Australian Society of Medical Imaging and Radiation Therapy
The national professional organisation representing medical radiation practitioners
ABN 26 924 779 836

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DRAFT Standards of Practice for Artificial Intelligence in Radiation Oncology

The Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) is the peak body representing medical radiation practitioners in Australia. Our aims are to promote, encourage, cultivate and maintain the highest principles of practice and proficiency of medical radiation science, always mindful that the welfare of the patient should be at the centre of everything we do.

Please find feedback on the above Consultation document.

ASMIRT congratulates the members of the working party which created the standards on a wonderful and thorough job. Overall, this document covers all relevant bases, particularly in context of the immaturity of clinical use. However, it has been observed that whilst the standards articulate the responsibility of the Radiation Oncologist, it is less clear around other members of the Multi-Disciplinary Team (MDT) with respect to evaluation, Quality Assurance (QA) and use of Machine Learning / Artificial Intelligence (ML/AI). An ML example of this is if an activity historically completed and approved by one part of the multidisciplinary team becomes automated via ML/AI and so now bypasses that team, what educational requirements are required by the team "downstream", as well as amendments to existing codes (laws) to approve the output now generated from the Machine Learning / Artificial Intelligence (ML/AI). This is separate to training on the usage of the technology. This is now about clinical decision making based on training within our professions and an expanding scope of practice.

Training	ASMIRT appreciates the discussion on the requirement for training, however it isn't clear what 'suitable' or 'appropriate' training is.
217 iii. The Practice's AIC must be a member of the principal governance body and provide input on behalf of the clinical team.	Is the Artificial Intelligence Committees (AICs) role to put forward the clinical team's perspective alone? Should it be more comprehensive than that to include R&D, implementation and Quality teams, and patients?
Line 224	ASMIRT feels that this statement needs to be more specific. Due diligence with regards to legislation and a patient's right to have the opportunity to consent when their data will be shared with third parties who may profit from the use of the data. Additionally, that there are formal agreements in place with regards to data usage by the third party.

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233-235 The radiation oncologist holds ultimate responsibility for patient care and should have the opportunity to input directly if required to the governance body put in place to manage ML systems or AI tools used in clinical care.	ASMIRT suggests providing more clarity and use the acronym AIC perhaps in place of governance body. Is this implying that every Radiation Oncologist should have direct membership of the AIC. If so, is this feasible – they perhaps should have direct input via their nominated members of the AIC.
236 Responsibility for the decision to use ML and AI for an individual patient primarily resides with the radiation oncologist.	ASMIRT agrees with this responsibility, however the practicalities of a patient-based decision-making process once an AI system has been evaluated, approved, and integrated into a Practice's protocols could lead to questions over equality of care and what is best practice.
246-247 The Practice and medical practitioners shall ensure that patient safety is the top priority in the delivery of care, and that patients have access to information to make informed decisions about their care.	This would seem vague enough that patients may/may not be informed of use of AI in their care. While many academic institutions are requiring disclosure of the use of AI, there is uncertainty if the national/international guidelines to date have addressed this in health care. Perhaps consideration of provision of information to patients and the disclosure of use of AI, and documentation of its use could be more explicitly outlined in the document.
Line 249 - 250	ASMIRT seeks clarity on whether the primary responsibility can be delegated via approved practice protocols. Or will the use of any ML/AI tool require a specific request - similar to a planning CT scan or any diagnostic scan?
249i. The radiation oncologist retains primary responsibility for all aspects of patient care, including the use of ML or AI for a particular patient, with input and support from a multidisciplinary team. ii. The AIC and, where relevant, radiation oncologist	These statements feel somewhat contradictory, though if you substitute 'liability' into line 254 then potentially this is what the statement is alluding to. ASMIRT is not certain that you can have it both ways.

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at the Practice will take responsibility for ensuring that ML and AI are used ethically and in line with these standards of practice. 254 Primary responsibility, however, rests with the Practice and the associated governance body that chose to deploy the ML or AI.	
256-257 iii. The Practice must have access to general information for patients about the use of ML and AI in clinical care.	Is this to provide to patients, or is it local documentation of AI use, or is it access to information of prior AI use in their care? If it is to provide access to info/education for patients, it doesn't designate responsibility for providing this. Do patients need to be formally informed of the us of AI and ML in the provision of their care or is this intended as just 'education'?
Line 262	What is general training? Is this defined as an understanding of the principles of different ML/AI models and data science (data management and legislation)?
Line 268	These outputs as well as the interaction that clinicians are able to have to examine the outputs will be specific to each individual tool, ASMIRT suggests making a sub point to the previous point that training is not only how to input the data but to also correctly interpret the outputs
Line 276	ASMIRT thoroughly agrees with this statement -just as a PET avid region on the scan cannot be interpreted as cancer without other supporting tests. If the ML/AI tool output doesn't make sense take a closer look. Do decisions to use or not use AI or ML outputs need to be documented as part of the patient medical record?
Line 279 - 280	What is a value judgement? ASMIRT suggests providing an example here.
Line 330	ASMIRT agree that patients should be given the opportunity to provide informed consent regarding the use of their information in ML and AI systems, particularly if it is going to be shared with a third party with commercial interests in the ML/AI system.

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Section commencing Line 363	Section 4 in the main body and in the self-audit tool covers algorithm development. ASMIRT seeks clarity on what oversight a practice has over a developer to ensure the AI application being developed, to be introduced, or in use in a practice meets the listed requirements? It is noted that in the self-audit tool there is an item where information is to be provided by the vendor, and wonder if this is sufficient. ASMIRT seeks to understand the insurance cover incidents involving AI? Do organisation's need to ensure they have sufficient insurance cover?
Line 365	ASMIRT seeks clarity on whether this is referring to a specific document outlining accepted ethical principles?
Line 369	Anything that is approved for clinical use should have FDA/TGA approval and resulting information will be what vendors choose to disclose. Therefore, if as per previous statements ultimate responsibility rests with the Practice, if vendors don't disclose sufficient information regarding sections 4.1-4.3 then don't buy or use them?
Line 464 Line 464 - 467	ASMIRT strongly agrees with this statement and wonders whether the information in the parentheses be made more explicit?
Line 418	Should "ground truth" be included in the terminology section? It is a concept in AI however it is only used once in the document.
Line 476 - 477	Is this record likely to be audited? Otherwise, is this a recommendation as part of the standard patient record regarding accurate documentation of all procedures carried out on a patient?
Line 481	Suggest re-wording to better align with iv and v below i.e only has access to data sets that are essential for its appropriate use?

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Line 544 - 545	This statement requires some additional information to clarify what level of understanding is required by the radiation oncology team. i.e just a knowledge of what systems have ML/AI tools in them? or what task is being performed or decision being made by the system and the QA processes required to be undertaken by members of the radiation oncology team before accepting the outcome/decision and proceeding with the next step in the clinical workflow or treating the patient?

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