Title

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

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ABSTRACT

Background and Purpose: The Radiation Oncology Safety Information System (ROSIS) was established in 2001. The aim of ROSIS is to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures.

Materials and Methods: A voluntary web-based cross-organisational and international reporting and learning system was developed (cf. the www.rosis.info website). Data is collected via online Department Description and Incident Report Forms. A total of 101 departments, and 1074 incident reports are reviewed.

Results: The ROSIS departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 brachytherapy units. On average, there are 437 patients per MV unit, 281 per radiation oncologist, 387 per physicist and 353 per radiation therapy technologist (RT/RTT). Only 14 departments have a completely networked system of electronic data transfer, while 10 departments have no electronic data transfer. On average seven quality assurance (QA) or quality control (QC) methods are used at each department. A total of 1074 ROSIS reports are analysed; 97.7% relate to external beam radiation treatment and 50% resulted in incorrect irradiation. Many incidents arise during pre-treatment, but are not detected until later in the treatment process. Where an incident is not/ detected prior to treatment, an average of 22% of the prescribed treatment fractions were delivered incorrectly. The most commonly reported detection methods were “found at time of patient treatment” and during “chart-check”.

Conclusion: While the majority of the incidents reported to this international cross-organisational reporting system are of minor dosimetric consequence, they affect on average more than 20% of the

patient's treatment fractions. Nonetheless, defence-in-depth is apparent in departments registered with ROSIS. This indicates a need for further evaluation of the effectiveness of quality control.

Introduction:

Safety is a vital aspect of radiation oncology (RO); past events highlight the need for ongoing vigilance and increased focus on the identification and management of real and potential dangers associated with this medical specialty [1-6].

Safety management in an organisation should encompass both proactive and reactive measures [7-8]. Data from reactive measures can also be used in a feedback process to enhance proactive safety management actions [9]. Proactive measures aim to identify potential hazards and prevent errors from occurring. These include process mapping, statistical process control and analytical methods e.g. Fault tree analysis, Failure modes and effects analysis (FMEA). Reactive measures focus on errors once an incident has occurred; e.g. root cause analysis among other methods but also incident reporting and investigation.

Although reporting of incidents and near-incidents is subject to biases, it reveals valuable information on the types, causes and detection of mistakes which occur [10]. A complication of using near-incident data to identify causes is that the relationship between causal factors in the occurrence of incidents and in the occurrence of near-incidents is not yet known for radiotherapy, although in the railway domain the common causes hypothesis is supported [11].

Effective learning from national and international incident reporting systems leading to safety promotion has been illustrated in other areas by systems such as the Aviation Safety Reporting System [12], and the Advanced Incident Monitoring System [13]. For example, Leape [14] identifies four methods by which external reporting (voluntary or mandatory) can promote safety:

- Alerts about new hazards
- Shared experience on prevention of errors

- Analysis of many reports to reveal trends and specific hazards
- Recommendation of “best practices” based on analyses

Mandatory reporting of incidents in RO at a national level is common practice in Europe, existing in several countries for decades under regulations deriving from radiation protection and/or health legislation. Departments in several countries have well developed local reporting systems for incidents and near-incidents. However information from these systems is not extensively shared. With a vision to reduce the potential for repetition of incidents in other settings by sharing information on local incidents and near-incidents with the wider community, the Radiation Oncology Safety Information System – ROSIS – was created as a learning tool. ROSIS is a voluntary, web-based reporting system which aims to:

- Establish an international reporting system in RO, and
- Use the system to reduce the occurrence of incidents in RO by
    - enabling RO departments to share reports on incidents with other departments as well as with other stakeholders such as scientific and professional bodies
    - collecting and analysing information on the occurrence, detection, severity and correction of RO incidents
    - disseminating these results and generally promoting awareness of incidents and a safety culture in RO

ROSIS was established in 2001. ROSIS reports have been a subject of, or have been recognised in, a number of scientific publications [1, 15-20, 22, 46]. This paper reports on the profiles of 101 participating departments and 1074 ROSIS incident reports (separately).

Materials and methods:

ROSIS has been designed to collect information on incidents and near-incidents, and to put these in the context of the infrastructure and procedures of the department.

Two distinct forms are used for data collection:

- A Department Form – to collect information on the department infrastructure and procedures
- An Incident Report Form – to collect information on the incident/near-incident

These forms were put on the Internet in January 2003, initially hosted by the ESTRO web-server. An outline of the basic topics in these forms can be seen in Table 1; the full forms can be viewed online at www.rosis.info.

A dedicated ROSIS website was developed under the domain name: www.rosis.info, and put on the Internet in October 2004. All anonymised incident reports are stored in an online searchable database and made available on the website in their original text. For the purposes of reporting, an incident is defined as any incorrect delivery of radiation. The magnitude of the incorrect delivery is defined by the local user. A near-incident is considered to be any event, which may have resulted in an incident. For the latter type, however, the responsibility of identification relies strongly on the local reporter.

In this paper, the focus will be on the existence, types, causes and detection of mistakes in the radiotherapy process, which have been reported to ROSIS.

Information from Department Forms and Incident Reports are entered into an MS Access Database, and data analysis is undertaken in MS Access and MS Excel. Each incident report is retrospectively examined to

identify the most likely stage of incident occurrence. All other data are reported directly. In keeping with best practice on reporting systems, simple descriptive statistics are used to evaluate the ROSIS department and incident data.

Results:

Results are divided into two sections:

1. Profiles of departments participating in ROSIS
2. Incident data reported to ROSIS

1. Profiles of departments participating in ROSIS

Registration of departments has grown steadily since the ROSIS reporting system was introduced. In early 2009, there were 101 departments registered; 70 from Europe and between 2 and 12 from each of the following regions:

- Africa
- Asia
- Australia and the Pacific
- North America
- South and Central America.

With respect to infrastructure, the departments represent a total of

- 309 Linear Accelerators (Linacs) (avg 3 per dept)
- 34 Cobalt Machines (avg 0.3 per dept)
- 114 Brachytherapy Machines (avg 1.1 per dept)
- and a patient population of over 150,000 new patients per year (average 1497 per dept; range 50-6500)

Twenty-three departments are equipped with Linacs alone, while 23 have a minimum of one Co-60 unit, and 76 have at least one brachytherapy

machine. The complexity of treatments within departments varies greatly, with an average of 74% CT planned treatments (range 0-100%).

While most departments have at minimum a method of networked data transfer from simulator or treatment planning system to treatment unit, 11 do not have any electronic data transfer (10%). There is considerable variation in the level of networking within the group as a whole, with only 24 departments having a single form of network throughout their department. It is also noteworthy that there are often several networking arrangements within one department – from four possible options, 2.4 options were selected on average. The network options and distribution are shown in Table 2.

A record and verify system is used on all units in 67 departments (68%), on some units in 26 departments (26%), and six departments have no R&V system in the department at all. This information is unknown for two departments.

The average number of patients per member of staff is displayed in Table 3.

Of the participating departments, 54 have contracts for equipment service/maintenance, whereas for 40 this is performed in-house. One department has a 50:50 mix between contracts and in-house, and there is no data for two departments.

Participants were asked to report quality assurance procedures present in their department (Table 4). This list encompasses the quality assurance (QA) planning and managerial activities, (e.g. formal quality management systems) as well as routine quality control (QC) monitoring activities (e.g. chart checking, portal imaging, in-vivo dosimetry). The most common procedures are regular quality control of treatment units (98

departments), portal imaging (94), chart checking (90), and quality control procedures (91). In-vivo dosimetry and formal quality management systems are the least common (34 and 35 departments, respectively).

The majority of departments (69) participate in at least one dosimetric audit programme:

- IAEA (International Atomic Energy Agency) – 10 departments
- EQUAL (ESTRO) - 18 departments
- RPC (Radiological Physics Center at MD Anderson) – 7 departments
- Other Regional/National - 23 departments
- Specific audit programme not specified - 24 departments

Most departments have a system of QA or QC that monitors the radiotherapy process at several steps. Thus, a defence-in-depth system is implemented to various degrees at different hospitals. Defence-in-depth is defined by the International Basic Safety Standards (BSS) as *"the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one protective measure fails" [21]*. If the category "Other QA" is excluded, the minimum number of remaining QA methods used in any one department is three; the maximum is 10. Both the average and median of number of methods used is seven.

2. Incident data reported to ROSIS

Of the 1074 reports submitted to ROSIS between January 2003 and August 2008, 1049 (97.7%) are on the use of external beam radiation, 20 (1.9%) on brachytherapy, and five (0.5%) on other occurrences (mainly non-process). Incidents are classified as being either process-related, where the occurrence of the incident is related to a failure in the process,

or non-process related, where the process had no real bearing on the occurrence of the incident (e.g. hardware or software failures, slips/trips/falls). Process-related incidents are classified as pre-treatment/treatment/follow-up, or into activity related processes (e.g. imaging/simulation/planning/treatment).

Only 258 of the reported process-related incidents were detected prior to treatment. Most reported incidents 754 were detected at the treatment sub-process of the radiotherapy process, and 23 were detected at follow-up. The remaining 39 reports were either non-process, or not classifiable.

The majority of the reported incidents were detected by Radiation Therapists at the treatment unit (RTs/RTTs) (figure 1), and were found during a patient treatment appointment i.e. *"found at the time of patient treatment"* (457/43%) (figure 2). Detection by the QC process chart check was the next most common method of detection (350/33%) (figure 2). Of these chart check detections, 168 were detected during pre-treatment, whereas the other half (167) were found when chart checks were performed during the treatment (151) or at follow-up (16 – from one centre).

Two reports relate to an incident involving staff or non-patient. A minor number of reports, 21, relate to incidents involving several patients (range: 2-7 patients).

Treatment was delivered incorrectly in 546 of the reports (51%). This refers to any incorrect delivery of radiation, and is an incident as defined by ROSIS. For 473 of these 546 reports, the number of fractions treated incorrectly is known:

- 1-3 fractions incorrect = 408 reports (86% of 473)
- 4-10 fractions incorrect = 53 reports (11% of 473)
- 11-24 fractions incorrect = 12 reports (3% of 473)

For 199 of these reports (42% of 473), the total number of fractions prescribed is also known. Using this information, the reported incidents range from between 3% to 100% of the treatment delivered incorrectly, with an average of 22% of the prescribed treatment fractions incorrect (Fig. 3).

Table 5 gives the relationship between the incident and the QA method by which it was detected. Where data is available, this table also illustrates the number of fractions where the treatment was given incorrectly. Chart-checking was the most common detection method of incidents in five of the eight activity related processes.

Discussion:

A major strength of ROSIS is that it enables direct analysis of reports from different departments and clinical situations internationally; this current review includes 101 departments and 1074 reports.

In considering incident reports, it must be remembered that

1. Voluntary incident reporting may not reveal the true cross-section of incidents (although it is likely that neither does most mandatory reporting) [10]; and that
2. All reporting is subject to biases: not all types of incidents might be reported, nor the true frequency of each incident type, nor the absolute relative frequency of the incidents [10].

For these reasons, it is important that incident data from reporting systems is interpreted carefully and not over-analysed.

As of early 2009, 101 departments have registered with ROSIS; initially registered departments were located within Europe, but there is now a more diverse global distribution of departments in ROSIS. Based on new patient numbers, the potential patient population covered by ROSIS is 150,000. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [22] 5.1 million people receive radiotherapy annually; this means that ROSIS covers approximately 3% of all radiotherapy patients.

Within the departments reporting to ROSIS, there is substantial variation in terms of infrastructure, and resources - overall, and per patient population. The patient population of 150,000 is served by a total of 343 Megavoltage (MV) units (Linac and Co-60), and an average of 437 patient treatments per MV unit per year. This is slightly less than the QUARTS recommendation of 450 treatments per MV unit per year for European countries [23], but does mask major differences between departments. [QUARTS stands for Quantification of Radiation Therapy Infrastructure and Staffing Needs].

Most departments (75) have both Linacs and brachytherapy equipment, at present the specific capabilities of these are unknown. Complexity is measured by the percentage of CT planned treatments. ROSIS departments cover a range of 0-100% CT planned treatments. This might not be representative of modern-day technology and complexity.

Data transfer is a safety critical step in the treatment chain. Electronic transfer can reduce the human error contribution to data transfer errors; ideally a department would transfer all data electronically. Networking capabilities are varied between and within departments; while ten departments have no network, typically departments have a mix of electronic data transfer options. It is noteworthy that only 14 departments are fully networked throughout, including images. It is likely

that including an element of human data transfer at any stage in the process will lead to an increase in data transfer errors [24, 49-50]. Where a subsequent part of the process is electronic, it can give rise to a false sense of security. One may also note that many electronic systems are not completely integrated, thus transfer between e.g. treatment planning system and R&V systems is performed, and import/export functions where human interaction is involved may still lead to transfer errors. However, neither is electronic data transfer completely dependable [25]. As the treatment complexity increases, we are more reliant on electronic data transfer, and must be vigilant as to its inherent risks.

It is difficult to compare staffing levels across different countries, due to the differing roles and responsibilities per discipline, different patterns of disease occurrence and detection, and varying complexities of treatments. The QUARTS project [26] reviewed radiotherapy staffing in 41 countries across Europe, 40% of which had guidelines for staffing. ROSIS departments have an average of 281 patients per Oncologist; and 387 per Physicist; these compare well with the QUARTS data (suggestion of 200-250 patients per Radiation Oncologist and 450-500 per Physicist). The data on the remaining disciplines (Radiation Therapists (RTs/RTTs), Dosimetrists and Technical Maintenance) are extremely dependent on such factors as mentioned above.

The main purpose in collecting information about the department infrastructure is to enable investigation into whether or not these variables in infrastructure affect the occurrence or detection of incidents. This is not yet possible with the amount and type of information in the database, but modifications are being made to capture more information on the department's equipment and technology; this will include an annual check to confirm the infrastructure of the participating departments.

A generally encouraging finding is the use of multiple QA methods in departments, with a reported average of seven methods per department. The International BSS recommends an approach which encompasses multiple layers of defences [21], and these methods can be seen as filter levels in a defence at depth or a multi-layered defence system. The least utilized QA methods were in-Vivo Dosimetry and formal quality management system (QMS); the most utilized was a Regular QA of Treatment Units. Nonetheless, three departments do not perform Regular QA of Treatment Units – this is cause for concern, and is inconsistent with general guidelines [27-30]. Alternatively, this result could be a misinterpretation of the department form leading to a failure to select the option “Regular QA of Treatment Units” when reporting the departmental status.

The existence of defence-in-depth is an important aspect of detecting mistakes and preventing adverse events. In the ROSIS database, the treatment was delivered incorrectly in just over one half of the reports. Most of these incidents were detected at an early stage (1-3 fractions), with a minority affecting 4 or more fractions (figure 3). Without knowing the total number of fractions prescribed, it is difficult to put this into the context of severity of the incident. For those incidents where the total fractionation prescribed is known (199), the reports represented a mistake in an average 22% of prescribed treatment fractions. Depending on the type and extent of the mistake, this could represent a very significant impact on the treatment outcome and/or incidence of adverse events.

A difference is observed in the ratio of reported incidents versus near-incident depending on the quality control method used (Table 5), e.g. “Found by chart check” results in proportionally more near-incidents than “Found at later patient treatment” and “in-vivo dosimetry”. “Found at

first patient treatment" seemed to incur more severity than when "Found at later patient treatment" (average 25% vs. 15% of the prescribed fractions treated incorrectly). This is probably an artefact of the reports (e.g. there was an average of 15 prescribed fractions per treatment for "Found at first patient treatment" vs. 20 for "Found at later patient treatment").

The literature has mainly focussed on the value of chart-checking [24, 30-35], in-vivo dosimetry [24, 30, 32, 36-38], and portal imaging [24, 30] as the most valuable tools. In 1992, Leunens [24] reported that combining in-vivo dosimetry and portal imaging would detect 95% of incidents in their study; in the present dataset these methods are responsible for the detection of approximately 10% of incidents reported (a total of 110). Although portal imaging is almost universally routinely used, in-vivo dosimetry is not used routinely in most departments (Table 4). The added value of routine use of in-vivo dosimetry at first fraction of treatment/phase of treatment, for all patients is quite controversial. There is general agreement as to its overall worth in the context of patient safety, particularly when used as a truly independent check of delivered dose, and the WHO Radiotherapy Risk Profile identified that it could mitigate 24 of the 81 risks identified [1]. It is suggested that the value of in-vivo dosimetry may be indirectly related to the comprehensiveness of checks prior to the treatment [39]. In terms of practicalities, its value is however moderated by its cost, and there is a lack of consensus with regard to its value in the context of its cost-benefit [33, 36, 40-42]. Although it is not a primary method of detection in the ROSIS database, one reason for this is that it is routinely used in a small minority of departments, leading to less opportunity for it to have detected incidents in the ROSIS departments.

Most departments participate in an audit programme, although none of the reported ROSIS incidents were detected by external audit. The extent

of the audit programmes in which the ROSIS departments participated is unknown: whether it related to purely physical and technical aspects, or also incorporated procedural aspects of the treatment. External audit is an extremely valuable activity, and although it is not yet reported to ROSIS as detecting incidents, it is well-documented as an essential activity to complement internal quality assurance programmes [27, 43-44].

The category “Found at time of patient treatment” (Table 5) highlights the importance of working with awareness. Working with awareness is a less tangible “safety layer”, but it is a major contributor to patient safety, resulting in as much detection as the sum of chart checking, in-vivo dosimetry and portal imaging. A distinction has been made between incidents discovered during the first patient treatment and those discovered at a later patient treatment. To date, the numbers collected under the sub-category of “First patient treatment” are consistent with the rest of our data where many reported incidents occur during pre-treatment, and could therefore be detected at the critical first treatment. This reinforces the fact that the first patient treatment is a step where careful consideration of all the components of the treatment by the treatment team is constructive to patient safety.

The importance of working with awareness has been documented in the literature [4, 6], and is a core component of a safety culture. A safety culture should create a situation where "all duties important to safety should be carried out correctly, with due thought and full knowledge, sound judgment and a proper sense of accountability" [45]. The ability of staff to be ever-vigilant will depend on their education and training, including training on new equipment and techniques. Reinforcement for working with awareness should come from management, and be facilitated by appropriate training and working arrangements (e.g. quiet areas for concentration, suitable workload) [45-46].

Chart checks constitute another major method of detection. In general, chart checks provide an excellent opportunity to detect incidents during pre-treatment, however, the reported incidents detected by chart check are evenly distributed between being detected during pre-treatment and once the treatment has begun. It is likely that this is mainly a fact of more reports being made where the treatment has been delivered incorrectly, than a reflection of the true ratio of detection. Nonetheless, it does suggest that a modification of the checking process in these departments may enable more incidents to be detected during pre-treatment (Table 5). The importance of, and sometimes failure of, chart checking is a common feature in the literature [6, 24, 31-32, 34, 36, 39, 47]. For future design of QA system one has to consider this finding especially when departments are going “paper-less” using electronic patient files.

Most reported incidents were detected by Radiation Therapists at the treatment unit (RTs/RTTs); however, it must be stressed that it does not follow that most incidents occur during the treatment. As reported previously [48], it seems that most reported incidents arise during pre-treatment, but are passing pre-treatment checks and are not detected until the patient is on treatment, or at follow-up. Opportunity to detect errors, and reporting bias could also explain the proportion detected by RTs/RTTs – differences between health care professionals have previously been identified [49].

A further hypothesis for the high proportion of errors that actually affect the patients may be a large number of un-reported near-incidents. In RO, a near-incident to incident ratio of 13.8 to 1 was detected for errors originating in the treatment preparation chain [31].

Finally, a reporting and learning system can yield interesting lessons; this is of value in itself, but may give further leads when combined with prospective methods. Data from prospective methods could be used to focus reporting on particular incidents, in order to obtain specific causative information. It can also be used as an estimate of how many such incidents/near-incidents could reasonably be expected to be reported, and as such could indicate the health of a reporting system. A reporting system may highlight particular incidents and/or procedures/processes which are error-prone, and potential failures can then be hypothesised and investigated using prospective methods.

Conclusion:

An international cross-organisational reporting system has been developed and implemented, yielding opportunities for learning from mistakes in Radiation Oncology. ROSIS covers a broad patient population, with reasonable averages of patients per MV unit, per oncologist, and per physicist. It is difficult to draw conclusions from the number of patients per RT/RTT. Some level of defence-in-depth is apparent in most departments.

The majority of ROSIS reports relate to external beam radiation treatment; half of the events reported resulted in some treatment delivered incorrectly. The results from reporting systems need to be carefully interpreted and not over-analysed; however, areas for improvement can be identified since many incidents appear to arise during pre-treatment, but are not detected until later in the treatment process. The most commonly reported detection methods were “found at time of patient treatment” and “chart-check”, with a higher proportion of near-incidents detected by chart-check. While the majority of the

incidents that are reported are of minor dosimetric consequence, they affect on average more than 20% of the patient's treatment fractions.

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Table 1: Basic topics of the ROSIS Department form and ROSIS Incident form.

Department Form	**Incident Form**
Dept name and location; contact person	Modality
Type and number of machines	Who Detected
No of patients treated/year	Error/Near Miss
Record and verify	Who and how many involved
Integration of network/areas	How Detected
Full Time Equivalent per Category of Staff	Outcome / potential outcome
Service Contract	Description, Cause, Suggestion for prevention
QA Methods	Comments

Table 2: Networking capabilities available in departments. Multiple selections may be made by each department.

Network options	**Number of Departments**
None (no network between units or treatment planning system, or record and verify system	10
Treatment planning system sends radiotherapy (RT) parameters to treatment unit	55
Simulator sends RT parameters to treatment unit	28
Full networking of RT parameters (i.e. field size settings, monitor units etc.)	69
Full networking of RT images (i.e. electronic portal images, digitally reconstructed radiographs etc.)	69

Table 3: Number of patients per FTE member of staff

Discipline	**Average**	**Median**
Oncologists	281	250
Physicists	387	320
Radiation Therapists at treatment units	159	125
Radiation Therapists at simulator / CT	546	450
Dosimetrists	549	467
Technical Maintenance	833	667

Table 4: Departmental Quality Assurance (QA) / Quality Control (QC) procedures

QA / QC Activity	Total (%)
Chart Check	90 (89)
In-vivo dosimetry	34 (34)
Peer review	56 (55)
Portal images	94 (93)
Regular clinical review	73 (72)
Quality control procedures	91 (90)
Procedures for clinical processes	69 (68)
Formal Quality Management System	35 (35)
Regular QA of treatment units	98 (97)
Audit programme	69 (68)
Other QA	28 (28)

Table 5. Cross-tabulation of reports where treatment has been delivered incorrectly with the eventual detection method.

	Chart check	Found at time of patient treatment	In-vivo dosim-etry	Portal Imaging	Clinical review of patient	Quality control of equipment	Other	External Audit
Total number of reports per detection method	335	451	7	103	22	20	164	0
Number of reports where treatment was delivered incorrectly (% of all reports for this detection method)	124 (37.0)	302 (67.0)	5 (71.4)	68 (66.0)	11 (50.0)	13 (65.0)	62 (37.8)	0
Range of number of fractions treated incorrectly per detection method	1-24# (n=107)	1-24# (n=262)	1-8# (n=4)	1-10# (n=56)	2-18# (n=11)	1-6# (n=12)	1-13# (n=56)	0
Average number of fractions treated incorrectly per detection method	3 (n=107)	2 (n=262)	3 (n=4)	2.2 (n=56)	3.7 (n=11)	2.4 (n=12)	2.4 (n=56)	0

Figure 1: Discipline who detected the incident

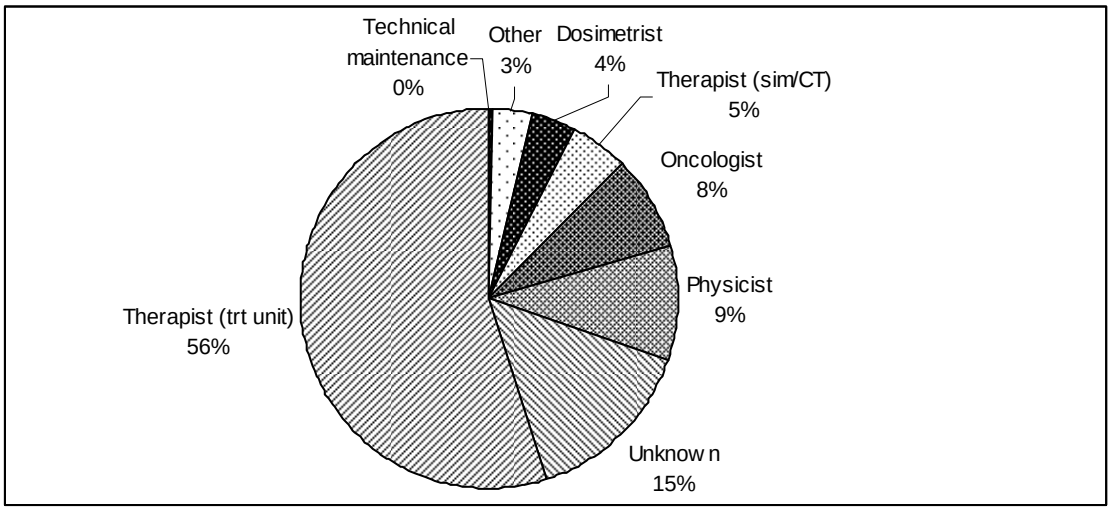

Figure 2: Quality assurance method by which the incident was detected

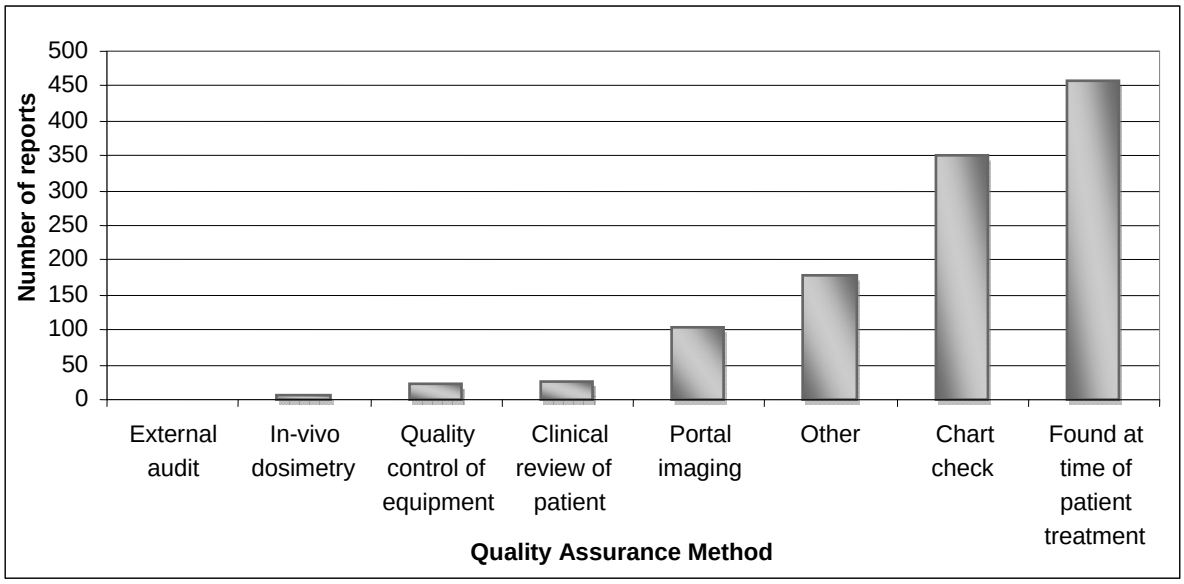

Figure 3: Percent of treatment fractions delivered incorrectly (N=199 reports)