Australian Government

Australian Radiation Protection and Nuclear Safety Agency

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CLINICAL ADVISORY GROUP (CAG) REPORT

2020 2021

Introduction

The Clinical Advisory Group (CAG) provides clinical and scientific advice to the Australian Clinical Dosimetry Service (ACDS) in relation to out of tolerance audits, development of audit methods and phantoms as well as evaluation of performance metrics. Membership is made up of representatives from the public and private sectors across the following professional bodies:

- Radiation oncologists – The Royal Australian and New Zealand College of Radiologists (RANZCR)
- Medical physicists – Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- Radiation therapists – Australian Society of Medical Imaging and Radiation Therapy/New Zealand Institute of Medical Radiation Technology (ASMIRT/NZIMRT)
- Clinical trials – The Trans-Tasman Radiation Oncology Group (TROG).

The chair of CAG is usually a radiation oncologist reflecting the clinical advisory role of the CAG. Meetings are held quarterly. Additional meetings are rapidly convened to discuss out of tolerance findings of concern.

How ACDS operations and audit findings have directly impacted patient care

ACDS audits are primarily a quality improvement tool and replicate the whole or parts of a patient's pathway from treatment planning through to treatment delivery as closely as possible. The ACDS may make recommendations or work with facilities to resolve unexpected results while positive audits give confidence to the facility and their patients.

Audits can identify potential harm to patients during pre-clinical tests and these may be remediated before any patients are treated. As an example, a recent audit identified underestimation of spinal cord dose by a new planning system that the facility was commissioning. The facility delayed the introduction of the new planning system to allow for further testing. The implication of excess dose to a spinal cord for a patient could include major neurological damage and lifelong reduced quality of life. If the department had proceeded to clinical implementation, the impact of treatment would be seen across all patients using this beam model.

The ACDS works collaboratively with facilities, which encourages the uptake of new techniques and technologies by giving the facility confidence that an independent check has been performed. If results were not as expected, the ACDS provide advice and guidance on the rectification of any issues before a repeat audit is performed.

Clinical trials are often used in radiation oncology to test and implement new technology developments. As such, quality assurance (QA) in radiation therapy clinical trials continues to be a key factor in ensuring safety of participants, effectiveness of trial interventions and robustness of trial results. Radiation therapy trials require participating centres to demonstrate that they can deliver trial radiation therapy interventions to a high degree of accuracy. ACDS audits have emerged as a fundamental contributor to this process, as they provide rigorous, independent auditing of contemporary radiation therapy techniques.

The relevance of the existing ACDS audit suite

The CAG supports, monitors, and advises the ACDS on maintaining and developing the audit suite, using its broad range of technical and clinical experience.

An audit of an existing technique can enhance patient outcomes via incremental improvements in dosimetry or early detection of systematic errors. Audits of newer techniques can give facilities the confidence to implement novel methods that may be beneficial to selected groups of patients. ACDS has a long established and cost-effective method of Level I – III audits that match the audit complexity to facility requirements at that time.

As a cost-recovered service, ACDS must be receptive to customer feedback for long-term viability. The range of audits matches the treatment techniques in common use and where there is potential for detectable deviations. The CAG reviews ACDS feedback surveys and verifies that ACDS is responsive to facilities comments and suggestions. When asked the question 'how would you rate the relevance and quality of the audit?', 94.6% of respondents replied good or excellent.

The audit suite must evolve and adapt to rapid technical changes and innovations. With numerous new modalities available or becoming available, a methodical approach is required to develop the audit suite to best serve the community and providers. Facilities are surveyed on the question 'Are there any modalities you would like to see in future ACDS audits?' In general, there is alignment between facility requests and CAG advice.

ACDS has a comprehensive Audit Development Plan that tracks progression of radiation treatment modalities from planned field trial to field trial to live audit. The CAG verifies and provides input into the relevance and appropriate prioritisation of the Audit Development Plan. Current modalities or soon to emerge from field trials include small fields, SRS, SABR and MR Linac. These audits are in high demand as many facilities are or will soon implement these techniques and technologies.

Horizon scanning is a critical aspect of the ACDS maintaining a relevant audit suite well into the future. The ACDS presents and seeks input from the CAG on emergent modalities. Prediction of future trends has identified the importance of 4D IGRT, adaptive RT and protons and possibly heavy ion treatment.

Maintenance of the audit suite is a complex task of retiring or downgrading less relevant audits, consolidating, and streamlining the productive and valued existing audits for common clinical practices and being innovative with new audits. The ACDS is well equipped to handle these challenges.

The resources required by facilities to participate in the ACDS audit program

Facilities need to invest significant resources in terms of people and time into each audit that may not be part of the normal clinical workflow. However, facilities recognise the benefits, which include compliance with national or state accreditation standards, assurance that patients are receiving the prescribed dose and motivation to safely develop new techniques.

The ACDS is seeking to streamline the data collection process as much as possible and works in cooperation with the facilities. The ACDS provides more than just an audit and report, it provides advice, repeat audits, help with problem solving and comparison with an extensive national database of results.

While the time taken to participate in an audit can be seen, there may also be time saved by sharing knowledge across sites. Systematic deviations of specific algorithms or equipment may not be identified or easily rectified within a single facility but when data is combined, there may be trends or specific tendencies that can be reviewed by ACDS.

Feedback from facilities is sought after each audit and facilities report confidence, satisfaction and improving safety culture because of their interactions with the ACDS. Details on the feedback findings are tabled at CAG meetings and provided in the report by ACDS.

How ongoing ACDS audit development will mitigate future clinical risk

Contemporary radiation oncology has observed a shift towards use of higher doses, delivered in fewer treatment sessions, with higher biological effect ('Stereotactic' body and intracranial radiotherapy). Historically stereotactic treatments were performed on specialised equipment by a handful of expert centres, however improvements in standard radiotherapy equipment and software have resulted in rapid uptake of stereotactic treatments in most radiotherapy centres in the past 3-5 years.

National and international best practice guidelines for quality and safety of high dose radiation treatment strongly recommend all institutions participate in external audits. Through consultation with customers and clinical trials organisations, the ACDS were proactive in setting up a stereotactic body radiotherapy audit which after 3 years in development, is now offered in the standard audit rotation. This audit is one of the most advanced and comprehensive in the world and has had a substantial impact in ensuring high quality radiation therapy in both routine clinical practice and in clinical trials. In addition, stereotactic intracranial radiotherapy audits (under development) are a welcome addition that has had direct impact in reducing errors in centres who have participated in its development.

Respiratory motion management, MR-linac and adaptive radiation therapy are examples of emerging complex techniques that utilise systems and technology with increasing levels of automation, vendor control and vendor configuration. These present new clinical risks to the radiotherapy community and consumers. The CAG welcomes the current development of ACDS audits in these technique spaces and strongly believe these will be key to ensuring quality and safety of service delivery to patients.

ACDS audits meet the specific requirements of radiation oncology providers for regulatory approval (required in some jurisdictions), access to Health Program Grants (federal funding for treatment machines) and credentialing requirements for TROG and other clinical trials.

The CAG would support a move for the ACDS to become a regulatory requirement across all jurisdictions to ensure consistency for radiotherapy providers in Australia and New Zealand.

Audit cost effectiveness

Measurement of cost effectiveness for quality and safety activities can be difficult as the implications of unsafe treatment and averted harm can be difficult to quantify. The ACDS has however, demonstrated its effectiveness by detecting potential dosimetry errors using an economical financial model of auditing.

During its time, the ACDS has made 295 recommendations to improve the delivery of radiotherapy treatments to patients and worked with facilities to resolve 85 Out of Tolerance (OT) results.

Since inception of the ACDS audit fees, costs have only increased marginally despite increasing complexity in audit development and data analysis. The service has moved from 2D and 3D conformal treatment audits to cover significantly more treatment modalities including IMRT/VMAT/SABR and kV. New phantoms suitable for measuring dose in an MR-Linac or treatment undergoing motion management or adaptive radiotherapy techniques are aiming to streamline the audit process. Investment in software for easier transfer of data between facilities and the ACDS have also helped reduce the burden on facilities to ensure audits are as cost effective as practical.

The effectiveness of the ACDS is best demonstrated by feedback from participating facilities:

- 'Audit is an important component as an independent check of facility services. Must be performed as per guidelines of the regulatory authority.'
- 'The audit is very resource intensive however we believe it is worthwhile given the rigorous nature of the testing and confidence it gives us in our service. The ACDS staff are very helpful and attentive.'
- 'This was a challenging audit as we were planning with a new planning system, but it was a good process to go through as it helped us identify different process issues that we needed to understand and helped familiarise us with the new TPS so that we were able to successfully complete the audit (including SABR)'
- 'The newly implemented small field dosimetry portion of the audit was very useful for us and provided confidence in locally acquired measurements'

ACDS research and international profile

The CAG noted the continuing involvement of ACDS in research and development. Given the need to develop new audits also in areas where very little international examples exist (motion management, adaptive radiotherapy, superficial/kV dosimetry) this is appropriate and gives Australian radiotherapy departments early access to audits of advanced technology.

It was noted that two papers were published in the reporting period and a third in July 2021:

1. Shaw M, Lye J, Alves A, Hanlon M, Lehmann J, Supple J, Porumb C, Williams I, Geso M and Brown R (2021) 'Measuring the dose in bone for spine stereotactic body radiotherapy', *Physica Medica*, 84:265-273 doi:10.1016/j.ejmp.2021.03.011
2. Kry SF, Lye J, Clark CH, Andratschke N, Dimitriadis A, Followill D, Howell R, Hussein M, Ishikawa M, Kito S and Kron T (2021) 'Report dose-to-medium in clinical trials where available; a consensus from the global Harmonisation group to maximize consistency', *Radiotherapy and Oncology*, 159:106-111, doi:10.1016/j.radonc.2021.03.006
3. Hughes J, Lye JE, Kadeer F, Alves A, Shaw M, Supple J, Keehan S, Gibbons F, Lehmann J and Kron T (2021) 'Calculation algorithms and penumbra: Underestimation of dose in organs at risk in dosimetry audits', *Medical Physics*, doi:10.1002/mp.15123

All of them are in international journals of high impact factor for the field. From a CAG perspective this has three important consequences:

- It highlights the quality of ACDS work, which would be helpful in ensuring ongoing recognition and perceived value of audit participation.
- It enhances international collaboration of ACDS with similar organisations worldwide. In particular, the second paper is a collaboration between many Dosimetric Audit Networks (DANs) through the Global Harmonization Group. This is a network of audit groups that aims to standardise audits and make them compatible. This avoids duplication and the need for hospitals to participate in many audits.
- It facilitates credentialing of participating centres for international clinical trials as mutual recognition of audits allows fast tracking of Australian facilities for trial credentialing. This is of considerable value for co-operative trials organisations such as the Trans-Tasman Radiation Oncology Group (TROG).

ACDS workforce

The years 2020 and 2021 have presented significant challenges to the ACDS. Many audits require ACDS staff to be on site. With sudden border closures and quarantine requirements, it has been challenging to maintain the audit schedule. Extraordinary efforts have been made by ACDS staff to maintain a close-to-normal service, which has involved prolonged hotel stays or temporary relocation to another state or New Zealand. Staff risked not being able to return home due to changed border restrictions while away.

The demonstrated commitment, persistence, and resilience of the ACDS staff has been appreciated by all involved in maintaining a demonstrably high-quality radiation therapy service across the jurisdictions served by the ACDS. An example of feedback received by ACDS from a facility was: 'Great effort under trying circumstances. We appreciate the challenging situation and all the hard work your team is putting in'.

Summary

The CAG group provides support and guidance for ACDS operations. ACDS maintains high standards as a world-class dosimetry audit service that benefits individual patients and the broader community.

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