EBreast II

Accidents and incidents in radiotherapy

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Content

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① Introduction

- In radiotherapy patients are intentionally exposed to radiation.
  - The aim is to deliver a dose that is adequate for tumour control, but which also minimizes complications and side effcts in normal tissues.
  - The medical therapeutic application of ionising radiation is irreversible, radiation doses are high and a deviation from the prescribed dose may have severe consequences to the patient.
- There is a high expectation of safety in radiotherapy and the aim should be to reduce risks.

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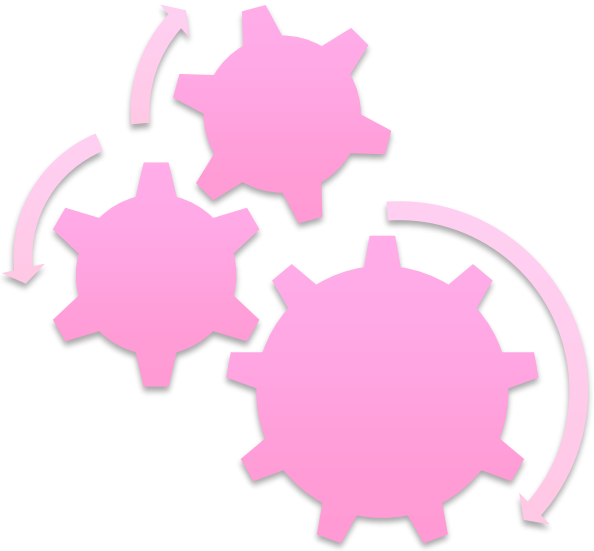
① Introduction

- Radiotherapy is a quite safe area in medicine, and the errors are rare.
- When errors do occur, the consequences can be significant to the patient.
- Errors need to be addressed promptly and appropriately to try to avoid future repetition and to try to diminish the expected effects.
- A variety of techniques and tools can be used to decrease occurrence of incidents and accidents. (1.)

① Introduction



- Radiotherapy community has increasingly adapted strategies and techniques from other industries like airlines, nuclear power, manufacturing, and engineering.
  - Incident learning system, process mapping, failure modes and effects analysis, and fault-tree analysis are some of the examples of such methodologies. (2.)

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① Introduction

- International safety guidelines have been developed and are regularly updated to deal with radiotherapy risks.
- The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) state that the regulatory authority should require all parties to develop a safety culture that includes measures to encourage a questioning and learning attitude and discourage complacency with respect to safety.
- European regulatory framework is consistent with the international BSS and provides a firm basis for management of accidental and unintended medical exposure.
- The reporting and learning of events is amply covered in both the international standards and the European requirements and. (1.)

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② Key concepts

- To avoid misunderstandings, it is recommended that the terminology used in radiotherapy errors be limited to certain key terms. All these terms are 'non-conformance' in the parlance of radiotherapy quality systems. [3.]

Radiotherapy error = *A non-conformance where the radiotherapy process followed or the radiotherapy treatment delivered deviates unintentionally from the planned protocol. For example, following the wrong radiotherapy plan is also a radiotherapy error and may lead to a radiation accident. However, not all radiotherapy errors lead to radiation incidents because the error is detected in time before the patient is treated, or because the error does not affect the delivery of treatment. [3.]*

Accident = *Any event related to controlled departments, controlled equipment and controlled materials that results or may result in radiation exposure that could cause personal injury, damage or harm to any person or the environment. This includes incidents involving or resulting from either intentional or negligent acts or omissions. [4.]*

Incident = *Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other accidents, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible in terms of safety or protection. [4.]*

Near miss = *Any radiation incident that was detected and successfully prevented before treatment was given. However, mistakes in plans, calculations, etc. are not near misses if they were detected and corrected as part of the inspection procedures prior to the start of treatment. [3.]*

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③ Potential accidents in radiotherapy

- Radiotherapy is a very complex process, involving many different steps and many different people in the planning and delivery of treatment. This complexity leads to many opportunities for mistakes. Major incidents are rare, but their consequences can be very serious. [3.]

- Major disasters almost always develop over a longer period of time and involve many broader elements. For example, a change in the radiotherapy planning system without a corresponding change in other procedures may lead to a sudden error when several events occur months later. [3.]

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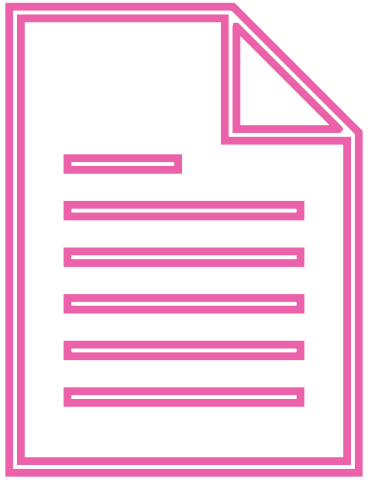
③ Potential accidents in radiotherapy



- A systematic international review of radiotherapy-related events that happened during 1976-2007 identified a total of 7741 incidents and near-misses.
  - 3125 incidents of these resulted in patient harm.
- The harms ranged from underdosing tumor, thus increasing the risk of recurrence, to overdosing, causing unacceptable toxicities.
- Thirty-eight deaths were also reported. (5.)

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③ Potential accidents in radiotherapy

- According to WHO 55% of the incidents occur in the planning stage, and the remaining 45% were due to errors that occurred during the introduction of new systems and/or equipment (25%), errors in treatment delivery (10%), information transfer (9%) or in multiple stages (1%) (6).
- Radiation treatment incidents are mostly related to human error (6).
- Accidents and errors do not only affect patients directly but might also undermine the public's confidence in the treatment.

ERROR

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③ Potential accidents in radiotherapy

WHO has identified and listed radiotherapy risks by stage in the radiotherapy process in following sections:

1) Assessment of patient
2) Decision to treat
3) Prescribing treatment protocol
4) Positioning and immobilization
5) Simulation, imaging and volume determination
6) Planning
7) Treatment information transfer
8) Patient setup
9) Treatment delivery
10) Treatment verification and monitoring (6).

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③ Potential accidents in radiotherapy

1) Assessment of patient
   - The major risks in the assessment stage are misidentification of the patient, and misdiagnosis leading to the incorrect treatment advice being given to the patient.
   - These risks are considered to be high-risk, resulting in the patient receiving incorrect management.
   - These risks may be prevented with solutions such as check-lists and patient identifiers. (6.)

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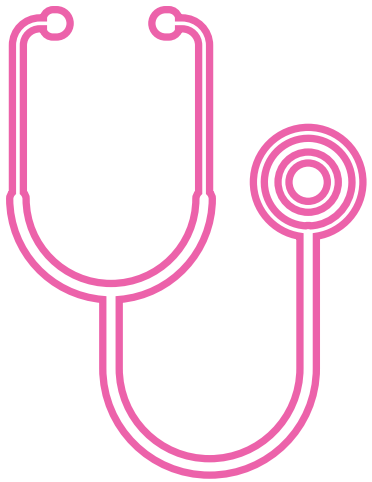
③ Potential accidents in radiotherapy



2) Decision to treat
   - Errors at early stage of the radiotherapy process will be magnified through the treatment process.
   - For example, wrong diagnosis or the use of the incorrect treatment protocol would have a major effect on treatment and outcome.
   - Standardized protocols and checklists as well as peer reviews have been shown to result in a major quality improvements. (6.)

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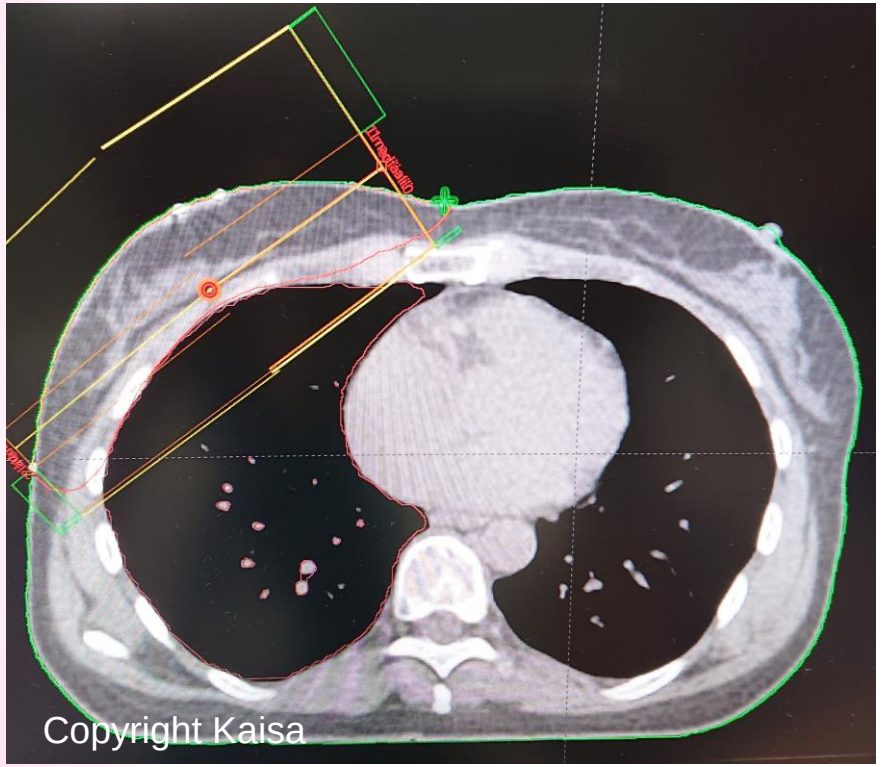
③ Potential accidents in radiotherapy



3) Prescribing treatment protocol
   - Errors determining the dose that is delivered, and the fractionation treatment schedule may reduce tumor control and or increase the complication rate. Small deviations may result in major biological effects.
   - Standard protocols such as comprehensive treatment prescription forms may reduce the risks of inappropriate prescriptions being delivered. (6.)

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③ Potential accidents in radiotherapy

4) Positioning and immobilization

- Incorrect positioning or poor immobilization will result in the tumor not receiving the intended dose, resulting in a greater risk of recurrence or in sensitive normal tissues being treated beyond tolerance.
- Patients need to be able to comply with the requirements of positioning.
- Risks could be reduced by careful positioning and planning protocol checklists. (6.)

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③ Potential accidents in radiotherapy

5) Simulation, imaging and volume determination
   - Random errors, such as defining the wrong volume, and systematic errors such as misalignment of lasers used in positioning may occur.
   - Errors are likely to have a high impact, because subsequent treatment stages are intended to reproduce the setup determined at simulation.
   - Planning protocol checklists, equipment quality assurance and competency programmes may reduce errors. (6.)

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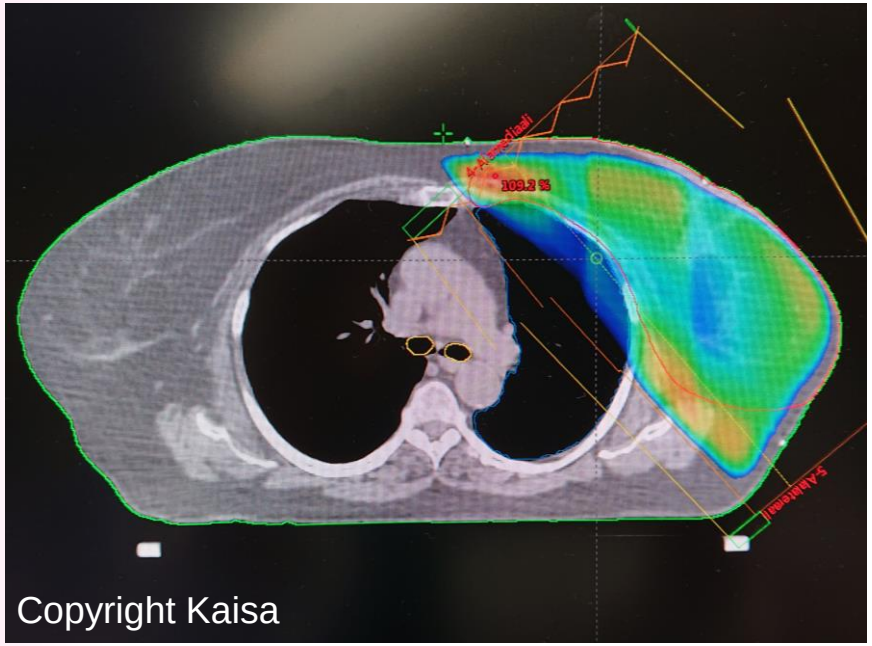
③ Potential accidents in radiotherapy



6) Planning
   - Errors can arise when using the treatment planning software.
   - For example, errors may occur due to incorrect inputs into individual plans.
   - Some solutions to reduce planning risks are quality assurance, planning protocols, competency certifications, and checklists. (6.)

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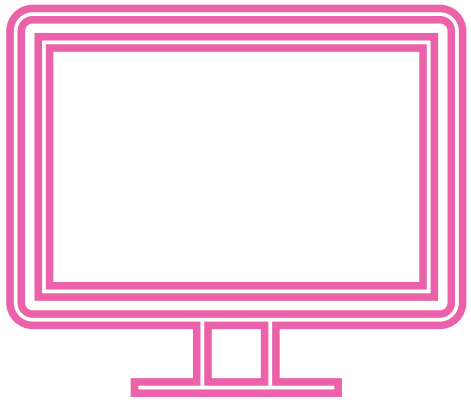
③ Potential accidents in radiotherapy



7) Treatment information transfer
   - Random and systematic errors may occur when transferring of information from the plan to the treatment machine.
   - For example, software from different vendors may not interface correctly or manual data entry is incorrect.
   - Clear documentation and protocols, checklists and verifying systems can be used to prevent the risks. (6.)

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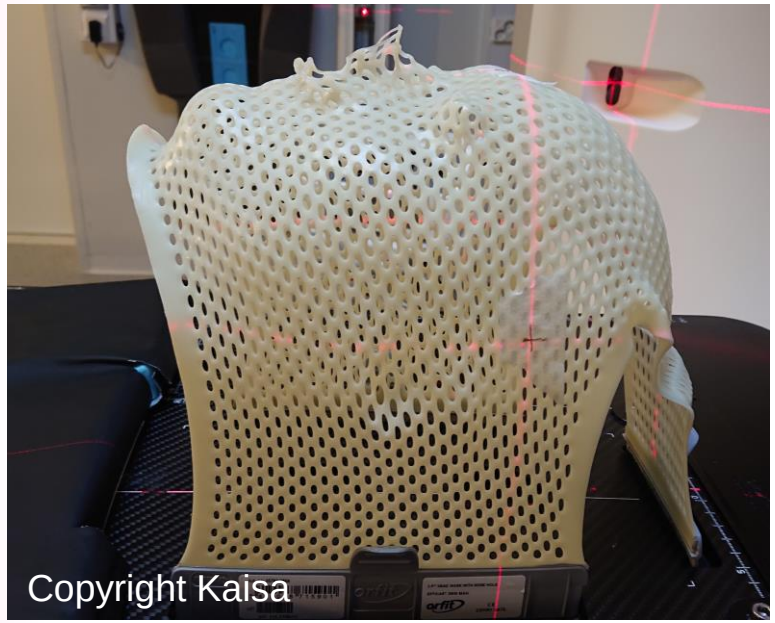
③ Potential accidents in radiotherapy



8) Patient setup
   - Daily setup accuracy for treatment is crucial to ensure that the patient is in the correct position.
   - Patient position may be affected by changes in their medical status, the patient may move during treatment, and organ movement may also occur during treatment. Setup errors can also occur.
   - It is widespread practice to employ a minimum of two RTs at each patient setup to reduce the setup errors.
   - Machine protocol checks, treatment protocols and visual monitoring of the patient can also reduce the risks. (6.)

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③ Potential accidents in radiotherapy

9) Treatment delivery

- The major risk in treatment delivery is incorrect beam output due to incorrect calibration of the beam at commissioning or at a later date, or the generation of incorrect data used to calculate treatment time or monitor units.
- Solutions such as machine protocol checks, in vivo dosimetry, and competency certification are used to reduce the risks. (6.)

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③ Potential accidents in radiotherapy

10) Treatment verification and monitoring

- Radiotherapy treatment is monitored by portal imaging. Portal imaging detects positioning errors and confirms the site of treatment delivery. However, there can be misinterpretation of portal imaging that may result in the patient's position being incorrectly adjusted.
- Competency certification and a protocol for error tolerances are required to reduce the risks of misinterpretation of portal imaging. Clear guidelines for the routine use and interpretation of portal imaging can also reduce the risk of error. (6.)

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④ What to do in case of an error?

- Different countries may have different practices on what to do in case of errors
- All radiotherapy departments should have clear guidelines in their quality system on error management, and actions to be taken when errors occur
- However, the main idea is the same everywhere; to avoid further damage and to find out what caused the error → report the incident to the relevant authority

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④ What to do in case of an error?

In the case of an abnormal situation involving a patient

→ When you become aware of the situation, prevent or minimise further injury to the patient

→ Take stock of the situation and request additional assistance if necessary

→ Inform other staff of what has happened and report the incident to them in accordance with the unit's guidelines

- In the case of a significant error relating to the patient and their care, it is important that the patient is kept informed throughout the process. [3.]

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④ What to do in case of an error?

When the situation is over;

→ Assess the significance of any dose deviation before continuing to treat the patient

→ If necessary, assess whether remedial action can be taken taking into account the radiobiological consequences

→ Investigate whether other patients under treatment may be similarly affected

→ Once the defect has been cleared, prevent or minimise harm to other patients receiving similar treatment

- It should also be noted that some errors may require a retrospective review of previously treated patients to determine whether a similar event occurred and was simply missed. [3.]

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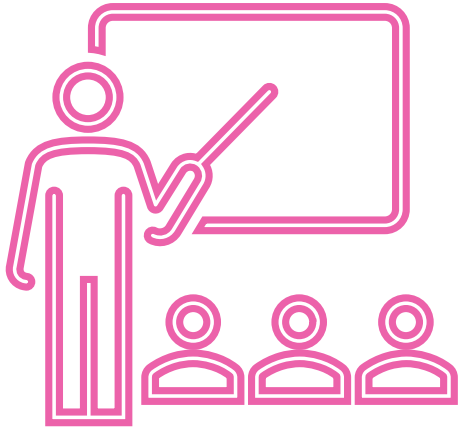
⑤ Contributory factors



Lack of training, competence or experience

Education and experience alone will not protect an individual from making mistakes. However, one of the benefits of experience is the ability to recognise your own and your colleagues' mistakes and fix them, before they lead to a adverse event. [3.]

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⑤ Contributory factors

Fatigue and stress

Stress and fatigue affect all of us, whether we are experienced or inexperienced staff, and can be caused by many factors in our professional and personal lives. Staff suffering from stress and fatigue can be less effective, so it is important that healthcare organisations consider strategies to reduce these negative effects in the workplace. It is worth noting that while it may seem that a less experienced person is more likely to make mistakes, a more experienced person may be more prone to errors due to work stress and distractions because they have more responsibilities. [3.]

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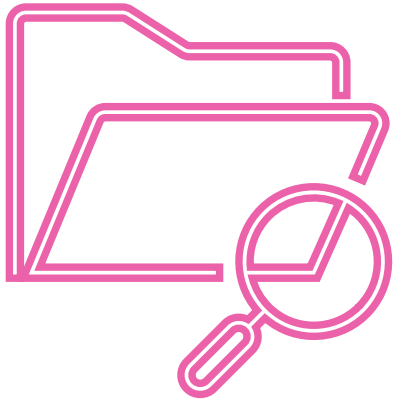
⑤ Contributory factors



Poor design and documentations of procedures

The more complex the process, the more opportunities there are for errors. If instructions and steps are not clearly documented, staff may be unclear about the correct sequence, and the likelihood of errors increases, especially for infrequently performed procedures. There are major challenges in documenting procedures, particularly in striking a balance between simplicity and completeness. As a general rule, the more difficult a process is to perform, the greater the need for clear instructions and the more difficult it is to document them. [3.]

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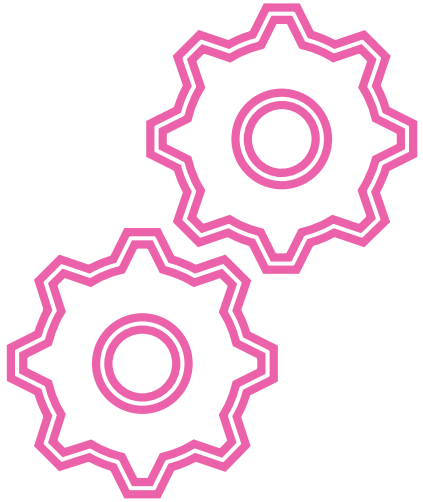
⑤ Contributory factors



Over-reliance on automated procedures

It is important to be aware that automated systems can also go wrong, especially in complex circumstances that the programmer cannot foresee or for which the programmed system may be unsuitable. In the absence of experience, it can be difficult to recognise that an error has occurred because the system has previously been proven to be reliable and safe. Over-reliance on such technology will undermine the expertise of individuals if they no longer need to use their skills on a regular basis. [3.]

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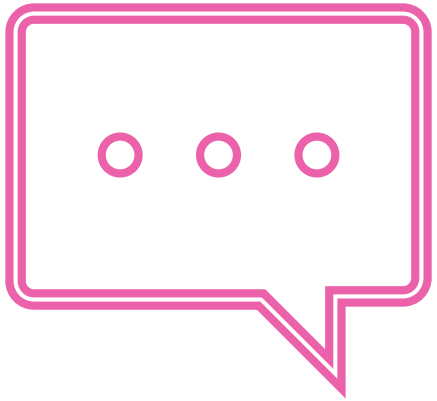
⑤ Contributory factors



Poor communication and lack of teamworking

This is one of the most common causes of error, and incorrect assumptions and misunderstandings have often been implicated in radiotherapy incidents.

Poor communication is more likely if staff roles and responsibilities are not clearly defined. Units that maintain strict professional boundaries rather than promoting multidisciplinary working are more likely to experience interprofessional communication problems. [3.]

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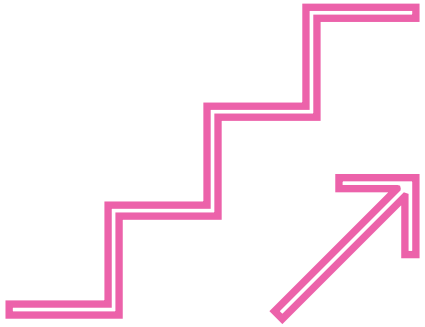
⑤ Contributory factors



Hierarchical departmental structure

The hierarchical structure in health care has historically made junior members of the work community reluctant to challenge senior staff. Hierarchical structures make it more difficult to point out non-compliance with protocol. [3.]

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⑤ Contributory factors

Staffing and skills levels

In order to meet the service requirements, there must be sufficient resources and staff with the right skills and experience to carry out a given amount of work. Staff must be given time to carry out the necessary tasks without undue pressure.

Inadequate support services may also compromise safety if staff are diverted from their clinical duties to routine administrative tasks. [3.]

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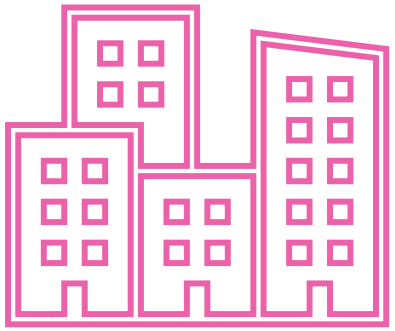
⑤ Contributory factors



Working environment

Errors can be caused by things like poor equipment design, poor room layout, or the physical characteristics of the workplace, such as excessive heat or cold. [3.]

Staff cannot provide a safe and efficient service with poorly designed, poorly maintained or outdated equipment. Management support and active involvement is critical to maintaining and sustaining a safe service. [3.]

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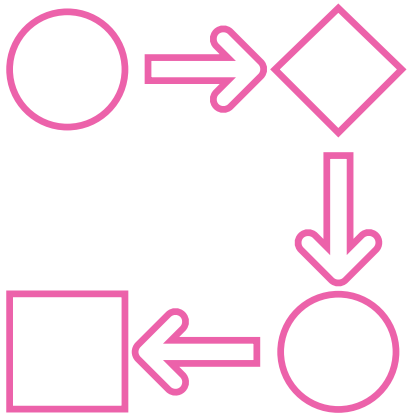
⑤ Contributory factors



Changes in process

Any change can have unexpected consequences many steps down in a complex process. This is particularly the case with the introduction of new technologies, such as new computerised design systems. [3.]

One of the effects of the introduction of new processes and equipment may be that inspection and verification procedures previously considered necessary become unnecessary. This issue should be taken into account when introducing change, as the continuation of an unnecessary step can potentially be detrimental as it may distract from other critical necessary procedures. [3.]

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⑥ Prevention

- Accurate and careful work is the basis of everything:

Good and functional Quality Assurance system [7.]

Relevant emergency equipment [7.]

Professional training of staff

- Specific training in the use of the machine, including not only radiation equipment but also treatment planning systems.
- Training to detect and deal with unusual events and situations.
- Re-assessment of staffing and training needs as patient numbers increase, and whenever new equipment or technology is introduced. [7.]

Careful observation of patients during the treatment period

- A significant reduction in the number of side effects may indicate underdosing
- An increased number of adverse reactions may indicate an overdose and that late effects are also expected to be higher.
- Experienced radiation oncologists can distinguish dose differences of up to 7-8% (with careful weekly follow-up of the patient). [7.]

Documentation/communication

- Communication procedures for safety-critical issues
- Recording and reporting of treatments according to protocols
- Rapid reporting of unexpected machine behaviour
- Prompt reporting of unexpected reactions of the patient or of a series of patients [7.]

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⑦Reporting and learning system

- The International Safety Standards (IAEA, 2002) requires that any error, mishap, or unusual occurrence with the potential to cause patient exposure that differs from the one intended should be investigated and that procedures should be developed for learning from events (1).

"Why did this error occur and what can we do to prevent it from occurring again?"

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⑦Reporting and learning system

- Reporting and learning system is pivotal for improving patient safety and for learning from radiotherapy errors.
- Aim is to prevent upcoming errors to happen.
- In order to learn from the errors and prevent them occurring again it is important to understand the processes leading to them.
- Monitoring of errors also enables the organization to measure the improvements. (1.)

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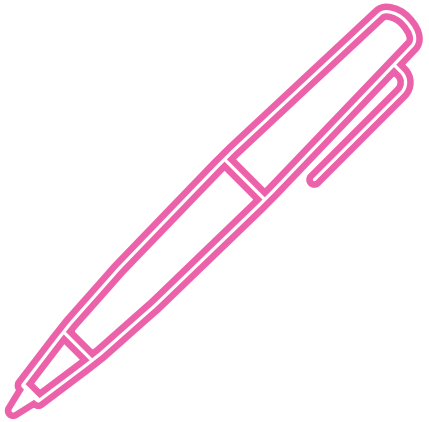
⑦Reporting and learning system



- Reporting errors helps to:
  - Reduce risks for all patients by not waiting for harm to occur
  - Provide information on the weak spots in the safety system
  - Alert other providers to possible vulnerabilities and gaps in training
  - Contribute to prioritizing safety improvement plans in radiotherapy
  - Evaluate the effectiveness of the safety system in reducing and mitigating errors that reach the patient (8).

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⑦ Reporting and learning system

- Keeping track of failures is also useful to:
  - Establish statistics for benchmarking
  - Identify hazardous procedures
  - Assess if corrective actions are effective
  - Provide feedback (9).

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⑦Reporting and learning system

- Some examples of reportable events in radiotherapy:
  - Misdiagnoses or misinterpretation of the diagnosis that results in patient injury or a wrong treatment choice
  - Misidentification of the patient, wrong site or wrong delineation of planning target volume or organ at risk
  - Wrong technique, treatment or dose prescription
  - Treatment equipment malfunction, failure in the calculations of the treatment planning system, error in the radiotherapy information system or in the transfer of data
  - Wrong acceptance or commissioning of the equipment involved in the radiotherapy treatment chain
  - Wrong acceptance of the plan
  - Wrong positioning of the patient
  - Procedure not performed as in the approved plan of treatment
  - Lack of adequate follow-up
  - Error in the communication between professionals (1).

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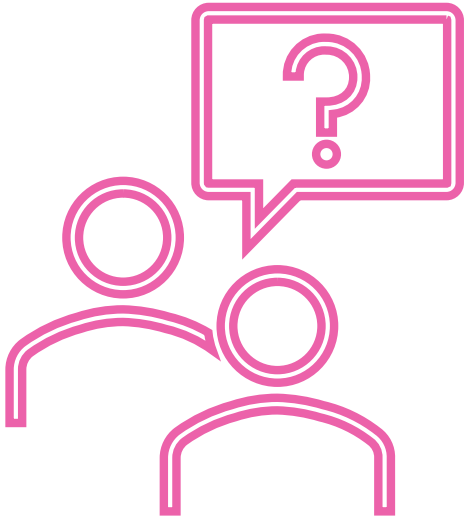
⑦ Reporting and learning system



The reports and analysis of the reports must be systematic and detailed to ascertain what can be learnt:

- What happened?
- Where did it happen?
- When did it happen?
- How did it happen?
- How was the error discovered?
- What were the main and underlying causes that contributed to the event happening?
- Professionals involved
- The impact (or potential impact) of the event to the patient
- What can we learn from what happened?
- What needs to change? (1.)

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⑦Reporting and learning system

- There are distinctive features or options of the reporting and learning systems in radiotherapy:

Mandatory event reporting systems
Reporting of certain events is required (e.g. reporting to regulatory authorities).

Voluntary event reporting systems
Reporting is encouraged (e.g. reporting to international organization).

Internal event reporting systems
Reporting inside organization (e.g. local incident reports).

External event reporting systems
Reporting outside organization (e.g. sharing with peers). (10.)

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⑦Reporting and learning system

Mandatory event reporting systems

- Focus on serious errors resulting in serious consequences such as injury or death.
- Ensure providers of medical care are held accountable to the public.
- Require reporting of information in a standardized format to a national database.
- Provide public with certain level of protection by assuring that most-serious errors are reported and investigated, and action is taken.
- Provide an incentive to hospitals to improve and invest in patient safety, helping to assure that hospitals offer comparable care.
- In some countries, it is mandatory to report radiotherapy incidents to a regulatory authority. In other countries radiotherapy incidents are reported to another regulatory authority. Some countries stipulate that local recording of incidents is mandatory. Potential incidents are covered in some countries. (10.)

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⑦Reporting and learning system

Voluntary event reporting systems

- Focus on errors that result in little or no harm to patients.
- Encourage hospitals to focus on improvement of safety environment.
- Should have mechanisms to ensure that information and lessons learned can be shared effectively.
- Should have mechanisms that allow for anonymous reporting of errors and allow handling in confidence. (10.)

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⑦Reporting and learning system

Internal event reporting systems

- Are spesific in relation to intra-organization procedures, equipment, and characteristics.
- “Lessons to learn” become more direct and explicit
- Follows up management of actual patients affected by the incidents. (10.)

External event reporting systems

- A general culture of safety awareness can be created by making information available on details of incidents, near-incidents and corrective actions.
- An incident in another hospital can lead to identification of the hazard before a similar incident is realized in another hospital. (10.)

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⑦Reporting and learning system

- Today's event report forms vary in content and structure and from organization to organization.
- Web-based reporting systems are now the norm although traditional reporting and learning systems still exists.
- Severity of consequences is used as the main classification criterion in many reporting and learning systems. The main reason is that when there are limited resources it is important to direct them to prevent and avoid those events with major effects. (1.)

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⑦Reporting and learning system

- There are few global resources available in which radiotherapy errors can be reported:
  - The Radiotherapy Incident Reporting and Learning System from the Center for Assessment of Radiological Sciences (http://www.cars-pso.org)
  - Radiation Oncology Safety Information System (ROSIS) (http://www.rosis.info)
  - Radiation Oncology Incident Learning System (RO-ILS) (http://www.astro.org/roils)
  - International Atomic Energy Agency's Safety in Radiation Oncology (SAFRON) (https://rpop.iaea.org/SAFRON)

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⑧ Conclusion

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- Radiotherapy is a highly complex process that requires the input of many different professionals in the planning and delivery of the treatment.
- Errors in radiotherapy are rare, but when they do occus the consequences can be significant to the patient.
- Safety-concious culture is important and radiation safety is the responsibility of all staff.
- Quality assurance system plays an important role in radiation safety.
- Radiotherapy departments must have a system for analyzing and reporting errors.

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