Incident description

When checking a treatment plan, one of the medical physicists noticed that the treatment table had been incorrectly modelled in the treatment planning system (Monaco 5.51, Elekta AB, Sweden). A 12x higher density had been assigned to the entire table for treatment calculations, which could lead to overdoses of around 10% for some patients.

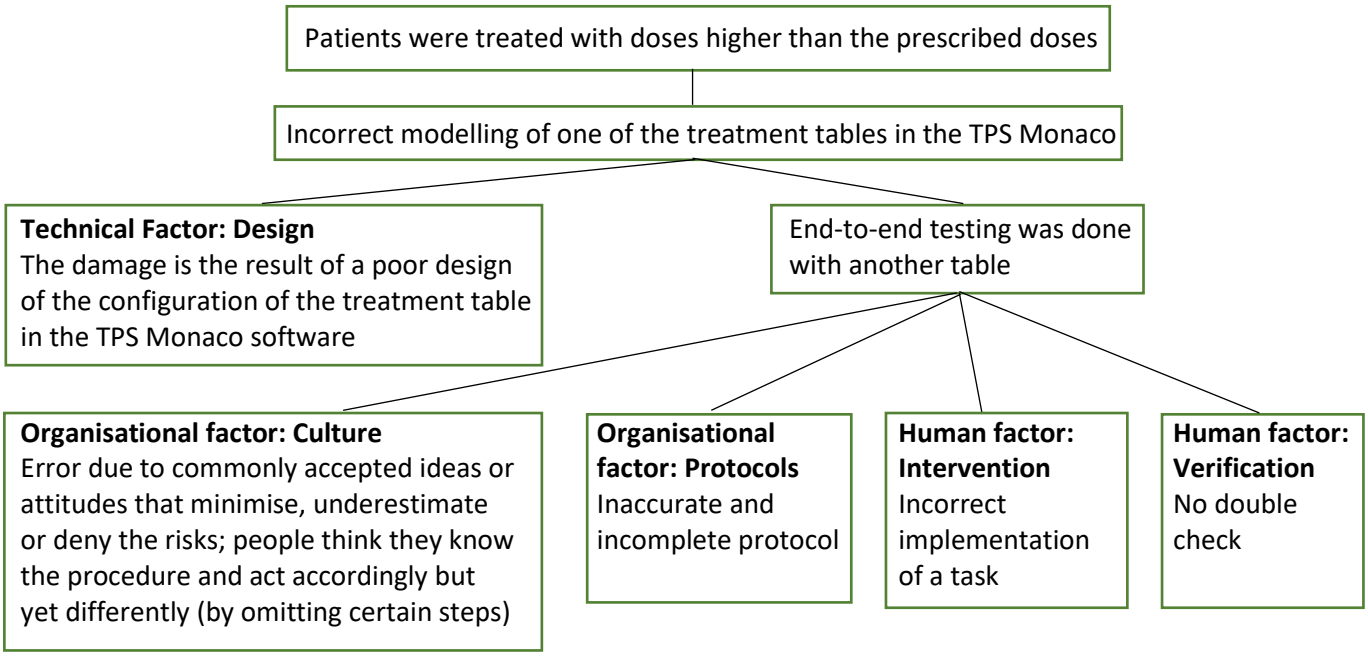
As soon as the error was discovered, an in-depth analysis of each patient, whether currently undergoing treatment or having completed their treatment, was systematically carried out, with priority given to the recalculation of the treatments of those patients who may have been most affected:

- Treatments not yet started (15 – 20) were recalculated to have zero impact for these patients.
- Current treatments (69) were all assessed and adapted if necessary and possible.
- 246 patients finished their treatment before the error was discovered:
  - 82 patients with little or no impact, as radiotherapy fields did not pass through the table (breast, ORL and skull).
  - 59 palliative treatments (1 or 2 fractions) probably without any impact given the moderate dose administered.
  - 105 patients with possible impact.

It should be noted that no abnormally high acute toxicity had been reported when the error was discovered.

An external audit of BELdART, for which measurements were done for both output and clinical scenarios (VMAT, SBRT and SRS), had been entirely reassuring and did not reveal the error.

Root cause analysis



Corrective actions:

1. Creation of a complete Excel file containing at least:
    a. Identity and number of the electronic medical record of all concerned patients
    b. Type of cancer
    c. Area irradiated
    d. Identification of cases with the highest risk of long-term toxicity, for example on the spinal cord
    e. Dose prescribed and name of the responsible radiation oncologist and MPE
    f. Dose interval indicated in the guidelines
    g. Dose received (on the tumour but also on organs at risk) recalculated and by which MPE
    h. Delta dose (dose deviations: define clinically acceptable deviations for the tumour and OAR)
    i. Date of next planned consultation and with which radiation oncologist + column to indicate the result of the consultation in terms of abnormal toxicities
    j. Subsequent consultation dates in order to ensure follow-up in the event of problems
    k. Any other data that seems useful

2. Communication to all radiation oncologists for the patients they follow:
    a. The radiation oncologists have received the list of patients concerned (N=246).
    b. A patient report is available initially in the ARROW software and also in the electronic medical record of each patient with significant clinical impact, so that all patients future doctors can take this data into account and make a possible link with a toxicity that may occur.

3. Decision on the status of each patient (clinically significant impact or not) and whether or not contact is required:
    a. Each referring radiation oncologist is responsible for the initial analysis: checking whether the dose deviation is clinically significant and deciding whether or not the patient needs to be contacted.
    b. A second analysis has been carried out at the senior radiation oncologists meeting, where the status of each patient has been discussed.

4. Determining how the concerned patients will be informed by their radiation oncologist. If toxicity or a patient complaint is identified, they must be referred to the hospitals mediator/medical director so that the file can be duly submitted to the insurer.

    Contact with the patient has taken place during the next consultation with the patient. If no consultation is scheduled yet, one will have to be. Telephone contact is also possible. This must be specified in the Excel file and will be monitored by the radiation departments Quality Manager.

5. Correction of the end-to-end test procedure and verification from start to finish.

6. Raise awareness amongst the medical physicists of the importance of double checking:
    - Task 1: Information of the physics team at the next meeting.
    - Task 2: Identification of the pairs in advance for the double check of each written procedure, with signature and date.

7. Notification of ELEKTA of the incident to prevent this type of incident from being repeated in another centre.