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D4.3 Potentials of AI approaches and advances in electronic patient records for medical application of ionising radiation research

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Abbreviations

AI	Artificial Intelligence
ECR	European Congress of Radiology
EHR	Electronic Health Records
RP	Radiation Protection
RSNA	Radiological Society of Northern America

Disclaimer

The opinions stated in this report reflect the opinions of the authors and not the opinion of the European Commission.

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1. Introduction

The use of digital technology is rapidly growing in many areas. In the meantime, this also holds in great extend for medical applications. For example, the use of electronic patient record systems in healthcare has grown significantly over the years, offering several benefits such as sharing of health information between professionals, and collection of structured data. One notable example, is Estonia, having implemented a national electronic health record (EHR) system that allows patients full access to their data. Other countries have implemented or are meanwhile setting up similar systems.

However, as these systems continue to evolve, new challenges and opportunities arise, including those using ionising radiation. In this report we explore the potential benefits and limitations of using electronic records for the use of ionising radiation and tracking individual patient health and medical decisions. This may include as an example the use of EHRs to define region-of-interest for individual patients and adopt imaging procedures accordingly or use limited imaging regions due to prior knowledge about the patient.

In addition, EHRs provide or help to provide structured data about therapies but also in terms of imaging databases. Such structured databases would be an important component for developing and implementing AI based methods for image reconstruction, optimisation, evaluation and therapy planning as well as decision support.

Process

During the planning and development phase of the rocc-n-roll project, our work package team engaged in a series of collaborative efforts to identify and establish consensus on the research questions. This involved conducting multiple online stakeholder meetings, which facilitated productive dialogue and exchange of ideas. To further strengthen our discussions, we participated in a real-life meeting at the European Congress of Medical Physics 2022 (ECMP) in Dublin, followed by additional deliberations at the Radiological Society of North America (RSNA) 2022 conference with relevant stakeholders present at the meeting in Dublin. The task leader oversaw the entire process, ensuring that all perspectives were considered and incorporated into the final set of research questions. After extensive deliberation, the team reached a consensus, and the research questions were bundled. This approach gave a strong foundation for the project's success, reflecting the commitment of all stakeholders involved.

After additional deliberations of the project team at the European Congress of Radiology 2023 (ECR), an additional gap was identified about artificial intelligence (AI). Additional questions were phrased by incorporating input from several sessions at ECR 2023.

2. Expert interpretation of the task

During several discussions with experts in the field, the experts have identified key advances in digital and AI applications which can be expected in the future and might impact medical applications of ionising radiation and the use of electronic health records. This list includes:

1) Moving towards more personalised medicine. In such an approach, data collected of an individual patient is used to provide the best individual treatment.
2) For radiation protection (RP) in X-ray imaging, there are individual diagnostic reference values for each country and/or region. How can we register the dose and image quality, are standards required here?
3) AI is increasingly being used in image reconstruction and in several medical imaging tasks. As typical very large datasets are required, is further standardisation required? What are the benefits for patients? Is a novel data format design a possibility for RP?

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4) The implementation of AI is lagging behind the development in research. How can we lift boundaries there and enable the use of AI in medical imaging, therapy planning, decision support and radiation protection while ensuring that the required quality in all of these aspects and procedures is guaranteed?

Each one of these items will be worked out in the next sections.

3. Towards personalised medicine

The application of artificial intelligence (AI) in medicine has grown significantly in recent years, with the goal of building models that allow to move towards personalised medicine. This approach involves using all relevant, available data collected from an individual patient to provide the best treatment approach, including data from CT or other radiological imaging, histopathological imaging, and genotype data such as whole genome and whole exome data. However, integrating such data into electronic healthcare records (EHR) raises questions about how to effectively manage and integrate annotated data, especially in distributed systems such as the Estonian system as most of the currently implemented systems.

One potential solution to this challenge is the use of interoperability standards such as Fast Healthcare Interoperability Resources (FHIR), which allows for the exchange of healthcare information in a secure and efficient manner. FHIR enables the integration of various types of data, including imaging data and genomic data, into EHR systems. Additionally, the use of standardised data models and ontologies can help to ensure the consistent interpretation and integration of data across different systems.

One critical component in the development of these models is the use of annotation tools, which enable e.g., the labelling of images to train AI algorithms.

The use of annotation tools is widespread, and various commercial and open-source tools are available. However, the lack of standardisation among these tools can lead to significant challenges in the development and deployment of AI models in medicine. Different annotation tools use different labelling conventions and data formats, making it difficult to combine datasets from multiple sources and compare results between different studies.

Standardisation of annotation tools can help to address these challenges. By establishing standard labelling conventions and data formats, it becomes easier to combine datasets and compare results between different studies. The use of standardisation can also improve the accuracy and reproducibility of AI models, reducing the risk of bias and errors in the training process.

In the context of EHRs, standardisation of annotation tools becomes even more critical. EHRs contain vast amounts of patient data, often including medical images, and the integration of AI models into EHRs can provide significant benefits in improving patient care. However, to ensure that AI models are developed and deployed correctly in the EHR, standardisation of annotation tools is crucial.

To store annotated data in EHRs, a standardised data format such as FHIR can be used. FHIR is a standard for exchanging healthcare information electronically and can provide a consistent and interoperable way to store annotated data in EHRs. By adopting FHIR as the standard for storing annotated data, it becomes easier to share data between different healthcare systems and integrate AI models into EHRs.

Another important consideration is the use of annotation tools to ensure the accuracy and completeness of data. Annotation tools can be used to identify and label specific data points within a larger dataset, making it easier to manage and analyse the data. For example,

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radiology annotation tools can be used to label specific regions of interest within an image, while genomic annotation tools can be used to identify specific variants within a genome.

The distributed nature of systems may pose challenges to the integration of personalised medicine data, as data may be scattered across multiple systems and healthcare providers including different operating procedures and parameters. However, the use of interoperability standards and standardised annotation tools can help to overcome these challenges by ensuring that data is consistent and accessible across different systems. Definitions of what is needed and what can be used and how data need to be quality assured have to be defined.

The relevance of personalised medicine approaches varies depending on the disease in question. For example, personalised medicine approaches may be particularly relevant for diseases such as cancer, where genomic data can be used to identify specific mutations and tailor treatment accordingly. Similarly, personalised medicine approaches may be useful in the management of chronic diseases such as diabetes, where data from continuous glucose monitoring and other sources can be used to tailor treatment plans to the individual patient.

In conclusion, the integration of personalised medicine data, including imaging data, patient biopsy material circulating biomarkers data and genomic data, into electronic healthcare records poses significant challenges but also holds great potential for improving patient outcomes. The use of interoperability standards and annotation tools can help to overcome the challenges, while the relevance of personalised medicine approaches varies depending on the disease in question. As AI continues to play an increasingly important role in medicine, addressing these challenges will be critical to realising the full potential of personalised medicine approaches.

Research questions on section “towards personalised medicine”

The consensus process, detailed in the introduction resulted in the following research questions:

1) How can the FHIR standard be leveraged to facilitate the integration of diverse data types, such as radiological imaging data histopathological data, circulating biomarkers data, histopathological imaging, and genotype data, into EHRs in support of AI-based personalised medicine?
2) How can standardised data models and ontologies be used to ensure the consistent interpretation and integration of medical data across different EHR systems?
3) What technical and ethical challenges must be addressed in order to enable the seamless integration of AI-based decision support tools with EHRs that incorporate patient-specific data from multiple sources, including imaging data and genomic data?
4) How can machine learning algorithms be trained and validated using the rich data contained within EHRs, and what role can FHIR play in facilitating access to these datasets while ensuring patient privacy and data security?
5) What barriers exist to the widespread adoption of AI-based personalised medicine approaches that rely on the integration of data from EHRs, and how can these barriers be overcome? Can the risks and limits of such methods be estimated and communicated in a suitable way to be taken into account by patients?
6) What impact will the adoption of AI-based personalised medicine approaches that leverage EHR data have on clinical workflows, and how can healthcare providers be trained and educated to effectively incorporate these tools into their practice?

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4. Electronic Health Records to advance radiation protection

Radiation protection (RP) is an essential aspect of medical imaging, particularly in X-ray imaging, where patients may be exposed to ionising radiation. To ensure that radiation exposure is kept as low as reasonably achievable (ALARA), individual diagnostic reference levels (DRLs) have been established for each country or region. These DRLs serve as benchmarks for radiation dose and image quality, helping to ensure that patients receive the necessary diagnostic information while minimising their radiation exposure.

However, the question remains of how to effectively register the radiation dose and image quality in X-ray and nuclear medicine imaging. Without proper registration, it may be difficult to ensure that DRLs are being met, and patients may be exposed to excessive radiation or receive inadequate diagnostic information. Therefore, standards for registration are crucial to maintaining high-quality medical imaging while minimising radiation exposure. This seems to be of growing importance as AI based methods might generate or destroy information without the possibility of detecting or documenting this.

One possible approach to registration is the use of electronic radiation dose monitoring (ERDM) systems. These systems can be used to record the radiation dose received by patients during X-ray imaging procedures, as well as other relevant information such as the type of exam and the patient's age and weight. ERDM systems can also be used to monitor the quality of X-ray images, ensuring that they meet the necessary standards for diagnosis.

However, the implementation of ERDM systems requires standardised procedures and protocols to ensure that data is collected and analysed consistently across different systems and providers. Standards for data collection and analysis may include guidelines for how radiation dose is measured, how image quality is assessed, and how data is recorded and stored.

In addition to standardised procedures and protocols, it may also be necessary to establish regulatory frameworks to ensure that ERDM systems are used consistently and effectively across different healthcare providers and regions. Regulatory frameworks may include requirements for data reporting, quality control, and ongoing monitoring and evaluation to ensure that DRLs are being met and that patients are receiving high-quality diagnostic information while minimising their radiation exposure.

In conclusion, the registration of radiation dose and image quality is crucial for ensuring that patients receive high-quality diagnostic information while minimising their radiation exposure. The use of ERDM systems and standardised procedures and protocols can help to ensure that data is collected and analysed consistently across different providers and regions, while regulatory frameworks can help to ensure that ERDM systems are used effectively and consistently to meet established DRLs. As the use of X-ray imaging continues to grow, it will be important to continue developing and refining these approaches to ensure that patients receive the best possible care while minimising their radiation exposure.

Research questions radiation protection and electronic health records

The consensus process, detailed in the introduction resulted in the following research questions:

1) What strategies can be implemented to ensure that EHRs accurately capture patient radiation exposure data, and how can this information be used to improve radiation protection in medical imaging?

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2) What role can patient engagement and education play in promoting better radiation protection practices in medical imaging, and how can electronic health records be used to support these efforts?
3) How can electronic health records be used to ensure compliance with radiation protection guidelines and regulations in medical imaging including to avoid duplication of procedures?
4) What are the benefits and drawbacks of using electronic health records to track radiation exposure in patients?
5) How can electronic health records be integrated with other technologies, such as ERDMs and quality assurance programs, to enhance radiation protection in medical imaging?

5. Standardisation of data formats

Artificial intelligence (AI) has the potential to revolutionise the field of medical imaging. With the ability to analyse large amounts of data quickly and accurately, AI can help improve diagnostic accuracy, reduce the need for invasive procedures, and increase patient safety. These potential benefits will need to be evaluated in a meaningful manner.

However, as AI is increasingly being used in image reconstruction and several other medical imaging tasks, there is a need for further standardisation to ensure interoperability between different systems and guarantee the important information being correctly presented without additional false information.

One of the challenges in AI-based image reconstruction is the use of proprietary input formats. This can make it difficult to share data between different systems and can limit the ability to compare results. To address this issue, there is a need for a standardised data format that can be used across different imaging modalities and vendors.

One example of such a standardised data format is the ISMRMRD format for MRI. This format provides a flexible and extensible framework for storing raw MRI data, enabling researchers to share data and collaborate on new algorithms and methods. Similarly, the Omero platform for digital microscopy provides a standardised way to manage and share image data, enabling researchers to collaborate more easily and effectively.

In the context of radiation protection, a standardised data format could help ensure that radiation dose and image quality information is captured consistently across different imaging systems. This would enable researchers to compare dose levels and image quality across different systems, helping to identify best practices and optimise patient safety.

However, there are challenges to implementing a standardised data format. For example, different imaging modalities may require different types of data to be captured, and it may be difficult to develop a format that can accommodate all of these requirements. Additionally, there may be resistance from vendors who have invested in proprietary formats and may be hesitant to adopt a new standard as well as allowing information about their proprietary formats.

Despite these challenges, the potential benefits of a standardised data format for medical imaging optimisation and radiation protection are significant. By enabling researchers to more easily share and compare data, such a format could help improve patient safety and optimise imaging protocols. As such, it is important for the medical imaging community to continue exploring the possibility of a standardised data format for radiation protection, and to work together to develop a framework that can accommodate the diverse needs of different imaging modalities and vendors. In addition, a framework for efficient and reliable testing of AI based methods defining patients' benefits is required and will strongly depend on structured and standardised data.

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Research questions on data structures

The consensus process, detailed in the introduction resulted in the following research questions:

1) How can we develop a standardised data format that can accommodate the diverse needs of different imaging modalities and vendors in the context of optimisation of medical imaging and radiation protection? How to strategically involve researchers, medical staff, and patients to jointly design an optimised documenting of the EHRs to facilitate research and data sharing?
2) What strategies can be implemented to ensure that EHRs accurately capture patient radiation exposure data, and how can this information be used to improve radiation protection in medical imaging?
3) What role can patient engagement and education play in promoting better radiation protection practices in medical imaging, and how can electronic health records be used to support these efforts?
4) How can structured and standardised data be used to help implementing procedures by evaluating the benefits for the patients?
5) How to manage and maintain the HER and data sharing in the longer term across Europe?

6. AI for Medical Imaging, Radiation Therapy, Decision Support and Radiation Protection

The advancements in artificial intelligence (AI) and machine learning technologies have shown great potential in various aspects of healthcare, including optimised medical imaging, therapy planning, decision support and radiation protection. Radiation protection is essential for ensuring the safety of both patients and healthcare professionals when utilising medical imaging procedures involving ionising radiation, such as X-rays, CT scans, and nuclear medicine. The increasing use of these imaging modalities highlights the need for innovative AI-based solutions to optimise medical imaging and radiation protection and minimise the risks associated with radiation exposure.

AI can play a crucial role in improving the safety and efficacy the use of ionising radiation by automating complex processes, enhancing decision-making, and enabling personalised radiation dose optimisation. However, several challenges must be addressed to ensure the successful implementation and integration of AI-based safety and efficacy enhancing systems in clinical practice. These challenges include addressing potential biases, ensuring generalisability, involving healthcare professionals in the design process, advocating for integration into European health data initiatives, establishing proper validation strategies including guaranteeing the quality of AI based technologies, and defining clear tasks for AI solutions that seamlessly integrate with existing workflows.

The research questions presented below aim to explore these challenges and guide the development of AI-based safety and efficacy solutions that effectively address the specific needs and challenges faced in this critical area of healthcare. By addressing these research questions, we can facilitate the development of AI systems that not only improve medical imaging, radiation therapy and related radiation protection efforts but also foster collaboration between artificial and human intelligence to optimise patient safety and healthcare outcomes.

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Research questions on AI for data protection

1) Address potential biases and enhance generalisability in AI-based safety and efficacy enabling systems by including diverse patient populations, imaging modalities, and clinical scenarios during the development and validation process.
2) Focus on developing robust, generalisable AI algorithms with strong user acceptance by involving healthcare professionals in the design and evaluation process, ensuring that these solutions are tailored to address the specific needs and challenges and guarantee sufficient quality for all patients.
3) Advocate for the integration of radiation protection in several European initiatives in large-scale data repositories and health data infrastructures that support the collection, storage, and sharing of radiation exposure data. This could facilitate the development and validation of AI-based safety and efficacy enabling solutions while ensuring data privacy and security.
4) Establish proper validation strategies for AI-based safety and efficacy enabling solutions, addressing potential discrepancies between reported performance in literature and real-world clinical effectiveness.
5) Define clear tasks for AI solutions and design systems that can be seamlessly integrated into existing workflows, fostering collaboration between artificial and human intelligence to optimise medical imaging, radiation therapy planning, decision support and radiation protection efforts.
6) Investigate human-AI interaction biases, including automation bias. Automation bias, the tendency to over-rely on AI and be less attentive, can compromise safety. It is essential to study how this and other biases impact physicians' interaction with AI-based systems. Develop strategies, such as training, to mitigate these biases, ensuring effective collaboration between human operators and AI, without reducing clinical performance.

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