalizable and easier to use across organizations, provided that the data schemas and terms used to specify data semantics are common to all organizations. Respondents reported that health data hubs are especially recommended for collaborating with standardization bodies to decide on the best data representation standards for a particular region or country.

Respondents complained about the lack of extensive anonymized data sets that can be used to develop AI models with fast ethical approval. They considered that National Health Data Hubs and centers for the secondary use of clinical data should promote these initiatives. To that end, national data anonymization programs should be initiated and funded. Respondents considered that research projects are often funded before having the raw materials to develop new methods, i.e., high-quality data. Respondents recommended the development of initiatives that guarantee data availability for research projects. An example is the plan in Spain to open anonymized clinical notes to train NLP models [31], funding the anonymization and manual annotation of data sets to advance NLP technologies in the Spanish language.

Respondents mentioned the need for several tools to learn from daily data processes and workflows. Visualization of processes and patient pathways is needed to understand complex processes and determine how to optimize them. Respondents pointed to the example of process mining, which allows for exploring databases and discovering workflows based on event data from health information systems.

3.7. Licensing structure, implementation and IP rights, data ownership

From the interview analysis, several licensing and development approaches were found attending to the profile of the organization that developed the AI model. The first type was AI models developed as part of a research project in health organizations that later became embedded in the clinical workflow. The second type was commercial third-party AI products fully developed by a private corporation. The third type was home-grown AI systems that evolved from a research project into an implemented product as a joint venture among universities, hospitals, and private vendors. The second and third types were, according to respondents, more likely to evolve into an AI implementation used in the clinical setting. When collaborations among vendors, academia, and health organizations occur, TTO guidance is crucial in establishing the conditions for use, Intellectual Property (IP) rights, etc. One respondent mentioned:

"The solution is very expensive. Who should cover the cost and how? To develop the solution, you need large amounts of images that someone has contributed to. Who can afford this, who owns it? At [the hospital name], in general, we have a dedicated department [a department name] that handles all IP-related questions. It is more like a company owned by [the university name] and [the hospital name]. They negotiate IP rights, ownership etc."

When hospitals are actively participating in developing an AI system,

the licensing model is a shared model with the vendor developing the system. One respondent reported:

"It [licensing] follows the Stanford model. It means the hospital has a major ownership stake in the system if it should ever be commercialized. We, as inventors, have about 40–45% ownership, I think."

3.8. In-house support or support from external vendors

The type of support required to operate an AI system depends on the kind of AI. Medical imaging AI systems need both local support and manufacturer support. Respondents reported that suppliers need close relationships with clinicians to successfully deploy the system in the clinical workflow.

"…among those we have developed in image, X-ray, or operation support, it is mostly clinician to clinician with external suppliers. Often, suppliers are in-house to do it."

In addition, one respondent reported they could not make the best use of the AI system because, despite asking for training on how to use it, they never received an answer from the vendor. They were learning by doing without knowing all the system's capabilities.

Respondents from health organizations who had participated in developing home-grown AI systems reported the need to count on an external vendor that commercializes it. Otherwise, the system maintenance cost is too high without a private company that commercializes it and implements it in several health organizations, thus lowering maintenance costs.

"It was in-house support when it was a research project. When we thought about commercializing the system, then we saw that it would be very difficult to maintain, or to support the system if the system should be sold or implemented in our hospitals. It would be necessary for a private company to take ownership of the system."

3.9. Transparency

Algorithmic transparency on how a model arrives at a particular recommendation is often pointed out as a challenge for implementing AI [9]. We deemed explainability (XAI) as not being a crucial factor for AI acceptance among clinicians. One respondent mentioned:

"There are probably some who write a bit about transparency and the need to be able to explain artificial intelligence and how it arrives at a recommendation and how it becomes a challenge from a legal point of view. For example, how do you document health care if artificial intelligence is very involved in health care and is based on a very decision-making basis that a human being would never be able to analyze? How do you document the health care and how do you inform the patient about the health care they have received?"

As mentioned in the previous sections, while some implementers are concerned by the opacity of methods such as neural networks, most of our clinical respondents were not. Most clinical interviewees perceived AI systems as a decision-support tool. They were not significantly concerned about how the method works if they had robust local evidence of its validity and safety.

3.10. Finance and resources

In general, respondents considered the funding of research projects to be good enough. However, they agreed that the most challenging activity to finance is to certify a new AI system as a CE-marked product. Another aspect where some respondents pointed out a need for more funding is to cover the expenses for the system implementation in the clinical setting. Many respondents from hospitals also sensed that they need more technical and human resources to develop new AI systems beyond the prototypical stage, to be used in the clinical setting. One respondent mentioned:

"You have funding for developing things and you have funding for buying things, but no funding for testing and figuring out how to use the implementation or to find the innovation gap."

This is vital to building evidence on an AI system's effectiveness and making pilots into CE-marked products. Respondents considered funding for AI development to be scattered among small research initiatives that still needed to reach the implementation stage. They recommended a concentration of the financing into larger projects to develop an extensive, shared ICT infrastructure to support AI implementation. Other respondents reported a lack of resources to continue operating a model that clinicians accepted due to a lack of resources to take it from a prototype in research to a CE-marked product.

The respondents who worked or collaborated closely with TTOs reported that a rough estimation of the time to transform an idea into a commercialized AI product is often 8–10 years. They reported that the process involves several stages, and careful planning is needed to facilitate the later stages involving CE marking and implementation in the clinic. Specifically, respondents mentioned the importance of a robust documentation system from the very beginning, appropriate planning, and partnerships to access data representative of the population the AI model was developed for, as well as an evaluation plan for the solution involving clinical users, resources for processing sensitive data, and early knowledge on the regulations, in particular, on CE marking of the product.

In general, health organizations need more legal experts on AI, Information Technology (IT) experts to run and maintain the necessary infrastructure for AI developments, and clinical domain experts with dedicated time to focus on implementing AI systems.

AI experts are difficult to retain in healthcare organizations due to the organizations' inability to compete with the salary levels for IT specialists in private companies. In addition, hospital IT infrastructure was called outdated and in need of big investments.

Beyond funding for testing and integrating AI solutions, the biggest hurdle regarding resources is allocating clinicians' time to prepare, assess, and validate AI implementations. The current healthcare model is under much pressure due to the need for physicians, which is worsening with the aging population. This makes it challenging to free them from clinical tasks to participate in AI implementation since the clinicians' priority is patient treatment. This has led to a cyclic dependency between clinicians and AI implementations. On the one hand, AI implementation projects sorely need clinicians to assess the intervention for the AI system to become useful and improve healthcare workers' efficiency. On the other hand, it is not possible to free healthcare workers from clinical tasks because they do not have the capacity to work on projects that, ironically, may increase their efficiency. This also affects the need for cross-disciplinary teams of healthcare workers, legal experts, AI experts, and IT implementers.

3.11. Perception of AI by clinicians and patients

In general, respondents reported a positive perception of AI by clinicians. They hoped AI could help them to work more efficiently and make the healthcare system more sustainable. Among clinical specialties, radiology and pathology were the areas that recognized a direct benefit of adopting AI tools to work more efficiently and relieve the increasing lack of clinical professionals.

"They [clinicians] are happy, helpful for them to have the algorithm giving the suggestion instead of going through the whole excel files. Patients do not really see the difference. Only when they see the difference, is in classification when they get the answers sooner."

"There is a great enthusiasm and commitment. They [clinicians] think that this is the future to provide the best medicine and that it will be a help

for the individual health professional instead of going with yellow notes and discussing in professional meetings etc. When it comes to patients, we have had the patient organizations and the user council in connection with [large national AI project]. They are only concerned with getting the best health care possible and have only welcomed this."

Clinical staff do not perceive AI as a threat to their jobs but as a potential support to work more effectively. However, one respondent reported that clerical staff did perceive AI as a risk, and one project failed for that reason. Several respondents reported support from their hospital management for AI development.

Regarding patients' perception, respondents agreed that in most cases, for patients, there is no difference since the AI does not directly interact with them but with the clinician. We did not have patient representatives among our interviewees. However, some participants reported that AI is not well understood by patients with a conception that an AI would treat them instead of a clinician.

3.12. Management and engagement: involvement and collaboration

Respondents reported that the involvement of legal experts, data scientists, clinicians, and health managers in all stages of the AI implementation is a primary success factor.

"Anchoring hospital leadership is very important for all the projects, then championing by the clinical department leadership becomes the most important."

Management team commitment and championing of AI implementations are other success factors. These factors facilitate the multidisciplinary collaboration of experts in the hospital and the connection with outside entities. Specifically, healthcare workers, data scientists, and computer scientists must collaborate closely to understand the task and challenges connected to it from different perspectives. To that end, some hospitals redesigned their strategies by hiring chief technology officers with a technological background and giving an active role to TTO offices. TTOs supported implementers in turning their AI research projects into CE-certified products that can be adopted and commercialized, hence facilitating both intra-organization collaboration and agreements with external entities. Examples include collaborations with vendors, IP rights, universities, and regulatory bodies during all the stages of the implementation.

Interviewees desired unified guidelines about AI implementation and the steps to minimize risks. There is a need for forums where academia, healthcare institutions, regulators, and vendors can meet and discuss each other's needs to design a better environment for AI proliferation. Examples of organizations working in this regard are AIDA, Medtech4Health, VINNOVA, Formas, and the Swedish Energy Agency. Respondents believed governments should support the development of competence networks and innovation hubs to agree on the best way to build a shared digital ecosystem with the technical, organizational, and political ingredients to facilitate AI implementations.

3.13. Human factors

Based on interviewees perceptions, national strategies for digitalization should consider increasing literacy about AI potentials and limitations. This knowledge building should be approached at several levels in society. For citizens, respondents recommended Massive Open Online Courses (MOOCs) to develop a basic understanding of AI, its role in making professionals more effective and demystifying unfounded myths. For healthcare professionals, such initiatives could include (as reported) an intensive 3-day competence-raising course that provided the basis with further training for those who desired more advanced knowledge about AI.

Clinical respondents emphasized the alignment of AI implementations with clinical and societal needs. They stated the need to be considerate with clinicians working at the bedside since every AI intervention would impact their daily routines while already being under a lot of pressure. It is essential to leverage the vision of the clinical workers affected and incorporate their requirements into the AI intervention. This vision will help use AI in parts of the clinical workflow, adding benefits with minimal disruption. To this end, AI implementation projects are recommended to be led by clinical champions inside the healthcare institution to help leverage the impact and benefits of AI implementations.

Respondents reported areas with high potential to benefit from AI, such as multimorbidity, mental health, and management tasks (e.g., reporting, reading medical records, etc.). Respondents also recommended further investigating such areas with significant potential for benefiting from AI and technology in general. Finally, some respondents recommended the inclusion of patient representatives to understand their point of view on AI implementations and determine to which extent the AI intervention should be better explained and transparent for them.

4. Discussion

Cost containment, high expectations, and innovation strategies are accelerating the adoption of AI [32]. Previous studies identified barriers and facilitators in AI adoption [16,20,32,33]. This study builds on previous literature by analyzing AI implementers' firsthand experiences to provide a deep understanding of these facilitators. In the following, we compare our findings with previous research, improving the understanding of the AI implementation stage. Table 2 displays previous findings and the new findings from this study.

4.1. Evaluation and replicability of AI models

Previous work proposes advancing AI explainability (XAI) to improve reliability and trustworthiness [9,34–36]. However, unlike previous work [7,9,17,37], our study deemed XAI not crucial for AI acceptance among clinicians. Our study also determined that those with more experience in AI, such as radiologists, have lower XAI concerns and more willingness to use AI [9]. Conversely, the most critical challenge reported by our respondents was the clinical evaluation of AI models. Respondents considered that most AI studies report tests based on laboratory validation, such as Area Under the Curve or prediction error. These findings are aligned with recent studies reporting the need for external validation of AI systems [1,19,38]. However, the data fragmentation and complexity of data access make cross-institutional validation studies complex [19,33]. In addition, there is a lack of methods for understanding the effects of implemented AI models on local data and clinical workflows. Recent research is advancing in assessing the value chain associated with implementing novel protocols within healthcare sectors [39]. In this regard, the utilization of AI methods that mix process workflow analysis with data-driven analysis is advancing explicable methods for understanding the intricate dynamics of how the integration of AI technologies impacts clinical workflows [40].

Respondents expressed that most countries need a strategy for enabling the secondary use of health data at scale to facilitate the development of AI models. Several countries are working towards improving data reuse infrastructures, but our respondents agreed that the first step should be to update the outdated IT infrastructures used for healthcare delivery. Otherwise, the information captured by the data reuse infrastructure will not be optimal. Regarding transnational initiatives such as EHDS, respondents reported that, in the short term, it is unlikely for EHDS to be used to perform research, given the differences in patient consent regulations across the EU.

Beyond validation, our findings were in line with previous work [11] in that the replicability of AI model evaluations is a principal issue that needs to be addressed. However, our respondents pointed out that current data reuse infrastructures do not allow cross-organizational studies

Table 2
A summarized comparison of established findings and novel insights emerging from this study.

Status of AI implementation
Established findings

- AI is believed to have the potential to revolutionize healthcare and clinical research.

Novel insights

- Most AI implementations are perceived as immature and need integration into the clinical workflow.

Perception about AI
Established findings

- Clinicians have diverse opinions on AI.

Novel insights

- Clinicians know the potential of AI and think it may contribute to making them work more efficiently.
- Programs for educating health workers and citizens on the potential and limitations of AI are needed.

Funding and resources
Established findings

- Many funding agencies are allocating funds for research in AI.
- Powerful Big Data infrastructures are needed to allow the training of large AI models.

Novel insights

- AI implementation and evaluation studies lack adequate financing.
- Hospital health information systems should be renewed before investing in large Big Data infrastructures.
- It is necessary to allocate time from the clinicians (including managers) who will be the users of the AI system so they act as champions of the AI implementation project.
- The long-term economic viability of home-grown systems requires that private vendors take ownership of it.

Evaluation and replicability of AI models
Established findings

- Explainability as the key issue for AI adoption in healthcare.

Novel insights

- Clinical validation supersedes AI explainability.
- Cross-organizational replicability emerges as an important requirement.

Regulation
Established findings

- Previously, we knew regulatory frameworks did not adequately address AI issues.

Novel insights

- New legislative efforts still fall short of addressing AI implementation issues in clinical settings, e.g., dealing with continuous learning by AI systems, allowing health data hubs to host curated datasets making them available for several projects, and unifying approval bodies to make data access approval workflows clearer and faster.

Support for implementers
Established findings

- Traditionally, regulations around health data have been firm but simple.

Novel insights

- Today, health data repositories and the regulatory environment around their establishment is a key issue for many implementers.
- Today, AI implementers need special legal training and upskilling to deal with complex ethical and legal issues related to AI in clinical settings.

Data access
Established findings

- Data access and interoperability are widely accepted as major challenges in AI.

Novel insights

- Many countries are establishing networks of interoperable data repositories, and nowadays attention is shifting towards the high quality of these data for AI and calls to educate the personnel that generate them.
- More open clinical datasets (e.g., medical images and clinical text) are needed.

Ethics and privacy
Established findings

- Ethical concerns have always been at the heart of health data.
- Previously, attitudes towards consenting to data reuse varied and it was difficult to implement.

Novel insights

- Our results show the same level of concern over ethical issues as has been raised in the literature.
- Implementing consent through emerging large-scale infrastructures, such as a European Health Data Space, is promising, but new strategies to deal with patient consent at scale are needed.

to replicate AI evaluations. This requires clinical organizations to perform a local evaluation each time a system is adopted in a new setting since no significant cross-organizational studies have been conducted to ensure the system is valid and robust in the context and population where it is deployed. This local evaluation leads to a significant hurdle regarding using healthcare workers already in short supply [1] to prepare, assess, and validate AI implementations.

Another finding not previously reported is the lack of innovation schemes to fund AI implementations. Other studies claimed that lack of funding is a primary barrier [33,41]. Our respondents agreed that AI research funding is generous, but finding funding for evaluation and implementation stages was particularly challenging. Deployment of an AI system in the clinical setting has to be funded with internal hospital resources. Organizations designing innovation funding schemes should consider and adapt to this issue; this applies to funding the implementation of other technologies [33].

Some countries have published general advice on AI systems acquisition [41]. However, our study reveals that more specific validation guidelines for AI systems are needed to lower the costs and risks of adopting AI systems in clinical settings. This is in line with the findings of Strohm et al., who reported on the need for more structured implementation processes [7,32]. Their effect on the workflow must be measured carefully for each context without disrupting healthcare workers [9].

While general training using as much data as possible is often desired by implementers to maximize the generalizability of their systems, local validation and, in many cases, re-training will be needed. Even if the system has been trained internationally, it will require local validation to ensure it performs well on data from local minorities. The transferability of models is reported to be highly problematic even within hospitals in the same municipality [33]. Funding schemes to organize more extensive validation clinical studies with a regional or national scope would help to decrease the costs and facilitate the adoption of AI systems.

4.2. Regulations

Some respondents desired more guidance on general topics, such as liability in the event of a failure of the AI system. However, these aspects require a case-by-case analysis and cannot be generalized to legislation since it is very context-dependent on the specific use of each AI model. For example, an AI used to classify patients with a high likelihood of colorectal cancer may have a much worse impact than an AI classifying hip fractures, which would only delay treatment, but not endanger the patient's life. Liability and attribution of negligence remain one of the

main concerns of clinicians [42].

Our study revealed that AI-related regulations are perceived as outdated when it comes to dealing with the challenges of AI implementation. This has previously been reported by Morrison [33]. Countries such as Norway have launched regulatory sandboxes to understand regulatory AI requirements better [43]. However, our interviewees did not perceive their usefulness when implementing AI systems in the clinical setting. Participants raised the issue of AI systems continuously learning online as EHR data becomes available. However, allowing continuous learning would require modifications in the legislation as reported elsewhere [19,33].

Other actions to help implementers with regulation compliance include establishing institutes to develop technological competence and regulations, such as the Danish Approval Technological Service [44]. Additionally, AI projects require collaboration with vendors from project inception to make them economically viable. Regulations should accommodate these collaborations, which sometimes conflict with procurement requirements currently oriented toward product acquisition rather than collaborative development.

4.3. Support for implementers

Our study elucidated several areas where implementers needed further support. Firstly, there is a need for actions to facilitate data access approval and data access itself. Examples of how it could be promoted are Findata and the French Health Data Hub. Countries with very restrictive legislation, such as Germany, are also advancing in improving data access by designing modular patient consents, which allow for a more generic consent for data use [45]. Secondly, actions to educate implementers in regulatory and ethical matters are needed. This could include standard networks to help researchers, AI vendors, and clinical professionals collaborate and become more knowledgeable on the applicable regulations [44,46,47]. At the EU level, this is also perceived as a need reflected in the Digital Europe Program and its upskills programs [48], as well as the European Digital Innovation Hubs. Thirdly, the area that, according to participants' opinions, requires better support is the current IT infrastructure used for healthcare delivery. Participants reported that most hospital IT equipment will end its economic life course in the upcoming years. As reported elsewhere [33], a better IT infrastructure for healthcare delivery is needed to improve efficiency and data quality. Only then will data reuse infrastructures be able to count on valuable data to enable AI research at scale.

4.4. Data access

Together with the regulatory framework, data access and interoperability are still the main barriers to developing AI models at scale [19]. Several countries have funded initiatives to build data reuse frameworks. In 2015, Germany launched medical informatics initiatives with the objective of building networks of hospitals standardizing information for research [49]. Finland and France have centralized data access requests and processing to facilitate data access for AI implementers and researchers [24,26]. Norway has also launched a new platform to centralize some data sets where researchers can request access [50]. According to our findings, health data hubs should help to centralize data access approval and reuse data cleaning efforts done in one project to benefit other projects and avoid duplication. In addition, data set management centralization is very much needed to improve data sets' discoverability and access. In this regard, a challenge yet to be overcome is the reuse of datasets that have been cleaned and normalized by researchers. Currently, most ethical approvals limit the use of a dataset to a narrow set of research questions and the lifespan of the research project, forcing researchers to delete the data after results are published or the project has finished. This means that the same dataset needs to be cleaned and normalized for other research studies. Our study suggests that this loss of resources could be alleviated if the appropriate legal provisions were made to allow health data hubs to act as trusted third parties where curated datasets are kept, making them Findable, Accessible, Interoperable and Reusable (FAIR) [51] (under the appropriate regulatory and access provisions). Recently, several projects have developed methods to make datasets in healthcare FAIR [52,53]. These methods can allow Health Data Hubs to expose data containers as machine actionable FAIR Digital Objects [54] which allow the automatic discovery and interoperability of the datasets using Linked Data Principles [55].

Although these infrastructures will help facilitate data access, multicenter data training requires high data quality with precise semantics. In this regard, respondents agreed on the need to measure the state of datasets based on factors such as accuracy, completeness, consistency, reliability, and whether they are up to date. Furthermore, it is imperative to ensure that administrative and clinical personnel are thoroughly educated about their impact on data quality. The precision and effectiveness of AI systems are unequivocally contingent upon the caliber of the input data. Failing to raise this awareness will negatively impact the performance of AI algorithms, ultimately eroding confidence in AI systems.

4.5. Ethics and privacy

While healthcare workers' view on AI varies [10], scientific literature and EU reports have reported concerns about AI aspects such as privacy, trust, accountability, responsibility, and bias [56]. Our results align with these studies, which recommend an optimistic approach with careful evaluation considering AI's ethical implications [56], carefully leveraging the ethical, legal, and social implications of AI in healthcare [12]. Regarding citizens' perceptions, previous work has reported that citizens knew about AI but were unaware of its specific health applications [57]. Our respondents perceived patients as unwilling to be treated by an algorithm. However, they explained that patients will not perceive the AI except for having more efficient clinicians if it is correctly implemented. This is in line with previous qualitative studies [33]. Hence, citizens are optimistic about AI acceptance, but they need more technology literacy to understand that the AI will not substitute the clinician. The significant variability in AI acceptance among clinicians and patients [32] should be reduced by appropriate education programs [33]. Tsopra et al. proposed the involvement of undergraduate medical students in clinical decision support system design to improve their digital literacy and knowledge of AI [58].

Regarding the secondary use of data, previous work has reported that the attitudes towards authorizing the use of data varied significantly depending on the intended use and goals. In Europe, EHDS will facilitate data sharing for several purposes. However, its success will depend on the trust of citizens and its perceived benefits since clinicians' and patients' acceptance of AI models varies among subpopulations [32]. Hence, large data reuse infrastructures such as EHDS should be carefully evaluated for cybersecurity risks to avoid harming trust. While the EU is advancing towards establishing secure infrastructures to increase resilience [59], the latest cyber-attacks demonstrate that even countries with a high level of preparedness, such as Spain and the US [60], are vulnerable to attacks exposing patient data [61,62].

Some studies have reported epistemic and normative concerns, such as algorithmic bias and unfair outcomes [63]. We found that, despite AI implementers having these concerns, they considered an AI's biased or discriminatory behavior as not directly attributable to the AI model. The AI models reflect the data used for their training, which, in turn, reflect the reality in the populations and organizations where these data were generated. Hence, if proper validation methods are used to detect discriminative behaviors, such concerns will not be a significant barrier for our respondents. Conversely, participants considered that analyzing the AI's undesired behaviors can be beneficial for detecting and consequently correcting discriminatory behaviors in healthcare organizations.

4.6. Other considerations

While clinicians are currently involved in the validation and implementation stage, we agree with previous work that clinicians' inclusion in the early stages of AI development [7,18] is desirable for considering the actual usefulness of the model. Otherwise, even though usability evaluations may be positive, clinicians may find AI useless for improving their work or even disruptive and harmful [17,32].

Our study reveals that AI will only provide a breakthrough with the proper ecosystem of regulations, public entities and professional support, citizens' education, and data access infrastructures. This must be considered by research and innovation funding agencies, which have overfunded algorithm development while downplaying data quality, clinical implementation, and clinical evaluation. Fortunately, this seems to be changing in national strategies [43].

Morrison [33] recommended that health trusts determine the areas that are most likely to benefit from AI and prioritize implementing them. In the short term, participants agreed with previous studies [28] on radiology being the most mature area to immediately benefit from AI. In the medium term, participants agreed with previous research that areas such as mental health and multimorbidity could benefit from AI [8]. As reported in previous work [33], participants agreed on the need to clarify the type of AI used when writing documents and guidelines about AI (e.g., machine learning vs. logic reasoning) since their algorithmic underpinning differs and other features should be evaluated. Our study identified, in agreement with previous work, that workforce shortages are a barrier to AI implementation [19]. Beyond availability, our participants shed light on the fact that the workforce must be managed in an interdisciplinary and intersectoral manner to allow collaborations among legal experts, AI specialists, healthcare workers, and organizations with different expertise. AI has a significant potential to help healthcare workers with tedious tasks, both clinical and administrative [8,42]. Local champions and multidisciplinary teams are needed to realize the promise of an AI that helps clinicians work more effectively [7], freeing some time for better patient communication and research [33]. However, more studies are needed to determine how to organize AI implementation teams to get the most out of the multidisciplinary and intersectoral organization.

Previous studies [16,64] mentioned the proper integration of AI in the clinical workflow as a critical success factor. A new finding of our study is our respondents' proposal to use the latest advances in process mining [65,66] for discovering and visualizing complex organizational workflows to determine in which parts of the workflow AI systems can be optimally embedded.

Fig. 1 summarizes the recommendations for successful AI implementation in clinical settings from our study. Recommendations for governments and regulators are marked with (G). Recommendations for local health organizations are marked with (L).

4.7. Limitations

The main limitation of the study is the imbalance of the sample. While the sample size is adequate, most of the respondents are based in Europe, and only two are in North and South America. We also lack representatives from Asian countries. Readers should be aware of these limitations since countries with other legislative frameworks may present different regulatory barriers.

A relevant topic found in the literature [19] is the need for appropriate governance frameworks at organizational and national levels to prioritize and drive AI implementations in the directions where it can be most helpful. Our participants did not cover this topic. Possible explanations for this can be our intentional selection of the interview

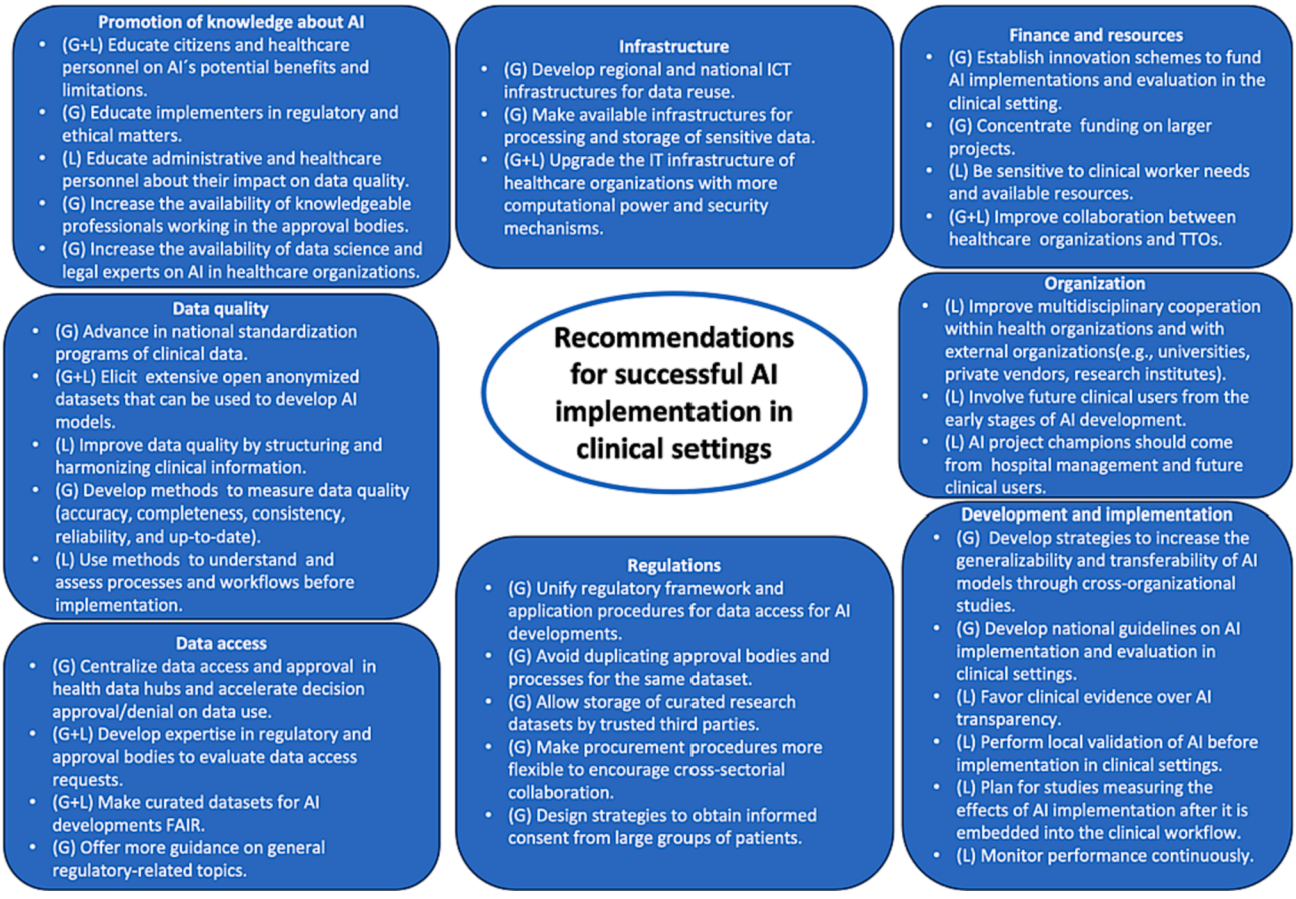


Fig. 1. Recommendations for successful AI implementation in clinical settings based on our study.

participants close to the implementation level in the clinical setting. This is a limitation of the study. Future works may consider using deductive frameworks with predefined constructs such as the Consolidated Framework for Implementation Research (CFIR) for elucidating other relevant aspects that did not arise in our study such as AI governance frameworks.

5. Conclusion

While the literature on AI adoption is extensive, direct experiences and recommendations from real implementers are difficult to find. Our study provides insights into implementers' main requirements for facilitating AI adoption in the clinical setting. The main findings of our study include 1) the lesser importance of AI XAI in favor of proper clinical validation studies, 2) the need to actively involve clinical practitioners, and not only clinical researchers, in the inception of AI research projects, 3) the need for better information structures to manage data access and the ethical approval of AI projects, 4) the need for better support for regulatory compliance, 5) the need to increase both clinicians' and citizens' literacy as respects the benefits and limitations of AI, and 6) the need for better funding schemes to support the implementation, embedding, and validation of AI in the clinical workflow beyond pilots. Finally, there is a unanimous vision about AI among the participants described by Miller [15] as "augmenting clinicians' intelligence" and by Sheth et al. as "prosthetics to augment human cognition" [14,67]. Respondents are optimistic about the use of AI as a tool to help clinicians work more effectively and partially alleviate the increasing work overload they bear.

Declaration of Generative AI and AI assisted technologies in the writing process

No generative AI was used for writing this paper.

Author contribution

All authors contributed in the inception of the study. LMR, MATH, PD, AM, TO, MT designed the study.TO and AM performed the recruitment of participants and managed the interviews. LMR, MATH, PD, AM, TO, and MT performed the interviews and transcribed them. LMR, MATH, and PD coded and analyzed the interview transcripts. LMR, MATH, PD, AM, KD, TC, CFL, JMG, and MT drafted the manuscript and its final version. All authors contributed to the article and approved the submitted version.

Summary table

What was already known?
- Significant funding has been invested in AI for clinical uses.
- Many AI projects stall at the prototype level.
- Translating AI research results into operational clinical systems has proved challenging.

What this study added to our knowledge?
- Data access regulations and procedures need to improve.
- Implementers request to favor schemes for AI clinical validation over clinical AI research.
- Clinical users deem clinical validation more critical than AI explainability.

CRediT authorship contribution statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Interview guideline

1. In your experience, what is the status of AI implementation in general?
2. Did your organization have any experience in the adoption/implementation of AI systems?
3. How about the regulatory framework? Nowadays there is a lot of uncertainty in this regard. Was it clear for you if the AI needs approval or certification? Do you perceive this procedure as a barrier that poses a risk for the success of the intervention?
4. Was the regulatory framework clear and did you feel knowledgeable about where to ask for support with regards to regulatory compliance?
5. Can you tell us about the organization of the project (planning, implementation, testing)? Who was championing and promoting the project (hospital management, research groups)?
6. What are the licensing structures, implementation and licensing costs, IP rights, and data ownership?
7. What sources of evidence are supported by your AI system? Directly dictated by clinicians? Was the clinical guideline encoded as an AI? Others?
8. Do you perform data quality pre-processing (cleaning, structuring etc.) before applying AI? Can you explain the procedure you followed to improve the data quality?
9. Is the new AI system integrated into the clinical workflow? (e.g., embedded in the EHR)
10. How was the new system evaluated? (Evaluation of model, software testing, near-life testing, and post-implementation)
11. Do you think your AI system is generalizable to different populations? Can it be used by another organization/country (interoperability of the model)?
12. Is there in-house support for the system or is it supported by an external vendor?

13. Currently, there is concern about algorithms discriminating against some population subgroups. Do you perceive a risk of discrimination arising from your AI system?
14. Did you detect barriers or challenges related to the lack of transparency of the AI model (explain this applies to black boxes that do not provide weight/significances of variables)?
15. How was the education/training plan structured? Who received training?
16. Were financial resources sufficient for the implementation of the project?
17. Can you think of other areas that would benefit from AI that have not been considered so far (within healthcare)?
18. What was the perception of AI by clinicians? And by patients?
19. In your opinion, what are the important barriers and facilitators for successful AI implementation?
20. If you could choose 3 actions to be undertaken at a national, regional, or local level to facilitate the use of AI in healthcare, which would you choose?

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