Incident description

A patient is treated with external radiotherapy (12 * 2 Gy = 24 Gy) for gastric lymphoma. Given the significant mobility of the stomach due to respiratory movement, it was decided to simulate and treat the patient using the Breath Hold (BH) inspiration technique. This technique has been in use at the radiation department for several years.

The treatment procedure is as follows:

1. IGRT with CBCT performed in BH.
2. Matching of the CBCT images with the BH simulation CT-images by a doctor (supervisor or assistant) to validate the position of the patient on the treatment table and the position of the target volumes (stomach + lymph nodes in this case) and organs at risk.
3. Delivery of the treatment by the RTT with the patient holding her breath (BH).

During the 11th fraction, the CBCT was carried out with the patient holding her breath (BH). The assistant was called in by the RTTs to check the CBCT images acquired against the simulation CT-images. While the assistant matches the images, the RTT at the treatment console goes to the waiting room to invite the next patient to the changing cabin. When the RTT returns to the treatment console, the assistant has validated the CBCT and the RTT starts treatment, without telling the patient to hold her breath. The treatment was therefore executed while the patient was able to breathe freely. The error was detected at the end of the fraction and the patient was immediately informed.

An accurate dose calculation of the erroneous treatment session could not be performed for the following reasons:

- The CBCT of the day (and on which the co-registration was done) was a CBCT done in BH and therefore does not reflect the situation of the treatment which was delivered in free breathing.
- There’s no free-breathing CBCT of the treatment fraction. The final position in which the treatment was delivered is the one achieved on the basis of a BH CBCT, with displacements for a BH position which is not the actual position, nor the position of the reference BH CT or the position of the free-breathing reference CT.
- There is a free-breathing 3D reference CT produced on the day of the simulation, but no 4D CT or audio-coaching (as planned for 4D scans). Therefore, there’s no idea about the possible movement of the stomach.

However, subject to all the inaccuracies that this entails, it was proposed to transpose the 95% isodose of the BH treatment plan calculated on the BH CT onto the free-breathing simulation CT and to estimate the CTV coverage. It is estimated that 50.33% of the target volume would have been "covered" by this fraction of the treatment, resulting mainly in coverage of the gastric contents and not the gastric wall.

Taking into account the many unknowns and inaccuracies recalculating the dose, it was therefore decided by the medical corps and medical physics team to apply a worst-case scenario, which would mean that 0% of the target volume would have received zero dose and 100% of the OARs would have received the daily dose, i.e. 2 Gy. This is not the reality either, but it allowed to make a decision on what to do to ensure optimal treatment while protecting the organs at risk.

In parallel, a review of the literature was carried out on haematological pathologies such as gastric maltoma (the patient's pathology), for which doses vary between 24 and 30 Gy according to the guidelines. The clinical benefit was shown to be identical for a dose of 24 Gy compared with a dose of 30 Gy, which is why 24 Gy is prescribed.

This information led to the following decision: an additional fraction of 2 Gy was prescribed to ensure complete coverage of the CTV with a minimum of 24 Gy (a review of the literature shows similar efficacy between 24 and 30 Gy - making an additional dose on parts of the CTV "acceptable"). The dose to the organs at risk remains clinically acceptable with no expectation of additional adverse effects, even in the worst-case scenario.

Root cause analysis

The following root causes have been identified:

Human factor: Intervention
RTT forgets to ask the patient to hold her breath when delivering the treatment.

Human factor: Coordination
The RTT at the treatment console was distracted by another task (during CBCT matching, the RTT got up to put another patient in the changing cabin).

Human factor: Monitor
During the treatment delivery, the RTTs were not focused on the IDENTIFY screen. This would have demonstrated that there was a discrepancy in respiratory monitoring.

Patient related factors:
- Treatments with blocked inspiration for indications other than the left breast are rare.
- It was necessary to plan the treatment of the stomach in blocked inspiration in order to cover the target volume well and minimize irradiation to surrounding healthy tissue.

Technical factor: Design
- The IDENTIFY surface imaging in reference position (= outside gantry) is installed in the department but is unreliable and therefore not used in clinical routine. Pre-treatment breath-holding exercises are therefore not performed.
- There is no communication between IDENTIFY's surface imaging (tracking) and the treatment machine. The radiation beam is therefore not automatically interrupted when the patient's respiratory tracking falls outside the set tolerances.
- Visualization of IDENTIFY surface deviations data is sub-optimal (out-of-tolerance deviations are poorly displayed).
- The workflow on the treatment machine and the treatment delivery itself are extremely fast, therefore the RTT's response time is shortened.

Organisational factor: Protocols
The patient does not receive any signal between the CBCT and the treatment indicating that treatment is about to begin. The patient can therefore not alert the RTTs if elements of the treatment are unusual or not present.

Organisational factor: Culture
Two RTTs working at the LINAC but whereby the second RTT has the tendency to have a passive role.

Corrective actions:

1. Prescription of one additional fraction. In total, the patient received 13 * 2 Gy.
2. Feedback to be given to the company (IDENTIFY) to optimize their product:
   - Need for surface imaging at reference position (= outside gantry) that is reliable (technical finetuning?)
   - Need for better visualization of surface deviations data.
   - Possibility of automatic interruption of the beam depending on the result of the surface imaging.
   - Lag time between the patients inspiration curve and the curve displayed on the IDENTIFY screen should be non-existent.
3. Implementation of blocked inspiration exercises at reference position (= outside gantry). The exercise enables this type of treatment to be differentiated from the other treatments.
4. Optimisation of the allocation of RTT tasks at the treatment console: the RTT at the console must not be distracted by other tasks such as putting the next patient in the changing cabin. If a doctor has to do a matching, it is recommended that the RTT stays in place to observe the procedure (see this as collaboration and additional training). The other RTT should stay concentrated on the treatment while carrying out the administrative and patient preparation tasks
5. For BH treatments, after the CBCT, the RTT turns a console key which blocks treatment delivery. As such, when the CBCT co-registration is done, the RTT is obligated to turn the key to apply the setup corrections and to treat. This acts as a physical reminder that a BH treatment is to be started.