Patient safety

Paving the way for progress

N°13

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Incident learning systems at the international level

Newsletter for radiotherapy professionals

> Editorial

The council directive 2013/59/EURATOM states that Members of the European Union shall ensure that a system of experience feedback is in place for the dissemination of lessons learned from significant events in the field of exposure to radiation for medical purposes.
In France, this system was implemented in 2011 through the publication of the present newsletter, "Patient Safety Bulletin".

The multidisciplinary radiotherapy working group felt it was appropriate to devote a special edition of the Patient Safety Bulletin to the event-reporting and experience-feedback systems implemented in other countries.

Experience feedback, why? What are the strong points of the existing reporting systems? Which on-line resources can enhance the quality procedure of the radiotherapy centres?

The editorial team invites you on a world tour of the main international reporting systems in North-America and Europe, selected for their interest as examples or the value of their publications.
Our interviews will let you find out how our Belgian neighbours have opted for a standardised internal system for recording and analysing adverse events, or how the experience feedback committee of the Gustave Roussy Institute in Paris integrates the international lessons learned in its work.

The managers of experience feedback systems share the view that their biggest challenge is to convince the radiotherapy centres to take part in a learning system based on past incidents. And what if your centre's safety process would benefit from this?

We wish you enjoyable reading.

The Editorial Team

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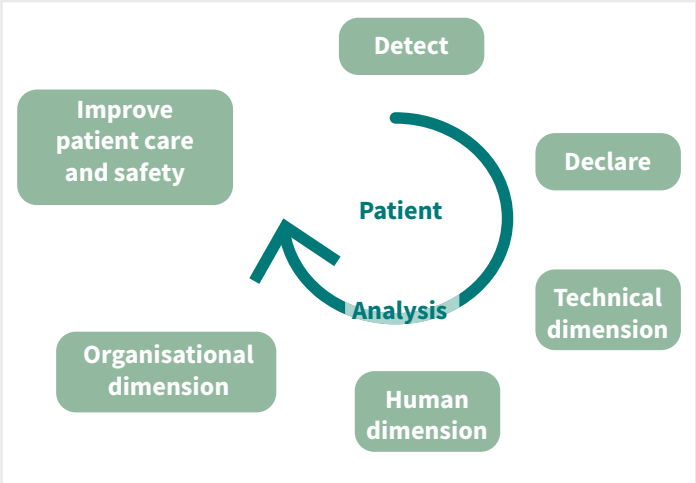
> Why have experience feedback?

Radiotherapy is one of the only applications of ionising radiation in which very high doses of radiation are deliberately administered to patients in order to treat a disease. Despite its reputation as being a safe method of treatment, radiotherapy is not devoid of adverse events and accidents have occurred all over the world.

The experience feedback process allows learning from adverse events in order to improve practices in the future.
It consists in:
- Collection of data on incidents, dysfunctions and accidents
- Analysis of their root causes
- Implementation of preventive and/or corrective actions
- Dissemination of lessons learned from the events to radiotherapy centres

From its publication 112 of 2009, the International Committee for Radiological Protection (ICRP) underlines the utmost importance of disseminating the lessons learned from accidental exposures:



"Lessons from accidental exposures are therefore an invaluable resource for revealing vulnerable aspects of the practice of radiotherapy and for providing guidance for the prevention of future occurrences."

> Decoding

The reporting and experience feedback systems that exist across the world are divided between:
- national and international systems
- voluntary and mandatory systems, which in the majority of countries exist side by side.

The organisational structures in place for reporting events frequently include a learning-oriented section, be it for training purposes (e-learning module) or for experience feedback (specific reports concerning an event).

In France, the reporting of significant radiation protection events (ESR) for nuclear activities has been part of a national and mandatory system since July 2007. In the field of radiotherapy it is based on criteria defined in ASN Guide No.16.

The large number of events reported in radiotherapy and their analysis by the centres enable lessons to be learned from them and recommendations to be issued, particularly through this periodic bulletin "Patient safety: Paving the way for progress", devised by the radiotherapy professionals and ASN.

> Focus: international systems

The two international systems SAFRON and ROSEIS function on the basis of anonymous and voluntary reporting of events.

ROSEIS

https://roseis.estro.org/

ROSEIS (Radiation Oncology Safety Education and Information System) is the international Web platform provided by ESTRO, the European Society of Radiotherapy and Oncology. As of March 2018, it superseded the ROSIS platform, developed in the early 2000's.

Scope :
draw the lessons from the incidents and "near-incidents" at local level and share knowledge and experience with the radiotherapy community as a whole

Resources :
ROSEIS proposes educational material on various subjects relating to the radiation protection of radiotherapy patients.

https://roseis.estro.org/rosis-educational/

IAEA
International Atomic Energy Agency

SAFRON (SAFety in Radiation ONcology) is an international database developed by the International Atomic Energy Agency (IAEA) in December 2012.

https://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safron

Scope :
share experience feedback in radiotherapy.
In April 2018 the SAFRON platform counted over 1500 cases.

Resources :
SAFRON publishes newsletters twice a year.
The incident reports for a specific type of treatment can be searched for in the SAFRON database using keywords (creation of a free account is necessary).

https://www.iaea.org/sites/default/files/18/01/17-12-safron-update.pdf

The IAEA's RPOP platform which hosts the SAFRON system offers a huge amount of educational material for all the medical disciplines that use ionising radiation.
https://www.iaea.org/resources/rpop

> The experience of the radiotherapy centres

"The reporting websites highlight new events and enable the solutions implemented elsewhere to be disseminated in our own networks"

Interview with
Gianfranco Brusadin,
Special Advisor for Radiotherapy Quality and Safety at the Gustave Roussy Institute (Paris)

What is your opinion of the events reporting systems in other countries?
JI embraced the events reporting process from the very beginning when ESTRO's ROSIS system was introduced nearly 20 years ago. It is sometimes difficult to report an event, but an error becomes positive if you can analyse it in depth, learn all the relevant lessons from it and share them with others.

What do you gain from consulting these systems?
In addition to the ASN bulletins and experience feedback (REX) sheets, I regularly consult ROSEIS, SAFRON, the Belgian and British REX sheets "Safer Radiotherapy", more particularly to enhance my centre's quality process. I use the collected data to prepare my CREX (experience feedback committee) meetings, which are held every 6 weeks or so and address three aspects:

> Focus: in North America

The Canadian and American voluntary events reporting systems were developed on the initiative of the professional radiotherapy societies following a series of incidents reported by the New-York Times in 2010.
In the United States, there is a mandatory reporting system run by the Nuclear Regulatory Commission (NRC) for medical events and by the Food and Drug Administration (FDA) for medical devices vigilance.

NSIR-RT (National System for Incident Reporting-Radiation Treatment) is the Canadian platform set up in late 2016 by the Canadian Partnership for Quality radiotherapy-CPQR.

http://www.cpqr.ca/programs/national-incidents-reporting/

Scope :
In the Canadian reporting system incidents are reported by health professionals. A study is in progress in order to establish the feasibility of reporting by patients or kinfolk.

Resources :
Since 2017, NSIR-RT has proposed two on-line "incident analysis" training sessions.
The module lasts seven weeks with weekly sessions of one and a half hours.

RO-ILS (Radiation Oncology Incident Learning System®) is the American platform launched in mid-2014 by ASTRO et AAPM
https://www.astro.org/RO-ILS.aspx

Scope :
RO-ILS collected a wide range of events including incidents, near-misses, and unsafe conditions.
In January 2019 the RO-ILS database counted more than 8000 cases, including more than 1400 therapeutic radiation incidents where the radiation dose was not delivered as intended, with or without harm to the patient.

Ressources :
"Aggregate" reports are published on the RO-ILS public website twice a year in order to facilitate shared learning in the area of radiotherapy. These reports provide a synthesis of the analyses of actual cases, including an analysis of the contributing factors and the associated actions and recommendations.
In 2016, ASTRO began offering continuing medical education to physicians based on RO-ILS reports.

1. benchmarking of the number of cases reported,
2. prospective risk analysis for the techniques/devices which as yet have never been used in our centre. When the 1st Cyberknife system arrived, a case reported in the ROSIS system drew our attention to the risk of an inappropriate selection of the alignment centre which could lead a collision of the machine with the patient.
3.analysis of concrete cases during CREX meetings (AFCN sheets).

We analysed the case of a tomotherapy treatment in which there was a 60-cm offset with respect to the projected position, as though it has occurred in our centre.
The limit of the current systems is the difficulty in finding precise information due to shortcomings in its structuring.

It would moreover be useful to introduce a simplified system for reporting near-events in order to have a better view of the potential risks.

Which recommendations can you draw from this for French radiotherapy professionals?
The reporting websites highlight new events and enable the solutions implemented elsewhere to be disseminated in our own networks. I particularly recommend analysing real events that have occurred elsewhere.

This lets the teams have a more detached - and therefore relaxed - approach, through which they can adapt or confirm their practices without actually having been physically confronted with the problem.

> Focus : in Europe

Both the United Kingdom and Belgium have a dual events reporting system: a voluntary system and a mandatory system of reporting to the regulator.

VOLUNTARY NOTIFICATION SYSTEM

The "National Voluntary Radiotherapy Reporting and Learning system" managed by Public Health England (PHE) results from the recommendations to improve patient safety made by the medical societies in 2008 in "Towards Safer Radiotherapy", following the overexposure of a 15-year old girl in 2006.

Scope :
reporting of incidents and near-incidents in radiotherapy 50,000 reports from 65 centres have been registered since December 2007. PHE receives 800 reports per month on average..

Resources :
An analysis of radiotherapy errors is published every four months, as is a summary of these analyses.

https://www.gov.uk/government/publications/safer-radiotherapy-error-data-analysis-report

MANDATORY REPORTING SYSTEM

The system is organised by country. In England it is the Care Quality Commission (CQC) that centralises the mandatory reports of accidental and unplanned exposures. The reports received by the CQC are shared with PHE on an anonymous basis.

Resources :
CQC publishes annual reports describing the types of incidents, but no individual incident reports.

https://www.cqc.org.uk/guidance-providers/ionising-radiation/irmer-enforcement-register-findings-reports

VOLUNTARY REPORTING SYSTEM

The Belgian "benchmarking platform" was set up in 2008 as part of the national cancer plan. It is managed by and for radiotherapy professionals on the basis of the PRISMA-RT methodology used by all the Belgian radiotherapy centres for their internal analyses since 2011.

www.PRISMA-RT.be

Scope :
sharing the lessons learned from near-incidents and incidents in radiotherapy.
Since 2008, 18,850 events have been recorded in the Belgian platform. In 2018, 408 analyses were performed from 2,132 incidents and near-incidents.

Resources :
The resulting analysis of the reports is exported anonymously to a national database for the sole use of the Belgian medical professionals.

SYSTEM OF REPORTING TO THE NUCLEAR REGULATOR

As is the case in France, the Belgian radiotherapy professionals report events to the FANC, the Federal Agency for Nuclear Control, on the basis of jointly developed criteria.
This reporting - voluntary until now - is going to become mandatory further to the transposition of the Euratom directive of 2013 (Basic Safety Standards Directive - BSSD).

Resources :
The FANC issues some 10 experience feedback sheets per year based on the events reported to it. These sheets contain an explanation of the incident, the actions taken by the radiotherapy centre concerned and the recommendations of the FANC.

https://afcn.fgov.be/fr/chercher?keyword=REX+radioth%C3%A9rapie

> The experience of the Belgian reporting system managers


Karen Haest


Aude Vaandering

- ***Karen Haest**, FANC special advisor.*
- ***Aude Vaandering**, Quality Manager / Doctoral student, Oncological Radiotherapy Department, University Clinics of Saint-Luc, UCL, Brussels.*

Why has Belgium adopted this highly committed approach through the 2008 cancer plan?

Karen : In 2007, a stereotactic radiotherapy event concerning a cohort of 17 patients occurred in the radiotherapy department of Gand University Hospital. This event, which was concomitant with the disclosure of the Epinal accident in France, had the effect of a loud wake-up call on the Belgian public authorities.

Why have a single internal reporting system?

Aude : There are 24 major radiotherapy centres in Belgium. This relatively small number of centres - compared with France for example - and above all the fact that each radiotherapy department has a quality manager, facilitated the adoption of a standardised system for internal recording and analysis of adverse events and near-incidents in radiotherapy.
The use of the same analysis methodology by all the centres since 2011 increases the effectiveness of disseminating the identified causes of events among the professionals. The ultimate aim is to have centralised operation in order to identify the causes and weak points at national level and take targeted measures accordingly.

How is the FANC's reporting system positioned compared with PRISMA-RT?

Karen : Since 2008, the FANC receives reports for specific radiotherapy events that correspond to criteria established with the radiotherapy professionals.
This is therefore a selection of the events recorded locally in each hospital. Adoption of PRISMA-RT has enabled the centres to enhance their skills in events analysis; the content of the reports sent to the FANC has become considerably more detailed since 2011!

What would be your message to our readers on the benefits of reporting systems?

Aude : It is important to encourage initiatives such as inter-CREX to bring together the professionals of several centres. The best solutions come from discussions.
Karen : Apart from the set framework of criteria for mandatory reporting to the Regulator, always bear in mind that the benefit of reporting is to prevent the events from occurring in other centres.

> Methodological reference

THE PRISMA METHOD

Developed in the Netherlands to analyse human errors in the chemicals industry, the PRISMA method was applied successively to the steelmaking and energy sectors, then to health. The Maastro clinic in Holland has adapted it to radiotherapy.

The PRISMA method postulates that an incident is the result of a combination of numerous causes. The analysis allows the identification of the root causes which are then classified in a predefined order to avoid focusing the analysis on the operator's errors and neglecting the technical and organisational factors:

1. The technical and material problems (e.g. equipment design);
2. The organisational problems (e.g. procedures and protocols, management priorities);
3. The human causes relating to the criteria of knowledge, skills and compliance with rules;
4. The specific causes associated with the patient.

Thanks to a matrix, guidance on preventive or corrective actions is then provided.

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