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**Evidence-based Series 21-1 EDUCATION AND INFORMATION 2011**

# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario

*A Quality Initiative of the*
*Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO)*

**Evidence-based Series 21-1 was reviewed and put in the Education and Information section in September 2011. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol).**
**The reviewed report consists of:**

**Guideline Report Overview**
**Section 1: Recommendations**
**Section 2: Evidentiary Base**
**Section 3: EBS Development Methods and External Review Process and Results**

**and is available on the CCO website (http://www.cancercare.on.ca)**
**PEBC Radiation Therapy page at:**
**https://www.cancercare.on.ca/toolbox/qualityguidelines/clin-program/radther/**

**Release Date: April 3, 2012**

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# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario

## Guideline Report History

| GUIDELINE VERSION | SYSTEMATIC REVIEW | | PUBLICATIONS | NOTES AND KEY CHANGES |
|---|---|---|---|---|
| | Search Dates | Data | | |
| Original version Jan 2008 | 1996-2006 | Full Report | Peer-reviewed publication[1] Web publication | Not applicable (NA) |
| Reviewed Version April 2012 | N/A | N/A | Updated Web publication | Guideline ARCHIVED |



[1] Whitton A, Warde P, Sharpe M, Oliver TK, Bak K, Leszczynski K, et al. Organisational standards for the delivery of intensity-modulated radiation therapy in Ontario. Clin Oncol (R Coll Radiol). 2009 Apr;21(3):192-203. Epub 2008 Dec 5. DOI:10.1016/j.clon.2008.10.005

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**Evidence-based Series 21-1 ARCHIVED 2011**

# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario

## Guideline Review Summary

**Review Date: September 2011**

***The 2008 guideline recommendations are***

***ARCHIVED***

***This means that the recommendations will no longer be maintained but may still be useful for academic or other information purposes.***



**OVERVIEW**

**Evidence-based Series History**

This guidance document was originally released by the Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO) in 2008. In September 2011, the PEBC guideline update strategy was applied, and the recommendations were archived. The Clinical Practice Guideline and Evidentiary Base in this version are the same as 2008 version.

**Update Strategy**

The PEBC update strategy includes an annual screening of our guidelines and if necessary, an updated search of the literature is completed with the review and interpretation of new eligible evidence by the clinical experts from the authoring panel and consideration of the guideline and its recommendations based on the new available evidence.

**Impact on Guidelines and Its Recommendations**

During the annual screening process, it was agreed that this document will no longer be maintained by PEBC therefore no update search was conducted. The 2008 guideline and its recommendations on organizational standards for the delivery of intensity modulated radiation therapy (IMRT) in Ontario have been ARCHIVED.

**Review outcomes definitions.**

1. **ARCHIVED** – An archived document is a document that will no longer be tracked or updated but may still be useful for academic or other informational purposes. The document is moved to a separate section of the Web site and each page is watermarked with the phrase "ARCHIVED".

2. **ENDORSED** – An endorsed document is a document that the DSG/GDG has reviewed for currency and relevance and determined to be still useful as guidance for clinical decision making. A document may be endorsed because the DSG/GDG feels the current recommendations and evidence are sufficient, or it may be endorsed after a literature search uncovers no evidence that would alter the recommendations in any important way.

3. **DEFERRAL** – A Deferral means that the clinical reviewers feel that the document is still useful and the decision has been made to postpone further action for a number of reasons. The reasons for the deferral are in the Document Assessment and Review Tool.

4. **UPDATE** – An Update means that the DSG/GDG recognizes that there is new evidence that makes changes to the existing recommendations in the guideline necessary but these changes are more involved and significant than can be accomplished through the Document Assessment and Review process. The DSG/GDG will rewrite the guideline at the earliest opportunity to reflect this new evidence. Until that time, the document will still be available as its existing recommendations are still of some use in clinical decision making.

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**Evidence-Based Series #21-1: Section 1**

# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario: Recommendations

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A Special Project of the Radiation Treatment Program, Cancer Care Ontario and the Program in Evidence-based Care, Cancer Care Ontario

Developed by the Expert Panel on Intensity Modulated Radiation Therapy

**Report Date: January 30, 2008**



## QUESTION

What are the optimal organizational standards for the delivery of Intensity Modulated Radiation Therapy (IMRT)[2] in an Ontario Cancer Program?

## SCOPE OF STANDARDS

The Ontario radiation treatment community, through Cancer Care Ontario (CCO), continuously evaluates new radio-therapeutic technology and its implementation for use in Ontario. In 2001, a CCO report concluded that there were limited capabilities for performing advanced radiation techniques in Ontario. This was in spite of the fact that recommendations for the enhancement of technology were made in prior CCO technology assessments. The report recommended upgrades to existing radio-therapeutic facilities, at each regional cancer centre, to support three-dimensional (3-D) conformal radiation therapy, including intensity modulated radiation therapy (IMRT).

At a CCO workshop in 2004, representatives from radiation oncology, medical physics, and radiation therapy reviewed evidence for the use of IMRT in specific disease sites and concluded that IMRT should be used to treat patients with breast and prostate cancer, as well as head and neck cancer, brain tumours, sarcomas, and pediatric cancer. Currently there is also an emerging consensus that IMRT is appropriate for the treatment of gynecological and

[2] IMRT is an advanced technique with functions in both treatment planning and treatment delivery. IMRT utilizes non-uniform intensities within a radiation beam. It involves the use of a formal optimization algorithm for the computation of appropriate beam orientations, aperture shapes, and dose-contribution weights based on:

i. specifically delineated (manual or automatic) anatomical structures of interest (diseased targets and normal tissues);
ii. prescribed dose objectives and constraints; and,
iii. data supporting the geometric targeting accuracy and precision of the treatment technique (devices and process).

gastrointestinal carcinomas, and is essential in all cases where retreatment with radiotherapy is utilized.

In March 2007, CCO's Radiation Treatment Program organized a large symposium entitled *The Future of Radiation Treatment in the 21st Century.* Experts in the field confirmed that IMRT was the radiotherapeutic treatment of choice for selected patients with breast, head and neck, lung, and prostate cancers, highlighting increased survival, reduced complications, and better overall quality of life. The main conclusion drawn from this event was that, to provide maximal benefit to patients across cancer centres in Ontario, standards, followed by a swift implementation strategy for IMRT, were necessary to ensure that this high-quality treatment is available to patients.

This report, created by the CCO IMRT Expert Panel, presents organizational standards for the delivery of IMRT in an Ontario Cancer Program. These standards apply to all institutions and hospitals delivering IMRT within the province, and address the following domains: the planning of new IMRT programs, practice setting requirements, tools, devices and equipment requirements; professional training requirements; the role of personnel; and requirements for quality assurance and safety. These standards are based on a synthesis of a systematic review of the evidence, found in section 2 of this report, and on the consensus opinion of the IMRT Expert Panel. The panel's goal is to raise the standard of care around IMRT provision and to accommodate the long-range needs of the province. This includes the ability to adapt to the projected increase in demand for IMRT over the next decade to reflect not only an advancing global standard of care, but also a growing and aging population in Ontario.

## STANDARDS

The standards presented below embody strong recommendations for the organization of the delivery of IMRT in Ontario. Please note that, while the process of standards development was as rigorous as possible, the evidence available to inform the organizational standards was limited. The standards are based upon the consensus opinion of the IMRT Expert Panel and the expert consensus of other credible content experts or organizations. Primary consideration was given to the perceived benefits for patients and the small likelihood of any harm arising from standards implementation.

### Implementation of an IMRT Program

- An IMRT implementation team is strongly recommended for each facility to guide the selection of IMRT-capable equipment and the development of appropriate multidisciplinary support. The implementation team will guide the development of general procedures and practice guidelines by disease site and coordinate the development and maintenance of skills through staff training. Once the implementation process has been completed, the IMRT team will periodically update the general procedures as lessons are learned.
- The clinical implementation process includes augmenting quality control programs, selecting appropriate accessories, such as immobilization systems, and training in treatment plan optimization and delivery. These steps require a coordinated effort, an emphasis on safety, and time investment by the team.
    - Patient-specific quality assurance is essential during implementation as well as on an ongoing basis, to ensure accurate and safe treatment. The process should begin with individual dosimetric validation through measurement (in phantom) for each patient.
- With the optimum technical and human resources, an estimated minimum four- to six-month implementation time is necessary to lay the groundwork prior to treating patients with IMRT.
- Success depends on the resources available at each institution; however, after the initial implementation and training phase, the process becomes sustainable and more efficient as experience with IMRT increases.

- In the interest of safety and effectiveness, the early phase of IMRT implementation in a clinical setting requires a considerable investment in organizational, technological, and human infrastructure. The initial increase in cost is anticipated to extend from approximately three to five years.
- While a detailed analysis of the costs of IMRT implementation is beyond the scope of this document, there will be significant incremental costs to upgrade or add additional treatment planning systems and licenses. This increase will also apply to treatment management systems, ancillary linear accelerator devices and software licences as well as additional quality assurance equipment.
- Proper documentation requirements must be established for the planned course of therapy and type and delivery of treatment.
- External validation of an IMRT program (e.g., which can be attained by engagement in credentialing with national and international clinical trials groups) is an essential part of an IMRT implementation program.

**Practice Setting**

- The evolving field of high-precision radiation therapy dictates the employment of a team-centred multidisciplinary approach. Adequate staffing of all radiation specialities, including radiation oncologists, medical physicists, radiation therapists, registered nurses specializing in oncology, and associated support personnel (Information technology personnel, electronics personnel or physics associates), are required for a successful IMRT program.
- IMRT treatment facilities must be designed and reviewed in each centre so that they provide adequate radiation protection, in terms of shielding, for the increased workload due to IMRT procedures. In fact, all new license applications to the Canadian Nuclear Safety Commission, as well as annual license reports, have to include an assessment of IMRT workload.
- Ontario facilities must be equipped with multiple IMRT-capable machines. The use of multiple matched IMRT machines at each facility will obviate the concern of unplanned downtime and avoid undue expense and delays associated with restarting the planning and treatment process. Each facility should have a contingency plan in the event an IMRT treatment unit undergoes extensive unplanned downtime.
- Depending on the configuration of the treatment planning resources, greater physical space may be required for items such as additional computer workstations, equipment, patient immobilization devices, and personnel.
- The delivery of IMRT will require additional staffing resources, at least in the first three to five years. There has been a noticeable increase in workload due to the growing use of 3-D planning; this trend is expected to continue because of the widespread implementation of IMRT as a standard treatment. Allowances for staff training and development with respect to evolving technologies need to be further explored within the province.
- Current planning projections for the province will need to be monitored and reviewed with respect to the number of patients treated per year, per linear accelerator.
- Resources for treatment management systems should be monitored and reviewed, given the anticipated increases in information storage/retrieval needs with IMRT, as well as other costs associated with target-localization technologies.
- Information systems should reside within the auspices of the medical physics department of the radiation oncology program to manage the support services provided by the hospital information systems department. Departmental staff with expertise in the field will be needed to provide immediate attention for the resolution of any technology-related issues.

**Tools, Devices and Equipment Requirements**

- There must be a means of soft tissue imaging for treatment planning. Computed tomography (CT)-based simulation is a minimum for the implementation of IMRT. However, it must be recognized that multiple imaging modalities may be required in certain cases, including magnetic resonance imaging (MRI) and positron emission tomography (PET) imaging. The treatment team should be adequately trained in regards to the various imaging modalities.
- A treatment planning system equipped and licensed with optimization software is required, which ideally includes multimodality image registration, and is integrated with conventional/traditional capabilities for conformal radiotherapy with dose-calculation algorithms of appropriate accuracy and computational efficiency.
- Each facility must have the means to deliver modulated beams (for example, have a linear accelerator equipped with a multileaf collimator). Equipment acquisition and replacement plans should ensure the availability of multiple matched IMRT machines. Resources may be needed to purchase or upgrade linear accelerators with multileaf collimators, IMRT software, and imaging systems.
- A treatment management system with charting integrated with planning and treatment process management, formerly called 'record and verify', is needed at each facility.
- There must be a means of achieving target/anatomic localization appropriate to the clinical objectives, for example, image-guidance using electronic portal imaging devices, ultrasound, cone beam CT, among others. Other accessories, such as planning (dosimetry) instrumentation, and appropriate immobilization devices are also required.
- Due to the increased time for planning and image segmentation (i.e., contouring), the number of workstations in each treatment facility should be increased according to the workload.
- With the advent of electronic documentation within departments, the maintaining and upgrading of radiation therapy software is essential. The integrity of the system is vital, as is a disaster recovery plan for the retrieval of information. Archived records must be readily available and in a suitable format to provide reference when planning re-treatments. Adequate resources should be set aside to meet the needs of archiving systems, now and in the future.

**Professional Training Requirements**

- All suitably certified personnel should undergo IMRT training during the implementation phase and as part of continuing education. A coordinated provincial approach is essential to design and conduct IMRT training courses and provide a coaching or mentorship program. If coordinated services are not available, sufficient funds need to be dedicated to allow providers to travel to and attend IMRT educational programs elsewhere.
- A clearly defined language or classification scheme for tumour and normal tissue structures needs to be developed.
- The following speciality-appropriate training should include, but is not limited to:
    - Radiation Oncologists
        - Interpretation and segmentation (anatomical contouring) of CT and other modality (MRI, PET, ultrasound) images
        - Multimodality image fusion
        - Localization and delineation of the patient's tumour and specification of target volumes with appropriate margin setting following the International Commission on Radiation Units (ICRU) formalism.
        - Contouring of normal structures

        - Defining objectives for the treatment plan in terms of dose prescription for the target volumes
        - Specifying dose constraints for normal tissues and organs at risk
        - Evaluation of IMRT treatment plans
    - Physicists
        - Management of treatment planning and delivery infrastructure
        - Leadership and participation in treatment planning and optimization
        - Leadership in radiation safety and protection
        - Must understand physical characteristics of different modality imaging systems (e.g., CT, MRI, PET, ultrasound): image quality specifications, limitations, and artifacts, for example.
        - Acceptance testing and commissioning of systems for treatment planning, management of treatment delivery, and imaging used for treatment planning.
        - Acceptance testing and commissioning of radiation treatment machines and associated imaging systems and treatment accessories
        - Design and implementation of the quality assurance program for treatment planning and delivery, including the tests to be performed, tolerances, and frequency of the tests
        - Technical evaluation and dosimetric validation of IMRT treatment plans
        - Direct and assure competence of support staff involved in information systems, accelerator maintenance, and ancillary systems.
    - Radiation Therapists
        - Training on the IMRT program of the treatment planning system, as well as patient data acquisition, radiation treatment design, and computer-assisted calculations of radiation dose distributions.
        - Data transfer between hospital PACS system, CT scanner, treatment planning system, record and verify, and treatment and imaging system
        - Contouring of relevant normal tissue structures e.g. lymph node regions in neck.
        - Identifying technical objectives for the treatment plan in order to meet the dose prescription and normal tissue constraints
        - Generation and documentation of the treatment plan, in consultation with the physicist and radiation oncologist
        - Active involvement in all aspects of the radiation planning and treatment processes, most notably patient positioning and immobilization, simulation or localization, plan verification, imaging, and treatment delivery.
    - All Disciplines
        - Characteristics and implications of organ motion for all sites
        - Design and testing of treatment protocols
        - Quality assurance and risk management
        - Radiation protection and safety
        - Training in the use of imaging systems (e.g., image acquisition, image fusion for treatment planning and target localization)
        - Training in the application of plan optimization software for all disciplines involved in treatment planning
        - Appropriate plan evaluation and prescribing practices according to the current guidelines published by the ICRU
        - Collaboration on the role of image guidance and appropriate PTV margin design
- Training and clinical practice should be conducted in accordance with the Canadian Association of Provincial Cancer Agencies standards, related professional associations, and colleges.

**Quality Assurance and Safety**

- There is an essential practical need to document and validate disease-specific planning and treatment procedures because, when a uniform and stable procedure is established, it greatly reduces the expense and resources associated with individualized patient measurements. A comprehensive quality assurance program for IMRT includes testing at three distinct phases of the planning and delivery process.
  - Commissioning and Testing of the Treatment Planning and Delivery Systems
    - Because the treatment planning process (patient positioning and localization, imaging, definition of the anatomy establishment of beam geometry, dose calculation, dose display, and plan evaluation and implementation) involves numerous uncertainties, a thorough quality assurance program must be implemented to ensure that the delivered dose distribution agrees with that produced by the treatment-planning computer.
    - A well-thought-out quality assurance program dictates that staff members have access to extensive training on the appropriate equipment (e.g., treatment units, imaging equipment, computerized treatment planning systems, computerized data acquisition systems, quality assurance equipment).
    - To verify ongoing system reliability, it is necessary to test the normal operations of the delivery system on a daily, monthly, and annual basis. This would include periodic testing of the treatment planning system, R/V software, treatment units, CT data input, and other systems.
    - Peer review of IMRT plans (chart rounds) should be completed prior to the start of treatment or before a significant amount of dose has been delivered to the patient.
  - Patient-Specific Validation of Treatment Plans and Positioning
    - Patient-specific quality assurance is essential to ensure accurate and safe treatment. The process should begin with individual dosimetric validation through measurement (in phantom) and potentially shift to an independent calculation for each patient as the disease-specific procedures mature.
    - IMRT fields vary due to the patient's disease, target location, planning target volume, anatomy, field arrangements, and dose prescription; therefore, each field for every IMRT plan must be verified independently before the start of actual treatment.
    - Due to the complexity of treatment, potential for dose escalation, and conformity resulting in tight margins, treatment guidance and verification using online imaging should be performed regularly, and in most cases daily, prior to treatment. Consequent dose implications need to be accounted for in the treatment plan, where appropriate. In vivo dosimetry (IVD) should be performed in the initial period of building up confidence in the IMRT system and whenever critical structures are in close vicinity of the treated volume.
  - Ongoing Quality Assurance
    - The quality assurance system needs to include ongoing equipment testing and verification of the IMRT treatment system reliability, but most importantly, it must persistently ensure that the precise IMRT treatment plan is delivered.
    - An ongoing process for quality improvement and to collect and record incident reports related to IMRT treatment should be implemented at each centre and reviewed frequently in order to make appropriate modifications that will improve treatment and increase patient safety. Incidents should be reported to CCO according to reporting requirements.
    - An annual quality management program report should be submitted to the radiation safety committee chair or medical director.
    - Regular discussion, review, and training sessions, as well as external validation of an IMRT program (e.g., which can be attained by engagement in credentialing with

national and international clinical trials groups) are essential parts of the continuing quality improvement program.

## DEVELOPMENT OF THE STANDARDS DOCUMENT

Evidence on organizational issues of IMRT delivery was gathered through a systematic search of the published literature and a scan of documents from key national and international organizations, cancer treatment centres, and insurance companies, as well as IMRT technology vendors in Canada, the United States, Australia, and Europe. Evidence was reviewed by members of the IMRT Expert Panel (Section 2: Appendix I), which included representation from radiation oncology, radiation therapy, medical physics, nursing, and Cancer Care Ontario's Radiation Treatment Program, Capital Projects Office, and Program in Evidence-based Care. The IMRT standards were developed using a combination of evidence-based analysis, existing guidance documents and recommendations, and expert opinion based on experience and consensus.

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**Evidence-Based Series #21-1: Section 2**

# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario: Evidentiary Base

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A Special Project of the Radiation Treatment Program, Cancer Care Ontario and the Program in Evidence-based Care, Cancer Care Ontario

Developed by the Expert Panel on Intensity Modulated Radiation Therapy

**Report Date: January 21, 2008**



## QUESTION

What are the optimal organizational standards for the delivery of Intensity Modulated Radiation Therapy (IMRT) in an Ontario Cancer Program?

## INTRODUCTION

Continuing advances in radiation therapy, especially within the computer hardware and software spheres, have led to the development of a precise form of radiation delivery known as Intensity Modulated Radiation Therapy (IMRT). IMRT can be used to treat tumours in any area of the body, but more importantly, it can treat irregularly shaped tumours that have wrapped around healthy tissue. By minimizing the impact on the surrounding tissue, IMRT can deliver higher and more effective doses to the targeted tumour site, thereby minimizing treatment-related morbidity and possibly improving cancer control and cure (1-8). In addition, there is a growing body of clinical evidence that the improved normal tissue sparing with IMRT leads to noticeable improvements in the quality of life of patients and the increased doses of radiation to the tumour made possible by IMRT are expected to lead to higher cure rates (9-18). In Ontario, IMRT is currently used in a limited number of facilities to treat patients with breast, prostate, lung, head and neck, and gynecological cancers, as well as patients with brain tumours, sarcomas, and pediatric cancers (19).

IMRT utilizes multiple beams of varying intensity; therefore, the process of delivering IMRT is significantly different from conventional, even three-dimensional conformal radiation therapy (3D-CRT). IMRT necessitates a computerized process, known as inverse treatment planning, due to the complexity involved in arriving at optimal radiation beam intensity patterns. Inverse treatment planning defines the desired dose and target volume constraints a priori and then uses a computer algorithm to find and apply the most appropriate (optimal) beam profiles. Thus, an individualized treatment plan is created for each patient. This approach can produce dose distributions not previously obtainable and is an essential step for complex planning

situations, such as head and neck cases, where multiple targets are carried to different total doses and dose limits have to be applied to numerous critical structures (20).

In 2001, a Cancer Care Ontario (CCO) report concluded that there was clearly a shortfall in the predicted demand for 3-DCRT, and the case was made for the advancement of IMRT for the treatment of patients in Ontario (21). In 2004, another CCO report concluded that IMRT was recommended as standard treatment for patients with breast and prostate cancer, as well as for selected patients with head and neck cancer, brain tumours, sarcomas, and pediatric cancer (22). In addition, since 2004, it has become clear that IMRT should also be used in virtually all head and neck cancers and in all sarcoma cases. Furthermore, there is emerging consensus that IMRT is appropriate for the treatment of gynecological and gastrointestinal disease. IMRT is also essential in all cases where retreatment with radiotherapy is utilized (19,22).

The following report, created by the CCO IMRT Expert Panel (Appendix I), presents organizational standards for the delivery of IMRT in Ontario. The standards apply to all institutions and hospitals delivering IMRT within the province and address the following issues: the planning of new IMRT programs, practice setting requirements, tools, devices and equipment requirements, and professional training requirements, as well as requirements for quality assurance and safety. The proposed standards represent a synthesis of a systematic review of the evidence, found in Section 2 of this report, and the consensus opinion of the IMRT Expert Panel. The purpose of this document is to guide the development of standards of care around IMRT provision. This includes the ability to manage the current and projected demand for IMRT to reflect an advancing global standard of care.

## METHODS

This Standards Report was developed by the IMRT Expert Panel, a collaboration of CCO's Program in Evidence-based Care (PEBC) and Radiation Treatment Program. The standards were written in accordance with a methodology adapted from the PEBC's practice guideline development process and reporting format (23,24). The report was designed to address professional and organizational standards around the delivery of IMRT in Ontario. A systematic review of the published literature and an environmental scan of unpublished documents from various organizations, pertaining to IMRT, comprise the evidence base.

Evidence was reviewed by members of the IMRT Expert Panel, which included representation from radiation oncology, radiation therapy, medical physics, nursing, and CCO's Radiation Treatment Program, Capital Projects Office, and the PEBC. The Panel met through teleconference and in-person meetings and used e-mail as the main vehicle of communication. Differences were resolved through consensus and the use of evidence that informed the standards document. The PEBC is supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

### Literature Search Strategy

The literature was systematically searched using MEDLINE (Ovid, 1996 - June 2006), EMBASE (Ovid, 1996 - 2006 week 23), the Cochrane Database (2nd Quarter 2006), the National Guidelines Clearing House, and the Health Technology Assessment Database available through the Centre for Reviews & Dissemination (CRD, United Kingdom).

The literature search strategy combined technique specific terms (radiotherapy, Intensity Modulated/ or radiotherapy planning, computer-assisted/ or IMRT.ti.) with search specific terms (guideline?.tw,pt,sh or standards.mp. or meta-analysis?.tw,pt,sh or systematic review.mp. or clinical trial?. sh,pt,tw.).

## Environmental Scan Strategy

A Web search using the Google© 2006 search engine was conducted in June 2006, using the terms “Intensity Modulated Radiation Therapy” and “standards” in combination with the following terms: cancer services, national standards, standards of practice, guideline, practice guideline, health technology, professional, education, training, equipment, device, integration, and policy. Keywords such as education, device, and integration were eliminated in the final search, since they produced articles and reports that were of limited relevance. Other search strategies included searching the Web sites of key organizations and cancer treatment centres, insurance companies, and IMRT technology vendors in Canada, the United States, Australia, and Europe. The bibliographies of retrieved articles were also searched for relevant reports. The Web sites of the following organizations were searched for IMRT organizational and resource standards (Table 1).

**Table 1. Environmental scan of Web sites for IMRT organizational and resource standards.**

| | |
|---|---|
| **Organizations** | **Organizations** |
| Canadian Association of Radiation Oncologists (CARO) | The Cancer Council Australia |
| Canadian Association of Provincial Cancer Agencies (CAPCA) | National Cancer Control Initiative (Australia) |
| Canadian Cancer Society | Medical Oncology Group of Australia |
| Canadian Association of Medical Radiation Technologists (CAMRT) | **Other provincial cancer agencies in Canada** |
| Canadian Organization of Medical Physicists | BC Cancer Agency |
| American Society for Therapeutic Radiology and Oncology (ASTRO) | Alberta Cancer Board |
| | Saskatchewan Cancer Agency |
| American Association of Physicists in Medicine (AAPM) | Cancer Care Manitoba |
| American College of Radiology (ACR) | Cancer Care Nova Scotia |
| American College of Radiation Oncology (ACRO) | |
| American College of Medical Physics (ACMP) | **Companies producing IMRT technologies** |
| National Cancer Institute- Radiation Therapy in Oncology Group (RTOG) | Computerized Medical Systems (CMS) |
| | .decimal (dot-decimal) Inc. |
| National Comprehensive Cancer Network (NCCN) | Elekta |
| Radiological Society of North America (RSNA) | North American Scientific/ NOMOS |
| European Society for Medical Oncology (ESMO) | Nucletron |
| Cancer UK | Philips |
| The College of Radiographers (UK) | Siemens |
| The Royal College of Radiologists (UK), Faculty of Clinical Oncology | Varian |
| Cancer Services Collaborative NHS Modernisation agency | |
| NHS (UK) | |
| New Zealand Cancer control Strategy | |

## Study Selection Criteria

Published or unpublished documents presenting guidance on organizational standards for the delivery of IMRT in a cancer program were considered eligible for inclusion. Specifically, guidance from credible content experts or professional organizations that address any one of the following were considered: the planning of new IMRT programs; practice setting requirements; tools, devices, and equipment requirements; professional training requirements; the role of personnel; and/or requirements for quality assurance and safety. The reference lists of related papers and recent review articles were also scanned for additional citations.

Articles were excluded if they were letters, editorials, comments, or articles in a language other than English.

## RESULTS

### Literature Search Results

The systematic search of the literature yielded 22 articles considered eligible for inclusion (25-47). Twelve published documents (25-36) and 10 unpublished reports (37-47) provided guidance on planning a new IMRT program; the practice setting; tools, devices, and equipment requirements; professional training requirements; the role of personnel, and/or quality assurance and safety. An overview of the included documents is presented in Table 2. Of note, four documents were commercial reports from IMRT vendor Web sites (43-46).

**Table 2. Documents eligible for inclusion.**

| Scope | Number of Studies Identified | |
|---|---|---|
| | Published Literature (References) | Environmental Scan (References) |
| **Implementation of an IMRT Program** | 6 (25,26,30,31,33,34) | 6 (40,41,43-46) |
| **Practice Setting** | 5 (27,30, 32,33,35) | 6 (37,40,41-44) |
| **Tools, Devices and Equipment Requirements** | 1 (32) | 2 (38,40) |
| **Professional Training Requirements** | 3 (30,32,35,40,42) | 2 (40,42) |
| **Quality Assurance and Safety** | 7 (25,27,30,32,33,35,36) | 3 (37,38,41) |

### *Implementation of an IMRT Program - Evidence*

Twelve documents provided guidance on the requirements for implementing an IMRT program (25,26, 30,31,33,34,40,41,43-46). Three documents reported on the estimated time to IMRT implementation (34,40,43), four documents provided guidance on the estimated workload (25,26,32,33), five documents addressed implementation steps (30,32,40,43,45), and three documents reported on IMRT document requirements (33,41,46).

*Implementation Time*

Grant and Woo (34) reported that commissioning an IMRT system for a new user requires approximately three to four months. The authors based their conclusions on a four-year experience (1994-1998) with a commercial IMRT system, the Peacock system, which was used on more than 300 patients at the Baylor College of Medicine/The Methodist Hospital. They also reported that the remaining part of the clinical implementation process, which includes creating quality control programs, testing immobilization systems, and training therapists regarding precision set-up, takes longer and varies depending on the resources available at each institution. However, following the initial implementation and training phase, two documents reported that the IMRT process became more efficient as personnel gained more experience (33,34). The estimated three- to four-month implementation timeframe was also reported in the documents by Trinity Health (40) and North American Scientific (43).

*Workload*

Ting and Scarbrough reported that, due to the complexity of treatment, IMRT implementation in small clinics should be slow, measured, and meticulous (25). Miles et al reported that the total planning time with IMRT is increased over conventional radiotherapy, with greater physics time spent but also with decreases in radiographer (radiation therapist in the North American nomenclature) time spent (26). The IMRT subcommittee of the American Association of Physicists in Medicine (AAPM) (32) stated that new users should consider

spending considerable time learning about the applications of IMRT to specific body sites. The subcommittee further pointed out the setup and testing of the IMRT process, the quality assurance procedures, and training require an initial investment of several person-months of work from the physics staff and the implementation team. The National Cancer Institute's (NCI) IMRT Collaborative Working Group (33) reported that increased workload values that may be a factor of two to five larger than that for conventional therapy should be considered for IMRT.

*Implementation Steps*

As seen in Table 3, the steps of planning for a new IMRT program were addressed in five documents (30,32,40,43,45). It was commonly stated that the successful implementation of an IMRT program involves extensive planning and cooperation among disciplines (30,32,40,43). One document recommended that a champion or project leader be established (45), and three documents (32,43,45) stressed the need for an IMRT implementation team or committee in order to guide the implementation process. North American Scientific suggested that in addition to radiation oncologists, treatment planners, therapists, and nurses the implementation committee should include administrators and directors of radiology (43). All five of the documents suggested that facilities should evaluate their staffing, spacing, and/or equipment requirements needed to implement an IMRT program (30,32,40,43,45). Initiating a planning phase (45); choosing a disease site (45); developing written policies (30), procedures (30,45), and responsibilities (45); providing training (32,30,33); testing the IMRT process (45); and performing quality assurance (32,30,33,45) were also suggested as essential steps in the process of establishing an IMRT program. One document reported that consideration should be given to the future operation of the program; the ongoing smooth operation of the program, keeping equipment up-to-date and keeping up with changes in technology over time (32).

The Trinity Health Report suggested that relatively new (less than seven years old) linear accelerators with an existing 3-D planning system, capable of an upgrade, can be retrofitted for IMRT functionality, rather than purchasing a full system. (40).

**Table 3. Steps in implementing a new IMRT program.**

| Steps of clinical implementation of a new IMRT program | ASTRO + AAPM (30) | AAPM IMRT Sub Comm. (32) | Health Trinity Report (40) | North American Scientific (43) | Varian (45) |
|---|---|---|---|---|---|
| Select a Program Leader | - | - | - | - | ✓ |
| Form an IMRT Committee | - | ✓ | - | ✓ | ✓ |
| Determine the need for IMRT | - | - | - | ✓ | - |
| Define the scope for the institution or choose a disease site | ✓ | - | ✓ | ✓ | ✓ |
| Evaluate staff requirement and fulfill staffing requirements | ✓ | ✓ | ✓ | ✓ | ✓ |
| Evaluate space requirements and prepare space | ✓ | ✓ | - | ✓ | - |
| Evaluate equipment needs and purchase or upgrade equipment | ✓ | ✓ | ✓ | ✓ | ✓ |
| Develop a program budget | ✓ | - | ✓ | - | - |
| Identify changes in treatment planning and delivery practice, scheduling, billing, and charting practice | - | ✓ | - | - | - |
| Develop written policies, procedures and responsibilities | ✓ | - | - | - | ✓ |
| Provide training for all personnel | ✓ | ✓ | ✓ | - | - |
| Develop and perform quality assurance procedures | ✓ | ✓ | ✓ | - | ✓ |

*IMRT Documentation Requirements*

Three reports addressed documentation requirements for the planning and delivery of IMRT (33,41,46). Two reports (33,41) recommend that facilities set minimum documentation requirements for dosimetry measurements, concerning dose prescription and volume requirements. The report by American College of Radiology (ACR) specified the proper documentation of various treatment verification methodologies, treatment parameters, patient positioning, and physical measurements of patient dosimetry (41). AdminaStar Federal Inc. (46), a Medicare contractor in the United States, recommends that the planned course, type, and delivery of treatment; the level of clinical management involvement; and any changes in the course of treatment be fully documented. The ACR suggests that all documentation be carried out in accordance with the ACR Practice Guidelines for Communication (41).

***Implementation of an IMRT Program - Summary of the Evidence and Consensus***

It was generally agreed across the documents addressing IMRT implementation, that the development of a new IMRT program requires considerable investment and planning. Under optimal conditions, starting a new program necessitates at least a three- to four-month timeframe, and would result in increased workloads for staff, at least initially, due to the complexity of treatment with IMRT. However, the IMRT Expert Panel agreed that an estimated minimum four- to six-month implementation time is necessary to lay the groundwork prior to treating patients with IMRT. It is clear from the documents that the steps required to implement an IMRT program are substantial; however, with a clear implementation plan, proper documentation procedures, consideration given to each physical and technical component, and established quality assurance practices, the development of a new IMRT program is practicable.

Aside from improvements in patient outcomes, especially concerning minimizing treatment-related morbidity, there are no data around the return on investment and the changes in practice with IMRT. If IMRT is a better option for suitable patients than conventional radiotherapy, it is not known what changes in practice will occur when patients require fewer treatments with fewer side effects. Once the IMRT program is up and running and additional resources are provided to train and support staff, the unknown factor will be the staffing requirements required on an ongoing basis. While there will certainly be the need for additional human resources, it is difficult to quantify which staffing needs or specific disciplines will be required, how many will be needed, nor for which period of time. Each cancer centre interested in developing an IMRT program will need to clearly evaluate and define their staffing, space, and equipment needs.

While most Ontario centres have linear accelerators that are capable of IMRT with multileaf collimators, new equipment and equipment updates would be required at some facilities. The leading treatment planning systems have IMRT included as an option within the overall system; therefore, strictly speaking, there is no need for a separate IMRT treatment planning system workstation with the newer systems. However, since IMRT planning takes much longer than conventional planning, especially in the early stages of implementation, additional workstations may be required to carry the extra workload.

An external validation program should be a part of IMRT implementation and a comprehensive documentation process needs to be developed and put into practice. The Panel also agreed that an IMRT implementation team or committee needs to be established in order to guide implementation, periodically update procedures, and share information with all staff as lessons are learned. Additionally, identifying a program leader or champion at each centre may be helpful in facilitating the IMRT implementation process. Training and education around IMRT treatment planning and delivery is necessary and should be provided to all involved staff.

***Implementation of an IMRT Program- Standards***

- An IMRT implementation team is strongly recommended for each facility to guide the selection of IMRT-capable equipment and the development of appropriate multidisciplinary support. The implementation team will guide the development of general procedures and practice guidelines by disease site and coordinate the development and maintenance of skills through staff training. Once the implementation process has been completed, the IMRT team will periodically update the general procedures as lessons are learned.
- The clinical implementation process includes augmenting quality control programs, selecting appropriate accessories, such as immobilization systems, and training in treatment plan optimization and delivery. These steps require a coordinated effort, an emphasis on safety, and time investment by the team.
    - Patient-specific quality assurance is essential to ensure accurate and safe treatment. The process should begin with individual dosimetric validation through measurement (in phantom) for each patient.
- With the optimum technical and human resources, an estimated minimum four- to six-month implementation time is necessary to lay the groundwork prior to treating patients with IMRT.
- Success depends on the resources available at each institution; however, after the initial implementation and training phase, the process becomes sustainable and more efficient as experience with IMRT increases.
- In the interest of safety and effectiveness, the early phase of IMRT implementation in a clinical setting requires a considerable investment in organizational, technological, and human infrastructure. The initial increase in cost is anticipated to extend from approximately three to five years.
- While a detailed analysis of the costs of IMRT implementation is beyond the scope of this document, there will be significant incremental costs to upgrade or add additional Treatment Planning Systems and licenses. This increase will also apply to treatment management systems, ancillary linear accelerator devices and software licences as well as additional quality assurance equipment.
- Proper documentation requirements must be established for the planned course of therapy and type and delivery of treatment.
- External validation of an IMRT program (e.g., which can be attained by engagement in credentialing with national and international clinical trials groups) is an essential part of an IMRT implementation program.

***Practice Setting – Evidence***

Eleven documents provided guidance on the practice setting requirements for an IMRT program (27,30,32,33,35,37,40,41-44). Five documents reported on the organizational requirements for an IMRT program (32,33,40,41,43), while seven documents provided insight into the number and type of personnel needed (27,30,32,35,37,40,42,44).

*Organizational Requirements*

According to the AAPM IMRT subcommittee (32), some facilities may need extra space for additional computer workstations and equipment such as add-on collimators, dosimetry phantoms, film scanners, and instrumentation. Space will also be required for patient immobilization devices and extra personnel (32). North American Scientific reported that an IMRT treatment planning system requires approximately the same amount of space as a conventional planning system; however, the authors also suggested the need for additional storage space for IMRT hardware and extra dosimetry equipment (43).

The AAPM IMRT subcommittee emphasized that room shielding should be re-evaluated, as IMRT treatments required about a factor of 2 to 10 more monitor units than conventional treatments (32). Similarly, two other reports (33,40,41) recommended improving shielding protection due to the increased radiation exposure with IMRT.

*Number and Type of Personnel*

Eight guidance documents outlined the professional structure of an IMRT team (27,30,32,35,37,40,42,44). The majority of reports outlined the various professionals who will be directly involved in the IMRT implementation and delivery. Emphasis was placed on the combined efforts of radiation oncologists, medical physicists, treatment planners, radiation therapists (30,32,35,37,40,42,44), and nurses (30,42,44) to ensure a safe and streamlined process. The inclusion of a service engineer, to maintain reliable equipment performance, was also suggested in one report (27). Hulick et al pointed out that, due to the rapid development of computer-based treatment controls, the information technology administrator has become a key person in the IMRT treatment process (27). The authors stated that, without a robust and reliable local area network, radiotherapy departments would not be able to use IMRT, dynamic field shaping, multileaf collimators, or treatment verification.

In the report by Trinity Health (40), the authors report that two full time physicists would be needed in order to implement IMRT in a program with 50 to 60 total radiation patient treatments per day (taking approximately three to four months). The document did not address ongoing staffing needs beyond implementation.

***Practice Setting - Summary of the Evidence and Consensus***

Estimating organizational requirements is an important step in IMRT implementation; each centre should investigate whether additional infrastructure-related investments are necessary. Facilities providing treatment with IMRT must have adequate radiation protection (eg. appropriated shielding) and should have multiple IMRT capable machines in order to avoid unnecessary expenses and delays due to unplanned downtime.

Most facilities rely on a specially trained team for IMRT delivery, composed of radiation oncologists, medical physicists and radiation therapists. It is important that adequate education and training be provided to registered nurses specializing in oncology, in order to ensure the proper management of possible side effects and to provide patient education. Associated support personnel, such as electronics, information technology staff, physics associates/assistants should also have a working knowledge of IMRT in order to accommodate the growing electro-technical demands required by IMRT. Furthermore, ongoing collaboration between physicists and electronics staff is important since quality assurance procedures for IMRT will also include procedures for electronics personnel.

It is essential that each facility evaluate their staff availability since, in many cases, the implementation of IMRT services necessitates increased staffing resources. There has been a noticeable shift in workload with increased 3-D planning, and this is expected to continue with the more widespread implementation of IMRT as a standard treatment. There should be allowances for staff training and development with respect to evolving technologies; this needs to be further explored within the province.

Ideally, every treatment planning workstation needs to IMRT capable. The appropriate number of IMRT capable workstations needs to be evaluated for each facility based on vendor licensing and patient volumes. IMRT capability may not be necessary in some cases, such as in CT simulations, or in some of the other areas where a treatment planning system is deployed.

***Practice Setting - Standards***

- The evolving field of high-precision radiation therapy dictates the employment of a team-centred multidisciplinary approach. Adequate staffing of all radiation specialities, including radiation oncologists, medical physicists, radiation therapists, registered nurses specializing in oncology, and associated support personnel are required for a successful IMRT program.
- IMRT treatment facilities must be designed and reviewed in each centre so that they provide adequate radiation protection, in terms of shielding, for increased workload due to IMRT procedures. In fact, all new license applications to the Canadian Nuclear Safety Commission, as well as annual

license reports, have to include an assessment of the IMRT workload.

- Ontario facilities must be equipped with multiple IMRT-capable machines. The use of multiple matched IMRT machines at each facility will obviate the concern of unplanned downtime and avoid undue expense and delays associated with restarting the planning and treatment process. Each facility should have a contingency plan in the event an IMRT treatment unit undergoes extensive unplanned downtime.
- Depending on the configuration of the treatment planning resources, greater physical space may be required for items such as additional computer workstations, equipment, patient immobilization devices, and personnel.
- The delivery of IMRT will require additional staffing resources, at least in the first three to five years. There has been a noticeable increase in workload due to the growing use of 3-D planning; this trend is expected to continue because of the widespread implementation of IMRT as a standard treatment. Allowances for staff training and development with respect to evolving technologies need to be further explored within the province.
- Current planning projections for the province will need to be monitored and reviewed with respect to the number of patients treated per year, per linear accelerator.
- Resources for treatment management systems should be monitored and reviewed, given the anticipated increases in information storage/retrieval needs with IMRT, as well as other costs associated with target-localization technologies.
- Information systems should reside within the auspices of the medical physics department of the radiation oncology program to manage the support services provided by hospital information systems department. Departmental staff, with expertise in the field, will be needed to provide immediate attention to resolution of any technology-related issues.

***Tools, Devices and Equipment Requirements - Evidence***

Three documents provided guidance on equipment requirements for IMRT, either by tomotherapy or with multileaf collimators (32,38,40). Two reports (32,40) provided information on imaging modalities, stating that CT is used by the majority of IMRT programs. Magnetic resonance imaging (MRI) and positron emission tomography (PET) are also commonly used, and as the authors point out, when MRI or PET are fused with CT, the images provide superior resolution.

The AAPM IMRT subcommittee (32) stated that the following changes in equipment may be necessary to implement IMRT:

- Upgrading existing accelerators, such as adding a multileaf collimator, upgrading an existing collimator to dynamic capability, or purchasing special add-on collimators
- Upgrading existing record and verify systems to accommodate IMRT treatments
- Improvement or enlargement of computer networks
- Additional planning (dosimetry) equipment, including small volume detectors, an efficient film scanning system, and additional phantoms, may be required for quality assurance procedures
- Providing IMRT planning capabilities, either as a stand-alone IMRT planning system or as an add-on IMRT module, to a conventional planning system
- Providing new immobilization techniques to safely use the technology, e.g., supplementing thermoplastic masks with bite block fixation or applying techniques to reduce or follow internal organ motion.

The Canadian Association of Provincial Cancer Agencies (CAPCA), in the quality control standards document for medical linear accelerators (38), reported a progressive trend with the addition of technologically complex accessories to linear accelerators, such as multileaf collimators and electronic portal imaging devices.

With citation to the Health Care Advisory Board, the Trinity Health report recommended that current linear accelerators should be retrofitted with IMRT functionality, if they are relatively new or less than seven years old, the existing 3-D planning system is capable of upgrade, or the

radiation therapy program is able to tolerate installation/retrofitting downtime (40). Purchasing a new system is suggested if the age of the linear accelerator prohibits retrofitting, the replacement of the linear accelerator is already planned, or growing procedure volume warrants an additional linear accelerator. The authors point out that a retrofitted IMRT system can save considerable investment for a facility; however, over time, the system can be less efficient (40).

***Tools, Devices and Equipment Requirements - Summary of the Evidence and Consensus***

Three guidance documents listing tools, devices, and equipment requirements were consistent in the message that upgrading existing equipment was an acceptable option over the outright purchase of new equipment, especially if the existing accelerators are less than seven years of age. CCO has a facility design plan for developing radiation therapy centres. At the treatment planning purchase phase, CCO typically plans for 50% of all treatment planning system workstations to be IMRT capable (personal communication with Lisa Favell[3] and Dianne Belfour[4]). IMRT-capable workstations are more costly, which poses a funding issue; however, IMRT-enabled workstations do not necessarily involve a space issue. They do not occupy any more physical space than any other treatment planning system workstation; however, with greater planning time with IMRT, more workstations may still be required to carry the extra workload. Design considerations include workrooms that are sized for treatment planning computer workstations, planners, and observers; treatment planning proximal to the CT suite (where practical); systems furniture layouts (which are recommended for all planning areas in centres, due to ergonomics needs) that accommodate large monitors and are suitable for one user (and potentially one observer); dimmable task and area lighting; approximately 54 square feet of space per person in planning; and one workstation for each work area.

The Expert Panel concluded that the capital replacement of IMRT-capable machines (linear accelerators with static and/or dynamic multileaf collimator IMRT capabilities or tomotherapy units) as well as all the supporting systems is necessary in all centres. For multileaf collimator delivery of IMRT, the optimal plan is converted into a series of intensity patterns that efficiently deliver the plan with a minimum number of segments, where there are fewer segments with less monitor units, less leaf travel, and less treatment time. The issue of minimizing the total number of monitor units and the delivery time is a rather important one from the perspective of radiation protection and throughput. It is mainly handled by improved IMRT optimization and leaf sequencing algorithms. In addition, with the advent of electronic documentation within departments, the Panel felt that it was essential that the radiation therapy software be kept current and upgraded when recommended. The integrity of the system was considered key, as was having a disaster recovery plan for the retrieval of information. Archived records must be readily available and in a suitable format to provide reference when planning retreatments. The planning and patient records are the most important part of documentation.

***Tools, Devices and Equipment Requirements for an IMRT Program - Standards***

- There must be a means of soft tissue imaging for treatment planning. Computed tomography (CT)-based simulation is a minimum for the implementation of IMRT. However, it must be recognized that multiple imaging modalities may be required in certain cases, including magnetic resonance imaging (MRI) and positron emission tomography (PET) imaging. The treatment team should be adequately trained in regards to the various imaging modalities.
- A treatment planning system equipped and licensed with optimization software is required, which ideally includes multimodality image registration, and is integrated with conventional/traditional capabilities for conformal radiotherapy with dose-calculation algorithms of appropriate accuracy and

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computational efficiency.

- Each facility must have the means to deliver modulated beams (for example, have a linear accelerator equipped with a multileaf collimator). Equipment acquisition and replacement plans should ensure the availability of multiple matched IMRT machines. Resources may be needed to purchase or upgrade linear accelerators with multileaf collimators, IMRT software, and imaging systems.
- A treatment management system with charting integrated with planning and treatment process management, formerly called 'record and verify' , is needed at each facility.
- There must be a means of achieving target/anatomic localization appropriate to the clinical objectives, for example, image-guidance using electronic portal imaging devices, ultrasound, cone beam CT, among others. Other accessories, such as planning (dosimetry) instrumentation, and appropriate immobilization devices are also required.
- Due to the increased time for planning and image segmentation (i.e., contouring), the number of workstations in each treatment facility should be increased according to the workload.
- With the advent of electronic documentation within departments, the maintaining and upgrading of radiation therapy software is essential. The integrity of the system is vital, as is a disaster recovery plan for the retrieval of information. Archived records must be readily available and in a suitable format to provide reference when planning re-treatments. Adequate resources should be set aside to meet the needs of archiving systems, now and in the future.

**Professional Training Requirements – Evidence**

Five documents provided guidance on the professional training requirements related to the provision of IMRT (30,32,35,40,42). Specific training recommendations by specialty are presented in Table 4. In the guidance document developed by the American Society for Therapeutic Radiation and Oncology (ASTRO) and AAPM (30), the authors emphasized that practitioners should not rely solely on the companies selling treatment-planning equipment for IMRT to provide training, but rather, they should learn the complexities of IMRT from multiple sources, including peer-reviewed literature, textbooks, formal course work, and hands-on training (30). They also state that, because IMRT is evolving and dynamic, continuing education will be crucial for maintaining skills (30)

The AAPM IMRT Subcommittee (32) reported that the IMRT process requires changes in practice for all clinic staff, since principles and time requirements vary significantly from conventional therapy. The authors recommend that training include all of the critical steps in the IMRT process and that new users spend a considerable amount of time learning how to apply IMRT correctly to specific body sites (32). They also pointed out that it is important to regard each site as a new commissioning effort, with implications for imaging, immobilization, set up, and verification (32).

Trinity Health reported that vendors often include training as part of the purchase agreement; however, they concluded that this type of training may not be adequate. Instead, they recommend that practitioners, especially physicists and physicians, seek further training or learn through visits to active IMRT programs (40).

**Table 4. Professional training requirements identified in the literature.**

| **Radiation Oncologists** |
|---|
| • Training for radiation oncologist should include (32):<br>  ○ Optimization process and its limitations<br>  ○ Image-guided treatment planning<br>  ○ Treatment planning and delivery uncertainties<br>  ○ Biologically effective equivalent-dose concepts<br>  ○ Clinical experience with conventional radiation therapy<br>  ○ Residency programs and special workshops |
| • Recommend hands-on instruction from an active IMRT program (40) |

- Off-site training can be supplemented with training from internal diagnostic radiologists (40)
- Training should involve diagnostic interpretation skills (40)
- According to the Canadian Association of Radiation Oncologists (42), training should encompass:
  - A high level of understanding of the technical and patient-related components of new technologies and an understanding of how to rationally integrate technology into clinical practice.
  - Detailed knowledge of tumour biology and natural history in order to optimally utilize new technologies that allow precise anatomic targeting. Gross tumour and potential sites of microscopic extension must be defined with the greatest possible accuracy. This implies a high level of understanding of the capabilities and limitations of medical imaging techniques and close collaboration with diagnostic imagers.
  - Complete understanding and knowledge of the treatment-planning process and associated uncertainties to rationally determine target volumes.
  - Familiarity with the purpose and scope, benefit, and regulatory requirements associated with technical quality assurance protocols that are widely accepted in the field.
  - An understanding of computers systems and medical informatics, which are the underpinnings of current and developing targeted-treatment planning and delivery systems

**Physicists**

- According to the IMRT subcommittee (32), training should include:
  - Mathematical principles of dose optimization
  - Computer-controlled delivery systems
  - Dosimetry of small and complex shaped radiation fields
  - Treatment set-up, planning, and delivery uncertainties and their impact on patients
  - Concepts of dose-volume objectives and dose limits for critical structures and target tissues
  - Implications of busy intensity patterns on treatment-delivery accuracy and efficacy
  - The quality assurance process
- Training should include understanding and appropriately responding to discrepancies or problems uncovered by the quality assurance process (35)
- Physicists require multiple days of training, usually a combination of classroom and site visits (40); training topics should include (40):
  - Equipment installation and acceptance, beam data acquisition planning system calibration
  - Beam data acquisition
  - Planning system calibration
  - Developing quality assurance protocols
  - The treatment planning system
  - Technical aspects of the equipment

**Radiation Therapists**

- Radiation Therapists should train with the facility radiation oncologist and physicist who have special training in the use of IMRT (32), and training should include all aspects of the treatment planning system, including (32):
  - Implications of dose-volume objectives on optimized dose distribution
  - Targeting localization techniques
  - Patient set-up technique
  - Process for handling mid-treatment equipment downtime and mechanical issues
  - Implications of treatment set-up, planning, and delivery uncertainties
  - IMRT new treatment procedures
  - Use and storage of specialized IMRT equipment
  - Use of any new immobilization or localization systems
  - Verifying that record and verify programming is correct
  - Response to unplanned events
  - Interruption and restarting of a treatment
  - Recovery from a partial treatment that requires the console to be programmed
  - Recognizing and acting on new error messages and interlocks
  - New procedures related to portal imaging
  - New daily quality assurance tests

- Training should include how to detect equipment deviations or malfunctions, the safe operating limits of the equipment, being able to judge when errors in treatment planning may have occurred due to equipment, patient-related problems, or human mistakes (35)
- According to Trinity Health, training topics should include (40):
  - Targeting localization techniques
  - How to handle mid-treatment equipment downtime
  - Mechanical issues
- There are often vendor training conferences and seminars on IMRT; however, the hands-on experience is often gained through interaction with the physicist (40)

***Professional Training Requirements - Summary of the Evidence and Consensus***

From the five guidance documents, it is clear that comprehensive training for the entire clinical team is a core component of a successful IMRT program. What is less clear is the manner in which practitioners should be trained. Radiation therapists in Canada are trained very differently from those in the United States. It is important to acknowledge that in Ontario, most radiation therapists also perform the roles of treatment planning. Depending on the institutional organization there may or may not be formal distinctions between the two roles. Thus, there will be differences between the recommendations made for American therapists and the actual reality in Canadian practice.

Practitioners should not rely solely on vendor training as part of their training experience. Cancer Care Nova Scotia (47) reported that radiation therapists rated radiation techniques (either new or standard) as very important topics for continuing education. They also indicated that new or improved procedures and/or techniques and new equipment were the most pressing needs. IMRT was the most frequently listed topic, the most preferred educational setting was the place of employment, and the preferred methods were person-to-person education, meetings, and conferences, formal courses, and practice-based workshops (47). There was also a high degree of interest in further formal education, including radiation science degrees and certification. In a related article, a survey of radiation oncologists in the United States found that practitioners learned how to use IMRT primarily from journal articles (72%), colleges (44%), and professional societies (44%) (48).

The IMRT Expert Panel concluded that training and clinical practice should be conducted in accordance with the Canadian Association of Provincial Cancer Agencies (CAPCA) standards, related professional associations, and colleges. Training should be provided during the implementation phase and also as part of continuing education. A coordinated provincial approach is needed to design and conduct IMRT training courses and also to provide a coaching or mentorship program. In the absence of coordinated services, there should be provision to allow providers to travel and attend IMRT educational programs elsewhere. The Panel also felt that a common nomenclature, which clearly defined language or classification schemes for tumour and normal tissue structures, should be developed. The nomenclature, whether developed internally at each centre or on a provincial level, will facilitate communication and minimize errors and redundancy.

While not the scope of this document, the IMRT Expert Panel would like to briefly point out that training is offered by different organizations, societies, and academic centres throughout North America. Organizations such as ASTRO, the European Society for Therapeutic Radiology and Oncology (ESTRO), the Medical Technology Management Institute (MTMI), the University of Texas MD Anderson Cancer Center, the University of Texas Medical Branch (with the support of Siemens and Philips), the University of Arkansas for Medical Sciences, Florida Hospital Advanced Medical Services, and the University of California Los Angles (UCLA) Medical Physics Division all offer IMRT training opportunities. IMRT system vendors such as Philips, Elekta, Varian, D3 Radiation Planning, North American Scientific, and Nucletron also offer IMRT training courses and sessions.

**Professional Training Requirements**

- All suitably certified personnel should undergo IMRT training during the implementation phase and as part of continuing education. A coordinated provincial approach is essential to design and conduct IMRT training courses and provide a coaching or mentorship program. If coordinated services are not available, sufficient funds need to be dedicated to allow providers to travel to and attend IMRT educational programs elsewhere.
- A clearly defined language or classification scheme for tumour and normal tissue structures needs to be developed.
- The following speciality-appropriate training should include, but is not limited to:
  - Radiation Oncologists
    - Interpretation and segmentation (anatomical contouring) of CT and other modality (MRI, PET, ultrasound) images
    - Multimodality image fusion
    - Localization and delineation of the patient's tumour and specification of target volumes with appropriate margin setting following the International Commission on Radiation Units (ICRU) formalism.
    - Contouring of normal structures
    - Defining objectives for the treatment plan in terms of dose prescription for the target volumes
    - Specifying dose constraints for normal tissues and organs at risk
    - Evaluation of IMRT treatment plans
  - Physicists
    - Management of treatment planning and delivery infrastructure
    - Leadership and participation in treatment planning and optimization
    - Leadership in radiation safety and protection
    - Must understand physical characteristics of different modality imaging systems (CT, MRI, PET, ultrasound): image quality specifications, limitations, artifacts, etc.
    - Acceptance testing and commissioning of systems for treatment planning, management of treatment delivery, and imaging used for treatment planning.
    - Acceptance testing and commissioning of radiation treatment machines and associated imaging systems and treatment accessories
    - Design and implementation of the quality assurance program for treatment planning and delivery, including the tests to be performed, tolerances, and frequency of the tests
    - Technical evaluation and dosimetric validation of IMRT treatment plans
    - Direct and assure competence of support staff involved in information systems, accelerator maintenance, and ancillary systems.
  - Radiation Therapists
    - Training on the IMRT program of the treatment planning system, as well as patient data acquisition, radiation treatment design, and computer-assisted calculations of radiation dose distributions.
    - Data transfer between hospital PACS system, CT scanner, treatment planning system, record and verify, and treatment and imaging system
    - Contouring of relevant normal tissue structures e.g. lymph node regions in neck.
    - Identifying technical objectives for the treatment plan in order to meet the dose prescription and normal tissue constraints
    - Generation and documentation of the treatment plan, in consultation with the physicist and radiation oncologist
    - Active involvement in all aspects of the radiation planning and treatment processes, most notably patient positioning and immobilization, simulation or localization, plan verification, imaging, and treatment delivery.
  - All Disciplines
    - Characteristics and implications of organ motion for all sites
    - Design and testing of treatment protocols
    - Quality assurance and risk management

- Radiation protection and safety
- Training in the use of imaging systems (e.g., image acquisition, image fusion for treatment planning and target localization)
- Training in the application of plan optimization software for all disciplines involved in treatment planning
- Appropriate plan evaluation and prescribing practices according to the current guidelines published by the ICRU
- Collaboration on the role of image guidance and appropriate PTV margin design

- Training and clinical practice should be conducted in accordance with the Canadian Association of Provincial Cancer Agencies standards, related professional associations, and colleges.
  - Training in the use of imaging systems (e.g., image acquisition, image fusion, treatment verification)
  - Training in the application of plan optimization software for all disciplines involved in treatment planning
  - Appropriate plan evaluation and prescribing practices according to the current guidelines published by the ICRU
- Training and clinical practice should be conducted in accordance with the Canadian Association of Provincial Cancer Agencies standards, related professional associations, and colleges.

***Quality Assurance and Safety - Evidence***

Quality assurance of the IMRT system was discussed in ten documents (25,27,30,32,33,35-37,41,42). The majority of these documents provided in depth discussions as well as details on particular quality assurance tests and measures. A summary of these steps can be found in Table 5. However, it is important to note that a large body of evidence exists that provides detailed instructions on various procedures for IMRT acceptance testing, commissioning, quality assurance, and safety. Assembling this information and deriving detailed recommendations on specific quality assurance procedures is beyond the scope of this document; therefore, the information discussed in this section is not intended to be exhaustive. The main intent of this section is to highlight the emphasis that the guidance documents placed on the importance of comprehensive commissioning and quality assurance procedures when implementing an IMRT program.

*Commissioning and Testing of the Treatment Planning and Delivery System*

The majority of articles discussing IMRT highlighted the need for comprehensive acceptance and commissioning testing before the implementation of new technology into clinical service. In addition, it was recommended that an exhaustive quality assurance program for linear accelerators should be in place before the start of an IMRT program (25). Four articles provided detailed discussions, along with examples, of commissioning and acceptance-testing procedures (27,30,32,35). The discussion, and subsequent recommendations, from these articles focused on verifying that the equipment meets appropriate specifications, establishing baseline parameters so that future quality assurance procedures may be successfully carried out, and acquiring additional measurement data.

The joint report by ASTRO and AAPM (30) recommends that centres implementing combined IMRT systems (treatment planning–treatment delivery) treat each combination as a separate capability during the commissioning and acceptance-testing stage. The authors further suggest that new techniques should only be implemented when the treatment team is fully competent with the recently installed capabilities and all commissioning procedures have been completed. When verifying the performance of the entire system, the report encourages the development of tailored tests for specific procedures as well as the use of manufacturer's tests, relevant AAPM Task Group reports, and treatment protocols, such as protocols from the Radiation Therapy Oncology Group (30).

*Patient-specific Validation of Treatment Plans*

Although at present there is no standard set of procedures for performing patient-specific quality assurance, the complexity of the involved inverse planning algorithms, the linear accelerator and the multileaf collimator hardware and software control systems, and the computer networks that connect them, necessitates thorough patient quality assurance procedures. As in all radiation oncology, the main intent of these quality assurance procedures for IMRT treatment is to ensure that the delivered dose distribution agrees with that produced by the treatment-planning computer and prescribed for treatment. (25,27,30). However, in the case of IMRT, this process is especially critical because treatment fields vary more significantly depending on the specifics of disease, target volume, location and shape, individual patient anatomy, field arrangements, and dose prescription; therefore each field for every IMRT patient must be verified before the start of actual treatment (25,30).

The AAPM IMRT Subcommittee (32) suggests separating this part of the quality assurance process into three sequential steps, 1) verification of calculation of the dose and monitor units, 2) correctness check of information transfer from the planning system to the record and verify system, and then to the delivery system, and 3) dose delivery verification. Each step of this process will require detailed verification measures in order to reduce the potential for error. Some of these measures have been described in the literature and may include a phantom plan approach combined with film or another means of 2-D or 3-D dosimetry, independent monitor unit calculations, analysis of leaf positions as recorded by the multileaf collimator controller, or verification of absolute dose measurements at specific points (25,27,30,32,33,35-37). Each of these methods has its own strengths and limitations, and its specific implementation will vary across the centres, depending on the available equipment, level of training and personnel available. Currently, implementing and performing patient-specific quality assurance measures is time consuming and resource intensive; however, recent advances in technology, such as the use of electronic portal imaging devices for IMRT dosimetry, may result in a more streamlined quality assurance process (25).

*Ongoing Quality Assurance*

The success of a comprehensive quality assurance program is critically dependent on a well-trained staff, an interactive and continuous review, monitoring, and an efficient quality improvement system, especially in the early stages of implementation (42). Hulick and Ascoli (27) recommended that the ACR communication guidelines (39) be followed to ensure that regular interaction between members of the IMRT team is part of the quality assurance program. The authors also endorse the ACR guideline recommendations for a yearly quality assurance review, in addition to a quality management program report that is presented to the radiation safety committee chair or medical director on an annual basis. At a minimum, the recommendations suggest that the chief radiation therapist, the medical physicist, and the radiation oncologist meet on a quarterly basis to discuss quality assurance (27). Similarly, the CAPCA Quality Control Standards report (38) suggests that at each centre the supervising physicist should maintain direct communication with the Quality Assurance Committee for the Radiation Treatment Program. It should be noted that, while the ACR communication guidelines (39) and the CAPCA Quality Control Standards (38) are not specific to IMRT, they nonetheless provide relevant radiation treatment recommendations that can be adapted for treatment with IMRT.

In addition to periodic (daily, weekly, monthly, and yearly) testing, it is recommended that a system log be created to monitor and record system malfunctions, error messages, and all corrective actions taken, as well as system hardware and software changes (33). In addition, emphasis is placed on the importance of peer review and on regular discussions with the treatment team, focusing on issues such as deviations and unplanned results, as well as on peer review (39). While quality assurance is prudent and should be performed frequently at first,

once the personnel gain more experience and become more efficient, past experience shows that some of the quality assurance procedures can be relaxed (33,37,42).

**Table 5. Quality assurance and safety aspects.**

Quality assurance and safety should include the following aspects (25,27,28,30,32,33,35-37):

*Commissioning and testing of the treatment planning and delivery systems*

- Validation of dose calculation algorithms used by the treatment planning system
- Evaluation of the effects of input parameters on the optimized dose distribution
- Evaluation of the accuracy of tissue heterogeneity corrections
- Verification of the modeling accuracy of output (scatter) factors and percentage depth doses for small fields on and off central axis of the radiation beam
- Verification of the dosimetric accuracy of penumbra modeling
- Verification of the calibration for radiation field offset
- Verification of the accuracy of modelling of leakage and transmission through the collimator (inter- and intra-leaf, between opposing leaf ends
- Validation of the leaf sequencing algorithm
- Additional checks specific to tomotherapy
- Check of System Data Input devices for functionality and accuracy
- Check of System Output devices for functionality and accuracy
- Verification of the dosimetric accuracy and dose linearity at low monitor unit settings
- Commissioning of the multileaf collimator: verification of physical limitations of multileaf collimator positioning and motion, calibration of leaf position, measurements of output factors for different field sizes and shapes, measurements of leakage and transmission
- Additional tests for dynamic multileaf collimator IMRT delivery: measurements of test intensity patterns
- Geometric accuracy and precision of the treatment couch and immobilization devices
- Evaluation of dosimetric properties (e.g., attenuation, surface dose enhancement) of the couch and immobilization devices
- Tests specific to tomotherapy (e.g. couch positioning, motion and synchronization with the radiation delivery system)
- Record and verify systems: tests of data transfer for IMRT plans and the associated treatment machine parameters, establishment of appropriate tolerances
- The quality assurance process should be tested using the clinical mode since it provides a system check, including data transfer between the treatment planning system, record and verify systems software, linear accelerator, and multileaf collimator controller. The service mode, or any other non-clinical mode of the linear accelerator, should not be used for quality assurance measurements
- Commissioning of image guidance systems used in conjunction with IMRT
- Evaluation and documentation of beam leakage and secondary scatter

*Patient-specific Verification*

- Review of appropriateness of delineation of and margins applied to the target and structures of interest
- Verification that the optimized dose distribution meets the appropriate objectives and constraints
- Verification of the monitor unit settings through an independent calculation or a measurement
- Verification of the correctness of data transfer from the treatment planning system to the record and verify system
- Verification of intensity patterns and/or dose distributions produced by all the IMRT beams
- Confirmation of planned leaf motions and verification (using the record and verify system) of initial and final positions of the multi-leaf collimator for each field
- Verification of isocentre placement before start of treatment through portal imaging or an alternative form of image guidance
- Verification of delivered dose at selected points through in vivo dosimetry

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| • Periodic treatment chart review to confirm correctness of daily treatment delivery<br>• Routine verification of treatment set-up accuracy through portal imaging or an alternative form of image guidance, at intervals prescribed by institutional or external (e.g., RTOG) protocols<br>• Individual facilities will need to balance patient-specific tests with standardized multileaf collimator and linear accelerator performance tests |
| *Ongoing Quality Assurance Programs*<br>• Periodic quality assurance testing of treatment planning and delivery systems (including imaging systems used for treatment planning)<br>• Quarterly quality assurance meetings between the chief radiation therapist, medical physicist, and radiation oncologists<br>• Yearly quality assurance review and a yearly quality management program report to be reported to the radiation safety committee chair or medical director<br>• Discussions of unintended deviations or misadministrations, results of patient treatment chart audits, peer review analysis, internal focus studies, and outcome studies are recommended by the ACR<br>• As experience is gained some of the quality assurance procedures (e.g., film dosimetry, in vivo dosimetry) may be relaxed<br>• An ongoing system log should be maintained to record system components failures, error messages, corrective actions, and system hardware/software changes<br>• Policies and procedures related to quality, improvement, patient education, and safety should be developed and implemented<br>• The lead radiation oncologist is responsible for the institution and ongoing supervision of the Continuing Quality Improvement program as described in the ACR guidelines. Holds the responsibility for identifying problems, ensuring that actions are taken, and evaluating the effectiveness of the actions<br>• The head supervising physicist should maintain direct communication with the Quality Assurance Committee for the Radiation Treatment Program<br>• Proper recovery of treatment interruptions (e.g., machine failure) should be tested, and a written procedure addressing this problem must be implemented |

***Quality Assurance and Safety - Summary of the Evidence and Consensus***

In radiation therapy, the technical components of the equipment used, the various software and hardware systems, and the flexibility in defining target volumes and dose requirements necessitate a comprehensive quality assurance program. The safe and accurate delivery of IMRT necessitates a well-thought-out quality assurance program, with appropriate equipment and qualified personnel.

The commissioning of a planning and delivery IMRT system, as well as patient-specific treatment plan verification, can vary across centres due to the numerous combinations of inverse planning approaches and dose delivery methods. Although commissioning guidelines and treatment verification methods have been reported, exact implementation tests will vary between cancer centres. It is crucial that each centre develop a comprehensive quality assurance program. In order to ease the implementation and learning process, it may be beneficial for centres using similar equipment to work together to overcome challenges and share quality assurance methodologies. Furthermore, centres need to ensure that ongoing system reliability checks are in place, including daily, weekly, monthly, and yearly quality assurance tests. Each centre, when verifying the performance of the entire system, needs to develop tailored tests for specific procedures, and, as the literature suggests, should also utilize manufacturer's tests, relevant AAPM Task Group reports, and treatment protocols. The Panel also suggests consulting various books written on IMRT[5-6] for additional information. Finally,

[5] Bortfeld T, Schmidt-Ullrich R, De Neve W, Wazer DE, editors. Image-guided IMRT. Berlin: Springer-Verlag ; 2006.

[5] Palta JR, Mackie TR. Intensity modulated radiation therapy: the state of the art. AAPM Summerschool Proceeding; 2003).

implementing proper monitoring, reporting, and documentation procedures is crucial and centres should establish forums for regular peer-review and discussion sessions.

***Quality Assurance and Safety - Standards***

- There is an essential practical need to document and validate disease-specific planning and treatment procedures because, when a uniform and stable procedure is established, it greatly reduces the expense and resources associated with individualized patient measurements. A comprehensive quality assurance program for IMRT includes testing at three distinct phases of the planning and delivery process.
  - Commissioning and Testing of the Treatment Planning and Delivery Systems
    - Because the treatment planning process (patient positioning and localization, imaging, definition of the anatomy establishment of beam geometry, dose calculation, dose display, and plan evaluation and implementation) involves numerous uncertainties, a thorough quality assurance program must be implemented to ensure that the delivered dose distribution agrees with that produced by the treatment-planning computer.
    - A well-thought-out quality assurance program dictates that staff members have access to extensive training on the appropriate equipment (e.g., treatment units, imaging equipment, computerized treatment planning systems, computerized data acquisition systems, quality assurance equipment).
    - To verify ongoing system reliability, it is necessary to test the normal operations of the delivery system on a daily, monthly, and annual basis. This would include periodic testing of the treatment planning system, the record and verify software, treatment units, CT data input, and other systems.
    - Peer review of IMRT plans (chart rounds) should be completed prior to the start of treatment or before a significant amount of dose has been delivered to the patient.
  - Patient-Specific Validation of Treatment Plans and Positioning
    - Patient-specific quality assurance is essential to ensure accurate and safe treatment. The process should begin with individual dosimetric validation through measurement (in phantom) and potentially shift to an independent calculation for each patient as the disease-specific procedures mature.
    - IMRT fields vary due to the patient's disease, target location, planning target volume, anatomy, field arrangements, and dose prescription; therefore, each field for every IMRT plan must be verified independently before the start of actual treatment.
  - Due to the complexity of treatment, potential for dose escalation, and conformity resulting in tight margins, treatment guidance and verification using online imaging should be performed regularly, and in most cases daily, prior to treatment.
  - Consequent dose implications need to be accounted for in the treatment plan, where appropriate. In vivo dosimetry (IVD) should be performed in the initial period of building up confidence in the IMRT system and whenever critical structures are in close vicinity of the treated volume.
  - Ongoing Quality Assurance
    - The quality assurance system needs to include ongoing equipment testing and verification of the IMRT treatment system reliability, but most importantly, it must persistently ensure that the precise IMRT treatment plan is delivered.
    - An ongoing process for quality improvement and to collect and record incident reports related to IMRT treatment should be implemented at each centre and reviewed frequently in order to make appropriate modifications that will improve treatment and increase patient safety. Incidents should be reported to CCO according to reporting requirements.
    - An annual quality management program report should be submitted to the radiation safety committee chair or medical director.
    - Regular discussion, review, and training sessions, as well as external validation of an IMRT program (e.g., which can be attained by engagement in credentialing with national and international clinical trials groups) are essential parts of the continuing quality improvement program.

[6] Memorial Sloan Kettering Cancer Center: A practical guide to intensity modulated radiation therapy. 2003.

## DISCUSSION

Since the organization of IMRT programs does not lend well to structured investigation, there was little definitive evidence, other than expert consensus opinion, with which to inform the IMRT standards. To make the process as rigorous as possible, the IMRT Expert Panel adopted an evidence-based approach whereby the literature was systematically searched and the identified evidence was synthesized through the systematic review process. The standards were then written based on the best available evidence, in combination with the expert consensus opinion of the Panel. In addition, external health care practitioners and administrators in Ontario were given the opportunity to provide feedback on a penultimate draft of the document; their comments and suggestions were then incorporated into the final document.

The twenty-two guidance documents identified through a systematic search of the literature were primarily consensus-based; however, they were instrumental in helping to inform the standards around the implementation of IMRT in Ontario. It was very important that the conclusions derived by the Expert Panel were consistent with the conclusions derived by that of the other content experts or organizations identified in the literature. The strength of the standards process is not only that they rely on the best available evidence and expert consensus opinion but also, more importantly, they reflect an ideal where the primary consideration is for the patient's health and well-being. In order to implement a set of standards, especially with limited high-quality evidence, there must be no doubt that the benefits of standards implementation far outweigh any potential harms.

## CONCLUSION

IMRT is an exciting mature technology that can now be used to reliably treat tumours in any area of the body, including irregularly shaped growths that may have wrapped themselves around healthy tissues. By minimizing the impact on surrounding tissue, IMRT can deliver higher and more effective doses to the targeted tumour, allowing for greater cancer control, reducing toxicity, and improving the patients overall quality of life. IMRT provides a method for handling many treatment-planning problems that were previously unmanageable or that required complex solutions with poor outcomes. For these reasons, interest and activity around the development of IMRT programs continue to grow at a fast rate. In fact, as concluded at the 2007 CCO Radiation Treatment Symposium, this is an area in which the province must move quickly over the next year. Organizational and professional standards for the optimal delivery of IMRT coupled with swift implementation strategies are necessary to accommodate the long-range needs of the province. While a detailed analysis of the human resources and technological costs associated with IMRT implementation are beyond the scope of this document, the implementation of IMRT programs should result in significantly improved patient outcomes and greater organization of care.

In this document, the IMRT Expert Panel offers organizational standards for the delivery of IMRT in Ontario. The intent is to usher in the next phase of enhanced patient care, where all the resources available in our jurisdiction will be used to make IMRT widely available.

## CONFLICT OF INTEREST

No conflicts of interest were declared, however it may well be that the standard definition of conflict does not readily apply in this context. While the individual authors may not have any direct interest in the establishment of IMRT programs in Ontario, it is acknowledged and duly declared that funding derived from IMRT vendors or the possible benefit to centres that provide training for IMRT could be construed as possible conflict in this scenario.

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**Evidence-Based Series #21-1: Section 3**

# Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario: EBS Development Methods and External Review Process

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Developed by the Expert Panel on Intensity Modulated Radiation Therapy

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## THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO) (1). The PEBC mandate is to improve the lives of Ontarians affected by cancer, through the development, dissemination, implementation, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs) and Guideline Development Groups (GDGs), as well as other groups called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other health care providers and decision makers, methodologists, and community representatives from across the province.

The PEBC is well known for producing evidence-based practice guideline reports, using the methods of the Practice Guidelines Development Cycle (1,2). The PEBC reports consist of a comprehensive review of the evidence base for a specific cancer care topic, an interpretation of and consensus agreement on that evidence by the groups or panels, the resulting clinical or organizational recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant.

### The Evidence-based Series

Each Evidence-based Series (EBS) is comprised of three sections:

- ***Section 1: Recommendations.*** This section contains the standards or recommendations derived from the review of the literature and its interpretation by the panel involved and a formalized external review by Ontario practitioners and key stakeholders.

- ***Section 2: Evidentiary Base.*** This section presents the comprehensive review of the clinical and other evidence on the topic and the conclusions reached by the Panel.

- ***Section 3: EBS Development Methods and External Review Process.*** This section summarizes the evidence-based series report development process and the results of the formal external review by Ontario practitioners and key stakeholders of the draft version of the report.

## DEVELOPMENT OF THIS EVIDENCE-BASED SERIES

This Standards Report was developed by the IMRT Expert Panel, a collaboration of CCO's PEBC and the Radiation Treatment Program. The standards were written in accordance with a methodology adapted from the PEBC practice guideline development process and reporting format (1,2). The report was designed to address professional and organizational standards around the delivery of IMRT in Ontario. A systematic review of the published literature and an environmental scan of unpublished documents from various organizations, pertaining to IMRT comprise the evidence base.

Evidence was reviewed by members of the IMRT Expert Panel, which included representation from radiation oncology, radiation therapy, medical physics, nursing, and the CCO Radiation Treatment Program, Capital Projects Office, and PEBC (Section 2. Appendix I). The Panel met through teleconference and in-person meetings and used e-mail as the main vehicle of communication. Differences were resolved through consensus and the use of evidence that informs the standards document.

### Report Approval Panel

Prior to the submission of an evidence-based series (EBS) for external review, drafts are reviewed by at least one member of the PEBC Report Approval Panel with expertise in clinical and methodology issues. The Report Approval Panel approved the series as written but requested the following clarification: As an organizational guidance document, it was questioned whether there was actual evidence to support that IMRT results in better patient outcomes than standard radiotherapeutic technique. It appears in the Section 2 Introduction that the benefits of IMRT are theoretical and not proven. It was requested that further information, supporting the benefits, or alternatively a rationale for why a technology is being promoted before its clinical effectiveness has been confirmed, be added.

In response to the RAP, the Expert Panel on IMRT clarified the Introduction, stating the following: There is a growing body of clinical evidence that the improved normal tissue sparing with IMRT leads to noticeable improvements in the quality of life of patients and the increased doses of radiation to the tumour made possible by IMRT are expected to lead to higher cure rates. Additional references were added (*Section 2 References #9-#18*) to the introduction to show that the benefits of IMRT are established in the literature.

## EXTERNAL REVIEW

### Survey Results

The organizational standards for the delivery of IMRT in Ontario were distributed to 182 Ontario stakeholders: 146 clinicians and related experts in the field of radiation and 36 regional vice presidents of cancer programs, senior administrators, and Local Health Integration Networks (LHIN) leaders. Responses were received from 73 and 19 participants in each group, respectively (overall return rate 50%).

As seen in Table 1, feedback across the clinicians and related experts was consistently supportive of the standards drafted. The majority of stakeholders agreed or strongly agreed that there was the need for standards for the delivery of IMRT (96%), that the standards reflected

their understanding of the evidence on the topic (90%), most agreed with the standards as drafted (82%), and most would be comfortable if patients received the care recommended in the standards (90%). Overall, 81% of respondents agreed that the standards should be formally approved.

The senior administrators were also very supportive of the standards (Table 2). The majority of respondents agreed that there was the need for standards for the delivery of IMRT (100%), that the standards were clear (88%), and that the implementation of the standards would lead to quality improvements in patient care (88%) and in the cancer system (77%).

**Table 1. External Consultancy Results - Clinicians and Related Experts.**

| Survey Item | Clinicians 146 invited participants 73 returned and completed forms | | |
|---|---|---|---|
| | **Strongly agree or agree** | **Neither agree nor disagree** | **Strongly disagree or disagree** |
| There is a need for a standards document on this topic. | 70 (96%) | 2 (3%) | 1 (1%) |
| The evidence (literature search and environmental scan) is relevant and complete (e.g., no key information sources or studies missed nor any included that should not have been). | 57 (78%) | 13 (18%) | 2 (4%) |
| I agree with the methodology used to summarize the evidence. | 64 (88%) | 8 (11%) | 1 (1%) |
| The draft standards are in agreement with my understanding of the evidence. | 65 (90%) | 7 (10%) | 0 (0%) |
| The draft standards in this report are clear. | 61 (84%) | 9 (12%) | 3 (4%) |
| I agree with the draft standards as stated. | 59 (82%) | 11 (15%) | 2 (3%) |
| The draft standards are suitable for the Ontario context. | 56 (77%) | 12 (16%) | 5 (7%) |
| The draft standards are too rigid to apply in the Ontario context. | 9 (13%) | 20 (28%) | 42 (59%) |
| When applied, the draft standards will produce more benefits for patients than harms. | 61 (85%) | 10 (14%) | 1 (1%) |
| The draft standards report presents a series of options that can be implemented. | 49 (68%) | 19 (26%) | 4 (6%) |
| To apply the draft standards will require reorganization of services/care in my practice setting. | 34 (48%) | 14 (20%) | 23 (32%) |
| The standards will be associated with more appropriate utilization of health care resources. | 39 (53%) | 31 (43%) | 3 (4%) |
| The draft standards in this report are achievable. | 56 (77%) | 15 (21%) | 2 (3%) |
| The draft report presents standards that are likely to be supported by a majority of my colleagues. | 60 (82%) | 12 (16%) | 1 (1%) |
| The draft standards reflect a more desirable system for improving the quality of patient care than current practice. | 53 (74%) | 16 (22%) | 3 (4%) |
| I would feel comfortable if patients received the care recommended in these draft standards. | 66 (90%) | 6 (8%) | 1 (1%) |
| These draft standards should be formally approved. | 59 (81%) | 11 (15%) | 3 (4%) |
| | **Very likely or likely** | **Unsure** | **Not at all likely or unlikely** |
| If these draft standards were to be approved and endorsed, how likely would you be to apply the recommendations to the clinical care or organizational and/or administrative decisions for which you are professionally responsible? | 50 (72%) | 14 (20%) | 6 (9%) |

* Numbers may not total 100% due to rounding

**Table 2. External Consultancy Results – Senior Administrators**

| Survey Item | Senior Administration 36 invited participants 19 returned and 17 completed forms | | |
|---|---|---|---|
| | Strongly agree or agree | Neither agree nor disagree | Strongly disagree or disagree |
| There is a need for standards on this issue. | 17 (100%) | 0 (0%) | 0 (0%) |
| The standards are clear. | 15 (88%) | 1 (6%) | 1 (6%) |
| The standards will be challenging to implement in my institution or region. | 10 (59%) | 2 (12%) | 5 (29%) |
| The standards will be supported by stakeholders in my institution or region | 15 (88%) | 2 (12%) | 0 (0%) |
| The draft standards reflect an effective approach that will lead to quality improvements in patient care | 15 (88%) | 1 (6%) | 1 (6%) |
| The standards reflect an effective approach that will lead to quality improvements in the cancer system. | 13 (77%) | 3 (18%) | 1 (6%) |

* Numbers may not total 100% due to rounding

**Written Comments**

Survey respondents were encouraged to provide written comments and revisions were made throughout the document in response to that feedback. Overall, the written feedback was consistently supportive and constructive across the majority of stakeholders who responded to the survey. Positive comments centered on the clarity, quality, and comprehensiveness of the report, as well as the usefulness of the standards for the implementation of IMRT programs. Some stated that they already followed most of the recommendations outlined in the standards document. A small number of negative comments focused on the length and layout of the report and the lack of high quality evidence to support the standards. Some practitioners felt that the standards were either too vague or not directive enough to set strong standards of care. While it is true that there is currently insufficient high-level evidence to warrant definitive step-by-step recommendations for practice, the reality is also that each jurisdiction will need to develop an IMRT program based upon their unique circumstances (e.g., geography, resources, demand for service).

Due to the large volume of written comments from the clinicians and other related experts, the comments were broken down into the following major themes: resources/funding; implementation; training; staffing roles, common nomenclature; staffing complement; imaging issues; treatment/planning time; professional training requirements; quality assurance; referencing/reporting; and other miscellaneous comments. The comments made by the senior administrators are addressed separately below.

***Written Comments from Clinicians and Related Experts***

*Resources/Funding*

Concerns were raised around IMRT funding and resources. A number of respondents questioned who would be responsible for funding the IMRT initiative, and as one respondent pointed out, implementation "will need financial and human resources which hopefully will be organized and provided provincially in order to provide fair and equitable treatment to all people in Ontario (not just GTA)." Respondents raised concerns about the various costs associated with IMRT implementation. Respondents also commented that implementing IMRT may negatively impact wait times; staffing resources (e.g., physicists, therapists, oncologists) may not be readily available; and other program priorities (e.g., brachytherapy) may suffer should operational dollars need to be utilized for IMRT start-up.

The IMRT Expert Panel acknowledges that the province-wide implementation of IMRT will require investment in organizational, technological, and human infrastructure. CCO's Radiation Treatment Program has submitted a budget proposal, encompassing the organizational recommendations put forth in this document, to the Ministry of Health and Long-Term Care. The requested budget takes into consideration various aspects necessary for IMRT implementation (e.g., human resources funding, training needs, development of coaching teams, educational tools). Plans for changes to the existing funding model, based on course complexity, are also being developed in order to facilitate the implementation of IMRT. It is important to remember that IMRT will provide patients with improved care, reduced toxicity, and better quality of life, and the challenge for the radiation community is to ensure that it does not adversely impact wait times. In addition, as the literature in this document demonstrates, once experience is gained in IMRT, the treatment process becomes much more efficient.

*Implementation*

Some respondents felt that there was insufficient evidence on the topic to warrant the province-wide implementation of IMRT. It was suggested that the document should be revised to be a guideline, especially since a number of centres have already began implementing IMRT and may not have followed the process outlined in this document. Respondents also wondered who would oversee that IMRT is appropriately utilized, that both short and long-term side effects are properly managed, and that cost evaluations are undertaken.

The benefits of IMRT have been discussed extensively in the literature, and treatment with IMRT has now been accepted as the standard of care. IMRT is increasingly integrated into clinical trials as the standard treatment approach, validating the fact that IMRT is now part of mainstream care. For these reasons, the IMRT Expert Panel felt that the level of evidence for developing a standards document was appropriate. The Panel recognizes the importance of disease-specific treatment guidelines for IMRT and will be collaborating further with the PEBC in their development. The standards document will also be updated as additional data become available. However, the notion of delaying the implementation of IMRT until treatment guidelines, clinical trials, or reports on long-term effects are published may unnecessarily deprive patients' access to a proven and effective treatment. In addition, prolonging the province-wide implementation of IMRT may result in workloads that are not sustainable for the limited number of centres that are currently offering IMRT.

*Training*

The need for accessible, formal, consistent, and comprehensive training, perhaps coordinated at the provincial level at a designated facility, was a theme consistently expressed by the respondents. Some commented that, in their experience, site visits or vendor training were not sufficient for training purposes; the evidence presented in Section 2 of this document also support this observation. Expert panels or forums and online training opportunities were also suggested since, as one respondent stated, "there is no point in re-inventing the wheel at each centre." Training was seen to be associated with an increased workload, and one suggestion was to train larger groups rather than smaller specialist groups to facilitate quicker uptake for gains in plan quality, efficient process development, and critical assessment of IMRT practice. The IMRT Expert Panel agreed that a provincially coordinated approach is ideal, and CCO's Radiation Treatment Program continues to advocate for such a system. To address these training needs, plans for IMRT courses, symposia, educational tool kits, and coaching teams are currently being developed at the provincial level.

*Staffing Roles*

The distinction between radiation therapists and dosimetrists was not clear in the draft document, and several practitioners commented that the standards should also address

computer/electronics personnel as part of the staffing complement. Although radiation therapists and dosimetrists perform different roles, it is important to acknowledge that in Ontario most radiation therapists also perform the role of treatment planner. In some centres there may or may not be formal distinctions between the two roles. Thus, for the purposes of this report, the IMRT Expert Panel chose to combine the roles and responsibilities of the radiation therapists and dosimetrists under one heading to reflect practice in most Ontario centres. The role of computer/electronics personnel was not addressed in the original version of the document, but a section on their role was added in response to the feedback from practitioners.

*Common Nomenclature*

The need for common nomenclature was identified as important to practitioners. Specific requests for consistent language across centres and a common definition of IMRT especially in regard to forward versus inverse planning were suggested. In response the IMRT Expert Panel agrees the need for common terminology needs to be developed. A statement has been added to the document.

*Imaging*

It was suggested that imaging and imaging equipment be emphasized more strongly in the standards as they pertain to the acquisition of equipment, training, and quality assurance. Additional emphasis on organ motion and patient motion was also requested. The IMRT Expert Panel acknowledges that imaging is an important aspect of IMRT and additions were made to the document where appropriate. Furthermore, stronger emphasis on imaging modalities, organ motion, and patient motion will be possible in the disease-specific technical recommendation for IMRT.

*Treatment/Planning Time*

Several practitioners commented that more emphasis was needed on the treatment/planning time required for IMRT. The suggested 500 treatment plans per planner was seen as appropriate if it were the sole responsibility of a planner who is also at a high level of comfort with treatment planning. There was also some confusion over the concept of the 50% capable strategy. In response, the IMRT Expert Panel clarified that overall treatment time may be increased with more demand placed upon resources; however, as experience/confidence is gained, and class solutions are developed, treatment efficiencies will improve. The sentence regarding the 50% treatment strategy was removed, and the number of treatment plans per planner was also removed.

*Professional Training Requirements*

A number of minor additions were suggested to the section on professional training requirements. These suggestions were mainly related to imaging, contouring, organ motion, and data transfer; changes were made to the document where applicable. It should be noted that due to the variation in professional roles or in staff availability, training requirements and expectations might vary from centre to centre.

*Quality Assurance*

A number of comments were raised in regard to quality assurance procedures, particularly around patient specific quality assurance (QA) measures, and where applicable changes were made to the document. A robust QA program should already be in place at each centre; therefore, implementing IMRT should augment the current QA program.

*Referencing/Reporting*

Several practitioners commented on the referencing/reporting of the standards, with suggestions for additional sources or specific details asked for within the document. Revisions were made to the draft standards to improve clarity; however, additional references were not added, because suggested references were outside the scope of the original literature search strategy (i.e., books were not searched and the literature search was not updated; however, the references were added as footnotes).

*Other*

Other comments focused on adding information related to the possibility of increased late effects with IMRT, the effect of increased monitor units, and the energy usage for IMRT. The IMRT Expert Panel believes that if the implementation of an IMRT program is done appropriately with the required human and organizational infrastructure in place, then the standard of care will be raised for patients across the province.

***Written Comments from Senior Administrators***

*Barriers to the Diffusion and Implementation of the Standards*

The commonly cited barriers identified by the administrators included the human, organizational, and financial resources required for the increased training and organizational demands involved in implementing an IMRT program. There was also concern over the impact that the new technology might have upon existing resources and patient care models. It was commented that there was no business plan presented to support the equipment and infrastructure changes, and current funding models do not account for increased costs associated with the complexity of treatment nor are they adequate for smaller volume sites. Some thought that a common definition of IMRT was needed as not all program leaders share the same definition, and others felt that if the appropriate resources were not in place to do IMRT well or safely, then centres should not be providing that service. Some administrators felt that there was inadequate detail to guide implementation, especially around staffing and educational requirements, while others commented that the required QA processes appeared to be quite extensive and may delay implementation. One administrator questioned the evidence base to support the leap from selected disease sites to a maximum number of disease sites being treated with IMRT. On a related note, continuing to meet increasing patient demand and productivity during IMRT implementation was seen as a barrier.

*Enablers to the Diffusion and Implementation of the Standards*

Enablers for the diffusion and implementation of the IMRT standards were seen as the motivation and interest of managers, clinicians, and scientists in IMRT and the Radiation Treatment Program, along with the overall desire for high-quality radiotherapy that will maximize benefits to patients and minimize the harms of radiotherapy. The appropriate funding, training, picture archiving and planning systems, infrastructure, and development of communities of practice were mentioned as further enablers of IMRT implementation.

*Issues Bearing on the Acceptance of the Standards*

While many respondents did not feel that there were any specific issues that would bear on the acceptance of the standards, other administrators commented that IMRT implementation would present a series of challenges in terms of the extent of funding, staffing, expertise, and capacity needed to deliver IMRT, especially at a newer centre or one that is a smaller volume site. The difficulty in retaining a highly skilled workforce and meeting wait times were also identified as issues.

## Comments

General comments from the administrators ranged from concerns over the report being too vague for an administrator to grasp its significance, including what exactly IMRT is and involves, to being too prescriptive, considering that IMRT is still an evolving technology. Some questioned what the responsibility is of CCO to evaluate and contribute to the further evaluation of this evolving technology. Others commented that centres to be considered for IMRT should be good performers relative to wait times (e.g., consult to planning, planning and treatment times). This was of particular importance given that wait times were likely to increase due to increases in planning complexity. One administrator was concerned with the sustainability of providing IMRT, with the perceived disconnect in evidence from providing only selected disease sites with IMRT to that of IMRT being available to patients for the maximum number of disease sites possible.

Overall, the comments received from the senior administrators were similar in nature to the concerns raised by the clinicians and other related experts. The main difference was a stronger focus on funding and resource-related issues. The responses and editorial changes offered by the IMRT Expert Panel for this section are similar to those stated above.

## Conclusion

This report reflects the integration of feedback obtained through the external review process, with final approval given by the IMRT Expert Panel and the Report Approval Panel of the PEBC. Updates of the report will be conducted as new evidence informing the question of interest emerges.

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