Incident description

A patient diagnosed with endometrial carcinoma underwent hysterectomy followed by adjuvant chemotherapy and external radiotherapy with a total dose of 50 Gy. It was decided that the patient should additionally receive 2 fractions of vaginal brachytherapy of 7 Gy each.

Within the RT-department, 2 templates exist for this type of vaginal brachytherapy, one with a dose prescription of 3 x 7 Gy and another with 2 x 5 Gy. Given the patient's history, it was decided to deviate from the standard template by adjusting the template from 2 x 5 Gy to 2 x 7 Gy.

Before each fraction of vaginal brachytherapy, a CT-scan is taken to verify that the applicator is inserted correctly. For the 1st fraction of vaginal brachytherapy, a standard plan is used without contouring of the OAR's and the target volume(s). In this way, the patient can be treated faster. If necessary, the dose of the second fraction can be adjusted to achieve an individualized treatment in an adaptive manner.

According to the standard operating procedure implemented in the department, the adaptive treatment plan is made on the images of the CT taken before the 1st brachytherapy fraction. This way, one has enough time to calculate the adaptive plan, since the second CT is only taken just before the second fraction and thus only used for applicator verification.

After the 1st fraction with a standard plan was administered to the patient, the radiation oncologist contoured on the 1st CT and the physicist calculated the dose distribution. The radiation oncologist then evaluated the dose distribution and noticed that the total dose of the two fractions of 7 Gy together could exceed the rectum constraint. Therefore it was decided in consultation between the radiation oncologist and a medical physicist to provide an adapted plan to lower the dose on the rectum for the second fraction.

The standard operating procedure for adaptation is as follows:

Flow of standard procedure
Take 1st CT
Verify applicator positioning on 1st CT
Treat patient with standard plan: standard dose and standard positioning
Contour on 1st CT
Plan on 1st CT
Evaluate dose distribution on 1st CT
Decide if adapted plan is necessary
If necessary, create an adapted plan for the 2nd fraction on the 1st CT
Supervision of the adapted plan on the 1st CT
Take 2nd CT
Verify applicator positioning on 2nd CT
Treat patient with adapted plan

The rectum, with a volume of 111.4 cc, was very full at the time of the 1st CT and the 1st brachy fraction. As a result, the radiation dose for the second fraction would have to be very low to spare the rectum, making it difficult to deliver sufficient dose to the target. Consequently, in consultation between the radiation oncologist and the medical physicist, it was decided to deviate from the standard operating procedure and to use the 2nd CT instead of the 1st CT to optimize the dose. The patient could have bowel preparation before the 2nd CT to obtain a less filled rectum. And indeed, the rectum volume on the 2nd CT was only 32.0 cc.

This results in the following flow:

Flow of deviated procedure
Take 1st CT
Verify applicator positioning on 1st CT
Treat patient with standard plan: Standard dose and standard positioning
Contour on 1st CT
Plan on 1st CT
Evaluate dose distribution on 1st CT
Decide if adapted plan is necessary
Take 2nd CT
Verify applicator positioning on 2nd CT
Contour on 2nd CT
Create an adapted plan for the 2nd fraction on the 2nd CT
Supervision on the adapted plan on the 2nd CT
Treat patient with adapted plan

This flow could also work, but due to a series of events it failed at the last steps.

The physicist knows that the 2nd fraction will be planned on a new CT and therefore he cancels the supervision of the plan on the first CT as this will not be adapted and delivered. In doing so he decides to not set that plan to the "completed early" status, as he is aware that it will not be delivered. Instead, he focuses on the organisation of the treatment planning on the 2nd CT. To this end, he adapts the CarePath with new tasks and sequences. In this process, however, he forgets to book another "supervising physics" task for the plan that will be made on the second CT. As a result there is no supervision task anywhere, which means that no one will verify the plan that will be made.

On the day the patient is to be treated with her second brachytherapy fraction, she's delayed due to problems at the company responsible for her transport. Therefore, the physicist in charge of calculating the treatment plan ran out of time and had to hand over the task to a colleague. This happened to be the colleague who had made the 1st standard treatment plan. A new plan is created as usual, using the normal templates and naming convention. But because the new plan is created on a different CT, the plan is created in a different treatment course. Normally the software does not allow plans in the same course to have the same name, but because the software does not look in different treatment courses, the new plan is given the exact same name as the old plan. Since the previous physicist "completed" the standard plan, the new physicist does not check it. Therefore, it goes unnoticed that the standard plan is still available for treatment. There is no additional supervision by another physicist either because no task is scheduled for it in CarePath. So there's no second pair of eyes that can detect that the old and new treatment plan have the exact same name and are both open for treatment.

Thus, at the time the patient is to be irradiated, there are 2 plans available at the treatment console, the standard treatment plan and the adapted treatment plan. Both have the same name and execution date, have been planned by the same physicist due to circumstances, have the same parameters such as channel length, are both on "planning approved" etc. The physicist at the console is now looking for a way to distinguish the plans. When choosing the plan, the physicist decides to choose the one that has the most recent time displayed, because the physicist assumed that this reflected the most recent plan. This was the wrong plan to select.

This causes the flow to end like this:

Flow of the incident
Take 1st CT
Verify applicator positioning on 1st CT
Treat patient with standard plan: Standard dose and standard positioning
Contour on 1st CT
Plan on 1st CT
Evaluate dose distribution on 1st CT
Decide if adapted plan is necessary
Take 2nd CT
Verify applicator positioning on 2nd CT
Contour on 2nd CT
Create an adapted plan for the 2nd fraction on the 2nd CT
~~Supervision on the adapted plan for the 2nd fraction on the 2nd CT~~
Treat patient with standard plan: standard dose and standard positioning

Discovery:

As the physicist had forgotten to calculate the biologically equivalent dose and would do so after the weekend, he opened the plan on Monday and saw that 2 fractions had been given with the standard plan. That is strange, because he expected 1 fraction with the standard plan and 1 fraction with the adapted plan. The physicist checked the "treatment report" of the treatment administered and found that the standard instead of the adaptive plan had been selected to treat the patient during the 2nd fraction. This was confirmed because on the treatment report, the dwell time of the source was the original 307 seconds, instead of 240 seconds in the adaptive plan.

As a result, the full 7 Gy was given instead of the prescribed lower dose for the second fraction, which corresponds to an overdose of 27% for this fraction at the normalisation point. Looking at the total vaginal brachytherapy treatment, the absorbed dose was 14 Gy instead of 12,5 Gy, which corresponds to an overdose of 12%. As a result, EqD2 of the full treatment (external radiotherapy + brachytherapy) on the rectum equals 78 Gy where the hard constraint is 75 Gy, thus increasing the risk of rectum complications for this patient.

Root cause analysis

The following root causes have been identified:

Organisational factor: Procedures

The standard operating procedure prescribes to use a standard plan for the first fraction instead of an individualised plan based on the CT and the contouring of the OAR and of the target volume.

Organisational factors: External

- The second fraction cannot be planned on the first CT, since the rectum's filling is too high on that CT and the patient will receive a bowel preparation before the second treatment in order to empty the rectum.
- The second CT is only available just before the delivery of the treatment.
- Due to transport problems, the patient arrives later than planned.
- The physicist who was supposed to calculate the plan of the second fraction, is only available for treatment planning in a certain time frame.

Human factors: Intervention

- The first physicist decides not to set the old plan to "completed early" status, because he knows he will have to create a new plan anyway based on the second CT.
- The first physicist forgets to book a "supervising physics" task in CarePath.
- The second physicist does not give the adaptive plan a customised name as the standard operating procedure dictates.
- The second physicist assumes that the displayed date and time of the treatment plan are related to the last editing of the plan.

Human factor: Verification

- The second physicist assumes that the displayed date and time of the treatment plan are related to the last editing of the plan and does not verify that the correct plan is selected.

Patient related factors:

- The patient's rectum was very full at the time of the first fraction, necessitating a deviation from standard procedures.
- The patient indicates she needs to go to the toilet when the second fraction is to be administered, thus increasing pressure to finish treatment on time.

Corrective actions:

- The importance of following the standard operating procedure was stressed:
  - ✓ The task "Supervision physics" should be scheduled and performed on the first and second fraction.
  - ✓ The name of the plan of the second fraction must be customised so that it is different from the name of the standard plan.

- The Brachytherapy working group will be called together to discuss following suggestions:
  - ✓ Improve the scheduling of the tasks of the physics team: physicists who have brachytherapy tasks often have other tasks as well. This creates errors and forgetfulness.
  - ✓ Revision of the standard operating procedure "vaginal cylinder":
    - ➢ RTT or radiation oncologist look together with the physicist when selecting the treatment plan = four-eye principle: one person calls items and another one checks off
    - ➢ The implementation of a checklist with checks that are feasible to be executed at the treatment console before proceeding to treat:
      - Check dwell times
      - Check correct date and time
      - …