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Technical Note

Credentialing of stereotactic radiosurgery and stereotactic body radiation therapy programs for quality and safety: The Novalis Certified Program

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ABSTRACT

The expectation of quality and safety is a fundamental tenet in all areas of healthcare, and a cornerstone of best practice is a process of continuous learning and continuous improvement. Independent audits and peer review of radiotherapy programs are an important mechanism for identifying process or technology gaps, for highlighting areas for improvement, and for incorporating within continuous improvement processes. In the field of radiotherapy, independent certification programs exist within various national and/or professional spheres, yet few focus specifically on specialty procedures such as radiosurgery or brachytherapy, despite several recommendations for such programs. In this manuscript we describe a specialized SRS/SBRT credentialing program founded on national/international standards and guidelines. We also present the results of an anonymous survey from institutions who have completed the program.

Keywords: Stereotactic radiosurgery, stereotactic body radiation therapy, quality and safety, independent audit, credentialing

INTRODUCTION

The fields of stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) have deep roots, with origins in both the surgical and therapeutic radiology disciplines dating back over a century. Since the initial development in 1951, SRS has been well studied through extensive collaboration between physi-

cists, radiation oncologists and neurosurgeons. SRS has been refined into an important element in the treatment of brain metastases, selected primary brain tumors, cerebral vascular malformations, trigeminal neuralgia, and functional disorders. Modern cranial SRS can be performed non-invasively, and on any platform, with an extremely high degree of accuracy. Developments in tumor targeting, image guidance and motion management have also allowed for the extension of SRS to lesions outside the central nervous system in the form of SBRT. With a plethora of positive clinical results in lung, liver, spine and other disease sites, the application of SBRT is now a relatively common practice. Ongoing technological innovation, including single isocenter-multi target delivery, ultra-high dose delivery (e.g., FLASH), automated anatomical delineation and treatment planning using artificial intelligence, augmented reality, and novel imaging modalities will continue to enhance efficacy and drive clinical innovation.

SRS / SBRT is fundamentally different from conventional radiotherapy in that the intent is to deliver an ablative dose that overcomes the capacity of a cell to defend itself. By most accounts, stereotactic radiosurgery and stereotactic body radiation therapy are safe and highly effective, and the reported complication rates of SRS/SBRT are acceptably low. Still, the early SBRT experience has ample evidence of adverse outcomes, and many readers may also be aware of a number of SRS and SBRT errors, documented by the Nuclear Regulatory Commission (NRC) and International Atomic Energy Agency (IAEA) as well as in the mainstream media

In its landmark 2000 publication, *To Err Is Human: Building a Safer Health System*, the Institute of Medicine examined the quality of healthcare in America [1]. Focusing on medical errors, the paper highlighted the need to establish a national focus on safety, to identify and learn from errors, to raise standards and expectations, and to implement safe practices at every level of care. A culture of safety, that is, the shared values, beliefs, norms, and procedures related to patient safety among members of an organization, unit, or team, is an essential foundation of any clinical program [2].

In 2008, a consortium of British organizations published *Towards Safer Radiotherapy*, outlining the complex nature of the radiotherapy process, highlighting the opportunities for errors, and making recommendations for enhancing safety [3]. Many of the overall recommendations are appropriate for SRS and SBRT programs, including: a multidisciplinary working environment with a culture that fosters clear communication and guards against inappropriate interruptions; careful planning and thorough risk assessment when introducing new techniques and technologies; appropriate staffing levels, with skills and specific training in each new treatment technique or process prior to clinical use [2,4]. In its *Radiotherapy Risk Profile*, the World Health Organization (WHO) proposed similar initiatives focused on patient safety interventions and addressing high-risk areas in the radiotherapy process. Among the recommendations are the use of peer review audit, systems for event reporting and learning, and the systematic use of checklists and time-outs [5]. The International Atomic Energy Agency has developed guidelines for their Quality Assurance Team for Radiation Oncology (QUATRO) Program. A key aspect of the QUATRO Program is application of comprehensive audits, that is, independent external reviews that "…. capture the actual level of competence of a department," addressing "…issues of equipment, infrastructure and operation of clinical practice" in a comprehensive and overarching way, to enable gaps in technology, human resources and processes and procedures to be identified so that the institutions can document and act on areas for improvement [6].

Similarly, the American Society for Radiation Oncology (ASTRO) document *Safety is No Accident: A Framework for Quality Radiation Oncology and Care* further addresses " … the specific requirements of a contemporary radiation oncology facility in terms of structure, personnel and technical process in order to ensure a safe environment for the delivery of radiation therapy [7]." Included among the recommendations are a comprehensive quality management program, a well-developed peer review strategy, accreditation by an established radiation oncology-specific program, and notably, external reviews of specialized modalities such as SRS and SBRT [7]. Additional SRS and SBRT recommendations are highlighted in the ASTRO document *Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy* [4], as well as ASTRO, and American College of Radiology (ACR), and American Association of Physicists in Medicine (AAPM) / Radiosurgery Society (RSS) practice guidelines [8-10].

Program Methodology

While ASTRO and the ACR have well-developed radiation oncology accreditation programs, neither address the unique clinical and technical aspects of SRS and SBRT. Foote et al noted that "…no group currently offers external audit of SABR implementation." They concluded by strongly recommending an on-site external audit and review of processes prior to commencing a clinical stereotactic program, with a scope that includes: a review of imaging, treatment planning and treatment processes per clinical site (emphasis added), a review of technology use and QA, and the application of end-to-end tests per-

formed with phantom geometry conditions that closely mimic the intended clinical applications. [11] Within the past year, two programs have been initiated - the International Stereotactic Radiosurgery Society (ISRS) launched the *ISRS Certified* program exclusively for CNS indications, and the American College of Radiation Oncology (ACRO), together with the Radiosurgery Society (RSS), added the *Distinction in Stereotactic Radiotherapy* for both SRS and SBRT applications.

In this manuscript we describe the *Novalis Certified* program, which was launched in 2014 to fill the need for SRS/SBRT specialization. A standards document, based on national and international consensus, was drafted by a multidisciplinary panel of experts that included three radiation oncologists, three neurosurgeons and three medical physicists. This comprehensive document outlines requirements in organizational and program structure, clinical application, personnel, training, technology, and quality management [Figure 1]. The primary focus areas are accepted standards-of-care with regard to clinical practice, technical oversight, and overall quality management program. Peer review, continuous learning and adherence to a culture of safety are also strongly emphasized.

The Novalis Certified Program is international in scope and tailored to national patterns of practice as well as the local regulatory environment. Further, the program is continually assessing and updating the clinical and technical knowledge base. The program is technology agnostic – centers with all types of commercially available planning and delivery systems have been certified. Regardless of technology, however, institutions must demonstrate end-to-end spatial targeting and absolute dosimetric accuracy in an appropriate phantom.

The certification process, modeled in part after the ACR, ASTRO and ACRO programs, includes an institution-generated self-study and extensive off-site document review, during which reviewers collaborate closely with each center. Once the document review is completed, an on-site review is scheduled. Importantly, the on-site visit allows the reviewer to observe clinical SRS/SBRT procedures, providing a first-hand assessment of the interactions of the program personnel. Reviewers subsequently generate a 77-point descriptive report, which is reviewed by the multidisciplinary expert panel. Outcomes of the review include observations and recommendations, and may also include mandatory items required for certification. The overall certification process is shown in Figure 2.

Certification is granted for 4 years, a period which is quite standard among similar programs. Following the initial certification, centers can apply for a second 4-year recertification. The recertification process does not require an on-site review. Rather, the center completes a recertification self-study, highlighting any changes relative to the initial submission (disease sites, clinical approach, technology, personnel, etc.), along with any updated material. The designated reviewer will review the self-study submission and schedule a remote review webinar to discuss areas of interest and provide feedback, following which a report is submitted to the Expert Group for further assessment. The resulting recertification is granted for another 4-year period.

Beginning in mid-2020, a provisional certification was also offered to institutions for whom COVID restrictions prevented an on-site review. The provisional certification required the same institution-generated self-study and extensive off-site document review,

NOVALIS STANDARD

TABLE OF CONTENTS

Figure 1. Key requirements of the Novalis Certified Program, with details from the Novalis Standard table of contents.

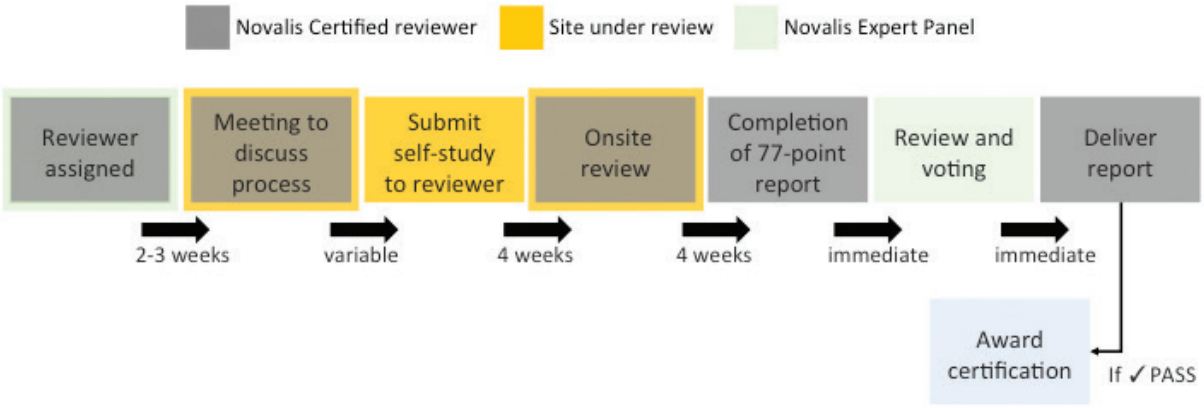

Figure 2. Process for completing the Novalis Certified Program.

followed by a half-day webinar-based discussion with the various team members. On one occasion, technical capabilities also allowed observation of clinical cases to be performed remotely. Successful provisional certification was valid for one year, during which period the on-site review would be performed. Several centers took advantage of the provisional mechanism, and all have followed up with the on-site review and subsequently received the full 4-year certification. While on-site reviews returned in early 2022, the provisional mechanism can be implemented again should conditions dictate.

RESULTS

Following the initial launch in 2014, the Novalis Certified Program has been received with widespread acceptance. To date, 70 institutions have received Novalis Certification, including 45 in Europe, 16 in North and South America, 7 in Asia Pacific and 2 in Africa. 17 centers have now recertified. Over 120 certification applications are at various stages of preparation and review.

Institutions have demonstrated a range of clinical practice. Every institution reviewed to date provides stereotactic services for patients with brain metastases, and six institutions treat brain metastases exclusively. Approximately 88% of institutions treat benign brain tumors, with vestibular schwannoma and meningioma the most prevalent. In contrast, just over half of institutions treat cranial arteriovenous malformations, and less than a third of institutions treat trigeminal neuralgia.

Approximately 84% of institutions treat SBRT indications, with lung the most prevalent followed by spine and liver. Approximately 20% of institutions treat intact prostate cancer, though we note that the use of five-

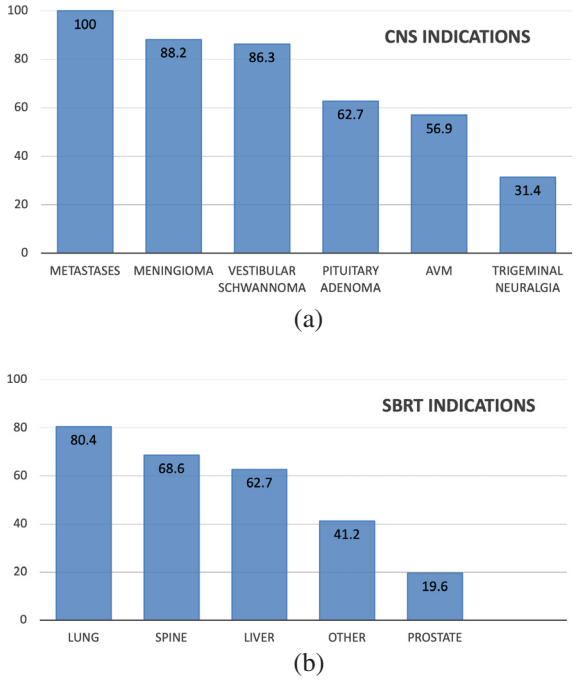

Figure 3. Proportion of institutions treating a) cranial SRS; and b) extracranial SBRT indications.

fraction SBRT for prostate cancer is increasing. Disease sites including bony metastases, pancreas, adrenal gland have also been treated. The distribution of institutions reviewed as a function of indication treated is shown in Figure 3.

Through the end of 2020, there were a total of 52 requirements and 241 recommendations. The majority fell into 5 categories: systems or equipment QA procedures, documentation (including lack of documented clinical guidelines and processes), program structure and personnel, independent dosimetry validation, and timeout procedures and use of checklists. The distribution of all requirements and recommendations is

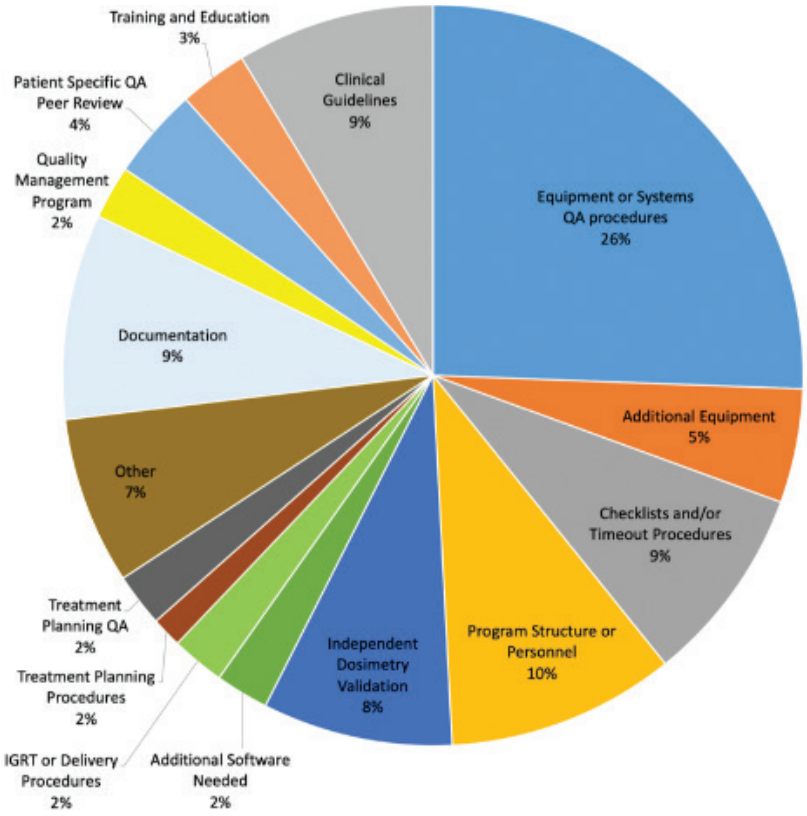

Figure 4. Classification of requirements and recommendations following the first 55 reviews.

shown in Figure 4. Examples of requirements include: Improving the documentation of clinical guidelines, developing a process to assess laterality and adjacency, developing an incident reporting system and associated review and response processes, performing an independent assessment of measured beam data, and implementing end-to-end testing into regular QA processes. Examples of recommendations include: documenting and disseminating actions of the quality assurance committee, identifying additional training opportunities for staff, and procuring additional dosimetry equipment and/or phantoms.

To the credit of the profession, no critical gaps have been observed. This may be attributed, in part, to the attention to highly publicized incidents of over a decade ago and the accompanying response on the part of the professional and clinical communities [4]. There is an increased diligence and reliance on accepted standard on the part of institutions and practitioners. Checklists and timeout procedures that verify patient, disease site, laterality, and technical factors, are now almost universally employed. Critical assessment of beam data, independent monitoring of machine output, and end-to-end (E2E) tests are now routinely performed as part of the commissioning and QA processes.

In 2018, a survey was performed of the sites Certified to that date. Results indicate an overwhelmingly positive response for the process and for the on-site review [Figure 5]. Table 1 provides a representative sample of the comments received on the Novalis Standard, communication and documentation process, on-site review, and final report. Much of the feedback has been incorporated into the current process.

The time and effort involved in the certification process varied significantly from center to center. Most centers are well prepared, and the effort consists largely of preparing the self-study document and assembling the accompanying information. For these centers the process can be completed in ~3-4 months, depending on scheduling of the on-site review. For some centers, however, it has been time consuming to prepare information if it is not already at hand. The biggest challenges have been in assembling the documentation to support the clinical practice, which naturally requires physician involvement, in preparing administrative policies and procedures, and in resolving some gaps in commissioning or QA of equipment. For these centers the time to complete the process may be over a year, during which there is significant discussion with the assigned reviewer.

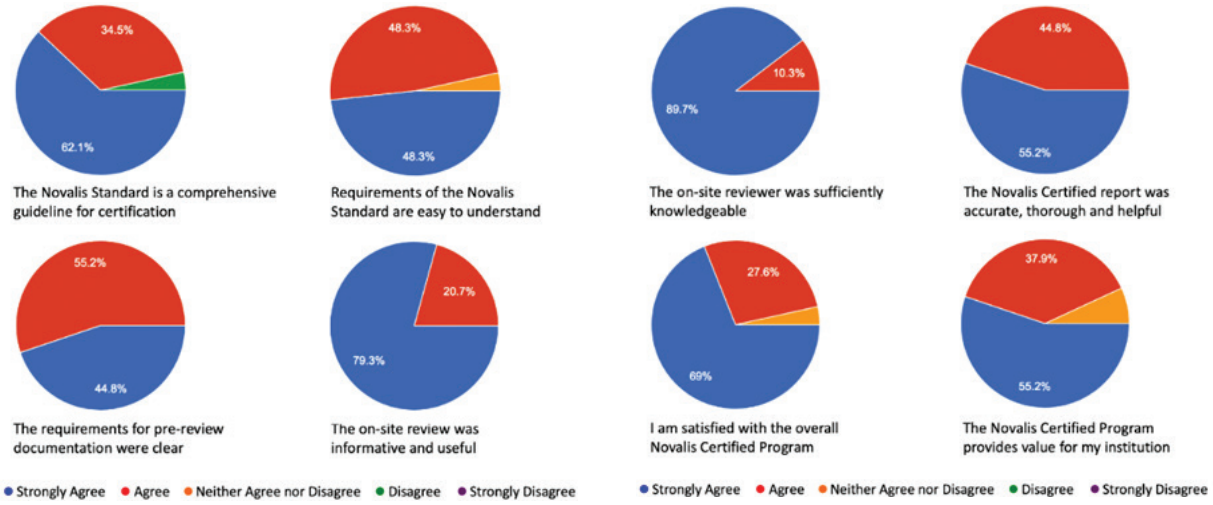

Figure 5. Survey results from centers completing the Novalis Certified Program.

Table 1 Comments received from sites following their Novalis Certification

Comments on the Novalis Standard Document
A more clear checklist with examples would be helpful
Clinical protocols should be better explained with respect to variability that is accepted. For instance, if different documentation is acceptable
Examples of expected documentation templates would help
Stress more the importance of clinical protocols based on the most recent evidence
The Novalis Standard should focus on face to face interaction as much as possible
Comments on the Documentation and Communication Process
Our reviewer has been very helpful and forth coming throughout the process, we value highly his ability to provide help and advice
The reviewer was very helpful in clarifying the documentation process
Pre-audit process was good we already had most of our documentation in order and it spurred us on to complete any outstanding documents
Scheduled teleconferences (defined frequency) would be helpful to gauge progress and answer questions in a timely fashion
We didn´t really require much interaction with the reviewer beforehand, but found the webinar very informative
Comments regarding the on-site Review
It was helpful that we could explain our way of working and receive directly some feedback about our way of working
The most useful part of the process
The on-site review was very beneficial to us, and I think is very valuable. Given that some accreditations do not require a site survey, I would STRONGLY recommend that this part of the process NOT be discarded
The reviewer was very attentive in clarifying the process step by step with the due documentation
The site review process is comprehensive as far as I can see. And we think that this should occur every time accreditation is sought even if it is re-certification
There was no physician on the on-site review
We had only a physicist that performed the site visit. It would be better if a physician would join the physicist during the visit
Comments on the Final Report
Great guidance tool to help improvements in our SRS program
The Novalis report was comprehensive and it highlighted the issues that needed to be addressed
The report was comprehensive covering all aspects of the audit process, however some more detailed probing of the processes would be beneficial
Our report was delayed, but this was mainly due to staffing issues, with some discontinuity with communication between our site and the auditor
The report was helpful in order to move on some topics

DISCUSSION

The *Novalis Certified* program promotes the delivery of stereotactic radiosurgery and stereotactic body radiation therapy at a level of efficacy and safety commensurate with the highest standards of clinical practice. *Novalis Certified* promotes the independent external review of specialized procedures, workflows and collaborative medical approaches necessary for high precision radiation oncology treatments.

Adhering to the highest standards of SRS/SBRT, a combination of offsite and onsite review of treatment programs provides an in-depth analysis of the major areas of quality, safety and procedure. Built on the recommendations of the Novalis Expert Panel, the program helps institutions to assess current practices in relation to other *Novalis Certified* centers of excellence, focusing on protocols and procedures, continual learning, self-assessment and quality improvement, and commitment to a culture of safety. As alternative payment models (APM) that focus on high-quality and cost-efficient care continue to gain importance, programs such as *Novalis Certified, ISRS Certified*, and RSS/ACRO *Distinction in Stereotactic* further serve to differentiate centers of excellence.

The use of hypofractionation in clinical practice continues to increase rapidly. We believe that adherence to good quality practices will allow SRS and SBRT to be delivered effectively and safely, enable treatment in new disease sites, and facilitate the use of future technologies such as FLASH. As a dedicated SRS and SBRT certification program, *Novalis Certified* is a valuable complement to programs offered by professional organizations such ACR and ASTRO, and well as overarching programs of the Joint Commission, Joint Commission International, and the International Organization for Standardization ISO 9001.

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Authors' disclosure of potential conflicts of interest

TDS is a partner in Global Radiosurgery Services, a consulting firm providing technical and educational services to industry; TDS is the CEO of Foretell Medical, a company developing AI applications in the medical space; NA is an instructor at the Brainlab Academy, and his institution receives research funding from Viewray; IG receives consulting fees from Seagen; JR is Chief Science Officer & Co-Founder of Adaptiiv, a company that provides 3D printing solutions in radiotherapy; NR's institution receives research funding from Novocure, Viewray and Varian; NR receives consulting fees from Brainlab; AW is the Director of Quality Management at Brainlab; TDS, NA, MDR, IG, NR, JR, RW and RW are members of the Novalis Expert Group.

Author contributions

Conception and design: [Timothy D. Solberg, Antonia Wurmseher, James Robar]
Data collection: [Timothy D. Solberg, James Robar]
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Final approval of manuscript: [Timothy D. Solberg, Nzhde Agazaryan, Mark De Ridder, Isabelle Germano, Naren Ramakrishna, James Robar, Ronald Warnick, Reinhard Wurm, Antonia Wurmseher]

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