PATIENT SAFETY

PAVING THE WAY FOR PROGRESS

#

October 2023

PROSPECTIVE RISK ANALYSIS: EXAMPLE OF INTERRUPTIONS IN THE TREATMENT PROCESS

Newsletter for radiotherapy professionals

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EDITORIAL

A failure, an urgency, or person absent: three cards, one risk situation. How do you best manage this type of degraded work situation? Improvise?
No, you plan ahead with *prospective risk* analysis.

This issue of *Patient Safety* focuses on the *prospective risk* analysis procedure. The challenge is to bring out a common vision of the patient care and treatment process, anticipate the potential risks, and define and improve the safety measures needed to control them. The procedure is particularly crucial when introducing organisational changes or new techniques.
It is also useful for identifying risk situations with few events to be addressed in the meetings of the Experience Feedback Committee (EFC).

Interruptions in the treatment process can be included in these situations. Following a machine failure, a technical fault or maintenance work, treatment interruptions disrupt the team's organisation and are source of potential risk for the patient, without necessarily resulting in a significant radiation protection event.

What are the risk factors or, conversely, the safety factors for the patient when there is a treatment interruption?
The multidisciplinary group behind *The patient safety newsletter* has tested the EPECT method, recently developed by IRSN, on a scenario combining different cases of treatment interruption. It presents its *prospective risk* analysis for us.
In "*The experience of the centres*", Bénédicte PETIT and Karim ZARFANI of the SENY group share their experience with the implementation of EPECT and its collective dynamics.

Whether using a functional approach with FMECA or a situational approach with EPECT, this newsletter decodes the two methods. Whatever your choice, do not omit the update of the *prospective risk* analysis, which offers an ideal opportunity to take a detached look at work organisation, medical practices and the quality system.

Wishing you enjoyable reading!

The Editorial Team

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- **Publications Director:** Olivier Gupta, Director-General of ASN
- **Chief Editor:** Nathalie Clipet
- **Author:** Nicolas Pirault, Sylvie Thellier
- **Editorial Committee:** French Society for Radiation Oncology (SFRO), French Society of Medical Physics (SFPM), French Professional Council of Radiographers (CNPMEM), French Association for Quality and Safety in Radiotherapy (AFQSR).
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- **Illustrations:** Julien Gremaud
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Key figures

Since the on-line notification portal entered service in 2011, more than 1,000 significant radiation protection events (SRPEs) in radiotherapy have been reported. The centres linked 19 SRPEs (i.e. about 2% of the notifications) to an interruption in the treatment process. They come under four risk situations:

1 **Resuming the treatment of a patient after an interruption** of variable duration, linked to a technical failure (6 SRPEs);

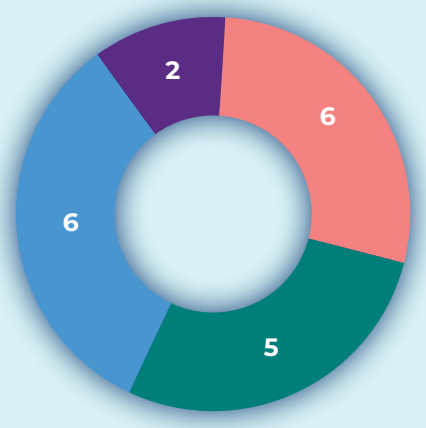
2 **Transfer of a patient to another machine** (matched or not) further to a failure or technical fault (5 SRPEs);

3 **Extension of the treatment on a machine** that has a known or unknown fault (6 SRPEs);

4 **Failure to detect a change of parameters** following a maintenance operation or other work (2 SRPEs).

The risk situation resulting from a failure, a technical problem or a maintenance operation is not always identified as a cause of the adverse event or the SRPE. This may explain the low number of notifications and must not mask the need for *prospective risk* analysis to maintain the safety of treatment in these situations.

BREAKDOWN OF THE 19 SRPEs ACCORDING TO THE RISK
(2011-2022)



Decoding

WHAT ARE THE IMPLICATIONS OF TREATMENT INTERRUPTIONS?

Treatment interruptions disrupt work organisation, cause delays in the treatment, worry for patients who are obliged to wait, tension in the team and stress for the medical staff.

Furthermore, an interruption of one or more days in a radiotherapy treatment that is not compensated for can reduce the patient's chances of recovery.

RISK FACTORS

- Failure to identify situations that could lead to treatment interruptions and to plan ahead for their management (quality control that is performed incompletely or not at all, etc.).
- The time frame context (treatment already suspended previously, urgency, late arrival of patient, etc.).
- The clinical context of the patients (therapeutic strategy and analysis protocols, etc.).
- The organisational context (change of team, etc.).

POINTS REQUIRING VIGILANCE

Quality control is strongly recommended following preventive or corrective maintenance on a treatment machine. The quality control must be appropriate for the maintenance work performed. This quality control is carried out by the technicians and engineers of the manufacturer or the maintenance service provider, but more detailed verifications must be conducted internally according to the organisation of the services.

The transmission of verbal and written information between the different activities helps to prevent risks: discussion with the maintenance operator, maintenance intervention reports, failure log, maintenance registers, computer-assisted maintenance management software, etc.

Methodological benchmarks

Risk management is firstly based on the "*prospective*" risk analyses (in preventive mode when there are no events) and "*retrospectively*" risk analyses (in reactive mode following an event). These procedures are closely linked and are mutually beneficial.

FMECA

(FAILURE MODES, EFFECTS AND CRITICALITY ANALYSIS)

Following the accidents in Epinal and Toulouse, the FMECA method was adapted for radiotherapy by a working group led by ASN in collaboration with the learned societies (see ASN Guide N°. 4). The method proposes characterising the risks faced by the patients based on the analysis of failure modes, their effects and their criticality.

The FMECA method is applied in 5 steps:

1	2	3	4	5
SETTING UP THE WORKING GROUP	**FUNCTIONAL ANALYSIS**	**QUANTITATIVE AND QUALITATIVE ANALYSIS**	**ASSESSMENT OF THE FAILURES**	**DEFINING OF ACTION PLANS**
Assign one experienced professional per activity within the service	Decode the utility of the treatment process, its functions and its operation	Analyse the failures, their modes and effects and the probable causes	Assess the severity, frequency, non-detection and criticality of the analysed failures	Define and plan action plans that are appropriate for addressing the identified problems

COMPARATIVE ANALYSIS OF THE TWO METHODS

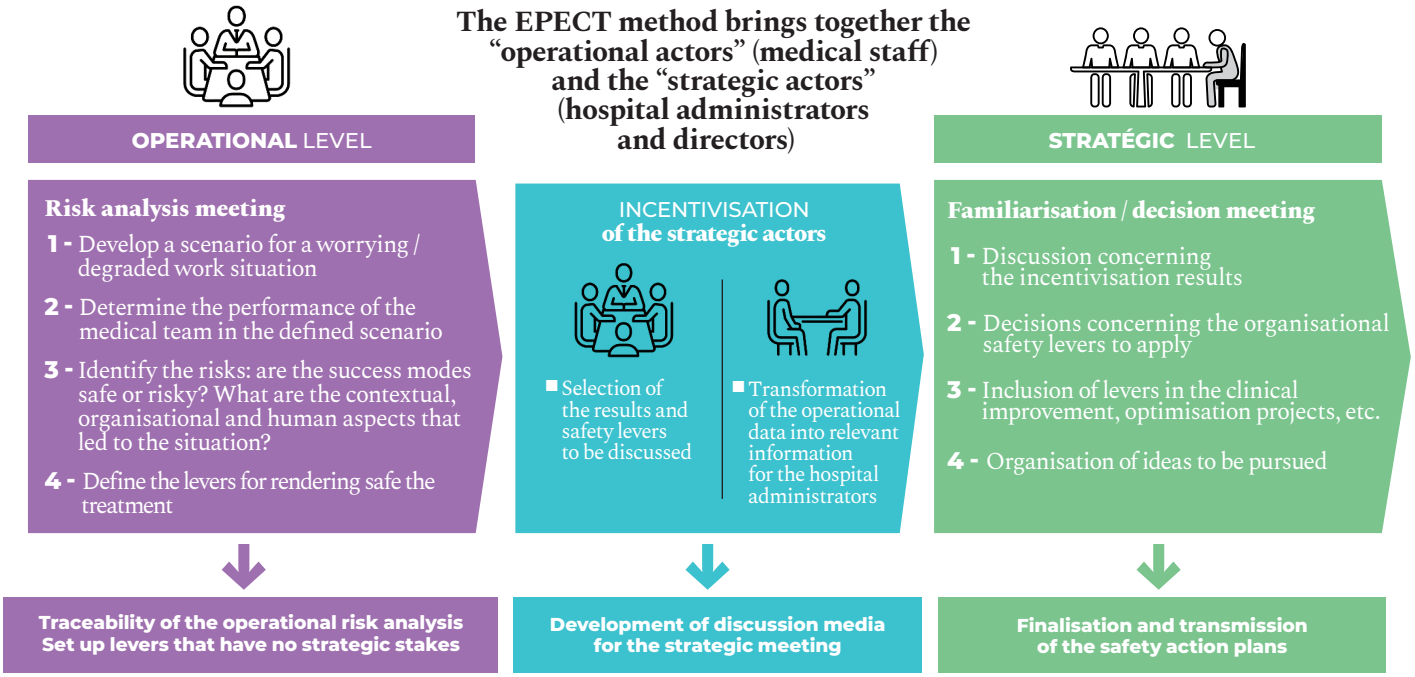
	FMECA
Type of approach	■ Functional approach (activities), deterministic (usage, causal relationship) and probabilistic approach
Analysis mechanism	■ Technical and human failure modes of the care process
Type of assessment	■ Semi-quantitative assessment (quantification of risks based on the subjective judgment of the analysis group)
Action levers	■ Normative safety (imagining the situations that could arise and putting in place rules and means of coping with them)
Strengths / Assets	■ Setting up of a multidisciplinary team ■ Identification and assessment of the risks of a new technique or device before it is actually deployed
Limitations	■ Sequential approach (analysis of the various steps of the process) limiting the systemic vision ■ Subjectivity of the assessment scales (severity, frequency, detectability) ■ Complexity of the method, source of confusion between the cause and mode of failure

The *prospective* analysis tools come from high-risk industries such as the military, aeronautics, nuclear, chemicals. Their objective is to characterise potential risks and establish barriers to prevent them from arising. This double page spread compares the two methods used in radiotherapy: The functional approach of FMECA and the situational approach of EPECT.

EPECT

(FRENCH ACRONYM MEANING "FORUM FOR SHARING AND EXPLORING WORK COMPLEXITY")

Developed in 2017 by IRSN, the EPECT method adopts a new approach stemming from research in the area of social sciences and the humanities. Its aim is to improve the coordination of risks between governance, management and the operational personnel. EPECT proposes identifying the strategic organisational and human factors that could undermine the performance of a healthcare team. The situational adjustments and adaptations (the "success modes") applied by the team when faced with a degraded situation are reviewed. Following this, the risks faced by the patients are questionned: the success modes are qualified as "safe" or "risky".



	EPECT
Type of approach	■ Situational, qualitative and explanatory approach
Analysis mechanism	■ Safe and risky success modes deployed by the professionals in a degraded work situation
Type of assessment	■ Qualitative assessment (contextualisation of the risks)
Action levers	■ Normative safety and adaptive safety (enhancing the reliability of practices and changing in work organisation)
Strengths / Assets	■ Establish spaces for collective discussion among actors with differents rationales, priorities, and stakes ■ Engage strategic actors, such as hospital administrators ■ Examine the organisational effects on treatment safety ■ Incorporate technical, human, and organisational levers into both existing and future projects
Limitations	■ The analysis is applicable to processes, systems, or techniques that are already in operation ■ Requires a shift in the conceptual framework: Analysing the team's adaptations in degraded situations (success modes) rather than failure modes

The experience of the centres

“The EPECT method’s great strength is that it reveals the complexity of the day-to-day work and the interactions between the different teams”

SENY / ELSAN Group:
Bénédicte PETIT
Operational quality manager of the Cancerology Institute, of the Scintigraphy Centre and of the Paris North PET Scanner Centre in Sarcelles
Karim ZARFANI
Operational quality manager and health supervisor at the Private Radiotherapy Institute of Metz

The radiotherapy services of the SENY group, a subsidiary of ELSAN, are located on six geographical sites. The group adopted the EPECT method further to its cross-experimentation in 2016 on the Sarcelles and Levallois-Perret sites. The method is now being deployed in nuclear medicine in addition to the radiotherapy services.

WHY HAVE YOU ADOPTED THE EPECT METHOD?

The SENY group has been implementing risk management since 2004. When Sylvie Thellier, an ergonomist at IRSN, approached us in 2016, the FMECA-based risk management approach was losing momentum. We found the approach innovative and wanted to try it.

WHAT ARE ITS ADVANTAGES?

The EPECT method puts the patient at the centre of the analysis. It highlights the interactions between the teams and the situational adjustments / adaptations put in place at each stage of the patient’s care pathway.

The method adopts a view of the users’ practices that is close to reality. The change of paradigm, based on the success modes and not on the failure modes, is better acknowledged by the professionals.

HOW DO YOU USE IT?

To begin the approach, our team of operational quality managers made up a set of cards representing an actual or potential risk situation or even a situational adjustment / adaptation.
We are collectively capable of managing uncommon situations, but the combination of circumstances creates an increased risk that can cause adverse events. These scenarios that we study using the cards (see example on right-hand page).

We subsequently use the EPECT method in the meetings of the experience feedback analysis unit (EFC) to retrospectively analyse the precursory events encountered by the service. We identify the weakening factors, the effective situational adjustments / adaptations and the corrective actions. The list grows over time, providing input for the activity risk analysis. It is a dynamic method.

WHAT ARE THE IMPEDIMENTS TO ITS USE?

The EPECT method requires a new mindset. Engaging all the professionals in the approach is essential.

When carrying out a *prospective risk* analysis, it is not easy to create a scenario because one must imagine the risk situations that could arise.

The commitment of the quality manager is important: the meetings are rich in information, and the discussions are lively and informal. It takes 2 to 3 hours to draw up the final analysis table. The support of management is also required to conduct the strategic level of the risk analysis.

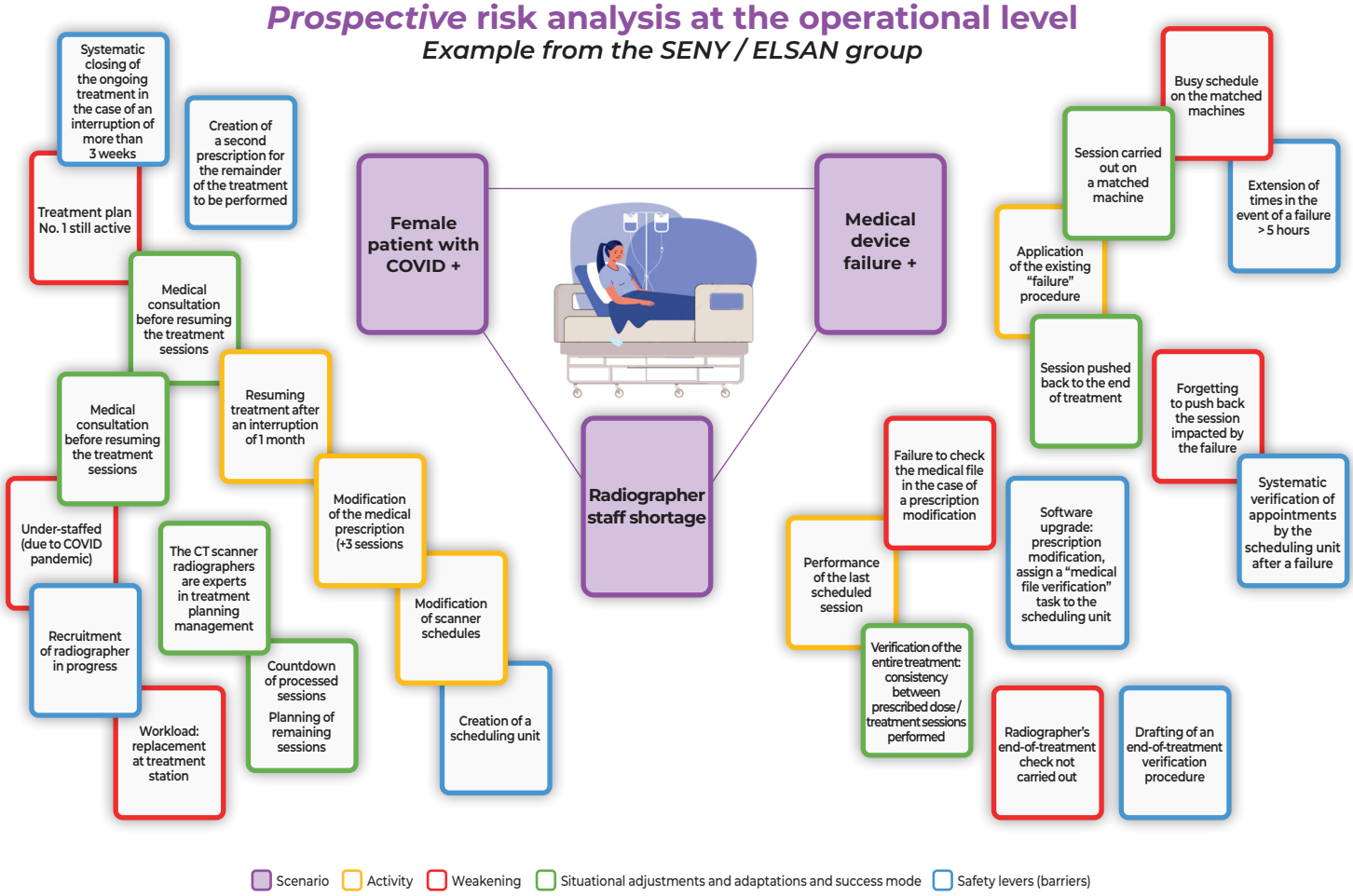
HAVE YOU USED THE EPECT METHOD TO SET UP STEREOTACTIC TREATMENTS?

We have not used it for the initial risk analysis because with the EPECT method we are limited by our ability to come up with totally unprecedented work situations. We favoured the FMECA method, which is more appropriate for an activity that has never been implemented.

However, we used EPECT to update the risk analysis and it consolidated the FMECA results. This example illustrates the complementarity of the approaches.

Prospective risk analysis at the operational level

Example from the SENY / ELSAN group



→ STEP 1 - ESTABLISHING THE SCENARIO

Each session is dedicated to analysing a degraded work situation, representing a collective concern. The scenario is supplemented by factors - known or imagined - that disrupt individual and collective work organisation (constraints, inertia, changes, tensions).

Example of combination of three risk factors:
female patient with COVID + shortage of radiographers + failure of medical device.

→ STEP 2 - IDENTIFICATION OF THE SITUATIONAL ADJUSTMENTS / ADAPTATIONS AND SUCCESS MODES

Discussions in this stage bring out different success modes or situational adjustments / adaptations mobilised to respond to the degraded work situation described in the scenario. There are four types of success mode: adaptation of the prescribed work, facilitating actions, individual adjustments and arrangements and reorganisation of the team.

Example of identified success mode:
medical consultation before resuming the treatments.

→ STEP 3 - IDENTIFICATION OF THE RISK FACTORS

Each success mode is studied to determine the contextual, technical, human, organisational and strategic factors that could create situations that are either risky or safe for the patients.

Example of weakening factors:
- **busy schedule on the matched machines;**
- **no verification of the medical file in the case of a prescription modification.**

→ STEP 4 - DEFINING THE SAFETY LEVERS (BARRIERS)

Lastly the group determines the levers for ensuring treatment safety: the success modes to be generalised to render the practices reliable; an action plan to avoid or to set bounds on situations that are risky for the patient; ideas to be pursued (working groups, seminars, commissions).

All the elements that emerge during the discussion are entered in a summary table. The data can be classified by theme (HR, skills, techniques, organisation, etc.).

Examples of barriers:
- **systematic closing of the ongoing treatment in the case of an interruption of more than 3 weeks;**
- **systematic verification of appointments by the scheduling unit after a failure.**

Steps for progress

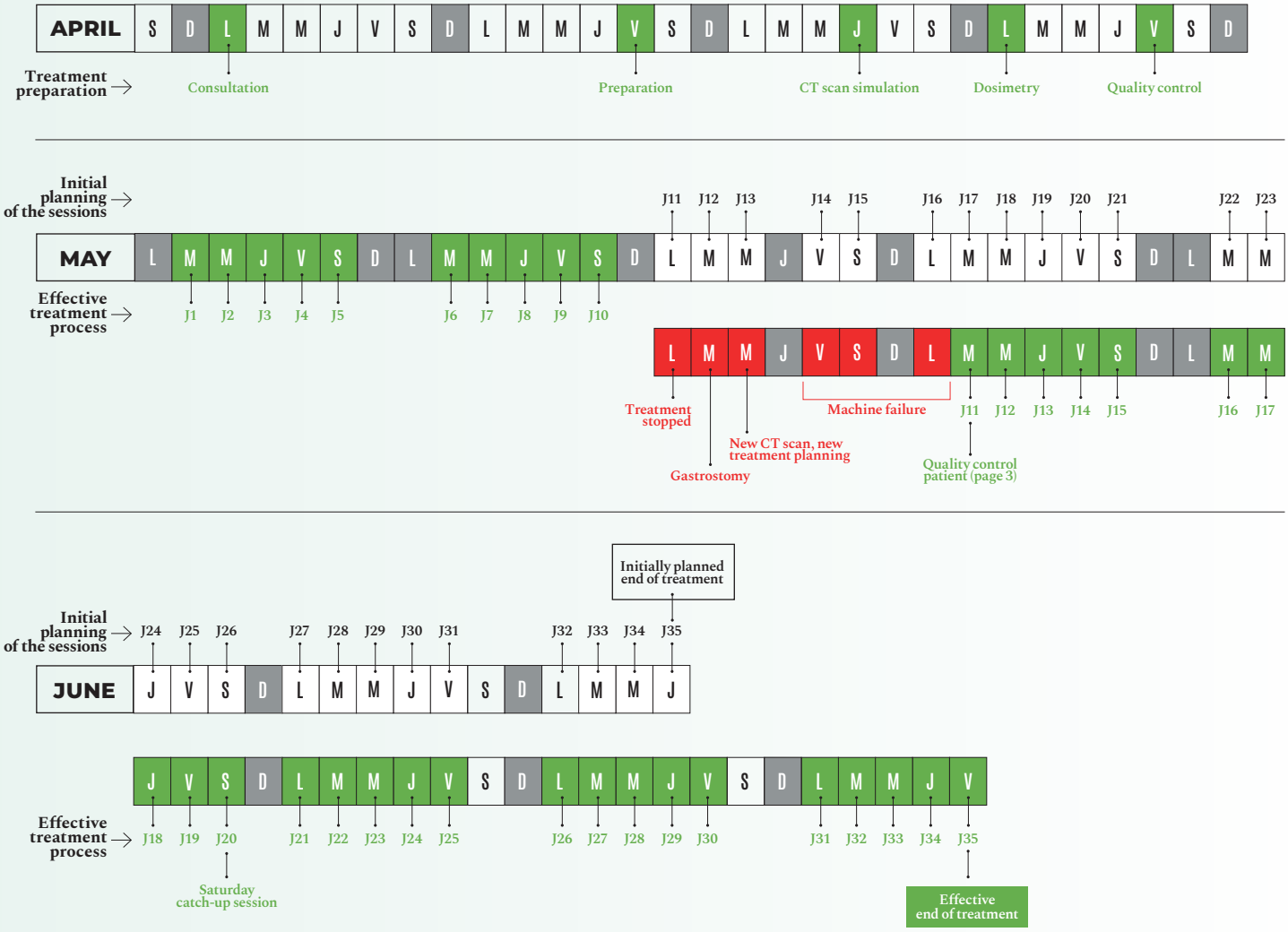
1. Innovative initiative: EPECT analysis in the case of treatment interruption

The editorial committee has experimented the EPECT method, presenting the operational risks analysis of a scenario chosen collectively.

ANALYSED SCENARIO

A patient is undergoing treatment for head and neck cancer (H&N). The treatment (35 sessions) is punctuated by several public holidays in the month of May. The radiation oncologist assured the patient that the treatment would be completed before the patient's vacation. After two weeks of treatment, the patient's condition deteriorated (grade-3 mucositis), leading to a three-day halt in treatment. A gastrostomy was performed to nourish the patient who had lost weight. The service's procedure requires dosimetry planning to be established within two days. When the decision to conduct a new CT scan and treatment planning was made, the referring physician was on leave. The patient was taken charge of by an intern he did not know. On the scheduled day to resume the treatment, the machine suffered a breakdown lasting three days. These cumulative events delayed the patient's effective end of treatment by six days.

Chronology of the treatment and its contingencies



This scenario is original compared to the approximately twenty SRPEs notified to ASN because it addresses:

- **a variety of interruption situations** (public holidays, change in general condition of the patient, treatment machine failure);
- **contexts unfavourable for the safety of the patient:** the patient'pressure on the team as his vacation approached, the absence of the referring physician during the new CT scan and new treatment planning. Furthermore, the machine failure complicates the continuation of the treatment.
  It means either waiting for the machine to be repaired or adapting the treatment so that the patient can be treated on another machine.

Conversely, this scenario does not present some of the risk factors identified in the SRPEs. That is why this newsletter presents the analysis (*retrospective*) of the SRPEs (page 3) and asks you to cross-compare it with a *prospective* risk analysis.

Based on this scenario, different safe and risky success modes were identified by the participants (see table below). The comparison of these extreme situations brings out organisational and human factors that favour one or the other.

FACTORS OF CONCERN OF THE SCENARIO	SAFE SUCCESS MODES	RISKY SUCCESS MODES
Absence of the referring physician	▪ **Several referring physicians** per body location (H&N) ▪ If there is no backup physician, **plan ahead** for treatment by a physician who **knows the body location**	▪ **No backup physician** ▪ Treatment by an unspecified **physician or an intern with little or no supervision**
Deterioration of the patient's condition	▪ Follow-up by a dietitian (weight monitoring) and anticipation of the laser photobiomodulation session (mucositis) ▪ **Pain monitoring**	▪ No weight monitoring analysis ▪ No actions (meeting) to anticipate the effects of the loss of weight
New CT scan of patient on his return	▪ Organisation of **new CT scan within 2 days** by a backup physician: CT scan and contouring within 24h, new treatment **planning and patient quality control (QA) within the next 24h** ▪ Postponement of treatment of other patients of the backup physician	▪ **New CT scan carried out as a top priority** ▪ Excess workload of backup physician not compensated for or taken up over by an intern with little or no supervision ▪ **Patient quality control (QA)** omitted to save time
Failure	▪ Procedure describing the decision to conduct a new CT scan associated with the group of patients concerned by the failure ▪ Patient **prioritisation meeting** (H&N, gynaecology, brain) ▪ Implementation of appropriate quality controls with the maintenance technician	▪ No procedure for deciding on a new CT scan and/or no prioritisation meeting ▪ **No criteria for prioritising patients:** taken in order of arrival ▪ No quality control
Catch-up treatment on Saturday	▪ **Catch-up preparation** to have a minimum of 3 days of treatment per week: scheduling a Saturday, rioritising the patients	▪ The patient (priority) is repositioned then added on another machine or a Saturday with a **short preparation time**
Patient's pressure on the team	▪ **Mobilisation of different medical professionals** (head of service, health supervisor, etc.) to reassure the patient ▪ **Training of the personnel** in the psychological management of patients ▪ **Mediator** personnel and/or physicians	▪ Management of the pressure by **an intern who is a newcomer to the service and does not know the patient** ▪ **The announcement increases the patient's stress**
New treatment planning in top priority situation	▪ A medical physics **procedure** exists ▪ Top priority criteria are defined ▪ Organisation to free-up, assign medical professionals to top priority situations	▪ **No top priority treatment protocol** or impossible to apply it ▪ No top priority criteria defined
Adaptation of the prescription and of patient planning	▪ **Change in the patients schedules is limited** to avoid disrupting the organisations ▪ **Collective decision** to adapt the prescription based on **criteria predetermined** according to the type of case and the context (duration of interruption, number of stoppages, patient's demands, etc.) ▪ **Top priority** treatments time slot (from 18h to 18h30 every day) to absorb the needs without disrupting the organisation ▪ Scheduling of the other patients **adapted to the machine workload** and the **available resources,** planning ahead for treatment push backs ▪ **Plan ahead** for the QA ▪ **Patient's context taken into account** in prescription after new contouring (illness, radiosensitivity, etc.)	▪ **Failure to plan ahead for changes** and **disruption** of the schedule of the **other patients** ▪ Adaptation of the prescription by a **physician other than the prescribing physician** ▪ Schedule changes managed by a single person (**critical resource** in case of departure) ▪ **Mismatch between material** and **human resources** due to the postponement of treatment sessions and failure to plan ahead for the QA ▪ **Patient's context not taken into account** ▪ Case-by-case and **increasing number of multi-parameter adjustments** with tools that do not permit it, a factor that induces errors and puts the team under tension

Steps for progress (continued)

Working from this experiment, the following safety levers have been defined:

- **Maintain or change the organisation** for catching up sessions to have the minimum of three days' treatment per week; carry out the new CT scan within two days; organise communication between the referent physician and the backup physician who will follow-up the patient in referent physician's absence (before departure, on return).
- **Develop a** procedure describing the decision to conduct a top priority new CT scan or new treatment planning.
- **Prioritise** the patients to avoid overloading the treatment team; identify the priority patients; train the personnel in the management of stressed patients; designate mediators.
- **Define** the criteria for choosing the backup physician who will follow a patient when their referent physician is absent; the conditions under which a patient will be managed by an intern; the number of referent physicians per body location; the things that are incompatible with the absence of radiation oncologists.
- **Conduct a reflection** on limiting schedule changes when a treatment machine is out of service: the criteria that will trigger an adaptation of the prescription; the organisation of a top priority treatments time slot for the management of priority patients, etc.

These safety levers are not binding in any way and must only be applied if they seem appropriate and suited to the effective organisation of a service.

2. Good practices - Recommendations

INTERRUPTION OF THE TREATMENT PROCESS

Facilitate the adaptation of the service to cope with contingencies

Material resources:

- Facilitate the transfer of priority patients when necessary, by reserving routine slots on the matched machines.
- Make use of computer software to gain in productivity. The software applications must be chosen to facilitate tasks and adapt to the organisation of the service, not the reverse (for example: notification in the patient's file of his inclusion in a clinical test, all transmitted information concerning the patient and easy viewing by the end user).
- Provide appropriate quality control equipment for the identified contingencies.

Organisational means:

- Define medical dosimetric validation procedures and criteria per body location.
- Put in place a top priority treatment planning channel.
- Organise the team members' vacations to ensure care and treatment continuity with no deterioration in patient management in the event of contingencies.

Human resources:

- Organise medical backups per body location.
- Check that there are enough dosimetrists to handle the additional workloads in the event of contingencies (machine failures, but also cyber-attacks).

Define a medical care management strategy

Be perfectly aware of the constraints resulting from care streamlining to take this into account in the risk analysis:

- identify the patients to prioritise in the event of a machine failure (priority patients and patients to arbitrate);
- evaluate the prescription modifications if applicable and the compensatory methods (extra session, Saturday, bi-fractionation, dosimetry updating);
- keep some flexibility with respect to the active list of patients.

Any interrupted task must be started from the beginning again.
Be sure to go through all the steps of the work task, including the identity monitoring questioning.

Example of categorisation by colour code when performing the dosimetry

ORDER	ACTION	MAXIMUM NUMBER OF PATIENTS
Priority	Do not push back treatment	as a percentage of the active file*
To be arbitrated	Treatment can be pushed back	as a percentage of the active file*
Non-priority	Push back the treatments	as a percentage of the active file*

** The percentage is to be defined for each centre according to its patient list and its organisation.*

PROSPECTIVE RISK ANALYSIS

In what situations do you carry out a prospective risk analysis?

Anticipating potential risks is particularly crucial when implementing organisational changes or new techniques. Prospective risk analysis is also useful in situations whith few events to address in the experience feedback committee meetings, such as interruptions in the treatment process.

How do you choose the method?

The best prospective risk analysis method is the one that well-mastered and suitable for the analysis needs. The time required to become operational when implementing a new method must not be ignored.

Both the FMECA analysis method, conventionally used in radiotherapy, and the EPECT approach, derived from social sciences and the humanities, can be used independently or complementarily.

Take the time necessary for the analysise

Whatever the method, risk analysis is a lengthy process that required dedicated time, spread over several meetings and involving multiple actors. It involves an in-depth examination of risks, stepping back to take a detached look at the practices and the organisation to finally enhance patient care through continuous improvement of healthcare processes. Operational quality managers must ensure that the discussions are brought to a conclusion and the results are documented as required by regulations (ASN Resolution 2021-DC-0708).

Integrate risk management in the management policy

Prospective risk analyses should be shared among field actors, managers, those responsible for nuclear activity and senior management.

This fosters a bottom-up and top-down information communication dynamic, ensuring collective approach to treatment quality and safety.

Further reading

EPECT METHOD

- **Description of a new prospective risk analysis method: EPECT,** IRSN, to be published in 2023.
- **Analysis of risks in radiotherapy.** S. Thellier, Radioprotection (Radiation protection), volume 54, No. 1 of January-March 2019, p11 to 30.

FMECA METHOD

- ASN Guide No. 4 Guide **to risk self-assessment in external beam radiotherapy,** January 2009.
- **Failure Modes and Effects Analysis (FMEA),** sheet 26, p171-173 of the HAS guide "*Managing the risks associated with treatments in healthcare centres: from concepts to practice*", March 2012.

QUALITY MANAGEMENT

- **General guidelines on risk management in external beam radiotherapy,** Radiation protection No. 181, European Commission with the ACCIRAD consortium, 2015.
- **Using quality improvement methods to improve healthcare,** module 7, p176-191 of the patient safety teaching guide, World Health Organisation, 2015.

TREATMENT INTERRUPTION AND RESUMPTION

- **Effective use of Timeout.** SAFRON updates experience feedback sheet, IAEA, March 2021.

PATIENT SAFETY

MARCH 2011 - PATIENT IDENTIFICATION

NOVEMBER 2011 - THE FIRST VERIFICATION SESSION

JULY 2012 - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

APRIL 2013 - WHAT EVENTS MUST BE NOTIFIED TO ASN?

DÉCEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MACH 2015 - RECORD AND VERIFY: RECORDING ERROR!

JUNE 2015 - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

MAY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

JANUARY 2017 - DOSE PROTRACTION / FRACTIONATION

SEPTEMBER 2017 - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

JUNE 2018 - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION ERROR

MARCH 2019 - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

JULY 2019 - IMPROVING THE USE OF CT SCANNER FUNCTIONS

MARCH 2020 - SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE

SEPTEMBER 2021 - IONISING RADIATION: LIMITING THE EXPOSURE OF WOMEN UNAWARE OF THEIR PREGNANCY

OCTOBER 2021 - PATIENT FOLLOW-UP FURTHER TO RADIOTHERAPY INCIDENTS - REVIEW OF 10 YEARS OF USE OF THE ASN-SFRO SCALE

MAY 2023 - MASTERING MEDICAL DEVICES IN FLUOROSCOPY-GUIDED INTERVENTIONAL PRACTICES: A COLLABORATIVE EFFORT

AUTORITÉ DE SÛRETÉ NUCLÉAIRE