Position Statement on the use of Artificial Intelligence (AI) in Radiation Oncology

NCCP AI in Radiation Oncology Working Group

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Abbreviations

AI	Artificial Intelligence
ART	Adaptive radiotherapy
BSH	Bon Secours Hospital
CBCT	Cone beam computed tomography
CRT	Chemoradiation
CSO	Central Statistics Office
CT	Computed tomography
CTV	Clinical target volume
CUH	Cork University Hospital
DoH	Department of Health
EC	European Commission
EHR	Electronic Health Record
EU	European Union
GDPR	General Data Protection Regulation
HSE	Health Service Executive
IT	Information technology
MDT	Multidisciplinary Team Meeting
ML	Machine learning
MLC	Machine learning compilation
MRI	Magnetic Resonance Imaging
NCCP	National Cancer Control Programme
NCRI	National Cancer Registry of Ireland
NCS	National Cancer Strategy
NMSC	Non-melanoma skin cancer
NPRO	National Plan for Radiation Oncology
NSAI	National Standards Authority of Ireland
OAR	Organ at risk
PET	Positron emission tomography
QA	Quality assurance
RO	Radiation Oncologist
RT	Radiotherapy
sCT	Synthetic computed tomography
SGRT	Surface-guided radiotherapy
SLRON	St Luke's Radiation Oncology Network
TPS	Test program sets
UPMC	University of Pittsburgh Medical Centre

1.0 Introduction

1.1 Patient numbers in Ireland

Cancer incidence data from the National Cancer Registry Ireland (NCRI) and population projections from the Central Statistics Office (CSO) have been combined by the NCRI to estimate the number of new cancer cases expected in five year bands from 2020 to 2045. The total number of new invasive cancer cases (including non-melanoma skin cancer [NMSC]) is projected to increase by 84% for females (from 10,240 to 18,840) and 111% for males (from 11,460 to 24,160) between 2015 and 2045, based only on changes in population size and age distribution (demography) (NCRI, 2019).

Demand for radiation oncology is expected to increase in line with increases in cancer incidence as it is estimated that approximately 50% of cancer patients will require radiation oncology for primary radical/adjuvant treatment and palliation at some point in their cancer journey (Barton et al., 2014). Similarly, NCRI data have projected that the number of male and female patients undergoing radiotherapy (for all invasive cancers, excluding NMSC) will increase from 3,369 and 3,852 in 2015 to 6,542 and 6,214 in 2045 respectively (NCRI, 2019).

1.2 Radiotherapy Treatment Pathway: An Overview

Before delving into the role and integration of artificial intelligence (AI) in radiation oncology, it is important to understand the radiotherapy treatment pathway. Radiotherapy, a cornerstone in cancer treatment, involves a complex, multi-step process tailored to each patient's unique medical needs.

Treatment Decision: This first step of the radiotherapy process typically begins with a discussion of the patient at a multidisciplinary team (MDT) meeting, reviewing the patient's clinical, pathological and radiological findings with colleagues. At the MDT, a preliminary decision to treat the patient is made and a referral to a Radiation Oncologist (RO) is made. Subsequently, the RO meets the patient at a clinic. Here, the patient's oncological diagnosis, comorbidities, performance status and preferences are assessed. A decision is made as to whether the patient is fit for and will benefit from radiotherapy.

Simulation & Treatment Planning: In this phase, a team of specialists, including radiation oncologists, medical physicists, and radiation therapists collaborate to design the patient's personalised treatment plan. This process begins with a detailed simulation, where the team employs advanced imaging technologies, such as CT, MRI, or PET scans, to accurately map the treatment and healthy tissue areas. A treatment plan is then created using multiple complex linear accelerator energies, beam angles and shapes. Each treatment plan is designed to be bespoke and optimised to a patient's anatomy, which is critical for maximising the therapeutic effect while minimising damage to healthy tissues.

Treatment Delivery: Using advanced linear accelerator technology, precise doses of radiation are administered to target the tumour. The duration and frequency of these sessions vary based on the cancer type, extent of disease and therapeutic aim. Throughout the treatment, ongoing assessment and adjustments are made using in-room imaging technology to ensure accuracy of delivery and that any anatomical changes are accounted for using adaptive radiotherapy strategies.

Monitoring & Follow-up: Post-treatment follow-up is a vital part of the pathway, encompassing monitoring for treatment response, managing late effects, and providing supportive care. This phase includes regular clinical assessments and may include imaging tests to detect any signs of cancer recurrence.

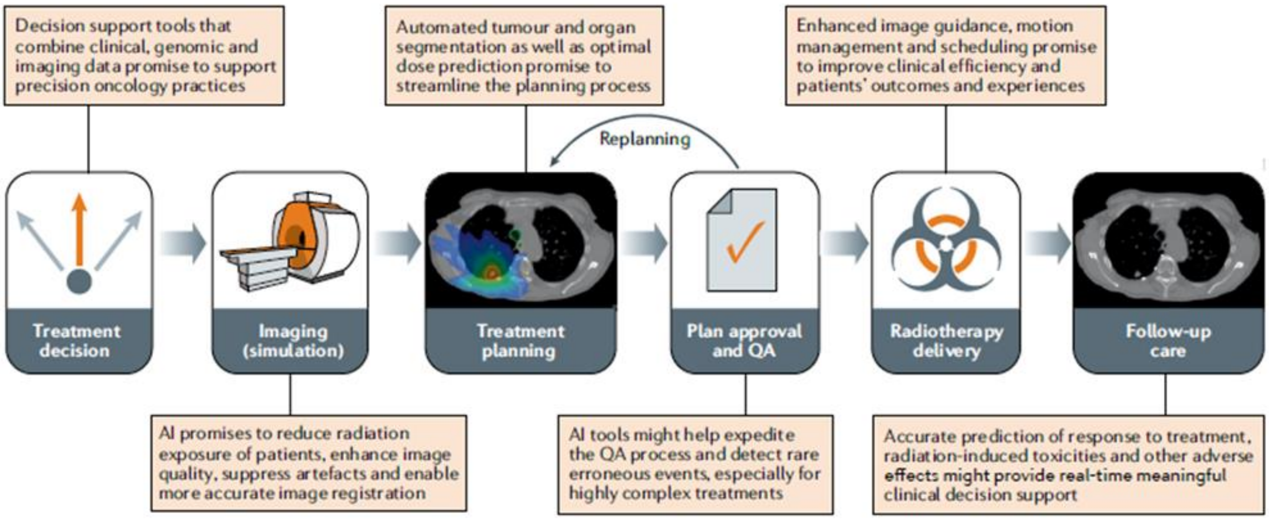

Figure 1. Applications of AI in the Radiation Therapy workflow

Figure 1 provides a general overview of the radiation therapy workflow with brief descriptions of expected applications of artificial intelligence (AI) at each step (Huynh et al., 2020).

1.3 Integration of AI in Radiation Oncology

Artificial intelligence (AI) involves the development and use of complex computer algorithms to perform tasks that normally require human intelligence, such as visual perception, pattern recognition, decision-making and problem solving, at a similar or improved level of performance (Huynh et al., 2020). Advancements in AI have revolutionised various sectors, including healthcare, which is evidenced by the rapid increase in clinical publications in this area (Jarrett et al. 2019; Zhao et al., 2021).

The National AI Strategy: AI - Here for Good (Government of Ireland, 2021) sets out how Ireland can be an international leader in using AI to benefit our economy and society, through a people-centred, ethical approach to its development, adoption and use. In terms of AI in health, the strategy highlighted that AI has huge potential in the area of healthcare from improving patient experiences to providing more accurate interventions for patients. AI has played an important role in the global response to the COVID-19 pandemic. Governments around the world are making use of AI in the development of vaccines, in outbreak prediction and modelling, automated contact tracing, intelligent supply chains and space mapping for social distancing, amongst other applications.

In the context of radiotherapy, AI could have particularly transformative applications given the highly technical nature of this field with heavy reliance on digital data processing and computer software. One of the significant drivers of AI adoption lies in the rapid growth of available data for diagnosis, prognosis, and treatment. This influx of data arises from diverse sources, such as genomic data, pathology reports, diagnostic imaging, Electronic Health Records (EHR), dosimetry data, radiomics data, biomarkers, demographic and socioeconomic data, etc. However, the management and interpretation of this vast and inhomogeneous data pose unique challenges to human capabilities alone.

This is where AI emerges as an invaluable asset to modern radiotherapy. Its computational power, combined with the ability to learn from each new piece of information paves the way for personalised, accurate, and efficient cancer treatment strategies. AI-driven algorithms can effectively parse and infer key information from these multiple data sources and recognise intricate patterns and relationships that may not be immediately apparent to human observers. Consequently, AI has the potential to provide efficiencies and unlock valuable insights to aid staff in making well-informed decisions, accurate prognosis, and personalised and optimal treatment plans. These improvements have the potential to address many of the challenges faced in radiation therapy and thereby improve the availability and quality of cancer care (Huynh et al., 2020).

This NCCP Expert Working Group report describes the role of AI in Radiation Oncology and the main challenges involved in ensuring that integration of AI applications into the clinical environment is carried out to high standards. The report concludes with recommendations on the best way to introduce and implement AI into the radiotherapy treatment pathway, making the best use of facilities and staff.

1.4 Governance and Strategic Considerations

Effective governance is essential in radiotherapy, involving stringent quality control, safety protocols, and adherence to best practice guidelines. As the adoption and integration of AI increases, governance will also encompass ethical considerations, data security, and regulatory compliance related to AI technologies. Section 4.0 outlines our position on the governance, ethics and strategic direction of AI in Radiation Oncology.

2.0 Rationale for AI in Radiation Oncology

The aim of radiotherapy is to deliver a high dose to a target (tumour), and give as low a dose as possible to surrounding normal tissues known as organs at risk (OARs). However much of the workflow requires time-consuming, manual input by a diverse team of healthcare professionals, including radiation oncologists, medical physicists, medical dosimetrists and radiation therapists.

According to Kresl and Drummond (2004), the growing complexity of human-machine interactions in conjunction with the increasing incidence of cancer has led to radiation oncology workforce shortages throughout the world and invariability in the quality of care. Variations in radiotherapy treatment-planning processes have been shown to negatively affect overall survival (Peters et al., 2010; Brade et al., 2018).

AI solutions are posed to be integrated into all aspects of the radiotherapy workflow. The solutions presented below show great potential benefits, and are either at early stages of development in the literature, or commercial solutions currently available for purchase.

Computational models based on AI variants have been developed and applied successfully in many areas, both inside and outside of medicine. However, the full potential of AI in the entire radiotherapy workflow is not fully understood. AI permits the processing of large quantities of information, data, and images stored in RT oncology information systems, a process that is not manageable for individuals or groups. AI allows the iterative application of complex tasks in large datasets (e.g., delineating normal tissues or finding optimal planning solutions) and might support the entire community working in the various sectors of RT, as summarized in this overview. AI-based tools are now on the roadmap for RT and have been applied to the entire workflow, mainly for segmentation, the generation of synthetic images, and outcome prediction. Several concerns have been raised, including the need for harmonisation while overcoming ethical, legal, and skill barriers (Santoro et al., 2022).

2.1 Treatment Decision

Making the decision to treat a patient, the first step of the radiotherapy process is arguably the most important and challenging decision that is made by the RO (Roques, 2014). Initially the patient details are discussed at the MDT and the RO recommends a review of the patient. The RO subsequently assesses the patient, reviewing their clinical, radiological and pathological details in addition to performance status, comorbidities and patient preferences. The benefit of radiotherapy versus the predicted toxicity is considered. The aim is to maximise cure /palliation while minimising the probability of normal tissue complications. At that initial clinical assessment, a recommendation is generally made to the patient as to whether they should undergo radiotherapy or not. Prognostication is often challenging as it is based on the clinicians perception of the patient's performance status, and may ultimately determine what dose, fractionation or combination treatment they may receive. It is generally accepted that there are limitations to the ROs ability to predict the benefits versus risks of treatment.

It would be very useful if we could predict outcomes for patients being referred for radiotherapy more accurately. If we could identify those for whom radiotherapy will be effective, those for whom it is futile and those who will have severe treatment-related toxicity. Activity trackers are increasingly being integrated into clinical trials aiming to assess a patient's fitness related metrics (Walsh et al., 2017; Schrack et al., 2018, O'Connor, Markicevic et al., 2019) and their potential to predict clinical outcomes, such as toxicity and quality of life.

Acute toxicity can be severe and life threatening, Late toxicity is also a major concern as it causes lifelong disabling symptoms. AI can analyse large volumes of patient data, The current availability of large pools of patient-specific information including biological and imaging information combined with AI developments would appear to have the potential to make sense of such a plethora of heterogeneous data and to aid clinicians in their decision-making process (Cui et al., 2022).

There is an increasing volume of research on using AI to predict toxicity of radiotherapy (Hong et al., 2020; Christopherson et al., 2021; Isakkson et al., 2020, Choi et al., 2023; van Velzen et al., 2022; Terrones-Campos et al., 2023; Saednja et al., 2020; Gaito et al., 2021; Zhu et al., 2021; Mayo et al., 2020). There is only a single randomised clinical trial in the literature where AI was prospectively used to identify patients at high risk of acute toxicity with radiotherapy (RT) or chemoradiation (CRT). AI accurately triaged patients undergoing RT and CRT, for more intense monitoring to prevent hospitalisation (Hong et al., 2020). Big data was used in another study to predict for both acute and late dysphagia in head and neck cancer patients successfully (Mayo et al., 2020). The remaining publications addressing acute and/or late toxicity tend to be either small single centre studies or literature reviews. The REQUITE study, a large prospective multicentric ongoing study may establish the use of AI in predicting late radiation toxicity (Seibel et al., 2019).

Another challenge for the Radiation Oncologist is deciding whether to recommend radiotherapy when dealing with patients with rare cancers where there usually isn't a strong evidence basis to aid decision making. There is some encouraging research on the use of AI to make treatment decisions in some rarer cancers e.g.malignant salivary gland tumours (De Felice et al., 2021) and retroperitoneal sarcomas (Zeh et al., 2023) but larger datasets and validation is necessary.

With regard to predicting oncological outcome there are an increasing number of publications that address using AI to predict outcome for patients being treated with radiotherapy (Jaberipour et al., 2021; Christie et al., 2021; Gangil et al., 2022; Luo, 2021; Appelt et al., 2022; Nieder et al., 2021; Oei, et al., 2021; Tomita, et al., 2022; Bang, et al., 2023; Pan, et al., 2023; Lin et al., 2023). Appelt and colleagues in a systematic review found the published literature on the use of AI for radiotherapy oncological outcome prediction is relatively scarce, and suffers from a number of general methodological issues, including small patient cohorts and a lack of external validation.

AI has the potential to improve recruitment of patients into clinical trials at that initial consultation (Ismail et al 2023). The importance of increasing patient involvement in clinical research is highlighted in the NCS 2017-2026 document

To summarise the use of AI to predict treatment toxicity and patient outcome during and following radiotherapy is in its infancy. The available studies conclude that AI could have a role to play in predicting patient outcomes. However, these are generally small studies and lack external validation. There is general agreement that collaboration between centres in order to obtain large datasets in addition to external validation is required before AI can be clinically useful in aiding decision making in the first step of the radiotherapy pathway. AI has the potential to drive recruitment into clinical research and accelerate our evidence base to optimise patient management.

2.2 Imaging for Radiotherapy

AI's integration with medical imaging processes holds the potential to detect diseases (Liu et al., 2019; Barragán-Montero et al., 2021), significantly improve contouring workflow times (Sarria et al., 2023), minimise imaging radiation exposure (Immonen et al., 2021), enhance image quality (Shen et al., 2018; Wu et al., 2021), enable more accurate image registration (Teuwen et al., 2022; Barragán-Montero et al., 2021), and even facilitate the conversion between various imaging modalities (Shafai-Erfani et al., 2019; Barragán-Montero et al., 2021). Today, AI and ML models have reached important milestones, demonstrating equivalence to healthcare professionals for certain diagnostic applications, such as skin cancer detection (Esteva et al., 2017) or breast cancer detection (Lotter et al., 2021) in medical imaging.

These advancements not only have the potential to enhance diagnostic precision but also contribute to a more efficient, effective, and accurate treatment planning workflow. For example, one of the most notable developments in this area is the widespread use of AI auto-segmentation (Hindocha et al., 2023; Heilemann et al., 2023; Cardenas et al., 2019; Men et al., 2020). This technology is already widely adopted in both public and private centers in Ireland, rapidly rendering manual contouring of organs and targets obsolete. Contouring time savings of over 50-70% are possible, depending on the treatment site (Sarria et al., 2023).

AI also has the ability to generate synthetic planning CT scans from MRI or cone beam computed tomography (CBCT) imaging, offering enhanced soft tissue detail for contouring and Adaptive Radiotherapy (ART), as shown by Shafai-Erfani et al. (2019). AI's impact on dose prediction is equally promising, as demonstrated by several groups, including Ahervo et al. (2023) and Hee Ahn et al. (2021). AI swiftly predicts doses from CT/CBCT imaging, providing rapid dosimetric assessments during treatment planning or to account for anatomical changes during treatment, making dose calculations more accessible and efficient for ART.

AI presents numerous potential applications to leverage diagnostic, treatment planning, treatment verification, and follow-up imaging studies. These range from auto-detecting recurrences (Zhang et al., 2022) to monitoring imaging data for treatment response and outcome prediction (Zhen et al., 2017). However, it's essential to acknowledge AI's sensitivity to variations in image quality (Dodge & Karam, 2016), vulnerabilities to adversarial examples (Kaviani et al., 2022), and known performance declines when tested on external data (Zech et al., 2018). Ensuring rigorous validation on local data and understanding the training data and its limitations are essential. In summary, AI's integration revolutionises radiotherapy imaging, from diagnosis to treatment, with profound implications for workflow and patient care.

2.3 Treatment Planning

AI tools can efficiently analyse medical images to delineate tumour and OAR boundaries. For example, Liu et al (2021) trained an AI model to identify the Clinical Target Volume (CTV) in cervical cancer. The results compared favourably to those CTVs contoured manually. AI can also be used to generate the imaging required for treatment planning. For example, Lerner et al. (2022) investigated MRI only radiotherapy for brain cancers by generating synthetic CT (sCT) from MRI scans using a commercially available AI tool. They demonstrated the clinical feasibility through a prospective study with endpoints for dosimetry and patient setup. The generation of the treatment plans using AI tools has been explored by a number of groups. Nicolae at al. (2020) showed the non-inferiority of treatment plans developed using an AI based planning system to those developed using conventional methods for Low Dose Rate prostate brachytherapy. In addition, the AI offered a significant improvement of workflow efficiency. Xia et al. (2021) demonstrated a full process AI-driven treatment planning process for rectal cancer. A single framework combined auto-segmentation for OAR and target generation together with automated treatment planning to predict the dose distribution. This was then used to generate the final treatment plans which compared favourably to clinical practice and again demonstrated significant workflow efficiency improvement. Commercial systems which combine multiple steps in the treatment planning process using AI tools are beginning to become available, for example for adaptive-RT (Archambault et al., 2020).

2.4 Adaptive Radiotherapy

During the course of radiotherapy treatment, which might take place over a number of weeks, there may be significant changes in tumour size and organ at risk position. Until now, this was addressed by applying sufficient margins around the tumour and OAR volumes. However, this often results in a larger volume of normal tissue being irradiated, limiting the dose that can be delivered and therefore affecting tumour control probability. An emerging radiotherapy approach is referred to as Adaptive Radiotherapy, where the treatment dose distribution is adapted to give the optimum dose distribution based on imaging the patient during treatment. This adaptive approach facilitates personalised treatment and improves response rates for certain cohorts of patients (Huynh, et al., 2020). AI has shown promising results in the prediction of which patients require adaptation of treatment (Iliadou, et al., 2022) and also the ideal time point at which it should occur. Adaptive radiotherapy requires a substantial increase in the number of images taken during treatment, rapid image segmentation and dose calculation. As this process has to happen while the patient is on the treatment bed, it requires rapid acquisition and processing of a lot of data. AI algorithms can continuously monitor and adapt treatment plans based on real-time patient-specific data (Zhang., et al 2023). This data includes motion management data, such as 4D breathing motion data, implanted fiducial tracking, and surface-guided radiotherapy (SGRT) data, on-treatment imaging to measure anatomical changes, including changes in tumour size, shape, or location during the course of treatment (Sibolt, et al., 2021; Le, et al., 2022).

2.5 Plan Approval & Quality Assurance

AI tools can help expedite the quality assurance (QA) process. For example, Men at al. (2020) created an AI tool to assess contours which had been submitted to a lung cancer clinical trial. The tool provides consistent and quantitative evaluation thus reducing investigator intervention. A number of groups, Valdes et al. (2017) and Nyflot et al. (2019) have used AI tools to predict failures in patient plan QA, especially for highly complex treatments. This could significantly optimise the QA process to focus attention to where failures can be anticipated. AI can also aid in the real-time monitoring of treatment delivery, ensuring accurate dose delivery and minimising the risk of errors. Li and Chan (2017) used an AI tool to monitor linac performance and were able to predict the beam characteristics better than current clinical practice with potential workflow efficiency improvements. A number of groups, Carlson et al. (2016) and Chuang et al. (2021) have used AI tools to predict MLC positional accuracy. Such tools could be incorporated into a commercial TPS to display a more representative delivered dose distribution. AI tools are also being used to investigate the performance of proton therapy delivery for use in second check systems Sun et al. (2018) and Grewal et al. (2020). This could further replace the need for time-consuming output factor measurements.

2.6 Radiotherapy delivery

AI has the potential to identify the most important factors contributing to waiting time durations (such as the time of day, number of radiotherapy dose fractions, median past duration of treatments, number of treatment fields and previous treatment duration) and predict waiting times, thus enabling optimisation of clinical workflow through optimised scheduling to improve clinical efficiency (Pham, et al., 2022). Using AI models, appointment scheduling could potentially be further optimised by taking into account anatomical treatment site and the immobilisation and treatment techniques used in order to decrease the room turnover time between patients and accommodate a higher number of patients (Huynh, et al., 2020).

2.7 Follow-up patient care

The follow-up care of patients receiving RT is multifaceted and intrinsically linked to the initial RT related treatment decision making process (Reddy, et al., 2023), much of which has been addressed in Section 2.1.

There are a small number of studies using radiological and histopathological data to investigate the use of machine learning (ML) tools to predict outcomes such as the benefits of treatment (Spratt et al.), the risk of local recurrence (Tomita et al., 2022; Zheng et al.) and treatment response (Kawahara et al.), and survival (Nieder et al., 2021). Such ML tools may also allow monitoring of change over time (i.e. imaging changes - size, enhancement, PET avidity, diffusion restriction, radiomic features etc) providing indication of therapeutic efficacy and suggested likelihood of radiation induced toxicities (Feng et al., 2018). However clinical implementation of such ML/AI tools to garner individualised risk based strategies is currently premature.

Wearable and mobile biometric tools, such as watches and vest, are increasing in use and may provide valuable additional post treatment data from patients in their daily environment. A recent systematic review (Chow et al. 2023) reported the most common use of wearables reported in the literature is for the purpose of rehabilitation, followed by patient monitoring and prognostication. In cancer care specifically, AI has the potential to process such information contributing to prognostication by providing objective, reliable, and relevant metrics informing the efficacy of various interventions on day to day physical activity which is associated with various clinical outcomes of interest. These tools may allow less frequent in person follow-ups, or conversely alert for more frequent follow-ups depending on the change in the day to day biometrics.

2.8 Scheduling of patients for Radiotherapy

Scheduling of patients for commencement of radiotherapy and for treatment slots can be challenging given that treatment planning is a multistep process involving many staff groups. Additionally, radiotherapy can vary from simple to highly complex treatment planning and delivery. Artificial intelligence would appear to have the ability to improve efficiency in radiotherapy departments by having the ability to predict the time needed for each step of the process more accurately (Xie et al., 2023, Bentayeb, 2019).

2.9 Conclusion

AI solutions have a clear role to play in the future of Radiation Oncology. The integration of AI into the radiotherapy workflow offers a range of transformative opportunities. From clinical decision support to prognosis and outcome prediction, and optimising treatment planning to real-time adaptive radiotherapy, AI-driven solutions support and empower clinicians with data-driven insights, personalised treatment strategies, and enhanced clinical efficiency. By harnessing the potential of AI in decision support, imaging, planning, and follow-up care, radiation oncology facilities can position themselves at the forefront of innovation, providing improved patient outcomes and elevating the quality of cancer care.

3.0 Alignment with National Cancer Strategy 2017-2026 (DoH, 2017)

3.1 NCCP Recommendations

The National Cancer Strategy (NCS) states that 60% of all patients with cancer will require radiotherapy treatment. Timely access to high quality multidisciplinary care is key to delivery of the radiation oncology service, as per the National Plan for Radiation Oncology (DoH, 2003). National guidelines describe key performance indicators and mandate required timelines for curative radiotherapy treatment (DoH, 2017). For example, all patients receiving curative radiotherapy treatment should start radiotherapy within 15 working days of being ready to start. Compliance with these guidelines is increasingly challenging given increased complexity of treatment, increasing cancer burden and recruitment challenges (DoH, 2022). The National Artificial Intelligence Strategy for Ireland highlights the efficiencies already gained by implementation of AI applications in the public service, including health. Experience to date with the implementation of AI in radiation oncology suggests that it will be invaluable in maintaining a high quality service going forward.

In addition, the NCS Priorities for the Next Ten Years' states that *"the NCCP must play a strong role in ensuring the incorporation of evidence based care pathways into the delivery of the services offered to patients with cancer in a manner which ensures that issues of access are appropriately addressed. The end goal must be that access to, and experience of, cancer diagnosis and treatment is related only to the clinical need of patients who must use these services"***.**

Several of the recommendations of the NCS support the implementation of AI in Oncology in Ireland:

- **Recommendation 14:** The NCCP, working with the other Directorates in the HSE and with the Department of Health, will develop a rolling capital investment plan, to be reviewed annually, with the aim of ensuring that cancer facilities meet requirements.

- **Recommendation 20:** To increase patient participation in clinical trials

- **Recommendation 22**: In line with NPRO, public sector radiation oncology facilities in Dublin, Cork and Galway will be expanded to meet patient demand and a planned National Programme of equipment refreshment and replacement will be implemented across the Strategy period.

- **Recommendation 48**: The NCCP and the National Cancer Research Group will examine mechanisms to ensure that newly appointed cancer consultants and Advanced Nurse Practitioners have protected time to pursue research interests in their new posts.

- **Recommendation 50:** The NCCP, aided by a cross-sector group, will draw up a comprehensive workforce plan for cancer services. This will include an interim assessment of staffing needs at medical, nursing and health & social care professional levels by mid-2018.

- **Recommendation 52**: The Department of Health will review the scope of the National Cancer Registry with a view to increasing and optimising the use of available data to drive improvements in cancer care for patients.

4.0 Governance, Ethics and Strategic Direction

Ireland acknowledges that existing legislation covers current AI use, but that some potential legal gaps may need to be addressed in the future which are actively being assessed and addressed by the Irish Government. Similarly, at the EU level, a horizontal regulatory framework for AI is being developed. Ireland is actively involved in shaping this framework, focusing on safeguarding fundamental rights, fostering innovation, and leveraging AI opportunities. The National AI Strategy was launched in 2021 and sets out its vision that Ireland will be an international leader in using AI for the benefit of its population through a people-centred, ethical approach to its development, adoption and use (Department of Health, 2017).

Per the EU Commission Ethics Guidelines for Trustworthy AI (2018), AI should always be trustworthy, which comprises three components – it should be lawful, ethical, and robust (from both a technical and social perspective). To support legal and ethical obligations regarding AI, compliance tools (including standards and certification) will be employed. The National Standards Authority of Ireland (NSAI) established the Top Team on Standards for AI in 2020 to lead this effort, developing a roadmap for AI standards and assurance (NSAI, 2023).

Until the adoption of a national strategy, the governance and strategic direction of AI applications in radiotherapy must be guided by the following key criteria:

Data Governance: Privacy and data protection are fundamental throughout an AI system's life cycle. AI may deduce sensitive personal information; individuals must always have control over their data to prevent harm or discrimination. Straightforward - but comprehensive - communication and transparency with individuals is critical. High-quality data is vital for AI performance; potential biases, inaccuracies, and integrity issues should be anticipated and minimised. Similarly, thorough documentation and testing at every stage are crucial, particularly for externally sourced AI systems. Future uses for data should also be considered and specific consent sought where necessary. Ethical principles, as outlined in the EU's Guidelines on Trustworthy AI (Communication 2019/168/EC), will guide AI adoption, supported by compliance tools like standards and certification to ensure alignment with national and international legal and ethical obligations.

Accountability: To ensure accountability for AI systems, both pre- and post-implementation auditability is crucial. Internal and external audits, along with publicly available evaluation reports, enhance technology trustworthiness. External audits are vital for applications impacting fundamental rights and safety. Identifying, assessing, documenting, and mitigating potential negative AI impacts using proportionate impact assessments is crucial. Addressing unjust or adverse impacts requires adequate redress mechanisms to be in place. The European Commission's Proposal for Laying down Harmonised Rules for AI (Communication 2021/206/EC) points out that periodic audits will be carried out for all AI systems to make sure that the provider maintains and applies a quality management system. As is currently the case, the clinical team retains ultimate responsibility for the care of individual patients.

Human Oversight: Human oversight is essential for preventing AI from undermining human autonomy and causing adverse effects. Control measures, including adaptability, accuracy, and explainability, should be tailored to the specific AI system and its application (the General Data Protection Regulation [GDPR] gives individuals the right not to be subject to a decision based solely on automated processing when this produces legal effects on users or similarly significantly affects them). Oversight methods like "human-in-the-loop," "human-on-the-loop," or "human-in-command" should be implemented. Public authorities must have oversight capabilities aligned with their mandates. When human oversight is limited, more extensive testing and stringent governance become necessary.

Safety: An extensive body of existing EU product safety legislation, including healthcare sector-specific rules, is relevant and potentially applicable to a number of emerging AI applications (General Product Safety Directive [Directive 2001/95/EC]). AI systems must be reliable, secure, and resilient against attacks or data manipulation. They should have fallback plans for issues, provide accurate decisions, and transparently communicate their accuracy levels. Risk assessment processes across different applications of AI systems should be established to address potential risks comprehensively. Ongoing involvement of the manufacturer should be required and back-up plans should be in place for system failures. All use of AI systems in radiation oncology should be evidence-based, clinically justified and with the primary goal of improving patient care. This is particularly relevant where a system may alter the clinical outcome for a patient.

Special Considerations for High-Risk Systems: A risk-based approach in AI regulation is vital for proportionality. It needs clear, universally applicable criteria to differentiate between AI applications, especially for identifying 'high-risk' applications. AI application employed in healthcare are considered high-risk, since, given the characteristics of the activities typically undertaken, significant risks can be expected to occur.

When strategising the European Commission's approach to AI (Artificial Intelligence for Europe [Communication 2018/237/EC]), a High Level Expert Group put down several key requirements for high-risk applications, including some of those used in healthcare:

- **Training Data:** Ensuring the quality and representativeness of data used in AI systems.
- **Data and Record-keeping:** Establishing rules for proper data management and documentation.
- **Information Disclosure:** Requiring comprehensive information sharing about AI systems to enhance transparency.
  Robustness and Accuracy: Mandating that AI systems be reliable and perform with a high degree of accuracy.
- **Human Oversight:** Implementing mechanisms for human control and accountability in high-risk AI systems.
- **Specific Application Requirements:** Tailoring regulations for particular uses, such as remote biometric identification.

These requirements aim to create a responsible and accountable environment for AI, particularly in areas where the technology poses a higher level of risk, such as healthcare. It recognises the significance of AI in the healthcare sector while highlighting the potential risks associated with medical AI. By focusing on high-risk applications and setting clear expectations, the aim is to balance the potential for innovation of AI in healthcare with the need for safeguards and ethical considerations, ensuring trust, excellence, and compliance.

For non-'high-risk' AI applications in healthcare which are exempt from mandatory rules, a voluntary labelling scheme may be an option. Operators not subject to mandatory requirements may voluntarily adhere to those rules or to a designated set of similar requirements. This participation could result in a quality label for their AI applications.

5.0 Facility Requirements

Introducing AI into a hospital, from a facility requirements perspective, typically leverages existing IT infrastructure. Hospitals are generally equipped with the necessary technology foundation to support AI implementation.

IT Infrastructure: Most hospitals already have a robust IT infrastructure in place, including high-speed internet connectivity, servers, and data storage capabilities. These elements provide the foundation for implementing AI systems.

Data Access: Hospitals have access to vast patient data repositories, including electronic health records (EHRs), medical imaging archives, and other relevant healthcare data. This data is essential for training and validating AI algorithms.

Computing Resources: Hospitals often have dedicated computing resources, which can be utilised for AI tasks. However, these resources may not include high-performance computing clusters or cloud-based services, allowing for efficient AI model training and inference.

Security Measures: Hospitals typically have stringent data security and privacy protocols in place to protect patient information. These measures are critical when implementing AI to ensure compliance with healthcare regulations like GDPR.

Technical Support: Hospital IT departments can provide technical support for AI system integration, including network setup, software installation, and troubleshooting.

6.0 Staffing and training

Getting staff to buy into AI in radiotherapy can be a crucial aspect of successful implementation. Strategies to encourage staff acceptance and engagement include:

Education and Training: Education and training should be considered in two streams:

- **Familiarity:** Provide general education and training programs to familiarise staff with AI technology, its benefits, and its potential impact on their roles. Offer opportunities for hands-on experience and practical training sessions to build confidence and competence in using AI tools.
- **Basic understanding:** Provide comprehensive education and training programs to ensure staff are capable of evaluating various AI models to identify those that align with their clinical requirements. Ensure understanding of the associated risks and constraints in AI use. Develop staff competence in performing Quality Assurance tasks related to AI systems.

Transparent Communication: Clearly communicate the goals, objectives, and expected benefits of AI implementation. Address any concerns or misconceptions that staff may have and provide regular updates on the progress of AI integration. Encourage an open and transparent dialogue to foster trust and understanding.

Demonstrate Value and Benefits: Highlight the specific ways in which AI can enhance staff efficiency, accuracy, and patient outcomes. Present case studies, research findings, and real-world examples that demonstrate the positive impact of AI in radiotherapy. Emphasise how AI can complement and support the existing expertise of staff rather than replacing them.

Involve Staff in Decision-making: Engage staff in the decision-making process by seeking their input and feedback. Encourage them to share their experiences, concerns, and ideas related to AI implementation. Inclusion creates a sense of ownership, leading to greater acceptance and engagement.

Address Staff Concerns: Understand and address any concerns or apprehensions that staff may have regarding AI. Common concerns may include job security, workflow changes, or fear of technology replacing human expertise. Provide reassurance, clarify misconceptions, and explain how AI can augment their skills and improve patient care rather than replacing their roles.

Start with Pilot Projects: Begin AI implementation with small-scale pilot projects or workflow improvement tools (such as AI auto-contouring) before progressing to more complex applications (e.g. clinical decision support/making tools). to demonstrate the benefits and feasibility. Their positive experiences and feedback can serve as testimonials and encourage wider adoption among peers.

Continuous Support and Collaboration: Provide ongoing support and technical assistance to staff as they navigate the integration of AI into their workflow. Foster a collaborative environment where staff can share challenges, best practices, and success stories related to AI implementation. Encourage a culture of continuous learning and improvement.

Recognise Success (communication strategy): Recognise staff contributions and achievements in using AI technology. Publicly share success stories and the positive impact of AI on patient outcomes, staff productivity, and overall radiotherapy processes.

7.0 Challenges in Implementing AI in Radiation Oncology

Human Oversight: Depending on the type of AI tool, it may not be clear who is responsible for making the final decisions regarding a patient's treatment. The two main challenges are to:

- Establish clear responsibility for decision-making with the integration of AI tools into the radiotherapy workflow
- Ensure effective communication and education on the role of AI within the workforce to ensure staff adoption.

Data Privacy and Ethical Use: There are recognised difficulties surrounding the rapidly changing environment of AI in radiotherapy. Firstly, ensuring AI tools meet GDPR requirements, especially since an increasing number of AI tools are "cloud based". Secondly, without clear descriptions of the data and processes undertaken in training a model, it is challenging to ensure a model is generalisable and unbiased for all patients in a clinical setting. Lastly, implementing a clear and understandable patient consent process can be challenging and will require education of the workforce on AI tools and clear communication to the patient.

Lack of Centralised Guidance: Currently, there is no centralised national body to provide guidance on AI in radiotherapy. Multiple fragmented groups exist within separate disciplines but without central oversight on a national level.

Model Validation: Rigorous validation and monitoring of AI algorithms is essential to ensure their reliability and accuracy. However, up-to-date guidelines on their use and specific QA requirements are sparse and slow to keep up in the rapidly changing AI environment.

Integration with Existing Systems: Achieving seamless integration of AI tools with the current radiotherapy systems, including treatment planning software and electronic medical records, is crucial for the successful adoption of AI in the Radiotherapy workflow. This integration, however, presents several formidable challenges. Firstly, the varying IT policies and infrastructures across healthcare institutions, as well as the different software and hardware used by various vendors, can pose substantial hurdles. Secondly, extracting the necessary data from these systems for model testing and implementation of AI tools can be a challenging endeavour.

Training and Education: Currently, within the HSE hospital network, there is no identified staff group that specialises in, or has received formal training in AI and/or machine learning. It is imperative to integrate or supplement appropriate AI and machine learning education into continuous professional development, current academic and clinical training programs, and university-level degrees. This step is essential to ensure that staff members gain the appropriate knowledge and competence to clinically implement, evaluate, and quality assure AI systems.

8.0 Recommendations for Introducing AI into the Radiotherapy Treatment Pathway

The recommendations outlined below have been developed through an extensive literature review and interdisciplinary collaboration. They are designed to tackle the significant challenges associated with integrating AI into the radiotherapy workflow, some of which are highlighted in section 8.0.

Recommendation 1

Human oversight

Any integration of AI tools into the radiotherapy workflow must have human oversight. AI should be seen as a valuable complement to human expertise, enhancing precision and efficiency while working under the guidance and supervision of experienced healthcare professionals. Clinical teams should retain ultimate responsibility for the decisions regarding the patient's treatment.

Recommendation 2

Working Group

Establishment of a NCCP multidisciplinary working group provided with dedicated administrative time and resources. The purpose of this working group is to ensure a consistent and well developed implementation process for AI in radiotherapy given the rapidly evolving landscape of AI technologies which are currently unregulated. The group will;

- Build a comprehensive understanding of clinical needs in radiotherapy relevant to AI.

- Develop guidance on a robust staff engagement process, centred around training, education and information. This guidance will ensure that all local services can ensure their staff members are well-informed about AI integration in radiotherapy. Industrial Relations issues arising from implementation are outside the remit of the working groups.

- Develop a framework for the appropriate introduction of AI tools in radiotherapy work. Any proposed introduction of AI tools into the radiotherapy service should include a detailed rationale, show clear benefits, have a specific timeframe for implementation, have measurable outcomes to track progress, and have a clear allocation of necessary resources.

- Develop collaborations with academia, industry and relevant HSE bodies.

Recommendation 3

Ethical considerations

It is recognised that this is a rapidly advancing field and that ethical and legal issues pertaining to AI will continue to evolve over time. Implementing AI in radiotherapy requires the development of and strict adherence to existing and future robust governance frameworks set within national and international regulatory guidelines. These frameworks should encompass essential aspects such as responsible data management and clear patient consent processes. Furthermore, the crucial role of patient involvement in shaping AI initiatives is emphasised; this ensures that the technology is aligned with patient values and preferences and promotes transparency and trust within the radiotherapy process. Ensuring the preservation of patient rights and maintaining equality and equity through the ethical use of AI must be paramount.

Recommendation 4

Quality Assurance

Quality Assurance (QA) to be a central pillar of any AI implementation in radiotherapy. Robust QA processes must be established to ensure the accuracy, reliability, limitations, and safety of AI-driven systems. This includes stringent testing, validation on local data, and continuous monitoring of AI tools. QA protocols should address data integrity, patient privacy, algorithmic bias, and the alignment of AI outputs with clinical goals.

Recommendation 5

Education and Training

Prior to the introduction of any AI tool in a clinical setting, staff members need to have an appropriate understanding of the capabilities, limitations and quality assurance requirements of the AI tool to ensure its safe and effective clinical use. Relevant professional groups should also consider the training and education requirements together with continuous professional development programmes for the future workforce.

Recommendation 6

Incremental Introduction

AI tools should be introduced in a way that ensures a gradual building of experience in parallel with staff education and training efforts.

9.0 Conclusion

In recent years, there has been pronounced interest in the use of AI in healthcare, with some AI-based tools already being introduced into clinical environments. This is expected to rapidly grow in the near future. Based on some direct experience as well as output from numerous studies on the subject, this expert working group believes it is essential to further deploy AI systems for use in the radiotherapy clinic. These offer the opportunity to significantly improve clinical workflows and patient care as well as to provide support to healthcare professionals in clinical decision making. In radiotherapy, AI applications are being developed to optimise patient treatment planning, enhance accuracy of delivery of radiation treatments, and facilitate new treatment approaches such as adaptive radiotherapy for personalised treatments. The rapid pace and scope of development in the area will potentially transform the field. However, clinical implementation of these systems presents many challenges and potential risks across a range of domains and these need to be addressed prior to widespread clinical use. There is an increasing awareness of AI applications in the general public and in particular among healthcare staff. A survey of some healthcare staff in Ireland (Ryan et al., 2021) showed the majority anticipated a positive impact of AI on patient treatment but noted the importance of professional involvement in AI application development as well as national legislation. Surveyed staff identified priority areas for implementation including the use of AI in workflow management tasks such as quality assurance, processing imaging, treatment planning, and auditing, while more patient-centred tasks such as image interpretation, consent, explaining benefits/harms and treatment delivery continue to require mostly or exclusively human input.

This group acknowledges both the advantages of AI and the challenges posed for safe implementation. The six recommendations outlined in this report are designed to take full advantage of the benefits of the AI tools as well address the main challenges in a way that makes full use of the ability for the NCCP to link the relevant centres and organise shared expertise.

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10.0 Definitions

AI (Artificial Intelligence): AI refers to the development of computer systems that can perform tasks typically requiring human intelligence, such as understanding natural language, recognising patterns, solving problems, and making decisions.

Human-in-Command (HIC): This approach empowers humans to oversee the AI system comprehensively, including its broader impact on economics, society, legality, and ethics. They have the authority to decide when and how to use the system in specific situations.

Human-in-the-Loop (HITL): In this approach, humans are involved in every decision cycle of the system. This level of involvement may not always be practical or desirable.

Human-on-the-Loop (HOTL): Here, humans have the capability to intervene during the design cycle and monitor the system's operation, providing a degree of control and oversight.

ML (Machine Learning): Machine learning is a subset of AI that focuses on developing algorithms and models that enable computers to learn from and make predictions or decisions based on data. It involves training a system to improve its performance on a specific task through exposure to data.

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