Can national clinical audits and quality indicators help the journey in further improving the quality and safety of radiotherapy treatments?

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Cubist depiction of the term « quality management in radiation oncology" generated through Artificial Intelligence (https://creator.nightcafe.studio/studio)

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ABSTRACT

Radiation therapy (RT) is an essential treatment modality for cancer care and cure. Over the years, radiation treatments have become more complex and more computerized leading to highly precise treatment approaches maximising loco-regional control while minimising toxicity. Safe and effective radiotherapy delivery however requires the implementation of adapted quality assurance (QA) programs and integral quality management (QM) systems, favouring continuous quality improvement. Throughout the past decades, the College of Physicians for Radiation Oncology Centres has been the source of numerous national initiatives, which have fostered and accompanied radiation oncology departments in taking the steps towards increased quality of care. This includes the implementation of peer reviewed clinical audits and the definition and monitoring of radiotherapy-specific structural, process and outcome quality indicators (RT-QI). The aim of this thesis work was to facilitate the implementation and to structurally analyse the quality criteria collected through both initiatives and to validate their use as quality improvement tools.

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List of abbreviations

AAPM	American Association of Physicists in Medicine
ASN	Agence de Surêté Nucléaire
B-QUATRO	Belgian Quality Assurance Team in Radiation Oncology
BSSD	Council Basic Safety Standards Directive
EFQM	European Foundation for Quality Management
ESTRO	European Society for Radiotherapy and Oncology
FANC	Federal Agency of Nuclear Control
IAEA	International Atomic Energy Agency
IGRT	Image Guided Radiotherapy
IMRT	Intensity Modulate Radiotherapy
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KCE	Belgian Health Care Knowledge Centre
LINACS	Linear Accelerators
MPE	Medical physics Experts
PROMS	Patient Reported Outcome measures
PREMS	Patient Reported Experience Measures
QA	Quality Assurance
QMS	Quality Management system
QUATRO	Quality Assurance Team in Radiation Oncology
QI	Quality indicator
QM	Quality Manager
QMRT	Quality Manager in Radiotherapy
RO	Radiation oncologists
RT	Radiotherapy (equivalent to radiation oncology)
RTT	Radiation therapist
TQM	Total Quality Management
VMAT	Volumetric Modulated Arc Therapy
WHO	World Health Organisation
3D-CRT	Three Dimensional Conformal Radiation Therapy

Chapter 1

"A culture of quality creates a mindset that pervades every aspect of healthcare delivery, from the top levels of administration to the front lines of care, driving continuous improvement and ensuring that patients receive the best possible care."

- Dr. Donald M. Berwick

CHAPTER 1: INTRODUCTION

1.1 Quality management in healthcare

Quality management in healthcare refers to a systematic approach in which structural and organisational elements are put into place to ensure that healthcare services are delivered with the highest degree of expertise, timeliness, efficiency, safety, and effectiveness and this within an environment that is equitable and patient-centred. The overarching goal of quality management is to improve patient outcomes and experience by identifying areas in need of improvement and implementing evidence-based practices [1,2].

There are several key components of quality management in healthcare, including:

- **Quality and performance measurement**: This involves collecting and analysing data on various aspects of healthcare delivery, such as patient outcomes, clinical processes, and patient satisfaction and/or experience. This data is used to identify areas for improvement and track progress over time;
- **Quality improvement**: This consists of the systematic and continuous approach of improving healthcare services and outcomes. Using data and evidence-based methods or tools, it identifies and addresses areas where the quality of care can be improved. Quality improvement initiatives can target specific areas of healthcare delivery, such as medication management, infection control, or patient communication;
- **Patient safety**: Ensuring patient safety is a critical component of quality management in healthcare. This includes identifying and mitigating risks to patient safety, such as medication errors, falls, and hospital-acquired infections.

Overall, quality management in healthcare is essential to ensure that patients receive the best possible care. It requires a collaborative approach between the healthcare providers, the patients, but also other stakeholders (health insurance, health economists, etc…), and a true commitment to continuous improvement within the organization [3].

The concept of evidence-based quality improvement was already revealed as early as in the 1850s by Florence Nightingale who observed that basic sanitation and hygiene standards led to a decrease in mortality when caring for soldiers wounded during the Crimean War [4]. However, the early 20th century really marked the moment when healthcare organizations began to focus on improving patient outcomes and reducing medical errors. One of the earliest quality management pioneers in healthcare was Dr. Ernest Codman who was an advocate of hospital reform and is considered to be the founder of what today is known as outcomes management in patient care [5]. Codman was an American doctor who developed in the 1910s the "end result system". This system followed the progress of patients through their recoveries in a systematic manner and tracked the outcomes of every surgery performed at his hospital. All cases would be discussed through an "efficiency committee" and points of improvement would be identified. Through this monitoring system, surgical practice in hospitals could be "standardised" and optimized, and claims to special surgical competence could be verified.

In the 1920s, Dr. W. Edwards Deming, an American statistician and quality expert, developed his ideas about quality control and quality improvement in the industrial field, which would later become known as the Deming Method. The Deming method or PDCA cycle is a continuous improvement cycle or loop consisting of 4 steps that help organisations in continuously improving their processes and outcomes (Figure 1) [6]:

- **Step 1 - Plan**: Phase where organizations identify the problem or area for improvement, define goals, and develop a plan to achieve those goals;
- **Step 2 - Do**: Step where organizations implement the plan and already collect data to measure the effectiveness of the plan;
- **Step 3 - Check**: Stage where organizations analyse whether the plan was successful in achieving the established goals and identify areas for further improvement or in need of adaptation;

- **Step 4 – Act (Adjust)**: Phase where organizations standardise or stabilise the implemented changes. If adaptations or improvements are necessary, the organisation will re-initiate the PDCA cycle.

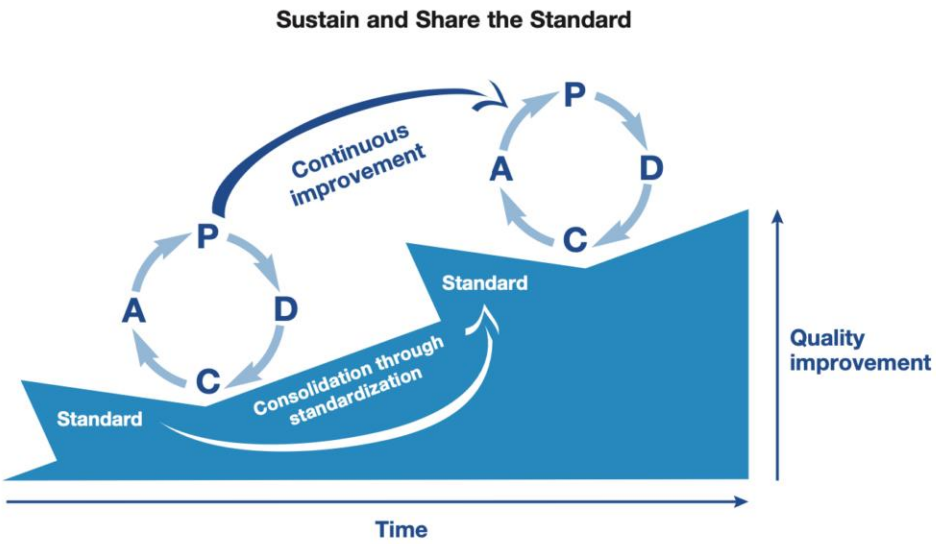


Figure 1 – PDCA (Plan – Do –Check – Act/Adjust) cycle with a continuous quality improvement framework [7]

Deming developed a philosophy of quality management that is often referred to as Total Quality Management (TQM). TQM focuses on the requirement that organisation-wide efforts should be implemented in order to establish an environment in which employees are encouraged to continuously improve their practice and the products they provide to customers by identifying and eliminating defects and inefficiencies [8].

These concepts were integrated into the healthcare environment in the 1950s as healthcare organizations began to focus on quality improvement as a way to improve patient outcomes and reduce costs. In the 1950s, the World Health Organization (WHO) introduced the concept of health system performance assessment, which focused on evaluating the quality of healthcare systems based on their effectiveness, efficiency, and equity [9]. In the USA, the Joint

Commission on Accreditation of Healthcare Organizations (JCAHO) was established to set standards for healthcare organizations and to accredit hospitals that met these standards. The standards were highly based on Avedis Donabedian's work that described three facets of quality measurement: **structure**, or the characteristics of health care delivery systems; **process**, or what and how care is provided and **outcome**, the result of the care provided [10]. JCAHO's focus on quality improvement helped to drive the adoption of quality management practices in healthcare. In the 1970s and 1980s, the quality movement also gained momentum in Europe. During this period, the European Foundation for Quality Management (EFQM) was established, which provided a framework for assessing organizational performance and quality in various sectors and became popular among healthcare organizations in Europe [11].

In the 1980s and 1990s, the concept of "managed care" emerged in which healthcare organizations began to focus more on cost control and efficiency. This led to the integration of new quality management frameworks, such as Six Sigma and Lean, which aimed to improve efficiency and reduce waste in healthcare delivery [12,13].

In the 2000s, the American Institute of Medicine released influential reports on patient safety and quality, which helped to drive further improvements in quality management in healthcare [14,15]. This includes the "To err is Human" report which broke the silence that surrounded medical errors and their consequences on patients and revealed that medical errors were the 3rd leading cause of death in the US. It pointed out that most of those errors were systemic and that they could not be resolved at the level of individual healthcare providers. It emphasized the need for a culture of safety; one that encouraged transparency, learning, and continuous improvement. The publication's recommendations also highly encouraged the implementation of quality management practices, such as the use of evidence-based guidelines, the standardisation of care processes, and the use of performance measures to monitor and improve quality. It also called for the use of technology to reduce errors and improve patient safety, such as computerized physician orders and electronic health records [14].

The "To Err Is Human" publication helped to raise institutions' awareness of the need for quality management in healthcare and encouraged healthcare

organizations to implement practices to improve patient safety. In the US, it led to the re-instauration of the Agency for Healthcare Research and Quality (AHRQ) and the funding of diverse patient safety-oriented projects such as the Patient Safety and Quality Improvement Act of 2005, which established a framework for reporting and analysing medical errors. The report went beyond the US borders and stimulated internationally wide research and discussions focussing on patient safety events and how to tackle these [16]. Following the release of this report, healthcare organizations began to implement a range of patient safety initiatives, including the development of protocols and guidelines for medication management, infection control, and surgical procedures.

Today, quality management is an integral part of healthcare delivery, and healthcare organizations around the world continue to adopt new approaches and tools to improve patient outcomes and experience.

1.2 Quality management and radiation oncology

1.2.1 Radiation oncology as a treatment modality

Radiation oncology is a specialized field of medicine that involves the precise delivery of high-energy radiation delivered to a target volume while minimizing the irradiation of surrounding healthy tissues. Radiation oncology plays a crucial role in cancer treatment and is used as a primary treatment option for certain types of cancer or in combination of other treatment modalities such as surgery, chemotherapy or targeted therapies. It is mostly used in a curative setting but it can also be used in a palliative setting to relieve symptoms and to improve the quality of life for patients with advanced or metastatic disease. In fact, 50% of cancer patients benefit from radiotherapy at least once during their disease history [17]. Radiation therapy can be delivered externally, where a machine directs the radiation beams towards the tumour from outside the body, or internally, through the placement of radioactive sources directly into or near the tumour. It requires highly specialized equipment – amongst which, linear accelerators (linacs), treatment planning systems, record and verify systems- but also highly dedicated personnel. As such, radiation oncologists work closely with a multidisciplinary team of healthcare professionals, including radiation

therapists (RTTs), medical physicists, and dosimetrists, to develop personalized treatment plans for each patient. Each treatment plan involves the close collaboration of each professional to carry out the necessary tasks that are needed to prepare, deliver and monitor the treatment. These different steps are summarized in Figure 1.

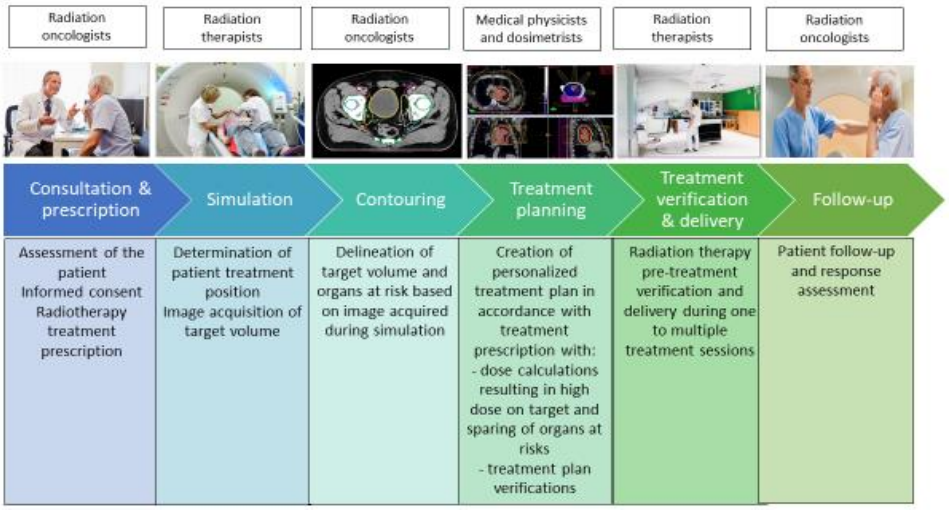


Figure 2 - Main steps involved in a radiotherapy treatment including the main professional groups that are involved in those different steps

The use of radiation for medical purposes dates back to the late 19th century with the discovery of X-rays by Wilhelm Roentgen and the development of radium as a radiation source by Marie Curie. Since then, the field of radiation oncology has undergone significant evolution over the years, driven by advancements in technology, research, and a deeper understanding of cancer biology [18]. After the first linear accelerator was launched in 1953, external beam radiation therapy (EBRT) using these machines gradually became the primary mode of delivering radiation over the following decades. The introduction of computerized tomography (CT) and computer-aided treatment planning systems in the 1980s and 1990s allowed for the precise shaping of radiation beams to conform to the shape of the tumour or target volume. This treatment technique – known as 3D conformal radiation therapy (3D-CRT) was further refined in the late 1990s with the development of Intensity-Modulated Radiation Therapy (IMRT) and Volumetric Modulated Arc Therapy (VMAT) which utilize multiple small radiation beams with varying intensities to shape the radiation dose distribution. Precision of radiation delivery also requires the accurate visualization of the

tumour and surrounding organs before and during treatment. This became possible in the 2000s with the integration of real-time imaging technologies such as portal imaging, Cone Beam Computerized Tomographies (CBCT) and even MRI within the treatment units. Image Guided Radiation Therapy (IGRT) has, as such, become standard practice whereby patient and target volume position and anatomy are verified before and even during the delivery of treatment. This has led to Adaptive Radiation Therapy (ART): ART involves modifying the treatment plan during the course of radiation therapy to account for changes in tumour size, shape, or location using frequent imaging and re-planning.
Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) were developed in the 1990s and early 2000s. These treatment techniques enable highly precise, high-dose radiation delivery within very limited treatment sessions. SRS is used for treating brain tumours and metastases, while SBRT is employed for tumours located extra-cranially such as the lung, liver, and spine.
As previously mentioned, external radiotherapy is mostly delivered using high-energy photons (X-rays). Hadrontherapy, introduced in the late 20th century, uses heavy particles such as protons - instead of X-rays - to deliver radiation. Protons have unique physical properties that allow for highly targeted radiation delivery, minimizing radiation exposure to healthy tissues. Proton therapy is particularly valuable for paediatric patients and tumours located near critical structures.

Over the past decades, the technology and techniques that are used to delivery radiotherapy have highly evolved and have led to significant improvements in radiation oncology. Techniques such as IMRT, VMAT, IGRT and stereotactic body radiation therapy have allowed for more precise and targeted radiation delivery, leading to improved treatment outcomes and better patient care.

1.2.2 Quality management in radiation oncology

Quality management, in the field of radiation oncology, has a relatively short history compared to other fields of healthcare. Yet in a short time, the culture of quality has immersed this specialised medical field. The history of quality management in radiation oncology can be traced back to the mid-20th century,

when technological advancements in radiotherapy allowed for more precise treatment delivery. In the 1950s and 1960s, radiation therapy was primarily delivered using cobalt-60 machines. Quality management in radiation oncology was limited, with little attention paid to the quality of the equipment, the calibration of the machines, or the accuracy of the treatment delivery [19,20]. However, in the 1970s, radiation therapy began to shift towards a more formalized approach of quality management. This was driven in part by the emergence of linear accelerators (linacs) becoming the main method of radiotherapy delivery, the more extensive use of medical imaging (such as CT scans) to define the treated volume and the development of computerized treatment planning systems. These systems increased the complexity of treatment plans and introduced the potential of new errors (software/technical bugs, data inaccuracies, etc…). These systems provided more precise and customizable treatment options, but they also required more rigorous quality management practices to ensure the accurate preparation and delivery of treatments to patients. Rigorous quality management practices became essential to verify the accuracy of treatment plans, ensure data integrity, enhance patient safety, and comply with regulatory and accreditation requirements. This led to the publication of the IPSM (Institute of Physical Sciences in Medicine) report 54 as a first comprehensive quality assurance (QA) guide [21]. In parallel, guidelines and standards for radiation therapy were developed, such as the International Commission on Radiation Units and Measurements (ICRU) reports, which still provide guidance on radiation measurement and dose reporting [22].

The American Association of Physicists in Medicine (AAPM) played a key role in developing quality management standards for radiotherapy during this time. In the 1980s, the AAPM established a task group to develop quality assurance standards for radiotherapy treatment planning, and in 1984, the AAPM published a report entitled "Quality Assurance in Radiotherapy," which provided detailed recommendations for quality management practices in radiation oncology [23]. In parallel, the World Health Organization and the European Society for Therapeutic Radiology and Oncology (ESTRO, now the European SocieTy for Radiotherapy and Oncology) also published guidelines to aid radiation oncology departments in practically setting up quality assurance programs [24,25]. In 1997, the International Atomic Energy Agency (IAEA)

published a report entitled "Quality Assurance in Radiotherapy," which provided guidance for developing quality management programs for radiation therapy. The report highlighted the importance of a multidisciplinary approach to quality management, involving physicians, physicists, dosimetrists, and radiation therapists [26].

The majority of the cited publications focussed on the development of quality assurance for radiotherapy; that is, "all those procedures that ensure consistency of the medical prescription and the safe fulfillment of that prescription in regard to dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment" [25]. This includes numerous publications detailing the various quality control procedures (QC) that are needed to be put into place as well as the recommended frequency and tolerance levels of these QCs. However, radiation treatments have become a "complex and multi-step process, necessitating input from various individuals that operate high-tech equipment, which calls for a structure" [27]. As such, quality management for radiotherapy should not be solely considered as being the development of a quality assurance program but should also consist of the establishment of all organisational and structural elements that favour the strive towards continuous quality improvement of all components involved in the radiotherapy process (Figure 3). This includes staff training, optimized process design and the establishment of audits to objectively evaluate practice.

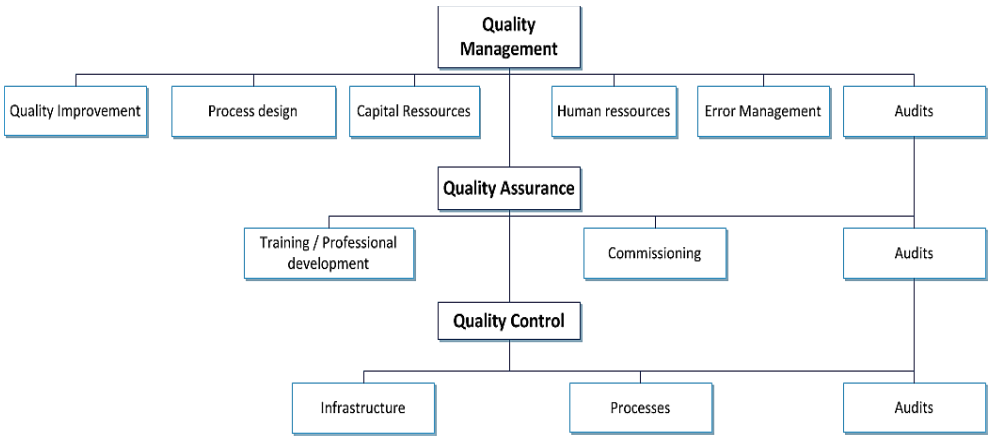


Figure 3 - Structure for a quality management system (adapted from Pawlicki et al. [28]

Within this quality management system (QMS), risk management must also be formally integrated to react to or assess any errors or risk of errors that could affect patient safety. The field of radiation oncology has indeed not been immune to accidents that have harmed patients either through [29–32]:

- Overdosage: situation in which the delivered dose to the patients exceeds by a significant amount the prescribed dose within the frame of the treatment. Overdosages can have serious consequences, as the excess radiation can damage healthy tissues and organs surrounding the tumor. This can lead to transient acute side effects such as skin irritation, hair loss, and gastrointestinal symptoms, as well as more serious long-term complications such as organ damage or even death;
- Underdosage: situation in which the delivered dose to the patient is lower that the intended/prescribed dose. Underdosage can also lead to serious consequences, as it can reduce the effectiveness of the treatment and potentially allow cancer cells to continue to grow and spread. Underdosing can increase the risk of treatment failure, leading to the need for additional or alternative treatments.

Indeed, The European Medical Exposure Directive of 1997 (Council Directive 97/43/Euratom) replaced by the 2013 directive (2013/59/Euratom) required that Member States take "all reasonable steps to reduce the probability and the magnitude of accidental or unintended [radiation] doses of patients" [33]. Quality and risk management system are thus two closely interrelated systems that continuously balance between "doing things well" and "how to prevent thing from going wrong" (Figure 4).

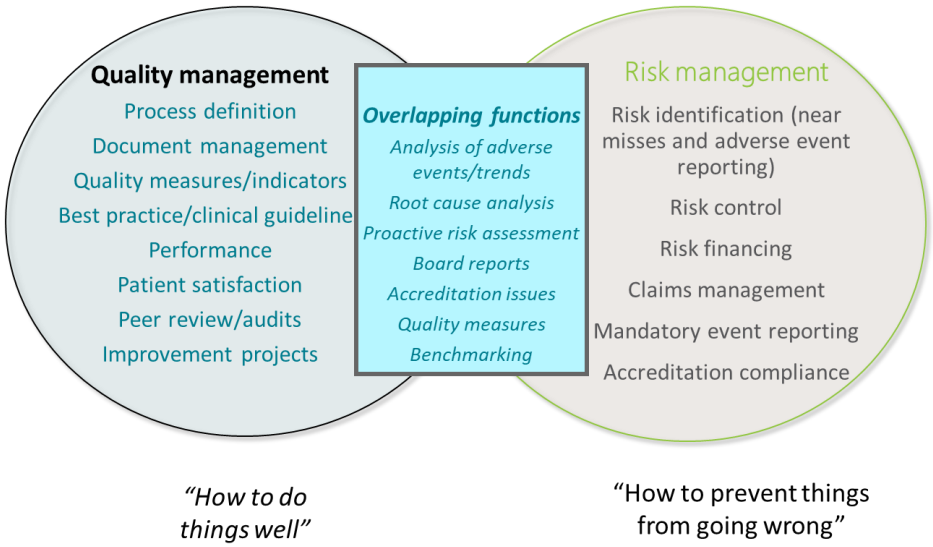


Figure 4 - Quality and risk management

Today, total quality management for radiation therapy is a critical component of patient safety and treatment efficacy. Quality management practices in radiation oncology include regular machine calibration and verification, treatment planning review, and patient-specific quality assurance measures, all in an environment that is oriented towards safety culture. These practices help to ensure that radiation therapy is delivered accurately and safely, minimizing the risk of adverse effects and maximizing the benefit to patients.

1.3 Quality improvement tools

Quality improvement tools are methods or techniques used to analyse and improve processes, systems, and outcomes in various fields not restricted to healthcare. They include [34,35]:

- Plan-Do-Study-Act (PDSA) cycles
- Lean methodology (Value stream mapping, Six Sigma, 5S,…)
- Root cause analysis (RCA)
- Failure mode and effects analysis (FMEA)

- Statistical process control (SPC)
- Audits
- Performance/quality indicator measurement and feedback
- Process mapping and flowcharting
- Fishbone or Ishikawa diagram
- Pareto analysis
- Voice of the customer (patient satisfaction/experience measurements)

The above list is not exhaustive and the choice of the tool(s) to use will depend on the matter needing to be analysed or improved and the resources available to support the quality improvement initiative. These quality improvement tools can be used within the local or departmental context, but they can also be favoured by national programs and incentives and lead to multi-centric quality improvement initiatives. Within the context of this work, the focus will be on two of such tools: clinical audits and quality indicators.

1.3.1 (Clinical) audits

An audit is a systematic and independent examination of records, processes, procedures, or activities to determine whether they conform to established standards or guidelines [36]. Audits can be conducted for a variety of purposes, such as identifying areas for improvement, ensuring compliance with regulations or standards, or verifying accuracy and completeness of records.

The notion of 'clinical audit' emerged in modern healthcare in the late 1990s as part of the process of clinical governance and is considered to be an important tool that can be used to improve patient care, safety, experience and outcomes. A "clinical audit is an appraisal that seeks to improve patient care and outcomes through systematic review of the current care against explicit criteria, and to suggest areas where the quality or safety of the processes could be improved" [27]. Audits can range from focussing on a specific aspect of an organisation or process to being a fully comprehensive external audit.

Clinical audits can be carried out at three different levels [37,38]:

- Self-assessment level: process whereby healthcare professionals evaluate their own practice against established standards and guidelines. It

involves examining one's own clinical practices, procedures, and outcomes to identify areas of gaps between the established standards and as such identify areas needing some improvement. This process can be carried out on a continuous basis as part of the quality assurance program and/or can be carried out as a preparation phase of an internal or external audit;

- Internal audit level: is the same process as described above but whereby the audit is typically carried out by members of the healthcare organization's staff who are not active in the audited department/entity;
- External audit level: Unlike internal clinical audits, external clinical audits are conducted by an organization or a group that is not affiliated to the organization being audited. External clinical audits are generally carried out by professionally active experts of the audited field. These audits provide a broader perspective in that they remove the potential inability of internal experts to recognize the weaknesses and elements for improvement in their own routine practice.

Each of these three levels of clinical audit are tools to be used in a systematic and continuous matter [37].

The process of internal and external clinical audit typically involves the following global steps, which are briefly described here below [39]:

- Preparation of the audit: The audited department prepares the necessary documentation and data and informs the team of the audits. The auditors review the preparatory documentation and background information;
- Audit: The auditors inform the audited department of their mission and the scope of their mission (entrance briefing). Through interviews, direct observation and review of documentation, the auditors assess the department's working practice that is compared to set standards and/or what is considered good clinical practice. Following this assessment period, the auditors share their observations and preliminary recommendations with the audited department (exit briefing);
- Audit report: within a fixed and minimal time frame, a written report of the auditors' observations and recommendations is generated and sent

to the department (and – if applicable – to the organisation's management and national authorities).

Based on these observations and recommendations, the audited departments are highly encouraged to set up improvement actions to tackle the various detected areas of weakness. As such, continuous quality improvement is achieved through the implementation of corrective actions based on the audit's recommendations. This leads to changes being made to processes, procedures, training, or equipment leading to a further improvement of the quality of care provided.

Clinical audits are considered to be an essential component of quality and patient safety by the Council Basic Safety Standards Directive (BSSD). As such, the 2013/59/Euratom requires European states' facilities that are equipped with medical application using ionising radiation to organise clinical audits. This directive defines clinical audits as being a "systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary" [33]. Well before the publication of the 2013/59/Euratom directive, the IAEA has been highly involved in the development and implementation of comprehensive peer reviewed clinical audits in radiotherapy. With the help of international experts, the agency published the "Quality Assurance Team in Radiation Oncology" (QUATRO) audit methodology in 2007 [40,41]. This comprehensive and peer-reviewed clinical audit focuses on the entire radiotherapy process and evaluates aspects such as the organisation, infrastructure, clinical and physical elements underlying a radiotherapy department. The audit team is composed of a radiation oncologist (RO), a medical physicist (MP) and a radiation therapist (RTT). Since its publication, this audit methodology has been used internationally to audit hundreds of radiation oncology departments [39,42,43].

1.3.2 Quality indicators (QI)

A quality indicator (QI) is a measure or a metric used to assess the quality of healthcare services or outcomes. QIs are often based on evidence-based guidelines or best practices in healthcare. They are used to monitor and evaluate healthcare performance and to identify areas for improvement. They can provide important information about the effectiveness, safety, and efficiency of healthcare services and help to guide quality improvement efforts. QIs can be used to track progress towards established goals over time or they can be used to establish benchmarks and targets for performance improvement [44]. A good quality indicator is a measure or metric that is reliable, valid, relevant, and actionable [45,46].

- Reliability refers to the consistency and accuracy of the data used to measure the indicator. The data should be collected consistently over time and across different healthcare providers or organizations;
- Validity refers to the extent to which the indicator measures what is it intended to measure. The indicator should be based on evidence-based guidelines or best practices in healthcare and should be relevant to the healthcare setting in which it is being used;
- Relevance refers to the importance and significance of the indicator in terms of its impact on patient outcomes or healthcare processes. The indicator should be meaningful to patients and healthcare providers and should reflect aspects of healthcare quality that are important to them;
- Actionability refers to the ability of the healthcare provider or organization to take action based on the results of the indicator. The indicator should provide information that can be used to guide quality improvement efforts and to identify specific areas for improvement.

In addition to these criteria, a good quality indicator should also be possible and cost-effective to collect and report. The data collection process should be manageable and not place an undue burden on healthcare providers or organizations as this will prevent QIs from being collected.

QIs can be used to evaluate various aspects of healthcare and are often sub-divided into three main domains or types according to the well-known Donabedian model [47,48]:

- Structural QIs: These QIs measure the physical, organizational, and human resources that are used to deliver healthcare services. Examples: the availability of medical equipment and facilities (such as number and type of available linacs), workload per staff, and the qualifications and training of healthcare providers;
- Process QIs: These QIs measure the actions and activities that are used to provide healthcare services. Examples of process QIs include the clinical procedures used to diagnose and treat patients, the treatment modality used to treat an affection or the delay between a diagnosis and a treatment. In radiation oncology, examples are the time between multidisciplinary treatment decision and start of radiotherapy, or the use of certain treatment techniques;
- Outcome QIs: These QIs measure the results or effects of healthcare services on patient health and well-being. Examples of outcome components include improvements in patient health status, reductions in complications or adverse events, and increases in patient satisfaction or experience. In the context of radiation treatments, they may include levels of toxicity observed after treatment.

While the Donabedian model continues to be used as a reference framework for the definition of QIs, some criticize it as being too simplistic, failing to recognize the possible interactions between the different domains and to incorporate patient and environmental factors [49–51]. Yet, despite the criticism, the model provides a strong backbone for QI definition and is still widely used for quality assessment purposes. In the last decades, there has been a growing interest in defining and collecting healthcare QIs that can guide programs, institutions and departments in monitoring and improving the quality of care provided to patients. Through the process of benchmarking, centres or countries can compare their results amongst each other, identify gaps in practice and put into place improvement actions that favour the delivery of best-quality care [52–54]. This increased interest for QIs has also conquered the field of oncology and even more specifically the field of radiation oncology [55–61]. In Belgium, the Belgian Health Care Knowledge Centre (KCE) has been at the forefront of numerous publications on the basis of which public authorities or healthcare providers can base their decisions in the field of healthcare and health insurance.

This also includes the development of oncology specific QIs favouring best practice [62–68].

1.4 Radiation Oncology in Belgium

1.4.1 Radiotherapy infrastructure in Belgium

Currently, Belgium possesses 24 primary radiation oncology departments involved in the delivery of approximately 40.000 radiation treatment courses per year. There is quite an even distribution between departments located in the Flemish and the Walloon region with a concentration of centers found in the Brussels region [69]. Of the 24 radiation oncology departments currently active, 8 possess at least one satellite site resulting in a total of 11 satellite sites. A satellite site is a site that is dependent on the primary site but located geographically away from the primary center. In 2021, there were 88 clinically active external beam radiotherapy devices. This current radiotherapy landscape will probably change with the publication of Belgian law amending the coordinated law of July 10th 2008 concerning hospitals and other healthcare establishments, which demands clinical networking between hospitals and the potential fusion of some radiation oncology departments [70].

1.4.2 The culture of quality in radiation oncology in Belgium

As described in the publication of Vaandering et al, in May 2000, the Belgian government established the College of Physicians for Radiation Oncology Centres (referred to as 'the College') with the aim of evaluating and improving quality of radiotherapy [71]. Eight radiation oncologists are appointed by the Minister of Health for a term of 6 years. The members are supported by a working group of experts, consisting of medical physicists, radiation therapists, radiation oncologists, quality managers, and, upon demand, delegates from the ministry and from the Belgian Cancer Registry. The missions of the College are financially supported by the Belgian Cancer Plan in addition to the College receiving operating money from the Belgian Ministry of Health.

Indeed, in parallel to the College, since 2010, action point 16 of the National Cancer Plan finances one quality manager (QM) per radiotherapy department with as main objective to implement and maintain a quality management system within radiation oncology departments [72]. Soon after having been integrated in radiation oncology departments, the newly hired quality managers formed an association known as the Belgian Quality Managers of Radiotherapy (QMRT.be). An internal initiative within this group highlighted the need for developing a document detailing the various elements necessary for the implementation and the evaluation of quality and risk management systems in radiation oncology departments. The complementary document called "QMRT's tool" was officially recognized and endorsed by the IAEA and the Federal Agency of Nuclear Control (FANC) [3].

Over the past decades, the College has been successful in developing and implementing a number of quality improvement initiatives, focusing on different aspects of radiotherapy practice (Figure 5).

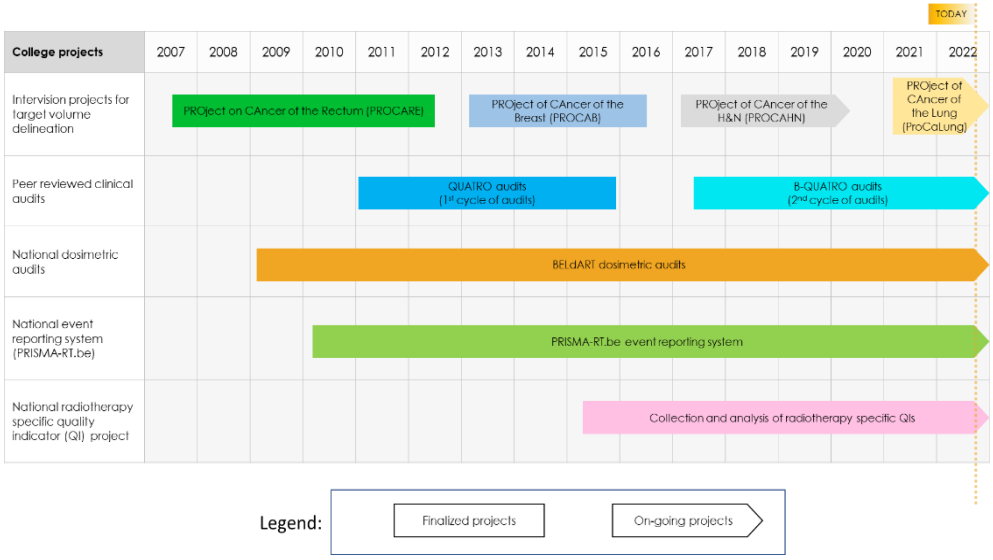


Figure 5 - Timeline of the various College projects

These include the support of national dosimetric audits (BELdART) and multiple intervision projects for target volume delineation (PROCARE (PROject on CAncer of the REctum), PROCAB (PROject on CAncer of the

Breast), PROCAHN ((PROject on CAncer of the Head & Neck)) and PROCALU (PROject on CAncer of the LUng)) [73–80].

The College has also coordinated the establishment of a national event reporting system known as PRISMA-RT.be. The main focus of this system is to drive quality improvement by inter-centre comparison of the root causes that lead to near-misses and adverse events in radiation oncology departments. This system is complementary to the existing mandatory declaration of accidents to the FANC, which is the national competent agency that, amongst others, governs all medical uses of ionizing radiation. This system requires that all departments analyse the safety events using a common methodology called PRISMA (*Prevention, recovery and Information for Monitoring and Analysis)* adapted to the radiotherapy context *(*PRISMA-RT) [81–84]. Currently, the majority of radiation oncology departments are participating in this network. The PRISMA-RT methodology of incident and near-incident analysis has thus been successfully implemented in all radiotherapy centers and experience shows that establishing a "common methodology of event analysis has served as a uniting factor in the Belgian radiotherapy quality management community" [71]. Surveys among the quality managers indicate that the event analysis using PRISMA-RT in combination with regular meetings and training sessions lead to valuable interactions and quality improvement projects. In addition, PRISMA-RT has been adopted as the analysis methodology used for the mandatory declaration of accidents to the FANC who shares them anonymously with all radiotherapy centres.

The College has also been at the forefront of two other national projects, which have been the focus of work realized in this thesis. These projects are summarized here below but further detailed in CHAPTER 2: CLINICAL AUDITS and CHAPTER 3: QUALITY INDICATORS.

1.4.3 Peer reviewed clinical audits

Since 2011, the College organises peer-reviewed clinical audits in all Belgian radiation oncology departments based on the International Atomic Energy Agency's (IAEA) QUATRO (Quality Improvement Quality Assurance Team

for Radiation Oncology) tool, quality criteria and philosophy [85]. The first audit cycle was initiated in 2011; with 5 departments being audited every year, all Belgian radiation oncology departments were successfully audited over 5 years. The multidisciplinary auditing team was composed of a medical physicist, a radiation oncologist and an RTT, delegated by the Belgian radiation oncology departments. The auditors were all professionally active members who had been trained in the audit methodology and who performed this task on a voluntary basis, with a budget only foreseen to cover for travel and accommodation. All departments actively collaborated in the process by accepting the audits.
In partnership with the IAEA, a modified version of the QUATRO tool, named B-QUATRO, was introduced in 2015 to further fine-tune the auditing tool for the Belgian context and to integrate concepts related to newer technologies. It also included a chapter focusing on quality criteria necessary to evaluate quality management systems based on the QMRT's tool developed by the Belgian quality managers [3]. As a result, a Quality Manager was also integrated in the auditing team [86]. Since 2017, a second cycle of audits has thus been initiated, using the B-QUATRO document, this time with a team of 4 auditors. This second cycle of audits ended in March 2023.

1.4.4 Radiotherapy specific quality indicators (RT-QI project)

In 2015, the College initiated another project, which focussed on the development of radiotherapy-specific quality indicators (RT-QI). As such, the College and the representatives of the Belgian Quality Managers in radiotherapy (QMRT.be), established a list of radiotherapy-specific structural, process and outcome indicators, considered as fundamental. The defined process and outcome QIs focussed on 3 pathology groups: head and neck, breast and prostate cancer patients. Once the QIs were defined and agreed upon, a test phase was launched in June 2015, collecting the full set of structural QIs for 2015, but limiting the patient-specific QIs to a restricted number of patients. Once the data collection test phase was validated and the collection process optimized, the full capture of the data necessary to measure the defined QIs was initiated in 2016. This QI collection has been repeated on a yearly basis and has led to the publication of benchmarking document, allowing departments to

visualize their own QIs as compared as to the other departments' and average national QIs.

1.5 Objectives of the thesis

Radiotherapy is an oncological treatment modality that combines under a single umbrella a multidisciplinary team and the use of complex equipment for the planning and accurate delivery of an ionizing radiation treatment to a selected target volume, while minimizing the dose delivered to the surrounding healthy tissue.

Radiotherapy is a highly effective cancer treatment that is safe for patients exposed to high levels of radiation, under the condition that precision and accuracy are strictly adhered to [87]. Radiotherapy has the potential to cure cancer or alleviate symptoms as long as it operates within a carefully regulated and controlled quality framework. If administered outside of this framework, it can become detrimental and lose its effectiveness, or even cause harm. A thorough quality assurance system compromised of regular and complete quality controls of equipment and processes must therefore be setup, along with the adequate training and continuous education of the dedicated personnel. In addition, quality assurance must be part of a total quality management framework - with the establishment of all elements necessary to ensure the strive towards a continuously improving system. This endeavour towards continuous quality improvement can be favoured using quality improvement tools and can be even further encouraged when these are used at a multi-centric or even national level supported by entities whose aim is to support quality-oriented initiatives. The College of Physicians for Radiation Oncology Centres ('the College') was established in 2000 with the aim of evaluating and improving quality of radiotherapy in Belgium. Amongst its initiatives are the organisation of **peer reviewed external clinical audits** of all radiation oncology departments and the **definition and national collection of validated radiotherapy-specific QIs**.

The aim of this thesis was
- to analyse the quality data collected through both initiatives and

- to validate their use as quality improvement tools

Along this project, it has been essential to ensure the congruence and consistency of the quality data collected. It has therefore been of paramount importance to establish solid, collective and constructive communication with the various radiation oncology departments throughout the project, in view of obtaining valuable input to support the recommendations during the clinical audits and collecting valid data with minimal inter-observer variability for the RT-QI project. This manuscript will detail the analyses that have been carried out in the two projects as well as the initiatives that have arisen as a consequence of these.

Chapter 2 of this manuscript will focus on **clinical audits** and the analysis of the recommendations emitted during the **1st cycle of peer reviewed QUATRO audits,** carried out between 2010 and 2015 in all Belgian radiation oncology departments. The audit reports were analysed to identify common areas for which improvements were recommended. In parallel, questionnaires were sent to all departments to obtain their feedback on the perceived usefulness, relevancy and impact of the emitted audit recommendations. This analysis served as a basis for the subsequent work of reviewing and updating the QUATRO methodology.

Chapter 3 of this manuscript describes the national implementation of the **RT-QI project** as well as the overall findings that have been made in the analysis of the data collected between 2016 and 2019. It moreover includes the results of a national survey that was used to evaluate the ease of data collection and submission, and the perceived importance and validity of the collected QIs by the participating radiation oncology departments.

Quality indicators can (and should) be adapted on a regular basis in concordance with scientific data, legislation, published guidelines and/or updates in what is considered to be good clinical practice. QIs can also serve as measurement tools in times of crisis. Not unlike other countries, the COVID-19 outbreak affected oncological services including the delivery of radiation treatments [88–91]. Adapted QIs monitored over time were considered useful tools to quantify the impact of the pandemic. **Chapter 4** describes the study that was carried out during the COVID-19 outbreak in Belgium, aiming at

quantifying the impact of the outbreak on **structural indicators** - such as number of patients treated and staff available - but also on **process indicators,** such as adaptation of treatment and/or fractionation schedules to optimise treatment availability and minimize patients' risk of infection.

Chapter 5 focusses on the further analysis of the data collected through the **RT-QI projec**t. A statistical analysis was carried out to determine the potential existence of associations between the patient's age and selected treatment parameters (**process QIs**) and the observed acute toxicities (**outcome QIs**) that have been recorded for breast, prostate and head and neck cancer patients, treated between 2016 and 2019. Through this work, potential links between clinical practice and its clinical impact on patients was explored using a large set of real-world data collected though the RT-QI project.

The status, requirements and limitations of both the clinical audits and RT-QI project are discussed in **Chapter 6**. These are already presented in chapter 2-5, but global findings will be shared. Finally, **Chapter 7** will give some conclusive remarks and advice for further work.

Chapter 2

"Quality means doing it right when no one is looking."

- Henry Ford

CHAPTER 2: CLINICAL AUDITS

Feasibility and impact of national peer reviewed clinical audits in radiation oncology departments

Vaandering A, Lievens Y, Scalliet P; Belgian College for Physicians in Radiation Oncology. Feasibility and impact of national peer reviewed clinical audits in radiation oncology departments. Radiother Oncol. 2020 Mar;144:218-223. doi: 10.1016/j.radonc.2020.01.012

ASBTRACT

Purpose/objective: A national incentive brought about the instauration of systematic clinical audits of all Belgian radiation oncology departments (n=25) from 2011 to 2015 using the International Atomic Energy Agency QUATRO (Quality Improvement Quality Assurance Team for Radiation Oncology) methodology. The impact of these audits was evaluated and the emitted recommendations originating from the audit reports were analysed to identify areas of weakness on a national basis.

Method: The QUATRO audits performed in each radiotherapy department gave rise to reports in which each department received a list of recommendations that it is free to implement. These audit reports were analysed to identify common areas for which improvements were recommended. Moreover, questionnaires were sent to all departments in order to evaluate the overall usefulness of the recommendations as well as the relevancy and the actual impact of each individual recommendation.

Results: Of the 381 emitted recommendations, 34% concerned process optimization of which a quarter involved process improvement and protocol development. Twenty-seven percent of the recommendations concerned infrastructure of which one-third was related to the quality of the equipment or facility. Nineteen and 20% of recommendations addressed department organisational and staff issues respectively. When analysing the departments' feedback questionnaires, 54% of the departments evaluated the audits' recommendations as being very useful. Furthermore, 42.7% of the recommendations were found to be very relevant and 23.5% were deemed to have an important impact.

Conclusion: This first round of audits in Belgium allowed for the identification of common areas for improvements of practice in radiation oncology departments, with a focus on process optimization and infrastructure elements. Similarly, the audits' emitted recommendations were globally deemed very relevant. Encouraged, by this analysis, a second cycle of audits has started in Belgium with a modified version of the QUATRO document (B-QUATRO).

2.1 Introduction

In 1997, EURATOM issued a directive (97/43) requiring member states to organise clinical audits in radiotherapy. The European Medical Exposure Directive of 2013 (Council Directive 2013/59/ Euratom), further defined clinical audits as "a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary". These two consecutive directives required Member States to ensure that clinical audits are carried out according to national procedures (to be developed), with a mandatory transposition into national legislation by February 2018 [92]. In Belgium, the 97/43 directive was transposed in a Royal Decree in 2002 and the mission to carry out clinical audits was implicitly entrusted to the newly founded College for Physicians in Radiation Oncology.

The potential benefits of clinical audits are multiple with the overall aim of achieving continuous quality improvement through the implementation of corrective actions based on the recommendations emitted by the audits. Moreover, in healthcare, quality improvement must necessarily be accompanied by safety improvement measures. Clinical audits therefore also play an important role in identifying areas of risk and promoting preventative measures [93].

The International Atomic Energy Agency (IAEA) published a document in 2007 entitled "Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement" which proposes a methodology to carry out comprehensive clinical audits in radiotherapy [40]. This clinical audit focuses on the entire radiotherapy process and evaluates aspects such as the organisation, infrastructure, clinical and physical elements underlying a radiotherapy department. This audit is a peer review process undertaken by an audit team composed of a radiation oncologist (RO), a medical physicist (MP) and a radiation therapist (RTT). Known as IAEA QUATRO (Quality Assurance Team in Radiation Oncology) audits, this audit methodology has been conducted in

over 77 radiation oncology departments located in Europe, Latin America, Asia and Africa [39,43].

In Belgium, it was decided to use the IAEA QUATRO methodology to carry out clinical audits in all radiation oncology departments. As such, a first cycle of audits took place in the 25 Belgian radiation oncology departments over a five-year period (2011–2015). The departments' perception of the relevance and actual impact of the recommendations emitted by the audit has been evaluated afterwards (2016). It was also of importance to review the recommendations in general in order to identify possible areas of improvement on a national basis. The aim of the present work is to report the results of the analysis of this first cycle of Belgian IAEA QUATRO audits.

2.2 Materials and methods

QUATRO audits in Belgium

Following the publication of the 2002 Royal decree, which translated the 97/43/Euratom directive into Belgian law, it was a shared opinion that neither the Belgian Ministry of Health nor the radiation protection regulatory body (Federal Agency of Nuclear Control (FANC)) had the human and financial resources necessary to implement clinical audits on a national basis [74]. Following multiple meetings between the involved parties, it was decided that the Belgian College for Physicians in Radiation Oncology would organise these audits on its own limited budget. This commission is composed of Radiation Oncologists (RO), appointed by the Ministry of Health and assisted by external experts such as medical physicists (MP) and RTTs. Its mission is to promote the quality of radiotherapy on a national level. It was decided that the IAEA QUATRO audit methodology was the most convenient solution to carry out these audits. QUATRO is an internationally validated tool whose peer review based methodology was considered to be in line with the vision of all involved parties [85]. Moreover, some members of the College were already active IAEA QUATRO auditors themselves. As such, a core group of 15 RO, MP and RTT auditors (5 per discipline) was trained during a two-day seminar in 2011 and the first audits were carried out by teams mixing composed of newly trained and experienced auditors. The audits themselves were organised in such as manner

as to audit 5 departments/year over a 5-year period (2011–2015). Each audit was carried out over 3 full consecutive days, as opposed to the 5- day audits proposed by the IAEA due to feasibility and efficiency reasons. The audits in Belgium solely focused on external beam radiotherapy (and not brachytherapy) and did not include the IAEA dosimetric audits as these were covered by existing national initiatives (BELdART dosimetric audits) [94–96]. Both participation to QUATRO and dosimetric audits is on voluntary basis. Each QUATRO audit gave rise to a structured audit report with a detailed description of the data collected and the observations made during the audit process. It also included a set of recommendations or suggestions that the department was encouraged to implement. These reports were sent to the department within a limited timeframe from the audit itself. In parallel, on a yearly basis, an anonymized report summarizing the results of the audits was sent to the Ministry of Health.

Emitted recommendations analysis

In the present analysis, all recommendations were extracted from the individual audit reports and loaded in an Excel spreadsheet. The recommendations were then categorized according to a 3-level taxonomy system as described by Izewska et al. [39]. The first category level uses four main divisions to classify recommendations into issues pertaining respectively to (1) staffing, (2) infrastructure, (3) process or (4) organisational factors. The second category level is then used to delve further into the four broad categories and the third level categorization is intended to provide even further differentiation. As such, each recommendation was assigned a 3 level classification code (Table 2).

Using this taxonomy, it was possible to classify the emitted recommendations and as such obtain a global view of the proportion of emitted recommendations that have been forwarded by the audits.

Table 1 - Likert scales used in the audit feedback questionnaires in which usefulness is defined as the possibility of the recommendations being acted upon, relevancy is the appropriateness of the recommendation and impact is the effect the recommendation has h

Overall usefulness of emitted recommend-ations	Not useful	Little useful	Moderately useful	Very useful	Primordial
Relevancy of individual recommend-ations	**Not relevant** to the department's situation/ context	**Little relevant** to the department's situation/ context	**Moderately** relevant to the department's situation/ context	**Very relevant** to the department's situation/ context	**Primordial** to the department's situation/ context
Impact of the individual recommend-ations	**No impact** on the department's organisational / infrastructural situation	**Little impact** on the department's organisational / infrastructural situation	**Moderate impact** on the department's organisational/in frastructural situation	**Big impact** on the department's organisational/ infrastructural situation	**Primordial** impact on the department's organisational / infrastructural situation
Attributed score	**0**	**1**	**2**	**3**	**4**

Audit feedback

Following the first 5-year cycle of audits, it was important to evaluate the audited departments' perception of the audits. A personalized Excel (Excel 2010) based questionnaire was sent in 2016 to each department's head RO and quality manager and in which the radiotherapy team was asked (1) to evaluate the overall perceived usefulness of the audits and (2) to evaluate the relevance and (3) actual impact of each individual recommendation that was addressed to their department following the audit. The respondents were asked to evaluate these different elements using a 5-point ordinal scale ranging from not useful/not relevant/no impact to primordial usefulness/primordial relevance/primordial impact (see Table 1). For analysis purposes, these scores –

although ordinal – were considered as continuous variables in order to evaluate the mean scores.
The departments were asked to provide feedback within one month of having received the questionnaires. The completed questionnaires were then analysed on a department and national level. Further analysis was carried out in order to evaluate the possible correlation between the type of recommendation emitted (as a function of the proposed IAEA categorization code) and its perceived usefulness and impact. In other words, we tried to estimate if the type of recommendation ((1) staffing, (2) infrastructure, (3) process or (4) organisational recommendation) had an influence on the scores attributed to the recommendation in the questionnaire. Statistical tests (Generalized mixed models – Multinomial logistic regression) were performed using SPSS 25.0 for Windows (IBM corp., USA).

2.3 Results

Twenty-five departments were audited during this first cycle of audits carried out between 2011 and 2015. Overall, these audits demonstrated a good and harmonious level of quality of radiotherapy treatment delivery.
All audits led to the formulation of a certain number of recommendations, highlighting areas of improvement on which the departments could work to further optimise the quality of practice. A total of 381 recommendations were formulated with a median of 15.5 recommendations per department. Of these recommendations, 34% concerned process optimization, 27% infrastructure and 20% and 19% of recommendations addressed organisational and staff issues respectively. The level 1 and level 2 classifications of the recommendations are illustrated in Table 2.

Table 2 - Classification of different recommendations stipulated in the audit reports: Recommendations have been classified at the 2nd level and regrouped by level one classification as

Types of recommendation	Proportion of recommend-ations	Types of recommendation	Proportion of recommendations
I. **Department Organisation**	**19,7%**	**III. Process**	**33,9%**
Staff responsibilities	**21,3%**	**Multiple clinical processes**	**24,8%**
Programme /service quality	81,3%	Checking/verification	12,5%
Programme availability	18,8%	Process quality	43,8%
Quality and safety management	**20,0%**	SOPs, protocols and policies	31,3%
Incident learning	**16,0%**	Access	9,4%
Other	16,7%	Documentation	3,1%
Programme /service quality	66,7%	**Treatment planning**	**14,7%**
Programme availability	16,7%	Checking/verification	73,7%
Discharge/Follow-up	**13,3%**	Process quality	10,5%
Programme /service quality	50,0%	SOPs, protocols and policies	15,8%
Programme availability	40,0%	**Treatment verification/imaging**	**14,0%**
Resources	10,0%	Checking/verification	5,6%
Other	**10,7%**	Process quality	66,7%
Radiation protection and safety	**9,3%**	SOPs, protocols and policies	22,2%
Referrals/admission	**5,3%**	Documentation	5,6%
Culture and patient centeredness	**2,7%**	**Quality assurance**	**10,9%**
Research	**1,3%**	**Quality and safety management**	**0,8%**
II. **Infrastructure**	**27,0%**	**RT imaging for planning**	**9,3%**
Facilities	**33,0%**	**Treatment delivery**	**7,8%**
Quality of facility or equipment	91,2%	**Treatment prescription**	**6,2%**
Other	5,9%	**Immobilization/ beam modifiers/patient marking**	**4,7%**
Opening hours	2,9%	**Other**	**3,9%**
Treatment machines	**19,4%**	**Informed consent**	**2,3%**
Equipment quality control	25,0%	**Patient work up**	**0,8%**
Quality of facility or equipment	30,0%	**IV. Staff**	**19,4%**
Equipment complement	25,0%	**RTT**	**37,8%**
Other	15,0%	Training and professional development	39,3%

Maintenance	5,0%	Communication within and across disciplines	3,6%
Immobilization/beam modifier/ applicators/mould room	**14,6%**	Complement	21,4%
		Distribution	14,3%
Equipment quality control	66,7%	Education	7,1%
Quality of facility or equipment	26,7%	Other	10,7%
Equipment complement	6,7%	Remuneration/Recognition	3,6%
RT imaging	**11,7%**	**All staff**	**27,0%**
Treatment planning system	**8,7%**	Training and professional development	30,0%
Dosimetry	**5,8%**	Communication within and across disciplines	55,0%
Other	**3,9%**	Complement	10,0%
RT data management system/ R&V	**2,9%**	Distribution	5,0%
		Radiation oncologist	**12,2%**
		Other	**12,2%**
		Medical physicist	**10,8%**

Of the process recommendations, one quarter concerned the overall optimisation of the clinical process and the development of Standard Operating Procedures (SOP) impacting multiple clinical processes (i.e.: optimisation of hygiene procedures, harmonisation of treatment techniques). Fourteen percent related to the treatment planning process and highlighted the need to increase the number of verifications that are carried out (i.e.: independent verification of generated treatment plans). Fifteen percent concerned the treatment verification/imaging process and mostly pertained to ameliorating Image Guided Radiotherapy (IGRT) procedures (i.e.: use of online co-registration).

One-third of the recommendations targeting infrastructure focused on structural features of the facility and the treatment machines (i.e.: accessibility and layout of the department, age of the equipment). A little less than 10 % of infrastructure recommendations focused on the need to increase the quality control procedures on the immobilisation systems, as a great majority of departments do not carry out regular checks on the immobilization equipment.

The recommendations focusing on the department organisational aspects were mostly addressing issues pertaining to the development of organisational charts (or lack thereof), the instauration of a paperless environment as an additional system of protection against the propagation of mistakes and the amelioration

of feedback concerning incidents and near-incidents. It is also important to note, that 13.3% of the organisational recommendations concerned the lack of systematisation of patient follow-up.

Finally, 37.8% of the recommendations relating to staff focussed on the RTT staff and pointed out the lack of training and professional development accessible to this professional group. The lack of communication within and across disciplines amongst all staff was also pointed out in 15% of the recommendations.

As previously mentioned, audit follow-up questionnaires were sent to all departments. Twenty-two out of the 25 audited departments responded to these questionnaires. Of the three missing departments, one did not officially respond as, in the meantime, it had merged with another department to become a single department.

Fifty-four percent of the departments evaluated the audit's recommendations as being globally very useful while the remaining departments perceived the recommendations as being moderately useful (one department did not score this element). When scoring the perceived usefulness of each individual recommendation, 42.7% were found to be very relevant with a median overall score of 2, which amounts to a mean score of 2.2 ± 0.4 (Figure 6). Of all recommendations pertaining to infrastructure, the largest part (38.2%) was deemed to be moderately relevant. Conversely, those recommendations pertaining to staff, process and department organisational matter were most frequently scored as being very relevant (45% of recommendations) (Figure 7). The recommendations' relevancy scores significantly varied from one department to another ($p < 0.05$). Yet, the type of emitted recommendation did not have an influence on the relevancy score ($p = 0.993$).

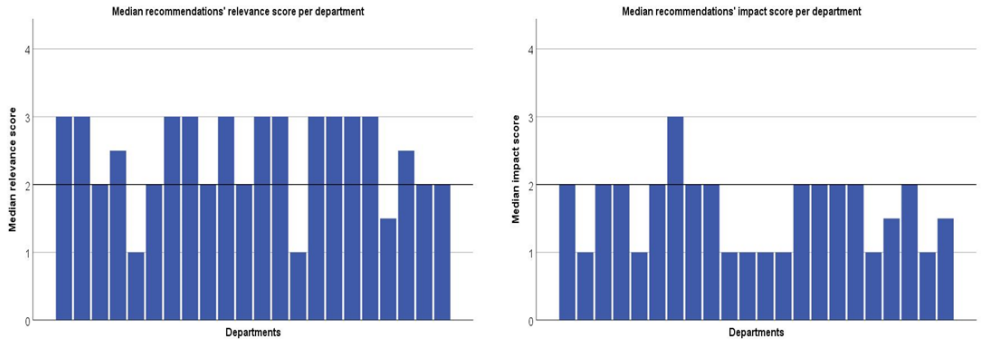


Figure 6 - Recommendations' relevance (left) and impact (right) median score as evaluated per department.

When scoring the actual impact the individual recommendations had on the department, 23.6% were deemed to have an important impact, while the largest part was scored as having a moderate impact (30.7%) (Figure 7). Not unlike the relevancy score, the median overall impact score was evaluated at 2 with a mean score of 1.6 ± 0.4 (Figure 6). Recommendations deemed to have the most impact were those pertaining to process optimisation. Unlike the relevancy score, the recommendations' impact score did not vary from one department to another. Nonetheless, as with the relevancy scores the type of emitted recommendation did not have an influence on the impact score ($p = 0.41$) (Figure 7).

In all cases, the relevancy and impact score were not influenced by the elapsed time that had occurred between the time the department was audited and the time of the questionnaire ($p = 0.3$ and 0.8 respectively).

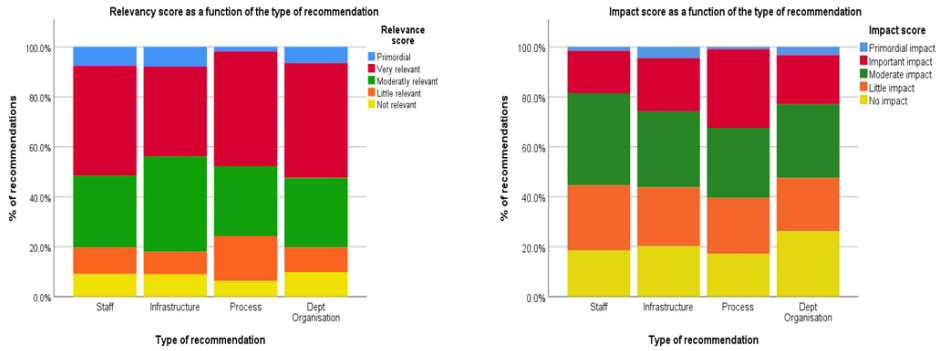


Figure 7 - Distribution of the relevance [left] and impact [right] score as a function of the level one classification of the emitted recommendations.

2.4 Discussion

Peer reviewed clinical audits of radiation oncology departments have been carried in a number of departments using QUATRO [39,43] or other methodologies such as IROCA and locally developed audits [97,98]. However, the situation in Belgium is unique in that these clinical audits have been successfully implemented on a national basis and identically carried out in all departments, even though variation does exist among different departments (i.e.: number of patients treated, academic or non-academic based department….). This underlines the fact that the QUATRO audit can be used in divergent environments and is, as such, a widely applicable methodology.

All 25 Belgian radiation oncology departments have been audited between 2011 and 2015, resulting in the formulation of 381 recommendations, but with the overall conclusion that all radiotherapy department were functioning with a harmonious approach to continuous quality improvement.

As expected, the majority of the recommendations focussed on clinical process optimisation since one of the main aims of clinical audits is to evaluate actual clinical practice [39,93].

The audits also highlighted the need for departments to address issues related to the quality of the facility or equipment. This is often outside of the control of the radiotherapy department itself and is thus mostly addressed at the hospital management level which itself faces limiting budgets and resources [99].

Lack of immobilisation equipment quality control procedures was also pointed out in forty percent of the departments. Contrary to treatment equipment, immobilization equipment-specific quality assurance programs are often overlooked in many departments for reasons that are quite nebulous but which can be due to lack of formal guidelines.

The recommendations focusing on organisational issues seem to point out the absence of clear organisational charts which formalize the hierarchical structure of the radiotherapy department as well as the staff responsibilities. The need to formally introduce backups for some key functions was also pointed out in 8 out of the 25 departments.

A significant amount of those recommendations also focused on the hierarchal position of the quality managers within the hospital. Indeed, since the advent of the National Cancer Plan in Belgium, each radiotherapy department has received

the financial support to hire one full time equivalent (FTE) quality manager (RT-QM) within its department. Practically speaking, RT-QMs come with different backgrounds although a majority do have a radiotherapy background (MP or RTT). As such, there is tendency to position these under the hierarchal responsibility of the head RO or head MP. Yet, good practice stipulates that a QM – in order to best practice its functions – should hierarchically be independent of the radiotherapy department.

It is worthwhile to mention that fewer recommendations were formulated relating to quality management system implementation than in other publications [39,43], which could partly be explained by the presence of one RT-QM in every radiotherapy department. It is important to note, though, that sixteen percent of the organisational recommendations highlighted the need to improve feedback of declared near-incidents and incidents to the department.

A significant number of recommendations (13.3%) addressed the lack of systematisation in patient follow-up after radiotherapy delivery. These mostly pertained to the lack of formal policies, specifically for high-risk patients, but also underline the necessity of using formal scores for acute and late toxicities follow-up. An alternative approach that could be introduced to tackle this issue is the use of surveillance programs directed by patient symptoms (Patient Reported Outcome Measurements (PROMs)). These would formalize the scores used as well as identify patients who experience significant side effects compared to those that do less and do not necessity require formal face-to-face radiotherapy follow-up with the RO [100–103]. Acute and late toxicity follow-up and clinical impact of radiotherapy treatment modalities are essential elements to monitor, amongst others, the "quality" of radiation treatments. This has been recognized by the College of Physicians in Radiation Oncology which, through the implementation of a national Quality Indicator project, aims at standardising the collection of toxicity data on a national level, while quantifying the quality of radiation treatments.

The recommendations focusing on staff were mostly addressed to the RTT staff and pointed out the lack of training and professional development of the RTTs. This observation is not unlike those observed by the publications of Rosenblatt et al. and Izewska et al. [39,43]. Unfortunately, this is mostly due to the lack of sufficient and dedicated training programmes for the RTTs working in radiotherapy: the Belgian law still stipulates that a nursing degree with no

supplementary radiotherapy-specific training is required (with the exception for 50 hours of radioprotection training). Although school-based or national society-based training programs have been developed to tackle this issue, the absence of a legal framework to encourage formal RTT training and continuing education remains a weak point in the education of Belgian RTTs.

Following the first cycle of audits, it was deemed of importance to obtain the audited departments' feedback of the usefulness, relevancy and potential impact of the audits. Without this feedback, the potential benefits of the audit might have been overlooked. The departments' feedback actually demonstrated that the audits were considered to be overall useful and that the resulting recommendations were, in the majority of cases, very relevant to the department. The actual impact of the emitted recommendations obtained a lower score. Indeed, an important number of clinical processes and clinical practices cannot be compared to formal standards and are, as a result, compared to what is considered to be "best practice". This means that there exists a certain level of subjectivity in the auditing process which can be and was indeed questioned by different entities. The actual impact of a clinical audit can therefore be influenced by factors such as how the audit is perceived by the audited department or hospital management. This can be further influenced by the actual quality of the feedback and report given by the auditors, but also by the establishment of a clear (and feasible) action plan by the department itself [104,105]. As such, the recommendations have to be used by the department in a quality improvement setting, in which an action plan is determined, put into place, evaluated and adjusted for [106,107].

The comprehensive, clinical and "patient-oriented" character of the QUATRO audits confers undeniable advantages. But it is also important to recognize that clinical audits need to evolve in accordance with changing practice and changing standards of care. It has become apparent, over the five-year auditing cycle that treatment modalities and treatment techniques greatly evolve over time. Within this context, it was decided to suspend the audits between 2015 and 2016 in order to review the existing QUATRO tool taking into account the Belgian context, the evolution of standards of care and the facilitation of the auditing process. In addition, an internal initiative of the association of the Belgian RTQM highlighted the need for developing certain parts of the QUATRO

audits in order to optimize the evaluation of quality management systems and this similarly to an initiative in France (QMS) [3,108].
Based on this, an adapted version of the QUATRO – a B-QUATRO tool – was created, which has been used in the second cycle of audits which started in 2017. Currently, 10 Belgian departments have been audited using this methodology.

2.5 Conclusion

In conclusion, peer-reviewed clinical audits based on the QUATRO methodology have been successfully implemented in Belgium with all radiation oncology departments having been audited between 2011 and 2015. Revisions of the emitted recommendations stated in the audit reports have allowed the auditors to encourage departments to optimize their clinical practice but also to identify some elements needing to be improved on a national basis. These include increasing the training level of the RTTs, enhancing the feedback and communication related to incident reporting, developing formal follow-up systems for radiotherapy patients and initiating quality assurance programs for immobilisation equipment.
When obtaining feedback from these audits, the majority of the departments evaluated the recommendations as being very useful and relevant. However, the global impact on the department's organisational and infrastructural situation was slightly lesser valued, partly due to factors outside of the department's control.
Encouraged by this analysis, a second cycle of audits has started in Belgium with a modified QUATRO document (B-QUATRO).

Chapter 3

"If you can't measure it, you can't improve it."

- Lord Kelvin

CHAPTER 3: QUALITY INDICATORS

Radiotherapy-specific quality indicators at national level: How to make it happen.

Vaandering A, Jansen N, Weltens C, Moretti L, Stellamans K, Vanhoutte F, Scalliet P, Remouchamps V, Lievens Y; Belgian College for Physicians in Radiation Oncology. Radiotherapy-specific quality indicators at national level: How to make it happen. Radiother Oncol. 2023 Jan;178:109433. doi: 10.1016/j.radonc.2022.11.022.

ASBTRACT

Purpose /objective: To promote best practice and quality of care, the Belgian College of Physicians for Radiotherapy Centers established a set of radiotherapy specific quality indicators for benchmarking on a national level. This paper describes the development, the collected QIs, the observed trends and the departments' evaluation of this initiative.
Material and methods: The Donabedian approach was used, focussing on structural, process and outcome QIs. The criteria for QI selection were availability, required for low-threshold regular collection, and applicability to guidelines and good practice. The QIs were collected yearly and individualized reports were sent out to all RT departments. In 2021, a national survey was held to evaluate the ease of data collection and submission, and the perceived importance and validity of the collected QIs.
Results: 18 structural QI and 37 process and outcome parameters (n = 25 patients/pathology/department) were collected. The participation rate amounted to 95 % overall. The analysis gave a national overview of RT activity, resources, clinical practice and reported acute toxicities. The individualized reports allowed departments to benchmark their performance. The 2021 survey indicated that the QIs were overall easy to collect, relevant and reliable. The collection of acute recorded toxicities was deemed a weak point due to inter-observer variabilities and lack of follow-up time.
Conclusion: QI collection on a national level is a valuable process in steering quality improvement initiatives. The feasibility and relevance was demonstrated with a high level of participation. The national initiative will continue to evolve as a quality monitoring and improvement tool.

3.1 Introduction

There has been a growing interest in defining and collecting quality indicators (QI) that can guide healthcare programs, institutions and departments in monitoring and improving the quality of care provided to patients. A clear definition and continuous collection of QIs allows for the monitoring of performance over time.

Even more, centres or countries can compare their results with others through the process of benchmarking if QIs are collected on a multicentric or multi national basis [52–54,109]. Through this process, it is possible to identify gaps in practice and to put into place improvement actions that favour the delivery of best-quality care.

This increased interest for QIs is also evident in the field of oncology and even more specifically the field of radiation oncology (RO)[56–61,110,111]. RO involves a complex and multi-step process that calls for the development of a thorough quality assurance program within a quality management system that promotes continuous quality improvement through audits, risk assessment and QIs [19,27]. Deploying a quality assurance program locally, within a department, can be facilitated by regional or national incentives. In Belgium, for instance, the College of Physicians for Radiotherapy Centers (later referred to as "the College") is a committee mandated by the Belgian Federal Government, whose mission is to improve the quality of radiotherapy delivered in Belgium. In order to carry out this mission, the College is allocated a yearly budget, based on an application estimating the operational costs to run the projects. The College is composed of a board of 8 radiation oncologists, nominated by the RO professionals and validated by the Belgian Federal Public Health Service. Additional experts are invited to participate to the meetings, including other radiation oncologists based on specific expertise, as well as medical physicists, radiation therapists and quality managers. All participants collaborate on a voluntary basis.

Over the past decades, the College has been successful in implementing and supervising a number of quality improvement initiatives, including the organisation of national delineation intervision projects, structured incident reporting using the PRISMA-RT methodology, national peer review clinical audits based on the IAEA QUATRO methodology and external dosimetry

audits (BeldART) [75,78–80,85,86,95,112]. Within this multifaceted national program of quality assurance and improvement, a Belgian RO-QI project was launched, with the aim to define radiotherapy-specific QIs that could be collected in all RO departments in the country.
This paper describes the development of the project, the definition of the QI data set and how data were collected by and reported to the participating centres. Beyond presenting some high-level data that were collected, illustrating the most important trends observed across RO departments in Belgium, an evaluation of the value of this national QI initiative, as perceived by the participating departments, is presented.

3.2 Materials and methods

In 2015, following the national requirement to collect quantitative data annually, the College members started the development of the Belgian RO-QI program. The aim was to generate data to evaluate Belgian RO practice in the context of established guidelines of good clinical practice and to provide feedback to individual centres to improve their practice. Figure 8 provides an overview of the different steps undertaken in the Belgian RO-QI project.

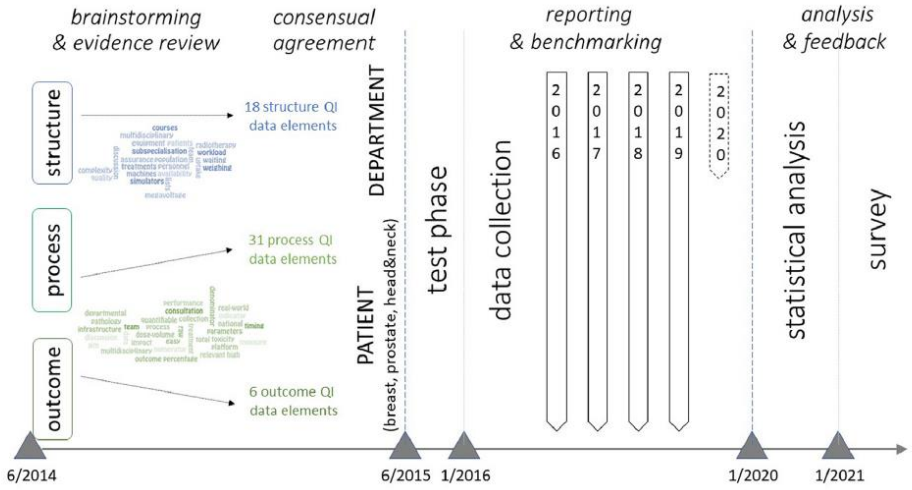


Figure 8 - Overview of the different steps undertaken in de Belgian RO-QI project.

Development of the QI data set

After an initial brainstorming session in June 2014, it was decided to follow the Donabedian methodology to define a set of QIs. This is a well-known model that provides a framework for healthcare quality evaluation based on information collected from three different dimensions of care: structure, progress and outcome [47,113]. For each dimension, a small group of experts composed of radiation oncologists, medical physicists and quality managers was appointed to review available evidence. The 'structure group' focused on radiotherapy utilisation, availability of human and capital resources, workload and treatment complexity, largely based on information from the ongoing Health Economics in Radiation Oncology (HERO) project of the European Society of Radiation Oncology (ESTRO) and references from the International Atomic Energy Agency (IAEA) [17,114–119]. The 'process group' worked on the concept of collecting indicators that would allow defining the gap between the actual and optimal clinical practice, mainly focusing on available reports from France and The Netherlands [120,121]. The 'outcome group' suggested a set of clinical parameters with a focus on acute toxicity, selected from the Common terminology Criteria for Adverse Events (CTCAE) [122].

Following two rounds of review and discussion by the entire College, a definitive set of QIs was agreed upon through consensual agreement. This set tried to strike the right balance between the desire to collect a large number of data and the recognition of the practical limitations and data availability within the departments: besides structure indicators pertaining to the departmental level, patient-level QIs were defined for process and outcome, limited in number and pathology (breast, prostate and head-and-neck cancer).

Collecting QI data at national level

Once the QIs were agreed upon, a test phase was launched in June 2015, collecting the full set of structural QIs, but limiting the patient-specific QIs to a restricted number of patients (n = 5 per pathology/department). This was done by sending forms (Microsoft Access, 2007–2010) to all Belgian RO departments. This preliminary step allowed to validate the feasibility of collecting the required data but also to refine some of the requested data elements in order to obtain homogeneous and consistent records.

Once the data collection form validated, a broader capture of process and outcome QIs was started in 2016 (n = 25 patients/pathology/department, randomly picked and ideally consecutive) along with the structural QI data. This number was defined balancing feasibility at departmental level with the generation of a considerable dataset nationwide that would allow for the formulation of meaningful observations and trends. This data capture, initially using Microsoft Access, was transferred in 2017 into RedCap's (Research Electronic Data Capture) web-based software platform [123,124]. Data collected were encoded into RedCap through a department-dedicated link, provided to the department's quality manager and the head of department.
QI collection of all primary accredited Belgian RO departments was performed on a yearly basis. In 2015, this amounted to 25 departments, but following the fusion of two departments, this became 24. Eight departments operate satellite sites and these were also included in the data collection process (13 satellite sites in 2016 that decreased to 11 in 2020) – two of which participate in the QI project independently from their primary site [69].

Data analysis

The collected data were centralised and analysed in Microsoft Excel (2016 MSO), to generate both a global yearly report for the Federal Public Health Service and individualized and anonymized benchmarking documents, in which the departments can identify their performance compared to the other Belgian departments.
This work was carried out by a quality manager dedicated for 0.3 full time equivalent to the College's QI project and clinical audits' organisation. Descriptive statistics were used to summarize both the individual department's and national data with most findings summarized in graphical format to allow for overall visualisation of the department's data versus the national trends.

Feedback on the QI project

In 2021, a survey sent out to the Belgian RO community evaluated the usefulness of the project, the ease of the data collection and the perceived importance and scientific validity of the collected QIs. This survey, consisting of 52 questions, was generated in REDCap and sent to all accredited Belgian RO departments in January 2021 including the 2 satellite sites that independently

participated in the project (n = 26). The data was extracted into Microsoft Excel for data analysis (Microsoft Excel, 2016 MSO).

3.3 Results

After validation through the feasibility test phase, a data set consisting of 55 QIs was defined, to be collected on yearly basis (see Table 3 and Table 4). This is composed of 18 structural QIs and 37 process and outcome site-specific QIs: 11 process and 1 outcome QI for breast, 11 and 2 for prostate and 9 and 3 for H&N cancer, respectively. Site-specific QIs were collected for 25 patients per pathology and per department - of which outcome QIs focused on acute toxicities.

The complete QI dataset was collected on a yearly basis from 2016 until 2019 with a mean overall participation rate of 95 % of all RO departments (24 primary departments). Sixteen of the 24 departments were actively involved in the QI project on a yearly basis; departments that did not clarified that this was mostly due to the lack of a quality manager within the department and/ or lack of time. Two departments were unable to collect data on 25 H&N cancer patients due to the limited number of patients treated in their department. For those departments that participated and for all included patients, there was a 98,8% QI data completion rate.

The majority of data from the satellite sites was collected through the primary departments. In most cases, satellite site activities are an integral part of the primary department's activities.

In 2019, 2 satellite sites requested to have their own data collection and benchmarking documents. During that same year, one department stopped collecting patient-related QIs and in 2020, it was decided to pause the collection of patient-specific process and outcome QIs in order to allow for a thorough analysis of the data. All departments participated to the 2020 set of structural QI data.

Table 3 - Structural Quality Indicators

Quality Indicators	Element measured
External beam radiotherapy (EBRT)	
Equipment availability	Number of EBRT equipment available per department
Mean age of EBRT equipment	Overall age of the available EBRT equipment
Type of radiation available on EBRT equipment	The types of radiation available on the EBRT equipment (photon/electron/both)
Equipment capable of Intensity Modulated Radiotherapy (IMRT) delivery	Number of equipment capable of IMRT delivery
Type of Image Guided radiotherapy (IGRT) available on equipment	Number of equipment capable of different types of IGRT (kV, MV, volumetric..)
EBRT treatments delivered	Number of EBRT treatments delivered
EBRT sessions delivered	Numbers of EBRT sessions(=fractions) delivered
Sessions per EBRT treatment	Average number of sessions (=fractions) delivered per EBRT treatment
Used EBRT treatment technique	Proportion of types of treatment techniques used per department (2D, 3D, static IMRT, volumetric IMRT, stereotactic)
Brachytherapy treatments (BT)	
BT activities	Number of BT treatments per department
Type of BT equipment	Types of BT equipment available (manual/manual afterloading/remote afterloading)
Used Isotopes in BT activities	Type of isotopes used per indication per department
Application types in BT activities	Types of applications used in BT activities (intracavitary, interstitial, other)
Used applicator types in BT activities	Types of applicators used in BT activities (strand of seeds, mini-cylinders, wire…)
Used operation modes	Type of delivery mode used in BT activities
Intraoperative radiotherapy (IORT)	
IORT activities	Number of IORT treatments per department
Human resources	
Staffing levels	Number and full time equivalent of staff (radiation oncologists, medical physicists, Radiation Therapists, quality managers) available per department
Radiation Oncologist (RO) specialisation	Level of pathology-specific expertise/RO

(EBRT: External Beam Radiotherapy / IMRT: Intensity Modulated radiotherapy/ IGRT: Image guided radiotherapy/BT: Brachytherapy/IORT: Intraoperative radiotherapy/RO:

Table 4 - Patient-related process and outcome Quality Indicators, per pathology.

Quality Indicators	Element measured	Type of QI
Breast cancer patients *(excluding breast external radiotherapy treatments (EBRT) requiring nodal irradiation or bilateral breast irradiation; excluding patients benefiting from intra- operative radiotherapy (IORT) or brachytherapy)*		
Discussion in multidisciplinary (MTD) meeting	Use of MTD for patient discussion (and availability of data)	Process
Timely delivery of treatment after simulation	Time necessary to deliver the first fraction of the EBRT treatment after simulation	Process
Timely delivery of the treatment	Time required to complete the EBRT treatment as a function of the number of fractions prescribed	Process
Used treatment techniques	Proportion of treatment techniques used for breast patients	Process
Used image guided radiotherapy (IGRT) techniques	Proportion of IGRT techniques used for breast patients	Process
Use of respiratory motion management techniques	Proportion of left breast patients for which respiratory motion management technique is used	Process
Use of prone position	The use of the prone position for the EBRT treatment of breast cancer patients	Process
Used fractionation scheme	Dose prescribed to the high dose PTV and the boost considering the use of SIB the number of fractions, the dose per fraction and the total dose (+ frequency at which it is delivered)	Process
Use of concomitant systematic therapy	Use of concomitant systematic therapy	Process
D2 of target volume (breast)	Measured D2 of CTV (=PTVeval) of breast (Gy) on treatment plan	Process
Mean heart dose	Measured mean heart dose evaluated on treatment plan	Process
Breast acute toxicity grading (radiodermatitis)	Reported maximum acute radiodermatitis grading for breast cancer patient treated with EBRT only	Outcome
H&N Cancer patient *(excluding T1N0 glottis)*		
Discussion in multidisciplinary meeting	Use of MTD for patient discussion (and availability of data)	Process
Timely delivery of treatment after simulation	Time necessary to deliver first fraction of EBRT treatment after simulation	Process
Timely delivery of the treatment	Time required to complete the EBRT treatment as a function of the number of fractions prescribed	Process
Used treatment techniques	Proportion of treatment techniques used for H&N patients	Process
Used IGRT techniques	Proportion of IGRT techniques used for H&N patients	Process
Used fractionation scheme	Dose prescribed to the high dose PTV and the boost considering the use of Simultaneous Integrated Boost (SIB), the number of fractions, the dose per fraction and the total dose (+ frequency at which it is delivered)	Process
Use of concomitant systematic therapy	Use of concomitant systematic therapy	Process
Mean homolateral parotid dose (Gy)	Measured homolateral mean parotid dose on treatment plan	Process
Mean controlateral parotid dose (Gy)	Measured controlateral mean parotid dose on treatment plan	Process
H&N acute toxicity grading (mucositis)	Reported maximum acute mucositis grading for H&N cancer patient treated with EBRT only	Outcome
H&N acute toxicity grading (radiodermatitis)	Reported maximum acute radiodermatitis grading for H&N cancer patient treated with EBRT only	Outcome
H&N acute toxicity grading (weight loss)	Reported weight loss for H&N cancer patient treated with EBRT only	Outcome

Prostate cancer patients *(Excluding patients with prostatectomy* *Excluding patients also benefiting from brachytherapy treatment to the target volume)*		
Discussion in multidisciplinary meeting	Use of MTD for patient discussion (and availability of data)	Process
Timely delivery of treatment after simulation	Time necessary to deliver first fraction of EBRT treatment after simulation	Process
Timely delivery of the treatment	Time required to complete the EBRT treatment as a function of the number of fractions prescribed	Process
Used treatment techniques	Proportion of treatment techniques used for prostate patients	Process
Used IGRT techniques	Proportion of IGRT techniques used for prostate patient	Process
Use of implanted fiducials	Use of fiducial markers for prostate EBRT treatments	Process
Daily Online correction	Frequency at which daily online IGRT corrections are used	Process
Used fractionation scheme	Dose prescribed to the high dose PTV and the boost considering the use of SIB the number of fractions, the dose per fraction and the total dose (+ frequency at which it is delivered)	Process
Use of concomitant systematic therapy	Use of concomitant systematic therapy	Process
Rectum V50	Measured rectum V50 (%)	Process
Documentation of toxicity grading	Proportion of prostate cancer patients treated with EBRT for which there is a recorded toxicity grading	Process
Prostate acute toxicity grading (cystitis)	Reported maximum acute cystitis grading for prostate cancer patient treated with EBRT only	Outcome
Prostate acute toxicity grading (proctitis)	Reported maximum acute proctitis grading for prostate cancer patient treated with EBRT only	Outcome

EBRT: External Beam Radiotherapy / IMRT: Intensity Modulated radiotherapy/ IGRT: Image guided radiotherapy/BT: Brachytherapy/IORT: Intraoperative radiotherapy/RO: Radiation Oncologist/ MTD: Multidisciplinary meeting/ SIB: Simultaneous Integrated boost/PTV: Planning Target Volume/CTV: Clinical Target Volume

Data analysis of the collected data and QIs generated department-specific reports sent to each department for inter-department benchmarking. An example of an analysis is illustrated in Figure 9, in which the number of days lost during treatment delivery for H&N cancer patients are shown. Large inter-department variations can be observed. It was found that some departments favor compensating external beam radiotherapy interruptions (e.g. machine breakdown, maintenance) with twice daily fractionation doses schemes, while others do not adapt scheduling.

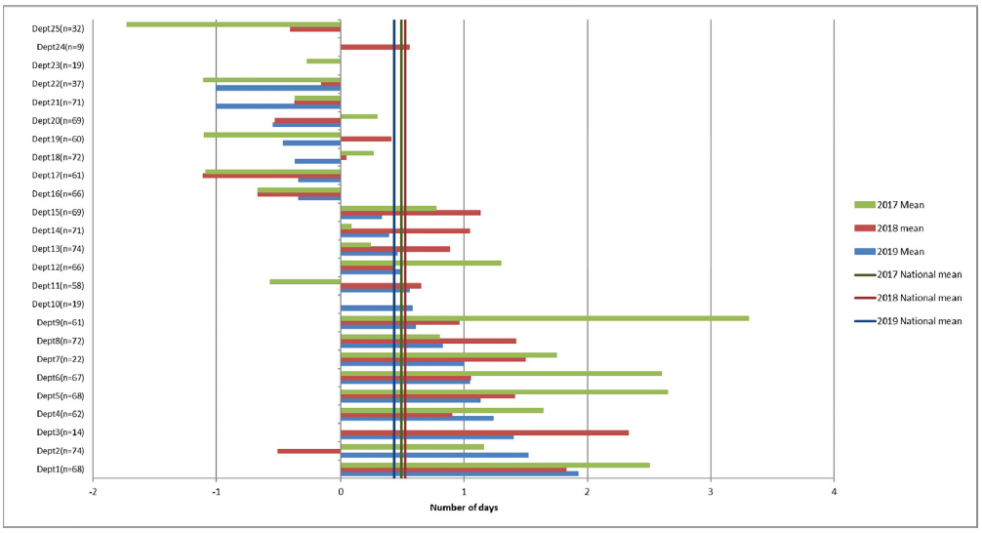


Figure 9 - Mean number of days lost in the delivery of EBRT treatment for H&N cancer patients per department from 2017 to 2019 (n = sum of the number of patients included in the analysis of 2017, 2018 and 2019))

Organisational and clinical practice trends were observed over time, communicated to the departments through the benchmarking report and during annual College and department heads meetings. The observed national trends are synthesized in Table 5.

Table 5 - National trends observed between 2016-2020 for the structural QIs and 2016-2019 for the process and outcome QIs

Structural QI (2016-2020)	**Process QI and outcome QI (2016-2019)**
Increasing overall number of EBRT treatments delivered, by 1%.	**Breast cancer patients**
Decreasing mean number of sessions/treatment (movement towards hypofractionation)	Trend towards more hypofractionation The use of static IMRT has overtaken 3D conformal treatments
Increasing use of IMRT and increasing number of stereotactic treatments	Low and decreasing proportion of patients affected by grade 2[1] radiodermatitis (from 20% of patients to 10% patients)
Stable workload of staff, although the number of sessions/RTT seems to have decreased (hypofractionation)	**Prostate cancer patients**
	Evolution towards hypofractionation (most importantly between 2018 and 2019) The use of volumetric IMRT and daily IGRT have become the norm Low and stable proportion of patients with proctitis grade 2 (10%) Moderate and stable proportion of patients with cystitis grade 2 (20%) Rare grade 3 and 4 cystitis (in less than 1% of patients)

	H&N cancer patients
	Stable fractionation schemes with a majority of treatments being delivered with 30-35 fractions
	The use of rotational IMRT has become dominant (80%)
	Decreasing percentage of grade 3 mucositis (-10%) Decreasing grade 2 and grade 3 radiodermatitis Stable proportion of patients suffering from grade 3 weight loss (5%)

(EBRT: External Beam Radiotherapy / IMRT: Intensity Modulated radiotherapy/ IGRT: Image guided radiotherapy)

Regarding the questionnaire sent in 2021 to obtain departmental feedback on the national QI project, 23 of the 26 (24 primary departments + 2 satellite sites) contacted departments responded.

Impact of QI project: Nine departments (38,5%) stated that the QI project stimulated a change in organisational practice, i.e. by favouring an increase of staff numbers and data centralization, necessary for QI monitoring. Five departments (22 %) stated that the project had an impact on their clinical practice with changes in fractionation schemes and treatment techniques used (i.e. implementation of breathhold techniques) and decreasing process times (e.g. between simulation and treatment start, overall treatment times). The QI project also stimulated better documentation of toxicities. All departments except one found the personalized yearly report of use to compare their performance levels to other departments/ national trends.

Ease of data collection: Most data elements where considered easy to collect, although some departments expressed difficulty in collecting full time equivalent figures for staff (complicated by long medical absence or maternity leaves) and the actual number of fractions delivered on a yearly basis. Patient-specific data was also deemed quite easy to collect, although some difficulty was expressed in collecting data on the use of systemic therapy and dates of the multidisciplinary team meetings (MDT) – mostly in sites where these activities are held outside of the radiotherapy department's organisation. Furthermore, access to patient toxicities was often hindered by the fact that this is not always found in a well-structured manner in the health records.

Importance of collected QIs (Figure 10A): All collected structural, process and outcome QIs were considered important to monitor, although questions arose concerning the workload parameter (number of treatments

(sessions)/professional group), estimating that workload cannot solely be captured by the number of treatments/ professional group. It was considered of less importance to monitor the use of MDTs as this is a national requirement.

Reliability of collected QIs (Figure 10B): All data collected for the estimation of QIs were deemed reliable except for the documentation of acute toxicities, as the sample size was limited and there seemed to be significant inter-departmental differences in toxicity grading.
Furthermore, some higher toxicity grading appearing after radiotherapy treatment delivery may not have been captured due to unavailability of patient follow-up data.

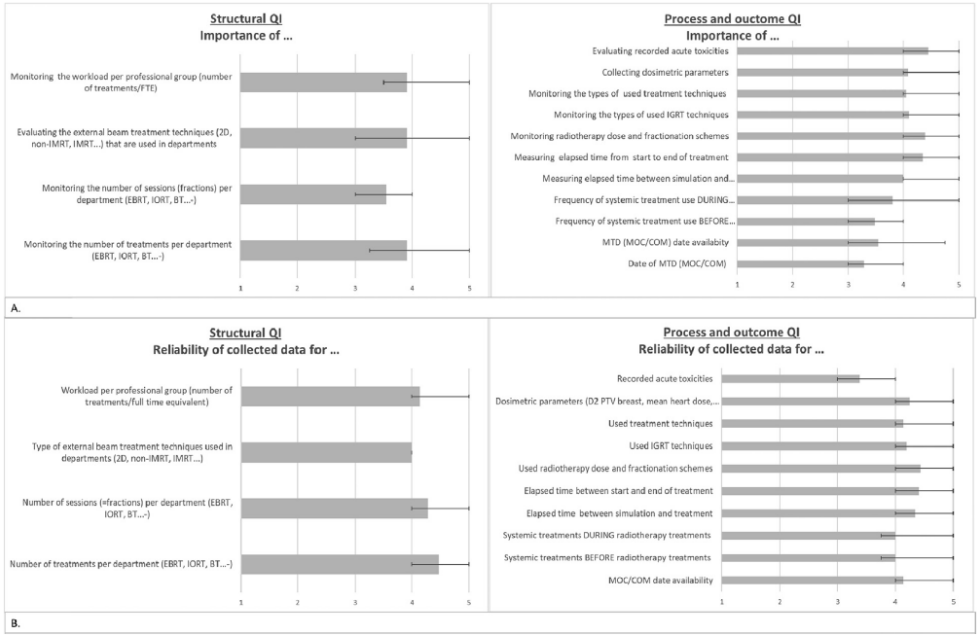


Figure 10 - Departments' evaluation of the level of importance of the collected QIs and of the level of reliability of the collected data (A) Departments' mean evaluation of the level of importance of the collected QIs (1- Not important; 5 - Very important). Error bars represent the interquartile range; (B) Departments' evaluation of the reliability of the data collected for the different QIs (1 – Not at all reliable; 5- Completely reliable). Error bars represent the interquartile range

All participating departments agreed that the national QI project should continue. Half of them suggested that adjustments would be needed, e.g. integrating Patient Reported Outcome Measures (PROMS) and favoring data

extraction automation to allow more patients and pathologies to be included in the project.

3.4 Discussion

Measuring the quality of care, using QIs, has in past decades slowly seeped into the healthcare setting with the aim to evaluate structures and processes impacting patient care and outcome [44,48]. Numerous publications have focused on the field of oncology, yet typically with a global vision on the oncological pathway of the patient and with little focus being attributed more specifically to radiotherapy [59]. As such, there has been a growing interest in defining radiotherapy-specific QIs that can be measured both locally and at a multicentric level and that can guide radiation oncology departments in setting up quality improvement initiatives. While several publications have mostly focussed on the development of general QIs [60,61,111,125,126], others have targeted disease-specific QIs with a focus on developing process QIs [110,127–132].

In Belgium, the development of radiotherapy-specific QIs has been recommended by the federal government, in the context of the National Cancer Plan, to help radiation oncology departments further optimise the quality of the delivered care. This task was embraced by the Belgian College of Physicians for Radiotherapy Centers, which successfully developed a set of QIs, collected on a yearly basis from 2016 until now and adhered to by almost all radiation oncology departments. Although mandated by the federal government, participation of individual departments is on voluntary basis without financial incentives or disincentives. Equally high adherence is seen in other College initiatives (BeldART, intervision projects...)[73,78,79,112], suggesting a radiation oncology community strongly motivated to improve quality. Engagement of departments in this and other College projects is further stimulated by the organisation of yearly meetings in which the status of the College's projects is shared with department heads and their peers. Lastly, participation may have further been aided by the nature of the QIs themselves, defined using the SMART principle [133], and facilitated by the presence of quality managers in the radiation oncology departments. Indeed, since 2010, action 16 of the National Cancer Plan supports the financing of one quality manager per radiotherapy department [72]. The crucial role of dedicated quality managers in the implementation of

quality improvement initiatives and setting up a quality management system has previously been demonstrated [134,135].

The yearly collection and analysis of QIs is a first step towards capturing real-life data portraying actual clinical practice and its potential impact on patient outcome, outside the context of controlled research settings. Although the number of patients included in the site-specific QIs was restricted, its analysis over time demonstrated the progressive clinical uptake of literature evidence, such as the increasing use of hypofractionation in prostate and breast cancer, and the uptake of IMRT and breathhold techniques [136–142].

The recorded acute toxicities have also shown encouraging results, with higher-grade toxicities (≥3) typically being limited to 1 % of patients, except for dermatitis and mucositis in H&N patients.

Anticipating that radiotherapy parameters play an important role in toxicity - along with patient and tumour characteristics - analysis is currently underway to further elucidate the link between practice and outcome. While the number of patients for which data was collected was purposely chosen to not overburden departments with the data collection process, this may limit the analysis. A larger number of patients and moving towards big data analyses is the ambition, but can only realistically be undertaken with the automation of data extraction from existing radiotherapy information systems or hospital electronic health records [143–147].

This path is currently investigated in the Belgian landscape. In the meantime, it is either foreseeable to slightly increase the number of included patients or to collect QIs on a department-based level (e.g.: treatment technique generally used for a pathology and not collected on individual basis).

When defining QIs, it is important to clearly document the attributes of the measured QIs including its definition and specifications, rationale, inclusion/exclusion criteria and its goals [46,48].

It is also important to ensure that the collected QIs are reliable (=level of reproducibility) and valid (=level of accuracy) [148]. In this context, it is noteworthy that QI data were collected by the departments themselves, possibly introducing a risk of bias or subjectivity.

The introduction of an independent data quality check might be considered to eliminate or minimize this risk.

While the level of reliability of the data was not statistically tested using the recommended procedures, the departments' perception on data reliability was sought through a survey in 2021.

In general, the data collected were deemed reliable for most of the measured QIs, with the exception of the acute toxicities, which were considered too variable between RO professionals and departments, and not always in line with what can be expected from the literature. Hence, it is recommended to standardise the grading amongst participants, either using detailed guidelines or through the organisation of courses meant to harmonize practice.

Another way to overcome this possible bias is to introduce PROMS, in which patients themselves evaluate their physical and psychological well-being and quality of life, and that have been found reliable in capturing actual side effects [102,149]. Another limiting factor in the collection of acute toxicities is the variable timeframe in which they could be collected, again a pragmatic approach to limit collection burden. However, it is well-known that toxicities may still vary considerably between end of treatment and 1 month thereafter, especially in hypofractionated regimes. This limitation could again be tackled by the implementation of PROMS [150,151].

Similarly, the validity of the collected QIs has not been formally tested. However, as stated by the paper of Rubin et al., the validity of a QI can be assessed by "evaluating whether the measure represents the process domain of interest as judged by the audience of users" [148]. The 2021 survey demonstrates that the majority of QIs were felt to be valid to collect and monitor, with the exception of the MDT meetings and the use of systemic therapy.

After the successful implementation of this project, it is of importance to define the next steps of the project keeping in mind the above-mentioned limitations and potential for improvement. This will include the discussion of the QI's dataset with pathology-specific radiation oncology experts outside the College, and may require consulting stakeholders outside de field, such as data scientists, health economists, health service managers or patients. The review of the QI's dataset should also be based on the experience acquired by other teams involved in QI implementation and monitoring.

While other national QI initiatives do exist, it is not always an easy task to obtain a comprehensive view on all on-going initiatives. The creation of an international

platform allowing for the centralization of QI initiatives and their results should be considered to foster exchange of knowledge and best practice.

3.5 Conclusion

In conclusion, the monitoring and benchmarking of QIs is recognised as a valuable tool in the establishment and evaluation of quality improvement initiatives. The establishment of a QI project for radiation oncology in Belgium has been shown feasible to implement on a national level, resulting in a high participation rate amongst radiation oncology departments, who positively evaluated the project. The analysis of the collected QIs and the generation of personalized benchmarking documents have shown to guide departments in setting up quality improvement initiatives on a departmental level.
However, the foundation that underlies quality is that it is a continuously evolving improvement process, requiring a regular update of the clinical, technical and organisational needs. Moreover, QIs should be embedded in a broader quality management framework, also including incident reporting and peer reviewed clinical audits, as required by the Euratom directive [33,86]. In Belgium, the former is addressed by PRISMA-RT, the latter by the national implementation of B-QUATRO audits [86]. It has moreover become clear that taking the QI project to a higher level will require optimisation and automation of the data collection process, ideally including external data quality checks and the patient perspective through PROMs.

Chapter 4

"The goal of healthcare is not to maximize the number of procedures and tests we perform or to maximize profits. It is to maximize the health and well-being of the patients we serve."

- Dr. Donald Berwick

CHAPTER 4: QUALITY INDICATORS IN THE COVID-19 ERA

Impact of the COVID-19 pandemic on patients and staff in Radiation Oncology departments in Belgium: a national survey

Vaandering A, Ben Mustapha S, Lambrecht M, Van Gestel D, Veldmeman L. Impact of the COVID-19 Pandemic on Patients and Staff in Radiation Oncology Departments in Belgium: A National Survey. Front Oncol. 2021 Mar 19;11:654086. doi: 10.3389/fonc.2021.654086.

ASBTRACT

Purpose: COVID-19 reached Belgium in February and quickly became a major public health challenge. It is of importance to evaluate the actual impact of COVID-19 on patients and staff in Belgian radiation oncology departments (RTDs). This was evaluated through a weekly national survey sent to departments measuring key factors that were affected by the pandemic. Materials and **Methods**: The Belgian SocieTy for Radiation Oncology (BeSTRO) together with the Belgian College for physicians in Radiation Oncology invited all 26 RTD to participate in a survey that started on March 2nd and was re- submitted weekly for 4 months to assess variations in time. The survey focused on: (1) the COVID-19 status of patients and staff; (2) the management of clinically suspected COVID patients and COVID positive patients; (3) the impact of COVID-19 on RTD activities; (4) its impact in radiotherapy indications and fractionation schemes.

Results: Seventy-three percent of 26 RTDs completed the first survey and 57% responded to all weekly surveys. In the RTD staff, 24 members were COVID-positive of whom 67% were RTTs. Over the study period, the number of patients treated dropped by a maximum of 18.8% when compared to March 2nd. In 32.3% of COVID-positive and 54% of COVID suspected patients, treatment was continued without any interruptions. Radiotherapy indications were adapted within the 1st weeks of the survey in 47.4% of RTD, especially for urological and breast tumors. Fractionation schemes were changed in 68.4% of RTD, mainly for urological, breast, gastro-intestinal, and lung tumors

Conclusions: Between March and June 2020, the COVID-19 pandemic resulted in an important decrease in treatment activity in RTD in Belgium (18.8%). The COVID-19 infection status of patients influenced the continuity of the radiotherapy schedule. Changes in indications and fractionation schedules of radiotherapy were rapidly incorporated in the different RTD

4.1 Introduction

In December 2019, the Chinese authorities alerted the World Health Organization (WHO) that a cluster of pneumonia cases of unknown origin had been detected. The cause was quickly identified as being a novel coronavirus tagged as SARS-CoV-2 (COVID-19) [152]. Since then, the epidemic has become a pandemic with the global spread of COVID19 leading to RTD having to reorganise and reschedule their daily throughput in accordance with government and institutional recommendations. In parallel, national, American, and European scientific societies have issued recommendations to guide RTD in the management of certain types of cancer [153–155]. Many publications from severely touched COVID-19 regions like China [156], Iran [157], and Italy [90,158] also shared the techniques and strategies they set up to help ensure patient and staff safety in the context of the pandemic. On behalf of the Belgian SocieTy for Radiation Oncology (BeSTRO) and the Belgian College for Physicians in Radiation Oncology, we decided that it was important to monitor the impact of the COVID pandemic on RTD and their treatment activities. This was realized through a weekly survey that was sent out to all departments. This article presents the results of this multicentric Belgian radiotherapy data collection project, which includes monitoring the status of COVID testing for patients and staff, the impact of the pandemic on the number of treatments, the management of clinically suspected and COVID positive patients and the actual changes made to radiotherapy treatment indications and/or fractionation schemes.

4.2 Materials and methods

Survey Design and Data Collection

A 25-question survey was designed to be addressed to the 24 primary RTD in Belgium to investigate how they adapted to the COVID-19 pandemic. Two satellite sites were also independently contacted as their treatment data is separate from their main site. The questionnaire was designated in order to collect the following items:

- Covid-19 testing of RTD staff and patients
- Impact of COVID-19 on the number of radiotherapy treatments

- Impact of patient COVID-19 status on treatment delivery
- Changes in radiotherapy indications and fractionation schemes.

The questionnaire was built by the authors according to the published recommendations [156,159,160]. In order to assess the validity and appropriateness of the survey, the first draft was sent to a panel of radiation oncologists (coauthors) from different institutions. Their remarks and proposals were incorporated within the final survey. Only one answer per contacted RTD was allowed to avoid a data redundancy from a single institution. The initial survey was sent on April 14th 2020 in order to capture data from the week of March 2nd till the week of April 6th. A weekly follow up survey was then sent from the week of April 13th till June 22nd included in which the department was asked to complete the data for the week in question. Data was collected and managed using REDCap electronic data capture tools hosted at the Cliniques Universitaires St Luc. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies [123,124]. Since the investigation didn't focus on patients or animals and no clinical files were considered, the endorsement of the ethics committee was not requested. All the answers to the surveys were gathered from March 2nd until June 26th included. The survey was closed in June 2020 as the response rate was dropping and as the first COVID-19 wave died out.

Data Analysis

The collected data was exported from RedCap into a Microsoft Excel file (2018) and IBM SPSS Statistics for Windows, Version 26. Descriptive statistical analysis was carried out in both systems. Data extraction was carried out beginning of April and at the end of the data collection period. This allowed us to re-contact departments if data needed to be reviewed. But this also allowed us to give feedback to departments by sending them personalized reports in which they could visualize the data that was collected in their own department in comparison to national trends. For the analysis of the departments' treatment activity levels, the number of treatments recorded for the 1st week of the survey (week of March 2nd) was set as the baseline to which the following weeks were compared to.

4.3 Results

Twenty-one of the 26 RTD responded of which 19 departments completed the initial survey (73% participation rate). The number of respondents dropped over time with 15 departments completing the survey during the last week.

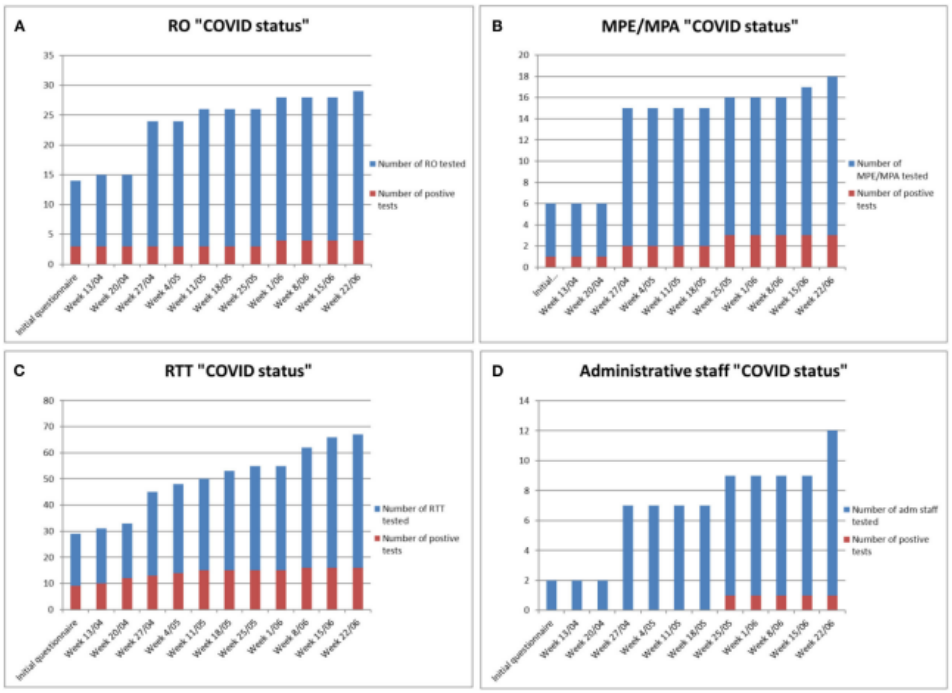


Figure 11 - Cumulative number of RTD staff members tested and number of staff tested positive for COVID-19: for (A) Radiation Oncologists (RO); (B) Medical Physics Experts (MPE) and Medical Physics Assistants (MPA); (C) Radiation therapists (RTTs) and (D) Administrative staff.

Among the 19 departments that responded were all 7 academic hospitals RTD (36.8%). The mean number of Linacs per department was 3.4 with a minimum of 1 and a maximum of 6 Linacs. The number of RTD staff members getting tested per week increased for all members of staff during the studied period, however the positivity rate seemed to stay quite low (Figure 11). At the end of the study period, overall, among 129 tested staff members, 24 were confirmed COVID-positive. This represents a positivity rate of 13.8, 16.6, 23.8, and 8.3% Radiation Oncologists (RO), Medical physics experts/medial physics assistants (MPE/MPA), radiation therapists (RTT) and administrative staff, respectively.

Based on the 2019 data collected in the framework of a national quality indicator project which, amongst others, collects national staffing level in RTD, this would amount to 3% of ROs being infected, 2% of MPEs & MPAs being infected, and 4% of RTTs being infected. The number of patients being tested increased from 124 patients in the initial questionnaire to 603 in the last week. Ninety patients were tested COVID-positive (15% positivity rate). The overall percentages of radiotherapy treatments decreased over the weeks (Figure 12) with a mean drop of 18.8% (Range: 2.5–45.4%) in the total number of treatments during the week of April 27th as compared to the number of treatments recorded for the week of March 2nd. During the studied period, there seems to be a decrease in the number of both curative and palliative treatments until the end of April 2020—at which time there is a sudden increase in the number of palliative treatments up to 18.2% as compared to the baseline week (Figure 13). The number of treatment starts per pathology was also collected over the studied period (Figure 14). The data collected seems to illustrate a drop in the number of treatment starts for all pathologies. More particularly, there was a drop in the number of treatment starts for lung, GI and "other" tumors from the week of April 20th until the week of May 18th. The other pathology groups show variations in activity over time. However, an increase in activity can be observed during the week of May 25th, in which the number of treatment starts for breast, urological, lung, brain, GI and "other" tumors suddenly increases.

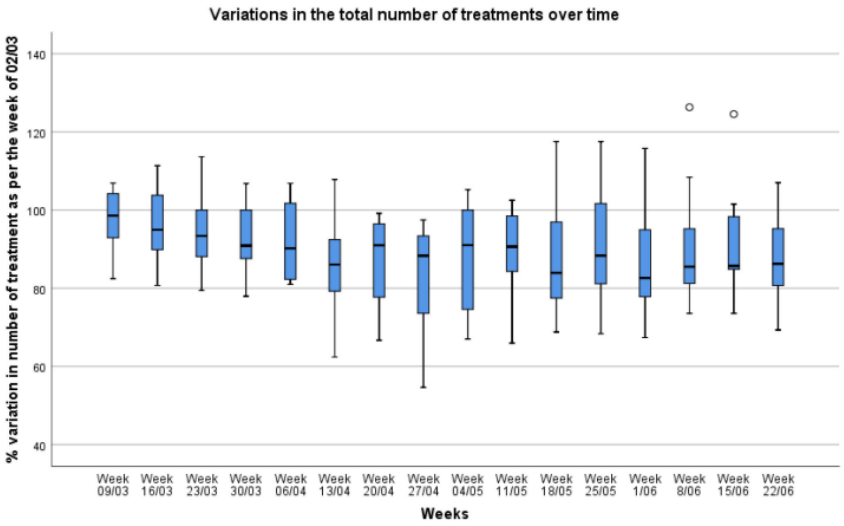
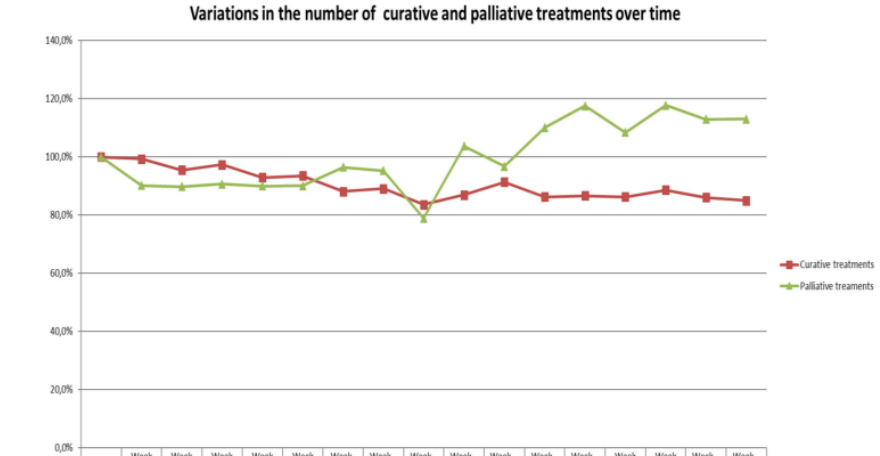


Figure 12 - Variations in the total number of treatments between March 9th and June 26th (assuming that the week of March 2nd is a week where there was a 100% activity level



	Week 2/3	Week 09/03	Week 16/03	Week 23/03	Week 30/03	Week 06/04	Week 13/04	Week 20/04	Week 27/04	Week 04/05	Week 11/05	Week 18/05	Week 25/05	Week 01/06	Week 08/06	Week 15/06	Week 22/06
Curative treatments	100,0%	99,3%	95,4%	97,3%	92,9%	93,5%	88,1%	89,1%	83,6%	86,9%	91,3%	86,3%	86,6%	86,3%	88,6%	86,0%	85,0%
Palliative treaments	100,0%	90,2%	89,8%	90,7%	89,9%	90,0%	96,4%	95,2%	78,9%	103,7%	96,7%	110,1%	117,5%	108,4%	117,7%	112,9%	112,9%

Figure 13 - Variations in the number of curative and palliative treatments over the studied period as compared to the week of March 2nd.

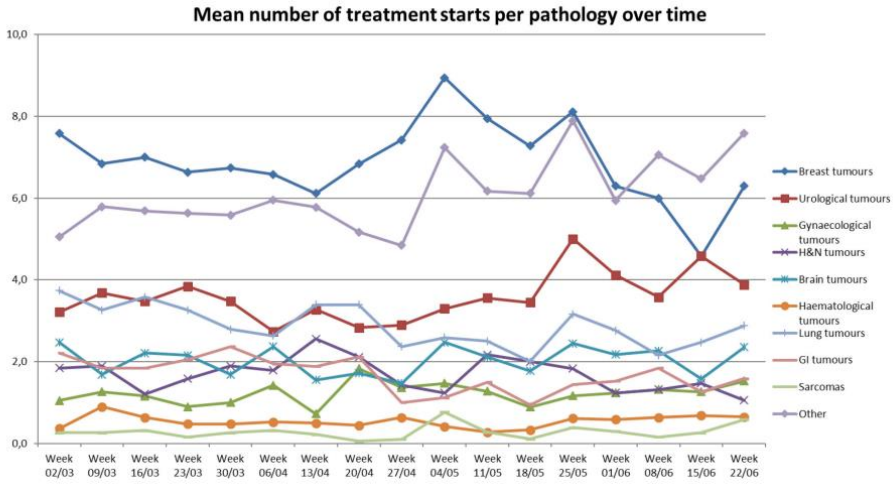


Figure 14 - Mean number of treatment starts per department per pathology over time

The impact of COVID-19 on the use of treatment modalities (LINACS) showed that 18 out of the 19 departments that responded, kept all their LINACS active. One department informed the authors that part of their equipment was dedicated to COVID positive patients. For COVID positive patients, treatment was delivered as planned in 32.3% of the cases with no interruptions in the treatment delivery process. In ~20% of the positive cases, the treatment was either delayed or interrupted. In 14% of COVID-positive patients, the treatment was prematurely stopped and in 6% of patients another element impacted the treatment (this includes patient death, patient's decision to stop their treatment or necessity to replan the treatment on a COVID-dedicated LINAC). For clinically suspected COVID-positive patients (patients presenting COVID-19-like symptoms), treatment continued as planned in 54% of patients while treatment was interrupted in 28% of patient and delayed in 12% of patients (Figure 15A &B).

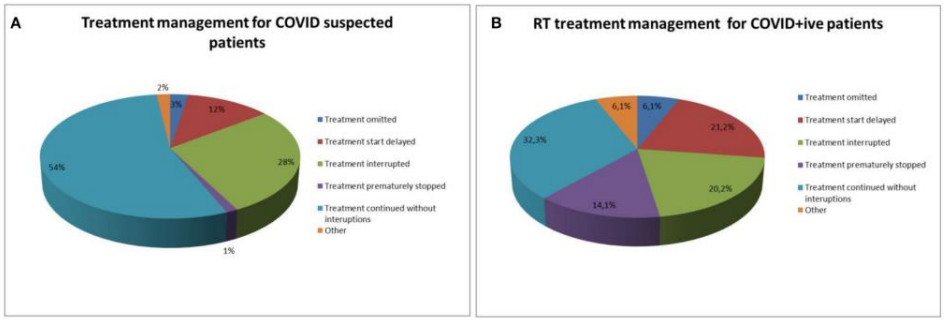


Figure 15 - (A) Treatment management for COVID suspected patients. (B) Treatment management for COVID positive patients

From the survey, it appears that roughly half of the departments changed some of their radiotherapy treatment indications. Indeed, 47.4% of departments changed their indication for breast tumors. Thirty-seven percent of departments changed their indication for urological tumors and 10% of departments changed their indication for gynecological, gastro-intestinal (GI), hematological, lung tumors and sarcomas. Sixty-eight percent of RTD made changes in their fractionation protocols with 31.6% of departments making these changes for urological tumors and 57.9% of RTD making these changes for breast tumors (Figures Figure 16A &B).

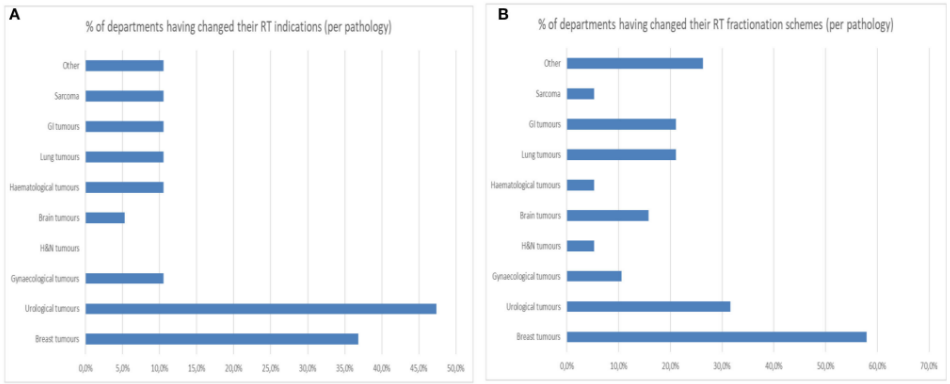


Figure 16 - (A) Percentage of departments having changed their radiotherapy indication per pathology. (B) Percentage of departments having changed their radiotherapy fractionation schemes per pathology.

4.4 Discussion

This survey shows the impact of the COVID-19 pandemic on RTD in Belgium while also assessing their reorganization. To our knowledge, this is the first survey composed of weekly follow-ups that monitor the situation during ~4 months. As seen in other national surveys; the number of radiotherapy treatments, in Belgium, dropped by a maximum of 18.8% (at week 8—last week of April). This is not unlike a study carried out in the USA where 55% of respondents reported a decrease in between 20 and 39% of the total number of patient volume [161], and in Switzerland where 45% of respondents reported a decrease in between 20 and 39% of the total number of patient volume, and in Switzerland where 45% of respondents reported <20% of daily activity reduction [91]. This is also in line with the recent publication of the Belgian Cancer Registry (BCR), which reports a 50% decrease in the number of cancer diagnosis in April 2020 (as compared to 2019). Although, this was followed up by a catch-up phase (significant increase in number of diagnosis) during the summer of 2020, the BCR still reports a difference of 14% of reported cancer diagnosis between the 2019 and 2020 March-September period [162]. This drop in cancer diagnosis and radiotherapy treatments is indeed not surprising, as the country has been thoroughly hit by the pandemic with more than 100 deaths per day observed between March 25 and April 29th 2020 (for 11.5 million inhabitants) [163]. The Belgian government declared a lockdown for the entire country on March 18th and imposed all hospitals to suspend all consultations and elective activities until May 4th and 11th, respectively [164]. Most publications measuring the impact of COVID-19 on RTD are based on a single questionnaire [90,91,161,165,166]. Our survey, which took place over several weeks, allows for the evaluation of the impact of the pandemic on RTH treatment over time and as such illustrates the dynamic nature of how COVID19 impacted treatment activity. It was observed that the number of curative treatments decreased until the end of April and then started to increase again without regaining a 100% activity as compared to the reference week of March 2nd. However, the evolution of the number of palliative treatments demonstrated a significant increase in the beginning of May with an overall increase in the number of treatments of 118% as compared to the week of March 2nd. One explanation for the important increase in palliative treatment could be

a catch up of primary delayed patients or patients that didn't respond to pain killers and other symptomatic medications used in a first attempt to avoid radiotherapy treatment. The analysis of the survey also demonstrated that RTD staff was not sheltered from the COVID-19 outbreak in which the RTT staff seemed to be the most impacted. But, when carrying out the comparison of proportions, the differences between the rates of positivity to COVID testing between the different groups of staff members, where not significant. Moreover, it is important to note that not all departments were able to report the exact number of staff being tested. When analysing the COVID status of RT patients, the data collected indicate a positivity rate of 15% among tested patients. However, it is important to note that the rate of COVID19 testing among RTD patients, could vary quite significantly among different hospitals and were also highly impacted by local recommendations and policies. There was also, as observed in Lombardy [158], differences in radiotherapy management of COVID-positive and COVID suspected patients whereby treatment was started and delivered as planned in 54% of COVID-suspected patients and only 32.3% of COVID-positive patients. These differences in management probably reflect the notion of having to maintain a balance between the risk of infecting other patients or staff members and the potential harm of delaying and/or interrupting radiotherapy on oncological outcome as was shown for certain types of cancer [167]. Finally, as seen in other publications [90,91], the data collected in the survey have put forth that a significant number of RTD have made several adjustments in their indications of radiotherapy in which 47.4% of departments adapted their indications for urological and breast tumors. Changes in fractionation protocols were applied mainly for urological, breast, GI and lung tumors as observed in Switzerland [91] where there was a 18% increase of hypofractionation use for breast radiotherapy and 23% increase of neoadjuvant short course radiotherapy for rectal cancer during the month of April 2020. The changes applied to the above mentioned pathologies was probably "facilitated" by the existing evidence for hypofractionation schemes that were later published as recommendations for COVID pandemic adaptation [168–170]. We acknowledge that there are several limitations to our study. Firstly, the survey contained a limited number of questions and most of the questions remained quite general. This was purposely done in order to increase the probability in which departments would respond to the survey on a weekly basis and this

during 4 months. Secondly, it is important to note that the thorough analysis of the data was limited by the fact that all treatment activities were compared to the reference week of March 2nd which only represents a snapshot of departments' treatment activities. We assumed that, at that time, the COVID pandemic had not yet had an impact on radiotherapy treatments. It might be possible that the week of March 2nd already had been subjected to a decrease in activity and that our study therefore underestimates the rate of decrease in treatment activity. Third, as previously mentioned, the rates and policies of testing were very different from one department to another and some respondents acknowledged difficulties of reporting test results especially among RTD staff for medical confidentiality issues. As such, this study may be underestimating the rates of testing and of COVID-positivity. Furthermore, there was variation in the data reported as some RTD reported the number of patients tested only during the treatment delivery process while other departments also reported the number of tests carried out for patients in the pretreatment phase (patients who had not started their treatment yet).

4.5 Conclusion

Between March and June 2020, the COVID pandemic impacted radiotherapy treatments in Belgium, mainly through a resulting decrease in treatment activity during the 1st months. Impact on staffing was limited. The management of patients who were COVID-19 positive or clinically suspected COVID-19 positive was also affected with treatment interruptions or delays in 68 and 46% of patients, respectively. Departments were rapid in implementing adaptations in treatment indications and fractionation schedules.

Chapter 5

"Quality in healthcare is not what you put into it, it's what the patient gets out of it."

- A. Donabedian.

CHAPTER 5: LINKING COLLECTED QUALITY INDICATORS

Linking acute toxicities and radiotherapy treatment processes - a possibility through a national quality indicator project?

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In preparation for submission

ABSTRACT

Purpose /objective: To promote best practice and quality of care, the Belgian College of Physicians for Radiotherapy Centers collected a set of radiotherapy specific quality indicators for benchmarking on a national level from 2016 to 2019. Analysing the real-life data collected, the aim of this study was to determine if there exist potential associations between the patients' and selected treatment parameters (process QIs) and the observed acute toxicities (outcome QIs) that have been recorded for breast, prostate and head and neck cancer patients.
Material and methods: A statistical analysis was carried out using a multilevel ordinal regression model in search of possible associations between the different patient and treatment parameters (predictors) and the observed acute toxicities.
Results: In total, the data of 6146 breast, prostate and H&N cancer patients have been explored. A statistically significant difference ($p<0,05$) was found between departments in how each of the toxicities were graded when running the empty multilevel logistic regression model. The overall observation following this analysis is that variables that seem to impact the most the recorded acute toxicities are those elements that are not specific to radiotherapy (i.e: use of concomitant therapy, post-op status, age…). Elements such as used treatment and IGRT techniques do not seem to have a significant impact on the probability of developing an acute toxicity.
Conclusion: The data collected though a national quality indicator project has been used to evaluate potential links between clinical practice and patient outcome. Although this evaluation may have been limited the existing variability in toxicity scoring between the different departments and the retrospective nature of the data collection, it is a first step towards linking radiotherapy treatment process with toxicity outcome for patient using real life data.

5.1 Introduction

Radiotherapy is an important and irrefutable treatment modality in cancer care. The optimal and safe delivery of a radiation treatment depends on organizations establishing a workflow supported by structural, organisational and process elements that continuously must adapt to a changing environment, facing new technologies, new techniques and changing healthcare policies, while implementing practice changes based on new evidence and guidelines. The extent to which a healthcare institution or radiation oncology (RO) department however can adapt its clinical practice to what is considered best practice can vary due to financial, structural or organisational reasons and this will, in many cases, impact patient outcome and quality of care.

The development and collection of quality indicators (QI) can be used to measure a departments' compliance with quality standards. The aim of a QI is to identify and quantify gaps in the quality of care offered to patients, and to favour quality improvement initiatives minimizing these gaps. A clear definition and continuous collection of QIs allows for the monitoring of performance over time. Moreover, if the provided QIs are collected on a multicentric or multi-national basis, institutions can compare their results with others through the process of benchmarking [52,54,59,110]. There has been an increasing interest in using QIs in RO over the past decade [27,57,59,61,171]. Within this framework, the Belgian College of Physicians for Radiotherapy Centers (later referred to as "the College"), a committee mandated by the Belgian Federal Government with a mission to improve the quality of radiotherapy delivered in Belgium, launched a radiation oncology specific quality indicator (RO-QI) project [71,172].

The aim of the College's RO-QI project was to define radiotherapy-specific QIs that could be collected in all RO departments in the country. Using the Donabedian's healthcare quality domain structure, a set of 55 QIs composed of 18 structural QIs and 37 process and outcome site-specific QIs were defined, validated and collected on a yearly basis. After a validation phase in 2015, the entire set of QIs has been collected from 2016 to 2019, after which data collection was limited to the structural QIs. Each year, a global report has been generated for the Federal Public Health Service, while all radiation oncology departments received individualized and anonymized benchmarking documents,

allowing them to identify their performance compared to the other Belgian RO centres. Thanks to a very high mean overall participation rate of 95% of all Belgian accredited RO departments, this project captured a wealth of real-life data portraying actual clinical practice and its potential impact on patient outcome.

In clinical research in RO, as in oncology in general, patient's outcome is typically measured using clinical parameters such as disease-free and overall survival, quality of life, acute and late toxicity. Innovations in RO aim at improving some, if not all, of these patient outcome measures. But to translate the clinical benefits defined in clinical research into real patient outcome in daily practice, it is crucial that the structures and processes in place support the optimal delivery of care. Hence the need to monitor QIs. In this endeavour, the strength of a selected QI will depend on the likelihood that improvements in that indicator will produce dependable improvements in the quality of care offered to patients, resulting in better outcome [113,173].

It is hypothesised that the process QIs collected in the Belgian RO-QI project may reflect the acute toxicities observed in the treated patients. Analysing the real-life data collected, the aim of this study was to determine if there exist potential associations between the patient's age and selected treatment parameters (process QIs) and the observed acute toxicities (outcome QIs) that have been recorded for breast, prostate and head and neck cancer (H&N) patients, treated between 2016 and 2019.

5.2 Materials and methods

Data collection

Within the framework of the College RO-QI project, radiotherapy-specific QIs were collected on a yearly basis. The collected QIs have been previously reported by Vaandering et al. and are comprised of structural QIs but also site-specific process and outcome QIs focussing on breast, prostate and H&N cancer patients [172]. In order to calculate and measure these QIs, it was necessary to collect the following data:

- Department-level data on equipment, human resources and treatment activities (=structural QIs) – *not included in the present analysis;*

- Patient-specific process and outcome data for 25 randomly picked and ideally consecutive patients belonging to the following pathology groups (=process and outcome QIs) :
    - Breast cancer: post-operative whole-breast radiotherapy, all or not with a sequential or simultaneously integrated boost (SIB). Nodal, bilateral or partial breast irradiation were excluded;
    - Prostate cancer: prostate radiotherapy only, all or not with a SIB. Post-prostatectomy and nodal irradiation were excluded;
    - Head and neck cancer: primary radiotherapy, all or not including lymph node irradiation and/or SIB, excluding T1N0 glottis treatments.

The collected data or variables are detailed in Table 6. Department were asked to report the highest acute toxicity grade evaluated from the beginning of treatment up till 4 weeks post-treatment using version 4 of Common Terminology Criteria for Adverse Events [122]. The data set was initially captured using Microsoft Access, but transferred into RedCap's (Research Electronic Data Capture) web-based software platform in 2017 [123]. As of then, data collected in the departments were directly encoded into RedCap through a department-dedicated link, provided to the quality manager and the head of department.

Table 6 - Patient specific data variables collected within the framework of the College RO-QI project (in italic: variables used in the present analysis)

Data type	Breast cancer patients	Prostate cancer patients	H&N cancer patients
Patient and tumour parameters	*Patient age at start of treatment*		
	Treated side		*Primary tumour location*
			TNM staging
			Treatment interruption due to medical reasons
Multi-modality treatment parameters	Date of patient discussion in multidisciplinary (MTD) meeting		
	Use of adjuvant chemotherapy		*Treatment in a post-op setting*
	Use of concomitant systemic therapy		
			Type of systemic therapy treatment
Radiotherapy specific parameters			
Dose prescription	Date of simulation		
	Date of first day of treatment		
	Date of last fraction of treatment		
			Nodal irradiation

	Use of SIB technique¥		
	Dose prescribed to the breast	*Dose prescribed to the high dose PTV*	
	Prescribed number of fractions		
	Prescribed number of fractions per week		
	Use of additional boost dose		
	Dose prescribed to the boost region	Dose prescribed to the low dose PTV	
	Prescribed number of fractions prescribed to the boost region	Prescribed number of fractions prescribed to the low dose region	
Technical parameters	Use of prone position	*Presence of implanted fiducials*	
	Used treatment technique		
	Used IGRT technique		
	Used motion management strategy	*Use of daily online corrections*	
Dosimetric parameters	*D2 of target volume¥ (Gy)*	*Rectum V50 (%)*	Mean homolateral parotid dose (Gy)
	Mean heart dose		Mean controlateral parotid dose (Gy)
Recorded acute toxicity (based	Date of toxicity scoring		
	Radiodermatitis toxicity score	*Cystitis toxicity score*	*Radiodermatitis toxicity score*
		Rectitis toxicity score	*Mucositis toxicity score*
			Weight loss toxicity score

MTD: Multi-disciplinary team meetings /IGRT: Image Guided radiotherapy / SIB: Simultaneous Integrated Boost / ¥:data collected as of 2017

Data analysis

The collected data were firstly centralised and analysed in Microsoft Excel (2016 MSO), to generate the QIs which were then published both in a global yearly report and individualized benchmarking documents sent to departments [172].

For the current analysis in search of a potential association between the patient's characteristics and treatment parameters (process QIs) with the observed acute toxicities, the collected data was imported into SPSS (IBM SPPS Statistics version 27). Descriptive statistics were used to summarize the collected data for the three patient groups. A set of variables – also called predictors - with a potential to impact the response variable acute toxicity were then identified by the College RO-QI core group. These are illustrated in Figure 17.

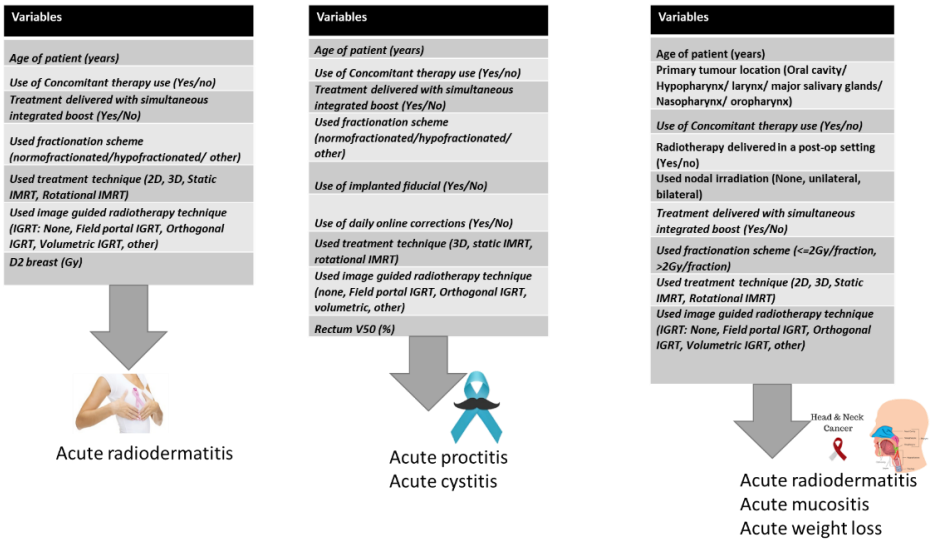

Figure 17 - Variables selected for the statistical analysis analysing the potential impact of patient characteristic and treatment processes on observed acute toxicities

Toxicity grading being an ordinal variable, ordinal logistic regression with random effect model was used, to determine the impact of the different predictors on the response. A first analysis was carried out using an empty multilevel ordinal regression model (generalized linear mixed model) in order to determine if there existed statistically significant differences between hospitals on how toxicity was graded for each toxicity (estimate of covariance) [174,175]. Then, a multilevel ordinal logistic regression model with the selected variables was used to determine the potential existence of an influence of the different predictors on the observed acute toxicities (1 model per studied toxicity).
For each of these models, further analyses were carried out to determine if there existed interactions between the different predictors on the response (*i.e.: effect of variable "a" on the observed toxicity varying as a function of variable "b"*). The two main assumptions of the models - independence of observations and proportional odds – were also tested using R statistical Software (v4.1.2) (R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/)[176–178].

5.3 Results

In total, data of 6146 patients have been explored. Table 7 and Table 8 report the descriptive analysis of the data collected for the 3 different populations of patients, captured from 2016 to 2019, except for some data elements that were only available as of 2017. The different radiotherapy prescriptions were also analysed and can be found in the supplementary data.

Overall, 1.2% of data fields were left empty by the respondents. As indicated with a (*) in Table 7 and Table 8, some patients' data were excluded from the analysis. This exclusion concerned:

- patients for which the respondents mentioned not to have data and where the collected item was thus categorized as unknown.
- categories of responses for which the sample size is insufficient and for which it was not possible or desired to regroup data with another category.

Table 7 - Descriptive analysis of the collected patient and treatment parameters data for breast, prostate and head and neck cancer patients

		Breast cancer patients (n=2169)	Prostate cancer patients (n=2008)	H&N cancer patients (n=1969)
Patient and tumour parameters				
	Age at time of treatment (mean ±1SD)	61,2 ± 11,9 years	73,5 ± 7,1 years	63,4 ± 11,1 years
	Site treated	*Left breast**: 50,6%* *Right breast**: 49,0%* *Bilateral**: 0,3%* *Unknown*: 0,3%*		Oropharynx: 32,7% Oral cavity: 22,8% Larynx: 15,5% Hypopharynx: 13,8% Salivary glands: 3,0% Nasopharynx: 4,3% Nasal cavity and sinuses: 0,2% Other: 7,8%
Multi-modality treatment parameters				
	Use of concomitant systemic therapy	Yes: 46% No: 54%	Yes: 69,1% No: 28,9% Unknown*: 2,0%	Yes: 57,1% No: 42,7% Unknown*: 0,2%
	Treatment in a post-op setting			Yes: 33,7% No: 66,0% Unknown*: 0,3%
Radiotherapy specific parameters				
Dose prescription	Fractionation scheme	Hypofractionated: 82,3% Normofractionated: 15,1% Other fractionation scheme: 2,6%	Hypofractionated: 46,9% Normofractionated: 53,6%	Dose/fraction =<2Gy: 73,6% Dose/fraction > 2Gy: 26,4%
	Use of SIB	Yes: 17,2% No: 82,8%	Yes: 46,1% No: 53,9%	Yes: 67,3% No: 32,7%
Technical parameters	Treatment technique	3DCRT: 46,7% Static IMRT: 47,3%	3DCRT: 1,6% Static IMRT: 13,5%	3DCRT: 1,0% Static IMRT: 19,7%

		Rotational IMRT: 4,5% 2D*: 0,5% Combination of rotational and static IMRT*: 1%	Rotational IMRT: 84,9%	Rotational IMRT: 79,0% 3D+ static IMRT: 0,2% Static IMRT + Rotational IMRT*: 0,1%
	IGRT technique	None: 2,6% FPI: 36,8% OPI: 14,2% OPI + FPI 16,8% Volumetric IGRT: 26,7% Volumetric + 2D IGRT: 2,8%	None: 1,4% 2D IGRT: 16,1% Volumetric IGRT: 78,1% Exactrac: 4,4%	None: 1,7% FPI: 2,5% OPI: 15,2% OPI + FPI: 2,2% Volumetric IGRT: 58,0% Volumetric IGRT + OPI: 14,2% Exactrac: 6,2%
	Daily IGRT		Yes: 89,0% No: 11,0%	
	Presence of implanted fiducials		Yes: 33,6% No: 65,2% Unknown*: 1,2%	
	*Motion management**	*Left breast: Breath-hold or gating used for 26,3% of patients* *Right breast: Breath-hold or gating used for 6,4% of patients*		
Dosimetric parameters	D2 PTV evaluation (Gy) (mean ± 1SD)	Left breast: 48,4 ± 6,4 Gy Right breast: 48,6 ± 7,0 Gy		
	Mean heart dose (Gy)* (mean ± 1SD)	*Left breast: 2,35 ± 1,5 Gy* *Right breast: 0,81 ± 0,9 Gy*		
	Rectum V50 (%)(mean ± 1SD)		31,0 ± 13,9%	
	*Mean parotid dose** (mean ± 1SD) *(Gy)*			*Homolateral parotid dose: 28,3 ± 0,4 Gy* *Contralateral parotid dose: 20,0 ± 0,3 Gy*

IMRT: Intensity Modulated radiotherapy/ IGRT: Image guided radiotherapy/SIB: Simultaneous Integrated boost / FPI: field portal imaging / OPI: Orthogonal portal imaging

Important to note:

- *The prone position was used for 4.6% of patients and was thus excluded from further statistical analysis*
- An overview of the different total prescribed doses to the high dose PTV (including boost) can be found in Appendix 1
- Items marked with a * have been excluded from the multilevel ordinal logistic regression model
- **: The site of treatment was not included as a predictor variable in the multilevel ordinal logistic regression model

Table 8 - Descriptive analysis of the collected acute toxicity data data for breast, prostate and head and neck cancer patients

	Breast cancer patients (n=2169)	Prostate cancer patients (n=2008)	H&N cancer patients (n=1969)
Recorded acute toxicities			
Radiodermatitis	None: 20,7% Grade 1: 63,5% Grade 2: 14,8% Grade 3*: 1,0%		None: 10,0% Grade 1: 44,4% Grade 2: 35,7% Grade ≥ 3: 7,9% Unknown*: 2,0%
Cystitis		None: 28,0% Grade 1: 49,2% Grade 2: 20,9% Grade ≥ 3: 0,3% Unknown*: 1,5%	
Proctitis		None: 59,5% Grade 1: 29,5% Grade 2: 9,1% Grade 3: 0,1% Unknown*: 1,8%	
Mucositis			None: 15,9% Grade 1: 24,0% Grade 2: 34,4% Grade ≥3: 24,0% Unknown*: 1,6%
Weight loss			None: 31,9% Grade 1: 41,9% Grade 2: 18,6% Grade >=3: 3,7% Unknown*: 3,9%
- Items marked with a * have been excluded from the multilevel ordinal logistic regression model			

Based on Table 7 and Table 8, the following general observations can be made:

- Patient and tumour parameters:
  - The mean age of the studied patient population is older in prostate cancer (73,5 ± 7,1 years) compared to breast (61,2 ± 11,9 years) and H&N cancer (63,4 ± 11,1 years);
  - There is an equal proportion of patient treated for left- and right-breast cancer while for H&N patients, the majority of treated tumours are located in the oropharynx and oral cavity;
- Multi-modality treatment parameters
  - Concomitant systemic therapy is used for the majority of prostate (69.1%) and H&N (57,1%) cancer patients with the notion that the majority of H&N radiotherapy treatments are given in a non post-operative setting;
- Radiotherapy specific parameters

- Hypofractionation is the scheme of choice for the breast cancer group while normo-fractionated regimes are still used in the majority of H&N and prostate cancer patients;
- Rotational IMRT and volumetric IGRT is primarily used for H&N and prostate cancer patients;

- Recorded acute toxicities
  - Grade 1 toxicity is the most frequently reported acute toxicity with the exception of mucositis. Grade 2 (34,4% of patients) and grade 3 (24,0% of patients) make up the majority of reported acute toxicity for H&N cancer patients.

A statistically significant difference ($p<0,05$) was found between departments in how each of the toxicities were graded when running the empty multilevel logistic regression model. As such, it was necessary to evaluate the possible impact of the predicting process variables on the response variable "acute toxicity" using multilevel ordinal regression models. As explained above, one model was generated per acute toxicity, modelling the impact of the different predictors on acute toxicity.

The results of the statistical analysis are summarized in Table 9. The statistically significant associations found between the predictors (patient characteristics and treatment process) and the recorded acute toxicities are shown numerically.

Table 9 - Results of the multilevel ordinal regression model analysis of the three patient groups

	Breast (n=1639) *Coefficient/Exp (p)*	**Prostate (n=1756)** *Coefficient/Exp (p)*		**Head & Neck (n=1473)** *Coefficient/Exp (p)*		
	dermatitis	***proctitis***	***cystitis***	***dermatitis***	***mucositis***	***weight loss***
Patient and tumour parameters						
Age	*-0,01/0,99 (p=0,032)*					*-0.02/0,98 (p<0,05)*
Tumour location					*1,20/0,62 (p<0,05)/ 0,86/0,23 (p=0,007)*	
Multi-modality treatment parameters						
Concomitant systemic therapy			*-0,27/0,76 (p=0,019)*	*-0,49/0,61 (p<0,05)*	*-1,18/0,31 (p=0,002)*	*-3,65/0,03 (p<0,05)*
Post-operative treatments					*0,43/0,17 (p=0,001)*	*0,52/1,68 (p<0,05)*
Nodal radiotherapy				*-2,0/0,13 (p=0,001)*	*-1,69/0,18 (p=0,002)*	
Radiotherapy specific parameters						

Dose prescription							
	Fractionation scheme	*0,85/0,43 (p<0,05)*		*-0,37/0,69 (p=0,004)*			
	Dose per fraction						
	Use of SIB		*-0,35 /0,70 (p=0,019)*	*-0,59/0,56 (p<0,05)*			
Technical parametres							
	Treatment technique						
	IGRT technique						*1,56/4,77 (p=0,019)*
	Daily IGRT						
	Fiducials						
Dosimetric parameters							
	Nominal D2PTV	*0,04/1,04 (p=0,003)*					
	Rectum V50 (%)		*0,01/1,01 (p=0,023)*				
Interaction between variables on toxicity			*Rectum V50 and treatment technique (p<0,05)*		*Nodal RT and dose per fraction (p>0.05)*		
						Concomitant therapy use and tumour location (p>0.05)	
							Patient age and concomitant therapy use (p>0.05)

The impact of one variable as a function of another variable on acute toxicity has also been tested; only those that were found statistically significant are shown. As such, the following statistically significant observations can be made for each of the different patient groups:

For the breast cancer patient group:

- A decreased probability of having higher grade radiodermatitis is observed with increasing age;
- There is an increased probability of having higher grade radiodermatitis with increasing nominal dose to 2% of the breast volume (D2) ;
- A normofractionated treatment scheme increases the probability of developing greater acute toxicity.

For the prostate cancer patients group:

- The SIB treatment schedule is associated with a greater probability of having higher grade proctitis;
- A higher rectal volume receiving 50 Gy (V50 (%)) is associated with greater probability of higher proctitis grade. This probability increased when rotational IMRT is used as compared to other treatment techniques;
- Concomitant therapy use, a SIB treatment schedule and a normofractionated treatment schedule is associated with a higher probability of higher grade cystitis;
- For the same value of rectal V50, there is a tendency for a lower grade cystitis if 3D or static IMRT is used. However, this is not statistically significant.

For the H&N cancer patient group:

- The delivery of concomitant therapy is associated with a greater probability of higher radiodermatitis;
- There is a higher probability of developing higher grade radiodermatitis when there is nodal irradiation and this is more so with fractionation schemes of ≤2Gy/fractions;
- Concomitant therapy use and a non-post-operative setting are associated with a greater probability of higher-grade mucositis;
- Irradiation of the oral cavity and oropharynx area with the use of concomitant therapy is associated with a greater probability of higher-grade mucositis but this probability diminishes when there is no use of concomitant therapy;
- There is a lower probability of developing higher grade mucositis when there is no nodal irradiation with fractionation schemes of >2Gy/fraction but this tendency decreases with fractionation schemes of ≤2Gy/fraction;
- Concomitant therapy use as well as radiotherapy delivered in a non-postop setting is associated a greater probability of weight loss;
- Increasing age seems to be associated with a lower probability of weight loss although this probability increases with the use of concomitant therapy;
- The absence of IGRT also seems to be associated with a higher probability of weight loss (however this concerns a low number of patients);

- The absence of concomitant systemic therapy is associated with a lower probability of weight loss. However, its impact is mitigated when the target volume is the oral cavity or oropharynx.

5.4 Discussion

The development of radiotherapy-specific QIs by the Belgian College of Physicians for Radiotherapy Centers has allowed for the monitoring and benchmarking of QIs deemed of interest by the Belgian radiotherapy community [172]. Patient-level process and outcome QIs have been collected focussing on breast, prostate and head-and-neck cancer patients from 2016 to 2019. The outcome QIs concerned the collection of acute toxicities recorded for patients on treatment and up to four weeks after the end of treatment. Contrary to the structural QI, the collection of process and outcome QI were interrupted in 2019 in order to allow for the thorough analysis of the collected data. A statistical analysis using multilevel ordinal regression models was performed to determine if patients and treatment parameters were associated with the measured acute toxicities in breast (radiodermatitis), prostate (rectitis and cystitis) and head-and-neck (radiodermatitis, mucositis and weight loss) cancer patients.

This analysis first demonstrated that statistically significant differences exist between the radiation oncology departments on how toxicities were graded. This is line with the feedback that was given by the departments when evaluating the RO-QI project [172]. The acute toxicity grading was felt to be too variable between RO professionals and departments, and not always in line with what can be expected from the literature. A way to counteract this could be by standardising the grading amongst participants, either using detailed guidelines or through the organisation of courses meant to harmonize practice. Another way to overcome this possible bias is to introduce Patient Reported Outcome Measures (PROMs), in which patients themselves evaluate their physical and psychological well-being and quality of life, and which have been found reliable in capturing actual side effects, on the basis of which quality improvement programs can be initiated [102,149,171,179].

However, this inter-departmental variability was considered when modelling the predictors with the different recorded acute toxicities. Several publications have

stated the potential for improved acute toxicity with the recent advances in radiotherapy treatment planning and delivery [180–183]. Yet, the direct link between a specific treatment parameter and outcome is often a difficult one to make. Toxicity is indeed multifactorial and not only related to the radiation treatment per se and can be impacted by other factors such as existing comorbidities, interaction with other treatments or even social factors [184,185]. Interestingly, the overall observation following this analysis is that variables that seem to impact the recorded acute toxicities the most are those elements that are not radiotherapy-specific (i.e.: use of concomitant therapy, post-op status, age…). Elements such as treatment and used IGRT techniques do not seem to have a significant impact on the probability of developing an acute toxicity. Three factors can explain this. Firstly, a great majority of patients included in the analysis are treated using the treatment techniques that are considered evidence-based practice. Rotational IMRT is predominantly used for prostate and H&N cancer patients while breast cancer patients are mostly treated using 3DCRT and static IMRT (sliding window) treatment techniques [180,186–190]. Secondly, process QIs such as used treatment and IGRT technique encompass more than just one activity; the quality of the process will highly depend on other elements such as the quality of the underlying treatment plan, established QC measures as well as the defined clinical goals. It might therefore have been too simplistic to solely look at the technique used without further defining the underlying processes. Thirdly, it might be noteworthy to mention that maximum acute toxicities might not have been fully captured in the RO-QI project. For pragmatic reasons, it was asked to provide the maximum toxicity with an allowed time range between the beginning of radiotherapy up to four weeks after treatment. The moment in which the patient was actually seen may have impacted the acute toxicity recorded, and may for instance be a confounding factor when evaluating skin toxicity in the context, for example, of hypo-fractionated breast radiotherapy. Moreover, these real-life data have been extracted retrospectively from the patient files, which makes them prone to inaccuracies and missing data. Toxicities may not have been recorded and reported, with loss of data due to absence of follow-up in the four-week period or follow-up grading not being recorded in the patient files.

Keeping these limitations in mind, some of the results obtained can be critically assessed and compared to existing publications.

For breast cancer patients, as observed in other publications, normo-fractionated treatment regimes do give rise to a higher probability of higher-grade toxicity [191,192] while the increasing toxicity observed with increasing dose to 2% of the breast volume has not been specifically mentioned in other publications [193]. Similarly, in the studied cohort of patients, age seems to be a protective factor in developing higher-grade radiodermatitis although this is not in line with publications [194–197].

In the cohort of prostate cancer patients, the use of a SIB during radiotherapy treatment delivery seems to increase the probability of higher grade of cystitis and proctitis. This does not necessarily coincide with published material [198,199].
However, without surprise, higher grade of proctitis is observed with an increase in the rectal volume receiving 50 Gy. The V50(%) should however not be taken as a sole predictor of toxicity as this parameter can be highly influenced or impacted by the delineation of the rectum itself (rectal wall only versus rectal wall and lumen) or the fractionation scheme used [78]. This increased rectal toxicity probability seems to further increase when rotational IMRT is used as compared to other treatment techniques.

Higher-grade cystitis has been observed in normo-fractionated treatment patterns although this is not in line with published material [200,201].

For H&N cancer patients, higher acute toxicities were observed – without surprise – when patients were benefitting from concomitant systemic therapy and radiotherapy delivery in a primary setting with nodal irradiation. Fractionation schemes also seemed to impact observed acute toxicities with fractionation schemes of ≤2Gy leading to a slightly higher probability of higher-grade toxicity. It is to be noted though that the use of preventative measures to avoid weight loss (i.e.: placement of a nasogastric tube) have not been collected, which might have biased the data.

Overall, the potential interactions between some of the patient and clinical parameters with recorded acute toxicity observed in this analysis seem to mostly demonstrate that the majority of these parameters do not predict the probability of patients suffering from the studied acute toxicities. It should be stressed that the proportion of patients suffering from acute toxicities higher than grade 2 are

rare in the studied patient population. The real-life nature of the data might have unwillingly affected or flawed the results obtained, as the data collected showed high variability due to limited standardisation and the retrospective nature of the data collection. As discussed, the uncertainty relative to patient toxicity grading may have led to corrupted data with some noise. Another limitation in this study, is the absence of data on late toxicities as this may impact patient quality of life well after treatment has ended. However, this parameter is quite hard to grasp over the long term at a multi-institutional level beyond the context of a formal clinical trial. Both limitations could thus be tackled – in some way – by the establishment of nationally defined PROMs with the hope that patients would be willing to partner in the data generation [171,179,202].

5.5 Conclusion

The potential of using real life data to investigate potential links between clinical practice and patient outcome is a step that must be taken. This can be favoured through the establishment of automatic data extraction, national and independently checked databases with a methodology that favours big data analysis [146,171,203,204]. Yet all initiatives should not solely focus on outcome and lead to the comparison of patient outcome between different hospitals or organisations without closely looking at clinical processes that lead to good practice and quality of care [173,205].

Chapter 6

"The secret of getting ahead is getting started. The secret of getting started is breaking your complex overwhelming tasks into small manageable tasks, and then starting on the first one."

- Mark Twain

CHAPTER 6: DISCUSSION AND PERSPECTIVES

6.1 Radiotherapy and quality

Radiotherapy is a treatment modality used in about 50% of patients diagnosed with cancer [17]. Some key factors, such as advances in treatment planning software and treatment delivery systems have allowed for the precise delivery of the prescribed dose to the target volume all the while minimising the dose to the surrounding healthy tissues [206]. Over the past decade, however, this treatment modality has become more complex, while relying on the close interaction and collaboration between the different professional groups gravitating around the patient. The development of quality assurance programs has supported the delivery of accurate and safe treatments. Yet, quality assurance must be integrated within a comprehensive quality management system that includes all the elements necessary to guarantee the optimal and safe delivery of radiotherapy to patients.

This includes, amongst others, the clear description and availability of processes and procedures, resource and risk management and the establishment of initiatives and tools favouring continuous quality improvement. In Belgium, some of those tools have been implemented on a multicentric and even national level through the College of Physicians for Radiation Oncology Centres. Two of these initiatives – the use of peer reviewed clinical audits and the monitoring of radiotherapy specific QIs – have been the focus of this work with the aim of answering the following question: "**Can these tools - implemented at a national level - be structured and used in such a manner that they can favour further quality improvement within radiation oncology departments?"** The following sections will detail the status of the two different projects and their role as quality improvement tools as well as the requirements that are needed for these tools to be successfully implemented at a national level. Finally, the limitations as well as the potential further improvement of clinical audits and QIs will be discussed.

6.2 The complementarity of clinical audits and quality indicators

In this work, clinical audits and quality indicators have been considered as being separate tools used to monitor and improve the quality of healthcare services, with a specific focus on the radiation oncology environment. In fact, both tools sometimes seem to be inverted or interchanged or considered to be one and the same. As an example, the extent to which clinical audits have been implemented within the European landscape has been described and shared amongst experts within the European QuADRANT project, which aimed at identifying the barriers and facilitators in the implementation of audits [207,208]. During the discussions, there seemed to exist a variability in how clinical audits were perceived by the different experts. In some instances, the clinical audit process seemed to be comprised "solely" of the collection of patient-level data, with the aim to obtain quantitative data of adherence to certain quality criteria and obtain a certain outcome. Such data is collected in the absence of actual observation of on-site practice, as it would be done – for example - in the QUATRO and B-QUATRO audits. This "QI approach" seems to be very much the system used by the National Institute for Health and Care Excellence (NICE) whose aim is to establish guidelines on what is considered best practice and to provide metrics to measure the extent of their application within the hospital organisations [209]. Thus appears a gray area that seems to intermingle the concepts of clinical audits and QIs. In this work, both concepts were considered separate tools. **Clinical audits** were considered to be a process whereby auditors will comprehensively assess - through observations, interviews, documentation and measurement - the clinical processes or patient care pathways and their supporting processes and compare these to standards or what is considered best practice. Through this process, areas needing to be improved were identified and communicated – through recommendations – to the audited organisation or department. **Quality indicators** were considered as the measurement of the quality of care through the collection of data allowing for the monitoring of the defined QI over time and/or their comparison across different healthcare organisations or systems. QIs are typically focused on measuring performance rather than driving improvement directly, but provide valuable information that can be used to guide quality improvement efforts.

C**linical audits** can be perceived as a qualitative evaluation of the quality of care provided to patient while **quality indicators** can be perceived as a quantitative measure. With QIs, improvement initiatives will originate through the process of benchmarking. In clinical audits, improvements arise when the audits' recommendations are addressed. QIs can of course be consulted during clinical audits and the fact that a department has been audited can be used as a quality indicator. Furthermore, observations made during clinical audits can be used to define new QIs that can be monitored over time and conversely defined quality indicators can be integrated within the audit checklist. Both tools are thus considered in this work to be different but complementary.

6.3 Clinical audits

6.3.1 Actual status of the project

As presented in **Chapter 2**, the peer reviewed clinical audits of all radiation oncology departments have been successfully carried out using the IAEA QUATRO methodology from 2011 to 2015.
The review and analysis of the audit reports performed within the framework of this thesis have allowed for the classification of the emitted recommendations according to the domain that they tackled. As expected, it has shown that the majority of the recommendations highlighted the need for departments to optimise certain aspects of their clinical workflow through process optimisation. The remaining 27%, 20% and 19% of recommendations addressed infrastructure, organisational and staff issues respectively. This analysis also allowed us to identify areas needing to be improved at a national level. This included the need to increase the training level of the RTTs, to enhance the feedback and communication related to incident reporting, to develop formal follow-up systems for radiotherapy patients and to initiate quality assurance programs for immobilisation equipment. Although not all of these have led to actual national improvement projects, some of these have served as arguments to justify the advancement of certain initiatives. This mostly concerns the issue of RTT under-training in Belgium. The audits' observations, amongst others, have been used to convince entities such as the ARES (Academie de Recherche

et d'Enseignement Supérieur) to create a program aiming at further training the medical imagery technologists and nurses working in radiotherapy (https://www.vinci.be/fr/formations/radiotherapie). The observations have also been included in additional analyses and studies focussing on this issue [210,211].
A second part of the work also consisted in obtaining the audited departments' feedback on the perceived usefulness and relevancy of the emitted recommendations. The majority of the departments favorably evaluated these but provided a more reserved feedback concerning the actual impact of these recommendations on quality improvement initiatives. This is mostly due to the fact that some of the emitted recommendations were addressing issues outside of the responsibility or scope of the department itself. Departments might for example have been limited by financial constraints and/or lack of support from their hospital management due to limitations of the audits that will be discussed in the subsequent chapter 6.3.3.
The analysis carried out through this work served as a basis for the subsequent task of updating and optimising the QUATRO document. In that respect, the quality criteria were updated as a function of the uptake of new technologies and treatment techniques. Also, an additional chapter defining the criteria needing to be to evaluated, when auditing the departments quality management system, was added [3,212].
The format of the quality criteria checklist has also been thoroughly reviewed in order to facilitate and further standardise the auditing process and the formulation of the audits report and to facilitate data analysis. This revised document – called B-QUATRO - has been endorsed by the FANC and has been partly used by the IAEA in order to review its own QUATRO document [213].

Encouraged by the analysis that was carried out in this work as well as the legal obligation to organise clinical audits as dictated by the Euratom directive and Belgian legislation, a second cycle of audits has been carried out using the B-QUATRO auditing tool [33,214]. This included auditing all radiation oncology departments and their satellite sites and, although interrupted by COVID-19,

ended in March 2023. In this process, 25[1] audit reports were generated – one for each primary radiotherapy department and two additional ones for satellite sites that are considered structurally different from their primary site. B-QUATRO audits have also been requested and carried out in Luxembourg and in two French departments (Centre Oscar Lambret (Lille) and Centre Pierre et Marie Curie (Arras)). Invited external auditors interested by the B-QUATRO methodology also had the opportunity to accompany the auditors during their mission with the hope that they could implement clinical audits in their own countries (France, Israel).

Not unlike the first cycle of audits, recommendations have been extracted from the audit reports and analysed - again with the aim of identifying common areas of weaknesses (or strengths) within the Belgian radiotherapy landscape. This second cycle of audits has confirmed the dynamic nature of radiation oncology departments and their quality management system as illustrated in Figure 18. As such, the compliancy rate during a department's re-audit can be seen to improve for a number of quality criteria while it can be seen to decrease for other items. Apart from the fact that some of the quality criteria themselves might have changed between the two audits, the time-driven evolution of available technologies, techniques and clinical guidelines will most probably have led to organisational and structural changes within the department. Re-audits are thus able to capture the impact of these changes on the departments' workflow and clinical practice. This has been observed in a significant amount of the audits but with the global notion that deficiencies observed in the first audits had been addressed by most departments.

[1] This should have amounted to 26 reports: 24 reports addressed to primary sites and 2 for the independent satellite sites. However, one audit in 2022 never led to the generation of an audit report.

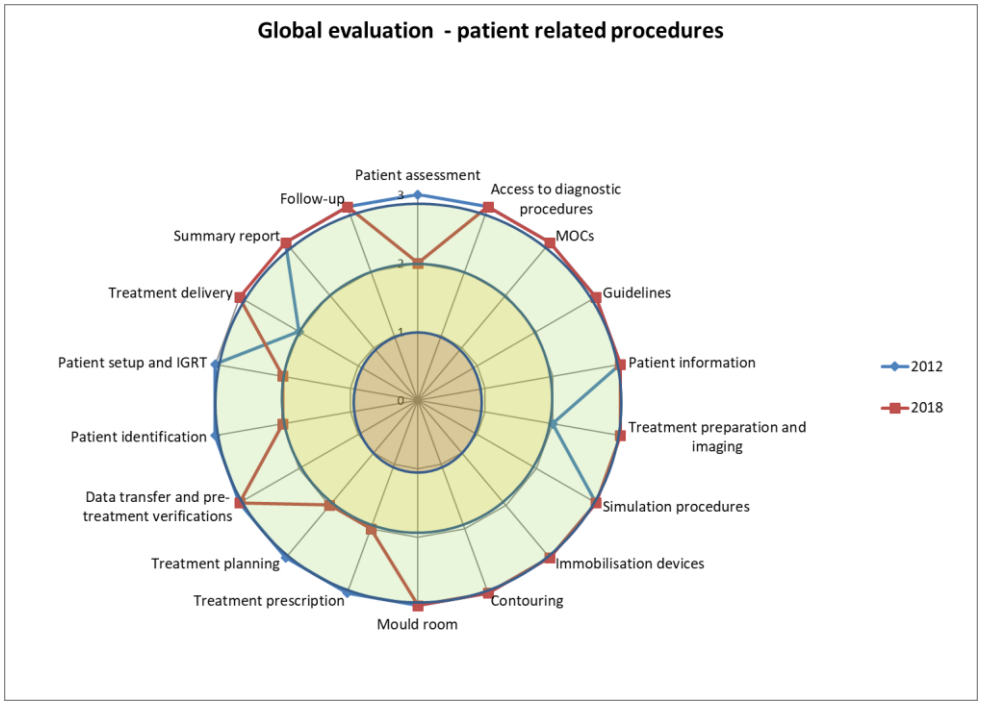

Figure 18 - Comparison of a department's audit results between the first cycle of audits and the second cycle of audits: 1= Non-compliant / 2= Partially compliant / 3= Compliant

Figure 19 illustrates the compliancy rates of the all the audited department with respect to the different checked items in the 4 domains of care that are audited with the B-QUATRO tool. The following national recommendations could be made on the basis of this second cycle of audits:

Infrastructural level

- Overall, the RT delivery equipment made available to patients is adequate;
- Some departments need an upgrade in infrastructure (too old, too crowded, privacy issues for patients) but this highly related to the age of the hospital hosting the department;
- The existence of satellite sites has a high impact on the human resources necessary to ensure patient workflow demanding more staff to cover for the multiples sites;

- Staffing levels are limited in a significant number of departments – this is the case for ROs, MPEs and MPAs and RTTs. This may quite quickly reach alarming levels especially for the RTTs, for whom the inflow of new qualified professionals is very limited.

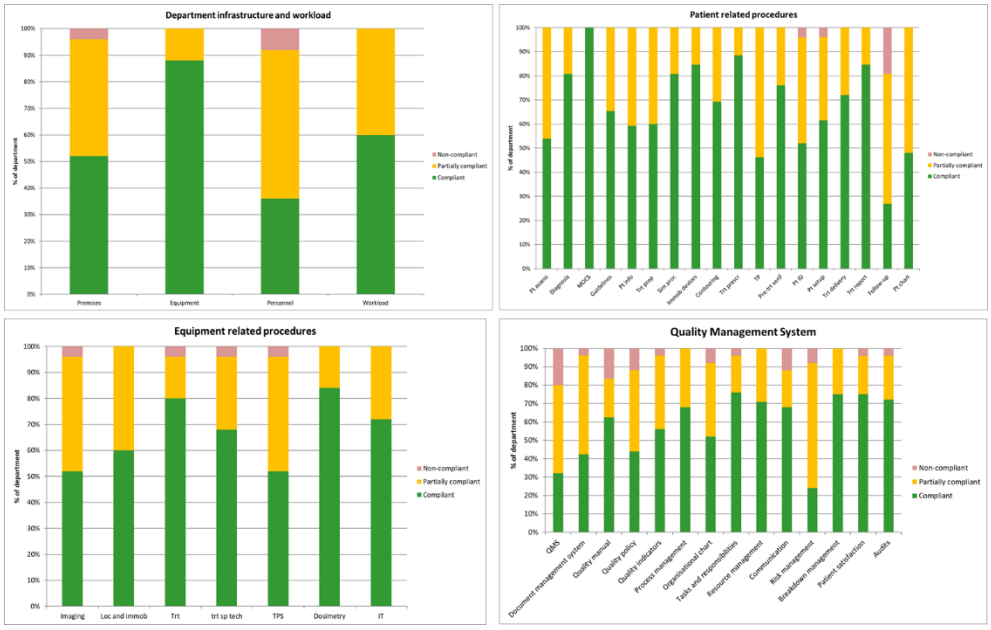

Figure 19 - Compliancy rates of departments in relation to the different audited domains

Patient related procedures

- Multidisciplinary Oncology Consultations (MOCs) are systematically implemented and used in line with publication that demonstrate their impact on treatment assessment and management [215];
- Pre-treatment geriatric assessment is underused considering the recommendations stating that this should be done for all patient over 75 years old [216];
- Efforts should be made to ensure the integration of the radiotherapy patient file within the hospital-based patient information system;

- The peer review of volume delineation and treatment planning must be encouraged in order to favour the detection of errors or systematic bias;
- The implementation of radiation treatment modalities with image guidance has allowed for the delivery of precise treatments. However, this has led to a shift of responsibilities/tasks in which the decision to treat (or not treat) heavily relies on the RTTs working at the treatment units with a lack of medical supervision (through either online or offline reviewing). Departments try to formalize this with protocols (= traffic light protocols) – yet, the proper training of these professionals must be ensured to allow for the safe delivery of treatments;
- The overall survival rate of oncological patients has risen over the past decade – this includes patients who have benefitted from radiotherapy and for which long-term follow-up needs to be ensured consequently. However, the follow-up is practically difficult to organise for all patients having benefitted from radiotherapy. National guidelines and tools (PROMS) could ensure that all patients benefit from a form of follow-up.

Equipment related procedures

- Novel and complex equipment as well as the software needed to run these have entered the department at a rapid rate – and this with the objective to deliver highly precise treatments. This can only be ensured through the development of thorough equipment quality assurance programmes and quality control procedures developed and adapted by medical physics experts. Again, their training must ensure the acquisition of the needed competencies to carry this out.
- Departments should also favour the implementation of specific QA programs dedicated to the imaging equipment used in the RT workflow (MRI, PET-CT…). This process might be aided through the creation of medical physics departments within the entire hospital network.

Quality management systems (QMS)

General observation: A significant number of recommendations were directed towards the department's QMS in comparison the previous cycle of audits. This is mostly due to the fact

that this chapter has been highly developed in the B-QUATRO audit tool (as compared to the QUATRO tool) and also correlated with the inclusion of QMs within the audit team.

- The financial support that the hospitals have received through the National cancer plan has allowed radiation oncology departments to benefit from 1 full time equivalent (FTE) quality manager. As demonstrated through the audits, their arrival in radiation oncology departments have greatly aided departments in implementing and continuously improving the components that underlie a QMS (risk management, process development and optimisation, document management, etc...). Quality managers (QM) also play an integral role in the development of various national quality improvement initiatives (PRISMA-RT, quality indicator project, etc...). It matters that radiation oncology departments continue to benefit from this support to ensure continuous quality improvement. The number of required FTE QMs should nevertheless depend on the number of patients who get treated in the department while keeping in mind that not all departments seem to benefit from at least 1 FTE QM;
- Although proactive risk assessment legally needs to be carried out for all new equipment or procedures, it still remains difficult to systematically implement and formalize this in all departments.

6.3.2 What is required for the successful implementation of external clinical audits?

Peer reviewed and comprehensive clinical audits have been successfully carried out in Belgium with each radiotherapy department having been audited twice since its implementation. Several factors eased the successful implementation of the audits [37,207]. In Belgium, these were established and maintained over the two cycles of audits and were as follows:

- **National legislation:** The legal requirement of audits will undeniably favour the implementation of audits, as this legal framework will serve as a platform to set this up. The 2002 Royal decree translated the 97/43/Euratom directive into Belgian law [203] and has as such formalized the legal obligation to organise audits;

- **Presence of an organising body**: An advisory group composed of clinical experts are essential for the development and coordination of the clinical audit. This group should preferably be established by the Health Ministry or other government organisation, in order to ensure appropriate authority and financing. But the group should stay independent from this national authority as to keep the clinical audit process separate from (legally required) accreditation processes. The group should provide advice on the overall implementation of clinical audits and should establish the training of the auditors. In collaboration with the experts of the different scientific and national bodies, it should provide the criteria for good practice. Ideally, it should also ensure that the global findings of the audits are shared with national authorities and associations. In Belgium, "The College" undertook the task of organising the audits and from this arose the creation of an auditor group coordinated by a member of the College and a person dedicated to coordinating the audits.
- **An audit tool:** A frame of reference or checklist describing the different quality criteria or standards of practice should exist to guide the audits. This guide should be available to all parties involved**.** In Belgium, the IAEA QUATRO tool was initially used and was subsequently revised to become the B-QUATRO tool;
- **Financing**: In the context of external audits, financial compensations has to be foreseen to cover the expenditure of the auditors themselves, a.o. the expenses relating to travel and accommodations, as well as the material necessary for the audits (computers, software, etc. Human resources should also be allocated to coordinate the audits. This was foreseen in Belgium, where a budget was financially supporting a person partly dedicated to College's audits and QI projects. In Belgium, the costs of the audits were covered through a yearly budget allocated to the College (±10.000 euros) which covered travel and accommodations of the auditors as well as software used for auditing purposes (OneDrive platform). It is to be noted that the auditors only received a compensation for their incurred costs and were not paid for their role and intellectual input in the mission itself. The auditors worked on a voluntary basis and/or were exempted by their service during the audit mission. Annual auditor meetings were also financed to facilitate

the analysis of the audits and to favour exchange of observation and practice amongst the auditors.

- **Well-trained auditors possessing the necessary clinical expertise**: Clinical audits require the eyes of auditors that are professionally active in the field and that possess the expertise needed to observe clinical practice and to compare it to good clinical practice. This matters even more in the context of the QUATRO/B-QUATRO audits, whereby the auditors need to observe practice based on the defined quality criteria but also based on their knowledge and experience of the field. This underlines the importance of having a multidisciplinary auditor team whereby each professional group will analyse clinical practice from the viewpoint of his/her own professional background. Becoming an auditor also requires additional qualities such as objectivity and integrity, as well as good communication skills. Training should thus be foreseen to cover both aspects: general training on the auditing process itself including the soft skills that are required to audit (*what is an audit? how should I behave?...*) as well as training of the auditors in using the tool itself (*what quality criteria should I be looking at and how? How do I write the report?*)

  Training of Belgian auditors was indeed organised but limited by financial and time constraints; all new auditors were trained during one day with the help of QUATRO and B-QUATRO experts and the trainees were then asked to participate – at a minimum- in an audit as an observer to appraise the practical modalities.
- **Constructive feedback:** During the audit, areas needing to be improved are identified and then formulated as recommendations in the audit report. Based on these, the audited department can then set up improvement actions in response to the various identified areas and are then subsequently verified during the next audit. This constructive audit cycle can only become possible if the recommendations are clearly formulated. Ideally, the report "should" also highlight the department's areas of strength.

  In line with this, the B-QUATRO report template has been created in such a manner that all recommendations and commendations appear clearly in tabular form with the integration of a colour coding system to clearly distinguish recommendations from suggestion of improvement from areas of good practice (Table 10).

Table 10 - Format and colour coding used in the audit report to communicate the observations made during the audit

Checklist	Evaluation	Observations/Suggestions/Recommendations
Example		
CL #	***Global evaluation :*** **Compliant or Partially compliant or Non complaint**	Observation in **black** / Suggestions in **green** /recommendations in **red**
Example (5) Patient information	***Partially compliant***	*Documentation is easily made available to patients, both concerning radiotherapy in general and the more specific aspects related to a particular pathology. More generally, as soon as he arrives at the LOC, the sick person is clearly at the center of the concerns. This demonstrates a great deal of attention and confirms the constant efforts to humanize care, a central value advocated by all within the LOC.* *On the other hand, great caution should be observed with patients of childbearing age. Routine pregnancy screening is recommended. An introduction and formalization of paramedical consultations would be a real asset*

- **Collaborative framework:**
  - **With other entities** (regulatory bodies, ministry of health, other accrediting systems):

Clinical audits are different from accreditation systems and from regulatory inspections. As such, clinical audits should be established and developed in a way that it minimizes unnecessary overlap, or duplication of efforts, with the other quality assessment systems and regulatory inspections.

In Belgium, a clear collaboration was established with the FANC to avoid overlap but also to ensure that there existed no contradictions between the regulatory body's requirements and the B-QUATRO tool. The B-QUATRO was also reviewed taking considering the current legislations regulating the radiation oncology departments and the professionals working within it.

  - **With the departments**

Clinical audits can only be welcomed if they are well prepared and perceived as an opportunity to improve. Belgian RT departments have all been active players in the audits – by welcoming the audits but also by liberating some of their own staff to carry out the audits as auditors. Through the work carried out in this thesis, it has become apparent that

the arrival of quality managers in all radiation oncology departments has also played a fundamental role in the acceptance and integration of clinical audits as quality improvement tools by departments. A similar conclusion was also made in France where quality managers have played a fundamental role in implementing the quality management elements made mandatory by Agence de Sureté Nucléaire (ASN) [217,218].

6.3.3 The limitations of clinical audits as a quality improvement tool

Despite these above-mentioned requirements being implemented in the Belgian radiotherapy audit landscape, the nature of these organised clinical audits do possess some limitations that could negatively influence the impact of those clinical audits on quality improvement initiatives.

- **Time and resource constraints**: Conducting a clinical audit is time-consuming and resource-intensive. The last set of audits necessitated 22 auditors (including a backup) who dedicated minimally two days to the audit mission itself without counting the number of days necessary to prepare the audit (1-2 days) and to write the audit report (2-3 days). Elements have been put into place to facilitate the auditing process such as the creation of clear checklist, an audit report template and a platform to easily share documents. Yet the amount of work to be provided to carry out these audits is finely balanced with the voluntarily-based nature of the work and could impact the quality of the audits provided.
- **Incomplete data**: In some cases, the audit on-site visit does not allow the auditors to observe all clinical practice (special technique, quality control procedure…). Furthermore, careful consideration of a range of factors is required including taking into account the contextual factors surrounding the audited department. The findings of the audit results can be complex to interpret, which is even further exacerbated when the number of days of the audit is limited. After the first cycle of audits, it was decided to shorten the second audit visit, as it assumed that these could be considered as re-audits. However, auditors of the second cycle of audits agree that the time frame for the audit visit was too limited and led to an overall feeling that this did

not leave enough time to properly cover all areas. This may have led to incomplete observations and conclusions within the audit reports.

- **The notion of subjectivity**: As previously mentioned, a number of clinical processes and clinical practices cannot be compared to formal standards and are, as a result, compared to what is considered to be "best practice". This means that there exists a certain level of subjectivity in the auditing process, which can be questioned by different entities, including the audited department itself or its hospital management. This can influence the impact the audits have on the initiation of quality improvement initiatives within certain departments.
- **Lack of accreditation:** it was purposely decided by the founding members of the QUATRO audits in Belgium not to use a scoring system to potentially differentiate centres of excellence from departments who globally have a higher rate of non-compliance, as the aim of the audits was not to benchmark departments against each other. However, this leads to some frustration as the results of the audit cannot be easily communicated internally or even with outside parties such as the patients themselves.
- **Lack of control/regulation:** As the audits are carried out on a voluntary basis, the completion of the audit tasks relies on the willingness (or ability) of the auditors to do this, and the willingness of their own departments to liberate their time. This may give rise to situations whereby the audit mission is not completed leaving the audited department without a formal audit report. This occurred once during the two cycles of audits and will need to be discussed before the next cycle of audits. On the other hand, this also means that if severe non-compliances are observed, the auditors do not have the necessary attributions to notify the concerned entities.

6.3.4 Future perspectives

The Federal Public Service (SPF/FOD) has stated that it would continue on financially supporting the College's projects. In this context, it will be necessary to ensure that the above-mentioned requirements are maintained. . It will also be necessary to review the current version of the B-QUATRO tool, considering new treatment techniques, standards of care, and the results of the previous audits. The inclusion of patients during this reviewing process could be foreseen as suggested by the QuAdrant project [208]. The optimal length of the audits

will also need to be discussed as well as the recruitment and training of new auditors as some auditors will no longer be able to participate in the future audits.

Future work might also include the dissemination of a similar questionnaire as the one cited in CHAPTER 2: CLINICAL AUDITS – whereby the departments' feedback on the relevance and usefulness of the recommendations of the second cycle of audits will be assessed. This feedback will also be considered during the update of the second version of the B-QUATRO. In all cases, just as during the second cycle of audits, the extent to which the recommendations of the audits led to planned or unplanned improvements within the department will be closely monitored by the auditors during the third cycle of audits. Complementary to the questionnaire, it might also be of interest to further analyse the audit reports in order to investigate potential links between deficiencies that might be observed at the organisational or staffing level and their impact on clinical practice and workflow.

It is also to be noted that until now, brachytherapy has been excluded from the B-QUATRO auditing process. Although the use of brachytherapy has dramatically decreased and is now performed by a selected number of radiotherapy departments, it remains an important and complex clinical process that could benefit from the organisation of audits [219]. Integrating this in the current B-QUATRO audits will be challenging if not impossible due to the limited time attributed to the audits and the lack of brachytherapy auditor experts. However, future work might need to foresee the possibility of favouring a European/international based brachytherapy audit. These same steps could be foreseen for protontherapy with external audits having already been carried out in the United States [220] – keeping in mind that Belgium has one clinically active center at this stage.

Finally, it is important to continue to inform and educate radiation oncology professionals in the importance of clinical audits for quality improvement purposes. This should be done through regular communication (during national conferences, professional associations,…) and by integrating quality management/managers and its tools within the educational programs of healthcare professionals.

6.4 Quality indicators

6.4.1 Status of the project

Clinical quality indicators are measures that provide insight into the quality of healthcare provided to patients. Through the implementation of College RT-QI project and the analysis carried out within the framework of this thesis, it has been shown to be feasible to collect data for the measurement of radiotherapy-specific QIs on a national level, resulting in a high participation rate amongst radiation oncology departments, who positively evaluated the project. The analysis of the collected QIs and the generation of personalized benchmarking documents have shown to guide departments in setting up quality improvement initiatives on a departmental level. Forty percent of departments stated that the QI project stimulated a change in organisational practice and 22% stated that the project had an impact on their clinical practice with changes in fractionation schemes and treatment techniques that are used.
In parallel, organisational and clinical practice trends were observed over time, and communicated to the departments through the benchmarking reports and during meetings such as the annual College and department heads meetings.

All participating departments agreed that the national RT-QI project should continue with half of them suggesting that adjustments would be needed, e.g., integrating Patient Reported Outcome Measures (PROMs) and favoring data extraction automation to allow more patients and pathologies to be included in the project. As such, the data collection for patient-specific process and outcome QIs has been put on hold since 2019 – judging that a thorough statistical analysis was advisable to confirm their validity. This analysis was realized within the framework of this thesis (CHAPTER 5: LINKING COLLECTED QUALITY INDICATORS) and has given rise to two important observations; (1) significant differences exist in how members of the different radiation oncology departments grade patient toxicities and (2) the variables that seem to most impact the recorded acute toxicities are those elements that are not specific to radiotherapy (patient age, chemotherapy...). This second observation must be carefully interpreted as the analysis only focussed on acute toxicities and a selected number of simplified process QI. Yet, the analysis supports the notion that data collected in a real-life setting can be used to evaluate trends in practice

and potential interactions between certain clinical process indicators and patient outcome.

The collection of structural QIs has been going on since 2015. Their analysis continues to generate the yearly-anonymized benchmarking documents, provided to each participating radiotherapy department as to reflect about the local practice compared to its Belgian counterparts. Moreover, their collection has also been useful to provide evidence for policy reports (KCE report 289) and international database (IAEA DIRAC database) [69,221].

The network that was created during the data collection for the national RT-QI project also proved to be useful during the COVID-19 pandemic. In this context, specific QIs were developed to evaluate the impact of the pandemic on staff, patients, and organisational and clinical practice. This allowed those parameters to be monitored when the first COVID-19 wave hit Belgium and showed that departments were swiftly implementing adaptations in treatment indications and fractionation schedules, conform to what has been observed in international reports [88,156,166,169,170].

. The continuation of the RT-QI will need to be discussed keeping in mind the requirements for its successful implementation described here below.

6.4.1 What is required for the successful implementation of national quality indicators?

As demonstrated through this work, it is possible to collect radiotherapy-specific QIs on a national level. This successful implementation has been favoured by the existence of certain factors, which are stated here:

- **Definition of a limited number of SMART quality indicators**: when defining the radiotherapy-specific QIs, it was deemed primordial to limit the amount of data needing to be collected as to not overburden the departments, while ensuring that the defined QIs would be "SMART" [46,133]. The acronym "SMART" stands for:
    - Specific: the QI should be specific – focussing on an explicit part of clinical care or outcome - and clearly defined;

- Measurable: the QI should be measurable, meaning that there should be a clear and objective way to collect data and track progress over time;
- Achievable: the QI should be achievable and realistic, meaning that it should be within the control of healthcare providers and organisations to improve performance;
- Relevant: the QI should be relevant to the healthcare organisation's goals and priorities, as well as to the needs of patients and the community;
- Time-bound: A SMART clinical indicator should have a clear time frame for data collection and reporting, so that progress can be tracked and improvements can be made over time.

Ideally, each QI should be defined by a grid that describes its characteristics as illustrated in Table 11 which ensure that the concepts underlying its QIs is well described and known.

Table 11 - Identity card of one quality indicator used in the RT-QI project

	Parameters	**Timely delivery of the treatment**
Measure definition	**Topic (what is measured)**	Time required to complete the EBRT treatment as a function of the number of fraction prescribed
	Rationale (why it is measured)	Estimation of the number of lost days between the expected number of days and the actual number of days required for the treatment
	Type of QI	Process
	Numerator	Time required to complete the treatment (= number of days between the last day of treatment and the first day of treatment) (excluding weekends and holidays))
	Denominator	Number of prescribed fractions taking into account the fractionation scheme
	Definitions and specifications	All H&N patients
	Exclusion criteria	Excluding T1N0 Glottis
		Excluding twice daily fractionation schemes
	Recommended stratifications	Primary departmental level

Goal setting	**Standard/target**	*Mean difference of 2 days*
	Time period/target number for data collection	25 patients
	Frequency of analysis	Yearly

- **Engaged stakeholders (and quality managers)**: The engagement of radiation oncology departments was paramount in the success of this project. This was facilitated by the existence of a culture of quality within the Belgian landscape – as demonstrated by the first cycle of audits – but also by informing the departments in the development of the indicators, providing regular feedback on performance. By showing the position of the own department in comparison to the other Belgian departments, this stimulated departments towards quality improvement. The radiotherapy quality managers have also been paramount in this project by serving as a central point for data collection and communication.
- **Resources and funding**: A national RT-QI project requires resources and funding to support its development, implementation, and ongoing maintenance. This should ideally include funding for data infrastructure, staffing, and ongoing monitoring and evaluation. As previously mentioned, a limited budget was financing 0.3 FTE of a dedicated quality manager, supporting the College's audits and QI projects, centralizing and analysing the data and providing the departments with the benchmarking documents. Although this financial support made it possible to initiate and drive this process through its early-stage period, without the dedicated personnel time devoted in the context of this research project, this would have been clearly insufficient. To further deepen the work and take it to the next level, more extensive and sustainable financing is needed.
- **Data collection infrastructure**: The collection of data for QI purposes, requires a robust data infrastructure to collect, store, and analyse the data. This includes systems for data collection, validation, and quality control, as well as secure storage and access to the data. The RedCap platform used in the context of this project provided these advantages by its capability of creating structured data forms with individual access given to the departments and a centralised database that allowed for the easy extraction

of the collected data. Although this free centralised database was sufficient in the initial project phase, the acquisition of more advanced and adapted tools and dashboard would have facilitated the process of giving feedback to the departments. Here too, additional financing would be needed to allow a more robust, automated, and sustainable system for data collection, storage and analysis for the years to come.

- **Feedback and communication**: Effective communication and transparency are essential to build trust and to ensure the project's success. This includes communicating the purpose and benefits of the project, providing regular updates on progress, and being transparent about the data and its interpretation. As previously mentioned, individual results were provided to the participating departments through the anonymized benchmarking documents but also through regular communications given during national conferences.

6.4.2 The limitations of quality indicators as a quality improvement tool

QIs have limitations that should be considered when interpreting their results or using them for decision-making. Some of the limitations of QIs include:

- **Limited data**: The necessity of manual data entry and its potential burden on departments was considered when defining the QIs. This limitation has already been identified in other publications [222–224]. A subtle equilibrium must thus be established between the need to collect enough data to allow for the proper measurement of quality of care and the need to limit the necessary resources required to collect the data. In the absence of automatic data extraction tools, this will remain a factor that will limit the extent to which data can be collected;
- **Limited scope**: Clinical QIs may only measure specific aspects of care and may not capture the full picture of a patient's overall health status or care experience. This is certainly the case for oncological patients who come with their own health and comorbidities, and their specific socio-economic background that may impact the way in which they tolerate treatment. Moreover, set into a multidisciplinary context, distinguishing the impact of

radiotherapy compared to that of the other treatment modalities is difficult. Furthermore, process QIs often encompass more than just one activity or one technique; the quality of the process will highly depend on other interrelated processes that might not necessarily be captured in the defined QI but which by themselves can highly impact the output of the QI;

- **Data quality issues**: The accuracy and completeness of QIs, not in the least for clinical indicator data, can be compromised by a variety of factors, including variations in documentation practices and coding inaccuracies as well as the lack of clear standards. Within the scope of the RT-QI project, both the absence of external control of data quality as well as discrepancies in the data encoded by departments (e.g. variability in toxicity scoring between departments) may both have affected the quality of the data.
- **Difficulty in selecting appropriate indicators and targets**: Choosing the right indicators can be challenging, as they need to be relevant to the specific patient population and the care processes being measured. In parallel, setting targets for QIs can be complex, as they need to balance the desire for high-quality care with the realities of resource constraints and other factors.
- **Limited ability to capture patient perspectives**: Clinical QIs may not capture aspects of care that are important to patients, such as patient experience, communication and shared decision-making. This is certainly a limitation of the RT-QI project as patients were not involved, nor in the Delphi process during project development, nor in the analysis of the data.

Overall, while QIs, and especially clinical indicators, can be useful quality improvement tools, it is important to recognize their limitations and thus to integrate QIs with the range of tools and methods that are accessible to assess and improve the quality of care provided to patients. This may include incorporating patient perspectives and experiences into quality improvement efforts, and using a variety of data sources to gain a comprehensive understanding of the quality of care provided [171,225,226].

6.4.3 Future perspectives

In light of the positive feedback arising for the RT-QI project, it is primordial to maintain the project keeping in mind the requirement stated above. The next

steps will, as requested by the departments, consist of the review of the collected QIs through the organisation of experts' meetings. Contrary to the definition of the first QIs, these meetings should also include other stakeholders such as health economists, epidemiologists and maybe even patients themselves. In parallel, the project will need to be inspired by existing QI projects including the international ESTRO project that looks at defining a common set of radiotherapy-specific QIs [227].
Moreover, future considerations will need to include the optimisation and automation of the data collection process, ideally including external data quality checks. The automatic data extraction from existing radiotherapy information systems or hospital electronic health records could eventually lead to big data analyses [146,171,203,204]. This path has been investigated in the Belgian radiotherapy landscape through either vendor solutions or alternatives proposed by hospital organisations [228,229]. Artificial intelligence might also play a role by facilitating data compilation and analysis [230]. If this approach would be pursued, it will be necessary to structure and standardise the data sets both at the department/hospital level and at the national level in order to generate usable but also used data. Moreover, the data extracted should be carefully selected so that they can be used to measure the quality of care we are offering (QIs) to patients while also having the potential to play a role in clinical decision-making [231–233]. Attaining this goal will require a substantial amount of work and resources but this is expected to be compensated for by the potential benefits of big data extraction for treatment optimisation [233,234]. This includes the notion of using real-life data to investigate potential links between clinical practice and patient outcome as attempted in chapter 5 (CHAPTER 5: LINKING COLLECTED QUALITY INDICATORS).

A seemingly more attainable goal that could be implemented in all radiation oncology departments and at a national level is the collection of patient-reported outcomes (PROMs). Their reliability and use in optimizing patient care has already been demonstrated [102,149,151]. Furthermore, their collection at a multicentric level could remove the differences in toxicity grading observed between different institutions in our project. Yet their definition and implementation is not simple and their subjective nature might lead to misinterpretations [235–239]. Within the framework of quality and outcome

improvement, the monitoring of PROMs is thus highly valuable but it should not be perceived as an all-in-one and effortless solution.
Patient outcome is evidently of primordial importance, but this should not come without assessing and evaluating the perceived quality of care experienced by patients through patient-reported experience measurements (PREMs). This involves collecting patient feedback and opinion about the quality of the interactions they have had with their healthcare providers, the facilities and the services. A project coupling an internal initiative within the Cliniques Universitaires St Luc and the RT QMs is aiming at collecting patient experience measures across all radiation oncology departments by using a common PREMS questionnaire [240].

With the collection and monitoring of QIs, also comes the notion of their use in public reporting. Within the RT-QI project, the collected QIs have been shared on an anonymous level though their publication in the benchmarking document and during conferences. Although, the notion of public reporting of these QIs has not been considered at this stage, it might become a matter of interest in the upcoming years. Public reporting of results may act as incentive of change and improvement. However, it should be implemented within a framework whereby it does not lead to unintended consequences such as patient selection biases, data manipulation or excessive use of medical interventions [54,241]. Recognizing that there are some potential drawbacks to public reporting of QIs, the benefits of increased transparency, improved accountability, and incentives for improvement may outweigh these concerns and could be discussed in the future. In all cases, it is important to ensure that the data is accurate, properly interpreted, and used to drive meaningful improvements in patient care.

Chapter 7

"Quality is not a goal in life, it is a way of life"

– Pierre Scalliet

CHAPTER 7: CONCLUDING REMARKS

The establishment of a QA program and quality management system is a necessary step that all radiation oncology departments should take to ensure the optimal and safe delivery of radiation treatments. This is particularly important in the context that radiotherapy is a potentially high-risk procedure relying on the accurate delivery of high doses to patients within a complex environment. Patients undergoing a radiation treatment must be able to benefit from optimal treatments with the best chances of local tumour control, survival and quality of life and with lowest risk of treatment morbidity and toxicity. The creation of national quality-oriented initiatives that favour continuous quality improvement can, as such, serve as guidelines for departments to ensure that this is the case. In Belgium, the College and the work carried out in the framework of this thesis have led to the successful realisation of two national quality improvement projects: The first is the implementation of peer-reviewed comprehensive external clinical audits allowing for the identification of areas and processes in need of improvement and favouring exchange of practice and good clinical practice. Second, radiotherapy-specific structural, process and outcome QIs have been defined and measured and have been used to provide feedback and guide departments in setting up organisational and practical changes. The work performed in the context of this thesis has also allowed to structure the information and data collected in both initiatives providing the evidence that the use of both tools favour quality improvement initiatives both locally and at a national level. By using these tools together, radiation oncology departments can identify areas needing improvement, measure progress in achieving quality improvement goals, and ensure that they are providing high-quality care to their patients. The findings of this study underline the importance of using QIs and clinical audits in radiation oncology departments, and they highlight the need for ongoing quality improvement efforts in this critical area of healthcare. Just like any quality project, both initiatives will need to be fine-tuned and adapted to ensure their continuation in the evolving Belgian radiation oncology landscape, keeping the patient at the center of our focus.

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Publications

Type	Title	Journal	Authors
Report	Required hospital capacity in 2025 and criteria for rationalisation of complex cancer surgery, radiotherapy and maternity services	KCE report 289, 2017	Carine Van De Voorde, Koen Van Den Heede, Claire Beguin, Nicolas Bouckaert, Cécile Camberlin, Piet De Bekker, Noémie Defourny, Harlinde De Schutter, Carl Devos, Sophie Gerkens, Cai Grau, Patrick Jeurissen, Florien Margareth Kruse, Mélanie Lefèvre, Yolande Lievens, Patriek Mistiaen, Aude Vaandering, Elizabeth Van Eycken, Ewout Van Ginneken
Editorial	Doing the right thing: Quality in radiotherapy, a European perspective	Radiotherapy and Oncology; 2018;127(2):161-163	Yolande Lievens, Pierre Scalliet, Nuria Jornet, Mary Coffey, Aude Vaandering
Original Article	Feasibility and impact of national peer reviewed clinical audits in radiotherapy departments	Radiotherapy and Oncology; 2020;144:218-223	Vaandering, A., Lievens, Y., Scalliet, P., & Belgian College for Physicians in Radiation Oncology
Original Article	Impact of the COVID-19 Pandemic on Patients and Staff in Radiation Oncology Departments in Belgium: A National Survey	Frontiers in oncology; 2021; 11, 654086	Vaandering, A., Ben Mustapha, S., Lambrecht, M., Van Gestel, D., & Veldmeman, L
Original Article	Barriers in education and professional development of Belgian medical imaging technologists and nurses working in radiotherapy: A qualitative study	Radiography; Volume 28, Issue 3, August 2022, Pages 620-627	F.Sousa, A.Vaandering, J.G.Couto, M.Somoano, D.Van Gestel

Narrative review	Favouring quality improvement initiatives: The experience of the Belgian College of Radiation Oncology	Precision Cancer Medicine; Vol 6, March 2023	Aude Vaandering, Sarah Roels, Burak Yalvaç, Nathalie Reulens, Brigitte Reniers, Frederik Vanhoutte, Vincent Remouchamps, Yolande Lievens, Reinhilde Weytjens
Original Article	Radiotherapy-specific quality indicators at national level: how to make it happen.	Radiotherapy and Oncology; Volume 178, January 2023	Aude Vaandering, Nicolas Jansen, Caroline Weltens, Luigi Moretti, Karin Stellamans, Frederik Vanhoutte, Pierre Scalliet, Vincent Remouchamps and Yolande Lievens On behalf of the Belgian College for Physicians in Radiation Oncology
Original Article	Linking acute toxicities and radiotherapy treatment processes - a possibility through a national quality indicator project?	In progress	