EURAMED ROCC-N-ROLL

EURAMED ROCC-N-ROLL
European Medical Application and Radiation Protection Concept

Project title: EURopeAn MEDical application and Radiation prOteCtion Concept: strategic research agenda aNd ROadmap interLinking to heaLth and digitisation aspects

Grant Agreement: 899995

Call identifier: NFRP-2019-2020

Topic: NFRP-2019-2020-13 Research roadmap for medical applications of ionising radiation

D4.4 Report on the ethical challenge of digitalisation

Lead partner:	UNEXE
Author(s):	Susan Molyneux-Hodgson (UNEXE); Alan Tkaczyk (UTARTU), Jean-Michel Dolo (CEA); Jonas Teuwen (NKI).
Contributing AB members and external experts:	Jim Malone (TCD); Jennifer Miller (Yale University)
Work Package:	WP4
Due date:	30/4/2023
Actual delivery date:	16/06/2023
Type:	Report
Dissemination level:	Dissemination level (PU = public)

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

Table of contents

Abbreviations

AI	Artificial Intelligence
IR	Ionising Radiation
ML	Machine Learning
RP	Radiation Protection
RRI	Responsible research and innovation
SSH	Social sciences and humanities

Acknowledgements

Many individuals participated in discussions and events as part of the activity conducted in this work package. The authors would like to acknowledge the following colleagues and contributors: EURAMED rocc-n-roll Work Package 4 project beneficiaries and expert panelists, especially those who engaged in online discussions and the physical WP4 Workshop held at ECMP 2022 in Dublin; participants at the EURAMED rocc-n-roll session at the RICOMET 2021 conference; colleagues in the SHARE Research Platform Working Group on Ethics; EURAMED rocc-n-roll Advisory Board members.

Disclaimer

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

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

1. Introduction

In the context of a drive to digitalise and to develop machine learning and AI for health, an overarching question arises: what are the ethical challenges of digitalisation and how do these manifest in the medical uses of ionising radiation?

The technical research agenda of expanding the use of electronic patient record systems in healthcare, the growth in use of large data sets, and development of associated ML/AI methodologies, raises a range of non-technical research challenges. As digital systems and approaches continue to evolve, new challenges and opportunities arise in what are better-termed as socio-technical systems i.e. systems that involve a combination of hardware, software and humans interacting with patients, including those subject to applications of ionising radiation. In this report, the deployment of electronic records (e.g. for the use of medical ionising radiation, radiation protection and tracking individual patient health and medical decisions), proposals for personalised medicine and the use of machine learning techniques are given critical consideration from a perspective of ethics, broadly understood. Healthcare is an area that the AI industry has yet to fully exploit but this situation is changing rapidly. Some significant results have been demonstrated but the value of clinical use has yet to be demonstrated and outstanding questions on patient benefit, quality and safety have not been explored adequately (Challen et al, 2019).

Ultimately, this report seeks to clarify the outstanding research questions that have been identified as relevant to the growth of digitalisation within healthcare systems and specifically those challenges arising from the advent of ML/AI.

2. Approach to the task

Several rounds of discussions with domain experts were conducted over an approximately two-year period. These discussions took various forms, including panel meetings, dedicated discussion groups and conference workshops. Additional information was gained from: a short survey of project members; via email correspondence with Advisory Group members and the wider SSH community; and an analysis of relevant literature. It should be noted that although discussion of the ethical challenges of digitalisation and of AI is reasonably extensive in the academic and professional literature, to date, there is very limited empirical work that provides evidence on challenges nor on practical outcomes nor is focused on specific contexts/applications. Most of the existing literature is of a generic nature with few examples drawing on specific ionising radiation (IR) applications or situations. The relative absence of empirical studies raises concern, and attention to both specific application contexts and in-situ empirical work, should be considered a priority for future funding programmes.

There is a pre-existing societal discourse around data privacy in general and on the role of AI in society more broadly. So, the research agenda on digitalisation in the areas of concern to EURAMED rocc-n-roll cannot be treated as if occurring in a vacuum and immune from wider societal concerns. There are also widely acknowledged concerns that have been identified across all applications of big data and machine learning (ML) e.g. known biases in data sets used for training algorithms. When considering the challenges posed by digitalisation in medical applications of IR, the research communities need to be mindful of these wider contexts.

The uses of digital approaches, ‘big data’, and AI/ML is varied in research and health systems and can include some of the following:

- Triaging / screening referrals
- Diagnostic support
- Risk predictions

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

- Personalising treatments

Ethical challenges immediately identifiable in these contexts include issues around:

- Data collection (e.g. consent, participation, purposes)
- Data use and re-use (e.g. consent, opt-outs, third-party use)
- Large scale data sets; amalgamation of data sets; re-use validity
- Data mobility, storage, security, privacy and ownership & other data management issues

Discussion of the risks and opportunities of digitalisation was one aspect of the work conducted during the EURAMED rocc-n-roll project. Opportunities that were identified included:

- Better healthcare in places that lack resources, including in remote regions
- Automation of repetitive tasks / avoiding mundane activities to refocus time and effort
- Integration of data to improve outcomes
- Better research tools
- Reduction in costs
- Better database as evidence for interventions
- Radiation dose reductions
- Better and faster diagnosis & reduction in repeated exams
- Quality Assurance (on direct patient images versus phantoms)
- Insights at individual and population levels (i.e. multi-scale possibilities)
- Empowerment of people to gain agency and/or make better informed decisions

Risks that were identified through discussions conducted within the project included:

- Energy use (and associated sustainability issues)
- Insufficient information on the economic benefits and absence of appropriate cost-benefit analysis
- Limited agreement on the risks posed
- Black box algorithms (lack of transparency; accountability; inability to question assumptions underpinning models; information leakage)
- Damage to doctor-patient relations and the loss of the ‘human touch’ in clinical settings
- A generalisation problem (e.g. effective use in one context is extrapolated to other applications where effectiveness not demonstrated)
- Difficulty in creating good regulation and, more importantly, the enforcement of regulations and provision of regulatory technical competence to oversee compliance and administer sanctions
- Use of biased data selections in training of algorithms; challenges of combining orthogonal datasets
- Increases in inequalities / discrimination / the digital divide
- Misuse/abuse in data access / use
- Privacy
- Errors in use
- Loss of expertise / de-education of skilled persons and professionals
- Lack of or inadequate training provision
- Lack of patient confidence / trust
- Overcomplication of work tasks and flows without clear benefits
- Lack of objective assessment against traditional non-ML models, or existing standard statistical approaches
- Current inability of algorithms to transfer to data ‘in the wild’ despite good validation in development.

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

There was a clear view that existing medical practices in the applications of IR were not that well understood. Concurrently, that, too-often, ethical matters were viewed solely as the need for principles and codes. The existence of such codes could then be taken as 'mission accomplished', without further inquiry into ethics-as-a-practice. As society moves towards a more digitised health experience for patients, the need to focus on ethics-as-practice becomes acute. Given that we have limited information on how ethics and data protection issues are handled currently, what needs to change with the growth in use of electronic records, image and data repositories? Are the ethical challenges the same or different between diagnostic and treatment contexts, for example? And what about between research, trials, and application?

3. Ethical challenges in personalised medicine, e-health, and AI

Discussants noted that the use of ML/AI in medical applications of IR may be less visible to patients than in other use cases. For example, while many patients can understand the use of electronic primary care medical records (from visits to a doctor for example), they are highly unlikely to appreciate how ML/AI is (or may be in the future) used. This 'hidden' character to digitalisation raises additional ethical questions as it prevents effective discussion and debate on ML/AI use. Transparency is already acknowledged as a challenge in the AI realm with the majority of companies that develop AI tools working in the private sector and expected to retain proprietary rights and intellectual property (IP).

Distinct sets of ethical challenges were identified in a wide range of arenas, for example:

i) ML/AI research and associated technology development raises a set of challenges that we may categorise using the term 'data ethics';

ii) the intersection of a) ML/AI and b) medical applications, in research and development settings, raises questions around the need to reformulate 'research ethics' and which may have implications for ethics of clinical trials, for example. Research integrity, reproducibility of AI systems, variations in reporting of findings, lack of access to databases, and the reproduction of bias and/or introduction of new biases, are all challenges yet to be investigated;

iii) the specific applications contexts of ML/AI raise challenges and questions on the interface of general professional, or 'medical ethics', and specific interventional ethics, and;

iv) health systems will need to adapt to the digitalisation imperative and thus require rethinking of ethics of governance and regulation.

The *complex intersection* of the above ethics regimes will require further understanding as the existing research, principles, and guidelines for those ethics fields are currently siloed. For more interdisciplinary and inter-professional dialogue is required to meet the range of challenges.

The work of this Task ran alongside that of T4.2. which reported on specific advances in the areas of personalised medicine approaches, e-health systems, and AI advances. These specific areas were subject to further consideration from an ethics perspective.

Personalised medicine

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

There is a fundamental tension between population health and the concept of personalised medicine. Unequal distribution of resources and variations in national health systems mean that the delivery of personalised medicine remains distant in most circumstances. Alongside, the limitations to the utility of personalised approaches need to be defined. There will be diseases and conditions for which personalised approaches deliver cost-effective benefits and others where a personalised approach remains questionable from a medical perspective.

The list of research priorities includes:

- How to develop effective oversight of personal data?
- How can ethical guidelines be translated into best day-to-day practice and with appropriate oversight?
- What are meaningful approaches to patient engagement in the context of digitalization and across the whole research, development, and implementation cycle?
- What safeguards and regulatory checks are required?
- What is the appropriate balance between personalised and public health approaches in the radiation protection (RP) space?

e-health

The promise of electronic health systems has been around for some time. Some countries have made significant advances in this regard, others are struggling and for a variety of reasons. Apart from physical infrastructure and connectivity required, the economic resources to develop in areas such as electronic patient records are limited. Alongside the techno-economic constraints, issues of governance of such systems and public trust are key. Standardised approaches e.g. EDRM, requires effective regulation and an appropriately trained workforce. How such standardised approaches work in practice, in particular across different national and cultural contexts is not currently understood. Transferability across borders (of systems, of countries etc) is yet to be investigated. We also know that public/patient trust in such systems is not uniform across Europe; how to advance public trust in electronic records is a major hurdle to their implementation.

The list of research priorities identified included:

- What are stakeholder perspectives on data privacy, ownership, storage, sharing, transparency, and management, and how can these inform digital health systems?
- How are legislative regimes and governance systems patterned across (& within) countries and what are the challenges of data mobility and integration between systems and across borders?
- How can we understand different perspectives on the protection of personal rights over data, and the generation of detectable information?

AI and its consequences

The advent of AI brings with it many promises and much hype. There are a range of technical challenges remaining yet attention to the ethical dimensions is imperative if even a fraction of the promise is to be delivered Patient engagement at the developmental stages of the technology development is needed. Attempts to engage patients at the end of the line run the risk of relegating technological advancements to the cupboard; non-implementation would be a costly mistake. Trust in the technology must be developed concurrently (Winter and Carusi, 2022) regardless of the application or clinical context.

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

The challenge of equity in the production and use of large data sets is widely stated and yet little attempt has been made to either a) understand the impacts of biased data sets in the medical applications arena and b) create data sets that are more representative of populations and inclusive of patient diversity. Future developments are reliant on a more integrated approach to research that draws together relevant fields of study from both the technical and social sciences.

The list of research priorities identified was extensive.

- How will current informed consent processes need to be changed when using AI/ML systems (both in the building of databases and the applications of ML)? How can we ensure data for future ML use is built to be representative of relevant patient cohorts social characteristics?
- What steps are needed for production of guidelines on safety assurance in applications and contexts of use for AI/ML systems – what does a quality assured system look like from a patient and practitioner perspective?
- How can issues around data quality, algorithmic fairness, built-in bias and both algorithmic and model transparency be managed appropriately and for the benefit of patients?

4. Relation to wider initiatives

There now exists a strong mandate for the inclusion of ethical considerations in assessing *all* aspects of the deployment of ionising radiation in medical diagnosis and treatment. This mandate has been developed over many years and has drawn on the efforts of many experts to enable its development and prominence (Malone et al, 2019; Malone, 2020). This work also continues e.g. WHO recently published a policy brief and identified further areas of work (2022); ICRP TG-109 has been working on new guidance that is open for public consultation (ICRP 2023). Although this mandate now exists, much additional work is required to translate the identified ethical values into widespread application and everyday clinical practice. The general base can, nevertheless, provide a solid grounding for the further development of ethical discourse and practice as the medical field evolves in the use of ML/AI in IT procedures and treatments.

During the period of the EURAMED rocc-n-roll project, several major initiatives relating to AI have emerged. One such is the European Commission's White Paper on AI (EC, 2020) which proposed policies to establish an "ecosystem of excellence" and an "ecosystem of trust for" AI. The 'AI Act' has also been published (EC, 2021). In analysing the AI Act, it has been noted that EU policymakers,

> rely on technical standards to provide the detailed guidance necessary for compliance with the Act's requirements for fundamental rights protections.
>
> (ALI, 2023: 3)

This policy analysis goes on to report that,

> Standards development bodies seem to lack the expertise and legitimacy to make decisions about interpreting human rights law and other policy goals.
>
> (ibid)

Furthermore, that

> This misalignment is important because it has the potential to leave fundamental rights and other public interests unprotected.
>
> (ibid)

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

Although not currently an explicit dimension of EC funding schemes, the earlier policies for, and funding of, responsible research and innovation (RRI) initiatives remain relevant. To a large extent it is expected that RRI approaches have become embedded within research and innovation programmes such that separate programmes are not required. The extant nature of this claim is untested. However, as Van Oudheusden et al reported (2018), deploying RRI methods and framing to all radiation protection research would see benefits in the longer term.

We need also to be mindful of how technical and non-technical dimensions of research and innovation do not necessarily progress concurrently and we should be wary of a technology-first approach in the area of AI and medical applications of IR. The dominance of a technology-first approach to research and innovation puts at risk the successful implementation of innovations in medical applications of IR in so far as societal acceptability of innovations is never guaranteed.

5. Summary

Contributors to Task 4.3 provided highly valuable perspectives through written and verbal input to the task work. The importance of ethical considerations alongside wider discussions in EURAMED rocc-n-roll was understood. An understanding of the need for ethics to be enacted *as a practice*, and not remain as a set of principles or codes, was also appreciated by large sections of contributors. A large number of wide-ranging challenges were agreed as requiring urgent exploration although prioritization was not a simple process. It was also recognized that there is a challenge in managing the introduction of AI when it is known existing, non-AI challenges still need to be met. Fundamentally there was a methodological question that sat alongside the substantive ethical challenges that were identified: what *approaches* are needed to address the ethical matters posed by the use of patient data, e-health systems, artificial intelligence (AI) and machine learning (ML) in use of ionising radiation (IR) in medicine?

In sum, from all of the work conducted, a large number of research questions were found to be outstanding. These questions must be answered to make progress toward radiation protection improvements. The unmet research needs were prioritized through discussion among SSH domain experts and the wider radiation protection community and include:

- How can we understand the existing patterns of public trust in electronic health systems and how then can any discrepancies be identified and addressed?
- What are the implications of the use of biased data sets on: training algorithms; on decision making; and on patient outcomes? How can bias be removed over time?
- How can ML-based developments be progressed in open and transparent ways, ensuring that trustworthy and responsible AI is the outcome?
- How can the drive towards standardisation (in all aspects) be assured to take account of equity, diversity, and inclusion criteria? How can relevant criteria be developed in a responsive way as AI interventions evolve?
- What are the most effective ways of engaging patients (and other relevant stakeholders) within the research and development process itself, such that the research communities ensure more meaningful results, more efficient technology diffusion, and better clinical outcomes?
- In what ways must informed consent procedures and privacy imperatives be adapted to e-health, personalized medicine scenarios and to AI advances?
- How can the whole RP community perform effective transdisciplinary research in the development of AI advances?

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.

References / Bibliography

ALI (2023) Ada Lovelace Institute Discussion Paper: Inclusive AI governance: civil society participation in standards development.

Challen R. et.al. (2019) Artificial Intelligence, bias and clinical safety. BMI Qual Saf, 28:231-237 doi: 10.1136/bmjqs-2018-008370

EC (2020) White Paper on Artificial Intelligence: a European approach to excellence and trust. https://commission.europa.eu/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

EC (2021) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS (The 'AI Act') https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

ICRP TG109 (2023) Ethics in Radiological Protection for Medical Diagnosis and Treatment. Bochud F et al. Available at: https://icrp.org/docs/report_tg109_for_public_consulation.pdf

Malone et al. 2019. Ethics for Radiation Protection in Medicine. e-version available Open Access at https://www.taylorfrancis.com/books/oa-mono/10.1201/9781315148779/ethics-radiation-protection-medicine-jim-malone-friedo-zölzer-gaston-meskens-christina-skourou

Malone J. (2020) X-rays for medical imaging: Radiation protection, governance and ethics over 125 years. Physica Medica: European Journal of Medical Physics. 2020 (79) 47-64. https://www.physicamedica.com/article/S1120-1797(20)30228-3/fulltext

Van Oudheusden M., Turcanu C. and Molyneux-Hodgson S. (2018) Absent, yet present? Moving with 'Responsible Research and Innovation' in radiation protection research, Journal of Responsible Innovation, 5:2, 241-246, DOI: 10.1080/23299460.2018.1457403

WHO (2022) Ethics and Medical Radiological Imaging: A Policy Brief (WHO, Geneva). Available Open Access at: https://www.who.int/publications/i/item/9789240047785

Winter P. and Carusi A. (2022) 'If You're Going to Trust the Machine, Then That Trust Has Got to be Based on Something': Validation and the Co-Constitution of Trust in Developing Artificial Intelligence (AI) for the Early Diagnosis of Pulmonary Hypertension (PH). Science and Technology Studies, 35 (4): 58-77. DOI: https://doi.org/10.23987/sts.102198

This project has received funding from the Euratom research and training programme 2019-2020 under grant agreement No. 899995.