Quality & Safety in Radiation Therapy Education Course

putting innovation to work

May 20-21, 2015, Toronto, Canada
Welcome to QSRT

In a field that is constantly evolving and pushing technological boundaries, the importance of considering quality and safety alongside innovation in radiotherapy is paramount to the delivery of high quality care. Recent attention in the media to quality and safety issues in our field has spurred efforts of those involved in radiation medicine to embrace the principles of quality and safety engineering and gain experience with the many tools it offers. The Radiation Medicine Program at Princess Margaret Hospital and the Department of Radiation Oncology at the University of Toronto have embarked on a journey of discovery, escalating implementation, research and education efforts in quality and safety. More importantly, our program has developed frameworks to integrate these principles into our routine clinical practice.

In the Radiation Medicine Program, we believe strongly that sharing what we are learning is an excellent opportunity to expand our perspectives and add richness to our work. As such, on behalf of the Program Committee and our enthusiastic interprofessional faculty, I am delighted to welcome you to our Quality & Safety in Radiation Therapy (QSRT) Education Course. Our goal is to engage you in an exploration of the theory and tools thought valuable in implementing and maintaining a quality program and culture in your environment.

We look forward to the opportunity to learn together and to share our individual experiences and lessons in quality initiatives.

Jean-Pierre Bissonnette PhD

“Nothing is particularly hard if you divide it into small jobs.”
-Henry Ford
Contributors

Planning Committee

Jean-Pierre Bissonnette
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Accreditation

Canadian Association of Medical Radiation Technologists:
11.25 Category A Credits

Medical Dosimetrist Certification Board: 10.5 Credits Pending

Royal College of Physicians & Surgeons of Canada: 14 Section 1 Credits
Wednesday, May 20, 2015

9:00 – 9:30  Breakfast & Registration  1B Red Room

Session 1: A Foundation for Quality

9:30 – 9:35  Welcome  
David Jaffray PhD

9:35 – 9:55  Course Overview and Participant Introductions  
Jean-Pierre Bissonnette PhD

Michael Sharpe PhD

10:25 – 10:30  Discussion

10:30 – 10:45  Break

10:45 – 11:45  Human Factors Engineering  
Tracey Herlihey PhD, Ashleigh Shier MHSc

11:45 – 11:55  Discussion

12:00 – 1:00  Lunch

1:00 – 1:30  RT Quality and Patient Outcomes  
Brian O’Sullivan

1:30 – 1:40  Discussion

1:40 – 2:10  Understanding your Activities: Process Chart Thinking  
Stephen Breen PhD

2:10 – 2:50  Activity: Building a Process Chart  
Michelle Lau MRT(T), Lyndon Morley MRT(T)

2:50 – 3:05  Break

Session 2: Appreciation of a System

3:05 – 3:55  Organizational Culture Group Activity  
Jean-Pierre Bissonnette PhD

Stephen Breen PhD

4:25 – 5:20  Workshop – Case Study  
Stephen Breen PhD

5:20  Wrap Up
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<td>Breakfast and Sign In</td>
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<td>9:00 – 9:30</td>
<td>Incident Learning: Building on the Canadian Incident Analysis Framework</td>
<td>Lyndon Morley MRT(T)</td>
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<td>The London Protocol: From Observation to Recommendations</td>
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<td>12:20 – 1:45</td>
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<td>From Chaos to Complexity to Routine</td>
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<td>The RMP Quality and Safety Framework at PMH</td>
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<td>The Many Faces of Quality and Safety in Radiotherapy: A Provincial, National and International Perspective</td>
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<td>4:35 – 4:45</td>
<td>Evaluation and End of Course Remarks</td>
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SESSION DESCRIPTIONS

WEDNESDAY MAY 20, 2015

Session 1: A Foundation for Quality

A Framework for Quality: Deming’s System of Profound Knowledge

Michael Sharpe PhD

W. Edwards Deming (1900-1993) is recognized as the central thought leader who propelled Japan to the forefront of innovation and manufacturing of high-quality products following World War II. His approach to management and quality were recognized subsequently in the revitalization of manufacturing in the United States, and by the U.S. Institute of Medicine’s important publications addressing quality and patient safety in healthcare. His “system of profound knowledge” provides a perspective for understanding his views regarding management, quality, and transformational change, which are often quoted (as well as omitted or misquoted) in patient safety and quality forums. This session will introduce W. Edwards Deming and summarize his system of profound knowledge, which serves as a framework for the QSRT course.

Human Factors Engineering

Tracy Herlihey PhD, Ashleigh Shier MHSc

The design of technology and processes are important considerations in radiation therapy. This session introduces basic principles of human factors engineering as well as strategies that may be used to improve quality and safety in hospitals. A thesis project on improving safety in radiation therapy via interface redesign will be presented to facilitate understanding of the relationships between human factors, processes, and patient safety.

RT Quality and Patient Outcomes

Brian O’Sullivan MD

The radiation therapy community has espoused the virtues of employing quality and safety initiatives to ensure the highest quality radiotherapy for its patients for many years. What has not been clearly studied and documented until recently, is the impact that quality of treatment actually has on patient outcomes. This session will review the results of a recent study analyzing the impact of protocol compliance and plan quality in the curative treatment of locally advanced Head and Neck Cancer to emphasize these key elements of high quality radiotherapy.
Understanding your Activities: Process Chart Thinking
Stephen Breen PhD
When undertaking any shared series of tasks - for example, radiotherapy - workers often form mental models of the work involved, how it is distributed, and the tasks' temporal relationships. Confusion ensues when these models are not explicitly shared. Fortunately, there are tools to reduce this confusion: relations diagrams, flow charts, and process maps all provide visual descriptions of how we operate as individuals, teams, and organizations. In this session, we will review practical application of these quality tools, and develop a strategy to implement them in our clinical practices.

Activity: Building a Process Chart
Michelle Lau MRT(T), Lyndon Morley MRT(T)
To be effective, process maps must be constructed by the team that will use them, for that is where the expertise to do the task lies. In this team exercise, a process map will be developed by first identifying, with an affinity diagram, tasks associated with radiotherapy. When the affinity diagram is complete, related components will be grouped to identify relationships between tasks and elements. This exercise will demonstrate methods that can be used to better understand clinical processes.

Session 2: Appreciation for a System
Organizational Culture – Group Activity
Jean-Pierre Bissonnette PhD
Organizational culture guides how individuals within an organization act by defining the values and norms shared by those individuals. Culture controls the way individuals interact with each other and with stakeholders. Different cultural orientations are aligned, to various degrees, with accepted quality and safety practices. This session will foster an appreciation for participants’ respective organizational cultures and compare them with those of others to reflect on their preparedness for sustained improvements in quality and safety.

Statistical Methods for Understanding and Controlling Variations
Stephen Breen PhD
Once sound processes for delivering radiotherapy are established and communicated to all team members, we must develop means to monitor those processes so that we create opportunities for continuous improvement. For every process we design, there is a target – for example, the calibration of a linac in cGy per MU, or the time it takes for an oncologist to complete a GTV contour after CT simulation. There is variation in every process: linac output changes day to day, and physician contouring time is not the same for every patient. Some of this variation is acceptable, and some must be investigated and possibly minimized. Statistical process control provides a means to do just that, and achieve Deming’s definition of quality: on target with minimum variation. After this session, participants...
will be able to draw control charts, and will be able to interpret these charts to make improvements to the processes they employ to provide high quality radiotherapy.

Workshop – Case Study

Stephen Breen PhD

Participants will tackle practical quality improvement problems with control charts. Using real clinical data, students will construct x-bar and moving-range control charts. Participants will learn how to differentiate common cause and special cause variation, and, guided by statistical process control principles, propose solutions to clinical problems.

THURSDAY MAY 21, 2015

Session 3: Knowledge of Variation

Incident Learning: Building on the Canadian Incident Analysis Framework

Lyndon Morley MRT(T)

Learning from adverse events requires reporting, investigation, analysis and follow-up. The Canadian Patient Safety Institute provides a framework for building such a system. This session will describe the components of an incident learning program with emphasis on three types of investigation an analysis: concise, comprehensive and multi-incident. Learners will gain an appreciation of the value of effective incident management in driving quality improvement.

The London Protocol: From Observation to Recommendations

Gaylene Medlam MRT(T)

Root cause analysis (RCA) is a valuable tool that can be applied in the investigation of complex errors in healthcare. The London Protocol, an example of such tools, provides a flexible process for conducting RCA that can be used in many ways. This session will include an in depth look at the various aspects of the protocol and some useful adaptations. A case example will illustrate how to obtain and document the information needed to conduct the analysis.

Group Activity: Application of QUINCy and The London Protocol

Gaylene Medlam MRT(T), Lyndon Morley MRT(T)

Tools for conducting incident investigations are just that – tools. The human element of incidents will inevitably introduce variability into the outcome of such investigations, and the potential impact of this on the outcome of investigations should be considered. Through an interactive case-based exercise, participant groups will perform a QUINCy investigation and systems analysis (using the London Protocol) on a simulated incident. They will have a chance to interview the team involved in the incident, review
the corresponding documentation, and work together to determine the key issues and potential actions to be taken. Different outcomes and recommendations between groups will be discussed.

Session 4: Theory of Knowledge

From Chaos to Complexity to Routine
Jean-Pierre Bissonnette PhD
Mistakes are inevitable in medicine. While a number of them can be explained by deviations from established protocols with predictable outcomes, we remain vulnerable to situations where knowledge of latent risk factors is unknown, resulting in unpredictable outcome, or chaos, when this latent risk factor becomes manifest. In this session, we will discern between chaotic and complex (unknowable), complicated (knowable) and routine (known and predictable) systems. We will also summarize how new knowledge is generated to migrate a chaotic system to routine use.

The RMP Quality and Safety Framework at PMH
Lyndon Morley MRT(T)
The landscape of radiation therapy is rapidly increasing in complexity. Competing demands for better treatment outcomes, greater efficiency and lower cost remain the key drivers for positive change and innovation. A strategically-built organizational structure and a robust quality assurance program are keys to thrive in such an environment. This session will provide an overview of our programmatic quality framework that has enabled the consistent delivery of high quality and safe care.

Session 5: Bringing it all Together

The Many Faces of Quality and Safety in Radiotherapy: A Provincial, National and International Perspective
Michael Milosevic MD
Effective and safe radiotherapy requires a coordinated, inter-disciplinary approach to program organization and oversight, patient and technology-specific guidelines and prospective monitoring to drive continuous quality improvement. Most radiotherapy centres have developed internal quality assurance programs but there is wide variability and little coordination from one to the next. A more consistent approach would elevate the overall quality of care provided to patients and facilitate communication, open discussion and learning. This session will focus on provincial, national and international efforts to unify radiation treatment quality and safety across jurisdictions, and the opportunities for individual programs to capitalize on these efforts.
FACULTY BIOGRAPHIES

Jean-Pierre Bissonnette is an associate professor in the University of Toronto Department of Radiation Oncology and a physicist in the Radiation Medicine Program at the Princess Margaret since 2003. He completed his PhD in Medical Biophysics at the University of Western Ontario. His research interests include IGRT, extracranial radiosurgery, intracranial radiosurgery (Gamma Knife), error elimination and process analysis, and quality assurance.

Stephen Breen is an assistant professor in the University of Toronto Department of Radiation Oncology and a physicist in the Radiation Medicine Program at the Princess Margaret. He followed his PhD in Medical Biophysics at the University of Western Ontario with a post-doctoral fellowship in the Joint Department of Physics at the Institute of Cancer Research and the Royal Marsden Hospital in London, UK. Since 2003, his work at PMH has focused on image-guided IMRT for H&N cancers, molecular imaging for target volume delineation, and the application of process control theory to quality assurance in radiotherapy.

Tracey Herlihey is a Human Factors Specialist at the University Health Network in Toronto. She holds a PhD in Psychology, specializing in human perception and performance, and a BSc. in Applied Psychology from Cardiff University. Tracey’s broad research interests have led her to investigate issues ranging from night vision goggle artifacts to cognitive stroke recovery and human-computer interaction. At UHN Tracey specializes in the development and evaluation of human centered technology to enhance safety and efficiency within the healthcare setting.
Michelle Lau is a radiation therapist in the Radiation Medicine Program at the Princess Margaret since 2002. She is a graduate of the Medical Radiation Sciences BSc/Diploma program offered jointly by the University of Toronto Department of Radiation Oncology and the Michener Institute. She obtained her CMD certification from the Medical Dosimetry Certification Board (MDCB) in 2006. She is currently the Clinical Specialist Radiation Therapist with the Palliative group. Her research interests include adaptive radiotherapy, quality assurance and treatment outcome in patients with metastatic disease.

Gaylene Medlam is a Supervisor and Professional Practice Lead for Radiation Therapy at the Carlo Fidani Peel Regional Cancer Centre. She graduated in England in 1980 and obtained her BSc in Radiation therapy in 2006. Her responsibilities include quality and patient safety for the Radiation Oncology program, with a concentration on incident reporting and analysis. Current interests are teaching and research with regards to standardization of incident reporting.

Michael Milosevic is a professor in the Department of Radiation Oncology at the University of Toronto and a radiation oncologist in the Radiation Medicine Program at the Princess Margaret since 1992, with clinical interests in gynecologic and genitourinary malignancies. He received his MD at Queen’s University. He is an Associate Director of the Radiation Medicine Program at PMH with responsibility for quality and safety, a Past-President of the Canadian Association of Radiation Oncology (CARO), and Chair of the Canadian Partnership for Quality Radiotherapy (CPQR).

Lyndon Morley is a radiation therapist in the Radiation Medicine Program at the Princess Margaret since 2003. He is a graduate of the Medical Radiation Sciences BSc/Diploma program offered jointly by the University of Toronto Department of Radiation Oncology and the Michener Institute. His professional interests include staff and student education, process development and practice assessment.
Brian O’Sullivan is a professor in the University of Toronto Department of Radiation Oncology and the Department of Otolaryngology / H&N Surgery and a radiation oncologist in the Radiation Medicine Program at the Princess Margaret since 1984. He received his MD at the National University of Ireland in 1974 and his specialist qualifications from the University of Toronto in 1983. He is the Head of the H&N Oncology Program at PMH, and he also holds the Bartley-Smith/Wharton Distinguished Chair in Radiation Oncology in the Department of Radiation Oncology at the PMH, University of Toronto. His research interests include sarcoma and H&N cancer, translational research, IMRT delivery and the principles of IGRT, chemo-radiotherapy and molecular-targeting.

Michael Sharpe is an associate professor at the University of Toronto Department of Radiation Oncology, and a physicist in the Radiation Medicine Program at the Princess Margaret since 2002. He received his PhD in Medical Biophysics at the University of Western Ontario. His research interests include external beam treatment planning, image-guided treatment, multimodality imaging in treatment planning, breath hold immobilization using Active Breathing Control, and radiation therapy for breast cancer and soft tissue sarcomas.

Ashleigh Shier is a Human Factors Analyst with the Healthcare Human Factors team, and a graduate from the Masters of Health Sciences in Clinical Biomedical Engineering at the University of Toronto’s Institute of Biomedical and Biomaterials Engineering, and from the University of Toronto with a Bachelors of Applied Science in Industrial Engineering, specializing in Human Factors. Ashleigh has experience in usability of medical devices and health IT with Healthcare Human Factors at UHN, and has previously worked in the Clinical Engineering Dept. at Draeger Medical Systems in Boston, MA. Her masters thesis topic was in ecological interface design applied to improving a radiation therapy monitoring and delivery interface.
GLOSSARY OF KEY CONCEPTS, DEFINITIONS & ACRONYMS

Adverse event: Healthcare term for any event that is not consistent with the desired, normal or usual operation of the organization; also known as a sentinel event.

Affinity diagram: A management tool for organizing information (usually gathered during a brainstorming activity).

Baseline measurement: The beginning point, based on an evaluation of output over a period of time, used to determine the process parameters prior to any improvement effort; the basis against which change is measured.

Best practice: A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as best by other peer organizations.

Block diagram: A diagram that shows the operation, interrelationships and interdependencies of components in a system. Boxes, or blocks (hence the name), represent the components; connecting lines between the blocks represent interfaces. There are two types of block diagrams: a functional block diagram, which shows a system’s subsystems and lower level products and their interrelationships and which interfaces with other systems; and a reliability block diagram, which is similar to the functional block diagram but is modified to emphasize those aspects influencing reliability.

Calibration: The comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy to detect any variation from the required performance specification.

Checklist: A tool for ensuring all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.

Check sheet: A structured, prepared form for collecting and analyzing data. It is a generic tool that can be adapted for a wide variety of purposes.

Commissioning: When baseline data and characteristics of the equipment are acquired to support the clinical delivery of precise and safe treatment.
Continuous quality improvement (CQI): A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve customer satisfaction.

Control chart: A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either control limit.

Critical processes: Processes that present serious potential dangers to human life, health and the environment or that risk the loss of significant sums of money or customers.

Error: A failure of a planned sequence of (mental or physical) activities to achieve its intended outcome when the failures cannot be attributed to chance.

Failure mode effects analysis (FMEA): A systematized group of activities to recognize and evaluate the potential failure of a product or process and its effects, identify actions that could eliminate or reduce the occurrence of the potential failure and document the process.

Five whys: A technique for discovering the root causes of a problem and showing the relationship of causes by repeatedly asking the question, “Why?”

Flowchart: A graphical representation of the steps in a process. Flowcharts are drawn to better understand processes.

Groupthink: A situation in which critical information is withheld from the team because individual members censor or restrain themselves, either because they believe their concerns are not worth discussing or because they are afraid of confrontation.

In-control process: A process in which the statistical measure being evaluated is in a state of statistical control; in other words, the variations among the observed sampling results can be attributed to a constant system of chance causes. Also see “out-of-control process.”

Latent error: Errors in the design, organization, training or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time.

Near miss: A potential radiation incident that was detected and prevented before treatment delivery. However, mistakes in plans, calculations etc do not constitute near misses if they were detected and corrected as part of the checking procedure before authorising for clinical use. Notice that the term ‘miss’ is used in the context of falling short of being an actual radiotherapy incident, rather than in the narrower sense of a geometric miss.
Out-of-control process: A process in which the statistical measure being evaluated is not in a state of statistical control. In other words, the variations among the observed sampling results can be attributed to a constant system of chance causes. Also see “in-control process.”

Overexposure: When more radiation was delivered than was intended.

Plan-do-check-act (PDCA) cycle: A four-step process for quality improvement. In the first step (plan), a way to effect improvement is developed. In the second step (do), the plan is carried out, preferably on a small scale. In the third step (check), the effects of the plan are observed. In the last step (act), the results are studied to determine what was learned and what can be predicted. The plan-do-check-act cycle is sometimes referred to as the Shewhart cycle and as the Deming cycle.

Process: A set of interrelated work activities characterized by a set of specific inputs and value added tasks that make up a procedure for a set of specific outputs.

Process flow diagram: A depiction of the flow of materials through a process, including any rework or repair operations; also called a process flow chart.

Process improvement: The application of the plan-do-check-act cycle (see listing) to processes to produce positive improvement and better meet the needs and expectations of customers.

Quality: A subjective term for which each person or sector has its own definition. In technical usage, quality can have two meanings: 1. the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies. According to Joseph Juran, quality means “fitness for use;” according to Philip Crosby, it means “conformance to requirements.”

Quality assurance/quality control (QA/QC): Two terms that have many interpretations because of the multiple definitions for the words “assurance” and “control.” For example, “assurance” can mean the act of giving confidence, the state of being certain or the act of making certain; “control” can mean an evaluation to indicate needed corrective responses, the act of guiding or the state of a process in which the variability is attributable to a constant system of chance causes. One definition of quality assurance is: all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality. One definition for quality control is: the operational techniques and activities used to fulfill requirements for quality. Often, however, “quality assurance” and “quality control” are used interchangeably, referring to the actions performed to ensure the quality of a product, service or process.
Quality audit: A systematic, independent examination and review to determine whether quality activities and related results comply with plans and whether these plans are implemented effectively and are suitable to achieve the objectives.

Radiotherapy error: A non-conformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol. Following an incorrect radiotherapy protocol is also a radiotherapy error and can lead to radiation incidents (defined below). Not all radiotherapy errors lead to radiation incidents – for example, because the error is detected before the patient is treated or because the error happens not to affect the treatment delivery.

Radiation incident: A radiotherapy error where the delivery of radiation during a course of radiotherapy is other than that which was intended by the prescribing practitioner and which therefore could have resulted, or did result, in unnecessary harm to the patient.

Reportable radiotherapy incident: A radiotherapy incident that falls into the category of reportable under any of the statutory regulation. A reportable radiotherapy incident will generally be clinically significant, but may not be if it is a correctable radiotherapy incident (such as a 20% overdose on the first fraction where the doses in the remaining fractions have been reduced to compensate).

Root cause: A factor that caused a nonconformance and should be permanently eliminated through process improvement.

Severity: The extent to which an agent or action causes harm.

Standardization: When policies and common procedures are used to manage processes throughout the system.

Tampering: Action taken to compensate for variation within the control limits of a stable system; tampering increases rather than decreases variation, as evidenced in the funnel experiment.

Tolerance: The maximum and minimum limit values a product can have and still meet customer requirements.

Underdose: When less radiation has been delivered than was intended.

Compiled & Modified from:
AEP PLANNING COMMITTEE

**Pamela Catton** was a professor and the Vice Chair of Academic Affairs of the University of Toronto Department of Radiation Oncology, a radiation oncologist and the Director of Oncology Education for PMH. She completed her MD at the University of Ottawa, her specialist qualification at the University of Toronto and a Masters of Health Professional Education at the University of Illinois at Chicago. Her research interests had included breast cancer survivorship program development and outcomes assessment, computer-based learning and information therapy.

**Mary Gospodarowicz** is a professor in the University of Toronto Department of Radiation Oncology and Medical Director at PMH. She obtained her MD and her specialist qualifications in internal medicine and radiation oncology at the University of Toronto. Her research interests include clinical trials, assessing the role of radiation therapy and combined modality therapy in lymphomas, prostate cancer, bladder cancer, and seminoma. With long standing involvement in late effects research, she is very interested in fostering the newly established survivorship clinical programs and research.

**Nicole Harnett** is an assistant professor and the Director of Graduate Programs in Medical Radiation Sciences for the University of Toronto Department of Radiation Oncology, a radiation therapist and Director of the Radiation Skills Lab at PMH since 2004. She completed her radiation therapy qualifications in 1984 and her Master’s in Education in 2003 at the University of Toronto. Her research interests include advanced practice and education for radiation therapists and interprofessional education and practice.

**David Jaffray** is a professor and the Vice Chair Academic Programs for the University of Toronto Department of Radiation Oncology, the Fidani Chair of Radiation Physics and the Head of Radiation Physics for the Radiation Medicine Program at PMH since 2002. He completed his PhD in Medical Biophysics at the University of Western Ontario. His research interests include the physics of x-ray imaging systems, contrast agents for image-guided therapy, advanced processes for image-guided procedures and integration of functional imaging data into the radiotherapy process.
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