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Implementation of artificial intelligence in Norwegian healthcare: The road to broad adoption

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Summary
Professionally designed and deployed artificial intelligence may provide many advantages to healthcare by improving efficiency and quality of medical care. We conducted a comprehensive study on the AI implementation in healthcare. The report provides an extensive description of the implementation process: from the planning phase until AI is deployed in a clinical process. We also propose the coordinated activities required for sustainable AI adoption in healthcare.

Keywords
Artificial intelligence, implementation, healthcare, adoption

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1 Executive summary

The development of artificial intelligence (AI) applications for the healthcare industry has seen a rapidly growing interest. Due to AI's potential benefits for patients, healthcare professionals, and Norwegian society in general, there is a great deal of optimism for its usage in healthcare. However, AI solutions that are not professionally designed and implemented might be unproductive for healthcare practitioners and can pose risks to safety, privacy, and equality.

This report investigates the barriers and facilitators for AI implementation in Norwegian healthcare based on empirical data from national and international AI implementation initiatives. We have focused on the implementations applying data-driven techniques, such as machine learning and computational statistics. The study has been divided into two phases. First, we conducted a literature review of recent AI implementations in healthcare settings by examining the latest scientific articles. Then, we used the literature review results to produce a set of interview questions to learn about the challenges of implementing AI in healthcare in Norway and other countries and to investigate what needs to be done to solve those problems by looking at first-hand experiences. To accomplish this, we interviewed a selected group of professionals with proven expertise in implementing AI in healthcare settings. With a rich ecosystem of researchers, small and medium-sized enterprises (SMEs), and AI professionals, Norway provides an ideal ground for developing AI-based healthcare solutions. However, AI implementation in healthcare remains limited, and most health-related AI solutions exist as research prototypes. Several actions must, therefore, be taken for the widespread adoption of AI in the Norwegian healthcare settings.

If an AI system is intended for diagnosing, preventing, monitoring, treating, or alleviating diseases, injuries, or disabilities, it is classified as medical device software under the EU regulation for medical devices (MDR). For medical devices, there is a set of requirements to be utilized in Norway. Among others, they must have a CE mark which indicates the system is compliant with the MDR and meets specific standards of performance, quality, safety, and efficacy. It is important to understand that a CE mark does not guarantee the system will properly work on the chosen patient population, nor does it say whether the data the system has been trained on has been ethically collected.

Trustworthy AI is 1) lawful, i.e., complying with all existing rules and regulations, 2) ethical, i.e., assuring adherence to ethical principles and values, and 3) robust, both from a technological and social standpoint. This calls for increased patient and healthcare professionals' knowledge of AI, focus on clinical needs and workflows when developing or purchasing AI solutions, enhanced interoperability and explainability, and involvement of healthcare professionals in the implementation process. There needs to be more access to healthcare experts and data scientists dedicated to work with AI in healthcare organizations. Cooperation across sectors and disciplines can enhance practical knowledge of the implementation process. Regulations pertaining to AI must be adapted to allow for data sharing between healthcare organizations, simplify data access procedures, and implementers should get guidance and assistance on the regulation compliance. AI solutions require standardized implementation and procurement procedures. Furthermore, there is a need for upgrade of the ICT (Information and Communication Technology) infrastructure both on a local and national level.

Our hope is that this comprehensive study on the AI implementation process will be a valuable resource for future evidence-informed policy- and decision-making and continuous dialogue about the topic.

2 Introduction

Within the healthcare industry, the focus on artificial intelligence has accelerated. AI has the potential to improve patient outcomes, reduce the workload of healthcare professionals, and benefit Norwegian society in general. However, without being professionally designed and implemented, it increases the risks to patient safety, privacy, security, and equality. In fact, in healthcare, AI implementation is still limited. Most health-related AI systems today are on the development level. In this project, we have investigated the current state of health-related data-driven AI implementations using machine learning and computational statistics both in a national and international contexts.

2.1 Project objectives and requirements

The steering group of the Norwegian Centre for E-health Research (NSE) has requested a knowledge summary on the topic of "artificial intelligence and implementation" as a follow-up to the knowledge summary on health analytics from 2018 (1).

The project has the following objectives:

- *Conduct a systematic knowledge review of how AI is implemented in healthcare around the world*
- *Characterize the barriers and facilitators influencing the AI implementation in the healthcare setting*
- *Provide recommendations for adoption of AI implementation in Norwegian healthcare*

The project has an impact for the wide range of actors involved in the AI implementation process from initiation to deployment: the authorities, healthcare providers, academia, vendors, and patients.

The following requirements have been established for the project:

- *The definition of AI differs between publications. The project should contribute to establishing consensus on what is meant by AI in health.*
- *The project should focus on implementations based on data-driven methods affecting more disruptively the field of AI in health.*
- *A distinction should be made between the development of AI solutions and the actual process of implementing such solutions.*
- *The study should identify public and private actors in healthcare that have achieved implementation.*
- *The project should study the requirements for CE marking.*
- *The project should study AI implementations in the national and international arena and describe as well as possible the entire process from the planning phase to after-implementation with extraction of learning points.*
- *There should also be a systematic overview of all prerequisites (certification, ICT infrastructure, etc.) that must be available before an AI solution can be implemented.*

2.2 What do we understand by AI?

Artificial intelligence *refers to computer programs that, with the aid of statistical methods and machine learning algorithms, can process large amounts of data to identify patterns, interpret those patterns, and then make predictions for new data entering the system.*

The first work using the term AI was developed in the 1950s by John McCarthy. He described AI as "the science and engineering of making intelligent machines" (2, 3). Machine learning (ML), computer vision (CV), robotics, and the use of intelligent agents (IA) are components of the broader field of artificial intelligence (AI) (4). Knowledge representation and logic have significantly contributed to information organization in the biomedical domain by making it feasible to keep enormous knowledge bases and ontologies, like SNOMED-CT, up to date. ML is distinct from other subfields in AI. As opposed to logic, ML is naturally suited to handling uncertainty and deriving models from data. ML contains methods capable of learning from representative data sets of the modeled domain (4, 5). As a result, the algorithms that explore data to generate an ML model are referred to as data driven. For example, ML can be used to classify health outcomes (like placing pathology images into risk classes of cancerous tissue lesions) (6) or predict a continuous outcome (such as determining how much oxygen is in the blood) (7).

The definition of artificial intelligence varies between publications. In this report, we associate AI with machine learning algorithms that employ data-driven methodologies. We use the term "artificial intelligence" to describe computer programs able to process large volumes of data using computational statistics and machine learning techniques, identify patterns, interpret them, and make predictions for new data entering the system.

2.3 What do we mean by AI implementation?

Implementation *implies deployment of the solution into a healthcare system when it becomes a part of a clinical process.*

We distinguish between developing a solution and implementing it in clinical situations. Development implies constructing a solution based on the given criteria, which includes creating a model, training it, and testing it. We define implementation as the integration of a solution into a healthcare system when it becomes a part of a clinical process.

2.4 Areas for AI use in healthcare

2.4.1 What area is mature for AI in healthcare?

The most developed area in healthcare in terms of AI use is medical imaging. There are several reasons for that.

- *Medical image processing does not require performing text analysis from EHR which is always a difficult and lengthy process because of language mixtures, typos, lack of standards, and a need for annotations by domain experts.*
- *There is an international standard for medical images, DICOM® (Digital Imaging and Communications in Medicine) (8). It defines the exchange formats for medical images with the data and quality necessary for clinical use.*
- *Usually medical images require little pre-processing: the raw material gives higher quality of analysis.*
- *Numerous medical images generated on medical examinations are available for analysis.*

There are numerous CE marked AI solutions in radiology and pathology. Here are some examples:

- *AI for radiology (9)*
- *Sectra Amplifier Marketplace for radiology (10)*
- *Sectra Amplifier Marketplace for pathology (11)*
- *Visiopharm® APP Center (12)*
- *Aiforia® Clinical Suite Viewer (13)*

There are also available CE marked AI solutions delivered together with MRI and CT scans, such as those provided by Philips (14) and Siemens (15).

2.4.2 Other areas in healthcare where AI can be beneficial

In the interviews, the following areas have been suggested as the ones that would benefit from AI:

Screening and triaging

- *Pulmonary embolism detection, when having a CT thorax: if it is not prioritized, a radiologist has a chance to look at it*
- *Suicide detection*
- *Screening by AI in night shifts*
- *Fraction detection: a technician can detect whether there is a fracture to send the patient home if it was not the case; then the radiologist might look at the images the next day.*
- *Discovery of critical patient information, such as allergies related to drugs, environment, or food, before preparing him/her for surgery*
- *Triage of the patients for their prioritization after disasters and huge accidents*

Support for complex treatments

- *Consequent cancer control: check of the examination and its comparison to previous ones, measure the metastasis, mark nodules and its visualization to radiologists.*
- *Cancer treatment based on cancer types (tumor morphology): what would be the treatment planning options and the best outcome for a kind of cancer.*
- *Integrated diagnostics, by AI tools helping cross-disciplinary decision making to work on all data sets including radiology, pathology, genomics, and other omics at once.*

Process discovery and optimization

- *Optimization of the planning of operations in healthcare organizations*
- *Readmission prediction*
- *Understanding the workflow in ICU*
- *Remote patient monitoring*
- *Improvement of patient pathways and health service accessibility*
- *Secretary work (appointments and similar)*

- *Allocating resources in terms of personnel, equipment, and tests*
- *Algorithmic control of infusion pumps and treatments*

Decision support for diagnosis

- *Psychiatry/ mental health*
- *Illness recognition*
- *Data-driven healthcare in terms of EHR systems*
- *Estimation of the patient's outcome and suggestion of different treatment options*

2.5 Approach

The project work on this report has been organized in two main phases.

2.5.1 Phase 1: Literature review

For identifying barriers and facilitators for AI implementation in healthcare sector, we have conducted a literature review by searching scientific publications related to recent AI implementations in clinical settings. The article "Artificial intelligence implementation in healthcare: A theory-based scoping review of barriers and facilitators" is submitted to a scientific journal. The summary of the paper is provided further in the text (see *Summary of the scoping review*).

2.5.2 Phase 2: Interviews with participants of AI implementation projects

The goal of this phase has been to explore national and international AI healthcare projects to deepen the barriers and facilitators identified in the literature review. We have exploited the results from Phase 1 to build an interview guide (see *Interview guide*). For finding the interviewees relevant for the topic, we have used the list of members of the Norwegian Network for AI in Healthcare (Kunstig intelligens i norsk helsetjeneste (KIN) in Norwegian) (16), the contacts from the previous projects at NSE, in addition to the Google search results on "Artificial intelligence in healthcare" in various languages. Unfortunately, we have not received response from all the potentially valuable projects, among others from Iceland, Germany, Italy, the USA, and the Netherlands. In total, we have conducted forty-six interviews with the representatives of private and public organizations, such as vendors for EHR and clinical systems, secondary healthcare providers, management of healthcare organizations, universities, and national authorities from the following countries: 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) (see Figure 1). AI implementations in the primary healthcare sector have not been included in the study. In 2021, the Norwegian Directorate of Health together with the Norwegian Directorate of E-health published a report covering the status, opportunities and needs of AI in primary health and care services (17). The findings from that report correlate with the outcomes of the interviews.

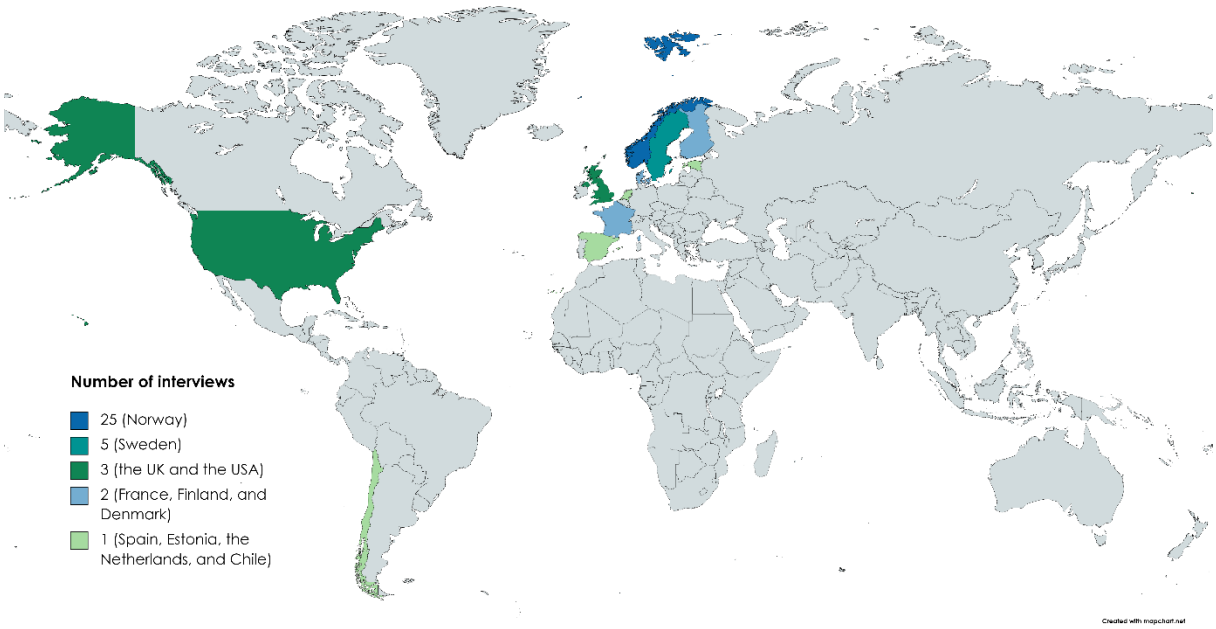

Figure 1: The interview map

The interviewees have shared their understanding of the status for AI as well as their experience of implementing AI solutions in healthcare settings. While investigating a specific topic within AI implementation, we have tailored the interview questions when they have not been completely relevant for the respondent. This includes the interviews with lawyers of one project, a technology transfer office, and the Norwegian center for clinical artificial intelligence. As a result, we have identified the needs and facilitating factors for implementation and broader adoption of AI in the healthcare sector. We are currently working on a qualitative article reflecting the findings from the interviews.

We have mapped stories of AI implementation in the healthcare settings in the international scope to determine requirements to accomplish in the Norwegian realm. We have studied relevant reports about AI implementation in healthcare and national strategies for AI in some EU countries, as well as the UK and the USA, to understand the trends and plans for further development of AI. We have drawn an action plan for the Norwegian authorities to facilitate AI implementation in healthcare organizations. We have illustrated the process of knowledge gathering for the action plan in Figure 2.

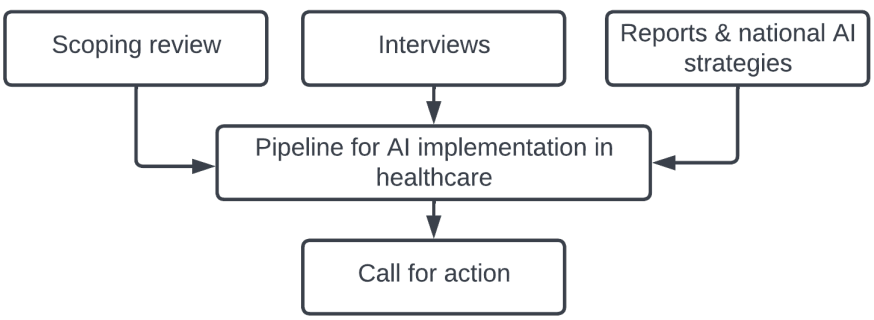

Figure 2: Investigation process of the actions required for broad adoption of AI implementations

2.6 Acknowledgement

We would like to thank all the interviewees who contributed to the project:

- *The BigMed project (https://bigmed.no/)*
- *The DoMore! project (https://www.domore.no/)*
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- *University of Oslo (https://www.uio.no/)*
- *Artificial Intelligence Research Centre (CAIR) (https://cair.uia.no/) and University of Agder (https://www.uia.no/en)*
- *Institute for Cancer Genetics and Informatics (https://www.icgi.net/) at Oslo University Hospital (https://oslo-universitetssykehus.no/)*
- *Sykehuspartner (https://sykehuspartner.no/)*
- *Sectra (https://sectra.com/)*
- *Helseplattformen (https://helseplattformen.no/)*
- *University Hospital of North Norway HF (https://unn.no/)*
- *DIPS (http://www.dips.com/)*
- *Ålesund Hospital (https://helse-mr.no/steder/alesund-sjukehus) at Helse Møre og Romsdal HF*
- *Deepinsight (https://www.deepinsight.io/en/)*
- *The Southern and Eastern Norway Regional Health Authority (https://helse-sorost.no/)*
- *Norinnova (https://norinnova.no/en/)*
- *The Norwegian Directorate of Health (https://www.helsedirektoratet.no/)*
- *The Norwegian Centre for Clinical Artificial Intelligence (https://www.spki.no/en/)*
- *The Danish Centre of Clinical Artificial Intelligence (CAI-X) (https://cai-x.com/)*
- *Radiological Artificial Intelligence Testcenter (RAIT) (https://www.rait.dk/)*
- *The Finnish Center for Artificial Intelligence (FCAI) (https://fcai.fi/) and Helsinki University Hospital (HUS) (https://www.hus.fi/en)*
- *Aiforia Technologies (https://www.aiforia.com/)*
- *Danderyd Hospital (https://www.ds.se/)*
- *Gävle Hospital (https://www.regiongavleborg.se/halsa-och-vard/sjukhus/)*
- *The Swedish National Board of Health and Wellbeing (https://www.government.se/government-agencies/national-board-of-health-and-welfare--socialstyrelsen/)*
- *Analytic Imaging Diagnostics Arena (AIDA) (https://liu.se/en/research/aida) at Linköping University*
- *Skåne University Hospital (https://vard.skane.se/skanes-universitetssjukhus-sus/)*
- *University of Tartu (https://ut.ee/en)*

- *Guy's and St Thomas' NHS Foundation Trust (https://www.guysandstthomas.nhs.uk/)*
- *the NHS Artificial Intelligence Laboratory (NHS AI Lab) (https://transform.england.nhs.uk/ai-lab/)*
- *AI Strategy at NHS Transformation (https://transform.england.nhs.uk/)*
- *Institute of Information and Communication Technologies (ITACA) of the Polytechnic University of Valencia (http://www.itaca.upv.es/)*
- *Université Paris Cité (https://u-paris.fr/en/universite-de-paris/)*
- *OWKIN (https://owkin.com/)*
- *University of Twente (https://www.utwente.nl/en/)*
- *Pontificia Universidad Católica de Chile (https://www.uc.cl/en)*
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- *IBM Thomas J. Watson Research Center (https://research.ibm.com/labs/watson/), and*
- *New York University (https://www.nyu.edu/).*

Your experience, knowledge, and willingness to share has given us the ground for the analyses we have performed and influenced the recommendations for the broad adoption of AI in the Norwegian healthcare sector we have produced.

2.7 Organization of the report

The report is organized as follows. In Chapter 3, we give background knowledge about AI as medical equipment: existing risk classes, requirements for medical equipment in Norway, CE-marking process, applicable regulations, and authorities responsible for those regulations and guidance about them, alternative ways to obtain AI solutions, and potential licensing models. In Chapter 4, we elaborate our findings from the scoping review about AI implementations and the performed interviews, describing the status of AI in healthcare emphasizing the hinders of its broad adoption in a clinic. In the next chapter, we describe the process needed for AI to be properly implemented in clinical settings based on the interviews, relevant reports, and national AI strategies. Finally, we provide the action points required for broad adoption of AI implementations in Norwegian healthcare.

3 Background

3.1 AI as a medical device

Healthcare providers can produce medical equipment for internal use. Further in the text, we provide background information on the regulative framework for development of AI systems in healthcare.

3.1.1 Medical device software

Software that is intended to be used, alone or in combination with other equipment, for the purpose of diagnosing, preventing, monitoring, treating or alleviation of a disease, injury, or disability, is considered medical device software (MDSW) (18) and falls under the EU regulation for medical devices (MDR) (19) or in vitro diagnostic medical devices (IVDR) (20). This includes software with AI algorithms. The MDR applies from 26 May 2021, and IVDR applies from 26 May 2022. Further in the text, only the MDR (but not IVDR) is referenced to.

3.1.2 Risk classes for medical devices

According to the MDR, medical equipment is divided into four risk classes which go from low risk (class I) to high risk (class III) (21). The risk class determines the procedure to be followed before the medical device can be placed on the market. There is a guidance for risk class definition under the MDR (22). Rule 11 states the following: "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- *Death or an irreversible deterioration of a person's state of health, in which case it is in class III,*
- *A serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb."

When classifying MDSW, there are some rules to remember (23):

- *MDSW that controls equipment or affects the use of medical equipment must belong to the same class as the equipment.*
- *MDSW that is independent of other equipment, must be classified separately.*
- *If MDSW is intended for several areas of use, it must be classified based on the use that is most risky.*

Hereby, an MDSW with AI will belong to a class IIa, IIb or III, which implies moderate, moderate to high, and high risk associated with use of the equipment, respectively. This requires conformity assessment by notified body to assure that a medical device performs in accordance with the manufacturer's intended purpose and is safe to use. This risk classification must be used by AI implementers to know the measures to be taken to mitigate the risks.

Additionally, there is a proposal for a regulation on artificial intelligence announced by the European Commission in April 2021 (24). This regulation aims for harmonizing AI systems by introducing four levels of risk: unacceptable, high, limited, and minimal. It is meant to be used by end users and build trust of Europeans towards the AI.

3.1.3 Quality and risk management of medical devices

Regardless of whether it is an in-house developed MDSW or a commercial one, production and use of the MDSW must follow suitable quality and risk management systems in accordance with the MDR Annex I (25) and Articles 5 and 10. The vendor (whether it is a healthcare organization or a manufacturer) must have documentation that describes the production facility, the production process, intended purpose of the device, design, and performance. It must be ensured that the equipment is produced in line with this documentation. The documentation must be sufficiently detailed for the Norwegian Medicines Agency to assess whether the general safety and performance requirements have been met. For this purpose, the following standards for documentation can be used: EN ISO 13485 “Medical equipment - Systems for quality management - Requirements to meet regulations” (26) and EN ISO 14971 “Medical devices - Use of risk management for medical devices” (27). If a healthcare organization decides to internally produce a medical device, it must also, among other requirements, justify that the medical device meets specific needs for a patient group that cannot be met by similar equipment available on the market. The Norwegian Medicines Agency might request such information. There are also requirements for the vendor to publish Periodic Safety Update Reports (PSUR) and monitor post-market surveillance of the medical device (the MDR Articles 83-86 and the MDR Annex III (28)). For the class IIa, PSUR should be updated at least every second year, and for the classes IIb and III, it should be updated yearly. This should be a part of the quality management system. To guarantee the safe use of the medical device by identifying and implementing preventive and corrective measures, the data on quality, safety, and performance of the device should be collected throughout its lifetime.

3.1.4 CE marking of medical devices

The main rule for medical devices on the EU/EEA market is to be assessed for conformity and CE marked.

The basic process of obtaining a CE mark has the following steps (30):

- *Determine whether your system meets the definition of a medical device (MDSW) according to the MDR.*
- *Determine the risk class of your MDSW.*
- *If your system is high-risk class III device, prepare a CE Marking Technical File or a Design Dossier which a comprehensive description of the system that includes detailed information about the design, function, composition, use, claims, and clinical evaluation.*
- *Implement a Quality Management System (QMS) using ISO 13485 standard.*
- *Prepare a Clinical Evaluation Report (CER) according to MDR. CER contains the results of the clinical evaluation of your device that involves the assessment and analysis of clinical data used in a medical device to verify the clinical safety and performance of the device.*
- *Have your QMS and Technical File/Design Dossier audited by a notified body.*
- *Obtain CE Marking and ISO 13485 certificates from a notified body.*
- *Prepare a declaration of conformity, a document which confirms that your MDSW complies with the MDR.*

A CE mark indicates that the product complies with the MDR and meets specific standards of performance, quality, safety, and efficacy. It does not assure whether the data the system has been trained on has been ethically collected. It neither guarantees the system will work properly on a given patient population.

The Norwegian Medicines Agency, which is the supervisory authority for medical devices in Norway, can grant exemptions from conformity assessment for medical devices justified by public health considerations or patients' safety and health (the MDR Article 59) (31). In addition to this exemption, medical devices under the following conditions do not require a CE mark (32): 1) equipment under clinical trials, 2) in-house medical device (an exemption described in the MDR Article 5(5)) with a prerequisite that the solution will not be transferred to any other organization in addition to justified absence of a similar CE marked device on the market, and 3) medical equipment produced for an individual patient on a written request from a healthcare professional (see Figure 3).

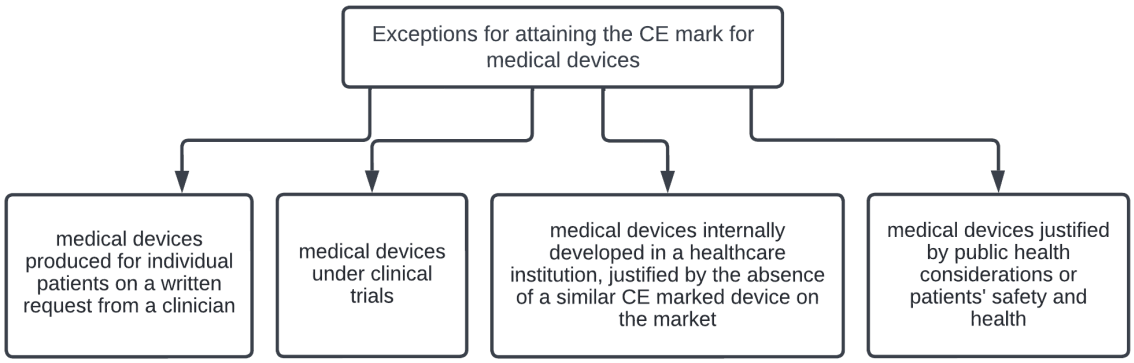

Figure 3: Exceptions for CE marking

3.1.5 Requirements for medical devices in Norway

In accordance with the MDR, for a medical device to be marketed in Norway, there is a list of requirements to be met (33):

- *Conduct a conformity assessment by a notified body*
- *Prepare a declaration of conformity*
- *Assign the device a CE mark*
- *Assign the device a UDI code and submit it to the European databank for medical devices (EUDAMED) (34)*
- *Send information about the manufacturer, the authorized representative, and the importer to EUDAMED*
- *Create the label and instructions for use following national language requirements*

3.2 Regulations applicable for development of AI solutions

The Norwegian Directorate of Health has created the Circular on the regulations for development of AI within research (including health research), development and use of clinical decision support tools and quality improvement (35). It contains information on different project types working with AI in healthcare and applicable regulations for each project type.

To sum up the content of the Circular, all types of AI projects must follow the Research Ethics Act (forskningsetikkloven) (36), the Personal Data Act (personopplysningsloven) (37), and the General Data Protection Regulation (GDPR) (38) while using personal and health data for the algorithm training. Further, depending on the project type, the following regulations can be relevant:

- *The Health Research Act (helseforskningsloven (39)) (§2, for medical and healthcare research on people, human biological material, or health information; §4a, for medical and health-related research activities that are carried out using scientific methodology to acquire new knowledge about health and disease; §33, a need for a prior approval from the Regional Committee for Medical and Health Research Ethics (REK))*
- *The Health Personnel Act (helsepersonelloven (40)) (§29, an exemption from the duty of confidentiality for making available information from patient records and other treatment-oriented health registers; §26, an exemption from the duty of confidentiality for research projects on AI for internal control and quality assurance)*
- *The Health Register Act (helseregisterloven (41)) (§19a, a consent from individuals; §19e, an exemption from the duty of confidentiality for making available information from the health registers)*
- *The Patient Records Act (pasientjournalloven (42)) (§22, information security of patient data)*
- *MDR or IVDR*
- *Regulation on the handling of medical equipment (forskrift om håndtering av medisinsk utstyr (99)) (§7, acquisition of medical equipment)*

For research projects, the authority to make decisions about a dispensation of duty of confidentiality is delegated to the Regional Committee for Medical and Health Research Ethics. The AI projects using anonymous or synthetic data do not require prior approval from REK or an application for a dispensation from the duty of confidentiality. For the development and use of clinical decision support tools and quality improvement projects, it is the Directorate of Health that takes such decisions.

For purchased AI solutions in healthcare, the MDR and IVDR together with the Regulation on the handling of medical equipment are applicable. For obtaining the data for validation of an AI system, the Health Register Act and the Patients Records Act are essential.

3.3 Authorities' responsibility for regulations

Different authorities in Norway are responsible for the different regulations, including guidance on those regulations (43).

The Norwegian Medicines Agency administers the product regulations for medical devices (including MDSW) and provides regulatory guidance on the MDR and IVDR in addition to § 7 of the Regulation on the handling of medical equipment, which must be followed when acquiring AI systems.

The Norwegian Directorate of Health is responsible for the Health Personnel Act, the Health Register Act, and the Patient Records Act. They can also grant a dispensation from the duty of confidentiality for the development and use of clinical decision support tools and quality improvement. It is possible for the projects working with AI in the healthcare to request guidance about regulations from the national coordination project "Better use of Artificial Intelligence" (44). To do that, the projects should follow the process described at Process for resolving legal issues (45).

The Norwegian Directorate for e-Health is responsible for the Regulation on standards and national e-health solutions (46), the information security in accordance with the Patient Records Act §22 (42), and parts of the Patient Records Regulations (pasientjournalforskriften) (47).

The Norwegian Directorate of Health in collaboration with *the Norwegian Directorate for e-Health, the Norwegian Medicines Agency and the Norwegian Health Inspectorate* have created an

information web page with all basic information needed while developing or acquiring AI solutions in healthcare (48).

The Norwegian Data Protection Authority has a regulatory sandbox for solutions with AI that use personal data (49). It is not limited only to the healthcare sector. The goal is to help projects comply with the regulations and develop privacy-preserving solutions under the supervision of the authorities. At the same time, the authorities gain understanding of innovative solutions and identify risks and issues.

From autumn 2022, it is also possible for AI projects to request interagency guidance about applicable regulations (50). On these meetings, the Directorate of Health, the Directorate for e-Health, the Norwegian Medicines Agency, and the Norwegian Health Authority with lawyers are present. Other authorities can also be invited. Such meetings help both sides of the participants. The projects get better understanding and mutual interpretation of the regulations, and the authorities can observe where the guidance and clarification of the regulations are needed for a broader audience. This measure is an appropriate response to the signals we have received from several interviewees.

3.4 Ways to obtain AI solutions in healthcare organizations

According to the interviews, there exist three alternative ways to get an AI solution in the healthcare service.

1. A research project in a healthcare organization with local clinical and IT enthusiasts ***for a certain clinical need.*** The approach has the following advantages:

- *The solution will be tailored to the identified need.*
- *The solution can be easily adapted and improved through testing, validation, and feedback from the healthcare professionals and patients.*
- *Healthcare professionals are motivated to contribute or even initiators of the project.*
- *The solution might be easier embedded to the clinical workflow since healthcare professionals are positive to and trust the solutions in development of which they have been involved themselves.*
- *There is a potential to collaborate with different research groups and universities.*
- *It is relatively easy to obtain financing for research projects from Regional Health Trusts or the Norwegian Research Council.*
- *It provides good control over the entire value chain of the solution including the data used for its development and testing.*
- *All IP rights (both the software and the data used for training) belong to the healthcare organization.*

However, there are disadvantages as well:

- *It takes several years to go from the idea to a research pilot and finally to a ready MDSW in clinical use.*
- *There are no funding calls for implementation of the solution.*
- *It requires extensive involvement of healthcare professionals in the implementation process despite their limited capacity.*

- *It requires IT competence for development, validation, implementation, and maintenance of the solution.*
- *It requires advanced infrastructure for development and further maintenance of the solution which can be expensive.*
- *It requires in-depth knowledge of several regulations: among others, about patients' data privacy preserving (with applications to REK and the Norwegian Data Protection Authority) and CE marking of the solution (with application to the Norwegian Medicines Agency).*
- *CE marking is an expensive procedure, and healthcare organizations might find it difficult to allocate funding for transitioning a research pilot into a CE marked product. They might need a vendor that is willing to make the investment.*
- *The healthcare organization is responsible for the quality of the solution and its compliance with the relevant requirements for safety and performance, including provision of the necessary documentation to the notified body.*

2. Cooperation between a healthcare provider and a private IT company. There are many advantages to this approach.

- *The solution will be tailored to the identified need.*
- *Healthcare professionals are involved in the process and motivated to contribute.*
- *The solution might be easier embedded to the clinical workflow since healthcare professionals are positive to and trust the solutions when they have been involved in their development.*
- *It requires less human and time resources from healthcare providers.*
- *The healthcare organization does not need to deal with the rules and regulation issues around CE marking of AI solutions.*
- *It allows the vendor to use data from the clinical setting where the AI model will be used.*
- *The healthcare organization can negotiate lower license fees with the vendor in exchange for their help and data availability for the solution development.*
- *The vendor is responsible for CE marking process.*

There are also some disadvantages.

- *It may require own funding from a healthcare organization for outsourcing.*
- *The representativity of the data set may not always be sufficient to guarantee the correct performance of the AI model in the new setting.*
- *It requires involvement of healthcare professionals in the implementation process which can be an issue in the case of the lack capacity of healthcare professionals.*
- *Some regulations do not allow the same vendor that participates in a product evaluation to be awarded the contract to avoid giving it a competitive advantage.*
- *The vendor needs to ensure their income pace while the product becomes CE marked.*
- *Employees of the healthcare organization have access to patient data but not the developers from the IT company.*

3. Acquiring a commercial CE marked AI solution. There are several advantages to this approach.

- *No need for local IT competence for development of the solution.*
- *The vendor takes responsibility for maintenance and user support of the solution.*
- *Healthcare professionals can continue with their primary job.*
- *The vendor is responsible for the solution's quality and its compliance with the requirements for safety and performance.*

Simultaneously, this approach brings several issues to be considered.

- *The solution is not tailored to a clinical need of a certain healthcare organization, and it may be difficult to embed it to the clinical workflow unless the AI solution vendor is the same as the EHR/clinical system vendor.*
- *Procurement process requires cross-disciplinary competence, which is a combination of juridical, IT, economical, and clinical expertise, to choose the right solution.*
- *It requires verification of the solution.*
- *It requires validation and testing of the solution on local health data before the solution can be taken in clinical use.*
- *It can be expensive: it includes both one-time costs for purchasing the solution and further licensing costs.*
- *Shelf CE marked AI products are available only for medical image analysis (radiology and pathology).*

Obviously, each alternative of obtaining an AI solution has both advantages and disadvantages. A healthcare provider can decide which way to take depending on available resources and competences. However, from the interviews, we see the AI implementations that are successfully deployed in a clinical workflow and beneficially utilized employ a "hybrid" approach: a cooperation between a healthcare provider and a vendor.

3.5 Licensing models

Among the interview respondents, there have been the ones driving in-house development, the ones developing AI solutions in cooperation with vendors, the ones using or purchasing the commercial AI products, and the ones using the AI solutions embedded into the medical equipment, such as CT scans.

Intellectual property (IP) rights are negotiated ad-hoc in each project. Among the projects participated in the interviews, the following licensing alternatives have been applied.

If an AI system is a complete ***in-house development***:

- *all IP rights (both the software and the data used for training of an AI algorithm) belong to a healthcare organization.*

When an AI system is developed in ***cooperation between a healthcare organization and a vendor***:

- *the vendor owns the solution and has the right to sell it to other customers; the healthcare organization owns the data provided for the algorithm training, can free of charge apply the*

solution on a certain number of patients per year which is proportional to the amount of data provided for training, and use the solution for other projects.

In the case of a ***purchased AI system***, there are two cases:

- ***For a solution embedded to a medical equipment****, it is a one-time fee when purchasing the equipment with installed AI in addition to annual cost for its maintenance.*
- ***For a standalone solution****, it is a pay-per-use license.*

When healthcare organizations participate in the development of AI, they often negotiate a schema that allows them to use the developed AI solution for a period with a reduced cost or even no cost. A healthcare organization is always a data controller and, in joint projects with external AI developers, it is responsible for being compliant with all the ethical and privacy regulations.

4 Status of AI implementation in healthcare

4.1 Summary of the scoping review

The performed scoping review has taken a theoretical approach to examine the barriers and facilitators for AI implementation in healthcare based on empirical data from the existing implementations. We have searched major databases of ICT and healthcare scientific publications for articles related to AI implementations in clinical settings published between 2015 and 2021. Implementations in the early phase of algorithm validation or proof-of-concept have been excluded from the analysis. We have used a deductive approach followed by an inductive one to extract facilitators and barriers. In total, nineteen studies have been included in the review. We have identified sixty-nine facilitators and forty-six barriers for AI implementation in healthcare. The most cited barriers are mentioned further.

Trust from clinical users is a key facilitating factor for AI implementation. Clinical users tend to be positive when they are given the tools to understand how the AI systems produce certain outcomes. While some AI algorithms such as logistic regression are straightforward for healthcare professionals to understand, AI systems using neural networks require specific visualization and explainability techniques to understand their conclusions. Research must be done on how to bring these techniques and embed them in clinical research and clinical practice. In some cases, it is not possible to understand the behavior of an AI system in detail, but healthcare professionals are willing to use the system if solid clinical evidence on its positive performance is provided.

Involvement of healthcare professionals in the design of an AI solution, its development and implementation is one of the most reported facilitating factors. In collaboration with clinical users and health institution management, implementers should define the clinical workflow and determine at which point the AI outcome should be provided. The studies reported the importance of iterative methods in collaboration with users to refine the system until it is fully adapted to the clinical workflow.

Data availability and ***low data quality*** are named among the most important challenges for AI implementation. AI algorithms learn from data. To ease the training of AI algorithms, structured, discretized data is required. However, nowadays health data are mostly in free text and is a subject to language idiosyncrasies. Using natural language processing for data preparation may help in some tasks, but it still does not provide the level of data quality and semantic precision required to train AI in a reliable manner. While some data (for example, laboratory results) can be standardized with technical work, missing and noisy data will always exist. Actions to minimize these issues by better structuring and tagging data should be considered. A national data quality plan is required. However, it should not be a standalone plan but a collaborative action that is well coordinated with existing standardization initiatives (such as health information standards, terminologies adoption, etc.). Access to new data is crucial to see whether the algorithm is valid over time and ensure its performance does not deteriorate. Data quality does not only refer to its syntactic and semantic dimensions but also to the representativeness of a training data set with regards to a population it will be applied for. To develop AI solutions able to be used in various organizations, professionally designed multicenter evaluations are needed.

Another related barrier is ***the generalizability of AI solutions***, i.e., their functioning with even performance in different settings. AI systems are highly dependent on the data and the context used for their training. This challenge especially affects AI solutions working with EHR text notes and laboratory or pathology reports. Clinical information standards and terminologies adoption are necessary

to improve data quality but also to allow for models' generalizability by training them across several organizations.

Lack of data interoperability between AI systems and the EHR is mentioned as another important barrier for successful AI implementations. This often relates to the lack of effective mechanisms to allow AI systems to use EHR data. This is particularly relevant for AI systems working with free text notes since the content requires extensive preprocessing and validation before data can be fed to the system.

Lack of integration with the clinical workflow forces healthcare professionals to deal with two different systems which is inconvenient and time-consuming. If an AI solution is intended to assist healthcare professionals during their practice, it should be integrated to the clinical workflow, for example, as a part of the EHR or PAC system. However, enabling this also involves challenges. Being a part of the clinical information systems, such solutions are difficult to update and retrain without affecting the whole workflow, and even require re-assessment and a new certification of the solution. Some AI systems are too complex to be embedded to the clinical workflow. To address this problem, some studies used AI to discover new evidence and then discretized that evidence as rule-based decision support modules embedded to EHR.

Legal framework and legislative compliance matters are named as especially challenging within the European Economic Area due to the requirement of CE marking. AI software is considered as Software as a Medical Device. Hence, it must adhere to CE marking rules. On the pilot stage, to be able to work with health data, ethical clearance is required but not the CE mark, and to use the AI system in clinical production settings, the CE mark is required. CE marking process is complex and expensive. Therefore, better support for implementers with regards to regulatory compliance is needed.

The barriers and facilitators identified in the scoping review correlate with the results of the interviews performed. The interviews have provided more detailed level of the challenges as well as action points required for successful AI implementation in healthcare.

4.2 Analysis of the interviews: hinders for AI implementation in healthcare

We have interviewed forty-six representatives of public and private organizations, such as hospitals, vendors of EHR systems, ICT platforms and AI solutions, universities, an ICT provider, a technology transfer office, and a center for clinical artificial intelligence.

When it comes to the status of implementation of AI solutions in healthcare, regardless the country the interviewees have come from and whether they have been working in private or public organizations, all of them have been agreed on a long way to go till AI will be a part of daily routine for healthcare professionals. In medicine, development of AI goes much slower in comparison with other fields. There is a huge interest in this topic: numerous research projects are exploring AI for healthcare, but just a few solutions are implemented in clinical practice. We see many projects without a proper plan for implementation and operation of their solutions. The AI implementation process is so new that even top institutions are still figuring out the implementation components, and just a few institutions have been able to implement and validate AI systems in clinical settings. As with every upcoming technology, it takes time before you can see the outcomes. Same with AI in healthcare: to deploy AI systems effectively and get measurable clinical benefit will take time.

In the interviews, we have identified the gap between AI in research projects and its implementation in healthcare organizations. One respondent has pointed out the reason for not going into implementation being the knowledge about the numerous barriers for making a research project into an

implemented solution and having the solution in operational use. Further in the text, we describe the barriers for AI implementation discussed in the interviews.

4.2.1 Perception of AI

The attitude towards AI varies among healthcare professionals and patients, depending on their experience with technologies, field of work, and age. Older adults are more conservative and often do not see a need for AI. More academically oriented healthcare professionals understand the need for technologies and have higher acceptance of AI. Radiologists and pathologists being already very technical are positive toward AI. The main concerns among these specialists are accuracy of AI algorithms and human involvement beyond screening procedures. Within other medical fields the attitude towards AI is more negative. Some healthcare professionals are skeptical but interested and have shown to ease into the concept with explanations, evidence, and actual benefits. There is also a doubt about who is responsible for diagnosis.

Healthcare professionals' trust in AI

One respondent believes it is easier to implement AI as software for administrative tasks than for patient treatment or to provide suggestions to the healthcare professionals on how to treat the patient due to ***a lack of trust from healthcare professionals***.

Interpretability of AI solutions

Interpretability is a property of a system which reflects how much it is possible to understand how the system functions and comes to a certain result. Terms "interpretability", "transparency", and "explainability" are often used interchangeably.

__Interpretability__ of an AI system reflects how much it is possible to understand internal work of the system and how it comes to a certain result.

Transparency is closely related to trust in the system. Some respondents explain this lack of trust from healthcare professionals by ***a lack of interpretability of AI solutions***. For example, some healthcare professionals have been skeptical of neural networks because it has been impossible trace back the answer. It is important for healthcare professionals to understand how the algorithm draws its conclusions. It is easier to trust AI solutions analyzing medical images because clinicians see the images beforehand or after and have their competence to analyze the images on their own to control the conclusions of the AI system.

It is more complicated when it comes to data and text in the EHR. It has been reported that nurses and doctors do not trust the systems when they do not understand how the AI system makes conclusions or whether the data used for its training is representative for the patients the AI will interfere with. They need the results to be evidence-based and understand why a system is producing such a result to make a record in the EHR: they cannot just type "because the system has said so."

However, ***transparency*** is not always a problem for healthcare professionals. Our interview results show healthcare professionals have more concern on building evidence on the positive effect of AI implementation than understanding its internals. They exemplify acceptance of little transparency in medicine with methods and drugs for which they do not know the mechanisms, but they know empirically that they work.

There has been a more categorical opinion about explainability of AI solutions. The respondent believes the explanation methods are "full of confirmation bias, and human trust is manipulatable by superficial features of a visualization."

Knowledge of healthcare professionals about AI

Missing knowledge leads to absence of trust. There is a bit of skepticism and fear to miss their jobs and lose professional competence if AI replaces a colleague. Healthcare professionals have also reported a change resistance. ***Not enough knowledge about AI among healthcare professionals***, including wrong understanding of the AI role by the healthcare professionals that AI would substitute them and not just assist, has been a decisive factor for one unsuccessful project when people have thought they will lose their jobs because of the AI, and they have been not willing to cooperate. There is a lack of understanding of where AI can be applied, how it can improve the healthcare system and change the way of working, as well as the challenges it brings.

Involvement of healthcare professionals in implementation

The adoption of a new AI system impacts clinical workflow. Being a part of the process promotes trust among the participants. It is ***not possible*** to implement an AI solution in a clinical workflow ***without including healthcare professionals in the implementation process.*** The management of a healthcare organization cannot force employees to change their workflows by using AI solutions purchased without a cooperation with them and studying their routines.

Overall, significant improvements in enthusiasm, knowledge and curiosity are reported. It is important to spread empirical evidence of effectiveness and knowledge about the fact that AI will not replace healthcare professionals but assist them in their routine tasks, and competence of healthcare professionals is needed to develop and utilize AI.

Perception of AI by patients

With higher acceptance among the elderly patients, healthcare professionals may get more time for care and interaction with them. Denmark has funded a survey over 10 years with 100 million DKK to see how data-driven solutions affect citizens (51). Surveys among English patients show most patients does not know what AI is (52): over half of the patients have been interested in using it to manage their own health but have been more skeptical about letting their GPs (General Practitioners) use it on their behalf. In France, the patients are more positive to letting a doctor rather than an AI oversee data from their wearables but would prefer it to be an unknown doctor to avoid surveillance and judgement (53). In general, when not informed about AI assistance, patients do not notice any change in treatment. Patient organizations in Norway are concerned with getting the best healthcare available and positive towards AI.

4.2.2 Organization and implementation process

Novelty of the implementation process, both for internally developed and purchased AI solutions in healthcare, contributes to underdevelopment in the area. Several respondents seem frustrated with the ***absence of a defined implementation process***. Projects wish to have good examples of AI implementation to know how to proceed with all the details in this complicated process.

Other interviewees, purchasing the algorithms, struggle with selecting the right tool for clinical needs among all available on the market due to ***a lack of expertise in procurement***. This expertise implies broad and extensive knowledge from juridical, clinical, IT, economical, and a management fields.

The respondents also mention ***a long and challenging process of validation*** of those algorithms trained on the data from other institutions or even countries, and their local adaption to the context they are working in. The others, understanding the importance of the local validation of purchased products, suggest doing it by implementing the solution in a “silent mode” without embedding the solution directly to the clinical use to be able to find all the errors, and only then implementing it into the clinical workflow. However, even if the algorithm has high performance in the research settings of retrospective study, there is no guarantee on it will work well in a clinical setting.

The respondents with the AI solutions embedded into the medical equipment have accepted the drop backs of the systems and adapted to them, doing manually the work for the parts of the software where it has performed poorly. Those solutions are updated by the manufacturer and do not learn with the time based on the feedback from users.

Several respondents consider ***organization*** a bottleneck. It is considered as fragmented when it comes to decision and financing. In addition, the existing organizational pipeline is not adapted for the incremental character of the AI implementation process: it takes years before a developed AI system can be released for clinical use.

Others mention ***a lack of national and regional strategy for AI implementation***. There is an expressed need for clarity, guidance, and support regarding implementing solutions from the authorities. The interviewees wish for an overall strategic approach to sustainable AI implementation.

4.2.3 Regulations

Several respondents mention regulations as a challenge for a smooth implementation process. The interviewees have reported issues when several entities responsible for ethics, data protection, and regulation need to be enquired. It has been mentioned several overlapping legislations that must be checked before it is determined which ones apply to the project. The ***AI regulations and their interpretation have been considered too complex and time-consuming***. Some interviewees have reported that they have developed AI systems that healthcare professionals have wanted to keep on using, but uncertainty about the regulatory framework has threatened the continuity of the system usage. Others have called it problematic to get approval for the system deployment in clinical production because the legislation does not facilitate the use of AI in a clinic.

The interviewees wonder about different AI implementation-related nuances, such as how to calibrate an AI model in production in accordance with the regulations, in which extent the algorithm is considered as AI, and how to combine the data from various sources and get approval to do so.

Some interviewees have enquired about the National Medicines Agency for guidance on regulations about medical devices. However, the undefined term to receive their advice and unclear responses has made the projects reach several other organizations and experts. In general, it is reported to be difficult to find people competent to answer the questions related to AI implementation. There is a ***need for more people in authorities knowledgeable about AI*** for advising implementers about regulation compliance.

Some respondents have also mentioned the ***limitations after the Schrems II judgement*** (54). Before it was possible to transfer personal data from the EU to the USA, while ensuring a strong set of data protection requirements and safeguards. Lately, it has been decided that the USA laws do not satisfy requirements that are equivalent to those required under the EU law. As a result, EU companies can no longer legally transfer data to the USA, i.e., they cannot use American cloud solutions without “an adequate safeguard.”

The lawyers believe the Norwegian health ***regulations are outdated and should be adapted to reflect the existing technologies***.

The ***CE marking process*** is perceived as ***complex, expensive, and time-consuming.*** Some respondents have reported the AI systems supported by healthcare professionals which they have had to stop using because the systems could no longer be considered research prototypes and, therefore CE marking has been required. Recent changes in CE regulations have introduced even more uncertainty on how to navigate the regulatory environment to reach full approval of AI products. Several interviewees believe the industry sector is much more knowledgeable on the regulations for CE marking.

4.2.4 Resources

Human resources

Shortage of resources is a widespread problem for all AI projects participated in the interviews. It concerns all forms of obtaining AI in a health organization. Resources imply both competent lawyers, clinical domain experts, data scientists with knowledge and expertise within AI, IT personnel for support and maintenance of infrastructure and AI solutions, as well as time (i.e., capacity of those experts) and finance.

There is ***a shortage of health professionals in general***, but especially ***a shortage of clinical domain experts with capacity to contribute to the AI implementation projects***. A lack of radiologists in Norway and Scandinavia has been mentioned by several respondents. It is challenging to find healthcare professionals with capacity for data annotation, testing, clinical evaluation, as well as to provide feedback and unearth potential issues, despite many of them are interested in the topic. They have little capacity to be engaged in AI implementation projects as they prioritize patient treatment rather than "*just develop solutions that benefit in the long run*". There is a professional leave for doctors ("overlegepermisjon" in Norwegian) when doctors are allowed having free time from their daily clinical duties to update themselves. In one project, due to the lack of time for the implementation work in their working hours, healthcare professionals have used their professional leave to prepare data for the algorithm.

Lower use of AI solutions can be explained by a combination of the low capacity among healthcare professionals and the ***absence of an arena*** for them ***to learn about AI, share their experiences and knowledge***. The last factor is caused by inadequate or even missing training of healthcare professionals about the purchased AI solutions and absence of healthcare professionals in other healthcare organizations in the region using the same solution or interested to use one.

There is also ***missing juridical support***. Several respondents reply they do not have a separate team of lawyers helping them with implementations. There has been a self-reflection of one interviewee about their experience that in their organization, they should internalize the regulation competence not to start over in every new implementation project.

Shortage of IT resources in healthcare organizations, including specialists with AI competence, has been raised in the interview discussions. The ICT departments able to comprehend AI are scarce in Norwegian healthcare organizations. The interviewees have complained that local IT staff running the EHR systems do not have the time and understanding of AI and importance of testing environments for AI. IT support in healthcare organizations is currently overly reliant on the vendor. They should obtain more computer science expertise and take responsibility for IT support of internal clinical systems and infrastructure.

Two reasons for lower availability of specialists with IT background in healthcare organizations are: 1) high demand for such specialists in general, and 2) healthcare organizations can rarely afford the same salary level as private companies. Data scientists are usually employed by healthcare organizations right after graduation and leave after a brief period. Vendors can partially compensate the lack of data scientists in healthcare organizations, but they are only hired in specific projects and are not as engaged as tribe-minded people working together on a permanent basis.

Regional and local transformations (such as transition to a new EHR system in a healthcare organization or some reforms in a region, etc.), in addition to daily practice, take a lot of time and energy from healthcare professionals and do not allow them to move forward with the upcoming technologies, including AI.

Financial resources

Many respondents state financials have been sufficient for the research or innovation projects they have been working on. However, one project has confessed they have had enough funding for research, but the plan has been to integrate and certify the developed AI system for use in the healthcare organization, which they have not managed.

A lack of dedicated funding for implementation projects is named among the reasons for the implementational gap. Healthcare organizations have limited budget when it comes to implementation works. One project has returned to the research work due to the deficient financing for implementation and maintenance of the solution to make the solution more generic, i.e., universal, and able to be used in several areas and get bigger financial support in the future.

Another issue mentioned in several interviews is that ***implementational costs are not*** even ***planned*** in the research projects.

Some respondents highlighted ***the lack of national investment in the area***. They emphasize funding in small portions to different projects instead of having a big project where there could be enough funding to build up the ICT infrastructure for AI. In Finland, they have another economy-related problem: healthcare organizations are treated as companies when it comes to state aid receiving 40-50% of total maximum cost from the national funding agency despite healthcare organizations are not making profit and are funded municipalities.

Private investments into development of health-related AI have been mentioned by the respondents from different countries. Sometimes, there is a ***lack of understanding*** from investors on ***how to assess when and whether AI projects will be profitable***. However, in the interviews, there was an example of a private AI company from France that got a big private investment.

Implementation of AI is quite ***expensive***. Both ***infrastructure*** for AI, ***validation process***, and its ***maintenance*** are costly. Healthcare organizations need external investments to ICT infrastructure if they plan for development of AI. Small healthcare institutions cannot afford AI development due to expenses related to infrastructure and CE-marking process: they must buy an AI solution from a vendor that has already obtained a CE mark for it and go through validation of the solution and workflow assessment.

Licenses for purchased AI solutions are ***expensive*** as well. There are different licensing models. The most common one includes a payment for a license to use the AI solution that must be updated each year, in addition to payments for every examination. For limited budgets of healthcare organizations, especially primary care funded by municipalities, it can be problematic.

4.2.5 Data

AI solutions necessitate substantial amounts of data for training. There have been several data-related issues raised in the discussions: 1) data access, 2) data location, 3) data quality, 4) data standardization and harmonization, 5) data sharing, and 6) combination of data from various sources.

Data is typically fragmented across many different systems. According to the interviews, ***data collection*** has been an extensively time-consuming process. To access patient data, you must get the REK approval and patient consent and then contact an ICT provider and ask for the data. Some respondents mean it takes at least a year of meetings and gathering information to get the approval from the regional ethics committees; others complain it takes that long to get approval for data access that research money is gone and there are no more other resources or there is not enough time for extensive use of available data. The reason for this is a very rigid attitude to privacy protection of health data in Norway. At the same time, it has been mentioned ***a lack of privacy-preserving routines for transferring and storage of health data in health institutions in Norway***. Then, it is a dilemma: how to compromise between a need for a lot of data for training of AI systems on one hand and protect the privacy of individuals on the other.

Explicit consent from patients required for AI solutions to be used in clinical practice has been also considered as a bottleneck for transition from research to clinical use. AI requires a lot of data for training. Hence, it is not realistic to have consent for all samples. The interviewees have expressed the need for anonymized data sets that can be used without patient consent.

4.2.6 Infrastructure

According to the interviews, ***the lack of proper infrastructure for AI and hardware with enough computational power to analyze the health data and secure its storage*** are significant challenges for development of AI solutions in healthcare.

There are also ***problems with the existing ICT infrastructure***. The available IT systems and setups in healthcare organizations are outdated and not able to handle the nowadays load with browsing in several clinical systems or simultaneous access to a remote system, not even talking about the demanding needs of recent technologies. According to the interviewees, with the technical infrastructure implemented in the universities, there are too many security issues.

Some respondents associate the poorness of AI solutions in healthcare with ***a lack of interoperability between the clinical systems*** caused by an amount of different data recording systems, different practices as well as doctors' "eagerness or non-eagerness" to record the data according to the requirements. In addition, it has been mentioned ***a lack of interoperability between the healthcare organizations*** with integration problems even within one municipality.

All the mentioned above barriers hinder adoption of AI implementations in Norwegian healthcare sector.

5 Framework for the AI implementation process in healthcare

Analysis of the interviews, reports on AI and national AI strategies in healthcare has allowed us to structure the favorable conditions for AI implementation in healthcare. Figure 4 illustrates the full AI implementation process with the required components from the AI project planning till AI is implemented in a healthcare institution.

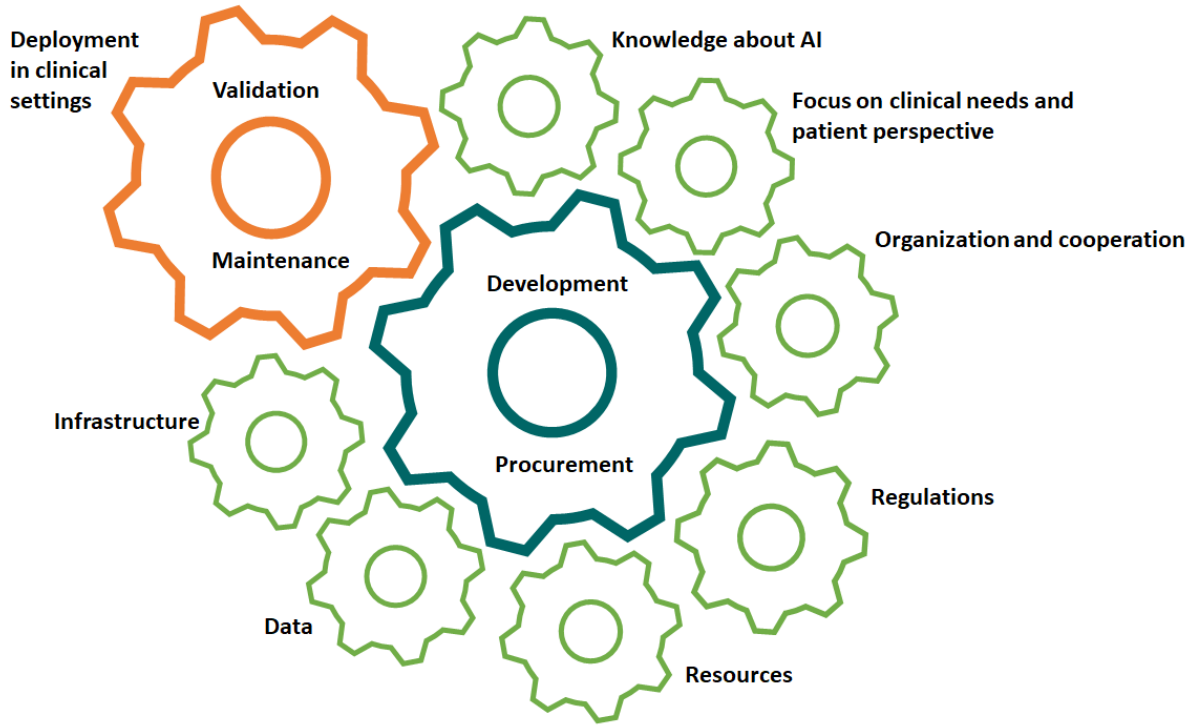

Figure 4: Framework for the AI implementation process

Our findings are in line with the requirements for trustworthy AI published by the European Commission (55): 1) human agency and oversight, 2) technical robustness and safety, 3) privacy and data governance, 4) transparency, 5) diversity, non-discrimination, and fairness, 6) societal and environmental wellbeing, and 7) accountability.

Further, we describe the action points for AI implementation in healthcare based on the interviews, AI-related reports, and the national AI strategies. The components are interconnected: all should be in place to make the whole "implementation mechanism" work, i.e., to promote AI implementation in the healthcare system. Some components have two levels of responsibility: national and local. The other components require effort only on one of the levels.

5.1 Knowledge about AI

National level

To increase people's level of confidence and comfort with the applications of AI in healthcare, we should raise their knowledge about AI. We need to ***raise people's awareness about what AI is and its potentials and limitations***. They need to know the fact that AI is a tool to help healthcare professionals improve their work but not a substitute for them. It is the healthcare professionals who control

the conclusions of AI systems and oversee the final decision. This can be done in several parallel actions.

AI-related courses should be included ***in the curricula of medical students***. They need to be taught in several aspects, involving transparency, data governance, and accountability. This will increase their awareness, trust, and understanding about upcoming technologies in medical practice and, at the same time, provide feedback to AI implementers on how to develop trustworthy AI tools utilized by healthcare professionals.

Healthcare professionals should have the opportunity to ***learn about AI implementation***. This knowledge can come through seminars on successful case studies which specifically help healthcare professionals to see where AI works effectively. They should be informed about the impact which an AI solution will have in their routine work. It should be explained that it will affect the daily routines of most employees of healthcare organizations who will need to use new tools and, in many cases, adapt their procedures (56). Russel and colleagues identified six competences of healthcare professionals for use of AI: 1) basic knowledge of AI, 2) social and ethical implications of AI, 3) AI-enhanced clinical encounters, 4) evidence-based evaluation of AI systems, 5) workflow analysis for AI systems, and 6) practice-based learning and improvement regarding AI systems (57). In Sweden, clinicians are offered an AI competence raising three-days course. Additionally, the healthcare service should together with healthcare professionals create a ***national competence service*** for all levels of healthcare, offering AI foundations to all healthcare employees (58).

Massive Open Online Courses (MOOCs) about AI should be promoted to the population to gain knowledge about AI. There are several online courses about AI, such as Elements of AI (59) (available in Norwegian), AI for Everyone (60), Introduction to Artificial Intelligence (61). These activities will help in building the social contract between implementers, healthcare professionals, and citizens for improving attitude to data accessibility and increasing the acceptance of AI as a part of the healthcare toolkit. For this social contract to be sustainable in the long term, the best privacy and security measures must be guaranteed.

These initiatives on the national level will help to demystify the use of AI and determine the areas to help healthcare professionals in performing their work more efficiently (56). In this process, it will be practical to monitor future needs and stimulate to upgrade and expand the workforce by attracting talents (62, 63).

5.2 Focus on clinical needs and consider patient perspective

AI implementation directly impacts clinical workflows and, if not properly done, can be disruptive both in terms of professional autonomy and patient care and safety. Hence, to reduce the risk of counterproductive implementations, AI projects should be healthcare professionals extensively involved in the entire process. Only then it will be possible to guarantee the AI functionality to be embedded in that part of the workflow where it answers clinical needs. This has been confirmed by our interviews where the most fruitful and relevant projects have involved clinical users affected by the AI implementation from the inception of the project.

<u>Local level</u>

The National health and hospital plan promotes four broad societal needs which AI should solve: larger and aging population, increased costs in new methods and technology, increased patient expectations, and prolonged treatment needs (64). ***Research, development, and implementation of AI*** in healthcare must be ***based on clinical needs***. At the same time, it is important to ***align clinical needs with the*** mentioned ***societal needs and available competence***, and when possible, ***try to impact*** those ***areas*** which do ***not use much technology***, such as mental healthcare.

When planning an implementation, one must consider that AI will affect the daily routines of most employees and that technical effort is only a small portion of the work (56, 65). It is critical to ***promote the development of AI systems*** that ***incorporate and accommodate the needs of healthcare professionals and affected patient groups*** (66).

AI implementations must be ***designed in collaboration with affected healthcare professionals*** to determine how AI will modify their workflow to make it more efficient. Ideas may come from outside, but they should always be aligned with clinical needs before going further. There should be some form of feedback loop in the system (55, 67) as well as rigorous documentation of the processes and the data used the system (55).

Several respondents consider it is important to ***include patient representatives*** into the implementation process, suggesting the algorithmic impact assessment as a point to get their opinion on whether the AI solution has a value, and provide easy information about usage of AI in treatment and information to assess risks and benefits (68, 69).

Another crucial point is the ***generation of evidence of AI systems in clinical settings***. Healthcare professionals want to know how AI works and its precision compared to traditional methods (58). This is especially important for ***building trust*** in the AI systems as healthcare professionals are used to relying on scientific evidence before taking new methods into clinical practice. Healthcare professionals will be more positive towards AI if they feel they are being heard and their professional considerations are taken seriously. They should be actively engaged in the implementation process accompanied by transparent communication (65). According to the MDR, there are three factors contributing to the generation of clinical evidence (29): 1) validation of clinical association between the software output and the intended use of the software (which may include clinical evidence generated through clinical investigation), 2) validation of technical performance (which can be generated through verification and validation activities), and 3) clinical performance validation. Those are supposed to be updated during the lifetime of the device.

Further, there are ***ethical and privacy concerns*** about AI implementation in healthcare. The need for large amounts of training data poses a risk of patients' privacy violation. Morley with colleagues identified three groups of AI-related ethical risks in healthcare: 1) epistemic, related to inconclusive, inscrutable, and misguided evidence, 2) normative, related to unfair outcomes and transformative effects, and 3) overarching, related to traceability of AI systems (70). It is important to ***take these concerns into consideration*** right from the planning of the AI project.

5.3 Organization and cooperation

The interviews have shown the importance of having good cooperation for a successful AI implementation. Cooperation-related success factors for AI implementation discussed in the interviews and taken from the reports about AI implementation and national AI strategies include cooperation both within and outside the healthcare organizations.

Local level

Having a ***multidisciplinary team of data scientists*** (AI developers), ***technicians*** (IT support), ***clinical domain experts*** actively involved into design, testing, and validation of AI systems, as well as the ones ***steering the administrative and regulations parts*** who can handle REK applications, documentation, and CE marking process, is emphasized by most of the respondents as essential for successful AI implementation. In multidisciplinary teams, people co-create and learn from each other through sharing their knowledge and experiences. Such teams contribute to good understanding of the clinical needs, workflow, possibilities of AI, and applicable regulation framework (65). They can also assess ethical and societal consequences of the AI systems (71) and discuss ethical issues as they emerge (58). The implementation process implies ***continuous, dynamic, and iterative*** communication and development ***processes***.

Many interviewees consider initiatives for AI implementation should be driven by ***clinical champions***, i.e., motivated enthusiastic and healthcare professionals taking the initiative and leading the implementation process from a clinical side. The interviewees stress the importance of ***being inside the healthcare institution*** to enable broader and deeper understanding of clinical needs, workflows and existing clinical systems for resilient AI implementation or finding new opportunities for improvements in the healthcare system.

Introduction of upcoming technologies in healthcare organizations does not go as fast and smoothly as can be imagined. For any AI implementation, it is important to have a ***mutual understanding of the needs and strategic support from the management of a healthcare organization***. Enthusiastic and knowledgeable leaders are of great benefit. Examples from Norway, Denmark, and France show that a strong initiative from management, paired with clinical engagement and champions is essential to success. Management support is crucial to ensure investments in ICT infrastructure and allowance for healthcare professionals to use their time to aid the implementation process.

An ***innovation office,*** or a technology transfer office (TTO), acts as a hub between healthcare organizations and industry. Innovation offices should facilitate agreements between university researchers, healthcare organizations, and vendors for the management of IP rights and terms of use before evolving an AI product into a commercial product. Several interviewees have had a TTO supporting them directly in the healthcare organization to find their way towards the best implementation options and the applicable regulatory framework. It is advisable to have a TTO as a part of a healthcare organization or have a representative there to get acquittance with the organizational culture.

National level

There are also measures to be taken on a national level to facilitate AI implementation in healthcare.

Healthcare organizations are waiting for a ***defined process for AI implementation***: *"Both a recipe for creating good AI systems in terms of how things can actually be used, but also the different levels in an organization to get things in a decision-wise, professional and simple way."* The Norwegian Directorate of Health has created an online information portal where they aim to include framework conditions for all phases of AI implementation, from R&D to clinical use (72).

Cooperation between authorities, academia, and healthcare institutions is required for comprehensive understanding of needs and challenges in AI implementation and coordinated work to overcome those (66). Such cooperation will also contribute to making AI trustworthy.

It is also required to strengthen ***cooperation between healthcare organizations*** for testing and validation of AI solutions as well as for knowledge and experience sharing (73).

Cooperation between healthcare organizations, patients, academia, technologists, and commercial actors is needed for access to health data, upcoming technologies, and financials, as well as sharing knowledge, experiences, and processes (55, 71, 74). Close cooperation of this type is important during commercialization of AI solutions (75).

An example of a successful cooperation is AIDA (76), an initiative within the Strategic innovation program Medtech4Health, jointly supported by VINNOVA, Formas, and the Swedish Energy Agency. AIDA is organized as a collaboration arena for academia, industry and healthcare and coordinated by the Linköping University Center for Medical Image Science and Visualization and is driven by clinical needs. The AIDA's activities include

- *Research & Innovation projects*
- *Clinical evaluations*
- *Fellowships*

- *Data, computing, and storage services (AIDA Data Hub)*
- *AIDA Days (around eight workshops per year)*
- *Training*
- *Network partnerships*

It is suggested to create a ***shared digital ecosystem*** for collaboration between industry, healthcare providers, and academia (56, 58, 77). This can also include ***competence networks*** and ***digital innovation hubs*** (58, 64, 74, 75). Such networks will enable competence sharing, guidance, establishment of best practices, and transition support (63, 74, 75). Norway has joined the European Digital Europe program (2021-2027) and received support from the EU to create two so-called European Digital Innovation Hubs (EDIH). The program aims to provide partners and resources in the areas of AI, supercomputers (heavy computing), ICT security, and advanced digital competence to Norwegian companies and research environments.

Before establishing new networks, it is important to ***make available competences visible***, so they can be utilized (17). The Norwegian Network for AI in Healthcare (KIN) can help increase AI competence visibility.

Long-term partnership with academia can support public organizations in attracting young talents, especially in technical subjects where the public sector is facing important challenges (56). National strategies of several countries promote public-private collaborations (62, 64, 74). For example, the Netherlands enhances this kind of partnerships, such as Commit2Data (78) and VWData (79) with focus on big data (80). There should be arranged standardized development contracts and public-private cooperation (81, 82).

5.4 Regulations

There is a perception among the Norwegian interviewees that the level of AI adoption in healthcare in Norway is lagging behind other countries, such as Finland, Denmark, the UK, and the USA. This is reflected in the large amount of funded research projects that produce scientific publications in the country contrasting with the low amount of Norwegian CE marked AI implementations. The respondents agree that Norway has the right prerequisites for AI implementation, such as availability of data scientists, health data registries, and positiveness towards technologies. However, several actions in the regulatory area are necessary to unleash the full potential of Norwegian AI implementers.

National level

Lawyers support comprehensive revision of the Norwegian health legislation. However, the government is reluctant to change the laws when a technology is in early phase of development because it may influence its development in an inadvertent way, skew the market, and limit potential for innovation (77). The Directorate of Health is investigating the action room within the current legislation and the need for regulatory changes (75).

There is a ***need for updates in regulation for secondary use of health data***. For example, Finland has the Act on the Secondary Use of Social and Health Data from 2019 (83). It applies to data collected in social and healthcare organizations and governs processing for secondary purposes. The organization applies for health data access for its secondary use. Within a limited timeframe, Findata (84), the social and health data permit authority evaluates the application and after granting the permit they compile, combine, and pre-process the data, and offer tools for analyzing. Hereby, no patient consent is needed for AI development in Finland. The Estonian Biobank contains health data of patients who have given the consent for their data to be used for R&D processes that would yield healthcare

information; for other health data registers, there is an application process to a special IRB board that evaluates the application.

The European Commission's proposal for a regulation on the European Health Data Space (85) aims to promote secure access to and exchange of health data across national borders. It establishes a set of rules, infrastructure, and governance mechanisms to promote both primary and secondary uses of electronic health data, while ensuring data protection and strengthening cybersecurity. The regulation is designated as relevant for EEA (European Economic Area), which implies that after decision in the EU, it must be processed for adoption into the EEA agreement signed by Norway. Incorporation will also require work on the Norwegian regulations. The Norwegian Directorate for e-health is assessing the consequences this may have for the national healthcare sector and the healthcare industry (86).

The interview respondents request ***harmonizing the interpretation of the regulations between healthcare organizations, lawyers, and the authorities***, especially the regulations about access to patient data. Correct interpretation of a law depends on a clear context and domain knowledge. Knowledge within the AI related legislation is scarce now. The interviews have revealed that some aspects of the legislation are not prepared to deal with the evolutionary nature of AI that continuously learn from data. Thus, only a "frozen" version of the AI solution can be CE marked, and a newer version will require remarking. The European implementers have pointed out that this makes the CE marking process clearer while the use of algorithms that self-adapt in real time by learning as new data enters the system is uncertain for them. In addition, the responsibility for the failure of an AI system should be clarified. To better understand these uncertainties, both regulators and implementers should communicate with each other for developing valuable cross-disciplinary knowledge (67).

According to the current regulations, the vendor, whose AI system is taken to a product evaluation by a healthcare organization as a preparation for the procurement, is not allowed to be awarded with the contract to avoid giving this vendor a competitive advantage. However, in the AI implementation process, this collaboration is needed. ***Eliminating of*** this ***regulatory barrier in the procurement process*** is requested by the implementers.

In general, ***more extensive and better guidance about the AI related regulations from the authorities*** is desired (58, 63, 67, 77, 81). In January 2022, there was issued the Circular on the regulations for development of AI within research (including health research), development and use of clinical decision support tools and quality improvement (see *Regulations applicable for development of AI solutions*). This, together with interagency guidance meetings available for AI projects and regulatory sandboxes organized by the Norwegian Data Inspectorate (see *Regulations applicable for development of AI solutions*) contributes to the request for clearer guidance about the regulations.

Awareness of the ethical and legal frameworks should be built. It means we need to ***develop bodies to inform and control how knowledgeable the AI implementers*** are ***about the regulation framework***. It helps to make the regulations clearer and interpreted in a unified way. There is a suggestion of having ***cooperative groups*** across academia, private and public sectors ***with support on regulations within AI*** to create unity and transparency across the healthcare industry within the AI related regulations.

5.5 Resources

5.5.1 Human resources

Introducing AI brings new task allocation, new roles, and responsibilities. Let us look at how implementation will influence staffing and maintenance of competence.

Local level

Absence of internal competence and resources may lead to challenges in setting up projects, managing development, validation, and maintenance of AI systems (56).

Cross-disciplinary competence from data science, medicine, and law is essential for successful AI implementation (17, 67). Some respondents believe healthcare professionals should raise their knowledge about data science, AI, and regulatory frameworks. Healthcare professionals absolutely need general knowledge about AI to understand its potential and limitations to work with AI solutions assisting them in patient treatment. However, it is reported a lack of capacity among healthcare professionals (see *Resources* in *Analysis of the interviews: hinders for AI implementation in healthcare* for more details), which means they do not have time for any extra responsibilities. Therefore, gaining specific IT knowledge about infrastructure, setups, and licenses, as well as knowledge about AI relevant legislations cannot be prioritized by doctors. At the same time, healthcare professionals should be involved in all phases of implementation of an AI solution: from design/procurement planning to validation. A solution for this problem can be ***employment of IT consultants and data scientists with AI competence*** at each department that is implementing AI, ***involvement of healthcare professionals into multidisciplinary teams*** engaged into implementation of the AI systems, and ***assistance from innovation offices*** with taking care of applicable regulations, required documentation, and technology transfer.

Healthcare professionals need a ***support team to facilitate the implementation process***. This team should organize the practicalities of the process so that when healthcare professionals must validate the AI system in clinical settings, they do not have to be responsible for the entire process. In such teams, there should be ***resources to work with the legal and organizational aspects***. Some interviewees suggest having available ***juridical support*** that could be shared between different organizations. There should also be ***IT consultants*** responsible for the maintenance of the infrastructure, setups, and AI systems (which includes updating, failure support, etc.), and purchase of licenses and similar.

There is also a need for ***a support team for the procurement process***. Such a team should in addition have people with ***competence in application processes and commercial contracts*** (65, 67, 71). Vendors find this also helpful when buyers (healthcare organizations, labs, etc.) use consultants to help them buy the AI systems by making proper specifications to the solutions the healthcare organization is looking for. ***Competence on licensing and patents for AI developments*** will help both vendors and healthcare organizations to choose the best licensing frameworks based on the needs of the healthcare organization.

However, the public sector cannot change the situation relying solely on internal forces. Some actions are required to be taken on the national level.

National level

It is a huge demand for medical specialists now, and it is going to be even higher in the future also because of a growing number of elderly people. Building empirical evidence for AI solutions is particularly important. However, ***educating more medical specialists should be strategically prioritized*** and include some incentives for students choosing medical specializations as well as improvement of salaries and working conditions in healthcare organizations to attract talents (63).

Administrative resources should be put into the healthcare sector to ***enable development of AI and cooperation on health data*** (56, 67, 87).

In Regulations, we have talked about the need for supervising support from the authorities. Then, there is a prerequisite for ***the authorities*** to ***have relevant competence*** to facilitate sharing of experiences in a timely manner (71): it must be a limited timeframe for the projects to progress.

5.5.2 Financial resources

In an organizational perspective of AI implementation, funding is important. Investment in AI can lead to better utilization of resources over time, both through assisting doctors, replacing patient travels, and enabling prevention of diseases and earlier or more suitable treatment for each patient (88, 89). However, there is a need for evidence and clinical studies that evaluate AI implementations, including the benefit-cost ratio. Having sufficient funds to see the whole implementation process of an AI system has been mentioned in the Nordic countries as the most important key to AI implementation.

Local level

Implementing AI in healthcare requires a substantial investment from the healthcare providers. However, their budgets are limited.

Over a half of all medical technical equipment (MTE) in the Norwegian public hospitals will exceed its economic life-course by the end of 2024 (88). Therefore, significant ***investments in MTE*** are needed in the upcoming years to avoid downtime and repairs and provide access to the new resource-saving methods (88).

It is reported by several successful AI implementation projects that ***ICT infrastructure*** is crucial to facilitate use of AI in healthcare. It requires huge ***investments*** and is not affordable for a healthcare organization alone. It should be input from the ICT provider, regional health trust, and the healthcare organization itself. Municipalities should also be a part of the joint technical elevation due to municipalities inflexible economy (75). In Finland, for example, when it comes to the investment into infrastructure, it is possible to get support from a national innovation funding agency, Business Finland.

Financing of regional centers for AI competence in healthcare, such as the Norwegian center for clinical artificial intelligence established at University Hospital of North Norway HF and The University of Tromsø – The Arctic University of Norway, in collaboration with Helse Nord RHF, should be considered.

National level

Making AI trustworthy - now and in the future - is critical (56, 66, 87). To develop and sustain the implementation and use of upcoming technologies, there must be long-term financial arrangements (17, 65). Recently in 2022, the WHO (World Health Organization) has published “Digital implementation investment guide (DIIG): quick deployment guide” which can help governments and technical partners plan a digital health implementation focusing on health programs supporting national healthcare system goals (90).

The Scandinavian interviewees have requested more funding for the AI implementation projects. They wish for a ***strategic national investment in implementation of AI in healthcare***.

The ***financial incentive system for*** healthcare organizations should be changed for ***the healthcare organizations*** with their limited budgets ***to have a stronger motivation to develop and use the AI solutions***.

The government should establish ***financial incentives to encourage cooperation between industry, academia, and healthcare*** (87). Business Finland promotes partnerships between business, public actors, and academia (87). In Sweden, AIDA is channeling government funds to innovation projects with a strong clinical side as a prerequisite. In 2021, the UK launched a £375 million program to encourage investors to co-invest with the government in the deployment of breakthrough technologies (73). The Danish government foresees to allocate investment fund to test and deploy upcoming technologies and solutions in municipalities and regions (68).

There should be ***R&D funds for short-term trials*** to experiment with AI in healthcare with the acceptance that many of the pilots will not be implemented in the end. Such initiatives are available in Finland at Helsinki University Hospital and in Sweden via Clinical fellowships in AIDA. In Estonia, there

are national programs where you can apply for proof-of-concept grants to help the data science companies to the pace where the VC (venture capital) or public funds would be willing to invest in those.

The interviewees have reported public funding programs that have incentivized the proliferation of start-ups that collaborate with health organizations in the development of AI products. For example, in Norway, it is Innovation Norway (91) (Innovasjon Norge, in Norwegian) who plays this role. They provide advisory and financial services for startups, including grants and loans for development and commercialization of the solutions. The Norwegian Research Council has a funding call called Pilot Health to support collaboration between private and public actors developing innovative solutions for healthcare and contribute to sustainability in the health and care services and at the same time create value in the Norwegian health industry (92). In addition, there are two funding calls for commercialization of the products from research projects aiming to optimize, clarify or demonstrate technology concepts, clarify market potential, business models and strategy, and establish contacts with potential investors, industry partners, customers, and users (93, 94). In the United Kingdom in 2019, the Artificial Intelligence in Health and Care Award program has been established with a large budget for AI implementation projects, from initial feasibility to evaluation within the NHS, to support the wider generation of evidence via generation of validation or performance data for broader adoption of AI (95). The program has four phases, where the last two are real-world clinical implementations, and it is the innovators' responsibility to prove their cost-effectiveness.

There should be ***investments in the improvement of data quality***. Germany is funding the development of data standards and formats to encourage wide collaboration between actors, as well as participation in international standardization processes (62). Finland has also invested heavily in data management and computing infrastructures and have developed policy instruments to go from a lab to the market (87).

5.6 Data

With regards to data, the interviews have revealed several needs which are important for contributing to AI implementation.

In some specific fields, the amount of data generated in the healthcare organizations is enormous. New policies for development and investments in data warehouses in healthcare organizations are required. There are often two approaches for data storage: centralized and distributed in local institutions or trustworthy research environments. Each alternative offers advantages and disadvantages in terms of cost, efficiency, and privacy.

Local level

Regional or local data warehouses shared by healthcare practitioners and academics would be beneficial in the short term. A data warehouse inside a healthcare organization, from which data is pulled directly, can simplify the data extraction process in comparison with pulling data directly from national databases, which is too costly and time-consuming.

An alternative to local data warehouses is to have regional warehouses supported by large commercial suppliers. A responsibly managed cloud system is far more secure than any local workstation. Moreover, there are several methods to be compliant with the GDPR and privacy regulations using cloud solutions. However, because of the Schrems II judgement limitations, the sentiments toward cloud health data storage options offered by large companies outside of Europe are not positive.

National level

The AI system must have access to fresh data to monitor its validity over time and prevent performance degradation. To improve data access, ***the approval process must be accompanied with local data***

extraction, cleaning, and storage infrastructure coordinated with the National Health Data Hub described further.

Data access needs to ***be managed by a small amount of coordinated ethical review boards and privacy authorities***. The secretariat for regional research ethics committees (REKs) in the south-east Norway serves the four REKs within healthcare in the region and the two national committees for the approval of clinical trials of medicines and medical devices, including AI solutions. The interview respondents have pointed out that data access should not be controlled only by healthcare organizations as this leads to a complex and time-consuming process of obtaining permission to use these data sets. Several countries are adapting their ethical consent and data access infrastructure by minimizing the number of ethical review bodies for all projects to be reviewed under the same framework.

There is also a need to develop ***long-term national strategies and regulations for data access and storage in healthcare***.

AI requires a lot of data for training. Hence, it is not realistic to have consent for all samples. Therefore, abundance of ***open anonymized data sets that can be used without patient consent*** is needed to enable AI implementers access to Norwegian data and improve the alignment with European Open Science initiatives (96). For this, ***competence on data anonymization should be increased*** (67). This initiative will facilitate the implementation of AI and ease the evaluation of AI systems trained on Norwegian data. In addition, it will help to ensure that implementers count on a rich availability of data sets to avoid biases that may lead to discrimination by the AI system.

To comply with the need of data access and infrastructure, the interview respondents have recommended the development of ***sandboxes for testing innovation ideas*** to determine if a solution is worth to be taken into a CE marking process with its further implementation in clinical settings. These sandboxes will require development and free access to anonymized clinical data sets for training and testing purposes with integrity and availability acknowledging the need to link and share data, also across the borders (58, 66). Sandboxes should not only provide infrastructure and data at a technical level but act as much as possible as aggregators of diverse professionals helping to develop connections between patients, researchers, technologists, and commercial actors to facilitate data access (67, 75).

AI systems require good-quality data for training. Most health data sets found in EHR systems possess data quality appropriate for use in healthcare delivery but not in the development of AI. It is necessary to ***improve data quality through data standardization and harmonization*** (66). Adoption of clinical information standards and terminologies will improve data quality and enhance generalizability of AI systems. Healthcare professionals should be involved in data quality assurance, structuring, and standardization (67). With this regard, Norway should continue ***promoting and accelerating*** as much as possible ***the adoption of interoperability information standards and APIs (application programming interfaces) across healthcare organizations*** as it is reflected in the national strategy (77).

Better tools to discover and learn processes from operational data are needed. Complex diseases require mechanisms to observe their pathway in the healthcare system and determine where these processes can be improved. The amount of data available and its complexity requires AI tools, such as process mining, not only to be used for prediction but for visualizing and understanding these processes.

Norwegian open anonymized datasets that do not require REK approval are scarce and small (64). For AI development to be promoted, there is a need to facilitate interoperability among health organizations and geographical areas (17, 65), and patient groups (64). The scale of this endeavor involves a ***national effort to lead and incentivize accessibility of health data for secondary use*** (81). This will help the healthcare sector to develop a mutual understanding for collecting, storing, and sharing data (69) across Norway in a uniform and coordinated way. The respondents have proposed this to be accomplished by establishing a ***national health data reuse center*** with special competence in law,

infrastructure, business, and management processes (63, 66, 77). This center will promote the ***adoption of interoperability and data quality standards for data reuse*** (63, 64, 67, 87) and lead the ***development of a national research data management and governance hub: the Norwegian Health Data Hub (NHDH)***. NHDH will index, manage, and make accessible research data sets from Norwegian health organizations in machine readable formats (73, 77). An example of a similar organization is the Estonian Biobank. It is a population-based biobank funded by the government and private sector. It contains longitudinal with periodic updates from EHRs (Electronic Health Records), National Health Insurance Fund, prescription data, laboratory data, infraction registry, cancer registry data, causes of death registry, regional hospital databases, research projects, and national registries and databases for enrichment of phenotype data.

Many respondents have considered a national opt-out option for patients as an important requirement. However, this may conflict with current regulations. A more sustainable option is to run a ***national program for data anonymization and make anonymized data sets available in the Norwegian Health Data Hub***. The NHDH would allow data access in two ways: (a) for anonymized data sets, direct access could be provided, and (b) for pseudonymized data sets, the data hub should track the informed consents of patients and the ethical review process before giving access to the data set. To that end, a requirement for the NHDH to operate is to reach a higher level of standardization in data representation, access contracts, and ethical approval. With regards to (b), the NHDH should provide the means to create and submit applications online to obtain ethical approval for a particular data set in the context of a research project. That will help AI implementers access diverse data sets for improving generalizability of the AI solutions in Norwegian settings.

The NHDH will encompass data sets curated along research projects and provide support to a national data reuse infrastructure. ***Synthetic data sets*** have been pointed as an alternative to the scarcity of open health data sets for the initial stages of AI developments (64). However, to be useful, their semantic, structural, and statistical data features need to faithfully resemble those of real data sets. Another technical aspect to be coordinated by the NHDH is the ability to perform federated learning across health institutions when data is sensitive and cannot be extracted from the organization where it has been created (67).

The European Commission has issued a proposal for a regulation on the European Health Data Space (EHDS) (85). The framework will underpin infrastructure and government mechanisms for responsible and secure exchange of and access to health data both to develop research and improve citizens' health. Norway as an EAA-member will be a part of the EHDS. The national data reuse center will serve as a coordinator for the EHDS.

Establishment of the Norwegian Health Data Hub and participation of Norway in the European Health Data Space will make access to health data for secondary use more sustainable.

5.7 Infrastructure

To adapt to AI technology, the ICT infrastructure in healthcare organizations should be upgraded.

Local level

A solid computing infrastructure at healthcare organizations will improve efficiency of AI training. Currently, healthcare organizations heavily rely on vendors. However, to construct their own infrastructure, the issues of who will be responsible for keeping the AI system running and ensuring that physicians can perform their procedures when the system fails, need to be addressed.

ICT infrastructure can also be established ***in collaboration with universities***. Although, there are privacy and security concerns with data transfer outside the healthcare organizations, university-established infrastructure, such as TSD (Services for Sensitive Data, "Tjenester for Sensitive Data" in

Norwegian) from the University of Oslo (100), has emerged as a secured solution and has been utilized by different AI research groups.

National level

In the long term, having ***national facilities and organizations*** is crucial, particularly with regards to data management and cost. It is essential to have national and international data infrastructures for collecting and storing data that are representative for the population when research is conducted in a bigger context, including ethical, legal, and user perspectives, among others. Moreover, having a ***national ICT infrastructure for AI*** is much more cost-effective than multiple ones on the regional or local level. National AI infrastructure is also more sustainable.

5.8 Development and procurement

5.8.1 Development of an in-house AI solution

Development of AI systems is a complex process that must consider clinical needs, existing clinical systems, clinical workflows in practice, and end user experiences, and must be compliant with several regulations. It relies on available data and infrastructure and is driven by professionals with the right competence. In this section, we assume that the described above components for AI implementation (*Knowledge about AI*, *Focus on clinical needs*, *Organization and cooperation*, *Regulations*, *Resources*, *Data*, and *Infrastructure*) are in place.

According to the technology transfer office, it takes on average 8-10 years from the idea to a commercialized product. The process is complicated by all the required documentation and costs for CE marking of a medical device, GDPR and other privacy regulations compliance, further maintenance of the solution which requires competence from different areas, in addition to required resources. In addition, before the solution can be introduced to clinical practice, it should be evaluated if it works on the targeted patient group and gives added patient benefit. Therefore, the TTO recommends having a solid ***documentation system*** from the start of the development and a ***plan for*** a) ***gathering valid input data***, b) ***testing*** of the solution, c) ***handling sensitive data***, d) ***implementation of the solution in a clinic***, including CE marking and validation.

Interoperability

Interoperability refers to the ability of different computer systems to readily connect and exchange information with one another without restrictions. EHR systems are set up and filled differently among healthcare organizations. To be used by healthcare professionals, an ***AI system must be implemented in the workflow and an existing clinical system***, such as EHR or PACS. PACS is an electronic system for the digital storage, retrieval, display and transmission of medical images. ***Use of common open standards and APIs***, such as HL7, Smart-on-FHIR, and openEHR embedded into the EHR, improves interoperability, and helps integration of AI systems into clinical workflow. If the system provides the results, for example, analyzed medical images with the heat maps directly in PACS, for the radiologist, it does not take extra time to use the assisting AI system. However, such a drawback of the embedded AI solutions as inability to make changes in the recommendations made by the AI has been mentioned in the interviews.

__Interoperability__ refers to the ability of different computer systems to readily connect and exchange information with one another without restrictions.

Studying and mapping clinical workflows is important to know where AI should be integrated and how it will affect the workflow. Working with healthcare professionals allows understanding of how AI tools will change the way they work. Medical guidelines and working habits should be considered for healthcare professionals to understand the system and not feel overruled by AI. During the validation process, the AI system and the results it will produce must be contextualized within the workflow

it will be implemented. ***User interface*** is also a facilitating factor for integration of AI into the clinical workflow. It needs to be intuitive and easy to use. To increase adaptability and performance, AI systems need to have ***continuous feedback from users***.

Interoperable systems provide sustainability of AI implementation in healthcare.

Generalizability

The ***generalizability*** of an AI system is the ability of the system to adapt properly to new, previously unseen data, drawn from the same distribution as the one used for the system training. It heavily depends on the data: its types, representativeness, and quality. Language is particularly difficult to generalize since it may even differ between healthcare organizations or even doctors within the same healthcare organization. Medical images are more generalizable because they are standardized across the globe. They are also easier to validate because healthcare professionals can evaluate the images and directly validate the decision of AI system. From the interviews, we know several examples of generalizable solutions: the DoMore! project, which has validated their solution across seven countries and 107 hospitals, scoping images of polyps in the colon generalizable across different ethnic groups, and the Unifractal, which identifies medical equipment. Even though many imaging systems are more generalizable and less dependent on ethnic groups and context, there may be challenges within the same country because of different equipment and protocols being executed differently.

__Generalizability__ of the AI system is the ability of the system to adapt properly to new unseen data.

Generalizability differs from use case to use case. AI systems should be validated, tested, and adjusted within the context they are to be implemented. A solution should be trained on the ***data that is representative for the patient group it will inference***. In Europe, there are legal barriers for moving data across borders which halters creation of multinational data sets. Denmark is solving this challenge by moving the AI algorithm across borders to train on more data and increase robustness. In addition to representative data, generalizability depends on ***competence and necessary understanding of data for its proper evaluation and validation***. Medical domain experts are much needed in this effort.

Further, the ability to use an AI solution in new environments depends heavily on underlying data structures and principles. ***APIs, open standards, and international models*** are tools to aid generalizability of AI across borders or healthcare organizations. Some AI solutions must be retrained, and ***data standardization*** makes retraining easier. Efforts must be made to standardize health data according to international standards.

Every country and every system have its own data and protocols. Even slight differences in characteristics of the data can affect the outcome of the system. Data structures affect generalizability of AI solutions. The lack of standardized data sets leads to AI systems that only work where they are trained. Health demographics vary regionally, and representative data is needed.

Privacy-preserving regulations can also affect generalizability of AI systems since data transfer across regions or countries is limited nowadays. ***Networks of healthcare organizations or other collaborative arrangements where AI systems could be cross validated*** in a sufficient way will improve the generalizability of AI.

Generalizability is intricately connected to discrimination. If we use AI systems on patients poorly represented in the training and validation data, we are at risk of making dangerous, wrong, or unfair clinical decisions. Some subgroups are harder to diagnose. It is, for example, difficult to get good-quality images of obese patients' arteries.

Interpretability

Interpretability of an AI solution is important. From a technical point of view, it is a compromise as we can get higher accuracy with systems that are less interpretable. However, healthcare professionals must grasp how an AI system performs and what information it utilizes to solve problems.

The importance of transparency depends on the area of AI application. While AI applications working with EHR text require a direct linkage to the document where a specific finding is reported, little interpreted medical image analysis is more likely to be tolerated. There is a higher tolerance for lack of transparency in time-critical situations, when a large amount of data is accessible, or when there is a lack of knowledge. Healthcare professionals are comfortable with these scenarios since they know the AI tool provides useful outcomes via validation and quality control. Furthermore, there is a lot of emphasis on clinical evidence in the medical area, and it is not always required to comprehend how a medicine works: for example, if studies, especially RCTs (Randomized Controlled Trials), show that treatment has beneficial effects, the drug will be used even if it is not completely understood.

AI systems should provide confidence of the outcome and inform if the prediction cannot be trusted. It is also critical for AI systems to have reproducible and reliable results. A reliable AI system functions correctly across a variety of settings and inputs, which is imperative for analysis of the system to prevent unintended harms. Reproducibility of the results implies the AI system provides the same results when repeated under the same conditions. ***Use of interpretable AI algorithms*** (such as decision trees, linear and logistic regressions) can help uncover already present bias in the population, and when known, it can be improved and adjusted. The science of machine learning, especially deep learning, is currently being developed to solve the problem of interpretability. However, the existence of unknown biases is essential to have in mind while designing, testing, and validating AI systems. ***Data visualization and interactive user interfaces*** are good tools to increase the interpretability of AI systems. For example, if the results of AI models are placed on top of the original images, users can understand where the systems suggestions come from.

5.8.2 Procurement of a commercial AI solution

Healthcare organizations can choose to buy an AI system or develop it. In any case, according to MDR, the ***system must meet the requirements for safety and performance for medical equipment***. It is a vendor who is responsible for documenting that the product works as intended. The buyer must decide whether the product fits the population.

Local level

A healthcare organization must ***safeguard the trust between patient and health personnel*** through controlling the quality of training data, methods used in development of the AI system, its performance, and explainability. These points must be demanded at procurement (64).

Adapting commercial products to healthcare organizations is not easy. It is hard from a clinical perspective to know how generalizable AI algorithms are, what data has been used for their training, how representative it is for the patients whose data they will be used on, as well as the ethical aspects related to data gathering. In addition, the results published by companies only show good performances of the products. Solutions imported to Norway must be validated and may have to be adjusted to the local population. If ***re-training*** is necessary, this can be done in cooperation with the vendor of the solution (17). One approach here can be to ***implement static algorithms*** and then ***train*** them ***on local data*** after having some experience from the first step. A ***validation process*** is needed to evaluate how the AI system performs on local data. It must be considered that even ***minor changes*** in input data may ***affect performance*** (64).

National level

The benefits from implementing AI technologies are exciting. However, deciding whether a specific AI solution is right for the healthcare organization can be difficult. Broad knowledge and competence are required to understand differences between similar technologies and ensure the chosen one is

safe and effective. There should be a ***streamlined process for public procurement*** that is ***understandable***, ***coordinated, and effective*** for healthcare organizations (75). Implementers want to have clarification on which assessments are necessary and whether they should be done at a local or national level (67). As a support in this process, NHSX, a UK Government unit responsible for setting national policy and developing best practice for National Health Service (NHS) technology, digitalization and data, including data sharing and transparency, has published a guide. "A Buyer's Guide to AI in Health and Care" (65) outlines ten questions to consider in the procurement process. This guide is a good starting point for healthcare organizations acquiring AI solutions.

It is reported that the vendor that has built the AI system together with the healthcare organization can be excluded from the validation and procurement process. Herewith, there is a need for both healthcare professionals and implementers to work together. Therefore, an ***adjustment of the procurement regulation*** to promote this kind of collaboration must be considered.

Cooperated procurements for several healthcare organizations and ***national procurements*** should be considered ***as a part of national plans*** to elevate certain fields through technology (58). ***Competence networks*** (such as the Norwegian Network for AI in Healthcare (KIN)) and ***cross-sectoral guidance service*** can be utilized to clarify which assessments are necessary for procurement projects and whether those should be done at a local or national level. Sykehusinnkjøp HF (97), which is one of Norway's largest procurement organizations for the specialist healthcare service, can also contribute to competence raise required for the procurement process (58, 67, 75).

5.9 Implementation (deployment)

5.9.1 Validation

Local level

Testing and validation are the last important steps in implementation of AI solutions. They must ***include all components of the system*** and ***be performed with the diverse group of expertise*** (55). In most of the interviews, healthcare professionals have expressed the need for clinical evidence beyond the performance testing of AI systems.

Both in-house developed AI solutions and purchased ones require validation. Early validation prevents healthcare providers from spending time and cost on solutions with unknown effect in clinical use (64). It will be efficient to ***use common validation guidelines*** for AI solutions which help implementers to master these processes. There should be a structured, well-defined procedure for validation that will become routine for healthcare organizations (56). While supervision of black boxes has been reported to require advanced technical competence and may be outsourced (71), the interview results show healthcare professionals are more concerned about building evidence on the positive effect of the AI implementation more than understanding the internals of it.

While CE marking is required for all medical equipment in the EU, it is not a guarantee for the high performance of the AI system in clinical settings or its successful adoption to the clinical workflow. For this reason, having ***evidence of the performance of a solution*** is needed. Evidence on the positive cost-benefit ratio of the AI system is considered the primary requirement before allocation significant resources to AI implementation. To that end, each new AI implementation ***requires clinical studies assessing its benefits*** (prospective or retrospective studies or RCTs). It is highly beneficial to have ***common guidelines on how to perform*** these ***studies*** for Norwegian healthcare organizations. These guidelines should also recommend the best strategies for such studies. For example, it could be faster to design a prospective study and get patient consents to test a new CE marked AI solution in medical imaging than retrieve data for a retrospective study. Norwegian health data can be used in retrospective studies to document the performance and safety of medical equipment (67).

We should emphasize ***providing the capacity for performing validation studies*** in healthcare organizations. In validation, special attention should be paid to quality of the training data, methods used in development, and explainability of the AI system (64). It is also useful to consider further health technology assessments. The risk class of the AI solution defines the scope of assessment (67). ***Re-use of assessments*** for a certain AI solution, used ***data sets, and applied methods*** can make implementation easier. AI products should prove robustness against population biases (when results are dependent on race, gender, etc.) and minimize the risk of discrimination. The ***evaluation*** is needed to assess the effect ***of the inclusion of AI models into the clinical workflow***.

National level

Performance of multicenter cross-validation of AI products promotes generalizability of AI systems. It is also suggested to have a ***national AI validation platform*** with the ICT infrastructure and environment equivalent to the settings in healthcare organizations. The National Health Data Hub, suggested earlier in *Data*, could oversee and safeguard a ***national validation data set*** where all healthcare organizations donor their health data. Creation of a national validation platform for AI with benchmarking data will make it possible for even smaller healthcare providers to evaluate AI solutions.

Testbeds are essential for researchers to use actual operational data to model and run experiments on real-world systems (63, 69, 81). Rural areas may be selected as testbeds, which in turn will influence the distribution of access to high quality healthcare (98).

Competence and guidance on whether a product can be implemented safely should be provided to clarify which assessments should be done locally and nationally (67, 81). The Danish government is setting up performance contracts with seven Approved Technological Service (“Godkendt Teknologisk Service” in Danish) institutes for ***building knowledge about upcoming technologies***, including AI, and ***development of technological competencies and services*** for Danish companies (68).

5.9.2 Maintenance

Implementation is not finished when the AI system is successfully validated and is ready to be taken into clinical practice. Maintenance of the system is an important, continuous part of the process.

Local level

AI will not replace humans. This is important to be aware of beyond a pilot phase of the AI solution to its maintenance. ***Continuous training and performance evaluation*** of the AI system are tasks that ***require involvement of domain specialists*** (56). Healthcare organizations should be ***clear about their responsibilities and capabilities*** in relation to operation and maintenance (65). There is a need for a ***spin-off*** or a separate ***private company for maintenance and user support of the in-house developed system***. They will continuously monitor the AI system performance in the clinical use to be ready to stop its usage in case of a risk to patients’ safety or privacy because of low performance. In the case with a commercial AI system, a vendor will play this role. A ***contract with a vendor*** should contain the level of the provided service, the approach to data storage and system updates, the plan for product support in case of failures, and the plan for addressing performance drift (65).

6 Call for action

Norway has several prerequisites for successful AI implementation in healthcare sector: several big health data registries with data collected for many decades, high availability of IT specialists, and competence research groups within the area. Nevertheless, broad adoption of AI implementations requires several actions on the national level to be taken.

6.1 Knowledge about AI

To increase knowledge about AI and trust in AI systems, we need to raise awareness about AI potentials and limitations of both healthcare professionals and patients. The following actions are recommended on the national level:

- *Include AI in curriculum of medical students and establish dedicated AI courses for healthcare professionals*
- *Establish a national competence service for all levels of healthcare, offering AI foundations to all healthcare employees*
- *Promote knowledge about AI among citizens through different activities*

6.2 Focus on clinical needs and consider patient perspective

Healthcare professionals are more positive towards AI if they feel they are being heard and their professional considerations are taken seriously. Implementation of AI in healthcare must be based on clinical needs, investigate the clinical workflow an AI system will be a part of and analyze how AI will change it. It is also important to include patient representatives in the implementation process and provide easy information about usage of AI in treatment, its risks and benefits. We recommend the following actions to be taken with this regard on the local level:

- *Focus on clinical needs and consider the changes in the clinical workflow while AI development*
- *Extensively involve healthcare professionals from the start of the implementation process*
- *Include patient representatives*

6.3 Organization and cooperation

It is difficult to underestimate the importance of having good cooperation both inside and outside healthcare organizations for AI implementation. On the local level, we advise

- *Build a multidisciplinary team of data scientists, technicians, and clinical domain experts in cooperation with an administrative part and juridical support*
- *Organize an iterative development and communication processes*
- *Achieve mutual understanding and strategic support from the management of a healthcare organization*
- *Exploit innovation offices to support regulatory compliance, licensing agreements, project planning, and commercialization*

Healthcare organizations are waiting for a defined process for AI implementation. Cross-disciplinary and cross-sectoral cooperation is required for knowledge and experience sharing, comprehensive understanding of needs and challenges in AI implementation, and coordinated work to overcome those. Therefore, on the national level, we propose the following actions:

- *Unify the implementation process in healthcare and publish a guideline on implementation*
- *Strengthen cooperation between healthcare organizations*
- *Promote and support cross-disciplinary and cross-sectoral cooperation through competence networks and digital innovation hubs*

6.4 Regulations

It should be built awareness on the existing ethical and legal framework across all AI implementation stakeholders. There is a need for a harmonized interpretation of the regulations between healthcare organizations, lawyers, and the authorities. This can be achieved by having cooperative groups across academia, private and public sectors for support on regulations within AI and guidance from the authorities. The collaboration between healthcare organizations and vendors of AI solutions is essential both in development and procurement. However, in the procurement process, it is hindered by the regulatory barrier which considers as competitive advantage for vendors to participate at the pre-assessment phase of the tender. To this end, on the national level, it is advisable:

- *Develop unified and concise legislation about secondary use of health data to ease data access routines and allow data sharing between healthcare organizations aligned with the future regulation for the EHDS (European Health Data Space)*
- *Establish cooperative groups across academia, private and public sectors for support on regulations within AI*
- *Adjust the procurement regulations to promote early collaboration between healthcare organizations and vendors of AI solutions*
- *Develop bodies to guide and control how knowledgeable the AI implementers are about the ethical and regulation frameworks*

6.5 Resources

Human resources

AI implementation will influence staffing and maintenance of competence in healthcare organizations. In addition to what has been recommended in the organization and cooperation part, on the local level, we recommend

- *Create cross-disciplinary support teams for implementation and procurement processes with experts in data science, legislation, application processes, and commercial contracts*
- *Facilitate incorporation of data scientists with AI competence in healthcare organizations*
- *Allocate time for the AI competence rise among healthcare professionals*

It is a huge demand for medical specialists now, and it is going to be even higher in the future also because of a growing number of elderly people. To overcome this challenge, educating more medical specialists should be strategically prioritized and include some incentives for students choosing medical specializations as well as the improvement of salaries and working conditions in healthcare

organizations. In addition, the authorities providing guidance and supervision on AI implementation must have relevant competence to facilitate sharing of experiences. To that end, on the national level, we advise

- *Incentivize medical education*
- *Raise AI implementation-related competence in supervising authorities*

Financial resources

To develop and sustain the implementation of upcoming technologies, there must be long-term financial arrangements on the national level. In specific, the following actions are advisable:

- *Establish strategic national investment in implementation of AI in healthcare*
- *Create financial incentives for healthcare organizations to develop and use AI solutions*
- *Create financial incentives to encourage cooperation between industry, academia, and healthcare*
- *Extend R&D funding programs for short-term AI trials*
- *Invest in data quality improvement*

Implementation of AI solutions requires investments in several areas as a joint effort of healthcare organizations, ICT providers, regional health trusts, and private businesses. On the local level, it is recommended

- *Plan for renewing medical technical equipment in healthcare organizations*
- *Invest in ICT infrastructure (both in upgrade of the existing infrastructure and building of a new one for AI exploitation) in collaboration with other actors*
- *Finance regional centers for AI competence in healthcare*

6.6 Data

Availability of high-quality data sets faithfully representative for the population is the cornerstone for development of reliable AI with minimized discrimination risks and improved generalizability. Our findings indicate significant challenges for the AI implementers in data collection. The constraints are related to ethical approval, privacy-preserving, and patient consent. Norway needs a national plan for the development of open anonymized data sets. This will allow implementers accessing data to start their developments without a significant regulatory overload and, at the same time, testing different AI models with Norwegian data to detect potential biases. To support approval and governance of health data sets, it is recommended to develop a National Health Data Hub. The established national data reuse center in the future will play the role of a coordinator for the EHDS when data access and exchange across the European boundaries are requested.

On the national level, the following actions are proposed:

- *Establish a long-term strategy for data access and storage in healthcare*
- *Develop open anonymized data sets*
- *Establish a national program for data anonymization and make anonymized data sets available in the Norwegian Health Data Hub*
- *Establish a national health data reuse center with special competence in law, infrastructure, business, and management processes*

- *Promote improvement of data quality, interoperability, and data governance*

On the local level, it is advisable

- *Improve patient data quality through use of standards and structured data*
- *Use common open standards and APIs, such as HL7, Smart-on-FHIR, and openEHR*
- *Establish regional or local data warehouses shared with universities*

6.7 Infrastructure

Healthcare organizations are willing to actively participate in AI development. To adapt to AI technology, the ICT infrastructure in healthcare organizations should be upgraded. It is needed to build the infrastructure for secure storage of health data and running of AI algorithms with high computational power demands, which is not affordable alone. Therefore, on the local level, we recommend

- *Engage with private sector, regional ICT providers, and innovation funds about financial resources for building ICT infrastructure*
- *Upgrade local ICT infrastructure or establish ICT infrastructure in collaboration with universities*

In the long term, having national facilities and organizations is crucial, particularly with regards to data management and cost. It is essential, sustainable, and more cost-effective to have national and international data infrastructures for collecting and storing data representative for the population. Therefore, on the national level, it is advisable

- *Establish national ICT infrastructure for AI*

6.8 Development and procurement

Both development and procurement of AI systems are complex and time-consuming processes. AI systems need to be as generalizable and interoperable as possible to be reused in clinical settings of different organizations. It is important for healthcare professionals to understand how the algorithm draws its conclusions. To this end, we have the following recommendations on the local level:

- *Study and map the clinical workflow to know where AI should be integrated and how it will affect the workflow*
- *Integrate AI systems directly into the clinical workflow whenever possible*
- *Establish documentation and quality assurance system from the start and throughout the AI implementation process*
- *Incorporate feedback from the healthcare professionals to increase the adaptability and performance of AI systems*
- *Incorporate medical guidelines and working routines into the AI development process for healthcare professionals to understand the system without feeling overruled by AI*
- *Utilize and prioritize AI solutions that have an elevated level of data visualization and intuitive user interfaces*

Use of common open standards and APIs embedded into the EHR improves interoperability and helps integration of AI systems into clinical workflow. In addition, healthcare organizations acquiring AI

products need national guidelines for the procurement and clinical evaluation of AI solutions. These guidelines should harmonize the procurement process across Norway. Therefore, on the national level, it is advised:

- *Unify and emphasize use of standardized data APIs*
- *Continue investment in open data standards and APIs*
- *Develop guidelines for procurement and evaluation of AI systems from the perspective of healthcare professionals*

6.9 Implementation (deployment)

Validation

Testing and validation are important steps in implementation of AI solutions, both in-house developed and commercial ones. Healthcare organizations should emphasize providing the capacity for performing validation studies. To create evidence on the use of AI, there is a need for clinical studies evaluating patient benefits of AI systems. To this end, on the local level, we advise

- *Provide the capacity to perform validation studies*
- *Exploit a diverse group of expertise to validate all components of the system*
- *Perform clinical studies to evaluate effects of AI systems in terms of patient benefits*
- *Evaluate changes AI has brought to a clinical workflow*

Creating a common validation guideline for AI solutions as a structured and well-defined procedure will help healthcare organizations to master this process. Performance of multicenter cross-validation of AI products will promote generalizability of AI systems. A national AI validation platform with the settings equivalent to those used by healthcare organizations and readily available benchmarking data sets would facilitate this. Then even smaller healthcare providers will be able to evaluate AI solutions. It should be also provided competence and guidance on AI product's safety for use in a healthcare setting. Therefore, on the national level, we recommend

- *Create a national guideline for validation of AI systems*
- *Establish a national validation platform with a national validation data set where algorithms could be cross validated in a sufficient way to improve AI's generalizability*
- *Provide competence and guidance on how to assess whether an AI system is safe for implementation in a healthcare organization*

Maintenance

Maintenance of the system is an important, continuous part of the implementation process. It is required to continuously monitor performance of AI systems in clinical use. It is a ground for safe use of the system. You should be ready to stop usage of the system in case of low performance to exclude the risk for the patients' safety and privacy. Healthcare organizations and vendors should be clear about their responsibilities and capabilities in relation to operation and maintenance of an AI system; it should be reflected in the contract. There is a need for a spin-off or a private company for operation and user support of the in-house developed system. In the case with a commercial AI system, a vendor will play this role. To summarize, on the local level, it is advisable

- *Exploit a spin-off/private company for continuous performance monitoring of the AI system in clinical use, its operation, and user support*
- *Clarify all maintenance-related details with a vendor/ private company in a contract*

7 Conclusion

Artificial intelligence (AI) is a popular topic in healthcare, with continuing discussion over the ethical, clinical, and economical benefits and drawbacks of using algorithms to provide patient care. Despite its potential to reveal new insights and ease the way healthcare providers and patients engage with health data, AI may pose significant risks in terms of privacy, ethics, and medical errors. To balance the risks and benefits of AI in healthcare will require a joint effort from technology developers, decision- and policymakers, healthcare providers, and patients.

There are numerous AI research projects in healthcare compared to the amount of AI systems in clinical use. To investigate the challenges and facilitators that impact AI adoption in healthcare settings, we conducted a comprehensive information gathering on national and international health-related data-driven AI implementations. This was accomplished in two steps. First, we performed a scoping review of scientific publications related to recent AI implementations in healthcare. Then, we interviewed forty-six representatives of the AI implementation projects from eleven countries to detail the barriers and facilitators identified in the literature review. The involved projects had various degrees of involvement of researchers, healthcare professionals, and vendors.

The interviews assisted us in determining the current state of AI implementation in healthcare by analyzing the needs and barriers for AI adoption expressed in discussions with the implementers as well as proposed facilitators. We also looked at the CE marking requirements for medical devices containing AI, as well as the applicable regulations and the bodies that provide guidance on them. We pipelined the AI implementation process and gave recommendations to authorities and healthcare organizations to facilitate broad AI adoption in Norwegian healthcare.

The recommendations for AI adoption embrace all the components of the implementation process: 1) increase of knowledge about AI among healthcare professionals and citizens, 2) focus on clinical needs and patient perspectives in the implementation process, 3) importance of cross-disciplinary and cross-sectoral collaboration and the concerted actions, 4) adaptation of regulations to the new technology, 5) allocation of medical and data science resources to AI implementation and improvement of funding opportunities, 6) enhancement of data-related issues, including data quality, access, storage, and exchange, 7) upgrade of current ICT infrastructure, 8) standardization of implementation and procurement procedures and improvement of the development process, and 9) importance of clinical validation before deploying an AI system in the healthcare practice and the system maintenance after its deployment.

The report does not explicitly mention primary healthcare services in terms of AI adoption. However, most of the findings and recommendations are generalizable for primary and secondary healthcare. Moreover, the findings from another report covering the status, opportunities and needs of AI in Norwegian primary health and care services (17) align with the outcomes of our study.

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9 Appendix

9.1 Interview guide

1. *In your experience, what is the status of AI (Artificial Intelligence) implementation in general?*
2. *Did your organization have any experience in the adoption/implementation of AI systems?*
3. *How is the regulatory framework? Nowadays there is a lot of uncertainty in this regard. Has it been clear to 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 you felt knowledgeable on where to ask for support with regards to regulations 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? Was the clinical guideline directly dictated by clinicians? Was it encoded as an AI? Others?*
8. *Do you have 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 (Electronic Health Records))?*
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 derived from your AI system?*
14. *Did you detect barriers or challenges related to the lack of transparency of the AI model? This applies to black boxes that do not provide significant variables for the decision.*
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 (within healthcare) that would benefit from AI that have not been considered so far?*
18. *What was the perception of AI by clinicians? By patients?*
19. *In your opinion, what are the important barriers and facilitators for successful AI implementation?*

20. *If you could choose three actions to be done at a national, regional, or local level to facilitate the use of AI in healthcare, which ones would you choose?*