

Joint AI plan for the safe and effective use of AI in the Norwegian health and care services 2024 - 2025

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Preface

In its letter of allocation for 2024, the Ministry of Health and Care Services (HOD) asked the Directorate of Health (Hdir) to continue the work on facilitating the safe introduction of AI in the health and care services in cooperation with the Medical Products Agency, the Norwegian Board of Health Supervision, the Norwegian Institute of Public Health, the regional health authorities and the Norwegian Association of Local and Regional Authorities (KS) in an appropriate manner. The Directorate of Health will lead this work. The work will promote the greater use of AI solutions that are safe and contribute to providing healthcare services of equal or better quality and help free up time for health professionals. Among other things, the Ministry asks the stakeholders to draw up a joint plan for which measures should be implemented by which stakeholders in 2024 and 2025 to support the needs of municipalities and health authorities. The Ministry asks the Directorate of Health to work with the other stakeholders to submit its proposal for a joint plan by 1 July 2024 [1].

This document has been prepared in response to the assignment of preparing a joint plan for the health and care services.

The plan was drawn up in collaboration with the stakeholders, especially through the former steering group for the AI coordination project and the newly created AI Council. A draft version of the plan was discussed with professionals from the sector at a separate consultation meeting, and businesses in the sector have provided written input. The plan has also been discussed by the Prioritization Committee (NUIT) and the National eHealth Council in the National council model for eHealth. The Directorate of Health is responsible for submitting the plan.

We would particularly like to thank the resource network “Better use of artificial intelligence in the Norwegian health service” (KIN) for its excellent and constructive cooperation during the preparation of the plan.

[1] TB2024-34: Kunstig intelligens i helse- og omsorgstjenesten i <https://www.regjeringen.no/contentassets/d8f63d7d01d64def982cb7c8ce1eeb64/tildelingsbrev-til-helsedirektora>

Summary

The National Health and Coordination Plan 2024-2027 notes that *artificial intelligence (AI) could make a substantial contribution to the sustainable development of our shared health service*. AI can help to automate tasks and improve work processes, which will be essential in addressing future challenges relating to health personnel capacity and service quality.

The Directorate of Health has been tasked with leading the work to facilitate the safe introduction of AI within the health and care services. This will be done in cooperation with the Medical Products Agency, the Norwegian Board of Health Supervision, the Norwegian Institute of Public Health, the regional health authorities and KS.

The overarching goal of the plan is to increase the use of safe and effective AI systems in the health and care services. This will contribute to services that are of equal or better quality and free up time among healthcare professionals. The plan includes both clinical and non-clinical applications, with an emphasis on realising benefits through the effective implementation of AI technology.

The principal direction of the plan:

- **Supporting the needs of the service:** The measures must support the needs of municipalities and health authorities. The involvement of patients and health professionals will be important in selecting relevant AI applications.
- **Medically appropriate, ethical and safe use** will be essential to ensure trust among healthcare professionals and patients. This includes preventing bias in AI systems that could lead to unfair treatment outcomes.
- **Greater use of AI:** The plan emphasises the increased clinical use of AI and risk mitigation measures to ensure safe use. There is also considerable potential for the use of AI in administrative functions, such as documentation and planning.
- **Use of commercial AI products:** The procurement and use of commercial AI products is considered to be a fast-track way to reap benefits in the health service. The plan places less emphasis on research and development concerning AI products.
- **Estimate and realise benefits:** Emphasis is placed on clarifying and highlighting the benefits of using AI, including learning from other sectors and countries.
- **Increased competence:** Increased competence concerning digital transformation and AI is needed among managers, health professionals and citizens alike to gain trust and ensure that AI solutions are used appropriately.
- **European cooperation:** Cooperation within the EU and Nordic countries is important to adapt, contribute to and benefit from experiences and resources.
- **Clear authorities:** From the government's perspective, clear frameworks, common guidelines, guidance, guides, standards and competence are important factors in building trust in the technology.

The structure of the plan is based on the following focus areas and measures for achieving the overall goals:

- **Sector collaboration concerning AI:** Creation of an AI council to provide strategic advice. Arrange thematic seminars to share experiences and clarify needs, measures and responsibilities. Assess the need for changes in areas of responsibility and strengthen European cooperation.
- **Cross-border information pages about AI:** Further develop cross-agency information pages that publish guidance, knowledge summaries and other relevant information.
- **Cross-agency regulatory guidance:** Continue guidance concerning current regulations and prepare for impending EU regulations, such as the AI Regulation and European Health Data Space (EHDS).

- **Framework for the use of AI:** Prepare a report on the quality assurance of AI and engage the healthcare sector in relevant standardisation work. Recommended topics on validation, benefits, funding, access to data and infrastructures, which are discussed and specified in the seminar series.
- **Use of large language models:** Prepare a knowledge base. Risk assessments for the use of large language models. Adapt language models to Norwegian conditions. Recommended topics on the use, development and fine-tuning of large language models, which are discussed and specified in the seminar series.
- **Strengthening AI competence:** Further develop knowledge and competence and prepare a report setting out recommendations aimed at meeting competence needs for digital transformation using AI.

The plan emphasises a flexible approach, where measures are regularly prioritised and initiated based on the needs and strategic goals of the healthcare sector. The measures must support the needs of the primary and specialist healthcare services, ensure the safe and effective use of AI, and realise benefits through competence enhancement and European cooperation. At the same time, the plan must also be sufficiently flexible to enable it to be adapted to the rapid development in technology, new challenges and opportunities that arise during the period covered by the plan.

This joint AI plan for 2024-2025 is a holistic plan aimed at ensuring the safe and effective use of artificial intelligence in the health and care services. Through collaboration, competence development and a clear framework and guidelines for implementation, the plan will help improve service quality, streamline work processes and meet future challenges in the healthcare sector. In addition, greater awareness concerning ethical use and increased European cooperation could help to ensure that the technology is used in a responsible manner that builds trust among health professionals and patients.

Introduction

Background

The National Health and Coordination Plan for 2024-2027 (the Coordination Plan) stresses that AI could make a significant contribution to the sustainable development of our joint health service.

The Coordination Plan states that there is considerable potential for establishing a more appropriate division of tasks and organisation of work processes among the healthcare services [2]. It is noted that tasks must be continually assessed to determine whether they can be performed in other, less personnel-intensive ways, e.g. by using artificial intelligence, automating tasks or altering work processes that were previously carried out manually. It is also anticipated that artificial intelligence and other personnel-saving technology will help us to maintain the quality of services over the coming years, and help to reduce waiting times in areas where it has been put to use.

The Health Personnel Committee's report *Tid for handling* (Time for action) states that the main priority for health policymakers over the coming years should be to develop measures and invest in solutions that result in the lowest possible growth in the number of staff in the health and care services. In this regard, AI can play a key role, a point which is also made in the report. It is also claimed that “*The digital transformation is characterised by the rapid development of new technologies, which are still evolving rapidly and offer major opportunities. Artificial intelligence and personalised medicine are examples of such technologies, which have led to, and can lead to, completely new types of healthcare and ways of working. If this happens, new types of jobs will also be created, along with new types of competence and knowledge needs.*” [3]

Through the so-called *AI billion*, the Government intends to establish up to six new AI research centres in 2025. A number of healthcare environments have taken the initiative to apply, but it is not certain that research centres will be established within the field of health [4].

Through the *National Roadmap for the Healthcare Industry*, the Government aims to promote and strengthen the healthcare industry in Norway. Artificial intelligence can be one of a number of relevant focus areas [5].

The Ministry of Digitalisation has announced that it will publish a digitalisation strategy after the summer holidays in 2024. The Minister of Digitalisation has also signalled that it will cover ambitions relating to the adoption of artificial intelligence, including in the health sector. She also stated that, by 2025, 80 per cent of the public sector will have adopted the use of artificial intelligence (AI) [6].

Digitalisation, including artificial intelligence, is also high on the agenda of the EU, which is developing and implementing policies through strategies such as the EU's *Digital Decade Strategy*, and initiating numerous plans, legislative changes and programmes to support the ambitions of the strategies [7].

About the assignment

In its letter of allocation for 2024, the Ministry of Health and Care Services (HOD) asked the Norwegian Directorate of Health (Hdir) to continue the work to facilitate the safe introduction of AI in the health and

care services in cooperation with the Medical Products Agency, the Norwegian Board of Health Supervision, the Norwegian Institute of Public Health, the regional health authorities and KS in an appropriate manner. The Norwegian Directorate of Health will lead the work [8].

The assignment states that the work must contribute to the greater use of AI solutions that are safe and contribute to healthcare services of equal or better quality and free up time for healthcare professionals.

The Ministry asks the agencies to continue work on the following:

- support and guidance relating to the validation of solutions, to ensure the safe introduction of AI.
- cross-agency guidance and updated information pages, which make it easier for the service and other stakeholders to navigate regulations and guidance.
- assess the risks that large language models introduce and identify measures to ensure that the health and care services have access to language model(s) which are adapted to Norwegian conditions.

Furthermore, the Ministry asks the stakeholders to:

- draw up a joint plan setting out which measures should be implemented by which stakeholders in 2024 and 2025 to support the needs of municipalities and health authorities. The Ministry requests that the Norwegian Directorate of Health, in cooperation with the other stakeholders, submit its proposal for a joint plan by 1 July 2024.
- Reference is made to the national coordination project *Better use of artificial intelligence in the health and care services* and the final report of 15 October 2023 [4].

Relevant assignments for other stakeholders are presented in Appendix 1. Collectively, the AI plan and the overview of other assignments provide a clear overall description of the stakeholders that are responsible for each of the measures.

Concerning recommendations from the final report from the AI coordination project

The health and care services have begun using artificial intelligence. The work of the national coordination project for artificial intelligence (the AI coordination project) showed that close cooperation between the stakeholders in the health and care sector remains essential. This is especially true for strategic topics so that measures and initiatives can be viewed in context. The aim of the collaboration is to ensure that the sector has a shared understanding of opportunities and challenges. Furthermore, the development and use of AI systems will require the entire sector, including government agencies, to regulate, control, set frameworks and quality-assure the use of artificial intelligence in health and care services. It is important that the stakeholders in the public health and care sector cooperate, are informed and have a common understanding so that they can use artificial intelligence safely and effectively.

In its final report in October 2023, the steering committee for the coordination project recommended areas that should be continued and new areas that should be specified [9]. These recommendations form the basis for the work to draw up this plan.

Concerning the joint AI plan for the health and care services

The steering committee in the AI coordination project has largely been continued as an AI council for this assignment. A unified AI council stands behind the plan.

The joint AI plan for the safe and effective use of AI in the health and care services (this report) states:

- Continuation of the work to facilitate the safe introduction of AI into the health and care services in collaboration with the other agencies is primarily described as initiated activities in the report.
- Recommendations concerning new activities are based on the recommendations in the final report from the AI coordination project and have been considered and clarified in a dialogue with the stakeholders involved.

The introduction and development of AI-based services is happening very quickly. It has thus been necessary to adopt a format for the plan which ensures sufficient flexibility and relevance. It is therefore proposed that a number of thematic seminars with broad involvement and a focused agenda be arranged to ensure that the work is relevant and topical.

The joint AI plan has been discussed in a number of rounds with the AI council [10]. The health and care sector discussed and provided input to an early version of the plan at the consultation meeting held on 23 May 2024. During the period from 16 to 31 May, it was also possible for stakeholders to provide written input concerning the same version. The plan has also been presented and discussed within the Prioritization Committee (NUIT) and the National Council for eHealth (which are national forums in the National council model for eHealth [11]).

The recommendations are anchored in the management of the Norwegian Directorate of Health, which is the sender of the plan.

[2] Meld. St. 7 (2019–2020). National Health and Hospital Plan 2020-2023. Ministry of Health and Care Services. <https://www.regjeringen.no/no/dokumenter/meld.-st.-7-20192020/id2678667>

[3] Norwegian Official Report (NoU) 2023: 4. Tid for handling.
<https://www.regjeringen.no/contentassets/337fef958f2148bebd326f0749a1213d/no/pdfs/nou202320230004>

[4] <https://www.forskningsradet.no/forskningspolitikk-strategi/ltp/kunstig-intelligens/>

[5] Veikart Helsenæringen (Ministry of Trade, Industry and Fisheries and Ministry of Health and Care Services):
https://www.regjeringen.no/contentassets/bb72ac44ee7a4ee1b8bb95a7b48210c8/no/pdfs/veikart_helsenae

[6]
https://www.nrk.no/norge/regjeringen-vil-at-80-prosent-av-offentlig-sektor-bruker-ki_-_-urealistisk_-mener-ki

[7] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age_en

[8] TB2024-34: Kunstig intelligens i helse- og omsorgstjenesten i
<https://www.regjeringen.no/contentassets/d8f63d7d01d64def982cb7c8ce1eeb64/tildelingsbrev-til-helsedirek>

[9]
<https://www.helsedirektoratet.no/rapporter/status-og-forslag-til-videre-arbeid-med-kunstig-intelligens-ki-i-hel>

[10] [Kunstig intelligens](#)

Goals for the plan

Collectively, the tasks entailed in the joint AI plan for the health and care services will help to achieve the goal of increasing the use of AI solutions that are safe and sustainable, contributing to health and care services of equal or better quality, streamlining resource use, and freeing up time for health professionals [12].

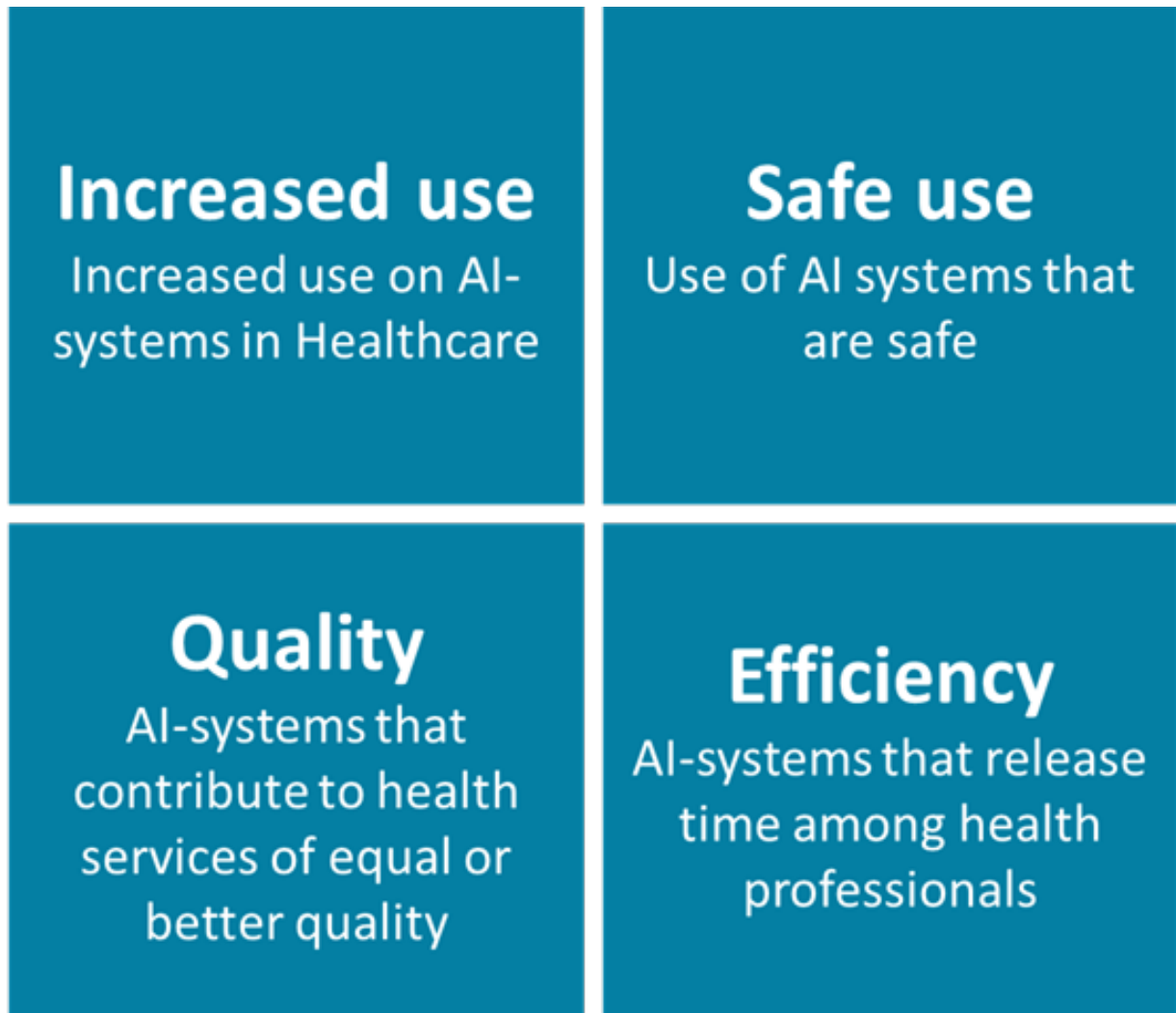


Figure 1: Goals for the joint AI plan

[12] TB2024-34: Artificial intelligence in the health and care service

The overall direction of the plan

Based on input from the sector, meetings with Prioritization Committee (NUIT) and the National Council for eHealth (in the National council model for eHealth) and the work of the AI Council, the following main direction is recommended for the joint AI plan for 2024-2025:

Support the needs of the primary and specialist healthcare service

The measures in the plan must *support the needs of municipalities and health authorities*. Involving patients and healthcare professionals in the development and implementation of AI solutions will help to ensure that relevant areas are selected for the use of AI.

Medically appropriate, ethical and safe use

The medically appropriate, ethical and safe use of artificial intelligence (AI) in the health and care services will be critical in ensuring trust in the use of AI among those who work in the health and care service and among citizens, patients and next of kin. AI has the potential to significantly improve healthcare, yet the failure or misuse of AI technologies could have grave consequences for patient health and safety. Ethical use will ensure that the technologies are used in a way that protects the rights and welfare of patients. It will for example be important to detect and prevent bias in AI systems. Algorithms can unintentionally learn and reinforce existing instances of bias from the data they are trained on, which in turn can lead to unfair treatment outcomes for certain groups of patients. The medically appropriate, ethical and safe use of AI is also necessary to promote innovation responsibly.

Greater use of AI

The AI plan emphasises measures that could facilitate the introduction of and increase clinical AI use. Clinical AI use is often associated with risks and will therefore necessitate risk mitigation measures to ensure safe use.

However, there is considerable potential as regards the use of AI to perform administrative functions. Examples of this include documentation, reporting, rota planning, help with text summarisation and generation, planning and logistics. Such low-risk applications can offer substantial benefits and can often be implemented quickly. Consideration must also be given to such AI use and relevant initiatives launched to help overcome many of the challenges that exist in the health and care services.

To bring about the widespread use of AI in the healthcare sector, we must recognise that the mechanisms of adoption will differ depending on the context and application. Unlike smaller clinics and municipal services, large hospitals often have better access to resources and advanced infrastructure. It is important to develop tailored procedures for implementation that address these differences, and ensure that all healthcare services have access to the necessary support and guidance.

Use of commercial AI products

Procurement and the adoption of commercial AI products are assumed to be the fastest way of deploying and extracting AI benefits in the healthcare service. Norway has also set out its ambitions to research AI and develop commercial AI products for the healthcare sector. This plan will place less emphasis on research and development of AI products.

Calculate and realise gains

The health and care services must be able to calculate and realise benefits. Emphasis is placed on measures that clarify and highlight gains, for example by facilitating learning from others, including other social sectors and other countries.

Increase competence

Increased competence concerning digital transformation using AI is an important prerequisite for achieving the necessary trust and adopting the most appropriate solutions. This applies to managers, employees in the health and care services, and citizens and patients.

European cooperation

The EU already has significant guidelines in place concerning AI through its strategies, legislation, programs and funding programmes. Facilitating European and Nordic cooperation will be important in enabling Norwegian environments to adapt, contribute to relevant work, and benefit from experiences and resources in the EU and the Nordic countries.

Clear authorities

From the government's perspective, clear frameworks, common guidelines, guidance, guides, standards and expertise will be important in building trust and facilitating the safe and effective use of AI in the health and care services.

How the plan is laid out

The health and care services have already adopted AI and are committed to broadening and scaling successful use. Start-ups and other commercial companies are constantly launching products that use AI to, for example, streamline the daily work of healthcare professionals. More AI solutions are also becoming available, increasingly enabling citizens, patients and relatives to handle health-related questions and tasks themselves, where appropriate in collaboration with the health and care services.

Due to this dynamic, where both the field of AI and the use of AI are developing rapidly, the implementation of the joint AI plan should adopt an agile approach so that it remains both relevant and flexible. Activities will be regularly prioritised and initiated, based on recommended topics and areas outlined in this report, while new topics can be prioritised in line with new or changing needs. This will necessitate considerable flexibility on the part of the participants in the plan.

Such an agile approach will be challenging to achieve with the existing organisation and decision-making processes in the health and care sector. Some measures may be implemented in an agile manner, for example in the form of line activities with the relevant stakeholders, where resource allocation is carried out internally. Larger initiatives will need to follow existing prioritisation and decision-making processes, and will thus take longer to start up and allocate resources to.

The prioritisation of new activities can be discussed within the AI Council and, where appropriate, in the National council model for eHealth.

The areas covered by the plan have one of the following statuses:

- **Initiated** is a subproject or management task that has been resourced by the participating organisation(s).
- **Prioritised** is a subproject or management task that currently has the highest priority and should be initiated.
- **Recommended** is a subproject or management task that is recommended, but not currently a priority.

The plan as it appears as of 1 July 2024

Initiated

Framework for quality assurance

Table 1: Overview of initiated activities (stakeholder responsible indicated in bold) [13]

Area/topic		Delivery	Time	Collaboration
Sector collaboration	AI Council for the health and care sector	Four to six meetings annually	2024 – 2025	Hdir , Htil, FHI, DSA, HSØ, HMN, HN, HV, KS. The KIN network acts as an observer. DMP participates depending on the agenda.
	Develop a cross-agency information page on AI	Further development	2024 - 2025	Hdir , DMP, Htil, FHI and DSA
Cross-agency regulatory guidance	Guidance concerning current regulations	Operate the guidance service	2024 - 2025	Hdir , DMP, Htil and DSA contribute on request
	Prepare for future regulations	Articles and other information about the AI Act	2024 - 2025	Hdir , in dialogue with DigDir, the Norwegian Data Protection Authority, Htil and DMP as and when necessary
Frameworks for use	Framework for quality assurance	Report on quality assurance of AI in the health and care services	October 2024	Hdir , in collaboration with a user panel: Htil, Sykehuspartner, HSØ, as well as a broadly composed user panel. DMP quality-assures the work within its remit
	Engage the healthcare sector in relevant standardisation work for AI	Participate in, mobilise and share information about relevant AI standardisation work	2024 - 2025	Hdir , Ahus, KS, DNV, Sykehuspartner, NIPH (Cancer Registry Norway), Norwegian Public Service Pension Fund, DigDir and Standards Norway
	Prepare knowledge base about large language models	Knowledge base	May 2024	Hdir , with input from environments in the sector and professional environments working on large language models
	Assessment of risks associated with the use of	Report to HOD	December 2024	Hdir , with input Professional and R&D environment within AI and language technology (including NB), central administrative

Use of large language models	large language models			bodies (including DigDir and the Norwegian Data Protection Authority), the health and care services and the business sector.
	Facilitate the use of language models adapted to Norwegian conditions	Report to HOD	December 2024	Hdir , with input Professional and R&D environment within AI and language technology (including NB), central administrative bodies (including DigDir and the Norwegian Data Protection Authority), the health and care services and the business sector.
Enhance competence	Further develop knowledge and competence concerning artificial intelligence among government agencies	Continue to build and share competence in the government agencies	2024 - 2025	Hdir , Htil, FHI, DMP and DSA.
	Prepare a report with recommendations to meet competence needs for digital transformation with AI	Report	October 2025	Hdir , in a broad dialogue, both cross-sectorally and with competence environments

Prioritised

Table 2: Overview of prioritised activities (stakeholder responsible indicated in bold)

Area/topic		Delivery	Time	Current cooperation
Sector collaboration	Seminar series concerning the integrated use of AI in the health and care services	Four to six seminars, based on recommended topics: validation and use, benefit potential and realisation, barriers and funding requirements, access to data and infrastructures for training, fine-tuning and validating AI models, competence concerning use, development	2024 - 2025	Hdir , in cooperation with relevant stakeholders in the health and care sector, R&D stakeholders and

		and fine-tuning of large language models, applications for large language models	cross-sectorally - depending on the topic
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Recommended, not yet prioritised

Table 3. Overview of recommended activities

Area/topic		Time	Current cooperation
Strengthen competence	Assess recommendations from the report on competence concerning digital transformation with AI	Assessed Q4 2024	Specified for each recommended measure in the report.
Sector collaboration	Clarify roles relating to AI use in the health and care services	Assessed Q1 2025	Probably Hdir, the regional health authorities (RHF), KS, health and care services, Htil, NIPH, DSA and DMP.
	Strengthen European cooperation	Assessed Q1 2025	Probably Hdir, RHF, KS, DigDir, NFR.
Frameworks for use	From research and development to use and possible commercialisation	Assessed Q1 2025	The technology transfer offices (TTO) at the universities, R&D stakeholders, including the health clusters, Hdir, the health and care services, DMP.
	Further develop health technology assessments	Assessed Q1 2025	DMP, the regional health authorities, FHI, Hdir.

[13] Abbreviations: The Norwegian Directorate of Health (Hdir), the Norwegian Board of Health Supervision (Htil), the Medical Products Agency (DMP), the Norwegian Institute of Public Health (NIPH), the Norwegian Radiation and Nuclear Safety Authority (DSA), South-Eastern Norway Regional Health Authority (HSØ), the Central Norway Regional Health Authority (HMN), the Northern Norway Regional Health Authority (HN), the Western Norway Regional Health Authority (HV), the Norwegian Association of Local and Regional Authorities (KS), Kunstig intelligens i norsk helsetjeneste (National network for artificial intelligence - KIN), the Norwegian Digitalisation Agency (DigDir), Akershus University Hospital (Ahus), Det Norske Veritas (DNV), National Library of Norway (NB)

Inputs and discussions about the plan

Summarised input from the health and care sector

The sector provided input to an early version of the joint AI plan at a consultation meeting held on 23 May. It has also provided written input on the same version.

The consultation meeting held on 23 May

More than 130 participants from a broad cross-section of the health and care sector physically attended the consultation meeting held on 23 May to discuss the plan, along with more than 140 digital participants [14]. During the meeting, participants were specifically asked to provide input on the chapters concerning the Use of large language models (5), Boosting competence concerning AI (6), and the Framework for the use of AI (4) in the health and care services.

In summary, the following input was provided:

The use of language models must include risk assessments, which are tailored to their respective applications. It was recommended that “low-hanging fruit be picked first”. It is important to facilitate use under the conditions in Norway and the Norwegian health service. The groups also pointed out that language models can have a wide variety of uses, with varying degrees of complexity and risk. A forum should be established for sharing experiences. The appropriate use of language models requires sufficient competence, and this must be incorporated into the health service, health courses and health management courses.

Competence relating to AI in the field of health includes competence among managers, employees in the health service and population-oriented measures. Competence must be linked to relevant applications, and preferably to cost/benefit assessments. Multidisciplinarity is important. It is often better to start with simpler tasks, build on them, and then gradually develop the complexity. Competence needs will change continuously as a result of the development or implementation of innovative solutions.

Framework for the use of AI in the health and care services. In this area, the exchange of experience should be facilitated nationally, regionally and locally – as well as cross-sectorally. A number of suggestions have been put forward to address the “low-hanging fruit first”, with a particular focus on what happens after an AI system has been adopted. Reference was also made to an urgent need for (national) coordination concerning standards, infrastructure, access to data and various types of data, rights and validation. There are many challenges ahead, so prioritisation will be necessary. There was also input on looking at the assessment and realisation of benefit potential and funding solutions.

Written input from the sector

The sector has provided 20 written contributions to the plan (deadline 31 May). A number of these overlap with the feedback from Prioritization Committee (NUIT) and the consultation meeting. Among other things, this includes the need for funding, arenas for collaboration and the exchange of experience, the differences between performing administrative and clinical tasks, and procurement and inhouse-development.

The importance of involving users of the solutions through development and implementation processes was noted by a number of stakeholders. This includes both patient and employee perceptions and experiences. It was explicitly noted that employees must be involved in selecting the work processes that are to be supported by AI, and in the trial, testing and validation of AI tools. Very specific proposals were also put forward involving the regional health authorities.

Summary input from the meeting of the National council model for eHealth

The same focus areas as above were discussed by the National Forum for Prioritisation (NUIT) and the National Council for eHealth, which is part of the National council model for eHealth [15].

Input from the Prioritization Committee (NUIT)

An early version of the plan was considered by NUIT on 15 May 2024.

NUIT generally supports the proposed initiative areas but believes that they are not sufficient in themselves. It was pointed out that a somewhat more offensive approach could be adopted to identify more appropriate applications and new opportunities. At the same time, the need to prioritise and sharpen the focus was highlighted, often linked to the assignments that were given. It was also stated that there are many legal challenges associated with the use of AI in clinical practice. It was therefore proposed that a closer look be taken at the use of AI for administrative tasks, a step that would also free up time for health personnel. There is a strong need to further develop the established guidance service. The need for close user involvement from citizens and patient associations was underlined. More healthcare technology solutions have AI built-in. Many municipalities are small and common approaches to benefits, risks, procurement, etc. will therefore be important. In this regard, established experiential structures, such as the Digi networks, can play a role. Finally, it was noted that AI must not be used at the expense of essential medical prudence, testing, validation, etc.

Input from the National Council for eHealth

An early version of the plan was presented and discussed at the meeting of the National Council for eHealth held on 13 June 2024.

Areas such as ethics, risk, privacy, training and the implementation of AI in the healthcare sector were highlighted as being of importance by many of those present. One challenge highlighted by several participants relates to the need to clarify the uncertainties surrounding AI and the importance of establishing a safe framework for the introduction and use of AI. This may help to maintain the trust of the population, especially among children and young people, who are concerned about their privacy. It was emphasised that ethical questions must be handled properly.

The need to conduct risk analyses and provide guidance services was highlighted as a pressing matter. It was also highlighted that measures aimed at the general population will be important in addressing the knowledge gap concerning AI. Digital security was mentioned as an area that creates uncertainty and should have been discussed more.

Some advocated the need to develop a Norwegian language model that is tailored to the health and care sector. Training citizens, employees and managers on AI was also considered necessary. Research and risk analyses are essential to ensure that AI solutions are of sufficiently high quality. A health technology assessment at the national level was sought to ensure a solid knowledge base, and it was pointed out that a standardised method is needed for the approval of AI.

Overall, meeting delegates reflected on the ethical aspects, risks and privacy challenges associated with AI, with a strong need for clear policies, legislation, and guidance to ensure the safe use of AI in the healthcare sector. Collaboration across sectors and the establishment of robust language models were considered to be essential for the effective and safe implementation of AI technology.

[14] [Consultation meeting in connection with the joint AI plan for the Norwegian health and care services - The Norwegian Directorate of Health](#)

[15] [Nasjonal rådsmodell for e-helse](#)

Definitions used in the plan

AI system: There are many definitions of artificial intelligence. We have opted to use the definition given in the European AI Regulation: “‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments” [16].

AI model: The term ‘AI model’ is used to refer to software that has been developed with the aid of training on large data sets to learn what are often complex patterns and relations. After this training, the model can generalise and perform predictions or classifications on new, unknown data. An AI model will normally be a component of an AI system. An AI model is also sometimes called an algorithm (which is somewhat imprecise, as all computer programs are algorithms) or a machine learning model.

Quality assurance: Quality assurance consists of planned and systematic activities that are carried out to ensure that a product or service will meet quality requirements. Quality assurance is part of an organisation’s quality management [17]. Before an AI model can be adopted, it must undergo quality assurance, which involves validation, among other things.

Validation: In this report, validation is used to confirm that the AI model performs as intended for a specific intended purpose [18]. If an AI model is intended to diagnose fractures on an X-ray image of a bone, this is precisely what the AI model should be validated for. When validating AI models, it is therefore important that the “intended purpose” is clearly defined.

Generative artificial intelligence: Machine learning models that can generate unique content based on the information they have been trained on. This content could consist of text, images, audio and video. Although the results are often impressive, the systems are not creative in the human sense. Examples include ChatGPT and Bard, which generate text, and Dall-E and Midjourney, which generate images [19].

Fine-tuning is a technique where a pre-trained language model is further trained on a narrower or task-specific data set to perform a particular task, or to adapt it to an environment with specific professional language. This could, for example, involve training the model on judgments to summarise case law and provide legal advice, or on health data to identify patterns in health records or make diagnoses [20].

Continuous machine learning: Continuous learning is closer to how people learn: Every time we experience, see or learn something new, we adapt the models we use to interpret the world around us. Several techniques are available to ensure that machine learning models can continually learn from new data. The first of these is to include the new data in the training data set, rerun the entire learning algorithm, and update the model that is being used. This is not a problem with small data sets, but with today’s large data volumes, it can require considerable computing capacity, costing time, money and energy. Other methods entail using the new data to adjust the existing model. Although this is much easier, it has in some cases resulted in the new data gaining a disproportionate amount of weight, with the result that the model “forgets” things it had actually already learned [21].

Bias arises when the data sets that are used to train artificially intelligent systems are affected by historical biases, contain errors or are incomplete. This can result in systematic errors in the model’s predictions [22].

[16] Article 3.1 of the AI Act: <https://data.consilium.europa.eu/doc/document/PE-24-2024-INIT/en/pdf>

[17] <https://snl.no/kvalitetssikring>

[18] In the standard ISO 9000:2015 “Quality Management System - Fundamentals and vocabulary”, “validation” is defined as follows: “Confirmation, through the provision of objective evidence, that the

requirements for a specific intended use or application have been fulfilled”:

<https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-4:v1:en>

[19] <https://teknologiradet.no/ordliste-for-kunstig-intelligens/>

[20] <https://teknologiradet.no/ordliste-for-kunstig-intelligens/>

[21] Taken from page 64 here:

<https://media.wpd.digital/teknologiradet/uploads/2022/02/Kunstig-intelligens-i-klinikken.pdf>

[22] <https://teknologiradet.no/ordliste-for-kunstig-intelligens/>

Sector collaboration concerning AI

This chapter describes focus areas that support collaboration in the health and care sector so that the health and care services can accelerate the adoption of AI and then extract the benefits of adopting AI.

An AI Council has been set up. A series of seminars will be launched at which stakeholders in the sector will be able to work together and share experiences and input and clarify needs and possible measures, in line with the rapid development and use of AI. It is also recommended that an assessment be carried out to determine whether there is a need to make changes to the responsibilities of the government agencies and stakeholders in the health and care services, and to assess whether additional measures should be implemented to increase cooperation with the EU and Nordic countries. The assessments should ideally be carried out after the plan has been in place for some time so that the needs become clearer.

Initiated: AI Advisory board for the health and care sector

Background

The Ministry of Health and Care Services has asked the Norwegian Directorate of Health to continue the work to facilitate the safe introduction of AI in the health and care services in cooperation with the Medical Products Agency, the Norwegian Board of Health Supervision, the Norwegian Institute of Public Health, the regional health authorities and the Norwegian Association of Local and Regional Authorities (KS) in an appropriate manner. The Norwegian Directorate of Health will lead this work.

Section 6.4 of the final report for the coordination project sets out the following recommendations:

- *that cross-agency cooperation concerning AI in the health and care sector continues.*
- *that the Ministry of Health and Care Services clarifies an expectation of continuing cooperation between government agencies within the field of AI.*
- *that an arena be established where the government agencies, regional health authorities, KS and the resource network "Better use of artificial intelligence in Norwegian healthcare services" (KIN) can continue to pursue a dialogue and hold strategic discussions, corresponding to the steering group meetings.*
- *that the cross-agency collaboration projects concerning AI in the health and care sector are considered and followed up in the National council model for eHealth*

Status

- The AI Advisory board has been established.
- Two AI Advisory board meetings have been held, on 8 May and 7 June 2024.

The AI Advisory board will advise the Norwegian Directorate of Health on strategic roadmap choices and fundamental questions and recommend prioritisation and implementation of measures to facilitate the safe and effective introduction of AI in the health and care sector [23]

Plans going forward

- The AI Advisory board will meet four to six times a year.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Norwegian Board of Health Supervision, the Norwegian Institute of Public Health, the Norwegian Radiation and Nuclear Safety Authority (DSA), the South-Eastern Norway Regional Health Authority, the Central Norway Regional Health Authority, Northern Norway Regional Health Authority and KS. The KIN network acts as an observer. The Medical Products Agency (DMP) participates depending on the agenda.

[23] [Mandat for KI-rådet](#)

Prioritised: Series of seminars concerning the integrated use of AI in the health and care services

What is the problem?

In the work on the joint AI plan, representatives from the sector have pointed to numerous challenges, wishes and needs. They have also contributed recommendations that will promote the safe and effective use of AI in the health and care services. For example, a number of stakeholders want to see arenas for the sharing of experiences, the re-use of materials or common methods to scale solutions more effectively.

Proximity to the health and care service will be important to ensure that needs are appropriately addressed and suitable measures implemented. AI-based services are being taken into use and developed at a rapid pace and needs will also change rapidly. Identifying suitable measures will be challenging given the rapid development and introduction of AI.

What do we want to achieve?

The Norwegian Directorate of Health will establish a series of seminars where the health authorities and health and care services work together to consider relevant topics relating to the use of AI. These seminars will facilitate the sharing of experiences, the discussion of needs and possible measures and the

clarification of responsibilities – in line with the rapid development and introduction of AI. The seminars will have broad involvement, with a more focused agenda aimed at the topic concerned, ensuring that the work is both relevant and current.

The topics will initially be chosen based on already identified needs and recommendations described in this report (mainly in Chapters 4 and 5). Possible topics include validation and use, benefit potential and realisation, barriers and funding needs, access to data and infrastructures for training, fine-tuning and validation of AI models, competence concerning use, development and fine-tuning of large language models, and applications for large language models. In addition, new topics can also be introduced, in line with new or changing needs.

How to do it

Around two to three such seminars will be arranged during the six-month period. Where possible, the meetings will take place in various parts of the country. The topic for each seminar will be prioritised by the AI Advisory board.

The target group for each seminar will vary depending on the subject matter. The series of seminars will identify and work with existing networks and meeting places relevant to the topics concerned.

Through the seminars, participants will be able to:

- Share experiences and possible ways of addressing challenges
- Promote and broaden appropriate AI applications
- Obtain specific input on and clarified needs for measures that will be close to the service
- Clarify roles and responsibilities and any need for new roles

After each seminar, an individual report or article will be produced and published on the AI information page. These reports could typically set out the status of the area, summarise experiences and/or identify challenges that must be overcome through national cooperation.

The Norwegian Directorate of Health will be responsible for the series of seminars, and the contributions will largely come from the area of the sector that is relevant to the chosen topic.

At the end of the period covered by the plan, the benefits of the series of seminars will be evaluated, and an assessment carried out to determine whether the series should be continued and possibly adjusted.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The health authorities, regional health authorities, health trusts, KS, municipalities, interest organisations, the health industry and research communities, KIN, NSE – depending on the topic concerned.

Recommended: Clarify roles relating to the use of AI in the health and care services

Background

Section 6.6 of the final report for the coordination project states the following:

A national AI strategy for safe and effective health and care services will help to:

- *clarify tasks, responsibilities and roles for the various stakeholders at the national, regional and local levels, including what constitutes government agency tasks and what must be handled under the auspices of the services.*

The Norwegian Directorate of Health has been tasked with drawing up a joint plan, and not an AI strategy, as recommended in the final report. It is equally important to clarify tasks, roles and responsibilities for safe and efficient health and care services.

Current roles

In the National Health and Coordination Plan for 2024-2027, the Government is concerned about ensuring the safe introduction of artificial intelligence within the area of patient treatment. It stresses that *the service* itself is responsible for quality assurance and validation of solutions, to ensure they are fit for purpose [24].

One valuable tool for ensuring the introduction of safe and effective treatments is health technology assessments (HTAs). From 2024, *the Medical Products Agency* (DMP) has been given overall responsibility for HTAs of medical products. The DMP is already responsible for the management of regulations concerning medical devices. This also includes medical devices in the form of software and artificial intelligence. In the efforts being made to further develop the *New methods* national system in the specialist health service, adaptation for the handling of medical devices is one area of focus [25].

The Norwegian Institute of Public Health's social mission is 1) knowledge: more, better and faster knowledge for health and sustainable services, 2) preparedness: new solutions for protecting life and health, and 3) infrastructure: future health data, laboratories and services [26]. Among other things, *the Norwegian Institute of Public Health* is responsible for mini-HTAs [27].

The Norwegian Board of Health Supervision's task is to help improve the safety and quality of services and promote legal rights and trust. Through supervision, the Norwegian Board of Health Supervision is responsible for monitoring compliance with the fundamental requirement incumbent on the health and care services to provide appropriate services and operate responsibly. The requirement to operate responsibly also applies to patient treatment using medical devices in connection with the provision of health and care services, including devices that include AI [28].

The *Norwegian Directorate of Health* strives to promote health and life skills and acts as a driving force for sustainable, cohesive and equitable health and care services. [The Norwegian Directorate of Health] coordinates the Norwegian health service on a common pathway towards digitalisation [29].

The primary tasks of the regional health authorities are patient treatment, training of health professionals, and research and training of patients and relatives. The regional health authorities have overall responsibility for implementing the national health policy within their region. The regional health authorities

are responsible for planning, organising, managing and coordinating the activities of the health authorities they own. *The role of the health authorities* is to provide high-quality, equitable specialist health services to everyone who needs them, when they need them regardless of their age, gender, residence, financial circumstances or ethnic background, and to facilitate research and teaching [28]

The *Norwegian Association of Local and Regional Authorities (KS)* is the municipal sector's interest organisation and development partner, as well as the country's largest public employer organisation. The development work being carried out by KS is aimed at the municipal sector's need for restructuring, quality improvement and streamlining. KS offers tools and meeting places for municipalities and county councils across a range of disciplines [29].

What is the problem?

Many of the stakeholders in the health sector believe it is unclear what constitutes government agency tasks and what must be handled by the service to ensure the safe and efficient use of AI in the health and care services. It would for example not be efficient if each hospital or GP surgery were to be required to perform the same validations on the same type of AI system, even though certain aspects of the validation process have to be carried out locally. It is unclear what should be done locally, regionally and nationally. It can also be difficult to know whether or not a particular product should be considered a medical device. The processes for carrying out the necessary assessments and approvals are also considered to be inefficient. There is also the question of whether there is anyone who can take overall responsibility for national cooperation - should it be an existing body or should a new one be created?

What do we want to achieve?

It is recommended that an assessment be carried out in early 2025 to determine whether there is a need to initiate a separate measure relating to the clarification of roles, or whether this is already being done through ongoing activities.

The activity should establish a common understanding of roles, clarify the responsibilities of different stakeholders within the health and care sector, and propose changes as and where necessary.

How to do it

The following activities are relevant:

- Clarify the roles through examples, e.g. through the guidance service (section 3.1) or the seminar series (section 4.3).
- A topical issue is effective validation processes: assessing how the validation of an AI product can be carried out effectively from a national perspective. This assessment should include how responsibilities can be distributed between the stakeholders and what needs the various stakeholders have as regards support. This is viewed in the context of the report on the quality assurance of AI in the health and care services (section 4.1) and a possible seminar on validation (section 4.3).

Numerous proposals have been put forward by the sector during the consultation round which could be included in the assessments:

- Establish an approval scheme, e.g. drawing on inspiration from Finland [30]
- Establish an implementation and innovation council for AI in the health services

- The regional health authorities could establish a network between the health trusts to meet the need for competence-sharing and the exchange of experience
- The regional health authorities could draw up an action plan for implementing AI among their own health trusts
- The regional health authorities could establish a dedicated centre of specialist expertise to support efforts to implement AI solutions among the health trusts
- The regional health authorities could work with health trusts to organise and implement targeted continuing education and courses
- The regional health authorities could work with the health trusts to initiate measures to adopt language models to streamline administrative tasks
- Increase regional cooperation between ICT companies across the four regional health authorities concerning the development, implementation and procurement of AI
- Formulate objectives and measures under the auspices of the municipalities, possible cooperation between the municipalities and the regional health authorities

Current collaboration

The Norwegian Directorate of Health, regional health authorities, KS, health and care services, Norwegian Board of Health Supervision, NIPH, DSA and DMP.

[1] <https://www.regjeringen.no/contentassets/4e5d9e6c63d24cd7bdab5d8c58d8adc4/no/pdfs/stm2023202400/>

[2] <https://www.regjeringen.no/contentassets/4e5d9e6c63d24cd7bdab5d8c58d8adc4/no/pdfs/stm2023202400/>

[3] <https://www.fhi.no/om/fhi/org-vision/>

[4] <https://www.minimetodevurdering.no/>

[5] <https://www.helsetilsynet.no/tilsyn/om-tilsynssaker/policy-for-tilsynssaker-i-barnevern-sosial-og-helsetjenest>

[6] [Om Helsedirektoratet](#)

[7] Sections 1 and 2a of the Health Authorities and Health Trusts Act:
<https://lovdata.no/dokument/NL/lov/2001-06-15-93>

[8] <https://www.ks.no/om-ks/hvem-er-vi>

[9] <https://www.inahta.org/members/fincchta/>

Recommended: Strengthen European cooperation

Background

Section 4.5 of the final report for the coordination project states the following:

- *The EU's focus on data and digitalisation is positive. There is a strong need to cooperate internationally, especially with the EU Member States, both because we cannot do everything ourselves and because there is much to learn from other countries' experiences and knowledge.*

What is the problem?

European cooperation can provide access to key expertise, infrastructures, data, funding and collaboration arenas. AI and health are areas of focus within the EU, which means that both competence and capacities/facilities are being built to innovate using AI generally, and within health in particular.

It is difficult to obtain an overview and understand the various initiatives aimed at exploiting the opportunities offered by the EU. This means we are not making sufficient use of the opportunities that the EU offers.

What do we want to achieve?

We want to establish closer links between the government agencies and health and care services and selected initiatives within the EU to learn, share experiences and access capacities/facilities that are being developed and offered in the EU systems.

It should be noted that many of the measures recommended in the joint AI plan will benefit from closer cooperation with the EU, and many of the measures are also designed to draw on and share experiences, competence and capacities/facilities within the EU.

What is happening within the area?

Many of the EU's initiatives are described under other measures in the plan. Here are some EU initiatives and projects that are not covered elsewhere in the plan and may be of relevance to artificial intelligence in the health service.

- The Norwegian Directorate of Health has established a separate programme for participation in EU4Health. Among other things, [the work programme for 2024 \(health.ec.europa.eu\)](https://health.ec.europa.eu) includes a call to promote the use of artificial intelligence in the health service amounting to EUR 4,500,000.
- [EdiHTA](#): is an EU project which seeks to develop a European framework for health technology assessments (HTA). From Norway, NSE, Det norske Veritas and Vestre Viken HF are participating.
- Norway is a full member of the European Committee for Standardization (CEN) and can exert its influence on an equal basis with other member states. Standards Norway (SN) has a national mandate to enable Norwegian stakeholders to exert an influence at the European level.
- The Council of Europe has adopted a [Framework Convention on Artificial Intelligence \(rm.coe.int\)](#) and issued a [guide to the Convention \(rm.coe.int\)](#). The Convention complies with the proposed EU Act. Opens for [signing on 5 September 2024 \(coe.int\)](#)
- The Council of Europe's Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) has prepared a report on how AI affects the doctor-patient relationship. This report will be published shortly; here is [some information about the "preparatory work" for the report and the work of the committee in the field \(coe.int\)](#).

How to do it

The following activities are relevant:

- Assess the need to establish closer European government agency cooperation. This includes considering the possibility of participating in EU projects.
- Consider monitoring selected EU projects more closely by, for example, participating in reference groups and the like.
- Assess whether there is an additional need for someone to monitor key initiatives and calls for applications within the EU and communicate important information, so that the healthcare sector can access (part-)financing and competence in relevant areas.

Current collaboration

The Norwegian Directorate of Health, the health industry, regional health authorities, the Norwegian Digitalisation Agency, the Research Council of Norway and others.

Cross-agency information page on AI

This section describes the further development of the cross-agency information page.

Initiated: Further develop the cross-agency information page on AI

Background

Section 6.4 of the final report for the coordination project sets out the following recommendations:

- *that the cross-agency information page continues to publish guidance, knowledge summaries and other information about AI from the public health authorities. It is recommended that the Norwegian Directorate of Health continue as editor.*

Status

The structures on the cross-agency information page were revised and the articles updated during the first quarter of 2024.

Plans going forward

- Developing the information page
- Define and translate AI terms that are specific to the health service and link to authoritative sources for general AI terms.
- Publish articles and, where appropriate, prepare new formats (e.g. webinars), particularly relating to experience and expertise being built up through other activities under the plan.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Medical Products Agency, the Norwegian Board of Health Supervision, the Norwegian Institute of Public Health and the Norwegian Radiation and Nuclear Safety Authority (DSA).

Cross-agency regulatory guidance

This section describes focus areas aimed at ensuring consistency as regards regulatory understanding relating to the use of AI in the health and care sector.

The cross-agency guidance service is continuing ([section 3.1](#)) and government agencies will continue to increase and share expertise relating to new regulations, particularly the AI Act ([section 3.2](#)).

Initiated: Guidance on current regulations

Background

Section 6.2 of the final report for the coordination project states the following recommendation:

- *that cross-agency regulatory guidance continues, with improvements and developments in certain areas.*
- *that the Norwegian Directorate of Health has primary responsibility for the guidance service from 2024 onwards, with contributions from the Medical Products Agency and the Norwegian Board of Health Supervision, in accordance with their respective administrative responsibilities.*

Status

Cross-agency regulatory guidance continues [33].

The purpose of the cross-agency guidance service is to provide targeted guidance on artificial intelligence for projects or environments that require assistance with regard to legal issues relating to a number of regulatory areas. The service aims to develop expertise and regulatory understanding both in the sector and among government agencies. This is useful specialist expertise which can help keep the sector moving forward as regards the safe introduction of AI and clarify existing regulations, propose regulatory changes and contribute to the introduction of new EU regulations. The guidance service has so far received a number of applications for guidance in 2024, and has found that there is increasing interest and need for this type of guidance.

The Norwegian Directorate of Health has primary responsibility for the guidance service from 2024 onwards, with contributions from the Medical Products Agency and the Norwegian Board of Health Supervision, in accordance with their respective administrative responsibilities. The Norwegian Radiation and Nuclear Safety Authority also wish to participate in the guidance service going forward.

It is the needs within the sector that guide the guidance service. As these needs vary and the various stakeholders have differing levels of expertise, the guidance service must be flexible as regards how guidance is offered and what cases are considered. There is a need to be able to scale the service both up and down.

If the need increases and becomes clearer, consideration should be given to expanding the service into a regulatory sandbox and whether other agencies and areas should be included in the service.

Plan going forward

- Receive applications for and offer regulatory guidance
- Update and produce new articles on the cross-agency information page on AI, including sharing relevant clarifications and answers to legal questions from the guidance service
- Continue to market the guidance service.
- Consider further areas for development of the guidance service
- Include the Norwegian Radiation and Nuclear Safety Authority in the guidance service
- Consider establishing a network for lawyers working with AI

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Medical Products Agency and the Norwegian Board of Health Supervision contribute upon request. The Norwegian Radiation and Nuclear Safety Authority (DSA) wishes to be included in the work.

[33] [Cross-agency guidance service - the Norwegian Directorate of Health](#)

Initiated: Prepare for future regulations

Section 9.5 of the report entitled "Tilgang til data til KI" (Access to data for AI) from the coordination project for AI sets out the following recommendation:

- *monitor work relating to the AI Act in the EU.*
The government agencies should monitor the development and process of implementing the AI Act within the EU, and disseminate consequences and opportunities for the health and care sector. This will lead to greater understanding and offer better opportunities to exert an influence regarding the regulation of AI and health data in the EU.

Status

The regulations are constantly evolving, and EU regulations such as the AI Act, the AI Liability Act, the European Health Data Space (EHDS), the Health Technology Assessment Regulation (HTAR) and the Data Governance Act (DGA) are of particular interest to the AI work. For sector-wide regulations such as the AI Act, there should be closer cooperation between the national bodies within the field of health and relevant agencies such as the Agency for Public and Financial Management and the Norwegian Digitalisation Agency concerning impact analysis and interpretation of the regulations within the sector concerned.

The re-use committee has submitted its report on the re-use of public data. In NOU 2024: 14, the committee proposes new legislation to make it easier for businesses, researchers, the press, civil society and others to find and use public data to create new products, services and solutions [34].

To ensure that AI can be used in a controlled, safe and secure manner, careful consideration must be given to the consequences of impending EU regulations that will impact the field. In connection with the introduction and implementation of new regulations, it will also be relevant to assess whether there is a need for further national regulation of the development and use of artificial intelligence in the health and care services. The AI Act is a horizontal regulation, so cross-agency cooperation is important.

The EU's AI Act was finalised and approved by the European Commission on 21 May 2024 [35]. The Norwegian Agency for Public and Financial Management (DFØ) has been tasked with assessing Norway's administrative structure under the AI Act. New laws and regulations are likely to result in more stakeholders, both within and outside the health and care sector, being given new responsibilities and thus new roles. Through the AI Act, the EU will establish new bodies that we in Norway will have to relate to, and Norway will be obliged to establish new functions as a result of the new legal regulations.

The leadership forum SKATE (Steering and Coordination of Services in E-Government) [36] has set up a working group for cooperation regarding EU policies and regulations in the field of digitalisation, in which the Norwegian Directorate of Health is participating.

Plan going forward

- Boost competence relating to new regulations, internally within the Norwegian Directorate of Health, across government agencies, for the health and care sector and cross-sectorally, e.g. in presentations, etc. on the AI Act.
- Use the cross-agency information page on AI to inform the sector about the AI Act and its consequences
- Prepare guidance on the AI Act
- Establish and communicate an understanding of which laws and regulations will come into force in Norway and when. Among other things, this includes clarifying how the AI Act and the regulations regarding medical devices should be viewed in context, such as understanding the risks and documentation requirements in the two certification processes.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Norwegian Digitalisation Agency, the Norwegian Data Protection Authority, the Norwegian Board of Health Supervision and the Medical Products Agency as and when necessary.

[34] <https://www.regjeringen.no/no/dokumenter/nou-2024-14/id3046520/>

[35] <https://data.consilium.europa.eu/doc/document/PE-24-2024-INIT/en/pdf>

[36] The leadership forum SKATE (Steering and Coordination of Services in E-Government) is a strategic cooperation council and advisory body to the Norwegian Digitalisation Agency and the Minister of Digitalisation. Skate will contribute to the coordinated digitalisation of the public sector, which will offer benefits for citizens, business and industry, the voluntary sector, and public enterprises:
<https://www.digdir.no/skate/skate/1259>

Framework for the use of AI in the health and care services

This chapter describes areas that could help to reduce uncertainties, increase knowledge and streamline processes so that health and care services can acquire, implement and realise benefits from AI solutions more rapidly.

Two focus areas have already been initiated. The first area is to prepare guidance for those who intend to procure and introduce AI systems. The Norwegian Directorate of Health has also taken the initiative to establish and lead a health working group in the mirror committee for artificial intelligence in Standards Norway [37] so that the sector can both build expertise on and contribute to standardisation work with its needs.

Some of the new recommended areas concern establishing structures for the sharing of experience and the re-use of methods for testing, validation and implementation between the stakeholders in the health sector. The recommendations also address the need to clarify possible benefits, barriers and needs relating to funding, as well as the need for data and infrastructures. To better understand the needs and clarify the most appropriate measures, along with who should take responsibility for them, these topics will be addressed in the seminar series on the integrated use of AI in the health and care services ([section 1.2](#)).

While the plan focuses on adopting commercial AI products, it also includes a focus area linked to the development and commercialisation of AI systems (section 4.4). Further development of health technology assessments (HTA), so that they also take account of AI, is recommended in section 4.5.

Background

Section 6.6 of the final report for the coordination project contains the following recommendation:

- *The need for national coordination measures should be investigated with a view to cooperation and joint solutions in fields where such an approach offers clear positive synergies for quality and resource utilisation. For example, there are overarching frameworks for quality assurance and validation, health technology assessments (HTAs) including cost-benefit analyses, requirements for collaboration between regions, common testing environments for AI models, cooperation concerning procurement, technical infrastructure and data access, and assessing the need to establish regional resource centres (such as the Norwegian centre for clinical AI (SPKI) at the University Hospital of North Norway (UNN)).*

[37] <https://standard.no/fagomrader/kunstig-intelligens/>

Recommended topics for the seminar series on a framework for use

[Section 1.2](#) describes a series of seminars on the integrated use of AI in the health and care services. This section describes the topics that have emerged in the work on a joint AI plan relating to a framework for use which should be considered further in the seminar series.

Recommended topic: validation and use

What is the problem?

The appropriate use of AI in the health and care services often presupposes that the AI system has been validated and/or tested for use in Norway, on the Norwegian population, is adapted to language use and culture, and is consistent with our ethical values. The testing, validation and introduction of AI within healthcare enterprises is challenging and resource-intensive, and there are few common ways of doing this. It is difficult to acquire sufficient personnel resources, such as clinicians who have the time needed to test and validate AI in an already busy working day.

What we want to achieve

There is a need to collaborate, share experiences and re-use methods and also to develop common methods and practices for testing, validation, adoption and management. This will enable the health and care services both to increase the rate at which benefits are realised and to reduce resource usage relating to the introduction and use of AI systems.

Consideration must be given to the fact that not all validation methodology is directly transferable between enterprises, management levels or regional health authorities.

What is happening within the area?

It should be noted that the topic of validation is also discussed in the areas 'Framework for quality assurance' ([section 3.1](#)) and 'Further development of health technology assessments' (section 3.5).

- There are already a number of promising initiatives and collaborations underway in the sector that will facilitate efforts to collate and share knowledge and experience concerning the validation and use of AI systems relating to image diagnostics:
 - *Vestre Viken* has set up the *Regional AI network in image diagnostics* for the health trusts in the South-Eastern Norway Regional Health Authority. Among other things, Vestre Viken is assisting with the transfer of experience, sharing and re-use, and supporting project groups in the planning of further work [41]. Vestre Viken is also developing an *AI starter kit*.
 - *The South-Eastern Norway Regional Health Authority* plans to establish a national network for image diagnostics. This network will act as an arena for coordinating the AI initiative nationally and sharing experiences linked to various initiatives, including validation of the solutions.
 - *The regional health authorities* are working together to procure AI platforms for applications within image diagnostics, which all health trusts will be able to order under a framework agreement. The South-Eastern Norway Regional Health Authority is leading this work.
- Validation and quality assurance can be viewed in the context of guidance and approval schemes under the health technology scheme, when AI is part of welfare technology, digital home follow-up or EPJ systems[42].
- Ethical principles for the use of AI can be found in the current national strategy for artificial intelligence [43].

How to do it

The following activities are relevant:

- Establish an overview of validated products, contact details of those who have experience with the product, and any available information on assessments that have been carried out.

- Assess the need and scope to gather, share and re-use experiences and assessments relating to validation, quality assurance, risk assessments and ethical assessments.
- Assess what should be done locally, regionally and nationally and by whom relating to the validation, use and scaling of AI systems.
- Disseminate relevant knowledge and research results concerning the validation, introduction and use of AI in the health and care services, e.g. through articles on the cross-agency information pages on AI.
- Identify the need to develop guidance or national guides and guidelines in selected areas, based on experiences and needs in the sector.
- Identify the need to establish/further develop the existing guidance service with advice on validation, procurement, ethics, introduction, benefit realisation, etc.
- Assess the need to establish an approval scheme to ensure that AI is used safely and effectively, thereby creating trust among health professionals and citizens.
 - One possibility could be to further develop the Health Technology Scheme.

Work should be commenced through the series of seminars proposed in [section 1.2](#).

Current collaboration

Health authorities, regional health authorities, health trusts, KS, municipalities, interest organisations, the health industry and research environments, including KIN, NORA and the National Centre for E-Health Research (NSE).

Recommended topic: benefit potential and realisation

Background

Section 6.6 of the final report for the coordination project states the following:

- *The health and care services face significant financial challenges, which limit their ability to adopt new and innovative technology. This has been documented in EU studies as one of a number of inhibiting factors for investing in AI solutions. The strategy should therefore discuss the need to establish national and regional incentive schemes to expedite necessary investments that could yield future returns, such as meeting the need for health professionals.*

What is the problem?

Using AI in the health and care services could introduce a risk of making mistakes, as well as uncertainties relating to technological choices, information security, privacy and benefits. As with the introduction of other technology, the benefits of using AI can be extracted in places other than where the investments are actually made, in addition to the fact that it may take time to extract the benefits.

In its R&D report, KS states that artificial intelligence offers considerable potential, and not utilising the opportunities that it offers would represent a substantial societal loss. Yet many municipalities are unsure of the potential benefits and are therefore awaiting further developments [44]. In the statistical publication Arbejdsgivermonitoren 2023, it is stated that realising benefits through digitalisation is perceived as being the biggest challenge, as 80 per cent of municipalities cite this as being very or fairly challenging [45].

What we want to achieve

We want the health and care services to use AI to better or more efficiently perform its tasks, and to accelerate the pace of realising the benefits of adopting AI. These benefits could include both short-term and long-term benefits, and for different target groups.

What is happening within the area?

The following activities are relevant:

- Under the leadership of the South-Eastern Norway Regional Health Authority, the regional health authorities will adopt artificial intelligence solutions that can help to free up time among health professionals and reduce waiting times. The effect of the solutions must be documented to facilitate further introduction [46].
- The Norwegian Digitalisation Agency has written about risk assessments and assessments of the benefits of using artificial intelligence [47].
- Examples of benefits
 - [Vestre Viken has introduced bone fracture AI at all hospitals – more than 11.000 patients have been checked \(dagensmedisin.no\)](#)
 - [Ålesund Hospital and St. Olavs Hospital use artificial intelligence in radiotherapy for breast cancer \(nrk.no\)](#)
 - Haukeland University Hospital [uses AI in cancer treatment – saving valuable time \(dagensmedisin.no\)](#)
 - [Examples of opportunities within health and care in the municipal health service \(section 4.1.1\) \(ks.no\)](#)

How to do it

The following activities are relevant:

- Assess the need to collect, share and re-use experiences and assessments concerning benefits and the work relating to benefits, both nationally and internationally.
- Identify areas where benefits can be realised, systematise who will benefit and what the benefits consist of. This also applies to non-clinical applications.
- Consider the preparation of guidance and templates for cost estimation and the work relating to realising the benefits of AI in the health and care services.
- Consider the preparation of guidance on strategic and financial considerations regarding the choice of in-house development versus the procurement of AI systems.
- Assess how the negotiating power of the sector as a whole can be better leveraged, e.g. through the scope to stipulate contractual requirements concerning AI system performance, for example by stipulating contractual requirements concerning AI system performance in operation (prospectively).
- Consider instigating follow-up research in certain areas where AI solutions have been introduced.

Work should be commenced through the series of seminars proposed in [section 1.2](#).

Current collaboration

The Norwegian Directorate of Health, the regional health authorities, the health and care services, the health industry and R&D organisations.

Recommended topic: barriers and funding needs

Background

Section 6.6 of the final report for the coordination project states the following:

- *The health and care services face significant financial challenges, which limit their ability to adopt new and innovative technology. This has been documented in EU studies as one of a number of inhibiting factors for investing in AI solutions. The strategy should therefore discuss the need to establish national and regional incentive schemes to expedite necessary investments that could yield future returns, such as meeting the need for health professionals.*

What is the problem?

Little is known about barriers and funding needs specifically linked to the introduction and use of AI in the health and care services. The fact that benefits are often extracted in areas other than where the investments are actually made can be perceived as a barrier to the adoption and use of AI systems. Furthermore, the scarcity of internal resources can make it challenging to procure and adopt quality-assured solutions. There may also be barriers that make it unattractive to hand over tasks to other occupational groups, the patients themselves and/or AI systems. There is a need to further investigate such barriers and consider the need for incentives that cut across management levels.

What we want to achieve

Map and clarify any AI-specific barriers and funding needs, so that the healthcare sector can accelerate the rate at which the benefits of adopting AI are reaped. Possible funding solutions can then be investigated based on the outcome of this work. The health and care services are included in this work.

What is happening within the area?

Some existing incentive schemes:

- Schemes such as [Diagnosis-related groups \(the DRG system\)](#) and [activity-based funding \(the ISE system\)](#) in the healthcare sector.
- Grant schemes under the [Norwegian Directorate of Health, Health technology assessment scheme](#)
- [The co-funding scheme \(digdir.no\)](#) under the Norwegian Digitalisation Agency.
- Impending schemes for *Tryggere helseapper* (More secure health apps) and *Verktøykatalogen* (The tool directory) on helsenorge.no

How to do it

The following activities are relevant:

- Investigate barriers and the need for additional financial incentives or funding that could boost the safe use of AI in the health and care services. In this regard, consideration should be given to whether the current funding solutions are sufficient or hindering the introduction of AI.
- Determine one or more suitable funding solutions if there is a need.
 - An example would be to consider further developing the grant scheme under the Health technology assessment scheme

Work should be commenced through the series of seminars proposed in [section 1.2](#).

Current collaboration

The Norwegian Directorate of Health, the regional health authorities and the health and care services.

Recommended topic: access to data and infrastructures for training, fine-tuning and validation of AI models

Background

Section 6.6 of the final report for the coordination project contains the following recommendation:

- *At present, data is often tied to proprietary administrative systems and is difficult to access. As a result, they are difficult to use for the training, validation and fine-tuning of AI models. One solution to this problem could be to establish a suitable secure and robust infrastructure for this. The strategy should revolve around how data and infrastructure in the health enterprises should be facilitated so that data can be re-used more readily and more holistically. Done properly, this could accelerate the pace at which such systems are introduced safely and appropriately.*

What is the problem?

Accessing data is cumbersome, time-consuming and resource-intensive for researchers, internal AI development in healthcare enterprises and suppliers looking to develop AI systems. AI development is taking place rapidly, and the need for infrastructure in the health and care services can change rapidly. It is therefore difficult to predict and clarify future needs. At times, there may be a shortage of computing and storage resources in the market, which will also affect prices. In addition, the environmental footprint is large, and a set of environmental accounts must be included in the full set of accounts. Using supercomputing resources can be both complicated and time-consuming for researchers and others. There is also uncertainty regarding access to and the need for the various types of data that are required for training, fine-tuning and validating different types of AI systems, including language models.

Accessing data is cumbersome, time-consuming and resource-intensive for researchers, for internal AI development in healthcare enterprises, and for suppliers seeking to develop AI systems.

What do we want to achieve?

We want to:

- establish effective and flexible ways of training, fine-tuning and validating AI models and contributing to safe solutions for the entire health and care service. The need for such infrastructure applies to different types of AI systems, including language models (Chapter 5). There may be differing needs as regards research, validation and operation respectively. The work must be carried out in a positive dialogue with the health services which have an overview of the opportunities and limitations inherent in today's infrastructure.
- provide appropriate information on how to access data and sufficient capacity for the processing of applications for access to data for AI by the Norwegian Directorate of Health and Helsedataservice
- provide appropriate support to researchers and others who need to use supercomputing resources, so that they can reduce the amount of time needed and effective use of limited supercomputing resources.
- better enable the Norwegian supply industry to effectively develop AI systems based on Norwegian data for the development, testing and validation of AI-based software, both for new products and for the further development of existing software products.
- strengthen the work relating to information management within the sector at the local, regional and national levels, including the use of common code values and terminology.

What is happening within the area?

Some key initiatives are underway to test, train and/or validate AI models and scale.

- **Commissioned reports: The need for supercomputing power for research and artificial intelligence** has been assigned to the Research Council of Norway by the Ministry of Education. The Ministry of Health and Care Services has requested the Norwegian Directorate of Health to link in with this work.
- **NOR-X-CHANGE:** The regional health authorities have a joint initiative to set up research PACS systems and establish a central support unit that supports common functionality such as data migration from clinical systems and data exchange between regions.
- **Sigma2 AS** is responsible for providing the national e-infrastructure for computational science in Norway, providing supercomputing services and large-scale data storage for research and education purposes. Sigma2 is owned by the Agency for Shared Services in Education and Research (Sikt). Sigma2 also assists researchers and others in the use of supercomputing resources.
- **EuroHPC** [48] is a major EU initiative which aims to bring together European resources within *supercomputing*. As of March 2024, Europe's most powerful supercomputer is LUMI in Finland. Europe's first exascale computer (i.e. a computer which can perform 10^{18} calculations per second) is scheduled to be in place in Germany in 2024: JUPITER. These supercomputers are becoming important for the further development of artificial intelligence in Europe. At the end of 2023, the University of Oslo was allocated a couple of weeks on LUMI to train three Norwegian large language models [49].
- **EHDS** (European Health Data Space) is a new regulation for establishing a common European health data space. The aim of EHDS is to promote secure access to and exchange of health data across borders. EHDS covers both the primary use of data (myHealth@EU) and secondary use (HelthData@EU).
- **TEF Health** [50] (Testing and Experimentation Facility for Health AI and Robotics) will provide certification and quality control standards to simplify processes for bringing responsible AI systems to market. TEF Health centres are being set up with environments that AI system developers can use to demonstrate the interoperability and functionality of their solutions. Norway does not participate in TEF Health as an "associated country", but Norwegian enterprises are still able to respond to calls for applications published by TEF Health.
- The **European Cancer Imaging Initiative** [51] is an initiative under Europe's Beating Cancer Plan. The goal here is to establish a federated European infrastructure for imaging data for cancer. This will link the EU-level and national initiatives and give clinicians, researchers and innovators access to cross-border cancer imaging data.
- The **EU Rare Disease Platform** [52] will provide researchers, healthcare institutions, patients and decision-makers with tools to improve knowledge, diagnosis and treatment of rare diseases. The platform will make it possible to search registry data at the EU level and will standardise data capture and data exchange.
- **Personalised medicine:** Among other things, a national strategy has been developed for personalised medicine covering the period 2023-2030 [53], a national genome centre is in the process of being established, and Norway is participating in various European initiatives.
- **Grand Challenge** in the Netherlands provides access to data for model development/evaluation.
- **AIMInd** is an established EU project [54] where the collaboration partners are seeking to establish a centre of excellence within innovation (SFI) aimed at creating a secure federated environment for the development and testing of AI models.

How to do it

The following activities are relevant:

- Identifying needs:
 - identify the needs of the specialist health service and assess possible approaches to a common framework for the effective training, fine-tuning and validation of AI models.
 - identify the needs of the municipal sector and assess possible approaches to a common framework for the effective training, fine-tuning and validation of AI models.
 - identify supply industry needs and assess possible approaches to access to health data for the development of commercial AI systems. Among other things, look at perceived legal and organisational barriers and infrastructure challenges for access to data. This applies both to new products and to existing products that are expanded with AI functionality.
- Consider establishing an overview of and collaboration with existing initiatives.
 - Establish one or more structures to monitor infrastructure initiatives relating to training, validation and fine-tuning in the Norwegian health sector, cross-sectorally and in Europe, such as Sigma2, LUMI and Jupiter.
 - consider closer collaboration to link us to relevant European and/or Nordic initiatives and programmes such as testing and experimental platforms for AI (TEF Health).
 - establish closer cooperation with educational and research institutions.
- Depending on needs and existing initiatives, consider, for example:
 - to better facilitate the storage, linking and use of both historical data and prospective data acquisition. This applies to data from medical examinations, such as EEG, neurography or ultrasound, data from patient records, data from registries, etc.
 - the need for and possible organisation of a national infrastructure to make available Norwegian training data for the use of large language models in the health and care services (see also the focus area concerning the use of large language models).
 - establishing a national organisation of federated machine learning, including, for example, common definitions of variables.
 - establishing national testing and validation data sets, which will facilitate the re-use of validations.
 - establishing registries of national and international datasets that are available for AI research.

Work should be commenced through the series of seminars proposed in [section 1.2](#).

This measure is viewed in the context of the assignment entitled "Secure access to language models adapted to Norwegian conditions" (*Sikre tilgang på språkmodeller tilpasset norske forhold*) and the Ministry of Education and Research's assignment concerning supercomputing and academia. The measure is also viewed in the context of relevant EU initiatives (see [section 1.4](#)).

Current collaboration

The Norwegian Institute of Public Health, the Norwegian Directorate of Health, the regional health authorities, the municipal sector, the health and care services, the research and education sector and the Norwegian Ministry of Trade, Industry and Fisheries (NFD).

[41] <https://www.vestreviken.no/om-oss/nyheter/bistar-andre-helseforetak-med-oppstart-av-ki/>

[42] <https://www.helsedirektoratet.no/rapporter/modell-for-kravstilling-veiledning-tilrettelegging-og-godkjenning-ir>

[43] Section 5.2:
<https://www.regjeringen.no/contentassets/1febbbb2c4fd4b7d92c67ddd353b6ae8/no/pdfs/ki-strategi.pdf>

[44] <https://www.ks.no/contentassets/0f1e4a68863e4df6a12a89edb638008c/KS-FOU-Barrierer-og-muligheter-i->

[45] Figure 1.1: Arbeidsgivermonitoren 2023:

<https://www.ks.no/contentassets/fab9b83db07a49dc8456efe845fe6d16/23088-KS-Arbeidsgivermonitor-202>

[46]

<https://www.regjeringen.no/contentassets/bd8a11644b744dec8a8dc452794000e4/oppdragsdokument-2024>

[47]

<https://www.digdir.no/kunstig-intelligens/hvordan-vurderer-jeg-risiko-ved-bruk-av-kunstig-intelligens/4537>

[48] https://eurohpc-ju.europa.eu/index_en

[49] <https://www.titan.uio.no/teknologi/2024/store-skritt-mot-norsk-svar-pa-chatgpt-.html>

[50] <https://tefhealth.eu/home>

[51] <https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging>

[52] https://eu-rd-platform.jrc.ec.europa.eu/_en

[53] [Strategy for personalised medicine - regjeringen.no](#)

[54] <https://www.ai-mind.eu/>

Initiated: Framework for quality assurance

Background

Section 6.2 of the final report for the coordination project states the following recommendation:

- *that the work to develop a framework for quality assurance be continued. This framework is being developed on an ongoing basis and in a dialogue with the sector, partly through the user panel, which both provides input concerning the deliverables and helps to prioritise themes that should be addressed in the subsequent steps.*

Status

The work to draw up a report on the quality assurance of artificial intelligence in health and care services is continuing.

A user panel from the sector provides input to the entirety as well as specific chapters during the process.

The report is aimed at those who will be using AI solutions in the health and care services in Norway. It points to challenges that must be given particular consideration in any procurement process for an AI system. The document is a supplement to existing guides.

Inspired by *A Buyer's Guide to AI in health and care* from the NHS in England, the overall structure is aimed at decision-makers, buyers and health professionals [38].

The content is also partly based on relevant and recognised sources, both nationally and internationally, and references can be found throughout the text and on a separate page.

This version of the report is limited to fully developed products that are procured, and thus does not include a framework for the in-house development of AI solutions. Systems with continuous learning fall outside the scope of this report.

Plan going forward

- Finalise the report on the quality assurance of artificial intelligence in the health and care services
Expected delivery: third quarter 2024
- Obtain experiences, maintain and further develop the guidance
- Prioritise the next deliverables

Identified new needs are to

- clarify when research is needed, i.e. additional clinical trials, before an AI product can be implemented in the health service.
- clarify what a CE mark signifies and what it does not signify
- provide support to smaller stakeholders such as GPs, contract specialists and municipal health services.
- clarify how enterprises can assess and validate new versions of products that are already in use, including requirements regarding data sets for the validation.
- clarify how AI products which learn and/or are fine-tuned continuously can be validated.
- develop guidelines on how AI systems should be validated. Validation should be carried out according to a pre-specified protocol and so that an estimate of the method's accuracy is obtained.
- establish a common methodology (or standards) to validate various types of AI systems, including those involving large language models.
- establish a nationally organised resource system to support the validation of AI solutions

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Norwegian Board of Health Supervision, South-Eastern Regional Health Authority and a broadly composed user panel. The Medical Products Agency quality-assures the work within its remit.

[38]

<https://transform.england.nhs.uk/ai-lab/explore-all-resources/adopt-ai/a-buyers-guide-to-ai-in-health-and-ca>

Who collaborates?

Standards Norway, the Norwegian Digitalisation Agency, Ahus, KS, Det norske Veritas, Sykehuspartner, Norwegian Cancer Registry and the Norwegian Public Service Pension Fund.

[39] <https://standard.no/fagomrader/kunstig-intelligens/>

[40]

<https://www.consilium.europa.eu/en/press/press-releases/2024/05/21/artificial-intelligence-ai-act-council-giv>

Recommended: From research and development to use and possible commercialisation

Background

Section 6.6 of the final report for the coordination project contains the following recommendation:

- *The plan should have a strategy for the development and procurement of AI solutions in the health and care services. The objective of the strategy should be to ensure that the health and care services contribute to the development of AI equipment in a cost-effective and future-proof manner.*

It should be noted that the assignment for the Ministry of Health and Care Services was to prepare a joint AI plan, rather than a strategy, which was proposed in the final report. In the work on a joint AI plan, one of the key priorities is to facilitate the adoption of commercial AI products. This area has therefore been given a low priority and has not yet been investigated.

What is the problem?

Stringent quality requirements have been imposed for the transition from research and development to AI systems for clinical use in the health service, and our consultation meetings indicate that these requirements are also challenging to understand. This makes it demanding for researchers and developers to both familiarise themselves with and comply with the applicable rules and requirements. It can be both difficult and time-consuming to secure funding for an entire R&D cycle, which includes commercialisation.

What we want to achieve

It should be more effective to both develop and commercialise AI systems. In the long term, this could lead to more research projects being developed into AI products that are taken into use and offer benefits in the health and care services.

Research and development communities should be more aware of frameworks and guidelines relating to AI systems, such as regulations relating to medical devices so that they can make the right choices in both research projects and any commercialisation processes. Furthermore, needs as regards support for AI

commercialisation processes should be identified, e.g. linked to regulations, practical considerations and funding.

What is happening within the area?

- The “[AI billion](https://forskingsradet.no)” (forskingsradet.no) is a government initiative which aims to boost research efforts relating to artificial intelligence and digital technologies by at least NOK 1 billion over the next five years.
- Existing structures for supporting commercialisation in the field of health, such as the [Health Catalyst](https://healthcatalyst.no) (healthcatalyst.no), the health clusters and the *Technology Transfer Offices* (TTOs) at universities and research institutions and others.
- The Medical Products Agency publishes and maintains guidance concerning regulations relating to medical devices [55] and provides a guidance service for innovation [56].
- *TEF Health* [57] (*Testing and Experimentation Facility for Health AI and Robotics*) will offer standards for certification and quality control to simplify the processes to bring responsible AI systems to market.

How to do it

The following activities are relevant:

- Investigate barriers and possible measures to develop more research projects into AI products.
 - For example, one possible measure could be to further develop existing structures for support for commercialisation.
- Assess the need for clearer management of and prioritisation support for the desired direction of development. Needs should be assessed in conjunction with the sector.
 - For example, relevant measures could include preparing an annual report on the desired direction.
- Consider preparing guidance relating to research, development and commercialisation of AI systems for the health and care services

Current collaboration

The Technology Transfer Offices (TTOs) at the universities, R&D stakeholders, the Norwegian Directorate of Health, the health and care services and the Medical Products Agency.

[55]

<https://www.dmp.no/medisinsk-utstyr/veiledning-og-regelverk/produktspesifikke-veiledere/medisinsk-utstyr-og-regelverk>

[56] <https://www.dmp.no/om-oss/veiledning-og-rad>

[57] <https://tefhealth.eu/home>

Recommended: Developing health technology assessments

Background

Section 6.2 of the final report for the coordination project states the following recommendation:

- *that health technology assessments (HTA) are further developed to be adapted to assessments of AI systems* [58]

Problem to be solved

Assessing whether a new health technology which uses artificial intelligence is safe, secure, ethical and cost-effective is important. Health technology assessments that we are accustomed to today are not well adapted to medical devices which use AI. AI systems are data-driven, which means that biases propagate rapidly and broadly. Generative models are difficult to test and validate. Many AI systems are likely to be launched on the market, and carrying out a health technology assessment (HTA) on every product would require considerable capacity. It will therefore be necessary to assess whether health technology assessments should be carried out at an overarching level or on specific types of AI systems, e.g. products in a particular area such as digital pathology.

Status

Many decisions will be made locally, and mini-health technology assessments may be relevant. Norwegian Institute of Public Health (NIPH) is responsible for mini-health technology assessments. A mini-health technology assessment is a scaled-down form of the national health technology assessments and is adapted for use by both hospitals and municipalities. The Norwegian Institute of Public Health's website contains guidance and a national database of all completed and started mini-health technology assessments, in addition to a contact person for third-party mini-health technology assessments [59]. Mini-health technology assessments can be published and re-used.

Work of relevance to health technology assessments involving the use of AI systems is underway:

- The Medical Products Agency (DMP) is leading a working group which will submit a report to the Decision Forum on a framework and criteria for medical devices in New methods (*Nye metoder*). The working group includes the medical directors and representatives of hospital procurement. The report will be presented in 2024. It will be appropriate to wait until this work has been completed before considering whether any specific aspects of AI need to be taken into account.
- How the systems for prioritisation will be further developed in line with advances in medical technology will probably be addressed in the next priority report, which will be launched in early 2025 [60]

Plan going forward

- Once the report on a framework and criteria for medical devices has been completed (scheduled for the end of 2024): follow up on any input and measures.
- Once the priority report has been completed: carry out the same assessment as above.

Current collaboration

The regional health authorities, the Medical Products Agency, NIPH and the Norwegian Directorate of Health.

[58] A health technology assessment (HTA) is a systematic way of mapping and assessing the efficacy, safety and health economic aspects of procurements. In addition, a health technology assessment (HTA) may include an assessment of accessibility, ease of use, ethical and legal considerations, and social and organisational consequences.

[59] [Mini-health technology assessments \(minimetodevurdering.no\)](https://minimetodevurdering.no)

[60]

<https://www.helseomsorg21.no/globalassets/satellitt/ho21/sakspapirer/sak-8-1-2024-prioriteringsmeldingen>.

Use of large language models

This focus area is based on results from the [knowledge base on large language models](#), which provides an overview of the use and development of large language models in the health and care sector in Norway. The report describes how such models can help to improve healthcare, including benefits and challenges, and identifies possible measures to meet the challenges and strengthen the use of language models in the sector (section 5.1).

Two measures were assigned to the Norwegian Directorate of Health in the 2024 letter of allocation: Assess the risks associated with the use of large language models (section 5.2) and facilitate the use of language models adapted to Norwegian conditions (section 5.3).

The other recommended areas concern the strengthening of expertise relating to the appropriate use of large language models and the highlighting of areas where large language models are suitable and can offer benefits in the form of more efficient work processes or better quality services in the Norwegian health sector. To better understand the needs and measures that will be most appropriate and who should take responsibility for them, these topics will be addressed in the seminar series on the integrated use of AI in the health and care services (section 1.2).

Background

In 2024, the Norwegian Directorate of Health delivered a knowledge base on large language models in the health and care services. The report recommends measures in the following areas:

- Risk assessment
- Secure access to language models adapted to Norwegian conditions
- Strengthening of expertise concerning use, development and fine-tuning
- Assessment of applications for large language models

The recommendations from the report have been incorporated and further developed in the description of the measures below.

Initiated: Develop report on large language models

Status

- The knowledge base entitled “Use of large language models in the health and care sector” (*Bruk av store språkmodeller i helse- og omsorgssektoren*) has been developed in a close dialogue with centres of expertise within the field of language technology in Norway [61]. The report was launched on 6 May 2024.

Plan going forward

- The proposed measures are developed further in the joint AI plan (this plan).

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

Meetings with environments in the sector and specialist communities working on large language models.

[61] [Store språkmodellar i helse- og omsorgstenesta](#)

Initiated: Risks associated with the use of large language models

Background

The Ministry of Health and Care Services (HOD) has tasked the Norwegian Directorate of Health with the following: *"as part of further work, the government agencies shall also assess the risks that large language models introduce."* [62]

The description of this measure is based on the recommendation concerning access to language models adapted to Norwegian conditions (5.1) in the knowledge base on the use of large language models [63].

What is the problem?

The use of large language models, especially generative language models, results in variable quality that is difficult to test and assess. Technology is evolving at an extremely fast pace. It introduces risks not only as regards poorer patient safety, such as misdiagnosis or mistreatment, and privacy breaches, but also as regards administrative and other non-clinical applications. There are both technical and psychological/human risks, such as automation bias, as well as the risk of health professionals taking longer to perform their duties. There is also a risk that the services will miss opportunities that could improve patient safety, diagnostics and treatment planning if the service does not have the courage or waits too long to adopt large language models.

There is a lack of expertise and knowledge about the risks introduced by the various applications. General methods are available for assessing risk, but these are rarely applied to language models in the health sector. There is also no overview of the types of risks that are associated with the use of language models.

As the development of language models accelerates, there is an increasing risk of such systems being introduced without adequate quality assurance. It is therefore important to afford a high priority to this work by introducing a framework for the safe use of language models in the health and care services.

What do we want to achieve?

There is a need to identify and/or (further) develop methods and frameworks to perform systematic risk analyses of large and different types of language models for different applications within healthcare. These should build on standards and general templates for risk analyses, while at the same time being dynamic given technological advances. It may be necessary to adopt a differentiated approach using a number of different methods and frameworks.

The risk assessment framework should introduce a risk analysis of the use of language models in the various areas. The methods used should be robust, balance risk and benefit, and include risk mitigation measures that maximise the benefits reaped. It may be useful to include success stories in the guidance to aid in understanding the factors that can contribute to positive outcomes. To obtain balanced assessments, multidisciplinary assessments should be encouraged.

What is happening within the area?

There are no national initiatives with regard to systematic work relating to risks in connection with the use of large language models in the health and care services.

Many sets of regulations, such as health legislation, the AI Act (adopted, but not yet in force), the GDPR and the medical devices regulations provide guidance on how both risk and quality assessments should/must be conducted.

How to make it happen

To gain a deeper understanding of the risks that large language models would introduce if they were to be used in health and care services, a report must be prepared that addresses the following topics at an overarching level:

- Identifies relevant types and degrees of risks relating to the use of language models, based on international experience and research, including privacy and information security.
- Identifies risk-mitigating and quality-enhancing measures. In this, there also lies an accepted level of error/bias etc. for public services.
 - For example, consider establishing a step-by-step approach to the risks associated with the use of language models in different applications, starting with the lowest-risk step, such as administrative tasks

In addition, the sector should build expertise relating to risk analyses by testing, adapting and applying the method(s) to different applications and using different types of language models.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The specialist and R&D community within the fields of AI and language technology (including the National Library of Norway), central administrative bodies (including the Norwegian Digitalisation Agency and the Norwegian Data Protection Authority), the health and care services and the business community provide input in the work.

[62] Letter of allocation 20204-34:

[63] <https://www.helsedirektoratet.no/rapporter/store-sprakmodellar-i-helse-og-omsorgstenesta>

Initiated: Facilitate the use of language models adapted to Norwegian conditions

Background

The Ministry of Health and Care Services (HOD) has tasked the Norwegian Directorate of Health with the following: *as part of further work, the government agencies shall also identify measures to ensure that the health and care services have access to one or more language models that are adapted to Norwegian conditions* [64].

The description of this measure is based on the recommendation concerning access to language models adapted to Norwegian conditions (5.2) in the knowledge base on the use of large language models [65].

What is the problem?

It is uncertain whether the available language models give sufficient consideration to the Norwegian language (both Bokmål and Nynorsk), professional terminology, culture, ethics and practice in the healthcare sector. There is no Norwegian test suite that can be used to determine whether this is the case.

What do we want to achieve?

The objective is to ensure that language models and/or applications based on large language models in the health sector function sufficiently well to perform tasks in a Norwegian context while ensuring that international knowledge is safeguarded. Texts for the general public should be written using clear and patient-friendly language so that they can be read by patients, users, relatives and citizens in general. Texts for health professionals should be consistent with Norwegian professional terminology. Nynorsk should work as well as Bokmål. Language models which are to be used in the administrative area for the Sámi languages must function in Sámi.

What is happening within the area?

As of 1 March 2024, the following stakeholders have initiatives in place relating to the development of large language models in Norwegian:

- NorwAI (NTNU and others) is currently based on Norwegian language models
- NORA (UiO, NB and others) is currently based on Norwegian language models
- Western Norway Regional Health Authority ICT is fine-tuning the base model NorBERT for the clinical domain: [Clinical NorBERT \(statics.teams.cdn.office.net\)](https://statics.teams.cdn.office.net)

The Norwegian Directorate of Health (and others) are testing adaptations of international models through what is known as *Retrieval Augmented Generation* (RAG) in, for example, DigiUNG and Helsesvar.

A number of enterprises in both the private and public sectors have developed guidelines for the use of generative AI [66]

How to make it happen

A number of measures could be used to secure access to language models adapted to Norwegian conditions. More experience will be needed to identify appropriate measures. Initially, it will be important to monitor the results of the ongoing initiatives.

A report should be prepared to identify measures which ensure that the health and care services have access to language model(s) that are adapted to Norwegian conditions. This can be achieved by:

- Monitoring and participating in national and/or Nordic projects that develop large Norwegian language models that can be used in the health and care sector
- Analysing the possible need for a national medical language model based on results from ongoing development projects, such as Clinical NorBERT, NorwAI and NORA.
- Monitoring projects that adapt open, international models to Norwegian conditions.
- Assessing what Norwegian medical training data is relevant and the extent to which it is available for the development, training and fine-tuning of language models, including copyright and privacy
- Developing Norwegian test suites that can be used to determine whether language models are adapted to Norwegian conditions, and developing Norwegian benchmarking
- Making available common semantic resources, such as knowledge graphs, for use in language models
- Analysing possible management regimes for one or more national medical language models
- Coordinating and compiling relevant guidelines for the use of generative AI development and, where appropriate, encouraging the development of guidelines in selected areas of the health and care services
- Establishing an overview of national and international data sets that are available for AI research.
- Facilitating the enrichment of language models using terminologies and classifications translated into Norwegian

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The specialist and R&D community within the fields of AI and language technology (including the National Library of Norway), central administrative bodies (including the Norwegian Digitalisation Agency and the Norwegian Data Protection Authority), the health and care services and the business community provide input in the work.

[1] Letter of allocation 20204-34:

[2] <https://www.helsedirektoratet.no/rapporter/store-sprakmodellar-i-helse-og-omsorgstenesta>

[3] The Norwegian Digitalisation Agency has developed guidelines for generative AI:

<https://www.digdir.no/kunstig-intelligens/bruk-av-generativ-kunstig-intelligens-i-offentlig-sektor/4670#genere>

. The Norwegian Board of Technology (NBT) has compiled numerous guidelines in the public sector:

<https://teknologiradet.no/blogg/mens-vi-venter-pa-ai-act-retningslinjer-for-kunstig-intelligens/>

Recommended topic for a seminar series on the use of large language models

Section 1.2 describes a series of seminars on the integrated use of AI in the health and care services. This section describes the topics that have emerged linked to the use of large language models during the work on a joint AI plan which should be considered further in the seminar series.

Recommended topic: Expertise concerning use, development and fine-tuning

Background

Section 6.7 of the final report for the coordination project states the following recommendation:

- *that government agencies continue to build expertise relating to language models.*

The description of this measure is based on the recommendation to strengthen capacity and expertise (5.1) in the knowledge base on the use of large language models.

What is the problem/challenge/barriers?

There is a lack of expertise concerning the use, development and fine-tuning of large language models at different levels within the health and care sector. There is also insufficient expertise available concerning change management linked to the introduction of language models. There is a shortage of funding for the necessary training within the service.

What we want to achieve

The Norwegian Directorate of Health and the entire health and care service should strengthen its expertise concerning the appropriate use of large language models. This expertise must be adapted to the different needs and levels that exist within the service. Future strategic decisions will be more closely linked to

digital transformation and technological development. Basic competence will therefore also be needed among managers relating to the risks and benefits of using language models in the health and care service.

A report is also being prepared which will set out recommendations to ensure that the necessary expertise is available for digital transformation based on AI in the health and care services (Section 6.2).

What is happening within the area?

Some universities offer courses on large language models, including:

- Topic under the subject area IN1140 Introduction to language technology (University of Oslo)
- Topic under the subject area DIGI117 Language technology (University of Bergen)
- Topic under the subject area HSI415 Understanding technology (University of Agder)

Language models are likely to be included in AI study programmes, e.g. at the University of Inland Norway and UiT The Arctic University of Norway. There are also numerous seminars and online courses, including those run by Digital Norway, for example.

AI and language models are not a major part of the curriculum of health informatics courses.

How to make it happen

The following measures are relevant:

- Clarify the need for a dedicated board or network of experts in language models and health sciences from both the health and care sector and the university and college sector
- Promote key projects through an annual AI award for the sector
- Ensure that expertise concerning language models forms part of course curricula, not just as a separate study programme, but also as an integral part of health education in particular. This is seen in the context of the report on competence (section 6.2).
- Identify measures to enhance leadership skills in the sector concerning AI and language models. This is seen in the context of the report on competence (section 6.2).
- Obtain experience from Nordic and other countries
- Determine what should constitute user competence for AI and language models

Work should be commenced through the series of seminars proposed in section 1.2.

Current cooperation

The Norwegian Directorate of Health, the health and care services, the higher education sector and the R&D sector.

Recommended: Applications for large language models

Background

Section 6.7 of the final report for the coordination project states the following recommendation:

- *that the government agencies, together with the health and care services, assess the applications where such [language] models may be useful and appropriate.*

The description of this measure is based on the recommendation to promote key applications (5.2) in the knowledge base on the use of large language models.

What is the problem?

It is still uncertain in which areas of application language models may be useful and suitable in the health service. This uncertainty could hinder development and use, even in cases where large language models can be both safe to use and offer savings and/or better healthcare. The distinction between pure language models and other AI models, such as image models, is likely to diminish as multimodal models become more prevalent.

What we want to achieve

The use of language models in areas where they are suitable, i.e. where they can offer benefits in the form of more efficient work processes or better quality health services in Norway. Applications entailing less risk may be faster to implement, yet also offer good value.

What is happening within the area?

None implemented, but testing/research is underway, e.g.:

- ClinCode: machine-supported ICD-10 coding (National Center for E-Health Research in collaboration with several other organisations)
- Citizen-facing chatbot (Norwegian Directorate of Health)
- Structuring of free text (Norwegian Health Archives)
- Risk prediction (Sørlandet Hospital). This project has been concluded.

How to make it happen

The following measures are relevant:

- Identify suitable applications and documentation of efficacy and benefits, in addition to the applications that should be introduced first (e.g. low risk, low cost and good efficacy, e.g. relating to administrative tasks) [67]
- Carry out a needs analysis to ensure applications originate from and are anchored among health professionals, administrative staff and patient representatives
- Highlight promising Norwegian initiatives and facilitate national use
- Monitor national, Nordic and international initiatives to disseminate knowledge and experiences
- Facilitate pilot projects and experimentation. This work can be carried out in collaboration with the business community
- Provide funding through a separate funding scheme for the most promising applications or use existing funding schemes, such as the Norwegian Medical Association's *Funds for quality improvement and patient safety* (see also Chapter 4)

The work should be initiated through the seminar series proposed in section 1.2.

Current cooperation

The health and care services, the Norwegian Directorate of Health, parties that have adopted large language models in other sectors?

[67] One possible useful application that was highlighted in the input is interaction with foreign language-speaking patients. High-quality language models may lower the threshold for translating good patient information into multiple languages. Appointment letters will also be easier for patients to understand in their own language. This could reduce the risk of non-attendance at appointments. Translating patient information is a major task and very resource-intensive. In this area, there is considerable potential for savings to be made and excellent opportunities to improve the quality of equitable healthcare.

Boosting AI skills

Artificial intelligence (AI) has an extremely wide range of possible applications within the health service broadly. AI systems are in use in the public and private health services, in the specialist health service and among municipal health and care services. AI systems are used for everything from administrative to treatment-related tasks, and are used by health professionals, technical personnel, managers, other employees in the health service and citizens.

In *Tid for handling (Time for action)*, the Health Personnel Commission states that the digital transformation is characterised by the rapid development of new technologies (...) that offer major opportunities. Artificial intelligence and personalised medicine are examples of such technologies, which have led to and can lead to completely new types of healthcare and ways of working". New types of jobs, skill needs, personnel groups and training may emerge in the wake of this. *"This will require new courses and create new tasks and routines for staff, patients, users and others. The introduction and use of technology will require digital and technical skills enhancement. This applies not only at individual and management levels, but also throughout the workforce and the population in general."* [68]

The greater use of technologies such as sensors, apps, welfare technology, etc. is leading to the creation of more data, thereby presenting more opportunities for a data-driven and more personalized healthcare service. These are changes that will affect how healthcare services are provided. Each of these changes will require a change in competence to a greater or lesser degree, which will temporally coincide with the skill requirements associated with artificial intelligence. The skill requirements linked to artificial intelligence should therefore not be viewed in isolation from knowledge of technology in general.

Artificial intelligence entails a need for skills concerning the actual use of artificial intelligence, to manage the consequences of using artificial intelligence as altered tasks, as well as the more unexpected effects associated with digital transformation.

The distribution of responsibility for the competence of health professionals is complex, with many different stakeholders, each of which has different responsibilities for basic training, specialist training and continuing professional development, courses and guidance. The Norwegian education system is complex and spread across a number of stakeholders, each of which has different roles, authorities and needs as regards autonomy. In times of stress and change, it is important to be wary about creating completely new structures that do not work with or complement the existing ones. A focus will therefore be placed on existing structures to meet competence needs, and how these can be developed and changed to meet new needs.

Norwegian municipalities, regional health authorities and health trusts vary greatly in size with regard to both geography and population catchment. Size is a factor in determining how much responsibility they can take when developing their own competence-enhancing material, and the extent to which they can contribute to others. There will therefore be an expectation from the health authorities that large regions, hospitals and municipalities will share with and assist the smaller ones, for the benefit of the community.

Background

Section 6.6 of the final report for the coordination project contains the following recommendation:

- *Access to adequate competence is a critical factor in implementing and deploying AI solutions responsibly.*

Initiated: Develop knowledge and expertise about artificial intelligence among the government agencies

Background

Section 6.3 of the final report for the coordination project states the following recommendation:

- *that the government agencies continue to build expertise within the field of AI.*
- *that the government agencies establish one or more permanent arenas that enable them to continue to collaborate on products and services that require cross-agency cooperation. For example, there could be a network of specialists who aim to arrange regular competence-enhancing events and low-threshold information exchange.*

Status

Artificial intelligence is being developed and introduced into use at a rapid pace, which is demanding to monitor and assess the relevance to the health and care services. Appropriate priorities require an overview, a high level of competence and a strong degree of involvement and coordination. There is a need to monitor, systematise and share knowledge about AI developments in the healthcare sector, nationally, in other countries and within the EU.

What is happening within the area?

- [Cross-agency information pages on artificial intelligence in the health and care services](#)
- [Cross-agency guidance service](#)
- [The Norwegian Digitalisation Agency's guidance on artificial intelligence \(digdir.no\) and thematic pages on artificial intelligence in the Datalandsbyen forum \(datalandsbyen.norge.no\)](#)
- [Artificial intelligence in the Norwegian health service \(KIN\) \(ehealthresearch.no\)](#)

This area is viewed in the context of the seminar series (section 1.2).

Plan going forward

- Continue to build competence among the government agencies
 - Systematic monitoring of selected reports and periodicals and attendance at conferences
 - Consider building (small) AI networks based on selected themes, such as cost-benefit/benefit realisation reviews or law

- Consider developing an AI competence plan for the health authorities. This could for example consist of webinars and videos concerning selected themes that are being developed in the joint AI plan.
- Share experiences and expertise
 - Publish articles and other information on the information pages
 - Make contributions and give lectures/talks at conferences and seminars

Consider developing new types of publications, such as “point of view” or brief reports.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

The Norwegian Board of Health Supervision, DMP, certain areas of the health and care services and KIN.

Initiated: Prepare a report on competence needs for the digital transformation based on artificial intelligence in the health and care services

What is the problem?

There is an expectation that AI will be increasingly used to streamline various areas [69]. To continue providing high-quality health and care services to an ageing population, it will be crucial to implement effective measures. This will lead to changes in competence needs for health managers, employees in the healthcare sector, including the health administration, and citizens.

As patients live longer, contract more medical conditions and the proportion of elderly people in the population rises, we are seeing more patients per health professional. This challenge cannot be overcome by simply hiring more people in the health and care services. Expectations concerning the use of AI have arisen parallel to a number of major changes: Personalised medicine will become an integral part of the health service, more health services will be provided at home using digital tools – both with and without AI – and the population will increase their health competence, including their digital skills.

The use of AI will lead not only to competence needs linked to the individual AI system in use, but also to more secondary competence needs, such as changes in the duties performed by different groups of personnel, in addition to changes in the performance of medical specialities. This will lead to a need for enhanced or new skills in addition to AI expertise.

These factors, most of which can be linked to artificial intelligence in diverse ways, thus influence how processes in the health service are provided and the extent to which the health system changes. These changes are expected to be both substantial and pervasive, meaning that digital transformation will be involved.

What is happening within the area?

The Norwegian Digitalisation Agency has created a competence framework for digital transformation that is being used as a framework for the work to prepare a competence report within AI [70].

A number of countries have implemented measures for competence-sharing and enhancement relating to AI in their health services. Examples of different types of measures include bringing together different stakeholders (public/private, research/health service) in labs, networks, HUBs or ecosystems. Some are aiming for more technology training at the primary or lower secondary school level, while others are aiming to raise the level of understanding of technology among managers. The United Kingdom has created a capability framework that is of interest in this work [71].

In Norway, a wide range of stakeholders offer training, courses and other competence-enhancing activities that are aimed at managers and personnel in the health service and/or general population. Relevant research is also being conducted in the area, and there are also a number of relevant national reports, documents and strategies.

What we want to achieve

The Norwegian Directorate of Health will prepare a report setting out recommendations to meet the competence needs for digital transformation based on artificial intelligence in the health and care sector. This will provide an overview of stakeholders who offer training, courses, etc. that are of relevance to AI and health. The report will then go on to describe unmet competence needs relating to the changes that the use of artificial intelligence in the healthcare sector will entail. The report will also identify competence measures linked to four different levels, where the first three levels are based on the Norwegian Digitalisation Agency's competence framework. These levels are explained below.

Politics and general guidelines

The work being carried out in the public health and care services takes place within a political framework and must underpin the government's wishes and ambitions. Politics and general guidelines [72] form the first level of the Norwegian Digitalisation Agency's competence model for the digital transformation, and help enterprises gain an overview of the political guidelines in the field and understand the societal importance of working on digital transformation. The level aims to bring about greater awareness of how to rethink the social mission and support the goal of one digital public sector with the user at the centre.

The report sets out proposals for measures that are in addition to the public guidelines, targeted specifically at the competence area. One of these measures concerns the establishment of a number of study places within artificial intelligence. This applies not only to pure ICT subjects, but also to more knowledge about artificial intelligence for students who will work in roles other than IT in the healthcare sector. As part of this work, there has been no attempt to determine what constitutes an appropriate number to support the *health* sector's needs, but it is believed that the supply of people with competence within ICT and AI in particular must be increased. ICT Norway recommends that the educational

institutions offer at least 1,000 new ICT study places from autumn 2024, and then increase this number to 2,500 new places from autumn 2025 (cross-sectorally) [73]. Funding must be provided for the creation of study places.

Management of the digital transformation based on AI in the health and care services

Management is the second level of the Norwegian Digitalisation Agency's competence model for digital transformation. This level aims to clarify what is required of those who hold leadership roles to succeed in the digital transformation of an enterprise. In digitally mature organisations, the digital transformation is led from the top. Managers and directors of the health and care services must therefore possess the necessary competence, understanding and interest to lead the digital transformation linked to the use of artificial intelligence. They do not need to master the technology themselves, but they must understand and see the opportunities that artificial intelligence offers.

The health service also has many highly trained employees with considerable responsibility and professional managerial tasks. The capabilities in this chapter are important to them as well. Many municipal leaders also need this expertise.

Various parts of the health administration must implement adopted policies and supervise the health and care services. It is therefore important that the health administration also possesses the same competence as health managers and health professionals.

The aim of the measures relating to management of the digital transformation is for:

- the managers to implement strategic planning, risk management and appropriate measures and projects linked to the use of AI
- the managers to be good change leaders, understand the implications for the workplace and healthcare services, and plan for the continuation of a good working life in the future
- the managers to implement, facilitate participation in, and follow up collaboration both within their own enterprise and across enterprises and national borders
- the managers to dedicate time to continuous and systematic competence-building to address changing competence needs
- the health managers to facilitate productive meetings between health professionals and patients with greater needs, and higher competence health managers to ensure that the use of AI also safeguards the patient's rights and provides better healthcare from a patient perspective

Professional knowledge and skills for digital transformation using AI in healthcare

This level will provide an overview of the collective competence that the enterprise should possess to succeed in the AI-based digital transformation.

In its report entitled *Tid for handling* (Time for action), the Health Personnel Commission points to the strong need for competence within the health service: *"Competence among developers, personnel, patients/users and relatives is a fundamental prerequisite for the use of technology and digital solutions. It is crucial that those affected by this master technological innovations and want to adopt them. They must also be perceived as useful by the users (in this context, this means health professionals) and make a difference in the way they work, such as contributing to greater efficiency at work or higher quality work. This means that targeted training measures must be implemented for the different personnel groups"*.

The impending competence report sets out competence measures relating to numerous groups of personnel in the health service (employees in the health sector at large, health professionals, personnel without any health or social science education, lawyers and technologists). The aim of the measures is to ensure that:

- all health professionals understand the basic principles of AI and can identify appropriate AI applications
- employees who use AI systems as part of their work use them safely and efficiently
- employees actively participate in streamlining based on AI and multidisciplinary collaboration relating to AI
- personnel with patient contact possess the competence to meet patients with greater needs, AI-based apps and a higher level of competence
- lawyers possess competence with regard to technology, the unique characteristics of AI, and legal implications associated with the development and use of AI in healthcare
- technologists/technical staff have sufficient knowledge of medicine and health to understand the key principles behind the development of AI systems for healthcare

Competence of the general population relating to the use of AI

The trend to relocate health and care services closer to people's homes and users entails a greater need to use digital tools – developed either with or without machine learning. In turn, this entails a need for greater digital competence among patients to master their own health [74]. The population needs to have a balanced understanding of why the use of AI is desirable, the benefits and disadvantages of AI, and the use of AI in healthcare.

In May 2024, ICT-Norway published an analysis entitled *Kappløpet på kunstig intelligens i Norden* (The race for artificial intelligence in the Nordic region) [75]. This analysis showed that Norway has a lower proportion of the population with a positive attitude towards AI compared with the other Nordic countries. Nevertheless, Norwegians are more positive than the OECD average.

Through the measures in the impending competence report, we aim to help the part of the population that is interacting with the health service to understand:

- why the streamlining of healthcare services and the use of AI are desirable
- the fundamental principles of AI
- specific use of AI as part of their own healthcare

How to make it happen

- Prepare a report setting out recommendations to meet the competence needs for digital transformation based on artificial intelligence in the health and care sector.
 - A version of the report will be distributed for consultation, probably during September and October.
- Work to follow up the recommended measures according to priority and capacity.

Who is responsible?

The Norwegian Directorate of Health

Who collaborates?

Who cooperates on the measures will depend on the types of measures concerned and who is responsible for the area. The Norwegian Directorate of Health is in dialogue with relevant stakeholders, and also wants relevant partners to contact them. Examples of some relevant partners include the Norwegian Digitalisation Agency, the Norwegian Board of Health Supervision, the Norwegian Radiation and Nuclear Safety Authority, the USHTs, Kompetansebroen (the Bridge of Knowledge), SKIL and the senior management programme for health leaders. We also received feedback during the input meeting at the end of May, which was attended by delegates from municipalities, hospitals, the research and education sectors, private enterprises and others.

[1]

https://www.nrk.no/norge/regjeringen-vil-at-80-prosent-av-offentlig-sektor-bruker-ki_-_-urealistisk_-mener-ki

[2] <https://www.digdir.no/digitalisering-og-samordning/kompetansemmodell-digital-transformasjon/3293>

[3]

<https://digital-transformation.hee.nhs.uk/building-a-digital-workforce/dart-ed/horizon-scanning/ai-and-digital->

[4] <https://www.digdir.no/digitalisering-og-samordning/politikk-og-overordnede-foringer/3294>

[5]

<https://ikt-norge.no/wp-content/uploads/IKT-Norge-Kapplopet-i-Norden-pa-KI-NyAnalyse-mai-2024-endelig->

[6] Development trends 2021. E-health trends, March

[7]

<https://ikt-norge.no/wp-content/uploads/IKT-Norge-Kapplopet-i-Norden-pa-KI-NyAnalyse-mai-2024-endelig->

Appendix 1: Relevant assignments given to other stakeholders

The following assignments have been given to other government agencies and stakeholders and are of relevance to the AI plan:

- **The regional health authorities shall**, under the leadership of the South-Eastern Norway Regional Health Authority, adopt solutions using artificial intelligence that can help free up time among healthcare professionals and reduce waiting times. The effects of the solutions must be documented to facilitate further implementation [76]
- Clinical research must form an integral part of patient care. The development, implementation and dissemination of technology, artificial intelligence, new ways of working and more precise diagnostics and treatment through innovation and business collaboration are central to creating a sustainable health service for all. **The South-Eastern Norway Regional Health Authority [and the other regional health authorities]** will, in this context, increase the use of health data in research and innovation, and facilitate research concerning health services and new ways of providing healthcare [77].
- Greater use of health data and artificial intelligence in health research must be emphasised and stimulated for clinical studies, health services research, research-based quality improvement projects, innovation and business collaboration [78].
- **The Medical Products Agency** will, in cooperation with **the regional health authorities**, the **Norwegian Institute of Public Health and the Norwegian Directorate of Health**, continue to work on the further development of New methods, in line with the Strategy for the further development of New methods (2023 – 2028), including contributing to the development of a new case management system (tool support) that will lead to greater transparency and simplify opportunities for input. A joint status report on the work will be submitted on 1 April 2024. The work is being led by the regional health authorities [79].
- **The Medical Products Agency** shall, in cooperation with **the regional health authorities**, facilitate the implementation of the European cooperation on health technology assessments in the national systems for health technology assessments. Reference is also made to the task of further developing New methods [80].
- **NIPH** will further develop Helsedataservice as a national access administrator and as a national entry point to health data for secondary use (National point of contact). This should be viewed in the context of the European Health Data Space (EHDS) and the roadmap for the health industry [81].
- In collaboration with the university and college sector, **NIPH** will develop more efficient and secure solutions for transferring data to existing data and analysis services. The Institute will present a plan for activities in 2024 that take into account the project work being carried out by SPUHiN, among other things [82].
- **NIPH** will develop a model for sharing health data and tailored statistics with the health industry that safeguards the value that the health data represents to the authorities. The work will be carried out in a dialogue with the Ministry.
- The Norwegian Ministry of Finance has tasked the Norwegian Agency for Public and Financial Management (**DFØ**) with investigating and submitting recommendations for the establishment of a new national management structure for the enforcement of the AI Act. This assignment was scheduled to be completed by 10 June 2024. DFØ has principal responsibility and will cooperate with the Norwegian Digitalisation Agency during the execution of the assignment [83].
- The **Norwegian Digitalisation Agency** (DigDir) will be a driving force behind the further development and strengthening of the work on the sharing and use of data, including high-quality information management. DigDir will also work on the appropriate use of artificial intelligence in the public sector [84].

- **The National Library of Norway** has had its grant increased by NOK 3 million to strengthen the work of the organisation on infrastructure for the development of language technology in Norwegian. This work will, among other things, contribute to the development of technology based on artificial intelligence, using Norwegian language and content as a starting point, and facilitate the development of Norwegian language models within copyright frameworks and agreements. In this context, the Ministry also refers to the letter of 8 December of this year, in which the National Library is asked to instigate a coordinated development project to investigate the value of copyrighted material in the training of Norwegian generative language models [85].

[76] The other regional health authorities have been tasked with similar assignments:

<https://www.regjeringen.no/contentassets/bd8a11644b744dec8a8dc452794000e4/oppdragsdokument-2024-hel>

[77]

<https://www.regjeringen.no/contentassets/bd8a11644b744dec8a8dc452794000e4/oppdragsdokument-2024-hel>

[78]

<https://www.regjeringen.no/contentassets/bd8a11644b744dec8a8dc452794000e4/oppdragsdokument-2024-hel>

[79] <https://kudos.dfo.no/documents/84909/files/38062.pdf>

[80] <https://kudos.dfo.no/documents/84909/files/38062.pdf>

[81]

<https://www.regjeringen.no/contentassets/4689a3fe8d0e4fc3ac13b9f37cf860ec/tildelingsbrev-folkehelseinstitutt>

[82]

<https://www.regjeringen.no/contentassets/4689a3fe8d0e4fc3ac13b9f37cf860ec/tildelingsbrev-folkehelseinstitutt>

[83] <https://dfo.no/sites/default/files/2023-12/Tildelingsbrev%202024.pdf>

[84]

<https://www.regjeringen.no/globalassets/departementene/dfd/dokumenter/statsbudsjettet-2024-tildelingsbrev-dig>

[85]

<https://www.regjeringen.no/contentassets/666fb1413e6d41338e6950eaedc85832/nasjonalbiblioteket-tildelingsbrev>

Appendix 2: Who provided input to the plan?

Consultation meeting held on May 23

- Ahus
- Aidn AS
- Akershus University Hospital
- General practitioner
- Automatix AS
- Department of Pathology, Oslo University Hospital
- Braive AS
- Braie AS
- Directorate for Children, Youth and Family Affairs (Bufdir)
- Capgemini
- Contair
- Crayon AS
- Diakonhjemmet Hospital
- DIPS AS
- DNV
- EHIN
- Eiksmarka Health Care Centre - GP Røskar
- Felleskatalogen AS
- The Norwegian Institute of Public Health
- Research Support, Oslo University Hospital
- Fürst Medical Laboratory
- Physicist and research group leader, Møre og Romsdal Hospital Trust and the Norwegian University of Science and Technology (NTNU)
- Associate Professor at NTNU
- Haraldsplass Diaconal Hospital
- Bergen Hospital Trust and Western Norway University of Applied Sciences (HVL)
- Central Norway Regional Health Authority
- The Northern Norway Regional Health Authority
- South-Eastern Norway Regional Health Authority
- Western Norway Regional Health Authority ICT
- Norwegian Health Archives Registry / National Archives of Norway
- The Norwegian Directorate of Health
- Helseplattformen AS
- The Norwegian Board of Health Supervision
- Western Norway University of Applied Sciences (HVL)
- ICT-Norway
- Kernel AS
- The Department of Radiology and Nuclear Medicine, St. Olavs Hospital
- Kompetansebroen (The Bridge of Knowledge)
- The Norwegian Cancer Registry, NIPH
- The Norwegian Medication Association
- Legevisitt AS
- Livv Health

- Medlytic
- Microsoft Norge AS
- The National Advisory Unit on Rare Disorders (NKSD)
- The National Centre for E-Health Research
- Nordlys Vikar
- Norsk Helsenett
- The Norwegian Computing Center
- The Norwegian Nurses Organisation
- Novartis
- Novartis Norge AS
- NSE
- The Norwegian University of Science and Technology (NTNU) / Norwegian Research Center for AI Innovation (NorwAI)
- The City of Oslo Nursing Home Agency (SYE)
- Oslo University Hospital Health Trust
- Oslo University Hospital, Department of Newborn Screening
- Oslo University Hospital, Regional advisory service for habilitation (RKHAB)
- Psykologenes forening for digital helse/DigPsyk (Psychologists' association for digital health)
- Radiolog VVHF
- Roche Diagnostics AS
- Safetec
- Sensio
- Centre for e-health, University of Agder/Østfold University College
- Senter for kvalitet i legetjenester (Centre for quality in medical services)
- SKIL
- Sopra Steria
- The Language Council of Norway
- St. Olavs Hospital
- Standards Norway
- County Governor of Oslo and Viken
- Vestfold Hospital Trust
- Sykehuspartner HF
- Sørlandet Hospital Health Trust
- Sørlandet Hospital Kristiansand
- Dental Service, Ostfold County Council
- TET/Ruter
- The Journal of the Norwegian Medical Association
- UiT
- The University of Oslo
- University Hospital of North Norway (UNN), Tromsø
- Vestre Viken
- Vestre Viken Health Trust/LOVePROM collaboration

Written input from the health and care sector

- Akershus University Hospital
- The Norwegian Radiation and Nuclear Safety Authority
- Haukeland University Hospital
- The Central Norway Regional Health Authority
- Møre and Romsdal Hospital Trust
- The Northern Norway Regional Health Authority

- Helseplattformen AS
- Ira Haraldsen from the AI MInd project
- Hired the Norwegian Directorate of Health (on behalf of the “Easier access to information” project)
- Kernel AS
- Artificial intelligence in the Norwegian health service – KIN
- Norwegian Association of Local and Regional Authorities (KS)
- The Norwegian Medication Association
- Lovisenberg Diaconal Hospital
- The National Advisory Unit on Rare Disorders (NKSD)
- The Norwegian Society of Radiographers
- Novartis Norge AS
- Oslo University Hospital, Research and Development, Division of Clinical Neuroscience
- The Centre for e-health, University of Agder
- The Norwegian Centre for Clinical Artificial Intelligence – SPKI
- Specialist in general medicine (also founder of Nordlys Vikar)
- The Language Council of Norway
- Standards Norway
- St. Olavs Hospital, Department of Radiotherapy, Cancer Clinic
- The University of Agder

