Incident description

A patient is referred to the radiation oncology department for bilateral irradiation of the breast. Dose prescription involves an initial treatment of 15 fractions, followed by a boost irradiation of 5 fractions.

The patient is the first to be irradiated in the department with the bilateral Hybrid VMAT technique (H-VMAT): the large volume of the breasts is irradiated with static fields and the glands are irradiated with VMAT. This allows for better sparing of the organs at risk and increased protection of lungs and heart.

During development of the H-VMAT procedure, it was decided to move away from kV/kV imaging and to opt for CBCT imaging which allows better localisation and matching of the glandular regions. kV/kV imaging is done with the table already in the prescribed treatment position. With CBCT, this is often not possible because it's not always possible to rotate around the patient when the table is in the treatment position, due to the lateral location of the lesions. Therefore, CBCT imaging is taken in a central table position and a delta couch is used. After the CBCT, the table is then moved to the treatment position. Since the images are taken in a central table position, it is not possible to detect incorrect table parameters when matching the CBCT. This leads to a risk of irradiating at the wrong position if the table is not subsequently moved to the correct treatment position. Consequently, safety nets have been rolled out to cover this risk:

- the medical physicist has to manually check the table parameters for errors before each irradiation with the new procedure. This is in anticipation of an automated script that can take over this task.
- for complex treatments, RTTs will also take kV/kV imaging at the first fraction of the series after taking the CBCT. This does not require rotating around the table and can therefore be done in the prescribed table position. Since the patient is already positioned and verified with CBCT, any deviation on the kV/kV could be an indication of incorrect table parameters.
- in vivo dosimetry is applied every irradiation. If an incorrect irradiation is still administered during a fraction, this can be seen with in vivo dosimetry and then it can be corrected and, if necessary, compensated for the rest of the irradiation series.

Because the new bilateral H-VMAT procedure hadn't been rolled out yet across the department and because the treatment for this patient was so complex (bilateral irradiation with the new procedure, using gating and a bolus on the right breast), a test-run was first done on a phantom. Based on that test-run, an individualised procedure was developed specific for this patient to support the RTT's at the treatment machine. This procedure prescribed kV/kV imaging at each fraction after the delta couch CBCT in order to check the table parameters. The procedure was printed out in the console room of the treatment unit where the patient is to be treated.

The patient is irradiated the first 15 fractions with the support of the people involved in the H-VMAT project. The first 6 fractions, kV/kV imaging is taken as prescribed by the procedure. This is not the case for the next fractions, as table parameters don't normally change during a treatment series of several fractions. Under the guise of ALARA (as low as reasonably achievable), no kV/kV imaging is taken from fraction 7 to 15.

When planning the boost irradiation, it was first considered to use electrons for one breast and photons for the other. As such, 2 treatments plans were made. Several versions were made before going back on the decision for electrons and opting for photons for both sides. As such, 2 treatment plans were made with photons, one for each breast. The RTTs were informed of the 2 treatment plans via the electronic patient record. Also, they were advised by the medical physicist to first irradiate the right breast and then the left one. The 2 plans are sent to the radiation oncologist for supervision. This doctor is actively involved in the H-VMAT project and approves the 2 plans. After that approval, the 2 plans were merged into 1 single plan by the medical physicist. During the planning, however, the physicist makes a wrong calculation for the delta couch. As this is also the physicist who would check all irradiations, the error remains undiscovered which is why the first safety net failed.

The first fraction of the boost irradiation is scheduled at the last time slot of the day, to provide enough time and to avoid pressure in case the complex treatment would run out. When starting the first fraction, however, confusion arises amongst the RTT's. They've read in the electronic patient record that there would be 2 plans, but there is only 1 plan. The radiation oncologist who supervised the treatment planning is called and the advice is given to first irradiate the left breast and then the right. The RTT's also ask the assistance of the medical physicist on-call, but as this one was not involved in the H-VMAT project nor in the treatment planning of this patient, he could not help. The physicist working on this project was not present that day, nor was the RTT who wrote the procedure. The radiation oncologist who was contacted earlier by phone was in a meeting, but still came by to support the RTT's.

With the help of the radiation oncologist, it becomes clear that both irradiations are in 1 treatment plan. The radiation oncologist assists with the CBCT and the matching and leaves the treatment unit afterwards. The confusion has caused a lot of wasted time and stress for the RTT's and the patient has also been on the table longer than foreseen. Then confusion arises amongst the RTT's about the kV/kV imaging. The individualized procedure worked out specifically for this patient states that kV/kV imaging should be done every fraction, but previously, the RTT's stopped taking kV/kV imaging after 6 fractions. As this is the first fraction of the boost, the RTT's call a second radiation oncologist, but he is not involved in the project and as such not aware of the importance of the individualized procedure. The radiation oncologist shares in the confusion and the RTT's, who by now were very stressed out by all the conflicting information, decide that kV/kV imaging is not necessary and proceed with the irradiation, which caused the second safety net to fail. The RTT's do not feel comfortable with their previous decision of not taking the kV/kV images and therefore it is decided to take kV/kV images for the other breast. There a 3 cm shift is noticed. The RTT's shift the table 3 cm to compensate and then irradiate the rest of the plan. The RTT's suspect that the irradiation of the first breast went wrong.

The next day, the in vivo dosimetry is immediately reviewed and it is seen that the dose administered differs from the planned dose, which confirms the suspicion of the RTT's. The plan is thoroughly reviewed and the physicist who made the plan discovers his error. The plan is corrected and a comparison between the incorrect and the new plan is presented to the radiation oncologist who co-supervised the plan. During the first fraction of the boost, the dose was shifted to the fat and muscle tissue of the thorax. None of the organs at risk received a dose too high but the target volume was 25,5% underdosed. It should be noted that the procedure allows for possible underdosing of the boost volume if protection of organs at risk should be compromised. Thanks to in vivo dosimetry, the plan was corrected and the remaining fractions went well, resulting in -1,1 % total underdose in the boost volume (mean dose to PTV) for the entire treatment (15 fractions of large fields + 5 boost fractions). This is acceptable for the treating radiation oncologist and no new plan had to be made to compensate for the error during the first boost fraction. The patient was not informed due to clinical irrelevance.

Root cause analysis

The following root causes have been identified:

Human factor: Verification

The medical physicist makes an incorrect calculation of the delta couch and upon verification fails to see his own error.

Human factor: Intervention

- The electronic patient record states that there are 2 plans, but in reality there is only 1.
- The radiation oncologist who approved the treatment planning also assumes 2 plans.
- The physicist recommends irradiating right first and the radiation oncologist recommends starting left first.

Organisational factor: Procedures

- The H-VMAT procedure is new and not yet rolled out in the department. The procedure does not anticipate discrepancies or possible errors and does not describe how to address or correct them.

- The individualised, patient-specific procedure prescribes kV/kV imaging for each fraction, but this is in fact only required for the first fraction. The procedure is not followed at the first fraction of the boost because no kV/kV imaging had been taken during the last 9 fractions of the first irradiation series.

Organisational factor: Management/Knowledge

- The RTT and physicist involved in the project were not present on the day of the first fraction of the boost.
- The physicist on-call was not involved in the project nor in the treatment planning of the patient and could not help.
- The radiation oncologist involved in the project was unavailable and the second radiation oncologist is not aware of the individualised, patient-specific procedure and is confused.
- One of the three RTT's leaves the department because irradiation of the patient takes a long time and it is already getting late.

Corrective actions:

1. kV/kV imaging will become mandatory at the first fraction for all treatments with the new procedure.
2. The rollout of the new procedure in the department is postponed until:
    a. the automated script for the delta couch is in place;
    b. the technical possibility of simplification is offered by suppliers;
    c. everyone is fully trained;
    d. enough support is always available for complex irradiations.
3. Because incorrect calculations aren't always discovered in independent medical physics checks, an additional automatic check in the form of a script is needed. An automated script was under development for this new workflow. The need to delay the clinical rollout until all checks are in place is herewith re-emphasized.
4. Introduce new and complex techniques step-by-step, giving the different actors time to master these procedures and identify and rectify any procedural gaps before proceeding to the next phase.
5. The procedure to take a CBCT in a central table position is complex because the surface scanning technology used cannot communicate with the treatment software. If a technical solution can be offered by the suppliers, the procedure can be simplified to such an extent that the risk of confusion and ambiguity would be greatly reduced.