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Preliminary communication

Improving radiation oncology through clinical audits: Introducing the IROCA project

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ABSTRACT

As radiotherapy practice and processes become more complex, the need to assure quality control becomes ever greater. At present, no international consensus exists with regards to the optimal quality control indicators for radiotherapy; moreover, few clinical audits have been conducted in the field of radiotherapy. The present article describes the aims and current status of the international IROCA "Improving Radiation Oncology Through Clinical Audits" project. The project has several important aims, including the selection of key quality indicators, the design and implementation of an international audit, and the harmonization of key aspects of radiotherapy processes among participating institutions. The primary aim is to improve the processes that directly impact clinical outcomes for patients. The experience gained from this initiative may serve as the basis for an internationally accepted clinical audit model for radiotherapy.

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1. Background

In recent decades, the effectiveness of radiotherapy has increased considerably due to the advent of ever more powerful, more precise technologies, such as intensity-modulated radiotherapy (IMRT). The use of more sophisticated technologies has also increased the complexity of radiotherapy delivery. As a result, every step in the radiotherapy process has become more demanding and multifaceted, requiring strict attention to detail to assure that the high doses of radiation are delivered precisely to the treatment target. To ensure the quality of radiotherapy delivery and treatment, it is essential to monitor the process carefully and systematically, with routine and frequent checks and assessments. However, the development and implementation of quality control measures have not kept pace with the remarkable technological advances achieved in recent years.[1–4]

A common approach to quality control in cancer care involves the use of quality indicators. Ideally—given the wide variety of processes and techniques involved in treating different types of cancer—these indicators should be specifically designed (or adapted to) each tumour type. In this sense, the availability of a set of internationally recognized and standardized indicators to permit international comparisons among radiotherapy centres would be highly desirable. Yet experience in this area remains limited, with no consensus with regard to the optimal indicators for radiotherapy.[3] Indeed, although several different groups[3–7] have attempted to identify a core group of quality indicators for radiotherapy, no widely-accepted or internationally-recognized core set of indicators is available at present.

While quality indicators are important to ensuring quality control, to be of any real value these indicators must be applied to actual clinical practice—preferably by external evaluators. This process, known as a clinical audit, provides an opportunity to conduct an in-depth analysis of the procedures and processes governing patient care. To date, such clinical audits have been used only sparingly in radiotherapy,[2,3,8] although measures to increase their use have been taken, including a European Union directive requiring their use.[4]

Interest in developing and implementing a system of quality standards in radiotherapy has increased greatly in recent years.[9–12] Nevertheless, only a limited number of clinical audits, including one by our group,[2] have been conducted to date.[2,13–15] It is in this context that the multi-institutional, international IROCA (*Improving quality in Radiation Oncology through Clinical Audits*; www.iroca.eu) project was born. The aim of this project is to compare radiotherapy processes among participating institutions [the Wielkopolskie Centrum Onkologii (WCO) in Poznan, Poland; the Institut Català d'Oncologia (ICO) in L'Hospitalet (Barcelona), Spain; the Instituto Português de Oncologia (IPO) in Porto, Portugal; and the Università degli Studi del Piemonte Orientale (UNIUPO) in Novara, Italy] using a core set of quality indicators. To our knowledge, this is the first project of its kind and scope.

In the present paper, we provide an overview of this international project, which involves the design and implementation of a clinical audit to assess adherence to a set of core quality indicators to evaluate departmental/institutional structure, radiotherapy processes and procedures, and clinical outcomes among the five participating institutions. The overall aim of the project is to improve quality and safety in radiation oncology by promoting adherence to quality indicators and by harmonizing radiotherapy processes among the participating institutions. Ultimately, the main objective is to improve clinical outcomes for patients. The approach used in this project to harmonize radiotherapy processes among different institutions may serve to promote a greater use of clinical audits in radiotherapy in Europe.

2. Methods & discussion

This study was modelled on two previous studies. The first was performed jointly by the ICO (Catalan Institute of Oncology) and the WCO (Greater Poland Cancer Centre), with results published in 2014.[2] In that study, which was conducted—in part—to generate more practical experience in quality control, the clinical audit assessed adherence to seven quality indicators for preoperative rectal cancer treatment. This experience was invaluable, both in improving key elements of care at the audited institutions, and in learning about how to develop and conduct a comprehensive clinical audit, a challenging and highly complex task. In addition, in the year 2015, the ICO (Catalonia, Spain) performed an in-house clinical audit among their three radiotherapy centres (in Badalona, L'Hospitalet, and Girona). Results from that study have not yet been published. Nevertheless, the combined experience of these two previous studies has helped to guide us in developing the model described here.

2.1. *Organization of the project*

A Steering Committee (SC) consisting of senior members of the IROCA project was formed to guide the development of this project. The IROCA members held a series of meetings to establish the aims and protocol for the study, including selection of the target cancer types for the audit. After a careful review of the literature and based on previous experience, the committee selected the most appropriate quality control indicators for those tumour sites and for general radiotherapy processes. A Technical Committee (TC) was constituted to perform the statistical analysis and to develop the reports. A detailed study protocol, including the questionnaire and all other relevant data, has been developed. The project's key aims are summarized in Table 1.

2.2. *Cancer types for evaluation*

Two cancer sites, prostate (ICD-9:185.9 and ICD10: C61.9) and rectal cancer (ICD-9: 154.1; ICD-10: C20.9) were selected for the clinical audit.

These specific cancer types were chosen due to their high incidence rate,[16] the relevant role of radiotherapy in their treatment, our prior experience, and because all participating institutions treat large numbers of patients for these two cancer types. In the case of rectal cancer, the high incidence and mortality rates associated with this cancer make it an

Table 1 – Improving clinical outcomes of radiotherapy through step-by step standardization of key elements in clinical practice at participating institutions.

1. Identify key aspects within the radiotherapy process that impact clinical outcomes and treatment efficiency.
2. Determine the most relevant indicators to measure these key aspects.
3. Design a clinical audit procedure to determine adherence to these indicators at participating institutions.
4. Identify the areas amenable to standardization of the following:
   - •treatment approach
   - •treatment planning and execution
   - •reporting the outcomes (results and side effects)
   - •patient comfort
   - •healthcare provider accountability and reliability
   - •efficient use of resources
5. Develop a minimum dataset for benchmarking.

ideal candidate for auditing due to the large impact even small improvements in cancer care could have on clinical outcomes.

2.3. *Target population and sample selection*

Patients diagnosed with either prostate or rectal cancer who underwent curative-intent radiotherapy during the study inclusion period (calendar year 2014). Patients who did not receive neoadjuvant radiotherapy and those with recurrent disease will be excluded. To minimize the risk of bias, patients will be randomly selected as follows: all patients who meet the inclusion criteria will be assigned an identification number; next, a separate register will be created for these eligible patients and a computer program will randomly select 60 clinical cases per tumour site. All patients who meet the inclusion criteria will be included in the audit, with a minimum requirement of 40 patients per tumour site.

2.4. *Selection of quality indicators, standards and questionnaires*

After a review of the available indicators, including those proposed by other authors,[3] those used in our previous study,[2] and the indicators used in the ICO study, we selected a set of clinical indicators applicable to all radiotherapy processes (Table 2), plus indicators specific to prostate and rectal cancer radiotherapy (Tables 3 and 4).

After selection of the specific indicators, we proceeded to develop three questionnaires, including a general questionnaire, to assess all the variables relevant to the quality indicators to measure overall performance of the radiotherapy process. The aggregate data needed to complete the general questionnaire will be obtained directly from the radiotherapy department and include the following key dimensions:

1. Organization (protocols, sessions, tumour boards)
2. Radiotherapy equipment
3. Work team
4. Research (publications, projects, and clinical trials)
5. Radiotherapy activity
6. Patient experience

Table 2 – General indicators.

1. Existence of technical protocols for treatment
2. Existence of departmental clinical meetings
3. Existence of departmental technical meetings
4. Existence of an action protocol in case of unplanned treatment interruptions
5. Existence of quality control protocol for treatment-related imaging
6. Existence of an informed consent form specific to each cancer type and/or technique
7. Existence of a protocol for irradiating patients with ICD/pacemaker (PM)
8. Existence of tumour-specific treatment guidelines
9. Number of articles published in indexed journals by radiation oncology, physics and radiation biology staff members
10. Number of published articles in which either the three first authors or the last author is a member of the team
11. Total impact factor of the articles published during the year by staff involved in radiation oncology, physics and radiation biology in which either three first authors or the last author is a member of the team
12. Number of projects submitted for funding to national or international bodies/institutions excluding trials financed by pharmaceutical companies
13. Number of projects approved for funding to national or international bodies/institutions excluding trials financed by pharmaceutical companies
14. Participation in European Union grant
15. Leadership of European Union grant
16. Number of clinical trials specific to radiation oncology and % of patients included in these trials
17. Number of patients included in clinical trials involving radiotherapy treatment and radiatio oncologist is primary investigator
18. Existence of patient satisfaction survey
19. % of patients who completed satisfaction survey
20. Patients treated per year
21. Patients treated per accelerator
22. Up/down time of the accelerators (according to recommended calculation formula; otherwise, the specific formula should be provided)
23. Average number of patients treated per hour per accelerator
24. % of reports completed within 2 months of treatment finalization

7. Quality of care (safety, efficiency, accessibility, and treatments delays)

The other two questionnaires are specific to the two cancer types (prostate and rectal cancer) and are designed to assess the core indicators for each tumour type. All data (>100 variables) required to complete the questionnaire will be obtained from clinical records.

The key dimensions of these two questionnaires are as follows:

1. Diagnostic phase: multidisciplinary tumour board assessment, clinical profile (stage, etc.), diagnostic tests, and treatment delays.
2. Treatment phase: treatment planned and performed; radiotherapy dose, fraction and duration (prescribed versus performed); quality of care; adjuvant treatments
3. Clinical results and follow up phase: treatment-related side-effects; clinical status (recurrence; mortality);

Table 3 – Prostate indicators.

1. % of patients evaluated in the clinical session in the Radiation Oncology (RO) department before treatment
2. % of patients with stratification (including PSA, Gleason, TNM)
3. % of patients with MRI staging
4. % of patients presented to the tumour board
5. % of patients with tumour localized with fiducial markers
6. % of patients with tumour localized by CBCT
7. % of patients with tumour localized by ultrasound
8. % of patients who experience an interruption in treatment
9. % of patients completing treatment in the prescribed time
10. % of high risk patients receiving long-term hormonotherapy
11. % of high risk patients receiving boost brachytherapy
12. Time elapsed between first visit at RO department and initiation of any type of treatment
13. Time elapsed between first visit at RO department and start of radiotherapy (EBRT, BRT)
14. Time elapses between CT simulation and start of radiotherapy (EBRT, BRT)
15. % of patients treated using new technologies (IMRT)
16. % of patients treated using new technologies (VMAT)
17. % of patients treated using new technologies (SBRT)
18. % of EBRT sessions with imaging controls performed during the treatment (kV, MV, CBCT, MVCT)
19. % of patients with rectal mucositis (grade 2 or 3) (less than 6 months)
20. % of patients with rectal mucositis (grade 2 or 3) (more than 6 months)
21. % of patients with cystitis-urethritis (grade 2 or 3) (less than 6 months)
22. % of patients with cystitis-urethritis (grade 2 or 3) (more than 6 months)
23. Biochemical survival
24. Regular follow-up after the treatment (Yes/No)
25. Regular follow-up during the treatment (Yes/No)

Table 4 – Rectal indicators.

1. % of patients evaluated in the clinical session in the Radiation Oncology (RO) department before treatment
2. % of patients with TNM staging
3. % of patients with MRI staging
4. % of patients presented to the tumour board
5. % of patients with tumour localized with CBCT-IGRT
6. % of patients with tumour localized with kV-IGRT
7. % of patients completing treatment in the prescribed time
8. % of patients receiving concomitant chemotherapy
9. % of patients prescribed long course radiotherapy
10. % of patients prescribed short course radiotherapy
11. % of patients receiving intraoperative radiotherapy (IORT)
12. Time elapsed between biopsy and first consultation at RO department
13. Time elapsed between first visit at RO department and start of radiotherapy
14. Time elapsed between CT simulation and beginning of radiotherapy
15. % of patients treated using new technologies (IMRT)
16. % of patients treated using new technologies (VMAT)
17. % of EBRT sessions with imaging controls performed during the treatment (kV, MV, CBCT, MVCT)
18. % of patients with rectitis (grade 2 or 3) (less than 6 months)
19. % of patients with rectitis (grade 2 or 3) (more than 6 months)
20. % of patients with cystitis-urethritis (grade 2 or 3) (less than 6 months)
21. % of patients with cystitis-urethritis (grade 2 or 3) (more than 6 months)
22. Overall survival
23. Local control
24. Regular follow-up after treatment (yes/no)
25. Regular follow-up during treatment (yes/no)

The questionnaires were primarily based on those previously used in the aforementioned ICO study (data not published), which in turn were based on the questionnaires used in the Fundowicz study,[2] and the International Atomic Energy Association (IAEA) QUATRO model.[17] We elected to use an online questionnaire due to the numerous advantages: minimization of registration data errors, data centralization in a single database accessible to participant centres and located at ICO servers), and centralization of the statistical analyses (ICO), which will be performed with the SPSS statistical software (IBM, NY, USA).

2.5. *Implementation of the clinical audit*

The pilot study is planned for September, 2016 at the WCO in Poznan, Poland. The pilot audit will serve as a model for future audits once completed. Here, we describe the current plans for the pilot audit, but based on our actual experience, we may need to modify the timing and structure of the official clinical audit (tentatively planned for the 4th quarter of 2016). After the first pilot audit has been completed, a meeting will be held to discuss any issues that have arisen and to correct and/or improve the auditing procedure. This will involve all members of the participating institutions.

2.6. *Audit schedule*

A checklist will be created to organize the audit program and to ensure coverage of all relevant topics. The working language of the audit is English. The clinical audit will be performed as follows: a) audit preparation (appointment of auditing team, review of the background information prepared by the institution to be audited, and preparation of the audit program); b) entrance briefing: to introduce the auditors to various staff members and to discuss the methods, objectives and details of the audit; and c) assessment: on-site clinical audit.

2.6.1. *Two-day pre-audit training and verifications*

The role of the specialists from the SC is crucial to the successful outcome of the audit. For this reason, before the Local Team (LT) begins to conduct the actual clinical audit, two specialists from the SC team will meet with the LT (i.e., the clinical auditor[s] and local leaders) for 2 days for training and verifications to assure that all procedures are clear and that everything is in place to properly conduct the audit.

Specific tasks during this two-day pre-audit period include:

- Assure access to the database
- Train the LT and verify the forms by reviewing 2 cases (randomly selected from the sample) for each pathology while jointly (i.e., the local auditor and the SC specialists) completing the online questionnaires.

- Confirm the accuracy of the data reported on the general questionnaire (which contains details about the centre and procedures). This questionnaire will be sent to the audited centre well in advance of the audit.

During this two-day period, in addition to the aforementioned training and verifications, the SC team will interview staff members from the institution about work practices and approaches, inspect the facilities, and review all procedures and relevant documentation (including the treatment records of rectal and prostate cancer patients included in the study). In addition, the auditors will directly observe the practical implementation of working procedures during the audit, including as many aspects of the patient treatment process (initial patient examination, diagnosis, evaluation, staging, treatment planning and delivery, and follow up) as feasible.

The medical records are to be reviewed by an 'external team' (i.e., not dependent on the departmental heads) to assure a bias-free ("neutral") assessment of the data collected. The audit teams will consist of at least one auditor, who should be a nurse (or other qualified health care professional) specialized in health information management with >two years of experience in clinical reviews (ISO or similar). It is strongly recommended that the audit not be performed by a radiation oncologist or medical physicist from the audited departments.

2.6.2. *Clinical audit*

After the two-day training and verification period, the local team will carry out the clinical audit during which the auditor(s) will review 40 randomly-selected cases per pathology and complete a relevant questionnaire. Based on our previous experience, we estimate that the time required to perform the audit will be approximately 20–30 min per case. For this reason, the local auditor(s) will need at least 2 weeks to audit all 80 cases.

After the data collection has been completed, the TC will carry out a quality control analysis on the data and then conduct the statistical analysis. Once this has been performed, an exit briefing will be organized to provide the host institution with preliminary feedback.

The estimated duration of the entire process, including review of clinical records and statistical analysis, is approximately 45 days, as follows: 15 days to review the medical records and 30 days for quality control of the data, statistical analysis, and preparation of initial results. Technical support (video conference) will be available during this phase should any doubts arise.

2.7. *Expected results and study limitations*

The IROCA project was created to promote quality and efficacy in radiotherapy. The project will compare radiotherapy processes among the member institutions using a core set of quality indicators selected by consensus among the participating institutions. The main aim of this study is to determine institutional adherence to the consensus standards jointly established by the project members in accordance with the best available evidence, and to compare adherence to these standards across the various institutions to identify best practices. Our broader aims are to develop a clinical audit model for radiotherapy that can be easily adopted by other centres around the world, thus expanding the use of clinical audits to improve the quality of care. To our knowledge, this is the first project of its kind and scope.

There can be little doubt about the importance of quality control in any area of medicine. However, in the area of radiotherapy, already considered among the safest areas, the use of high-dose ionizing radiation is important to monitor quality because of the risk of patient harm.[18] Moreover, modern radiotherapy requires numerous procedures and processes involving a large number of health care professionals, including radiation oncologists, medical physicists, other physicians, nurses and technologists. As a result, quality control is essential to guarantee optimal quality throughout this complex process.

The importance of performing a clinical audit to ensure adherence to treatment protocols in medical care cannot be understated,[19] and this is especially true in radiotherapy, in which even small deviations from standards can have a large negative impact on treatment quality and outcomes. The benefits of using quality indicators to assess adherence to clinical protocols was recently demonstrated by Cheng et al.[9] Those authors evaluated 10 quality indicators to measure the quality of care in 1378 breast cancer patients. They found that most patients received good care (defined as reasonably good adherence to the quality indicators); however, they also found that 100% adherence to the entire set of quality indicators was significantly associated with better overall survival. This finding underscores the crucial importance of strict adherence to established clinical protocols; moreover, this result also demonstrates the value of performing a clinical audit to assess compliance: without a clinical audit, it is not possible to assess adherence. As the authors of that study conclude, "100% adherence to evidence supported quality-of-care indicators is associated with better survival rates and should be a priority for practitioners".

In recent years, there has been a surge in interest in quality control in radiotherapy. As Donaldson et al.[12] recently wrote, all health care practitioners share the goal of conducting "best practice" medicine but the obstacles to doing so are enormous given the vast amount of quality standards, guidelines, recommendations, and indicators currently available. For these reasons, Donaldson and colleagues argue that we need to identify the essential dimensions of quality. However, it can be challenging to select the appropriate indicators of quality, particularly given the wide range of procedures, processes and techniques in radiotherapy; moreover, treatment varies widely depending on the cancer type and location. Consequently, it is not possible to evaluate, for example, prostate cancer and rectal cancer, in exactly the same way. In other words, specific indicators are necessary, which is what we are attempting to develop with the IROCA project.

At the time of drafting this manuscript, we have not yet begun the IROCA pilot study; however, we believe that the groundwork laid thus far will be immensely valuable, not only for the current project but also for future clinical audits to be performed by other institutions. Importantly, in line with the study aims, we have developed detailed questionnaires that evaluate most (if not all) of the key aspects within the radiotherapy process that impact clinical outcomes and

treatment efficiency. In addition, we have identified and selected (by expert group consensus) the most relevant indicators to measure these key aspects. The selection of quality indicators in radiotherapy has been keenly debated in recent years.[3,20] In prostate radiotherapy, several groups have developed quality indicators[6–8] although it should be noted that many of these indicators have not yet been validated.

3. Conclusions

Although identification and selection of the most relevant quality indicators is essential, the design and implementation of the clinical audit is equally if not more important. Our experience with the previous audit has demonstrated the importance of establishing well-defined procedures for the clinical audit. In addition, we have learned that the selection and components of the audit team are critical to guarantee an unbiased audit. When this audit is completed, members of our group will have completed three separate radiotherapy audits: 1) the initial WCO/ICO audit[2], 2) the local audit performed by the ICO at its three centres, and 3) this multinational, multicentre audit involving five cancer care centres across Europe from Portugal to Poland. The experience gained in this project will provide knowledge that will be transferrable to other centres wishing to perform a similar clinical audit.

The primary value of this project is that it represents a step towards increased harmonization of radiotherapy processes among five large European radiotherapy departments. Although we do not expect to immediately unify all aspects of diagnosis, treatment, and follow up at these centres, we do believe that—upon completion of the project—we will have achieved a much more detailed understanding and appreciation for the need to compare clinical practice at the home institution to the practices observed at the audited institutions.

There is an inexorable and growing interest in improving quality control in radiotherapy and the role of clinical audits can only grow. The value of the present study is that the auditing protocol and quality indicators developed here to assess rectal and prostate cancer can be adapted to improve treatment of other tumour localizations at other radiotherapy centres worldwide. Although clinical audits are time-consuming and complex undertakings, the potential benefits in terms of identifying and rectifying deficiencies in quality control procedures are potentially enormous. External clinical audits can undoubtedly improve both patient safety and quality of care.

Conflict of interest

None declared.

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