FMEA in developing a QM program in protontherapy

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Abstract

Radiotherapy technologies significantly improved in the recent years, reaching a very high degree of complexity and sophistication. The rapidly increasing use of newer techniques, including hadrontherapy, is expected to represent an added value for the patient in terms of clinical outcomes, however it places new demands on quality assurance programs, as well as new attitudes and approaches for patient safety. This study aims to contribute at increasing the safety of patients undergoing protontherapy, through proactive analyses of the risk of incidents, "near misses", and, in general, events leading to a deviation from the adequate treatment, in terms of over- or under-dosage. Failure Mode and Effects Analysis (FMEA), a prospective tool successfully applied in industry, and recently recommended by the International Commission for Radiological Protection for use with modern radiotherapy techniques, was applied.

The radiotherapy process based on the use of active scanned proton beams for fixed target irradiation, typically located in the head and neck region, was considered. In this work the detailed process trees of the stages "positioning and immobilization", simulation, imaging and volume determination", "planning" and "patient set-up" are shown and discussed.

Key Words: Hadrontherapy, Risk Analysis, Failure Mode and Effects Analysis

1. Introduction

New technologies and irradiation modalities have been introduced into radiation therapy with the principal aim of improving treatment outcome by means of dose distributions which conform more strictly to clinical target volumes. A highly conformal dose distribution allows for dose escalation in the target volume without increasing the radiation dose to neighbouring normal tissues, or for a reduction in radiation dose to normal tissues without decreasing the dose to the target. In case of hadrontherapy, the physical advantages deriving both from the interaction properties of these particles with target tissues and from technological improvement in the beam-delivery (like intensity-modulated particle radiotherapy), are strengthened by the radiobiological benefits. Most recent advances in radiation therapy have only been achievable through the

increasing complexity of both equipment and treatment techniques. However, complexity may also increase the opportunities for accidental exposures.

Radiotherapy-related errors are not uncommon, even in the countries with the highest level of health-care resources. The risk of mild to moderate injurious outcome to patients from these errors was about 1500 per million treatment courses [1]. A number of accidents in conventional external radiotherapy have been extensively investigated and the lessons learned have been disseminated by the International Atomic Energy Agency (IAEA) [2]. The International Commission on Radiological Protection (ICRP) has also summarised causes and contributory factors for conventional external radiotherapy accidents [3].

In order to fully assess and manage the risks of accidental exposures deriving from the use of innovative radiotherapy methodologies, retrospective approaches are not enough adequate, since they have the intrinsic limitation of being confined to the reported experiences, thus leaving unreported events or latent risks unaddressed. In order to overcome the limitations of perspective and retrospective methods of risk analysis, prospective approaches, widely applied in high-risk industry, have to be implemented to find out all the elements that could go wrong and identify, a priori, all the potential hazards that might occur during a radiotherapy treatment. Recently, the interest in using these methodologies for safety assessment in complex medical practices like radiotherapy is gaining importance and the literature on this topic is rapidly increasing [5-13].

At present, a proactive analysis of the risk of incidents, “near misses”, and, in general, events leading to a deviation from the adequate treatment, in terms of over- or under-dosage during protontherapy treatments is in progress by using Failure Mode and Effects Analysis (FMEA) approach. The study is performed considering as a specific RT process the one implemented at CNAO Foundation (Centro Nazionale di Adroterapia Oncologica), however, the proposed methodology, and likely most of the findings, can be easily generalized to other hadrontherapy centres, operative or under construction. In this work preliminary results of this analysis are reported and discussed.

2. Materials and methods

2.1 Protontherapy process tree

Following the general guidelines recently proposed by the World Health Organization (WHO), [1], a generic radiotherapy treatment process can be divided into ten stages: 1) assessment of patient, 2) decision to treat, 3) treatment protocol prescription, 4) positioning and immobilization, 5) simulation, imaging and volume determination, 6) planning, 7) treatment information transfer, 8) patient set-up, 9) treatment delivery, 10) treatment verification and monitoring.

This scheme was used to generate the process tree of the clinical programme under study, which reflects the structure of the programme and the sequence of activities and instruments used to complete the process.

Some assumptions and limitations in the process were considered. In particular, the analysis was initially focused on the use of active scanned proton beams for fixed target irradiation in adult patients. For the process tree delineation, as well as for the following risk analysis, a multidisciplinary and multi-institutional

team composed by experts in different areas including radiation therapy, oncology, medical physics, dosimetry and radiation protection was set up.

2.2 Failure Modes and Effects Analysis (FMEA)

FMEA is an established method for proactive risk analysis, widely employed in industry, and recently recommended by the International Commission for Radiological Protection (ICRP) for use with modern radiotherapy techniques [4]. The FMEA approach enables to identify potential failures of an equipment, system or process and to analyze the resulting effects.

After the identification of potential failure modes (what could go wrong) at each sub-process, possible causes and potential effects of each failure mode have to be evaluated. Afterwards, the occurrence rating (O), the severity rating (S) and the detectability rating (D) are assessed and the risk priority number (RPN=OxSxD) of each failure accordingly calculated.

3. Results and discussion

Process trees related to the stages "positioning and immobilization", "simulation, imaging and volume determination", "planning" and "patient set-up" are shown in Figures 1-4, respectively.

A total of 46 sub-processes were recognised within these stages: 10 for "positioning and immobilization", 6 for "simulation, imaging and volume determination", 22 for "planning" and 18 for "patient set-up". The remaining steps of the analysis, consisting in the completion of the process tree delineation and identification of the potential failure modes occurring in each sub-process, followed by their causes and effects are currently under evaluation.

4. Conclusions

A proactive analysis of the risk occurring during protontherapy treatments is in progress, by performing a Failure Mode and Effects Analysis on the RT process developed at CNAO. Process trees of several stages composing the whole protontherapy process were set down. These schemes will be the basis for the following identification and analysis of the potential failure modes, as well as estimation of risk indexes.

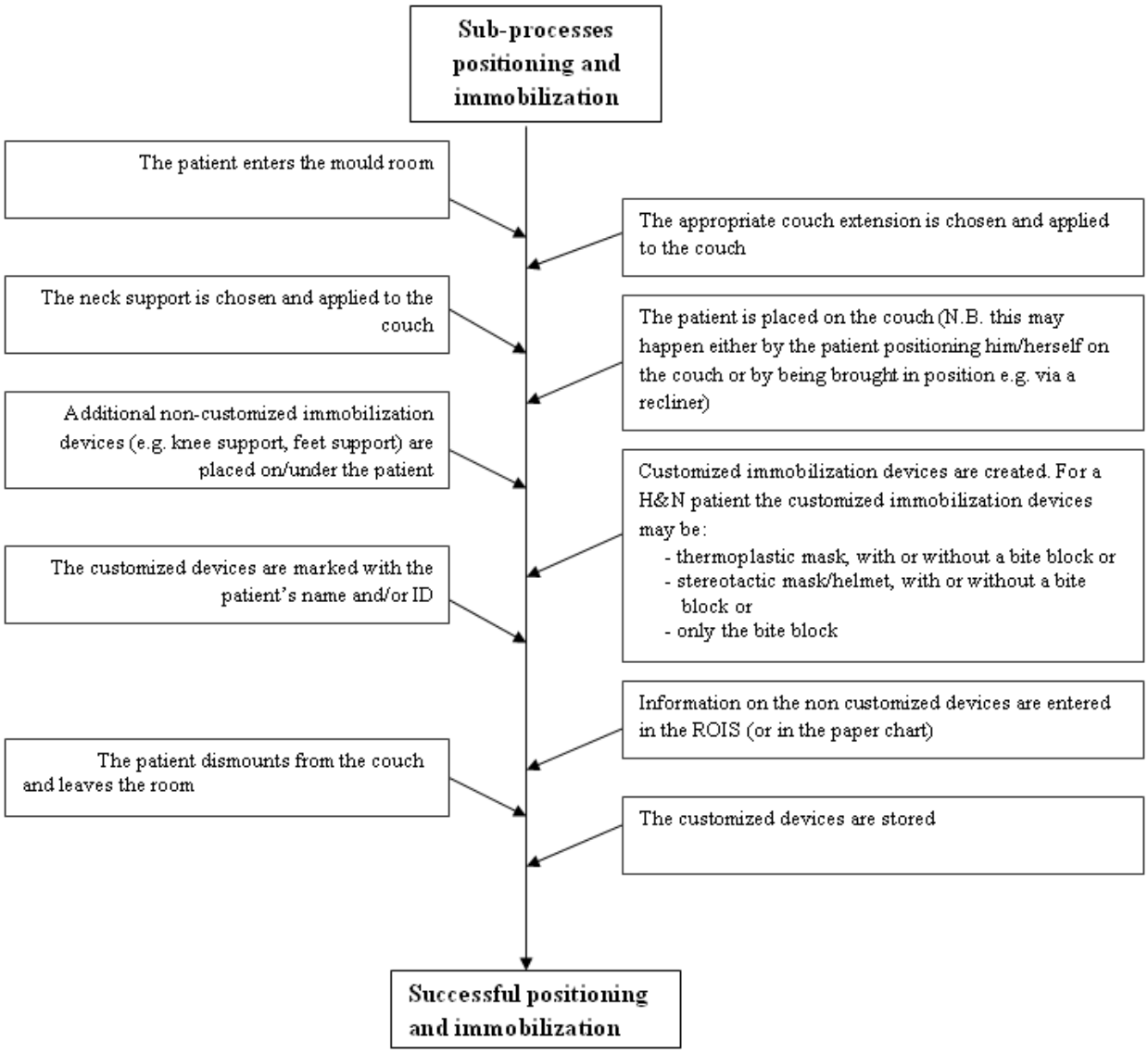

Figure 1. Sub-processes of the stage "positioning and immobilization"

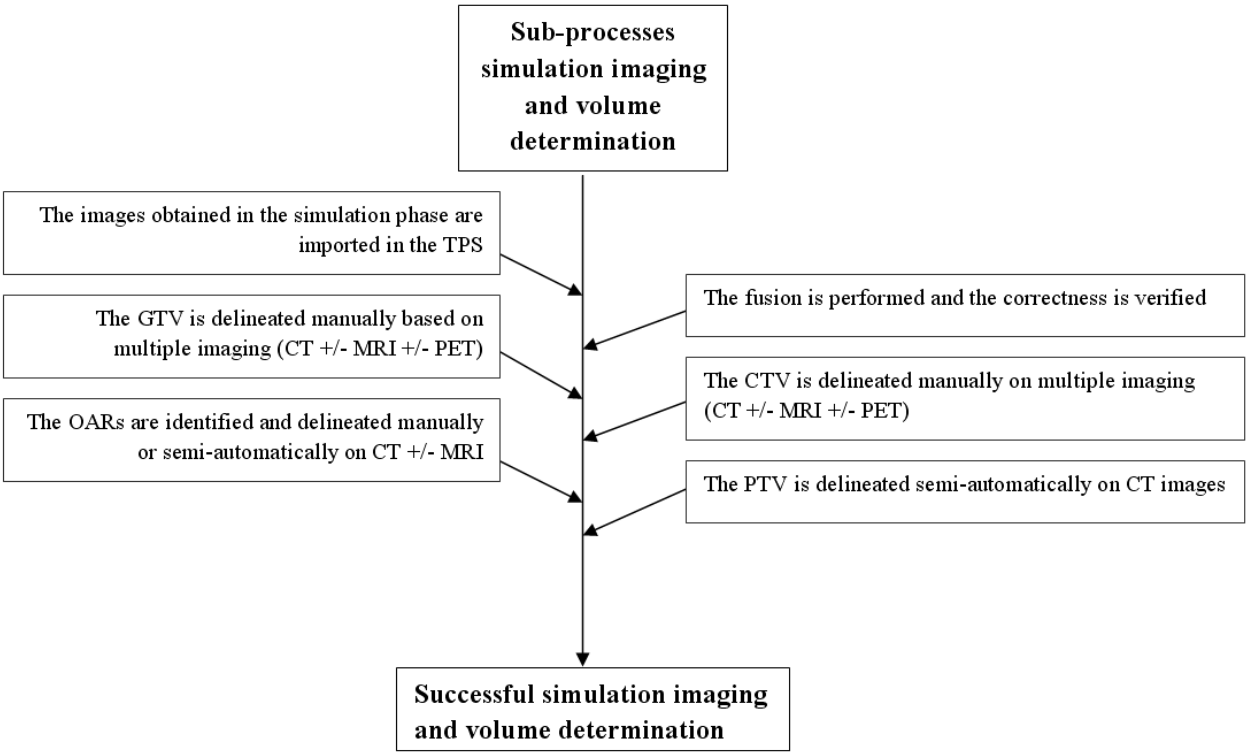

Figure 2. Sub-processes of the stage “simulation imaging and volume determination”

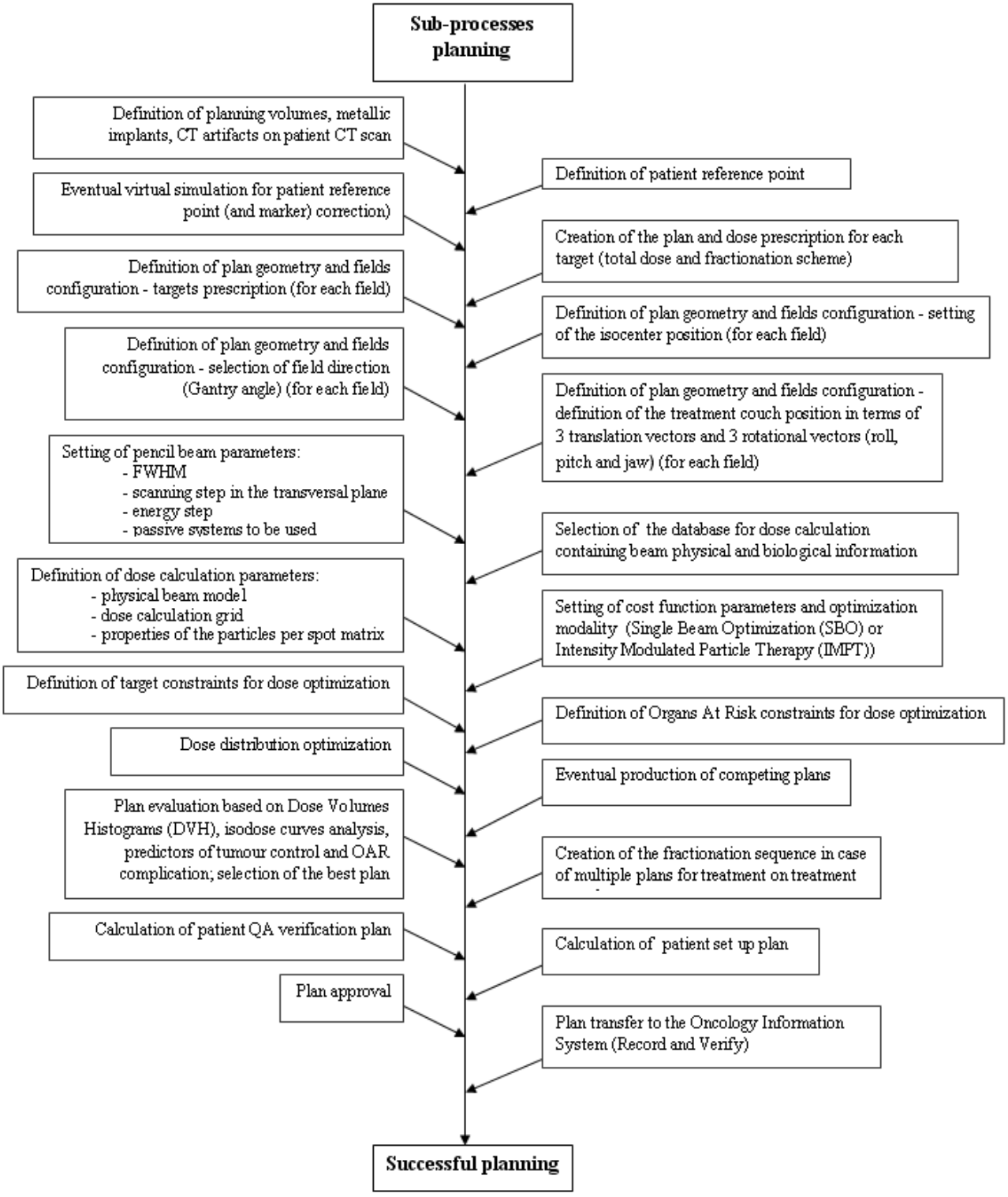

Figure 3. Sub-processes of the stage “planning”

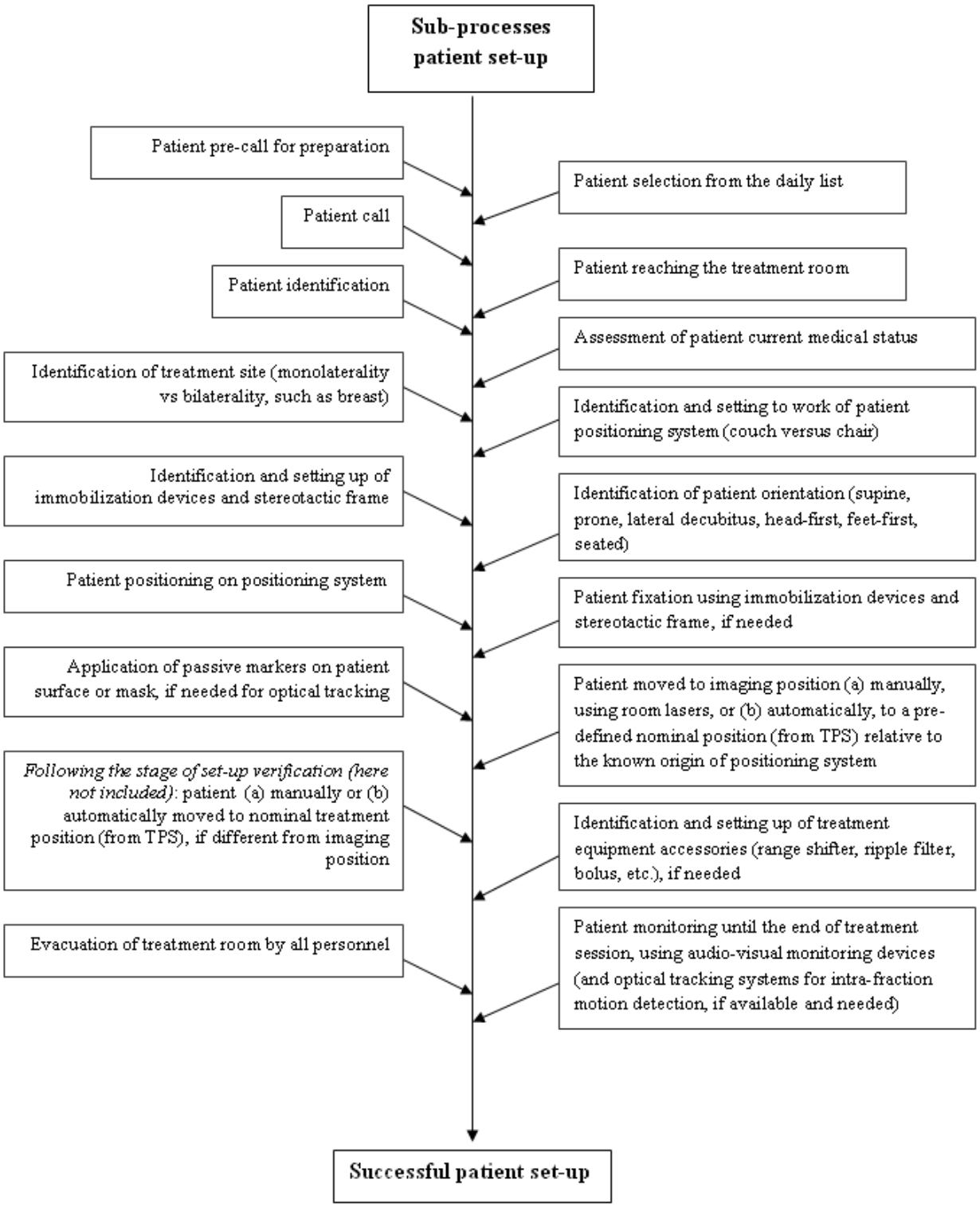

Figure 4. Sub-processes of the stage “patient set-up”

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