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Updates on Patient Safety in Radiotherapy

December 2018

The Bad Apple Theory

The Bad Apple Theory

"When faced with a human error problem you may be tempted to ask 'Why didn't they watch out better? How could they not have noticed?' You think you can solve your human error problem by telling people to be more careful, by reprimanding the miscreants, by issuing a new rule or procedure. They are all expressions of the 'Bad Apple Theory' where you believe your system is basically safe if it were not for those few unreliable people in it. This old view of human error is increasingly outdated and will lead you nowhere."

Sidney Dekker, Professor,
Griffith University in Brisbane, Australia

The Bad Apple Theory maintains that the complex systems work fine, medical errors occur because of the behaviour of unreliable people, human cause medical errors and dominate as the contributor to errors and that medical errors are a surprise.[1]

By focusing efforts on the human "bad apple" we miss the opportunity for prevention, using the person who made the error as fully responsible is a management short-sightedness for those wishing to provide high quality of care and safe radiotherapy. Not only are staff encouraged not to report errors because they are punished, there is a lack of support for implementing robust safety systems to prevent errors. The culture of safety in these organization can have both negative impact on patient care and staff morale.

What is solved in finding a person to blame?

How errors in radiotherapy are handled is important in improving and maintaining safety and quality.

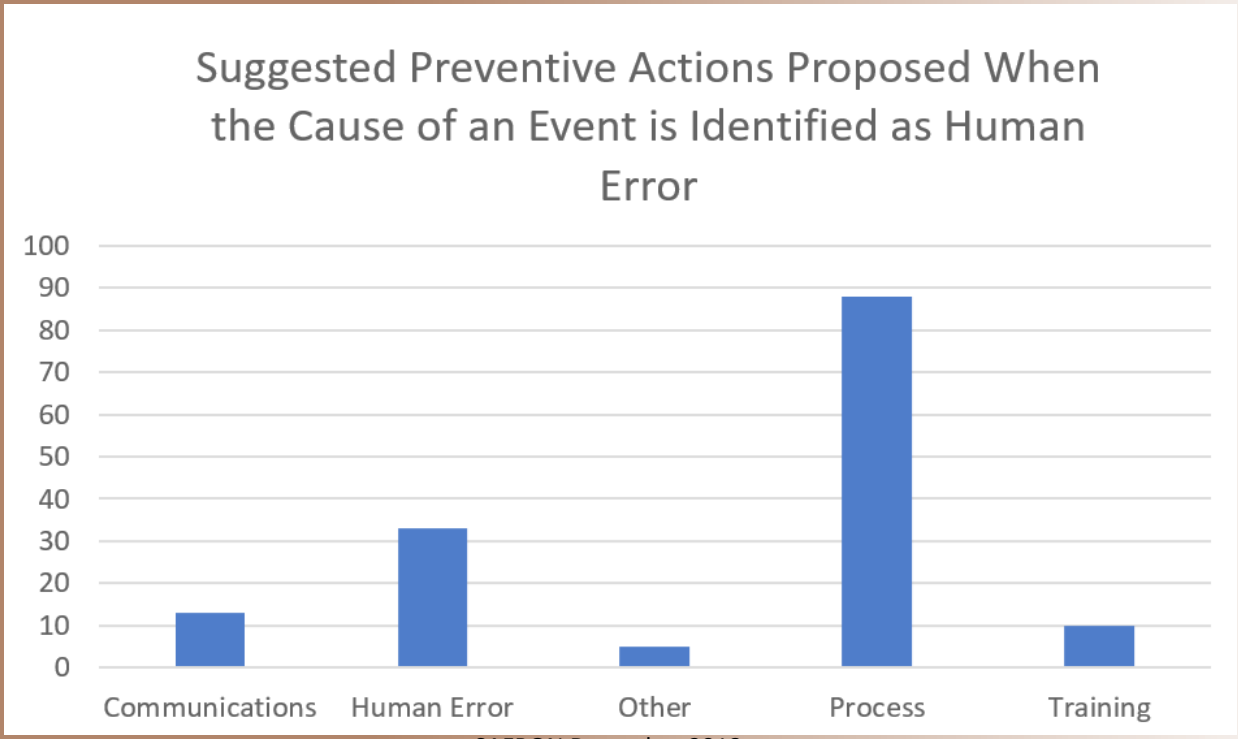
According to leaders in the subject of error prevention, human error is just a label. It is an attribution, something that people say about the presumed cause of something after-the -fact."[2]

In medical event investigations, human error should not be the end but the beginning to ask questions on why or what happened and how it happened. The opportunity to evaluate the event for systematic or process errors is lost and this may lead to a reoccurrence of a similar event.

SAFRON has 174 events that have been attributed to human error, some of these are missed opportunities to evaluate and improve the robustness of safety systems. For 23 of these events there were no suggestive preventive actions, for 151 of these events, even though human error was identified as the cause of the event (33), preventive actions were provided for 118 events, these remaining events can be categorized as improvements in the processes, communication and training. Of the 174, facilities indicated that 54 were human error and no changes were implemented in prevention of errors. For those 54, there is a missed opportunity to improve safety.

When human error is identified as the cause of the event and facilities begin to look for a causation and prevention through improvements in communication, procedures, and training, this is an evolution towards rejecting the bad apple theory.

Human errors are just a step in the process of dealing with a failure and participating in the process to make changes to the process to prevent the failure from happening again. Facilities that acknowledge that errors will happen, will achieve a better understanding of the need to have a safety system in place, improve processes, interjecting safety barriers into the system and support a positive response when an error happens. When we eliminate human error as the cause of the event, we can address the real solutions of improving procedures, rules and monitoring, adding more automation and standardizing practices.[3]



SAFRON December 2018

1. The Field Guide to Human Error Investigations, S. Dekker, Taylor & Francis, 2017.

2. Behind Human Error, D.D. Woods, S. Dekker, R. Cook, L. Johannesen, N. Sarter, CRC Press 2010, accessed 12-03-2018 https://www.researchgate.net/publication/50387403_Behind_Human_Error

3. How could this Happen, edited by J. Hagen, Palgrave Macmillan, 2018.

New IAEA Safety Guide SSG-46: Radiation Protection and Safety in Medical Uses of Ionizing Radiation

This Safety Guide provides recommendations and guidance on fulfilling the requirements of IAEA Safety Standards Series No. GSR Part 3 for ensuring radiation protection and safety of radiation sources in medical uses of ionizing radiation with regard to patients, workers, carers and comforters, volunteers in biomedical research, and the public. It covers radiological procedures in diagnostic radiology (including dentistry), image guided interventional procedures, nuclear medicine, and radiotherapy. Recommendations and guidance are provided on applying a systematic approach to ensure that there is a balance between being able to utilize the benefits from medical uses of ionizing radiation and minimizing the risk of radiation effects to people.

IAEA RPOP Radiation Protection of Patients

Links to IAEA Publication for Radiotherapy Training on Radiation Protection of Patients Website:
https://rpop.iaea.org/RPoP/RPoP/Content/index.htm

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Attention to details → Scheduling

SAFRON has received several reports where scheduling of the patient's treatment contributed to the medical event. New treatment protocols such as SBRT and hyper-fractionation are being introduced and scheduling is no longer "the standard five fractions per week."

Some radiation oncology management systems default to 5 treatments per week. Radiation Oncologists, Medical Physicists and Radiation Therapists need to have a procedure in place where they verify the number of fractions per week and the number of treatments planned for the patient.

Some methods of identifying this include colour coding instructions that are different from the "standard" treatment, verifying the prescription at the time of treatment planning and at the time of first treatment.

With complex radiation oncology management systems, the receptionist may be scheduling the patient's treatments. They too need to verify the number of fractions the patient is to receive each week, recognizing that this is an area where errors can occur is the first step.

"In the successful organization, no detail is too small to escape close attention."
Lou Holtz, University Coach

To help prevent these errors, radiotherapy facilities should consider standardizing the prescription, add verification step to include the number of fractions per week before developing the treatment plan and add the verification of the prescription to include number of fractions each week to the first day of treatment checklist.

Independent verification of treatment plans early in the therapy could also identify the error early in the process. As treatment protocols evolve, the number of fractions per week may be less standard and more patient specific. Publications that might be helpful to further the understanding of how to prevent these errors are provided below:

- Standardizing dose prescriptions: An ASTRO white paper, S B. Evans MD, MPH, B.A. Fraass, P. Berner CMD, FAAMD, K.S. Collins PhD, RT(R)(T), CMD, T. Nurushev PhD , M. J. O'Neill MD, J. Zeng MD, L. B. Marks MD, Practical Radiation Oncology (2016) 6, e369–e381 MPH https://www.practicalradonc.org/article/S1879-8500(16)30157-6/pdf
- Medical Physics Practice Guideline 4.a: Development, implementation, use and maintenance of safety checklists, JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 16, NUMBER 3, 2015, Task Group Authors: L. E. Fong de los Santos, S. Evans, E. C. Ford, J. E. Gaiser, S. E. Hayden, K. E. Huffman, J.L. Johnson, J.G. Mechalakos, R. L. Stern, S. Terezakis, B. R. Thomadsen, P. J. Pronovost, L.A. Fairobent, AAPM Staff, https://aapm.onlinelibrary.wiley.com/doi/epdf/10.1120/jacmp.v16i3.5431
- Reducing errors in radiation therapy through electronic safety checklists, Applied Radiation Oncology, July 2014, J. Greenwalt, MD, K. Mittauer, MS, C. Liu, PhD, R. Deraniyagala, MD, C. G. Morris, MS, and A.R. Yeung, MD, http://cdn.agilitycms.com/applied-radiation-oncology/ARO_07-14_Greenwalt.pdf

SAFRON Events Where the number of fractions and frequency of treatment variation contributed the eventvariation contributed the event

#	Title of the Event	Event Details	Preventive Actions
1.	Transcription error of dose	An old woman with an oesophagus cancer treated by radiation therapy only. The initial prescription was 50Gy but after staff discussion it was proposed 20Gy in 5 sessions 3 times. The prescription was modified on the prescription file but with a mistake i.e. 10Gy/week. When the simulation was realised on the chart the resident transcribed the initial prescription (i.e. 50Gy) and this was modified but only the total dose and not the dose per fraction. In the chart the dose for each beam was correctly reported according to the initial prescription and the dosimetry BUT when the calculation of the MU was done, the total doses for each beam were modified and the doses per fraction were not modified so the patient received 20Gy in 15 days 10 fractions, instead of 20Gy in 5 days 5 fractions. Then the treatment was stopped during 2 weeks before a new series will be done. And the error was seen at this moment and was modified by a senior. (ROSIS 1052175742)	First, clear prescription. Second, check the chart by a senior. Third, all modifications must be identified and if done by a physicist (in this particular case) must be confirmed by the physician in charge of the patient or by a senior.
2.	Prescription in chart differs from the sent treatment plan	Patient should start with 6 new fields. In the treatment chart it is written as if the patient should receive the treatment in two groups, 3 fields a day, each group every other day. But in Visir all fields are in one group (all being treated each day). Dosimetrist confirms that the plan is made so that all fields should be treated every day. I contact physicist and physician who writes this in the chart. Had I not asked, and the patient had got 3 fields a day, only half of the dose had been given. (ROSIS 1120777915)	Don't always assume that treatment is as it always has been.
3.	Bi-daily treatment booked as one fraction per day in booking system and V&R	Treatment with curative intent, 10 fractions/week, 2 fractions/day was prescribed. The personnel at the treatment machine observed (during routine pre-treatment control) that booking of the treatment in the booking system, as well as in the calendar of Mosaiq was done with one fraction per day.	Regular independent chart checks
4.	Frequency delivered for SBRT did not match the prescribed frequency	The physician prescribed 54 Gy over 3 fractions (18Gy/fx) to be delivered once weekly. The patient received 54 Gy over 3 fractions in 7 days. Fraction 1 and 2 were delivered in the same week resulting in a weekly administered dose to the intended site differing from the weekly prescribed dose by > 30%.	There was an immediate Time Out policy change by the facility to include a review of the prescription and previous treatment prior to each treatment delivery by the treatment team.
5.	Patient did not receive 3 fractions of 18Gy each at 3 fractions per week. The third fraction was received almost 3 weeks later.	The patient was prescribed SRS with 3 fractions of 18Gy each, 3 fractions per week. The second fraction was rescheduled and actually performed on the date of the scheduled third fraction. The third fraction was not rescheduled at that time. There was a total time interval of almost 3 weeks between the second and third treatment, resulting in one third of the dose delivered beyond the weekly prescribed dose.	A new electronic monitoring system was implemented to track patients from simulation to completion of treatment. Also, all SRS patients will have the appropriate number of appointment cards placed in the paper chart at the time of initial scheduling. At each dose, the next card will be completed by checking the appointment in the electronic charting system and populating the card for the patient with the appropriate date and time.
6.	Incorrect MU and fractions planned	Incorrect MU and fractions planned	Attention to details, Proper communication and endorsements, No interruption zones. Review of treatment plans before approval and execution, Regular chart checks and time outs
7.	Incorrect no. of fractions (25 instead of 20)	Incorrect no. of fractions (25 instead of 20)	Attention to details and chart review
8.	Patient received incorrect dose for 16 fractions because the dose per fraction and the number of fractions were reversed in the treatment plan and sent to the R&V system.	This 91 year old male patient with a history of recurrent melanoma was undergoing outpatient treatments at the hospital. Treatment covered neck and scalp areas. The following treatment plan was ordered by the Radiation Oncologist - Intensity Modulated Radiation Therapy (IMRT) plan of 6 MV photon to a total dose 5500 cGy in 20 fractions (275 cGy x 20 fractions). Instead of the ordered dose, the patient was receiving 20 cGy each session (20 cGy for 275 fractions was entered into the treatment delivery system from the treatment plan). In vivo dosimetry done during the 3rd fraction showed under dose. This finding did not receive additional review immediately (there was no written Policy and Procedure to address such findings). A repeat dosimetry carried out during the 16th treatment indicated lower dose than expected levels, which triggered additional review of the chart. It was then discovered that the treatment plan dose and fractionation numbers were reversed in the system.	To prevent recurrence: The radiation oncologist's prescription included the total dose and the number of fractions. It was a complex plan and the physicist assisted the dosimetrist in developing the plan, then did the double check (not a totally independent double check). The plan that was uploaded (transposed) was not identified as incorrect by the treatment delivery system as it only checks for the cumulative dose which was correct. The checklist does not include a reconciliation process from the treatment planning system to the treatment delivery system (needed revision) which may have caught the error earlier in the process. It was noted that during the third fraction (dose) a dosimetry reading was done which did not match the prescribed dose. This finding did not trigger immediate review (needed a written Policy and Procedure for such findings of discrepancies) and a repeat dosimetry reading was reading was done on the 16th fraction (dose) which also did not match the prescribed dose (low). Having identified these deficiencies, the facility developed Policy and Procedure to ensure (1) The radiation oncology will verify dose fractionation and total dose dose along with otehr items before approving the plan (2) The therapist checklist was revised to include reconciliation of initial script to what was in the R&V (3) Patient dose verification with dosimetry had new Policy and Procedure to address unexpected findings within 2 days. The facility maintains that standard IMRT QA does not include absolute dose verification because it is difficult to do and they have not made changes to that practice. The state recommended to the facility that the first weekly physics check be done a different physicist, not the one who did the double check. This patient's chart had undergone 3 physician reviews as well as 3 weekly physics check
9.	4/33 fractions delivered over a two-day period (BID) for single fraction per day prescription	The oncologist ordered 33x180 cGy daily treatments. A Rapidarc plan was generated and approved with correct fractionation and daily dose limit. On the morning of 4/15 the patient was mistakenly scheduled for two fractions per day (BID). On the afternoons of 4/15 and 4/16 therapists overrode the daily dose limit and delivered two fractions earlier than expected. This error was caught by nurses and physicians in the afternoon on 4/16.	The primary oncologist has been notified and decided that no corrective action was needed. Fractionation was to be continued at one fraction per day and end when 33 fractions were reached. User rights for therapists will be revised and future overrides of daily dose limits will require a physicist's sign-off.

SAFRON Events Where the number of fractions and frequency of treatment variation contributed the eventvariation contributed the event

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10.	Weekly administered dose differed from the weekly prescribed dose by more than 30 percent	Patient was receiving radiation therapy for melanoma in the supraclavicular areas. The physician wrote the prescription for a 3D radiation therapy plan to deliver 5 fractions of 6 Gy each to the area for a total dose of 30 Gy. The prescription also specified to treat the patient 2 fractions per week. The therapists treating the patient failed to notice the specification of 2 fractions per week and scheduled the patient for daily treatment (7/1/14 to 7/3/14). After the long weekend, the patient was treated again on 7/7/14 when the deviation from the prescribed treatment schedule was noticed. The patients 5th and final treatment was delayed until the following week (7/14/14).	Patient was receiving radiation therapy for melanoma in the supraclavicular areas. The physician wrote the prescription for a 3D radiation therapy plan to deliver 5 fractions of 6 Gy each to the area for a total dose of 30 Gy.The prescription also specified to treat the patient 2 fractions per week. The therapists treating the patient failed to notice the specification of 2 fractions per week and scheduled the patient for daily treatment (7/1/14 to 7/3/14). After the long weekend, the patient was treated again on 7/7/14 when the deviation from the prescribed treatment schedule was noticed. The patients 5th and final treatment was delayed until the following week (7/14/14). "
11.	A patient intended to be treated 2 fractions per week instead received 3 fractions in a single week	The radiation oncologist intended to treat 2 fractions per week, but did not specify this in the prescription document. He did note 2 fractions per week in the radiation oncology record and verify system, ARIA, but neither the dosimetrist nor the physicist who checked the plan noticed the discrepancy between the intended fractions per week and the plan. The therapist scheduling the patient did see the discrepancy and sent a note to the dosimetrist asking for clarification, but the dosimetrist was on vacation and did not receive the note until the following week. In the meanwhile the therapist scheduled a standard fractionation of 5 treatments per week. The patient received 3 fractions in one week, plus a 4th fraction on Monday of the following week. On that Monday the dosimetrist received the note and forwarded it to the radiation oncologist, who received it Tuesday. The radiation oncologist realized the patient had not been treated according to his intent and cancelled the final fraction on Tuesday, rescheduling it for Friday.	Change the required information in Epic to include the fractions per week. Therapist will not treat if there are questions or lack of information in the record and verify system. If there is a discrepancy then the therapist will not treat.
12.	Mistake on the protraction (number of days between 2 fractions) for a treatment of axillary nodes	The radiation oncologist discovered that an error has been done on the protraction (at the time the appointments were planned). The prescribed treatment planned to deliver the total dose in 9 fractions of 5 Gy each, 3 fractions per week. But the patient received 8 fractions, 5 fractions per week (ie each day with no interruption) until the radiation oncologist discovers the mistake during a medical consultation of the patient. The estimated 2Gy equivalent dose received by the irradiated area is 66 Gy instead of 42 Gy initially prescribed. However, the OARs of this area (lungs, heart, spinal cord) received doses below the recommended dose constraints.	1. The R&V should be modified in order to be able to manage the treatment duration (protraction). The number of days between 2 fractions should stops the treatment if not correct. 2. The name of the treatment plans are now modified to have an information on the number of fractions "x / week" if the number of fractions per week is different from 5.
13.	Patient received treatment on the wrong day	A patient should receive two fractions in the cobalt unit on alternate days, but he was treated on consecutive days. (ROSIS 1084748839)	More explicit information concerning treatment schedule in the prescription form.

Another resource to improve safety and quality in radiotherapy

i.treatsafely.org provides free access to high quality, practical training videos that show step-by-step instruction for performing common clinical tasks. These educational videos range from contouring and treatment planning to device QA and the clinical implementation of quality and safety tools. Because the videos are created by radiation medicine professionals, you get real clinical information from people who actually practice in the clinic.

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