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Original Article

Feasibility and impact of national peer reviewed clinical audits in radiotherapy departments

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ABSTRACT

Purpose/objective: A national incentive brought about the instauration of systematic clinical audits of all Belgian radiotherapy 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 analyzed 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).

In 1997, EURATOM issued a directive (97/43) requiring member states to organize 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 [1]. 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

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role in identifying areas of risk and promoting preventative measures [2].

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 [3]. 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 radiotherapy departments located in Europe, Latin America, Asia and Africa [4,5].

In Belgium, it was decided to use the IAEA QUATRO methodology to carry out clinical audits in all radiotherapy departments. As such, a first cycle of audits took place in the 25 Belgian radiotherapy 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.

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 [6]. Following multiple meetings between the involved parties, it was decided that the Belgian College for Physicians in Radiation Oncology would organize 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 [6]. 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) [7–9]. 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 time frame 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 spread sheet. The recommendations were then categorized according to a 3-level taxonomy system as described by Izewska et al. [4]. 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 (see 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.

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).

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

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 had on the department's infrastructure, organisational situation and/or clinical practice.

Overall usefulness of emitted recommendations	Not useful	Little useful	Moderately useful	Very useful	Primordial
Relevancy of individual recommendations	The recommendation was **not relevant** to the department's situation/context	The recommendation was **little relevant** to the department's situation/context	The recommendation was moderately relevant to the department's situation/context	The recommendation was **very relevant** to the department's situation/context	The recommendation was **primordia**l to the department's situation/context
Impact of the individual recommendations	The recommendation had **no impact** on the department's organisational/ infrastructural situation	The recommendation had **little impact** on the department's organisational/ infrastructural situation	The recommendation had a **moderate impact** on the department's organisational/ infrastructural situation	The recommendation had a **big impact** on the department's organisational/ infrastructural situation	The recommendation had a primordial impact on the department's organisational/ infrastructural situation
Attributed score	**0**	**1**	**2**	**3**	**4**

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.

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 (Fig. 1). 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) (Fig. 2). 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 ($p = 0.993$).

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%) (Fig. 2). Not unlike the relevancy score, the median overall impact score was evaluated at 2 with a mean score of 1.6 ± 0.4 (Fig. 1). 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 ($p = 0.41$) (Fig. 2).

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)

Discussion

Peer reviewed clinical audits of radiotherapy departments have been carried in a number of departments using QUATRO [4,5] or other methodologies such as IROCA and locally developed audits [10,11]. 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 radiotherapy 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 [2,4].

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 [12].

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 proposed by Izewska et al. [4].

Types of recommendation	Proportion of recommendations	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%
Equipment quality control	66,7%	Distribution	14,3%
Quality of facility or equipment	26,7%	Education	7,1%
Equipment complement	6,7%	Other	10,7%
RT imaging	**11,7%**	Remuneration/Recognition	3,6%
Treatment planning system	**8,7%**	**All staff**	**27,0%**
Dosimetry	**5,8%**	Training and professional development	30,0%
		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%**

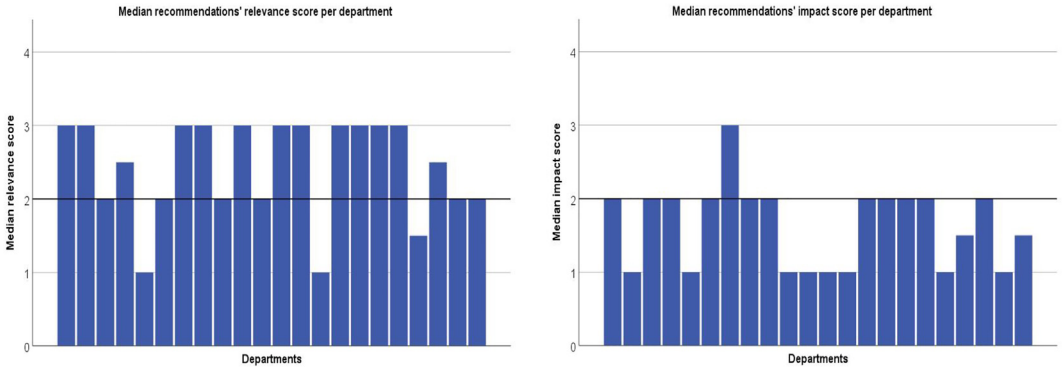

Fig. 1. Recommendations' relevance (left) and impact (right) median score as evaluated per department.

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.

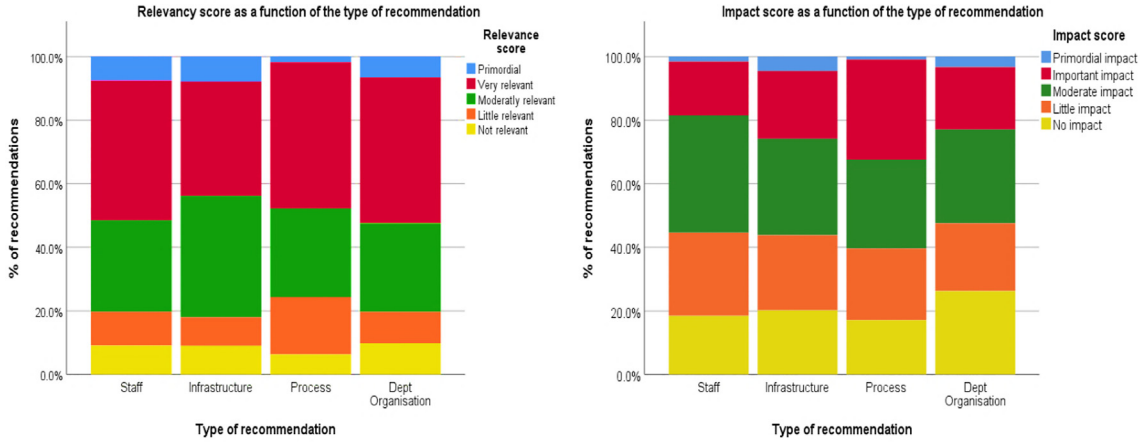

Fig. 2. Distribution of the relevance [left] and impact [right] score as a function of the level one classification of the emitted recommendations.

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 [4,5], 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 [13–16]. 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 standardizing 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. [4,6]. 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 [17,18]. 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 [19,20].

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 RT-QM 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) [21,22].

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.

In conclusion, peer-reviewed clinical audits based on the QUATRO methodology have been successfully implemented in Belgium with all radiotherapy 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).

Conflicts of interest

All the authors declare they have no conflict of interest.

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