Introducing stereotactic radiotherapy safely: credentialing centres and staff

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Abstract. Stereotactic radiotherapy treatments use high doses of radiation delivered in relatively few fractions compared with conventional radiotherapy. Specialist planning, immobilization and image guidance techniques are needed to achieve accurate treatment. Because doses are high and fractions few, the consequences of treatment errors are more severe than for conventional therapy. A credentialing program for staff and equipment is one strategy that can be used to reduce risk. The Icon Group runs a network of 20 radiotherapy centres in Australia. There has been a rapid growth of stereotactic treatments at Icon. In order to reduce the risks of introducing stereotactic therapy, an in-house credentialing and endorsement program was developed. A multi-disciplinary working group comprising medical physicists, radiation oncologists and radiation therapists was established to develop endorsement policies and procedures. Elements considered included the purchase, commissioning and quality assurance of equipment, the establishment and documentation of safe work practices and staff competency assessment. The endorsement program is in the process of being implemented across the Icon network.

1. Introduction
Stereotactic radiotherapy treatments use high doses of radiation delivered in relatively few fractions compared with conventional radiotherapy. Specialist planning, immobilization and image guidance techniques are needed to achieve accurate treatment. Because doses are high and fractions few, the consequences of treatment errors are more severe than for conventional therapy. There have been several well-publicized cases where errors in the planning and delivery of stereotactic treatments have resulted in serious patient harm and even deaths [1-4].

Solberg and Medin published a review entitled “Quality and safety in stereotactic radiosurgery and stereotactic body radiation therapy: can more be done?” in 2011 [5]. While recognizing that general recommendations for quality in radiotherapy already exist, they presented comprehensive additional recommendations specifically for centres performing or planning to perform stereotactic treatments. Their recommendations are divided into three categories: program planning, commissioning and patient specific aspects. The importance of having thorough documentation, a trained workforce and enough time and resources to carry out procedures was highlighted.
The recommendations of Solberg and Medin have subsequently been adopted in the “Novalis Certification [6]” program developed by Brainlab\(^1\), a commercial vendor of stereotactic planning and treatment equipment. Centres seeking Novalis Certification must undergo a comprehensive external review of all stereotactic procedures and workflows, including both an off-site review of documentation and a site visit. Participation in an external accreditation program such as Novalis Certification gives centres confidence that their stereotactic practices conform with international recommendations. However, the opportunity to participate in an external accreditation such as Novalis Certification may be limited by costs and availability.

An article specifically addressing practices in Australasia, “Guidelines for safe practice of stereotactic body (ablative) radiation therapy” published by Foote et al in 2015 \[7\] made similar recommendations. They said that safe implementation of SABR is enhanced by standardization of protocols, formal processes to audit technical QA, state or nationally based collection of disease control and toxicity outcomes, participation in clinical trials and institutional credentialing.

The Icon Group runs a network of 20 radiotherapy centres in Australia. Some Icon Australian centres have extensive experience with cranial stereotactic radiotherapy (SRT), cranial stereotactic radiosurgery (SRS) and stereotactic ablative radiotherapy (SABR), such as the Icon Richmond centre, which treats more than 700 stereotactic courses per year. Some Icon centres have little or no stereotactic experience. The demand for stereotactic treatments is growing rapidly and Icon wishes to provide stereotactic services at more centres while maintaining patient safety and state of the art service delivery. The Icon Stereotactic Project was established in 2018 with the following aims:

- To develop safe, high quality stereotactic practice capability at Icon’s Australian centres
- To cater for the full range of stereotactic techniques including cranial and extra-cranial sites
- To make use of existing stereotactic expertise within the Icon network.
- To develop a framework for staff training and competency assessment

The Icon Stereotactic Project comprised several sub-projects. A “Stereotactic Clinical Stream” was established to provide clinical governance overseeing all stereotactic practices. Teams known as “SRS/SABR Service Area Groups” were established to manage the technical aspects of implementation of specific types of therapy. The Service Area Groups are: SABR Lung, SABR Liver, SABR Oligometastases, SABR Spine, SABR Prostate, Cranial SRS/SRT and Cranial Multimetastases SRT. A separate team was established to develop policies for staff credentialing and endorsement of centres for stereotactic treatment, which is the subject of this article. For the purposes of this article “credentialing” refers to formal recognition of the competency of individuals. “Endorsement” refers to official authorization of an Icon centre to perform stereotactic treatments.

2. Development and key concepts of stereotactic endorsement

A multi-disciplinary team comprising physicists, radiation therapists and a radiation oncologist, all with extensive stereotactic experience, was established to lead the stereotactic endorsement and credentialing project. The recommendations of Solberg and Medin [5] and Foote et al [7] were used as the basis for the program. The fundamental policy proposed by the team was that no Icon centre would be authorized to perform stereotactic treatments without first being endorsed to do so. The workflow for endorsement of a centre is as follows:

- The manager of an Icon centre requests endorsement for a stereotactic treatment technique
- The Service Area Group works with the staff of the centre to ensure that commissioning is completed satisfactorily and that staff are trained and credentialled.
- The centre manager collates all required documentation as described in Sections 2.1 to 2.4.
- The documentation is reviewed independently by the Service Area Group

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If the review is satisfactory, a recommendation is made that the centre is endorsed. If there are deficiencies, the centre is provided with feedback and requested to re-submit their documentation for another review. This feedback process is repeated as often as required.

After satisfactory review, the centre receives endorsement for the technique. In order to achieve endorsement, an Icon centre must provide evidence that it has the appropriate equipment, that the equipment has been properly commissioned, that it has appropriately qualified personnel and comprehensive clinical guidelines and work instructions as described in 2.1 to 2.4.

### 2.1. Clinical Goals

Clearly defined, evidence-based clinical goals are an essential pre-requisite. Clinical guidelines describe the fundamental requirements for patient selection, simulation, dose prescription, treatment planning, quality assurance, image guidance and treatment delivery. To ensure consistency, guidelines apply to all Icon Australia sites. Clinical guidelines are developed and reviewed by multi-disciplinary teams with stereotactic expertise and must be approved by the Icon Stereotactic Clinical Stream. To ensure that patient treatment complies with the clinical guidelines, each patient should be reviewed at a multi-disciplinary meeting attended by appropriate specialists before commencing treatment.

#### Table 1: Schematic of Icon Stereotactic Capability Matrix.

| Icon Centre | LUNG SABR | OLIGOMET SABR | CRANIAL SRS | CRANIAL MULTI-METS | SPINE SABR |
|-------------|-----------|---------------|-------------|------------------|------------|
| Centre 1    | Technically ready | Technically ready | Clinical | Not capable | Technically ready |
| Centre 2    | Technically ready | Not commissioned | Not commissioned | Not capable | Technically ready |
| Centre 3    | Clinical     | Clinical      | Clinical    | Clinical         | Clinical    |
| ....        | ...         | ...           | ...         | ...             | ...         |
| Centre 20   | Clinical    | Clinically ready | Not commissioned | Not capable | Clinically ready |

- Not capable: the centre does not have the required equipment to perform the technique
- Not commissioned: the centre has the required equipment, but it has not yet been commissioned
- Technically ready: the required equipment has been fully commissioned
- Clinically ready: equipment fully commissioned, staff credentialed, documentation is complete
- Clinical: the technique is in clinical use

### 2.2. Suitable equipment that is fully commissioned

The equipment requirements for specific types of stereotactic therapies are determined by the relevant Service Area Group. This may include specialist software and equipment for patient planning, quality assurance or treatment delivery. The requirements are different for different therapies. Some Icon centres will be debarred from some treatments due to lack of appropriate equipment. For example, not all centres will be able to treat cranial multi-metastases due to lack of the appropriate image guidance and patient position correction equipment. The variations in capabilities between different Icon sites are summarized in a Stereotactic Capability Matrix, which is shown schematically in Table 1.

All equipment must have been thoroughly commissioned with a full commissioning report. Commissioning must include an independent end to end test, whereby an anthropomorphic phantom is simulated, planned and treated following the clinical workflow. Dose in the phantom is measured independently by a physicist from a different centre. Commissioning must demonstrate that the equipment performs within appropriate tolerances for stereotactic use. For example, linear
accelerators and their associated image guidance systems should comply with the requirements of the AAPM Task Group 142 [8] tolerances for a linac used for stereotactic treatments. Once commissioned, there must be a robust quality assurance program to demonstrate ongoing compliance.

2.3. Work practices
Each Icon centre must have written work instructions for all steps in the stereotactic planning, quality assurance and treatment delivery process that are current, clear, complete and comprehensive. The work instructions supplement the clinical guidelines. All Icon centres with the same equipment should use the same work instructions but where equipment is different, work instructions may also differ. There must be evidence that work practices are subject to ongoing quality improvement, including monitoring of incidents and near misses recorded in the Icon incident management system.

Table 2: Staff competency requirements.

| Staff                      | Initial credentialing                                                                 | Maintenance of credentialing                                      |
|----------------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Radiation oncologists      | Commencing oncologists may be requested to enter a mentorship program.                 | **Brain and Spine**: Treatment of a minimum of 12 cranial/spine cases per annum |
|                            | **Brain and Spine**: presentation of first 12 cases at stereotactic chart round AND a course specific to brain/spine stereotactic therapy | **Extracranial**: treatment of a minimum of 12 extra-cranial cases per annum |
|                            | **Extracranial**: presentation of first 12 cases at stereotactic chart round AND a course specific to extra-cranial stereotactic practices. |                                                                  |
| Radiation therapists and physicists | Technique specific online education material. On-the-job clinical training. | **Brain and Spine**: Direct involvement in treatment of a minimum of 12 cranial cases per annum |
|                            | Formal performance-based competency assessment.                                         | **Extracranial**: Direct involvement in treatment of a minimum of 12 ‘body’ cases per annum |
| All                       |                                                                                        | Attendance at a minimum of 12 Icon stereotactic chart rounds per annum |

2.4. Staff credentialing
Stereotactic procedures must be carried out by competent staff. The requirements for different staff groups are summarized in Table 2. There are criteria which must be met for initial credentialing and for ongoing maintenance. There are two recognized areas of practice: cranial/spinal treatments and extra-cranial stereotactic treatments. Staff may be credentialed in one or both these areas of practice.

Radiation oncologists with little experience in stereotactic treatments may be required to participate in a mentorship program with an experienced practitioner at the discretion of the Stereotactic Clinical Stream. All oncologists must complete a training course specific to their area of practice and present at least 12 patient cases to a multi-disciplinary chart round for peer review. For physicists and radiation therapists, on-the-job practical training is supplemented by completion of online educational material. Participation in training is not in itself a guarantee of competency so staff must undertake formal competency assessment before being credentialed.

3. Implementation of stereotactic endorsement
The policies and procedures for stereotactic endorsement and staff credentialing were approved by the Icon Medical Advisory Committee in September 2018. A national register has been established to record the credentialing status of radiation oncologists, therapists and physicists at all 20 Icon centres. The register is shown schematically in Figure 1. Staff may be classified as being in training, able to perform a task under supervision or having achieved competency with a given technique. As the
register shows, a radiation therapist may be credentialed in on or more of three categories: simulation, planning and treatment. Physicists and radiation oncologists are given an overall credentialing for the treatment technique. The credentialing register is constantly updated as training and competency assessment occurs. A centre would not receive stereotactic endorsement until at least one radiation oncologist, one physicist and three radiation therapists have been credentialed.

![Staff Credentialing Register for Centre 1](image)

**Table 3**: Current status of stereotactic endorsement at Icon centres.

| Technique               | Current status          |
|-------------------------|-------------------------|
| SABR Liver              | 3 centres in progress   |
| SABR Lung               | 4 centres in progress   |
| SABR Oligometastases    | 1 centre endorsed, 1 centre in progress |
| Cranial SRT             | 2 centres endorsed, 4 centres in progress |

Table 3 summarizes the current status of the stereotactic endorsement program at Icon for different stereotactic techniques. Two centres have received endorsement for Cranial SRT and one for SABR Oligometastases. Eight centres are in the process of achieving endorsement for techniques including SABR Liver, SABR Lung, Cranial Multi-Metastases and Cranial SRT. The mix of techniques for which a centre is to be endorsed is dictated by clinical demand. This table does not include a number of Icon centres who were already performing stereotactic treatments prior to September 2018. These
centres have been allowed a period of six months to achieve formal stereotactic endorsement. This recognizes the existing expertise within these centres and will allow them to continue treating patients whilst they collate the required documentation and evidence for endorsement.

4. Discussion and conclusions

The fact that Icon consists of 20 separate radiotherapy centres at different locations poses risks for stereotactic treatments but also offers strengths. A key risk is that the relatively low patient numbers in some centres may mean that there is a lack of experience in stereotactic techniques and a consequent loss of staff expertise. As noted by Foote et al [7], it is difficult for many radiotherapy centres in Australasia to treat a minimum case load of 25 stereotactic patients per year. For Icon, the minimum requirement to maintain credentialing was chosen to be 12 patients per year. This was felt to be a reasonable compromise between what is desirable and what is achievable. The risks of treating lower patient numbers are mitigated by using of common policies at all Icon sites, the national staff competency register, and the requirement for participation in multi-disciplinary chart rounds.

An important benefit of being part of such a large organization is that less experienced centres can draw on the expertise of other more experienced centres. Experienced staff assist with commissioning, training and review of documentation. The Icon physics team can provide dosimetric and geometric validation of stereotactic treatment through independent end to end testing. In smaller organizations it would be difficult to provide this kind of independent validation in-house. The availability of experienced staff has enabled the establishment of independent review groups such as the Icon Stereotactic Clinical Stream to oversee clinical governance and the SRS/SABR Service Area Groups to oversee the technical aspects of stereotactic treatment.

Our experience to date shows that centre managers are happy about the stereotactic endorsement process. Although it creates some work for the centre seeking endorsement it also provides a high degree of confidence that the centre can deliver stereotactic treatment safely and in accordance with best practice. Because stereotactic endorsement and credentialing is new to Icon, it has been important to keep all stakeholders informed about the requirements of the program. Centres must plan ahead to complete all the preparatory work and collate documentation prior to seeking endorsement.

The Icon stereotactic endorsement of centres and credentialing of staff has shown how an organisation can adapt the guidelines recommended in the literature [5] [7] to establish their own system for ensuring safe, high quality stereotactic treatment. A similar process could be used by other centres wishing to establish a new treatment technique.

5. References

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