Favouring quality improvement initiatives: the experience of the Belgian College of Radiation Oncology

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Contributions: (I) Conception and design: All authors; (II) Administrative support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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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 minimizing 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. These improvements can arise within the local or departmental context, but they can also be favoured by national programs and incentives. The Belgian College of Physicians for Radiation Oncology Centres ('the College') is a federal entity—composed mainly of radiation oncologists, medical physicists, radiation therapists and quality managers—whose mission is to improve the quality of radiotherapy by organizing peer review activities. Throughout the past decades, the College has been the source of numerous national initiatives, which have fostered and accompanied radiotherapy departments in taking the steps towards increased quality of care. With this review, we aim to share these national quality-oriented projects instigated by the College. These include the introduction of peer-reviewed target volume contouring programs, the organisation of clinical audits and external beam dosimetry audits as well as the implementation of a national adverse event analysis system and the collection and analysis of RT-specific quality indicators.

Keywords: Quality assurance; radiation oncology; quality improvement; audits

Received: 15 April 2022; Accepted: 24 November 2022; Published online: 16 December 2022. doi: 10.21037/pcm-22-15 View this article at: https://dx.doi.org/10.21037/pcm-22-15

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Introduction

Background

Radiation therapy (RT) has an integral role in multidisciplinary cancer treatment in a curative setting, e.g., in a radical approach for organ preservation or as a (neo-) adjuvant approach before or after other oncology treatments. It also has an important benefit in the palliative setting and to a lesser extend in the treatment of nonmalignant diseases (1). The accurate delivery of a radiation treatment is of primordial importance in radiation oncology, particularly as patients benefit from ever shorter treatment approaches delivering high doses to the target volume, a strategy referred to as hypo-fractionation (2). This requires conformal and intensity modulated treatments to minimize the dose delivered to surrounding organs at risk. Hence, all possible measures should be put into place to ensure the safe and effective delivery of those treatments (3,4).

Rationale and knowledge gap

The European Council Basic Safety Standards Directive (BSSD) Directive of 1997 (Council Directive 97/43/ Euratom) required that Member States take "all reasonable steps to reduce the probability and the magnitude of accidental or unintended [radiation] doses of patients" in radiotherapy. This is further detailed in the more recent 2013/59/Euratom directive (5). This directive requires that member states establish incident reporting and learning systems, carry out prospective risk analysis of all the processes involved as part of their quality assurance (QA) programme, as well as take all the steps necessary to ensure radioprotection of exposed citizens in terms of justification, optimisation and dose limitations. In addition, the directive states that departments need to carry out clinical audits "in accordance with national procedures" in order to assess good clinical practice. As such, European member states have the obligation to translate these requirements into their own legal framework. However, the extent to which this is actually converted into practice in the different countries varies greatly. A survey on carried out by the European Society of Radiology on BSSD compliance showed highly variable responses in between radiology departments and countries and this even more so following the COVID-19 pandemic (6). The European commission's QuAdrant [Quality Improvement Through Clinical Audit in Diagnostic (including Interventional) Radiology, Radiotherapy and Nuclear Medicine including Therapies] project aims at promoting and enhancing BSSD

2013/59/Euratom compliance, and supporting clinical audit practice. Its work packages have also demonstrated variables degrees to which radiology and radiotherapy departments have implemented the requirements with a limited number of countries such as the UK, Finland, Switzerland, Norway and Belgium sharing their successful implementation of clinical audits (7).

In May 2000, the Belgian government established the College of Physicians for Radiation Oncology Centres (further referred to as 'the College') with the aim of evaluating and improving quality of radiotherapy. Eight radiation oncologists are appointed by the Minister of Health for a term of 6 years. A balance is sought between men and women, academic and non-academic, Flemish and French speaking members. The members are supported by a working group of experts, consisting of medical physicists, radiation therapists (RTT), 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.

Objective

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 1). From a clinical point of view, contouring guidelines have been published, followed by national intervision projects, important to optimise and homogenise radiation treatment preparation. Covering the entire radiotherapy process, national peer review clinical audits are undertaken, based on the International Atomic Energy Agency (IAEA) Quality Assurance Team for Radiation Oncology (QUATRO) methodology (8). In parallel, the College also supports external dosimetry audits to ascertain the correctness of the delivered dose, per beam and for various complex techniques. In addition, a structure to analyse, report and benchmark radiotherapy events has been installed. Finally, the College has also defined a set of structural and patient-related process and outcome quality indicators (QIs), which have been collected and analysed on a yearly basis to serve as a reference for all participating centres.

The objective of this paper is to describe these various quality-oriented projects. Each of these initiatives have the common aim of identifying areas of possible improvement



Figure 1 Timing of the different cited projects of the College. QUATRO, Quality Assurance Team for Radiation Oncology; BELdART, Belgian Dosimetry Audits in RadioTherapy.

in the delivered care, and defining collective improvement actions through sharing of experience and benchmarking.

Intervision projects for target volume delineation

Optimal target volume definition and delineation is a prerequisite to ensure optimal radiation treatment and benefit from technical improvements. To ensure consistent target volumes, persistent efforts are needed from the radiation oncology community to provide detailed contouring guidelines and hence reduce interobserver variability.

Because of the great diversity between the different hospitals in Belgium, both in the treatment of rectal tumors and their outcome, a national platform, PROCARE (PROject on CAncer of the Rectum) was set up by a multidisciplinary working group to advocate for standardization and quality control in rectal cancer care. In 2007, the PROCARE group outlined a number of national guidelines with recommendations for diagnosis, treatment and follow-up (9). In a next phase, about forty QIs were formulated in order to be able to test the quality of care (10). An accurate analysis of the registered data made it possible to provide feedback to the various hospitals in a constructive manner.

In addition to mapping the quality of care and offering "best clinical practice" guidelines, the PROCARE platform also offered concrete assistance in implementing these guidelines through training programs provided to surgeons as well as online review platforms such as PROCARE RX in which the radiologists could anonymously have their findings on computed tomography (CT) and/or magnetic resonance imaging (MRI) revised by an expert radiologist. Besides activities in the diagnostic and surgical setting, a central review platform for clinical target volume (CTV) delineation was launched, in an attempt to improve delineation uniformity in rectal cancer radiotherapy (11). Between March 2010 and September 2012, 20 centres submitted 1,255 rectal cancer cases, of which 1,224 were analysed. A high level of agreement on CTV delineation was observed between the participating centres and the central review facilities from the beginning of the project. Moreover, the instant feedback by e-mail gave the centres the opportunity to pick up the reasons for the suggested modifications. This resulted in a significant improvement in CTV delineation and reduction of interobserver variability across participating Belgian radiation oncology departments.

In 2013, a national QA project for breast radiotherapy was started, named PROCAB (PROject of CAncer of the Breast). Guidelines for the delineation of the regional lymph node areas (RLNAs) were published, approved on a national and European level (12) In contrast to previous experiences, the guidelines were based on the anatomy of the blood vessels, rather than on bony structures, which made them more patient-tailored, precise and applicable, independent of the treatment position. The delineation guidelines provided a meticulous description, supported by a clear delineation atlas using CT-images.

Subsequently, the project investigated the effect of central review on the interobserver variability and quality of the delineation of the RLNAs (13). In total, 1,009 CTVs from 23 RT departments were centrally reviewed and scored. A significant decrease in errors over time (learning curve) was observed, supporting the benefit of a central review on the conformity to the guidelines.

After these rectal and breast cancer projects, ProCaLung is now being introduced with the aim to improve the quality of mediastinal node positive non-small cell lung cancer radiotherapy through peer-review of mediastinal nodal target Volume Delineation (14). This project is discussed extensively in another article in this issue.

In 2017, the PROCAHN project (PROject on CAncer of Head and Neck) was supported with the goal to map the interobserver variability in tumor delineation in the head and neck region between the different radiotherapy centers in Belgium (15). Since availability of guidelines did not guarantee uniform delineations, the investigators recently set up a subsequent study, where the implementation of most recent delineation guidelines by Grégoire *et al.* [2018] on interobserver variability will be assessed (16).

The precision of radiotherapy treatment execution relies on the accurate delineation of target volumes. The College's intervision projects have, as such, actively participated in diminishing the variability of target volume delineations all the while ensuring the dissemination of guidelinebased good practice. Ideally, this type of initiative should be instigated for all radiotherapy indications but also for all major updates in clinical guidelines.

B-QUATRO peer-reviewed clinical audits

Clinical audits is a process in which actual clinical practice is compared to standard of care in order to identify potential areas of improvement leading to better quality of care. More particularly, peer-reviewed external clinical audits consist of the review of actual practice by expert individuals that are professionally active in the field. Clinical audits lead to the identification-by the auditors-of areas of practice needing to be improved (5). As described by Scalliet et al. [2015], since 2011, the College organizes peer-reviewed clinical audits in all Belgian radiation oncology departments based on the IAEA QUATRO tool, quality criteria and philosophy (17-19). The multidisciplinary auditing team is composed of a medical physicist, a radiation oncologist and an RTT, delegated by the Belgian radiation oncology departments. The auditors are all professionally active members who have been trained in the audit methodology and who perform this task on a voluntary basis, with a budget only foreseen to cover for travel and accommodation. The first audit cycle was initiated in 2011: 5 departments being audited every year, resulted in the successful auditing of all Belgian radiation oncology departments over 5 years. 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 defined to evaluate quality management systems. As a result, a quality manager was also integrated in the auditing team (20,21). 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 should be finalized by beginning of 2023, the coronavirus disease 2019 (COVID-19) pandemic having led to a one-year pause of the audits.

Following each audit, the audited department is provided with a written report covering a set of recommendation emitted by the auditors. This will assist departments in setting up quality improvement initiatives. Anonymized audit reports are presented to the College, at yearly auditors' meetings, and via the College report to the health ministry.

Following the first cycle of audits, departments were surveyed in order to evaluate the relevancy and impact of the emitted recommendations (20). The survey revealed that clinical audits are used by departments in a constructive way to identify areas in need of improvement. Furthermore, the audited and the auditing team both benefit from this peer review process through in-depth exchange of experience and good clinical practice, and this, for the benefit of both the patients and the teams.

Peer reviewed clinical audits established in Belgium since 2011 and have thus shown to be a constructive tool for

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quality improvement though the identification of elements or processes needing to be improved but also through the communication and exchange of best practice between auditors and auditees. The continuity of these valuable audits relies on the existence of active and trained auditors and entities that formally support the organization of these audits.

National dosimetric audits—Belgian Dosimetry Audits in Radio Therapy (BELdART)

The success of radiotherapy is also impacted by the correctness of the delivered dose. Independent dosimetry audits can be conducted to identify eventual discrepancies in the dose delivered by the clinical equipment versus the dose that is expected to be delivered and they can provide support in the solution of identified discrepancies. In this way, continuous improvement in the accuracy of dosimetry can be brought into daily practice and severe failures can be prevented. To make access to dosimetry audits easily available to all Belgian RT centers, the Belgian Cancer Plan supports another action: BELdART based on alanine/ Electron Paramagnetic Resonance (EPR) and radiochromic film dosimetry (22-28). A steering committee composed of five medical physicists functions as advisory body.

Since 2009, BELdART has been developing audit programs for basic dosimetry for photon and electron beams. This beam calibration audit is basic and fundamental, as it affects all patients for any specific treatment machine. Since 2016, BELdART also offers audits for various complex techniques. In the proposed so called end-to-end (E2E) tests, an anthropomorphic phantom is put through the entire chain of procedures that a patient would go through including simulation, planning and treatment delivery.

As a consequence, current services offered by BELdART to the Belgian RT departments are two-fold.

First, beam output checks, performed in reference conditions for photon and electron beams are performed, along with the possibility for more measurements in nonreference conditions for photon beams using alanine/EPR dosimetry (29). A second part consists of E2E tests executed in anthropomorphic phantoms for intensity-modulated radiation therapy (IMRT), prostate volumetric-modulated arc technique (VMAT, intracranial Stereotactic Radiation Surgery (SRS) and lung stereotactic body radiation therapy (SBRT) using a combination of alanine/EPR and film dosimetry (27,28). Between December 2016 and November 2021, the beam output has been measured for 116 beams and 86 of those beams have received a complete verification in water. E2E audits have been performed for prostate treatment for 55 beams, while 26 beams for cranial SRS and 14 beams for SBRT have been evaluated. Due to an increase in the request of audits for flattening filter free (FFF) beams, the configuration of the alanine detectors had to be adapted. As a general observation, the measurements done by BELdART did not deviate from the stated calculated dose by more than 5% for any center. For the 116 Beam Output audits, 90% was within 2% of the stated dose. For the 86 beams that were fully verified in water, 84 beams had an agreement within 5%. For 2 tests in small fields, the difference with the stated dose was just slightly above 5% and it is still unclear what the contribution of the positioning uncertainty is in those small fields. For the E2E tests, in the prostate, the measurements for 87% of the centers were within 3% of the calculated dose, and all were within 5%. In SRS E2E tests, 77% of the participating centers could deliver the dose within 3% and all centers within 5%. The E2E audit for SBRT is still new but of the 14 participating centers, 13 had measurements within 3% of the calculated dose and all were within 5%. The results for the film measurements are confirming these numbers.

The dosimetric validation of the dose measured by the alanine detectors has been performed by the IAEA using the BELdART material and showed results within experimental uncertainty for all clinical MV energies. The BELdART team also conducts R&D to develop future audit procedures for additional treatment techniques. This includes projects regarding the development of movable phantoms (in collaboration with Maastro, NL), the use of alanine in proton therapy [in collaboration with Studiecentrum voor Kernenergie (SCK) or in Ultra-High Dose Rate (FLASH)-RT (in collaboration with UAntwerpen] (30).

The accurate delivery of radiotherapy highly relies on the preciseness of the dose delivered by the equipment in place in radiotherapy departments. The external dosimetric audits organized though BELdART have allowed to provide an objective independent evaluation of the dose delivered by Belgian radiotherapy equipment all the while having to stay in line with the new treatment modalities that have become available in the recent years.

A national event reporting system—PRISMA-RT.be

As part of the requirements for the Belgian Cancer Plan, a national event reporting system had to be set up. The main focus of this system is quality improvement by inter-

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centre comparison of the causes leading to near-misses and adverse events. The system acts complementary to the already existing mandatory declaration of accidents to the Federal Agency of Nuclear Control (FANC), the national competent agency that, amongst others, governs all medical uses of ionizing radiation. For such a system of intercomparison to succeed, a common methodology is needed across all radiotherapy centres.

The PRISMA (Prevention, Recovery and Information for Monitoring and Analysis) analysis methodology was developed in 1992 by T. W. van der Schaaf at the Technical University of Eindhoven initially for the chemical process industry, but shortly thereafter adapted for use in the medical field (31,32). At its core a fault tree analysis methodology, which distinguishes itself by also focusing on near miss reporting and the various factors leading to human behavioural error. Its function in an effective safety management system is the identification of root causes underlying near-misses and accidents, an essential feedback mechanism that supplements Healthcare Failure Mode and Effect Analysis (HFMEA) and other proactive process risk analysis techniques.

Identified root causes are categorized with the Eindhoven classification model (ECM) of system failure. It distinguishes between technical, organizational, human behavioural and external root causes that can affect a human operator. A simplified version of Rasmussen's skill-rule-knowledge model of human errors is implemented in the human behaviour root cause subcategory (33). The ECM is a goaldirected classification, aimed at effective mitigation and prevention, not at attributing guilt or blame. Root causes with different classifications will typically have a different type of corrective action associated with them. Examples of such actions are technical changes, reviewing of procedures, information sessions and additional staff training.

The emphasis on human factor engineering principles led to PRISMA being adopted in 2008 as methodology of choice for the Dutch radiotherapy quality improvement organization PRISMA-RT, initiated by Petra Reijnders and Huub Backes of Maastro clinic (Maastricht, The Netherlands) and Anne Joustra, Catharina hospital (Eindhoven). This project deployed a web-based analysis application and a benchmark application, developed by TPSC (Alkmaar, The Netherlands), to all 17 participating radiotherapy processes and patient safety by an intercentre comparison of root cause profiles. This is supported by regular training sessions to standardize the use of the analysis methodology. In addition, the PRISMA methodology was augmented by including radiotherapyspecific context variables to the root cause classifications. Context variables serve as tags to the otherwise unqualified ECM categories, for example highlighting a specific technique or the process involved in a root cause. The context variables allowed the organization to use the benchmark to steer specific projects (34).

In 2010, the College started PRISMA-RT Belgium. Following the Dutch example, a network was created of radiotherapy quality managers and the TPSC applications were made available to the participating centres. The context variables were extensively reviewed and adapted to the Belgian radiotherapy landscape. A similar programme of training sessions was started. During the lifetime of the project, an interface to the benchmark was developed by TPSC so users of third-party software would be able to contribute. At this time, one additional vendor, Infoland (Veldhoven, The Netherlands), has added the necessary functionality in their software.

Currently, the majority of radiotherapy centres are participating in this network. The experience shows that establishing a common methodology of analysis has served as a uniting factor in the Belgian radiotherapy quality management community. It acts as a common language to discuss projects and issues during biyearly meetings and training sessions. In addition, PRISMA-RT has been adopted as the analysis methodology for the mandatory declaration of accidents. These analyses are shared anonymously with all radiotherapy centres by the competent authority FANC.

The PRISMA-RT methodology of incident and nearincident analysis has thus been successfully implemented in all radiotherapy departments. Surveys among the quality managers indicate that the analysis of near-misses with PRISMA-RT together with regular meetings and training sessions are experienced as valuable driving forces in quality improvement projects. The intrinsic utility of the benchmark is currently being evaluated. An extensive analysis is in progress of the approximately 20,000 root cause classifications collected in the database.

National radiotherapy-specific QI project

In the quest to offer the best quality of care to RT patients, it is of uttermost importance that departments assess the actual performance or quality levels attained and compare these to expected or desired outcomes.

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QIs are measurable and objective elements or data points that can be used as guides to evaluate and improve overall quality of patient care. More often than not, these QIs are developed using the Donabedian model in which the QI covers either the structural dimension or measures actual processes and outcomes (35,36). A clear definition and continuous collection of expert approved QIs allows for the monitoring of quality 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 (37-41). Through this process, it is possible to potentially identify disparities between the QIs that are collected and what is considered standard of care or optimal quality of care. The identification of those gaps can then lead to implementation of improvement actions aiming at minimising those gaps and optimising overall quality of care. While a QI program may be developed at a local level (department or institutional level), it may also be driven by a regulatory demand and/or be initiated by a scientific or professional body, with the ultimate goal to favour quality improvement.

With this objective, a collective work—bringing together the College and the representatives of the Belgian Quality Managers in radiotherapy Association (QMRT.be) established a list of radiotherapy-specific structural, process and outcome indicators, considered as fundamental. The process and outcome QIs focused 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 optimized, the capture of the defined QIs was initiated in 2016 and repeated on a yearly basis with an overall department participation of 95%.

This voluntary and yearly QI data collection has given rise to individualized benchmarking reports that are sent out to the participating centres. Although the overall Belgian landscape of radiation oncology departments is quite harmonious, comparison of QI data between departments has allowed the identification of areas for improvement and has favoured departmental and national quality improvement projects such as changes in treatment techniques used (i.e., use of breath hold for breast cancer patients) or decreased delays between simulation and start of treatment. The yearly collection of QIs has also allowed the monitoring of trends such as the number of equipment, estimated workload per professional group or the number of radiotherapy treatments over time, and has shown to be useful to monitor the impact of COVID-19 on the Belgian radiotherapy practice, as was also done in other countries across Europe (42-46).

As such, through this College initiative, it has been shown that it is feasible to collect defined QIs at a national level, and that such a project can boast of a very high participation rate. It is the hope of the College to be able to collect and analyze QIs at a larger scale by including more patient specific QIs and increasing the number of patients for which this data is collected. This can be favoured through tools that would allow for the automation of data extraction from existing radiotherapy information systems or hospital electronic health records (47-49). This path is currently investigated in the Belgian landscape along with the national collection of Patient Reported Outcome measures (PROMs) (50).

Conclusions

For Radiation Oncology, the Belgian government established the College of Physicians for Radiation Oncology Centres 20 years ago with the aim of evaluating and improving quality of radiotherapy. The 8 radiation oncologists, appointed by the government, are supported by a working group of experts, consisting of medical physicists, RTT, radiation oncologists, quality managers, and, upon demand, delegates from the ministry and from the Belgian Cancer Registry. In the recent decade, radiation oncology has become more and more complex requiring thorough QA programs and continuous quality improvement initiatives.

In the last 15 years, the College has been successful in implementing national quality improvement projects. These include the implementation of peer-reviewed target volume contouring programs, clinical audits, external beam dosimetry audits, national adverse event analysis systems and RT-specific QIs.

Contouring programs have shown that clear guidelines, continuous education of professionals and extensive quality control can reduce the interobserver and intercenter variability in target delineation. Clinical audits are used by departments in a constructive way to identify areas in need of improvement and are a way of exchange of experience and good clinical practice.

Dosimetric audits can support the implementation of new, more complex techniques and because of the national basis with feedback to all centers, it is possible to

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benchmark with other centers with similar equipment. The experience with our national event reporting system showed that establishing a common methodology of analysis can serve as a uniting factor, facilitating discussions. Finally, it has been shown that it is feasible to collect defined QIs at a national level, and that such a project can boast of a very high participation rate leading to change in organisational and clinical practice.

The establishment of a QA program and quality management system is a necessary step that all radiotherapy departments should take in order to ensure the optimal and safe delivery of radiotherapy treatments. This is particularly important in the context that radiotherapy is potentially a high-risk procedure relying on the accurate delivery of high doses within a complex environment. Patients undergoing a radiation treatment must be able to trust that they are treated optimally and in this way have the lowest chances of treatment morbidity and toxicity and the best chances of local tumour control, survival and quality of life. The creation of national quality-oriented initiatives can, as such, serve as guides that can help and accompany departments in ensuring that this is the case. The existence of the Collegecomposed of professionally active RT members-has been a necessary structure that favoured the implementation of these in Belgium. The existence and sustainability of entities such as the College is thus of uttermost importance if these types of initiatives are to be maintained.

Acknowledgments

The authors would like to thank all Belgian radiotherapy departments for their involvement in the various quality improvement initiatives.

Funding: This work was in part supported by the Belgian Federal Government for Public Health through the reimbursement of operating costs.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (Paul Van Houtte and Dirk Van Gestel) for the series "Quality Assurance in Radiotherapy" published in *Precision Cancer Medicine*. The article has undergone external peer review.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://pcm.amegroups. com/article/view/10.21037/pcm-22-15/coif). The series

"Quality Assurance in Radiotherapy" was commissioned by the editorial office without any funding or sponsorship. AV declares being paid part time by the Belgian College of Radiation Oncology as well as being lecturer for the Internal Atomic Energy Agency. BY, NR, BR are members of the BELdArt initiative and benefits from a contract with the Institut Roi Albert II within the framework of the Belgian Cancer plan. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/pcm-22-15

Cite this article as: Vaandering A, Roels S, Yalvaç B, Reulens N, Reniers B, Vanhoutte F, Remouchamps V, Lievens Y, Weytjens R. Favouring quality improvement initiatives: the experience of the Belgian College of Radiation Oncology. Precis Cancer Med 2023;6:4.