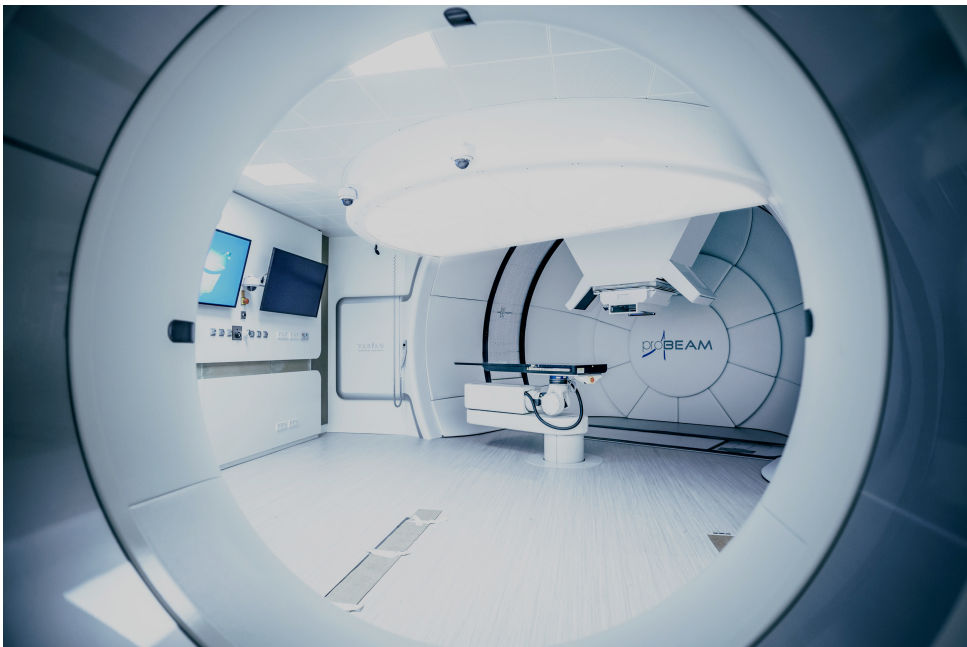# A STRATEGY TO MONITOR AND MITIGATE RISKS ASSOCIATED WITH THE PLAN-ADAPTATION PROCESS AT HOLLANDPTC

Author
Miranda Visser

A STRATEGY TO MONITOR AND MITIGATE RISKS ASSOCIATED WITH THE PLAN-ADAPTATION PROCESS AT HOLLANDPTC

by

Miranda Visser

to obtain the degree of Master of Science
at the Delft University of Technology,
to be defended publicly on Thursday August 22, 2019 at 2:00 PM.

Printed by: Miranda Visser
Front: Treatment room at HollandPTC. Image derived from [1].

An electronic version of this thesis is available from 22 august 2021 at
http://repository.tudelft.nl/.

SUMMARY

BACKGROUND The steep rise of advanced technology in healthcare and the required specialisation of staff causes healthcare systems to have become increasingly complex. This increased complexity poses great challenges on the risk management of systems. Many different methods have been developed the past decennia to identify potential risks in these system to enhance safety. A commonly used prospective risk analysis method is HFMEA, which is based on the linear view on system safety. Another relatively new method is FRAM which meets the dynamic systemic view on safety and focusses more on potential risks in a system due to "everyday performance". An example of a complex healthcare system is proton therapy; a novel type of radiotherapy to treat tumours in the proximity of the central nervous system. The first operational clinic in the Netherlands providing this therapy is HollandPTC. During the therapy the tumours are irradiated with a high precision in multiple sessions. When anatomical variation is observed between these sessions, the treatment plan of a patient has to be adjusted. This critical process is called plan-adaptation and has to be both time-efficient and safe. To ensure the safety of the plan-adaptation process at HollandPTC, currently controls are designed based on potential risks identified with HFMEA.

OBJECTIVE The aim of this thesis is to identify an effective strategy to identify which controls are able to monitor and mitigate risks associated with the process of plan adaptation at HollandPTC.

METHODS Independently of the HFMEA, a FRAM was conducted on the plan-adaptation process at HollandPTC. The resulting set of potential risks were compared with the potential risks identified with HFMEA. Furthermore, the effectiveness of the controls proposed by HFMEA were assessed on the set of potential risks identified with FRAM. Based on these results a strategy is proposed to monitor and mitigate the potential risks.

RESULTS The analysis of the FRAM models revealed among others potential risks related to: informal communication lines between caregivers, discrepancies between caregivers ideas about task division and identified multiple causes for time delays. These risks were not identified with HFMEA. The controls proposed by HFMEA do not mitigate the potential risks identified with FRAM. By combining the strengths of both HFMEA and FRAM, an effective strategy is proposed to monitor risk and to identify effective controls. This strategy can be used as a prospective risk-analysis method and on ongoing processes.

Contents

ABBREVIATIONS

Caregivers:

LP	Logistic Planner
MP	Medical Physicist
MPA	Medical Physicist Assistant
RO	Radiation Oncologist
RTT	Radiotherapy Technologist

General:

CTV	Clinical Target Volume
ETTO	Efficiency Thoroughness Trade Off
FMV	FRAM Model Visualizer
FRAM	Functional Resonance Analysis Method
GDPR	General Data Protection Regulation
HFMEA	Healthcare Failure Mode and Effect Analysis
IRS	Incident Reporting System
OAR	Organs At risk
QA	Quality Assurance
rCT-scan	Repeat CT-scan
WAD	Work as Done
WAI	Work as Imagined

Software:

	Description
ARIA	Oncology Information System
IBA	Dosimetry (Quality Assurance)
NeoZis	Electronic Healthcare Record
ProBeam	Software for the gantry
PACS	Picture Archiving and Communication system
RayStation	Treatment Planning System

DEFINITIONS

Background Function	An activity that is solely described by an input or an output. [26]
Coupling	Dependencies that arise between activities due to shared aspects. Couplings in a FRAM model are often many to many. [26]
Downstream Function	Description of an activity in a FRAM model that has occurred prior to the function that is currently under consideration. [26]
Functional Resonance	The noticeable performance variability of a complex socio-technological system that can happen when multiple approximate adjustments coincide [26].
Foreground Function	An activity that is described by multiple aspects in a FRAM model. [26]
rCT-scan	The CT-scan that is used to design the adapted treatment plan.
Upstream Function	Description of an activity in a FRAM model that occurs after the function that is currently under consideration. [26]
Treatment CT-scan	The CT-scan that is used for developing the treatment plan .
WAD model	A Work As Done model reflects how the work is done according to the participants. [26]
WAI model	A Work As Imagined model reflects how the work should be done according to the the various procedures/protocols that are in place [23] [26].

1

INTRODUCTION

The goal of this chapter is to introduce and motivate the research done in this thesis. Section 1.1 describes two major perspectives on accident causation. In section 1.2 the fundamentals of proton therapy are introduced which is used as case study for this thesis. Section 1.3 describes the main research question of this thesis and the motivation for this research from a scientific and societal point of view. Finally, in section 1.4 the outline of this thesis is provided to guide the reader through this thesis.

During the last decades, a technical revolution has taken place in healthcare; many new technological advances have been introduced, existing processes are automated and optimised by technology and most patient related information is now digitally available. Many systems that are now in place are therefore often denoted as complex socio-technical systems. These systems are characterised by: 1. all what cannot be automated is left for humans, 2. the tolerance for errors and accidents is descending rapidly due to increased safety standards and 3. a high number of couplings [12] [34] [39] . In parallel, the performance variability of systems are increased due to underspecification of the system, human factors and limited resources which poses great challenges on the use of risk-analysis methods [16]. Proton therapy qualifies as such a complex socio-technological system as the treatment involves many caregivers that are required to make decisions on elaborate procedures while using advanced software and hardware and rely on the interaction between completely automated devices under varying working conditions [20] [21] [42] [58].

1.1. PERSPECTIVES ON SAFETY

The steep rise of technological advances together with accident investigations have introduced new perspectives in safety science. Here two major perspectives on safety are discussed; the linear- and systemic view on accident causation.

1

The third law of Newton postulates that every action has an equal and opposite reaction. When this law is applied to accident causation this would mean that for every accident a cause can be found which is equal in magnitude (i.e. a large accident has a large cause) [12]. The past decennia many models have been developed that are in line with this view on accident causation; events precede in a linear and fixed order and an accident is the last event of this chain of events and is triggered by an event at the beginning of the chain [11] [25] [31]. The identification and understanding of the cause is usually obtained by breaking down the process by the functioning or non-functioning of constituent components [39].

A conceptual framework which is based on the linear view is the Swiss cheese model (latent failure model) developed by James Reason and is illustrated in figure 1.1. According to this model a single failure (human, technical or organisational) is not sufficient to initiate an accident, it is the combination of latent- and active failures at different levels together that causes an event to result in an accident [52]. Introducing barriers/defences in the system reduces the consequences of an erroneous action [12]. An accident can best be prevented by learning how to detect latent failures that cause an accidents to accumulate through the system. Examples of linear methods are among others: healthcare failure and mode effect analysis(HFMEA), event tree analysis and hazard and operability(HAZOP) [17].

The increased complexity of (healthcare) systems poses challenges on the use of linear methods as sole prospective risk analysis method as technology is constantly innovating, becoming more and more complex and the tolerance for accidents is descending even more due to increased safety standards [21] [29] [39].
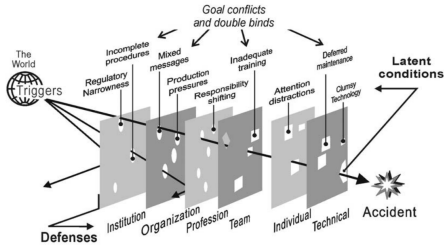
Copyright (c) 2004 by RI Cook. Modified from Reason, 1999.

Figure 1.1: The Swiss cheese model (latent failure model) developed by James Reason which illustrates the linear view on accident causation [52]. Image derived from [12].
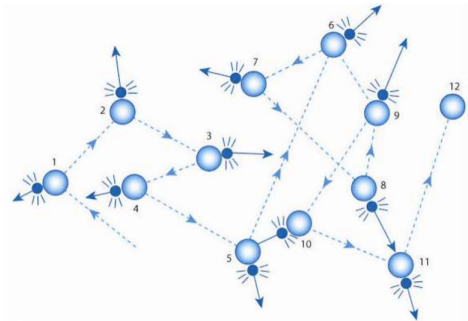
Figure 1.2: Systemic view on accident causation. Accidents are the result of every day events that breach the safety constraints. The inter-complexity causes the effect of a breach to result in an accident. Image derived from [16].

The tight intertwined interplay of technology and human factors that is present in many systems now a days, raises the question whether systems should not be considered as a whole, rather than by its individual human, technical and organisational components

as is proposed by the linear view. Moreover, reducing the complexity of socio-technical systems can only be done to a certain limit. From that point on we need to look for new ways to increase safety. The systemic view on safety provides a framework that treats a system as one modality which is constantly adapting to remain in a dynamic stable equilibrium. Here, an accident is considered to be the result of unanticipated interactions across all system components that violate the safety constraints. Due to the interactions in the system, breaches of safety constraints can grow at an exponential pace. When the system is not able to adjust its functioning to restore the breach of safety constraints, the resulting combinatorial explosion can be an accident [12] [24].

Different frameworks have been developed that meet the systemic view on safety such as the normal accident theory and resilience engineering. Accident causation methods that meet this systemic view are among others: the functional resonance analysis method (FRAM) and Systems-Theoretic Accident Model and Processes (STAMP) [17] [28] [39] .

1.2. HOLLANDPTC AND PROTON THERAPY

Radiotherapy uses high doses of radiation to treat cancer patients and is currently used in more than 50% of all cancer patients [32] [58] [64]. The ultimate goal of radiotherapy is to target a tumour uniformly while minimising the damage to surrounding tissues [43].

Radiotherapy can be depicted as a complex socio-technical system because of the following reasons. First, it requires the integration of many nested levels of decision making such as: medical physics, radiobiology, radiation safety, dosimetry and interaction of radiation with other treatment modalities [33]. Second, many different type of caregivers are required to make decisions on elaborate procedures while using advanced software and hardware and rely on the interaction between completely automated devices under varying working conditions [20] [21] [42] [58]. An overview of all the steps involved in a treatment is illustrated in figure 1.3.

Several types of radiotherapy exist such as photon therapy and proton therapy. Proton therapy delivers protons (positively charged particles) with a high precision at the desired location in the body. Compared to photon therapy it is still a relative novel clinical technique. HollandPTC is the first clinic in the Netherlands that provides clinical proton therapy and facilitates scientific research and education. Whether a patient is selected for proton treatment in the Netherlands depends on whether an individually validated Normal Tissue Complication Probability (NTCP) model predicts clinically relevant less toxicity compared to photon treatment for the tumour [38].
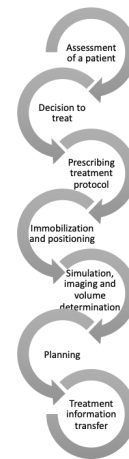

Figure 1.3: Sequential steps of a radiotherapy treatment. Image adjusted from [33].

PHYSICS OF PROTON THERAPY

Figure 1.4 shows the difference in relative dose required to treat a tumour with photons and protons. The area under the curve represents the energy of the particle that is deposited in a medium by ionising radiation and is called the Bragg curve [61]. The

1

distance (depth) that a proton can travel before the energy deposited is almost zero, also called the range of a particle, depends on: the matter the particle is traversing, the type of particle that is being used and the initial energy of the particle before entering matter. The force, also called the stopping power, that acts on the particles and causes them to lose energy, increases near the end of the range and creates the distinctive Bragg peak. In proton beam therapy, the final dose (spread out Bragg peak (SOBP)) is acquired by adding multiple proton Bragg peaks. The addition of the peaks is required since a single mono-energetic Bragg peak is too narrow to cover the entire volume of most tumours [43]. To obtain approximately the same relative dose at the tumour location with photons as for protons it is required to start with a much higher initial dose. As can be observed in figures 1.4 and 1.5, photons deposit their maximum energy at a short depth compared to protons. As a result surrounding structures receive a very high dose when photons are deposited compared to protons which poses a challenge on the treatment [43]. Especially tumours that are within or close to the central nervous system are challenging to treat with photons since a lot of secondary damage is initiated as is shown in in figure 1.5 [57].
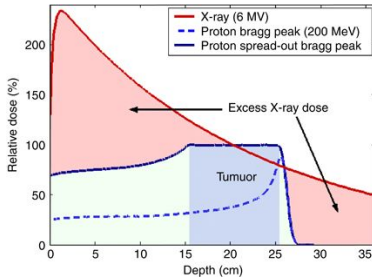
Figure 1.4: Comparison of the relative dose required to irradiate a tumour with the same relative dose for the treatment with high energy X-ray photon beam (red) and a spread-out Bragg peak which combines multiple proton beams (solid blue). Image derived from: [14]
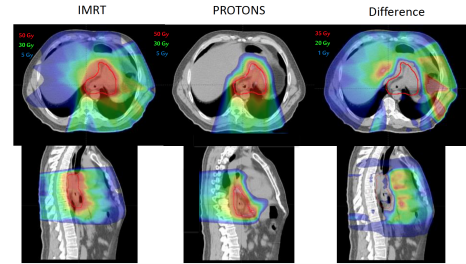
Figure 1.5: Comparison of the dose distribution of a patient with esophagus cancer treated with a high energy X-ray photon beam (left) and proton beams (middle) and their difference (right). At the isocentre of the tumour the same dose is received. Image derived from: [62]

1.2.1. SCOPE: PLAN-ADAPTATION

When a patient is eligible for receiving proton therapy a treatment plan is designed by a multidisciplinary team that consists of a: logistic planner(LP), medical physicist (MP), medical physicist assistant(MP), radiation oncologist(RO) and radiotherapy technologist (RTT). A description of their specific tasks is provided in table 1.1. Patients with a tumour in the head-and-neck region often have noticeable anatomical changes during the treatment due to for example weight loss or swelling [22] [66]. The use of conformal treatment techniques such as proton therapy requires to adapt the treatment plan due to these inter-fractional changes to ensure dose conformity and to prevent under-dosage throughout the treatment course [3] [35] [45]. Figure 1.6 illustrates a typical timeline of a patient for whom anatomical variation is observed. A treatment plan consists of multiple fractions to deliver a certain dose to the tumour. The goal of plan-adaption is to
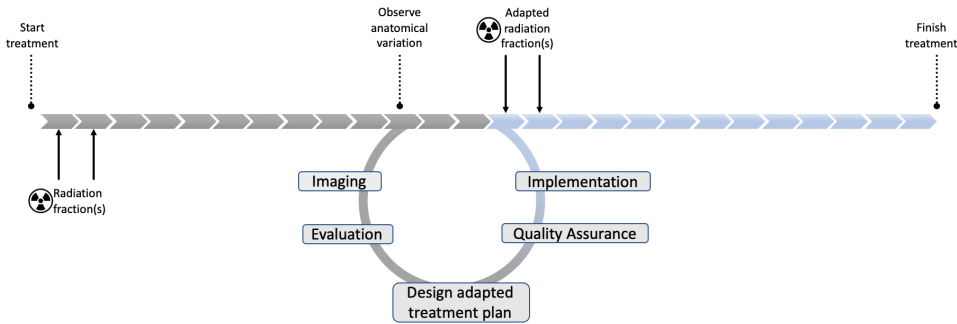
Figure 1.6: Overview of the impact of plan-adaptation on the treatment of a patient. A patient receives consecutive fractions of radiation. When anatomical variation is observed that might effect the dose conformity the plan-adaptation cycle is initiated. During the adaptation of the treatment plan, the patient still receives the initial fractions. Once completed the patient receives an adapted fractions.

create an adapted treatment plan within a short period of time after noticing anatomical changes. Haste is called for because the plan-adaptation pathway is executed while the patient still receives the initial treatment plan. Yet, this treatment plan is no longer optimal to deliver the correct dose at the tumour location [37].

The plan-adaptation pathway consists of the following five steps and is illustrated in figure 1.6 [35]:

1. **IMAGING** CT-images are made to capture the inter-fractional (anatomical) changes of a patient.
2. **EVALUATION OF THE TREATMENT PLAN** The robustness of the treatment plan is tested on the new set of images. If the treatment plan is not robust for the changes, the plan-adaptation process is initiated.
3. **DESIGNING THE ADAPTED TREATMENT PLAN** A new treatment plan is designed to deliver the desired dose at the correct location.
4. **QUALITY ASSURANCE** Measurements and calculations are performed to asses the accurate delivery of the absorbed dosTe.
5. **IMPLEMENTATION** The treatment plan is replaced with the adapted treatment plan in the pathway of the patient. The patients now receives adapted fractions.

Table 1.1: Overview of the various roles involved in the process of plan-adaptation of proton therapy.

Role	Description
Logistic Planner	Is concerned with the scheduling of the treatment of a patient.
Medical Physicist	Ensures quality and safety by applying principles of physics on the treatment plan during planning and commissioning.
Medical Physicist Assistant	Is concerned with the quality assurance of a treatment plan.
Radiation oncologist	Concerned with the design and prescription of the complete course of treatment of a patient.
Radiotherapy technologist (Gantry/CT-scan)	Mobilises and positions a patient for imaging and treatment. Delivers the treatment to a patient.
Radiotherapy technologist (Dose planning)	Creates the (adapted) treatment plan for a patient.

1.3. Problem statement

In this section the main research question of this research is introduced. First, gaps in literature are explored. Subsequently, the main research question is presented and the scientific and societal relevance of this research will be discussed.

Gaps in literature

Proton therapy can be qualified as a complex socio-technical system as discussed in section 1.2; all involved professionals rely heavily on the interchange of information about a patient which is generated by machines and processing systems. Furthermore, highly technical measurements and calculations are required to ensure an accurate and reproducible treatment for a patient [20] [42] [58]. Over-reliance in the technological advances designed to mitigate risks throughout the complex planning and treatment of proton therapy, potentially have an antagonistic effect on the safety of the treatment [30]. The critical handovers of information and the heavy reliance on technology causes a considerable need for formal error mitigation and process analysis methods that are able to identify weaknesses in treatment planning and delivery processes and the equipment and software systems [20] [33]. The process analysis methods should "act scientifically and pragmatically; knowledge of existing evidence needs to be combined with knowledge of the unique initial conditions of a system, and interventions need to adapt as the complex system responds and learning emerges about unpredictable effects" [53]. Many of the current process analysis methods to identify risks associated with a process such as HFMEA, provide a fix for the direct and visible failure modes rather than addressing the underlying key issue in the design of the clinical guidelines[5][17]. The clinical guidelines are often compromised during everyday performance by constraints such as a lack in resources [36]. FRAM is able to capture the variability that arise during "everyday performance" for many complex socio-technical systems [5] [41] [23] [48]. However, so far no research with FRAM has been conducted in a radiotherapy setting to explore how "everyday performance" effects the process. Furthermore, to the best knowledge of the researcher no systematic strategy has been described in scientific literature on how to effectively incorporate the knowledge from "everyday performance" identified with FRAM in a process to mitigate and monitor risks. This research aims to alleviate this gap.

Main research question

This research is conducted to design effective controls from identified potential risks to monitor and mitigate risks throughout a process. The main research question of this study is:

> *What is an effective strategy to identify which controls are able to monitor and mitigate risks associated with the plan-adaptation process at HollandPTC?*

1

Subquestions have been formulated strategically to be able to answer the main research question of this thesis. The subquestions enable to construct conceptual models of the process plan-adaptation according to the functional resonance analysis method (FRAM) which is elaborated on in chapter **??**.

- How is the plan-adaptation process organised at HollandPTC?

- How does "everyday performance" affect the plan-adaptation process at HollandPTC?

- How can the identification of potential risks associated with everyday performance contribute to the design of effective controls to mitigate risks?

SCIENTIFIC- AND SOCIETAL RELEVANCE

From a scientific point of view this research will contribute to existing literature by focussing on the above described literature gaps. A strategy to mitigate and monitor potential risks in a complex-socio technical system which are associated with "everyday performance" has not been proposed in literature until now. Furthermore, this research is specifically designed for the plan-adaptation process at HollandPTC which is a process that needs to be both highly efficient and safe to ensure dose conformity throughout the treatment of patient [37] [45]. However, HollandPTC, like every radiotherapy facility, faces challenges for this process due to both growth of the organisation and the strong dependency on digitalisation and automation to implement treatment [18]. To the best of the author's knowledge no contributions have been published in scientific literature that describe empirical research with FRAM for assessing the effectiveness of controls for the plan-adaptation process of proton therapy.

From a societal point of view this research will contribute to the knowledge of the quality assurance manager and the involved healthcare professionals on which actions and controls are effective to manage risks for the plan-adaptation process at HollandPTC. The quality assurance manager is responsible that throughout the sequential process of treatment, the quality is maintained and that the patient receives the correct prescribed treatment with a high confidence [33]. The clinical implementation of the plan-adaptation process at HollandPTC is still a novelty, but the clinical benefits for patients by optimising the plan during the treatment are highly promising as a more robust dose distribution can be ensured [40][37]. Assessing the plan-adaptation process at HollandPTC by investigating how "everyday performance" affects the process and investigating which controls are effective to mitigate risks, will contribute to the quality of the overall treatment of patients.

1.4. THESIS OUTLINE

The outline of this thesis is illustrated in figure 1.7. Chapter 2 describes the theoretical framework that is used for the case study at HollandPTC to identify whether the complex prospective risk analysis method FRAM results in different potential risks compared to the linear prospective risk analysis method HFMEA. The conceptualisation section, chapter 3 and 4 reveals how the plan-adaptation process is done according to the procedures and according to the involved actors during "everyday performance". This leads

to detailed conceptual models of the plan-adaptation process. Chapter 5 discusses potential risks identified with the FRAM method. These potential risks are compared with the risks identified with the linear method HFMEA in chapter 6. Based on these findings a general strategy is proposed in chapter 7 to identify which controls are able to mitigate and monitor risks . Lastly, chapter 8 concludes and discusses the outcomes of this research.
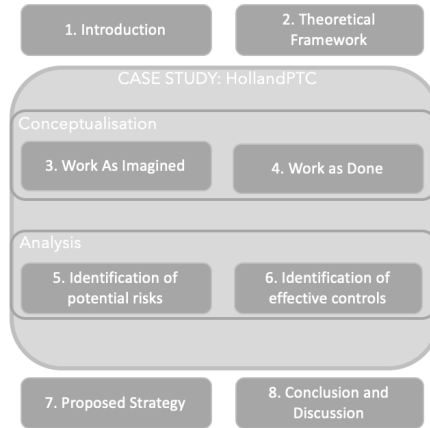
Figure 1.7: Thesis outline. The number in each quadrant refers to the corresponding chapter in this thesis.

2

RESEARCH APPROACH

This chapter covers the research approach that was developed to conduct this research. Section 2.1 describes the risk analysis methods that are used in this thesis. Section 2.2 introduces the case study conducted at HollandPTC. In section 2.3 it is discussed how the results are verified and validated. Lastly, section 2.4 describes how the strategy is developed.

As discussed in section 1.3 the aim of this research is to design a strategy that allows to identify which controls are able to monitor and mitigate risks in a process. Figure 2.1 illustrates the research approach used in this thesis to develop this strategy. Each step is elaborated on in the sections below.
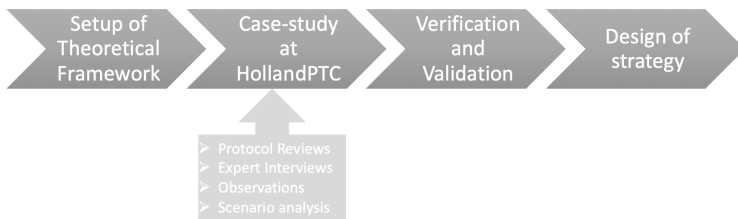
Figure 2.1: Research approach developed and used to conduct this research.

2.1. SETUP OF THEORETICAL FRAMEWORK

During the setup of the theoretical framework prospective risk analysis methods suitable to assess complex socio-technical systems were reviewed as part of a literature study [63]. Additionally, the gaps in literature which were discussed in section 1.3, were identified with help of this literature study.

2

Since the deliverables of this research is a strategy for assessing the effectiveness of controls to mitigate risks, the characteristics of a potential risk are first explored. Secondly, the prospective risk analysis methods FRAM and HFMEA will be introduced which were identified with the literature study. Both methods can be used to identify potential risks in a complex socio-technical system; HFMEA meets the linear view on safety and FRAM meets the systemic view on safety. Many complex socio-technical systems have integrated HFMEA already as prospective risk analysis method to asses processes. FRAM allows to capture variability due to "everyday performance" in processes which might lead to different potential risks that cannot be identified with HFMEA. In this research we aim to see whether risks are present in the process that cannot be identified with HFMEA and to design a strategy that allows to capture process related risks and "everyday performance" related risks. In order to make a reliable comparison between the results obtained with HFMEA and FRAM the methods should be applied independently on the same case study.

POTENTIAL RISKS
Throughout this thesis a potential risk is defined as: *An event that can result in an adverse effect —either minor or serious— which is not negligible from the point of view of protection or safety. All treatment-related side effects are excluded." [46] [64].* To be clear; when we talk about a risk in this thesis, these risks are related to the process under review. Treatment related side effects for the patient due to the process under review are outside the scope of this thesis.

HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS (HFMEA)
The healthcare failure mode and effect analysis (HFMEA) was designed by the National Center for Patient Safety and was derived from high-risk industries to meet the need to conduct a prospective analysis of healthcare settings [13]. A HFMEA consists of the following five steps [13]:

1. DEFINE THE HFMEA TOPIC: choose a potentially high-risk process to review.
2. ASSEMBLE THE TEAM; a multidisciplinary team should be assembled from staff members that are involved in the process. Furthermore, a team leader should be assigned to lead the analysis.
3. GRAPHICALLY DESCRIBE THE PROCESS: the process under review should be described with a flow diagram such as an IDEF0 model.
4. CONDUCT A HAZARD ANALYSIS: all the potential failure modes of the process under review should be listed by the team. Next, the cause, likelihood and severity of each potential failure mode should be determined and the Hazard scoring matrix should be used to determine the hazard score. Lastly, the HFMEA Decision Tree should be used to determine whether a potential failure mode requires further action based on criticality, absence of effective control measures, and lack of detectability.
5. FORMULATE ACTIONS AND OUTCOME: For those failure modes that require further action, actions should be formulated and assigned to a single member of the team.

Functional Resonance Analysis Method (FRAM)

The functional resonance analysis method (FRAM) originally developed by Hollnagel et al, [24] [50] focuses on how an activity/function is achieved within a system and is suitable for highly inter-dependable systems. It distinguishes two types of work: work-as-imagined (WAI) and work-as-done (WAD). WAI reflects how the work should be done according to the the various procedures/protocols that are in place. WAD reflects how the work is done according to the participants. Capturing WAI and WAD with FRAM models during a prospective risk-analysis allows to implement guidelines more smoothly as performance variability due to workarounds such as naturally developed individual systems can be identified in an early stage [5][8]. A FRAM model is created by applying the following four steps [26] [48]:

1. IDENTIFY ALL THE FUNCTIONS/ACTIVITIES AND CHARACTERISE THE SIX ASPECTS OF EACH FUNCTION/ACTIVITY FOR A CHOSEN INSTANTIATION [26] A function/activity describes what a person(s) has to do to execute a task in the system. The aspects (input, output, time, resource, control and time) characterise a function. Couplings can arise between the aspects of various functions.

2. CHARACTERISE THE POTENTIAL AND ACTUAL VARIABILITY OF EACH FUNCTION/ACTIVITY [26] Three types of variability are recognised; internal, external and functional upstream-downstream coupling. Internal variability refers to variability of the activity itself. External variability refers to the conditions in which an activity is executed. Functional upstream-downstream coupling variability refers to variability due to the output of upstream functions that affect the aspects of the function under review [26] [48]. Potential variability describes what might happen under different conditions. Actual variability describes what should be expected realistically.

3. DETERMINE THE POSSIBILITY OF FUNCTIONAL RESONANCE BASED ON COUPLINGS AMONG SYSTEM FUNCTIONS/ACTIVITIES GIVEN THEIR VARIABILITY [26] Identify how variability may resonance throughout the instantiation.

4. FORMULATE RECOMMENDATIONS ON HOW TO MONITOR AND INFLUENCE THE IDENTIFIED VARIABILITY [26] Look for ways to control, amplify or dampen a certain variability rather than to alleviate the variability.

Box 1.1 shows how a function/activity is visualised in a FRAM model; a hexagon represents an activity ○ TO DO X. The circles connected to the hexagon represent the six aspects and characterise an activity/function : input, output, time, resource, control and precondition.

2

Box 1.1 - Graphical representation of FRAM
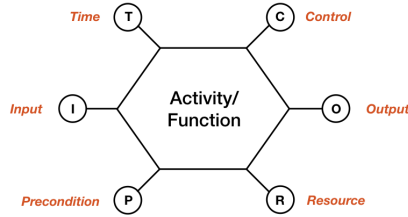
Input (I) ; That what activates the activity/function and/or what is transformed by the activity/function[24] [51] [49].
Output (O); The result of the activity/function which can be either a state change or physical product[24] [51] [49].
Precondition (P); Systems conditions that need to take place/exist prior to the activity of the activity/function[24] [51] [49].
Resources (R); That what is needed or consumed by the activity/function[24] [51] [49] .
Time (T); Temporal constraints that effects the activity/function [24] [51] [49] .
Control (C); Object or state that supervises or regulates the activity/function [24] [51] [49] .

2.2. CASE-STUDY

During the case study at HollandPTC empirical evidence is collected to be able to make an analytical generalisation for constructing a strategy to identify which controls are effective to monitor and mitigate risks in a complex socio-technical system [67]. The plan-adaptation process was assessed prior to this research by the organisation with a HFMEA to release the plan-adaptation workflow for clinical practices. The researcher of this thesis received the results of the HFMEA only after completing the FRAM which makes an independent comparison possible.

MOTIVATION

The plan-adaptation process at HollandPTC was chosen as case-study because proton therapy is a multistage process that involves many types of professional expertise and can be classified as a complex socio-technical system as is shown in section 1.2. Throughout all stages of a treatment: 'tumour localisation, patient immobilisation, field placement, daily patient setup, dose calibration, calculation, treatment delivery and verification, as well as for equipment commissioning and maintenance' a high accuracy and precision is required from each involved actor and system, to ensure maximum targeting of the tumour with the lowest risk for a patient [64]. As discussed in section 1.2, the efficiency of the plan-adaptation process is critical because the treatment plan is no longer optimal to treat the patient. Adherence of protocols, skills and competence need to be in place to prevent incidents during this complex process. Where an incident is

defined according to the International Atomic Energy Agency (IAEA): "any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorised act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection and safety" [2].

APPROACH
First, the protocols of the process of plan-adaptation at HollandPTC were reviewed. The literature study together with the information from the protocols were used as input to design the conceptual work-as-imagined (WAI) model of the process plan-adaptation. Secondly, 6 semi-structured interviews were conducted with the various actors involved in the process of plan-adaptation at HollandPTC (see appendix A). To identify which actors should be involved the actor identification technique proposed by Mitroff was used [10] [15] [44] . Each identified actor is involved in the treatment on a daily basis, has extensive knowledge on the treatment, is able to adapt itself to the varying work scenarios, is involved in policy making and is therefore highly valuable to involve in the risk-analysis [15]. All actors are validated by the problem owner. Observations were done during the treatment of 5 unique patients as a supplement to the interviews and to supplement the knowledge of the researcher [28]. HollandPTC has joined PRISMA-RT; a collaboration of seventeen radiotherapeutic institutions in the Netherlands that have created a benchmark database for reporting incidents. The main goal of this organisation is to "compare radiotherapy at the level of process reliability and thus to improve the whole radiotherapy process in safety and quality by learning from each other" [54]. The affiliation with this organisation serves as an indicator of the presence of a safety culture at HollandPTC; the actors are willing to report and learn from incidents [58] [65]. The in-depth interviews together with the observations served as input for the conceptual work-as-done (WAD) model of the process plan-adaptation.

2.3. VERIFICATION AND VALIDATION
The WAI and WAD models were verified with the involved healthcare professionals during validation meeting. During this meeting context scenario's were described by the involved healthcare professionals by challenging them to to come up with realistic failure scenario's to identify potential failures and by comparing the variability of the couplings of the WAI with WAD model [15] [23] [55]. The identified potential risks were validated during this meeting. Finally, the potential risks identified with FRAM are compared with the potential risks identified with HFMEA to assess effectiveness of the proposed controls designed with HFMEA.

2.4. DESIGN OF STRATEGY
The results of the case-study served as input for the design of the strategy to assess the effectiveness of controls to monitor and mitigate risks. By using the risk analysis methods independently for the same case study, strengths from both methods can be identified and united to create a strategy that is the best of both worlds.

CONCEPTUALISATION

3

WORK AS IMAGINED

Work-as-imagined (WAI) represents the various ideas that people have on how the plan-adaptation process should be done based on procedures/protocols. Every activity that is described within a hexagon in the Work-As-Done model in figures 3.6 and 3.7, is indicated by ⬡ TO DO X in the text. Furthermore, the colour of the hexagon and the underlining of the text corresponds to the health care professional mainly responsible for the execution of this specific activity. Functions which are defined by having an input or an output only, are visualised by a quadrant in the model.

3.1. IMAGING

⬡ TO CREATE CARE PATH RCT-SCAN When a patient has a tumour in the head/neck region the logistic planner has to schedule a weekly rCT-scan appointment for the patient in ARIA. The logistic planner receives this task from the treating radiation oncologist of the patient. An extra request to schedule the care path rCT-scan can be placed by the radiation oncologist when anatomical variation is observed in between these weekly rCT-scans that is so severe that the patient cannot wait until the next scheduled rCT-scan.

⬡ TO MAKE A RCT A rCT-scan of a patient is made by a radiotherapy technologist (Gantry/CT-scan) according to the schedule in ARIA. When the radiotherapy technologist (Gantry/CT-scan) has finished the rCT-scan of a specific patient, the task is manually signed off in ARIA.

The instantiation imaging of a patient is illustrated in detail in figure 3.1.

3.2. EVALUATION OF THE TREATMENT PLAN

⬡ TO MERGE CT-SCANS The radiotherapy technologist (dose planning) checks the work list in ARIA regularly to see whether a rCT-scan has been made for a specific patient. When this is the case, the rCT-scan is merged with the treatment CT-scan by the radiotherapy technologist (dose planning).

⬡ TO EXPORT OAR AND CTV FROM TREATMENT PLAN CT-SCAN For the specific patient, the contoured organs at risk (OAR) and the clinical target volume (CTV) are copied from

3
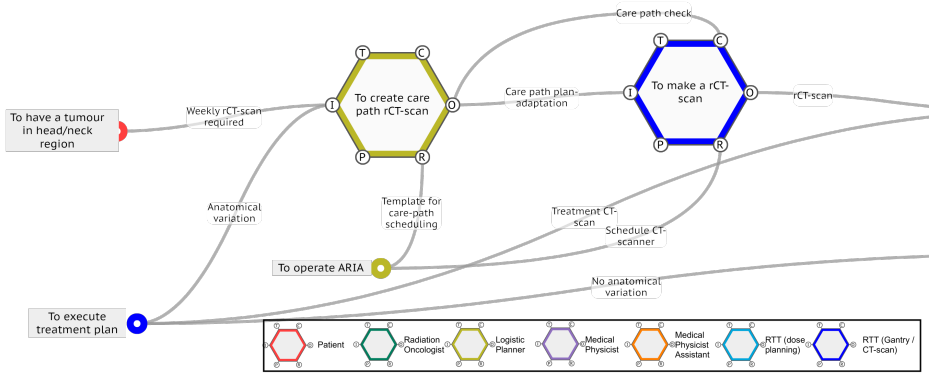
Figure 3.1: Instantiation of the WAI-model that represents imaging of the patient. There are two ways to start the instantiation; a patient has a tumour in the head/neck region and thus requires a weekly rCT-scan or urgent anatomical variation at the gantry is observed that is so severe the patient cannot wait until the scheduled rCT-scan. This also includes a misfit of the mask.

the treatment CT-scan to the rCT-scan.

○ TO TEST ORIGINAL TREATMENT PLAN FOR ROBUSTNESS The treatment plan is tested on the rCT-scan for its robustness.

○ TO EVALUATE OUTCOME OF ROBUSTNESS TEST As soon as the test results are ready the radiotherapy technologist (dose planning) contacts the radiation oncologist of the day. The radiation oncologist evaluates the results together with the medical physicist of the day and the radiotherapy technologist (dose planning). The decision whether plan-adaptation is required, is documented in NeoZis by the radiation oncologist of the day. The radiotherapy technologist(dose planning) documents the decision in a journal of ARIA.

The instantiation evaluation of the treatment plan is illustrated in figure 3.2.
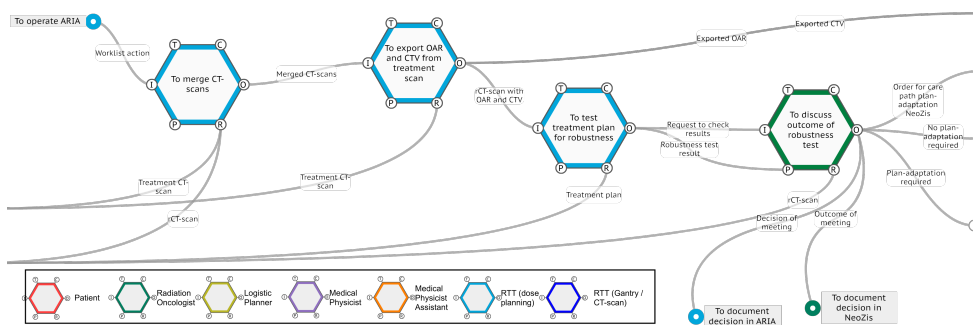
Figure 3.2: Instantiation of the WAI-model that represents the evaluation of the treatment plan. The outcome of the evaluation determines whether the care path plan-adaptation is initiated.

3.3. Designing the adapted treatment plan

○ To continue treatment with treatment plan When it is decided that no plan adaptation is required for the specific patient, the patient continues to receive the fractions according to the treatment plan.

○ To adapt OAR and CTV When it is decided that plan-adaptation is required for the specific patient, the radiation oncologist of the day adapts the OAR and CTV to perfectly match the rCT-scan structures.

○ To create care path plan-adaptation The radiation oncologist of the day requests the logistic planner to create the care path plan-adaptation for the specific patient in NeoZis. The care path plan-adaptation is created by the logistic planner in ARIA with a template that contains all the checks for this specific care path.

○ To create the adapted treatment plan When the OAR and CTV are adapted the radiotherapy technologist(dose planning) creates the adapted treatment plan in RayStation. The template for the total number of fractions is used to create the adapted treatment plan.

○ To check the adapted treatment plan and to adapt no. of fractions When the radiotherapy technologist (dose planning) has created the plan the radiation oncologist of the day is contacted to check the adapted treatment plan. If the radiation oncologist agrees with the adapted plan, the number of fractions of the adapted treatment plan is adjusted in RayStation. This is required because the number of fractions of the adapted treatment plan should exactly match the number of fractions that are left in the treatment plan when the adapted treatment plan is started to prevent a mismatch in dose.

○ To import adapted treatment plan in ARIA When the number of fractions are adjusted the radiation oncologist of the day approves the plan in RayStation. The plan is imported into ARIA by the radiotherapy technologist (dose planning).

The instantiation design of the adapted treatment plan is illustrated in figure 3.3.
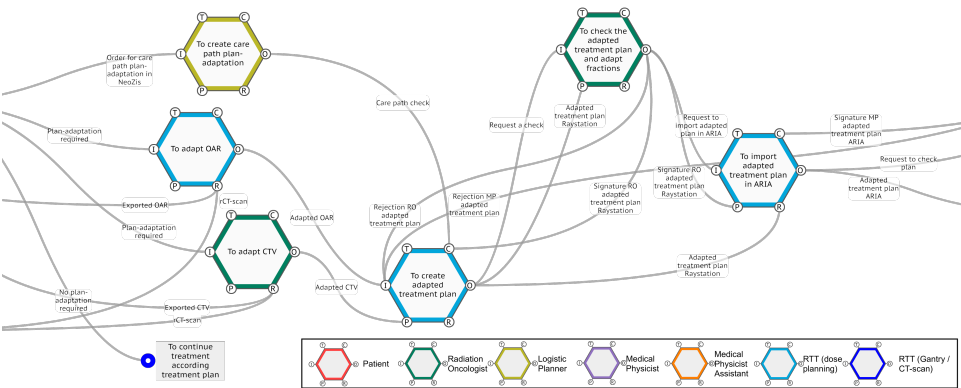
Figure 3.3: Instantiation of the WAI-model that represents the design of the adapted treatment plan.

3.4. QUALITY ASSURANCE

◌ TO CHECK THE ADAPTED TREATMENT PLAN IN ARIA The medical physicist of the day is contacted by the radiotherapy technologist (dose planning) when the plan is imported in ARIA. The medical physicist performs a physics check. If the adapted treatment plan is approved this is signed off in ARIA.

◌ TO PREPARE QA The medical physicist assistant checks the work list regularly for updates. When the medical physicist has approved the adapted treatment plan, the task to prepare the QA will appear in the work list. The medical physicist assistant will then start to prepare the QA.

◌ TO EXECUTE QA As soon as the QA is prepared and a gantry is available the QA is executed by the medical physicist assistant.

◌ TO CHECK THE QA RESULTS The medical physicist of the day is contacted by the medical physicist assistant when the results of the QA are ready. The medical physicist checks these results.

The instantiation quality assurance (QA) is illustrated in figure 3.4.
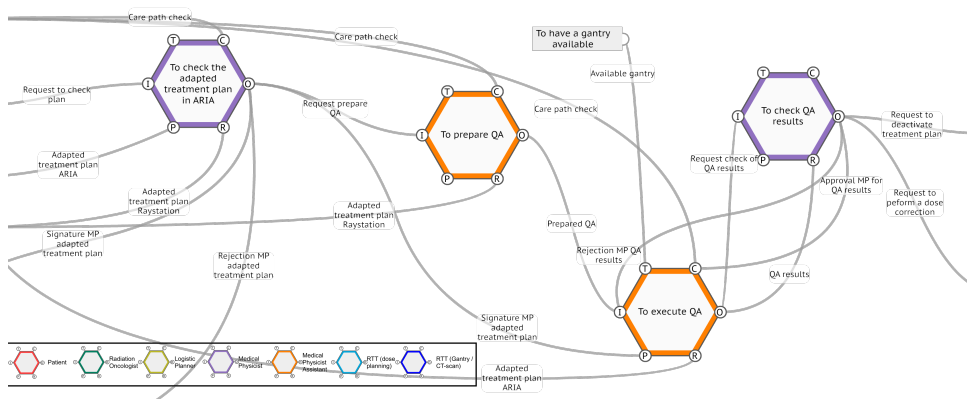
Figure 3.4: Instantiation of the WAI-model that represents the quality assurance of the adapted treatment plan.

3.5. IMPLEMENTATION OF THE ADAPTED TREATMENT PLAN

◌ TO DEACTIVATE THE ORIGINAL TREATMENT PLAN When the medical physicist approves the QA results, the original treatment plan is deactivated in ARIA by the radiotherapy technologist (dose planning).

◌ TO PERFORM A DOSE CORRECTION The total dose of the adapted treatment plan is manually adjusted with the dose committed to the specific patient with the treatment plan.

◌ TO EXECUTE ADAPTED TREATMENT PLAN The adapted treatment plan is approved in ARIA by the medical physicist and is executed by the radiotherapy technologist (Gantry/CT-scan).

◌ TO CHANGE MASKS In case a new mask was created, the masks are interchanged in the closet by the radiotherapy technologist(Dose planning). *The implementation of the adapted treatment plan is illustrated in figure 3.5.*
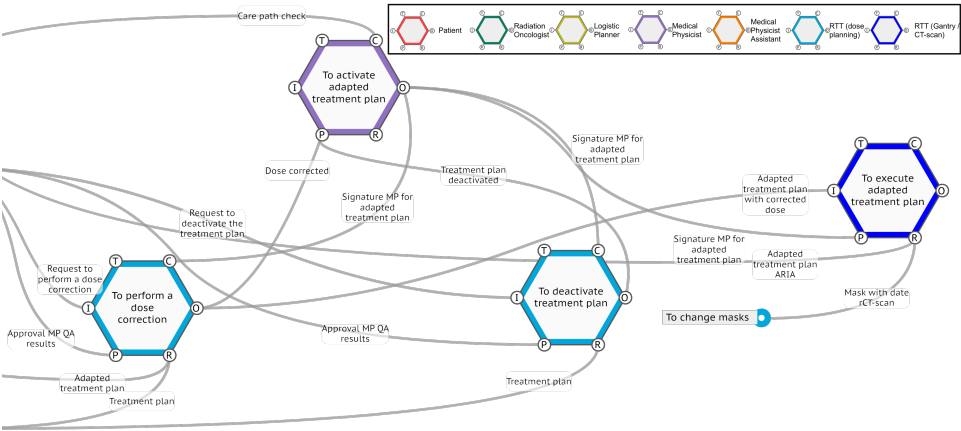
Figure 3.5: Instantiation of the WAI-model that represents the implementation of the adapted treatment plan.
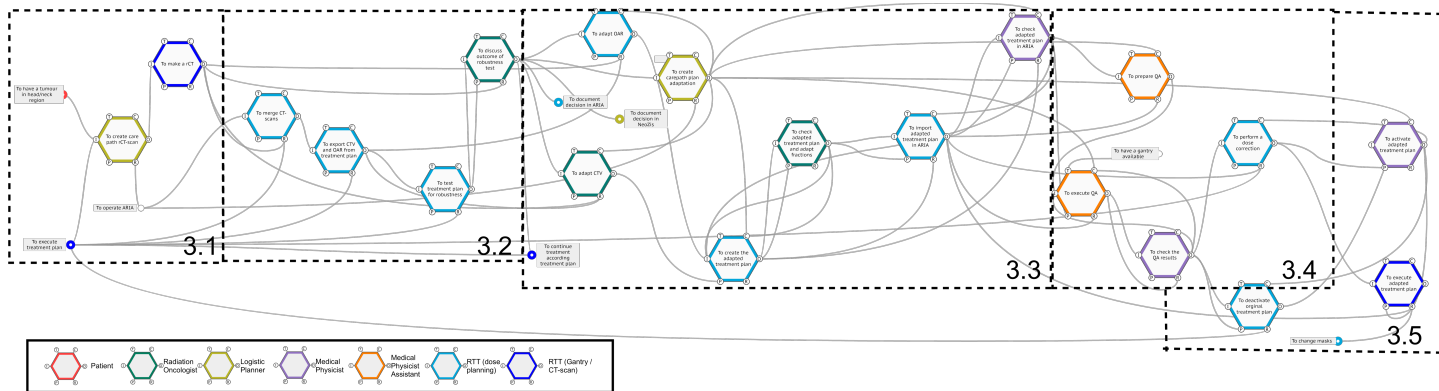
Figure 3.6: Work as imagined (WAI) model of the care path plan-adaptation model. The circles connected to the hexagon represent the aspects related to a function: **I** = input, **O** = output, **C** = control, **T** = time, **P** = precondition and **R** = resource. The hexagons are presented in an arbitrary order. The number in each corner refer to the section in which this instantiation of the model is discussed.

Figure 3.7: Work as imagined (WAI) model of the care path plan-adaptation model including all the labels of the aspects that are used. The circles connected to the hexagon represent the aspects related to a function: **I** = input, **O** = output, **C** = control, **T** = time, **P** = precondition and **R** = resource. The hexagons are presented in an arbitrary order.

4

WORK AS DONE

*This chapter describes how the plan-adaptation is actually executed: 'work as done'. To get an impression of the actual proces of plan-adaption, health care professionals involved in the process of plan-adaptation were interviewed and observed. Every activity that is described within a hexagon in the Work-As-Done-model in figure **??**, is indicated by ⬡ TO DO X in the text. Furthermore, the colour of the hexagon and the underlining of the text corresponds to the person who is mainly responsible for the execution of this specific activity. Functions which are only defined by an input or an output are visualised by a quadrant in the model. Figure 4.7 shows the complete WAD-model with boxes that refer to the various sections described below.*

4.1. IMAGING

⬡ TO SCHEDULE rCT-SCAN CARE PATH For the radiation of a patient with a tumour in the neck/head region it is pivotal to have actual and detailed anatomic information on the tumour region. During the radiation-treatment process, anatomic changes are expected. Therefore, a weekly rCT-scan is scheduled by the logistic planner by creating a rCT-scan care path in ARIA. The template that is available for scheduling this pathway contains both the correct appointments and care path checks for the caregivers. These checkpoints ensure that the next activity of the pathway becomes available in the schedule of the next caregiver. While scheduling the care path, the logistic planner has to pay attention to the fact that a patient has other consults including appointments at other institutes for, for instance chemotherapy. Furthermore, the logistic planner has to take in consideration that both a CT-scanner and staff have to be available when the appointment is scheduled. Next to taking care of all the scheduling, the logistic planner is a nurse as well. As a result the daily activities have to be prioritised to urgent/normal. Requests to plan an extra rCT-pathway are given to the logistic planner by the radiation oncologist when urgent anatomical variation is observed at the cone beam CT-scan on the gantry in between the regular weekly CT-scans.

⬭ TO MAKE A RCT-SCAN The radiotherapy technologist that works at the CT-scanner uses ARIA to obtain the schedule of patients for the CT-scan. The care path check ensures that the work list in ARIA is updated as soon as the radiotherapy technologist gives the signature that the scan has been completed. Rescheduling or time delays can occur when there is a malfunctioning of the CT-scanner.

Figure 4.1 illustrates this specific instantiation of the plan-adaptation process.
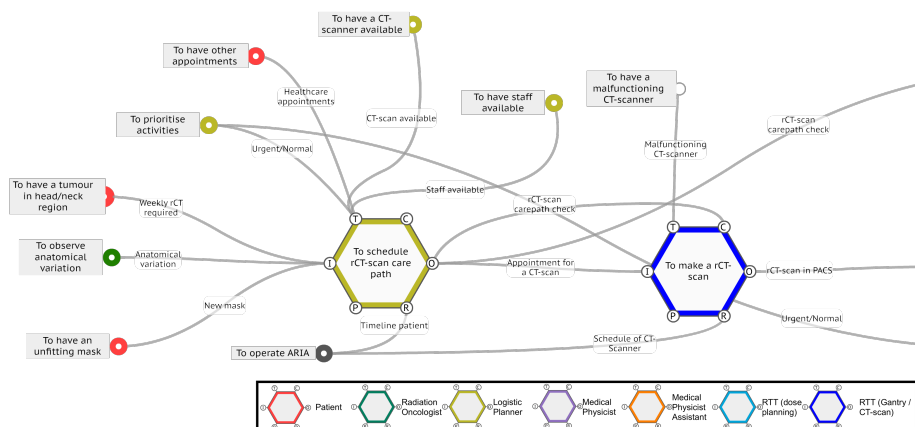
Figure 4.1: Instantiation of the WAD-model that represents the imaging of a patient. Interviews showed that there are three ways to start the pathway; 1.a patient has a tumour in the head/neck region and thus requires a weekly rCT-scan. 2. Urgent anatomical variation at the cone beam CT-scan is observed that is so severely one cannot wait until the scheduled rCT-scan. 3.The mask does not longer fit the patient.

4.2. EVALUATION OF THE TREATMENT PLAN

⬭ TO CHECK WORK LIST REGULARLY A radiotherapy technologist(dose planning) checks the work-list in ARIA regularly during the day in between the regular activities. When the rCT-scan of the patient is still on the status pending the radiotherapy technologist(dose planning) will continue the regular work. If the status of the rCT-scan has changed to available in the work list upon checking, the radiotherapy technologist(dose planning) will prioritise this rCT-scan over the regular work if it concerns the scan of a potential plan-adaptation patient.

⬭ TO IMPORT RCT-SCAN IN RAYSTATION The rCT-scan is selected in the archive of PACS and transferred to RayStation.

⬭ TO MERGE CT-SCANS The organs at risk(OAR) and clinical target volumes(CTV) are copied to the rCT-scan from the planning CT-scan to make it possible to compare the rCT-scan with the planning CT-scan. Furthermore, a rectangular box needs to be drawn around the external of the patient in the rCT-scan. This is required for the script that merges the rCT-scan with the planning CT-scan. The merger is done with both a rigid fusion and a deformable fusion. As soon as the merger is finished the radiotherapy technologist(dose planning) contacts the radiation oncologist to check the merger. If the regular radiation oncologist is not available the radiation oncologist on call will be con-

tacted to check the merger.

○ TO CHECK THE MERGER OF THE CT-SCANS. The radiation oncologist checks the merger together with the radiotherapy technologist(dose planning). If the merger is correct the radiotherapy technologist(dose planning) will continue with the evaluation of the rCT-scan.

○ TO RUN A ROBUSTNESS TEST AND TEST SCENARIOS The robustness of the treatment plan is tested on the rCT-scan with the copied OAR and CTV. The availability of a computer and its process power influence the time it takes to run the tests. When the test results are available the radiotherapy technologist(dose planning) phones the medical physicist on call and the radiation oncologist on call to arrange a meeting to present the results.

○ TO EVALUATE TEST RESULTS During this meeting it is decided whether plan adaptation is required or not. If no plan adaptation is required, the treatment will continue as planned. A note is made in ARIA by the radiotherapy technologist(dose planning) with the decision whether plan adaptation is required or not. The radiation oncologists documents the same decision in NeoZis.

○ TO CONTINUE WITH TREATMENT PLAN When it is decided that plan adaptation is not required, the patient will continue with the treatment plan. The other radiotherapy technologists are informed at the morning meeting on this decision. Figure 4.2 shows the instantiation of evaluation of the treatment plan.
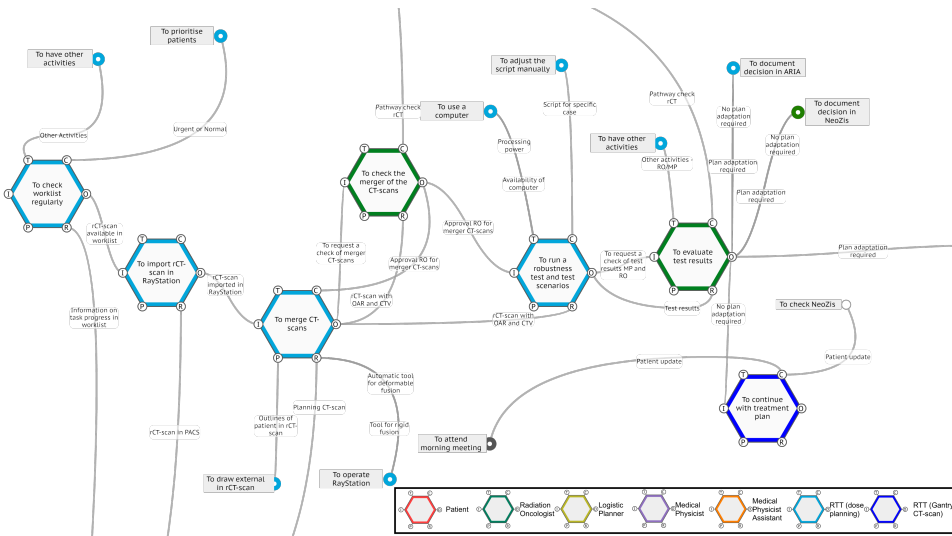
Figure 4.2: Instantiation of the WAD-model that represents the evaluation of the treatment plan. The outcome of the evaluation determines whether the care path plan-adapatation is initiated.

4.3. DESIGNING THE ADAPTED TREATMENT PLAN

○ TO ATTEND MORNING MEETING The logistic planner is notified during the morning meeting on the decision when plan adaptation is initiated.

○ TO CREATE CARE PATH PLAN-ADAPTATION The logistic planner creates the plan-adaptation pathway as soon as possible after attending the morning meeting, but delays can occur due to other activities related to patient. The care path plan-adaptation is created with a template for plan-adaptation which contains the checkpoints for the workflow.

○ TO EVALUATE OAR AND CTV Once it has been decided that plan adaptation is required, the radiotherapy technologist and radiation oncologist will review the fusion of the OAR and CTV on the rCT-scan again to ensure that the correct volumes will be treated.

○ TO ADAPT OAR AND CTV If required the OAR and CTV are adapted to perfectly match the structures present in the rCT-scan.

○ TO CREATE ADAPTED TREATMENT PLAN The adapted treatment plan is created by a radiotherapy technologist(dose planning) when the OAR and CTV match the rCT scan. A template, that contains a full treatment, is used to design the adapted treatment plan. When the new plan is created the radiotherapy technologist(dose planning) phones the radiation oncologist on call to set up a meeting to check the adapted treatment plan.

○ TO ADJUST NR. OF REMAINING FRACTIONS ADAPTED TREATMENT PLAN Since some radiation fractions are already administered to the patient, plan-adaptation also includes the subtraction of fractions administered to ensure the correct total dose to be administered. The radiation oncologist validates this number in RayStation and approves the adapted treatment plan in RayStation. If approved, credentials are provided in the care path plan-adaptation in ARIA. Once the fractions are adjusted it is not possible to change it again later on in the process. Only creating a new radiation plan offers the opportunity to change the number of remaining fractions.

○ TO IMPORT THE ADAPTED TREATMENT PLAN IN ARIA When the radiation plan with the adjusted number of fractions is signed by the radiation oncologist, the radiation plan is imported in ARIA. The radiotherapy technologist(dose planning) contacts the medical physicist on call to inform that the adapted radiation plan is ready to be reviewed.

○ TO CHECK THE ADAPTED TREATMENT PLAN The adapted treatment plan is checked by the medical physicist thoroughly and if approved it is signed in ARIA. Furthermore, the medical physicist contacts the medical physicist assistant to start preparing the quality assurance. Figure 4.3 shows the instantiation of rCT-evaluation.

Figure 4.3: Instantiation of the WAD-model that represents the adaptation of the treatment plan. During this instantiation of the process a new treatment plan is created.

4.4. QUALITY ASSURANCE

◯ TO CHECK WORKLIST REGULARLY The medical physicist assistant checks the work list regularly in between other activities. The task to start preparing the QA becomes available in ARIA when the MP signs of the evaluation of the adapted treatment plan.

◯ TO PREPARE QA The QA is prepared when the task is either available in ARIA or the MPA is called by the MP to start preparations. The MPA prepares the QA by manually exporting the adapted treatment plan in ARIA to the local I-drive of the computer. This plan is imported manually into IBA-dosimetry software.

◯ TO EXECUTE QA When the preparation of the QA is finished and the medical physicist has validated the adapted treatment plan in ARIA the execution of the QA can start. The availability of a gantry is critical here; if there is no gantry available the process will be delayed. To execute the QA the dosimetry hardware has to be installed at the gantry. Furthermore, the QA-mode has to be selected in ProBeam. If this mode is not used during the QA, a fraction will be lost.

◯ TO ANALYSE QA When the results are finished a report of the analysis is automatically compiled by the IBA-software. The report is analysed by the medical physicist assistant and uploaded into ARIA.

◯ TO VALIDATE QA RESULTS As soon as the results of the analysis are ready the medical physicist is called by the medical physicist assistant to inform that the results can be reviewed. The medical physicist validates the analysis. If not agreed the QA has to be done again or the entire adapted treatment plan has to be designed again by the radiotherapy technologist(dose planning). At this point the MP should not give his credentials in ARIA, as other actions still need to be taken. Figure 4.4 shows the instantiation of rCT-evaluation.

Figure 4.4: Instantiation of the WAD-model that represents the quality assurance of the model. During this instantiation of the process the adapted treatment plan .

4.5. IMPLEMENTATION OF THE ADAPTED TREATMENT PLAN

○ TO CHANGE STATUS TREATMENT PLAN TO 'COMPLETED EARLY' When the MP agrees with the results of the QA the RTT is requested to inactivate the treatment plan. This is done by activating the box 'completed early'. The credentials of the MP are required to confirm this action. Currently, the user rights for this action are only given to the account of the MP.

○ TO PERFORM A DOSE CORRECTION The RTT is also requested to perform a dose correction in ARIA. The total dose given in the treatment plan has to be manually added to the dose of the adapted treatment plan. Currently, the user rights for this action are only given to the account of the MP.

○ TO ACTIVATE THE ADAPTED TREATMENT PLAN The adapted treatment plan becomes available when the MP activates it with his credentials. The activation should not take place before the dose correction and the inactivation of the treatment plan. However, it is possible to activate it when these actions have not yet taken place.

○ TO CHANGE MASKS If it was required to design a new mask for the patient, the masks need to be exchanged in the closet prior to the treatment with the adapted treatment plan. This usually happens after being informed at the morning start.

○ TO USE THE ADJUSTED TREATMENT PLAN When the dose correction of the adapted treatment plan, the inactivation of the treatment plan and the exchange of the masks has taken place the adjusted treatment plan can be used. As it concerns a new plan, the RTT have to calculate the table position prior to the treatment. Furthermore, lines need to be drawn on the mask if a new mask was designed. This causes the first treatment to last approximately 15 minutes longer compared to a regular treatment session.
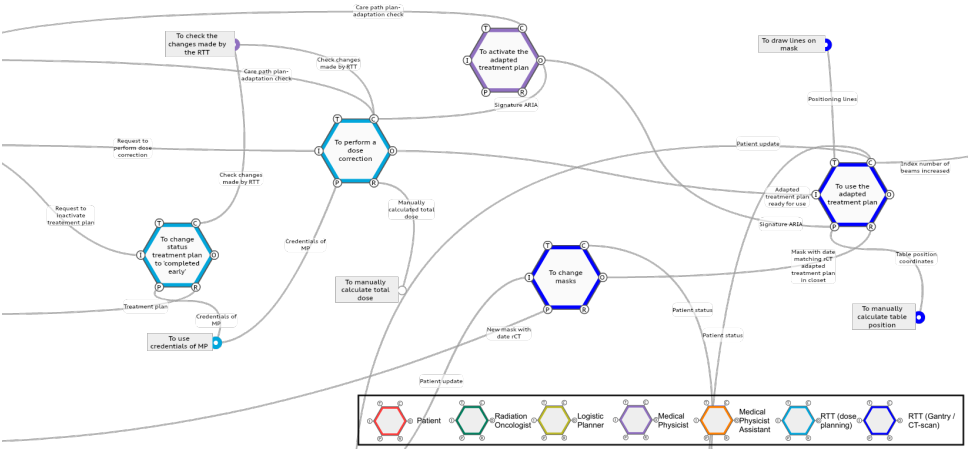
Figure 4.5: Instantiation of the WAD-model that represents the administering of the adapted treatment plan.
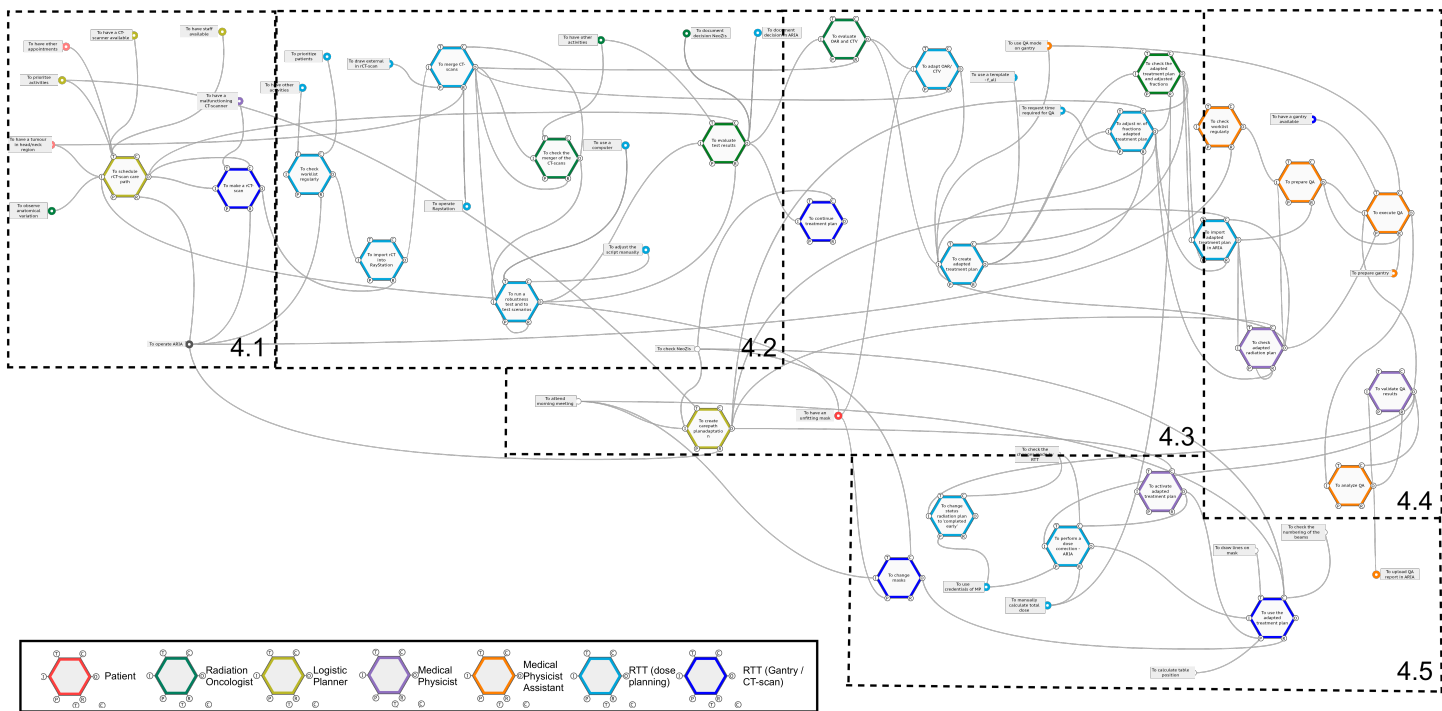
Figure 4.6: Work as Done (WAD) model of the care path plan-adaptation including all the labels of the aspects that are used. The circles connected to the hexagon represent the aspects related to a function: **I** = input, **O** = output, **C** = control, **T** = time, **P** = precondition and **R** = resource. The hexagons are presented in arbitrary order

Figure 4.7: Work as Done (WAD) model of the care path plan-adaptation including all the labels of the aspects that are used. The circles connected to the hexagon represent the aspects related to a function: **I** = input, **O** = output, **C** = control, **T** = time, **P** = precondition and **R** = resource. The hexagons are presented in arbitrary order

ANALYSIS

5

WAI VS WAD

This chapter describes the analysis of the collected data; potential risks (functional resonance) within the process of plan-adaptation are identified by comparing the couplings and their variability in the work-as-imagined (WAI) model with the work-as-done (WAD) model. In section 5.1 activities are discussed which are affected by performance variability. Sectoin 5.2 activities are discussed which are affected by time. The potential risks and the feasibility of the opportunities for improvement in the process of plan-adaptation were discussed during a group-session in which all interviewees participated. The validation is based on three plan-adaptation cases.

The goal of plan-adaption is to create an adapted treatment plan within a short period of time (ideally within 2-3 days from the rCT-scan). From interviews it was observed that work-as-done, i.e. "everyday performance", resulted in performance variability throughout the process of plan-adaptation. All functions are analysed by comparing them with the functions of the work-as-imagined model. Figure 5.2 shows the activities that are identified in the WAD model but were not identified for the WAI model. Figure 5.1 provides an overview of the impact of an activity's timing and/or precision on downstream functions in the work-as-done model. The identification of the impact of a function in the downstream couplings helps to identify risks.

5.1. PERFORMANCE VARIABILITY
The functions that are damped or increased due to performance variability are discussed below and have been validated with the involved actors. Moreover, the potential risks that arise from the performance variability are explored here.

5.1.1. CARE PATH PLAN-ADAPTATION
◯ TO CREATE CARE PATH PLAN-ADAPTATION The procedures used to create the WAI-model showed that the care path plan-adaptation is created in ARIA by the logistic planner when the radiation oncologist sends an order in NeoZis to create the pathway.
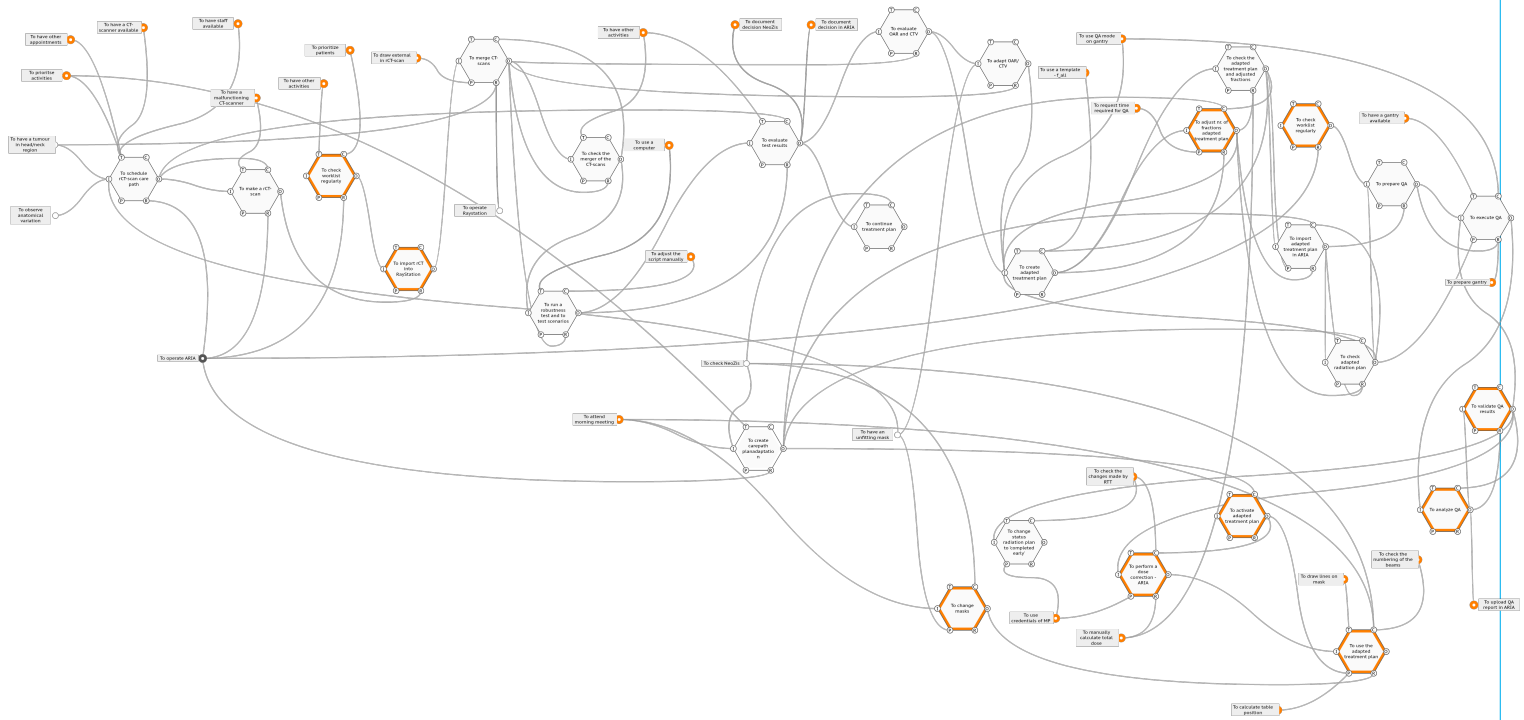
Figure 5.1: Comparison of the WAI model with the WAD model. All the activities shown in orange are activities that were solely identified for the WAD model. All activities shown in white were present in both models.

Activity	Impact	T/P	Activity	Impact	T/P
1. To schedule care path rCT-scan	red	T	15. To check adapted treatment plan and adjusted fractions	red	TP
2. To make a rCT-scan	yellow	P	16. To check worklist regularly	green	
3. To check worklist regularly	green		17. To prepare QA		T
4. To import rCT into RayStation	green		18. To execute QA	red	TP
5. To merge CT-scans	yellow	P	19. To import adapted treatment plan in ARIA	green	
6. To check merger of CT-scans	green		20. To check the adapted treatment plan	yellow	P
7. To run a robustness test and to test scenarios	green		21. To analyze QA results	green	
8. To evaluate test results	green		22. To validate QA results		P
9. To continue with treatment plan	green		23. To change status treatment plan to completed early		T
10. To create care path plan-adaptation	red	T	24. To perform a dose correction		P
11. To evaluate OAR and CTV	green		25. To activate the adapted treatment plan		T
12. To adapt OAR and CTV	yellow	P	26. To change masks	red	T
13. To create adapted treatment plan	red	TP	27. To use the adapted treatment plan		
14. To adjust nr. of fractions	yellow	TP			

Legend:

red	Function's timing and/or precision have a serious effect on how downstream functions are performed.
yellow	Function's timing and/or precision have a potential effect on how downstream functions are performed
green	Functions' timing and/or precision have a limited/negligible effect on how downstream functions are performed.

T/P Predominantly affected by **T**iming or **P**recision

Figure 5.2: Overview of the impact of a function's timing and/or precision on downstream functions.

The logistic planner checks NeoZis regularly, notices the task and schedules the care path plan-adaptation. From interviews it was observed that the order from the radiation oncologist for creating the care path plan-adaptation in ARIA is received by the logistic planner during the morning meeting instead of checking NeoZis. During the morning meeting a very brief update is given per patient. Interviews showed as well that the radiation oncologist gives the order to create the care path plan-adaptation in ARIA by creating a request in NeoZis.

The validation meeting showed that the radiation oncologist was not aware that the morning meeting was used by the logistic planner as main communication line to receive the order for creating the care path plan-adaptation instead of the communication in NeoZis. A potential risk arises here because the logistic planner also has nursing tasks besides the logistic planning task. When the plan-adaptation is thus not mentioned during the morning-meeting the risk arises that the adapted plan is created but cannot be passed on to the next caregiver as the care-path does not exist in ARIA. Normally, this goes well as the team is still very small and a lot of informal communication takes place.

○ To operate ARIA A potential risk that was revealed by the interviews on the care-path plan adaptation concerns the use of ARIA. When the caregiver executes a task too early compared to the planning of the task in the care path and does not change the time and date to the actual time while giving his credentials to verify the task, the system will not reveal the task for the next caregiver in the care path. This is caused by the mismatch in date and time; the scheduled care path date and time does not match the actual date and time and therefore ARIA blocks future care path actions.
Another risk that has been identified regarding the care path plan-adaptation in ARIA involves the description of the tasks in the work list. The caregivers cannot distinguish in the work list whether the task is linked to a plan-adaptation. Usually all caregivers are

aware of the plan-adaptation due to the morning meeting. However, the medical physicist assistant does not attend this meeting and is thus not always aware of an upcoming plan-adaptation. Table 5.1 provides an overview of the differences in couplings for the work-as-imagined and work-as-done model for creating the care path plan-adaptation. Table 5.2 summarises the potential risks that are concerned with creating the care path plan-adaptation in ARIA.

Table 5.1: Overview of difference in WAD compared to WAI for the activity ○ To create care path plan-adaptation.

○ Activity	WAI	WAD
To create care path plan-adaptation	Request is created in NeoZis by the RO.	LP gets the request during the morning meeting.

Table 5.2: Summary of the identified potential risks for the activity ○ To create care path plan-adaptation.

○ Activity	Potential Risk
To create care path plan-adaptation	◐ When the decision to initiate plan-adaptation for a patient is not discussed during the morning meeting; the logistic planner is not aware that the care path has to be created. All other care givers will not receive the plan-adaptation actions in their work list. ◐ The actions in the work list are executed too early compared to the scheduled time in the care path plan-adaptation in ARIA. If the scheduled date and time are not actively changed of the activity in ARIA upon execution, the next activity in the care path is blocked because the chronological order of the care path is disrupted.
To check work list regularly	◐ The caregiver is not aware of an upcoming plan-adaptation action since in ARIA the description of a task within the care path plan-adaptation is the same compared to a regular treatment plan. Furthermore, not all caregivers are present at the morning meeting.

5.1.2. EXCHANGE OF MASKS

○ TO CHANGE MASKS The WAI-model shows that the exchange of masks is a task which was designed in the procedures to be executed by the radiotherapy technologist (dose planning). The assignment of this task to the radiotherapy technologist (dose planning) in the procedures is the result of the assignment of activities which are more upstream in the model to the radiotherapy technologist(dose planning). The design of this workflow protocol allows the radiotherapy technologist (dose planning) to know exactly at which moment in time the masks need to be changed because the radiotherapy technologist (dose planning) deactivates the treatment plan and is involved in activating the adapted

treatment plan. Furthermore, the exchange of masks by the radiotherapy technologist (dose planning) allows for an extra control in the plan-adaptation process; at the start of the treatment the radiotherapy technologist(gantry/CT-scan) checks whether the masks with the correct date is taken out of the closet.

From interviews it was derived that the radiotherapy technologist (gantry/CT-scan) considers the task of changing masks as their job. This is because the radiotherapy technologist (gantry/CT-scan) has created the new mask for the patient and is thus aware of the existence of the new mask. The radiotherapy technologist (gantry/CT-scan) knows from the patient update at the morning meeting and the numbering of the beams in ProBeam that the adapted treatment plan is active. Based on this information the radiotherapy technologist (gantry/CT-scan) will change the masks in the closet of the treatment room. However, interviews showed as well that the radiotherapy technologist (dose planning) considers the changing of the masks as their task because the radiotherapy technologist(dose planning) knows exactly when the plan is activated and when the masks should be changed.

The group discussion showed that neither in NeoZis nor in a journal of ARIA it is documented when a new mask has been created by the radiotherapy technologist (gantry/Ct-scan). Only the radiotherapy technologist (gantry/CT-scan) who physically created the new mask for the patient is aware of the existence of a new mask. Currently, with the small team there are a lot of informal situations in which the patients are discussed. This causes everyone involved to know about the situation of a patient. However, the lack of documentation on the creation of a new mask should be considered as a risk in the process. Furthermore, the group meeting revealed that it is desired to have the radiotherapy technologist(dose planning) changing the masks. An extra control is then generated when the radiotherapy technologist(gantry/CT-scan) starts the treatment.

Lastly, a potential risk is present for the date that is marked on the new mask. Prior to the treatment of a patient the radiotherapy technologist(gantry/CT-scan) takes out the patients mask of the closet in the gantry room. The mask is marked with a sticker containing the name of the patient and a date. The date matches the date on which the rCT-scan has been made with this mask. However, the patient data that is present in the gantry room does not contain this information. Only the date when the patient has started his treatment. A potential risk is therefore that the radiotherapy technologist(gantry/CT-scan) considers it to be wrong. A summary of the potential risks related to changing the masks are shown in table 5.3 and 5.4.

Table 5.3: Overview of difference in WAD compared to WAI for the activity ○ To change masks.

○ Activity	WAI	WAD
To change masks	Mask is exchanged by the RTT(dose planning).	Mask is exchanged by the RTT(Gantry/CT-scan) and mask is exchanged by the RTT(dose planning).

Table 5.4: Summary of the identified potential risks for the activity ○ To change masks.

○ **Activity**	**Potential Risk**
To change masks	⊙ The radiotherapy technologist (dose planning) is not aware that a new mask has been created because it is not mentioned in the patient file in NeoZis or in a journal of ARIA. The masks are not changed in the closet of the treatment room. At the start of the treatment the radiotherapy technologist (gantry/CT-scan) will not notice that the wrong mask is in place.
	⊙ The mask is changed twice by both the radiotherapy technologist (dose planning) and radiotherapy technologist (gantry/CT-scan) because they both consider it as their job.
	⊙ The mask is considered to be wrong by the radiotherapy technologist (Gantry/CT-scan) because the date of the new mask does not match the date that the patient has received its very first treatment at the facility.

5.1.3. IN-HOUSE COMMUNICATION

It is desired that plan-adaptation is a fast process compared to the regular design of a treatment plan. Ideally within 2-3 days after the rCT-scan has been made the adapted treatment plan should be ready to be implemented. As a result the in-house communication on the various tasks involved in the process of plan-adaptation are designed in the procedures to be very direct. In the WAI-model this is reflected by the care path checks in ARIA. Signing off the task in the care path of ARIA upon completion causes the active task to change to the status 'completed' and the next task in the workflow will change from 'pending' to 'available'. The data for the WAD model showed that in addition to these care path checks, most of the caregivers phone calls the person responsible for the next task to accelerate the process and make them aware a task is coming up. Some tasks are even started while the current task have not been finalised yet. For example; when the adapted plan is evaluated by the medical physicist for the physics check, the medical physicist assistant is phone called by the medical physicist with the request to start preparing the quality assurance. This way the medical physicist is completely sure that the medical physicist assistant knows a QA is coming up and they can already start preparing even if the check is not completely done. As soon as the medical physicist has signed off for the physics check and a gantry is available the medical physicist assistant can start the QA.

GENERAL DATA PROTECTION REGULATION (GDPR)

Since may 2018 the General Data Protection Regulation (GDPR) is incorporated in the law of all EU nations [59]. This regulation is created by the EU to ensure that the data privacy laws across Europe would be in more conformity regarding privacy and data breaches [7]. The implications of this law for healthcare institutions are complex; confidentiality must be maintained throughout all processes and confidentiality breaches must be reported within 72 hours. Therefore, it is crucial for an institution to know where

all the data is collected and stored and to ensure a high level of encryption on the storage and communication channels. All requests to use the data from third parties should be provided in a clear language to ensure that a patient preferences will be maintained [6]. HollandPTC complies with the GDPR in the plan-adaptation process by communicating through NeoZis and a journal in ARIA on all patient related matters. work-as-done disclosed that communication occur as well through e-mail and phone when a quick response is required. To comply with the GDPR the caregivers use only the first letter of the last name in e-mails or the last name in phone calls. A potential risks that derives from this communication is mixing up patients. Furthermore, the group discussion on in-house communication revealed that not all caregivers were aware that the name of the patient was not to be used in e-mails. This would contribute to the potential risk of miscommunication and mixing up patients. An overview of the potential risks related to in-house communication is provided in tables 5.5 and 5.6.

Table 5.5: Overview of difference in WAD compared to WAI for in-house communication.

◯ **Activity**	**WAI**	**WAD**
To check adapted radiation plan	The work list in ARIA is checked regularly by MP to see whether the task has become available	The RTT (Dose planning) calls the MP of the day to inform that the plan is ready to be reviewed.
To prepare QA	The work list in ARIA is checked regularly by MPA to see whether the task has become available.	The MP calls or e-mails the MPA to inform that the preparation of a QA can be started.

5.1.4. ACTIVATION OF THE ADAPTED TREATMENT PLAN

Both the procedures and the interviews showed that the activation of the adapted treatment plan is a critical moment in the process of plan-adaptation. Prior to activating the adapted treatment plan, the treatment plan has to be deactivated and a dose correction has to be performed on the adapted treatment plan to ensure dose conformity.

WAI revealed that an 'admin account' is required to execute these operations. Moreover, the dose correction and the deactivation should only be executed when the patient has received its last fraction and the plan has been approved by the MP. If the plan is deactivated too early, the adapted treatment plan lacks one or more fractions and the treatment plan can no longer be treated at the gantry. When the plan is deactivated too late, the adapted treatment plan has too many fractions. As this would both result in an incorrect dose administration it should be considered as a potential risk.

Interviews showed that work-as-done differs from the procedures as the radiotherapy technologist(dose planning) executes the dose correction in ARIA with the credentials of the medical physicist. As a result the 4 eye principle is maintained. However, the radiotherapy technologist(dose planning) does not have the correct user rights to perform these changes and uses the credentials of the MP. A potential risk here is that the adjustments have not yet been checked by the MP when the plan is used for treatment as the

Table 5.6: Summary of the identified potential risks regarding in-house communication.

○ **Activity**	**Potential Risk**
Patient related communication	⟲ Mixing up patients as a result of using only the last letter of a patient in e-mails or last names in phone calls. (Example: patient V. or patient Visser in phone calls).
	⟲ Not informing all caregivers on changed policies regarding the exchange of patient information.
To request a check	⟲ When the activities in the process of plan-adaptation have to be performed quickly after each other, caregivers tend to call each other to ensure the next person knows the task is available. A potential risk is that the caregiver forgets to check the task in ARIA. Caregivers that are related later in the process, are not up to date regarding the current status of the plan-adaptation.
	⟲ Caregivers rely on receiving a phone call to get informed on the task progress and when their task should be initiated. A potential risk is that caregivers do not check the work list regularly in ARIA and if the phone call is forgotten the process stagnates.

radiation technologist is able to change it without the medical physicist.

Furthermore, the dose correction requires to manually calculate and add the dose from the treatment plan to the adapted treatment plan. A potential risk is present both in the calculation as in changing the total dose in the adapted treatment plan. A summary of these risks are provided in tables 5.7 and 5.8.

Table 5.7: Overview of difference in WAD compared to WAI for activation of the adapted treatment plan.

○ **Activity**	**WAI**	**WAD**
To change status treatment plan to 'completed early'	The MP executes this activity as the user rights are assigned to this account	The RTT(dose planning) executes this activity with the credentials of the MP. And MP checks it.

5.2. POTENTIAL TIME DELAYING FUNCTIONS

As stated in section 5.1 the adapted treatment plan should preferably be ready within 2-3 days. As shown in section 5.1.4 a delay in time is a potential risk for the process. Therefore, it is of great interest to review the activities and their couplings that can cause a delay in time of the process. Table 5.9 shows a summary of all activities and their couplings that are considered as a potential cause for time delay. The related potential risks are exemplified in table 5.10. Every activity is described in more detail below.

Table 5.8: Summary of the identified potential risks regarding the activation of the adapted treatment plan.

○ Activity	Potential Risk
To change status treatment plan to 'completed early'.	◐ The deactivation of the treatment plan occurs too early. As a result the adapted treatment plan lacks one or more fractions and 2 plans are available for treatment. ◐ The deactivation of the treatment plan occurs too late. The adapted treatment plan contains too many fractions. ◐ When the dose correction is done by the MP instead of the RTT, there is no extra control (4 eye principle). ◐ When the dose correction is executed by the RTT with the credentials of the MP, the plan could be used without being checked by the MP. ◐ The dose correction is wrongly calculated or entered wrong in the adapted treatment plan.

○ TO SCHEDULE RCT-SCAN CARE PATH From interviews it was showed that performance variability was present in the work-as-done of scheduling the care path for the rCT-scan. The logistic planner schedules all the weekly rCT-scan care paths at once at the start of the treatment for a patient with a tumour in the head/neck region . Scheduling requires a lot of time due to the many variables and the systems are not optimised to take other appointments at other healthcare facilities into account. The logistic planner has to call the healthcare institutions to gather insight in the appointments of a specific patient. Scheduling all the appointments at once allows planning to become more easy for the logistic planner. When a patient requires an extra rCT-scan due to observed anatomical variation in between the weekly scheduled rCT-scans the performance variability is increased. The logistic planner has to squeeze this patient in the already tight schedule of the CT-scanner and has to mind all that is stated above.

○ TO CREATE ADAPTED RADIATION PLAN Work-as-done revealed that there are 5 unique inputs possible for creating the adapted radiation plan in RayStation. Figure 5.3 shows this instantiation with its inputs. The inputs: physica plan not approved, no QA-mode used during QA execution, incorrect adjustment of nr. of remaining fractions and incorrect nr. of remaining fractions are couplings that can cause a delay in the plan-adaptation process as they evolve from an undesired output. Especially the coupling incorrect nr. of remaining fractions has a lot of impact on the process. When it is discovered during the activation of the adapted treatment plan, the process is already busy for 2-3 days. Creating a new plan would take another 2-3 days. The two other couplings are discovered earlier in the process, but are still a potential risk because a completely new adapted treatment plan has to be created.

○ TO RUN A ROBUSTNESS TEST AND TEST SCENARIOS From interviews it was observed that the variability of the function is increased by the lack of available computers and their processing power. Furthermore, in parallel no other activities can be performed because these tests are computationally challenging for the computers. This causes a potential time delay for the process plan-adaptation.
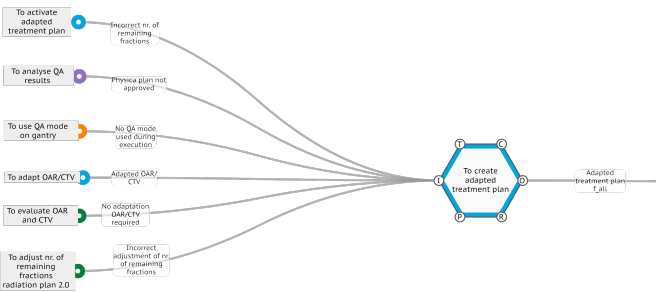
Figure 5.3: Isolation of the activity to create adapted treatment plan in the WAD model. Work-as-done revealed that there are 4 unique inputs for the activity.

Another coupling which showed an increase of performance variability is the request for the remaining nr. of fractions when the number of fractions is adapted. The procedures are not clear that this has to happen. Work-as-done disclosed that not all RTT(dose planning) are therefore aware that this has to be done. This could cause a delay in time when the remaining number of fractions are not known at the moment the radiation oncologist checks the plan and adapts the fractions.

The group meeting revealed that not all caregivers were aware of these potential causes for time delays. Discussing these potential causes for time delays created awareness among the caregivers.

Table 5.9: Overview of the identified functions and their couplings that can cause a time delay in the process plan-adaptation.

○ Activity	Potential time delaying couplings
To create carepath rCT-scan	No staff available
	No gantry available
	Other healthcare appointments
To create adapted treatment plan	No QA mode used during execution
	Physica plan not approved
	Incorrect adjustment of remaining nr. of fractions
To run a robustness test and test scenarios	Availability of computers
	Processing power of computers
To make a rCT	Malfunctioning CT-scanner
To execute QA	Available gantry for QA
To check work list regularly	To have other activities

Table 5.10: Summary of the identified potential risks related to time delays.

◌ Activity	Potential Risk
To create carepath rCT-scan	⬡ No staff is available to make the rCT-scan. ⬡ The CT-scan schedule is completely booked or the CT-scanner is broken down, so there is no room for an extra scan. ⬡ The patient has a very busy schedule and is not able to come in for a rCT-scan.
To create adapted treatment plan	⬡ The QA Mode is not used during the QA on the gantry. A fraction of the adapted treatment plan is lost. A new adapted treatment plan has to be created. ⬡ The MP does not validate the adapted treatment plan because it does not pass the check. A new adapted treatment plan has to be created. ⬡ The number of remaining fractions of the adapted treatment plan is not in agreement with the remaining fractions of the treatment plan.
To run a robustness test and test scenarios	⬡ There are no computers available for running the robustness test. ⬡ The tasks of the RTT are piling up because the computers are not capable to perform parallel tests.
To execute QA	⬡ There is no gantry available for an extra QA due to an unexpected break down of the gantry, running late of other treatments at the gantry or the MPA's are busy with another QA.
To request remaining nr. of fractions	⬡ This activity is not noted in the work procedure. Therefore, RTT(dose planning) who have not yet done a plan-adaptation could forget this. When the RO check the plan and wants to adapt the nr. of remaining fractions a delay of time could occur.

5

6

IDENTIFICATION OF EFFECTIVE CONTROLS

This chapter compares the potential risks for the plan-adaptation process identified with FRAM, with the potential risks identified with HFMEA to explore whether the proposed controls by HFMEA cover the approximate adjustments required to cover the risks due to "everyday performance". Section 6.1 discusses potential causes for differences in potential risks identified with HFMEA and FRAM. In section 6.2 the potential risks identified with FRAM are assessed with the controls available from HFMEA.

According to literature both FRAM and HFMEA can be used as prospective of a complex-socio technological system [5] [49] [13]. In this research we aim to use FRAM for assessing the effectiveness of proposed controls formulated with the outcome of HFMEA. Figure 6.1 contains an overview of all the potential failure modes, their associated risks and the proposed controls identified with HFMEA for the process of plan-adaptation.

Failure Mode	Potential Risk	Proposed control(s)
Fault in rigid registration	Incorrect decision on whether plan-adaptation process should be initiated.	1. Registration check after the merger of scans by the RO to confirm the contours.
Fault in deformable registration	Incorrect decision on whether plan-adaptation process should be initiated and incorrect contours.	2. Registration check after the merger of scans by the RO to confirm the contours.
Fault in case labelling	Messy administration.	3. Add case labeling to the checklist of RTT and MP.
Variation between assesments of radiation oncologists	No uniformity in treatment of patients.	4. Work-instructions to ensure conformity
Failure in importing adapted treatment plan	Suboptimal treatment plan	5. The final plan is assessed.
Incorrect number of remaining of fractions	Too many/too little fractions remaining	6. The number of fractions is adjusted by 1 RTT and 1 MP to meet the 4 eye principle.
Wrong dose specification point	Messy administration.	7. Add to checklist of RTT and MP. Extra: develop a script to automate it.
Fault in scheduling	Too many/too little fractions remaining	8. Add to checklist of RTT and MP.
Incorrect dose correction	Too many/too little fractions remaining	9. Add to checklist of RTT and MP.
Plan is not available anymore; closed too early	No treatmentplan available at the gantry	10. Add timing of closing the treatment plan to the checklist of RTT and MP.
Treatment plan is not 'closed' while using the adapted treatment plan	Two treatment plans available at the gantry.	11. Add timing of closing the treatment plan to the checklist of RTT and MP.
Treatment plan added to wrong prescription	Messy administration.	12. Add to checklist of RTT and MP.
Multiple masks available for a patient	Wrong mask used during treatment.	13. Update workinstruction of moulage with: write down the date of the rCT-scan on the new mask. Masks that are no longer in use should be destroyed.

Figure 6.1: Overview of all the failure modes, potential risks and control(s) to monitor and mitigate risk throughout the plan-adaptation process.

6.1. CAUSES FOR IDENTIFYING DIFFERENT POTENTIAL RISKS

Here, potential causes are discussed for identifying different potential risks with FRAM compared to HFMEA.

6.1.1. TEAM COMPOSITION

The investigation teams for HFMEA and FRAM were slightly different in composition as is depicted in table 6.1. This is the result of HFMEA requiring a multidisciplinary team that consists of at least subject matter expert(s), an advisor, and a team leader [13]. Whereas the FRAM requires that the lead researcher identifies all involved healthcare professionals by exploring the protocol to ensure all persons that are involved in the process are included [26]. By including all healthcare professionals that have a task within the plan-adaptation process, the FRAM generates new perspectives on the process and also identifies contradictions in activities.

Table 6.1: Overview of the team compositions used for conducting the risk-analysis with the HFMEA and FRAM method.

#	HFMEA	#	FRAM
1	Radiation Oncologist	1	Radiation Oncologist
4	Radiotherapy Technologist	2	Radiotherapy Technologist
2	Medical Physicist	1	Medical Physicist
		1	Medical Physicist Assistant
		1	Logistic Planner

6

EXAMPLE
The following potential risk was identified with FRAM and not with the HFMEA, most probably because of the participation of all healthcare professionals involved in the plan-adaptation process:
⟳ *When it is decided to initiate the plan-adaptation process for a specific patient, the radiation oncologist places a request to create the care path plan-adaptation in NeoZis and often it is communicated to the team during the morning meeting. If the start of a plan-adaptation of a specific patient is not discussed during the morning meeting the logistic planner will not create the care path plan-adaptation in ARIA because the logistic planner is not aware that NeoZis is used as primary communication channel. Furthermore, the logistic planner is not aware that creating the pathway is critical for all other caregivers because all other care givers will not receive their actions in their work list. The potential risk arises here that a delay in time occurs.*

6.1.2. GATHERING DATA ON PROCESS

The multidisciplinary team that is assembled for the HFMEA creates a flow chart or diagram of the process together, to identify and describe all the functions of the process under review by discussing all the steps and identifying process steps and their subprocesses. With FRAM the protocols are reviewed by the researcher to acquire information on all the activities that are involved (work-as-imagined). Furthermore, semi-structured

interviews are conducted by the researcher with all identified involved healthcare pro-
fessionals and observations of related processes are done, if possible, to gather informa-
tion of how the process under investigation is done (work-as-done).

EXAMPLE
*For the activity changing masks both FRAM and HFMEA identified potential risks. These
risks are shown in table 6.2. The risk identified with HFMEA is identified with FRAM as
well but vice versa this is not true. The additional risks identified with FRAM were recog-
nised as a potential risk due to the questions asked by the researcher during the interviews
for the design of the model.*

Table 6.2: Identified potential risks for the activity to change masks with FRAM and HFMEA.

FRAM	⊙ The RTT (gantry/CT-scan) is not aware that a new mask has been created as it is not mentioned in the patient file in NeoZis or in a journal of ARIA. At the start of the treatment the RTT (gantry/CT-scan) will not notice that the wrong mask is in place.
	⊙ The mask is changed twice by both the radiotherapy technologist (dose planning) and radiotherapy technologist (gantry/CT-scan) as they both consider it as their job.
	⊙ The mask is considered to be wrong as the date of the new mask does not match the date that the patient has received its very first treatment at the facility.
HFMEA	⊙ The wrong mask is available at the gantry.

6.1.3. PRESENTATION OF PROCESS UNDER REVIEW

The HFMEA for the process of plan-adaptation used a descriptive flowchart to describe
all the process (sub)steps. In the FRAM each activity of the process is described with 6
aspects; input, output, time, resources, controls and preconditions. The incorporation
of these aspects allows to visualise the complex interconnectivity of all the activities by
connecting these aspects. Furthermore, a distinction is made between WAI and WAD.
The aspect time often reveals work arounds in the work as done model. Often these
workarounds are not recognised in the workflow of a HFMEA because they are the direct
result of variability in the system.
Due to the presentation of the process the risks identified with HFMEA are often more
directly related to the visible functions in the protocols, whereas the risks identified with
FRAM could be related to other steps in the process or workarounds.

EXAMPLE
*ARIA, the oncology information system, is used to manage a patients journey. The care
paths ensure that all the the caregivers are aware of their upcoming tasks and can review
the progress of a patient. The HFMEA did not identify any potential risks regarding the use*

of ARIA for the process of plan-adaptation. FRAM identified a potential risk by looking what happens under time pressure; when tasks are partly finished the next caregiver is already updated by phone or e-mail as a result the care path is no longer up to date with the most recent information. Furthermore, due to the GDPR a potential risks arises with communicating by phone or e-mail on patient related matters as no full information can be disclosed.

6.1.4. ANALYSIS OF DATA
With a HFMEA potential risks are identified by the multidisciplinary team by listing all the possible failure modes of the specific subprocesses. These potential risks are analysed with a table that requires to identify the severity, probability, the potential causes and proposed solutions of each identified risk. The FRAM aims to identify resonance within a system rather than to identify potential failure modes. The researcher identifies the potential risks with FRAM by comparing the couplings of the WAI model with the WAD model in both the matrix as in the visual model. For each coupling it is analysed whether internal, external and functional upstream-downstream variability is present. The identified variability and ways to dampen or amplify this variability are verified during a group meeting with all involved actors which results in a set of proposed solutions for a potential identified risk.

EXAMPLE
HFMEA identified having too little/many fractions in the adapted treatment plan as a potential risk caused by either a mistake in scheduling or by a wrong dose correction. The proposed solution was to add it to the checklist of the RTT and the MP because these task belong to these caregivers. FRAM identified having too many/little fractions as well as a potential risk. However, the identified potential causes for having too many/little fractions were partly different; wrong dose correction, incorrect adjustment of number of fractions during scheduling, no QA mode used on gantry, no deactivation of the treatment plan, validating the adapted treatment plan too early and defect gantry. The proposed solution of HFMEA of adding it to the checklist was considered to be insufficient to cover all the potential risks identified with FRAM during the validation meeting.

6.2. EFFECTIVENESS OF THE HFMEA CONTROLS
An effective control anticipates on the impact and the aggregation of a potential risk in the process under review. Here, it is assessed whether the thirteen proposed controls by HFMEA, shown in figure 6.1, are capable to to control the 25 potential risks associated with "everyday performance". Below it is discussed whether the identified controls from HFMEA are effective to control the 25 potential risks associated with "everyday performance".

6.2.1. HFMEA CONTROLS FOR POTENTIAL RISKS RELATED TO PRECISION
Figure 6.2 provides an overview of the potential risks related to precision identified with FRAM. For each of the potential risks it is assessed whether the risk requires an active control or whether raising awareness by discussion is sufficient. Furthermore, it has been indicated whether the control is identified by HFMEA.

Activity	Potential risks related to precision	Control Required?	HFMEA Control Available?
To create care-path plan adaptation	1. The logistic planner is not aware that the care path has to be created when an order is placed in NeoZis.	No, Awareness	No
To create care-path plan adaptation	2. The care path plan-adaptation is executed too early compared to the scheduled time in ARIA. If the scheduled date and time are not actively changed of the activity in ARIA upon execution, the next activity in the carepath is blocked because the chronological order of the care path is disrupted.	Yes	No
To prepare QA	3. The MPA is not aware of a a plan-adaptation since in ARIA the description of a task within the care path plan-adaptation is the same compared to a regular treatment plan. Furthermore, not all caregivers are present at the morning meeting.	Yes	No
To change masks	4. The radiotherapy technologist (dose planning) is not aware that a new mask has been created because it is not mentioned in the patient file in NeoZis or in a journal of ARIA. The masks are not changed in the closet of the treatment room. At the start of the treatment the radiotherapy technologist (gantry/CT-scan) will not notice that the wrong mask is in place.	Yes	No
To change masks	5. The mask is changed twice by both the radiotherapy technologist (dose planning) and radiotherapy technologist (gantry/CT-scan) because they both consider it as their job.	Yes	No
To change masks	6. The mask is considered to be wrong by the radiotherapy technologist (Gantry/CT-scan) because the date of the new mask does not match the date that the patient has received its very first treatment at the facility.	Yes	No
To prepare QA	7. Mixing up patients as a result of using only the last letter of a patient in e-mails or last names in phone calls. (Example: patient V. or patient Visser in phone calls	Yes	No
To request a check	8. A potential risk is that the caregiver forgets to check the task in ARIA. Caregivers that are related later in the process, are not up to date regarding the current status of the plan-adaptation	No, Awareness	No
To request a task	9. Caregivers do not check the work list regularly in ARIA.	No, Awareness	No
To change status treatment plan to " completed early"	10. The deactivation of the treatment plan occurs too early. As a result the adapted treatment plan lacks one or more fractions	Yes	Yes
To change status treatment plan to " completed early"	11. The deactivation of the treatment plan occurs too late. The adapted treatment plan contains too many fractions.	Yes	Yes
To perform a dose correction	12. When the dose correction is done by the MP instead of the RTT, there is no extra control (4 eye principle).	Yes	No
To perform a dose correction	13. When the dose correction is executed by the RTT with the credentials of the MP, the plan could be used without being checked by the MP.	Yes	No
To perform a dose correction	14. The dose correction is wrongly calculated or entered wrong in the adapted treatment plan.	Yes	No

Figure 6.2: Overview of the identified potential failure modes with FRAM related to precision. For each potential failure mode it is indicated when a control is required and whether the control is available from HFMEA to prevent the failure mode.

Control required: Yes; Control available: Yes; Effective: No
For two potential risks a control is required and is based on the HFMEA. However, the controls are classified as not effective because work-as-done revealed that a problem occurs due to the mismatch of user rights. The RTT(doseplanning) does not have the required user rights and is therefore required to use the credentials of the MP. This causes the extra control to be lost as the RTT(doseplanning) validates the plan immediately by entering the credentials. The potential risk that the plan is closed too early is enhanced due to this cause and is not effectively reduced by having a checklist.

Control required: Yes; Control available: No
In total nine potential risks were identified for which a control is required but is not provided by HFMEA.

Control required: No awareness; Control available: No
Three potential risks were identified for which no control has to be designed, but rather require awareness from the healthcare professionals that this potential risk is present and affects certain up- and/or downstream activities activities. For each potential risk is illustrated why no control is required.

1. The logistic planner is not aware that the care path has to be created when

AN ORDER IS PLACED IN NEoZis
During the morning meeting the logistic planner receives information from the radiation oncologists on a patient status. That is why the logistic planner knows a care path for plan-adaptation has to be created. Discussing the use of NeoZis as main stream communication channel is enough to mitigate this risk.

8. The caregiver forgets to check the task in ARIA upon completion. Caregivers that are related later in the process, are not up to date regarding the current status of the plan-adaptation.
Raising awareness among the different healthcare professionals on the use of ARIA will likely prevent this from happening. Furthermore, the immediate next person is often called when the task is completed. That is why this often goes well.

9. Caregivers do not check their work list regularly
Often the next caregiver in a care-path is called upon completion of a task. Therefore, this potential risk is believed to mitigated by raising awareness among the team that the work-list in ARIA should be used as main information source on tasks.

6.2.2. HFMEA Controls for potential risks related to timing
Figure 6.3 provides an overview of the potential risks related to precision identified with FRAM.

Activity	Potential risks related to timing	Control Required?	HFMEA Control Available?
To create carepath rCT-scan	15. No staff is available to make the rCT-scan.	No, Awareness	No
To create carepath rCT-scan	16. The CT-scan schedule is completely booked or the CT-scanner is broken down, so there is no room for an extra scan.	Yes	No
To create carepath rCT-scan	17. The patient has a very busy schedule and is not able to come in for a rCT-scan.	No, Awareness	No
To execute QA	18 The QA Mode is not used during the QA on the gantry. A fraction of the adapted treatment plan is lost. A new adapted treatment plan has to be created.	No, Awareness	No
To validate adapted treatment plan	19. The MP does not validate the adapted treatment plan because it does not pass the check. A new adapted treatment plan has to be created.	No, Awareness	No
To validate adapted treatment plan	20. The MP activates the adapted treatment plan in ARIA when the QA is finished as this is common practice for normal treatment plans.	Yes	No
To validate adapted treatment plan	21. The number of remaining fractions of the adapted treatment plan is not in agreement with the remaining fractions of the treatment plan.	Yes	Yes
To run the robustness test and test scenarios	22. There are no computers available for running the robustness test.	No, Awareness	No
To run the robustness test and test scenarios	23. The tasks of the RTT(dose planning) are piling up because the computers are not capable to perform parallel tests.	No, Awareness	No
To execute QA	24. There is no gantry available for an extra QA due to an unexpected break down of the gantry, running late of other treatments at the gantry or the MPA's are busy with another QA.	Yes	No
To adjust number of fractions	25. The remaining number of fractions is not requested. When the RO checks the plan and wants to adapt the nr. of remaining fractions a delay of time could occur.	Yes	Yes

Figure 6.3: Overview of the identified potential failure modes with FRAM related to timing. For each potential failure mode it is indicated whether a control is required and whether the control is available from HFMEA to prevent the failure mode.

Control required: Yes; Control available: Yes; Effective: Yes/No
Two potential risks related to timing require a control and these are available due to the HFMEA. However, the control is not effective for potential risk 25; work-as-done revealed that the execution differs from the protocols. Not the RTT and MP execute the adjustment of fractions of the adapted treatment plan, but rather the RTT and the RO. There-

fore, this proposed control by HFMEA is considered not to be effective. The control for risk 21 is believed to be effective.

CONTROL REQUIRED: YES; CONTROL AVAILABLE: NO
Three potential risks require a control but the control is not available from HFMEA.

CONTROL REQUIRED: NO AWARENESS; CONTROL AVAILABLE: NO
Six potential risks were identified for which no control has to be designed, but rather require awareness from the healthcare professionals is present and affects certain up- and/or downstream activities.

15. NO STAFF IS AVAILABLE TO MAKE THE RCT-SCAN
The shortage of staff is covered by flexibility of the healthcare professional; the RTT dose-planning) cover the open shifts due to a shortage of RTT (Gantry/CT-scan). However, awareness of the shortage of staff need to be present as it could conflict with the tasks of the RTT (doseplanning) on the long term.

17. THE PATIENT HAS A VERY BUSY SCHEDULE AND IS NOT ABLE TO COME IN FOR A RCT-SCAN.
A patient receiving treatment often has many other appointments at other institutionsThis could potentially lead to a delay in the plan-adaptation process.

18 THE QA MODE IS NOT USED DURING THE QA ON THE GANTRY. A FRACTION OF THE ADAPTED TREATMENT PLAN IS LOST. A NEW ADAPTED TREATMENT PLAN HAS TO BE CREATED.
Several barriers have been built in the software to prevent that no QA mode is used. Therefore, raising awareness of the time-delaying effect of this potential risk among the MPA's is thought to be enough.

19. THE MP DOES NOT VALIDATE THE ADAPTED TREATMENT PLAN BECAUSE IT DOES NOT PASS THE CHECK. A NEW ADAPTED TREATMENT PLAN HAS TO BE CREATED.
Awareness on the effect on the time-delaying effect of this potential risk among the healthcare professionals is thought to be sufficient.

22. THERE ARE NO COMPUTERS AVAILABLE FOR RUNNING THE ROBUSTNESS TEST.
Awareness that this could effect the efficiency of the pathway especially when the number of patients increases

23. THE TASKS OF THE RTT(DOSE PLANNING) ARE PILING UP BECAUSE THE COMPUTERS ARE NOT CAPABLE TO PERFORM PARALLEL TESTS.
Awareness that this could effect the efficiency of the pathway especially when the number of patients increases.

6

7

PROPOSED STRATEGY

This chapter describes the design of a strategy to generate effective controls to monitor and mitigate risks throughout the lifecycle of a process. The strategy aims to continuously monitor the effectiveness of the controls designed for the system and to develop strategies to amplify the couplings/pathways that create safety by actively monitoring work-as-imagined and work-as-done.

The main research question of thesis is: "What is an effective strategy to monitor and mitigate risks associated with the plan-adaptation process at HollandPTC?". The case study conducted at HollandPTC showed that HFMEA resulted in a set of controls that effected the activity of the failure mode directly. In other words; the designed control has a direct effect on the identified failure mode of the process. The prospective risk analysis conducted with FRAM identified a different set of potential risks for the same process due to exploring what the system does during "everyday performance". The effectiveness of the HFMEA controls were tested on the subset of potential risks identified with FRAM that required a control. It was shown that the HFMEA identified controls were not effective to monitor and mitigate the risks identified by the FRAM. Nevertheless, the controls from HFMEA are effective for the specific process step risk for which they have been designed. The set of potential risks that did not need a direct control but rather required awareness raised an extra question on how to monitor and mitigate these set of risks. The proposed strategy here is based on these findings and combines the strengths from both HFMEA and FRAM for the design of controls and actions.

7.1. DESIGN OF THE STRATEGY

The proposed strategy consists of the following seven consecutive steps and is illustrated in figure 7.1: 1.the topic/scope of the risk-analysis needs to be defined by a quality assurance manager, 2. Construct a FRAM model based on the protocols, 3. Conduct semi-structured interviews with at least one delegate of each involved profession, 4. Construct a FRAM model based on the interviews, 5. List all potential risk associated with the pro-

cess, 6. Validate the model and verify/identify the risks with at least one delegate of each
involved profession and 7. Implement controls/actions and monitor process.
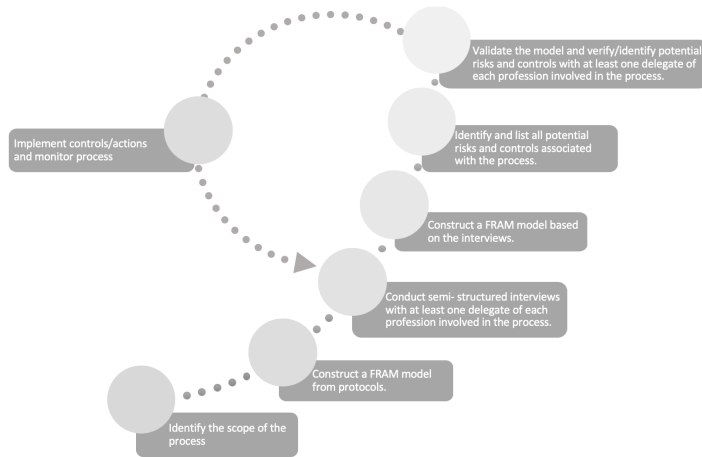
Figure 7.1: Proposed strategy to monitor and mitigate risks for HollandPTC.

Below is discussed how the strategy enables to reconcile the strengths of HFMEA and
FRAM and how the strategy differs from conventional approaches to mitigate and mon-
itor risks in a process.

CONDUCTING SEMI-STRUCTURED INTERVIEWS
Semi-structured interviews are proposed by FRAM to identify how "everyday perfor-
mance" affects the process. Having an interviewer/lead researcher who does not par-
ticipate in the process under review is preferred [4]. It is proposed that during these
interviews, the interviewee reflects individually on the risks directly related to the var-
ious functions he/she is involved with during the process. Adding this question to the
interviews, allows to capture both the potential risks associate with a specific activity
which are normally captured by HFMEA, as well as the potential risks associated with
"everyday performance". The individual reflection on specific activity to identify risks
allow to formulate risks more freely without being overruled by others in the team.

LIST ALL POTENTIAL RISKS AND CONTROLS ASSOCIATED WITH THE PROCESS
In addition to the potential risks formulated during the interviews it is proposed that
the lead investigator systematically compares the couplings of the FRAM model based
on the protocols with the FRAM based on interviews. The matrices that contain all the
couplings should be used to conduct this systematically [50]. HFMEA proposes to list all
potential risks and to identify which risks require a control. However, the use of prob-
abilities and severity scales is believed to be highly affected by personal believes [17].
Therefore, it is proposed to rather use how the downstream couplings are affected by the
risks and identify the impact on downstream couplings in terms of precision and timing
[49]. Lastly, it is proposed that in this step the effectiveness of the controls in the proto-

cols are tested on these list of potential risks.

VALIDATE THE MODEL AND VERIFY/IDENTIFY THE MODEL WITH AT LEAST ONE DELEGATE FROM EACH INVOLVED PROFESSION.

A meeting should be held with at least one delegate from each involved profession. The validation meeting should be used to validate the work-as-done model by discussing various scenarios. The potential risks identified by the lead researcher are presented and an additional brainstorm session should be held to formulate additional potential risks. Next, for each potential risk it should be discussed and listed whether a control is required to mitigate or monitor its risk and whether an appropriate control is already available in the protocols. These controls should be designed by the team.

IMPLEMENT CONTROLS/ACTIONS AND MONITOR PROCESS

All the actions/controls should be added to the various protocols. The potential risks that require awareness rather than control and the updated protocols should be communicated by the lead investigator to all the involved professionals. Inline with the PLAN-DO-ACT-CHECK cycle from Deming it is advised that an incident reporting system (IRS) is used that allows to track the instantiations of the FRAM model involved with accidents [60]. Incidents should be reported to the quality assurance manager and reported in the IRS. The quality assurance manager reviews the incident together with the involved professionals and assesses to which activities/functions in the WAI model the incident is related and why it often does not result in an incident. By keeping track of these vulnerable activities in the WAI model and their normal workarounds valuable information will be disclosed on the process.

7

CONCLUSION

8

CONCLUSION AND DISCUSSION

This is a concluding chapter summarising the scientific implications of the research findings in considerable detail. Section 8.1 will elaborate on the main research findings by first answering all the subquestions, followed by the main conclusion in section 8.2. The research approach and the outcomes of this thesis are discussed in section 8.3. Recommendations for future work are elaborated on in section 8.4.

8.1. MAIN RESEARCH FINDINGS

The main research question of this thesis is:"What is an effective strategy to identify which controls are able to monitor and mitigate risks associated with the plan-adaptation process at HollandPTC?" To answer the main research question in a systemic way, the following three sub-questions were formulated in chapter 1 and are answered below.

1. How is the plan-adaptation process organised at HollandPTC?
For the radiation of a patient with a tumour in the neck/head region with protons, it is pivotal to have accurate and detailed anatomic information on the tumour region because the tumour is irradiated with a high precision [47]. Anatomical changes in the patient due to weight loss and tumour volume changes during the treatment, causes deviations in the targeting precision of the protons and therefore dose perturbations will arise in the tumour region. Corrections are required in the treatment plan of a patient who suffers from these anatomical changes to ensure dose conformity throughout the treatment. The adaptation of a patients treatment plan while receiving treatment, is called plan-adaptation.

In chapter **??** five subprocesses were identified in the plan-adaptation process; imaging of the patient, evaluation of the treatment plan, designing the adapted treatment plan, quality assurance of the adapted treatment plan and implementation of the adapted treatment plan. These subprocesses are characterised by the handover/exchange of patient information by a strong collaboration of many different healthcare professionals through many digital and partly automated processes. Information on the progress of a

patients treatment is monitored in ARIA, oncology information software, and is available for all involved healthcare professionals. (In)formal checks such as: the four-eye principle and several checklists are currently used to mitigate and monitor risks throughout the plan-adaptation process.

2. How does "everyday performance" affect the risks associated with the plan-adaptation process at HollandPTC?

The objective of the process of plan-adaptation is two-fold (chapter 1.2); developing *efficiently* a *safe* adapted treatment plan for a patient suffering from anatomical changes. Where efficiently refers to the time required by the involved healthcare professionals from detecting anatomical changes to implementing the adapted treatment plan and safe in terms of radiation exposure for the patient.

The Functional Resonance Analysis Method (FRAM) was used to identify the effect of "everyday performance" on the plan-adaptation process in chapter 4. The analysis of the FRAM models revealed among others: informal communication lines between caregivers, discrepancies between caregivers ideas about task division and identified multiple causes for time delays in the process as potential risks. In chapter 5 it has been shown that potential risks related to "everyday performance" for the process of plan-adaptation have a direct or indirect effect on the the efficiency and/or safety and are present in the entire plan-adaptation pathway as was shown in figure 5.1. The impact of a potential risk on the plan-adaptation process is affected by the ability of the pathway to respond to the variability caused by a potential risk and the accumulation speed of a potential risk. The efficiency of the plan-adaptation process is affected by the availability of resources, time available for conducting an activity, (in)formal communication lines and the allocation of tasks among the caregivers. Safety is influenced by (in)formal communication, digitalisation and automation. The potential risks identified with FRAM were compared with the risks identified with HFMEA to asses how everyday performance influences risks associated with the plan-adaptation process in chapter 6.

3.How can the identification of potential risks associated with "everyday performance" contribute to the design of effective controls to mitigate risks?

Effective controls anticipate on the impact and the aggregation of a potential risk in the process under review. Recognising potential success- and failure modes of a process allows to identify the instantiations through which a potential risk might aggregate. These instantiations are valuable for the design of effective controls to mitigate risks; effective controls should amplify the success modes and dampen the failure modes of such an instantiation. In chapter **??** the controls available from HFMEA are assessed with the potentials risks associated with "everyday performance" to provide information on the effectiveness of the designed controls by HFMEA for the plan-adaptation process.

8.2. CONCLUSION

This research was conducted to help HollandPTC identify which controls are effective to monitor and mitigate risks throughout the plan-adaptation process by exploring potential risks associated with the process. The functional resonance analysis method

(FRAM),a qualitative risk analysis methodology, was used to identify how everyday performance affects the plan-adaptation process. A strategy to monitor and mitigate the identified potential risks identified with this method was not covered in literature. To fulfil the aim of this research, the identified risks with FRAM were compared with the identified risks with the HFMEA method to answer the main research question: "What is an effective strategy to monitor and mitigate risks throughout the plan-adaptation process at HollandPTC?". The strategy illustrated in figure 8.1 (chapter 7) is proposed to create effective actions/controls throughout the lifecycle of a process to monitor and mitigate risk. It combines the strengths from both HFMEA with FRAM to contribute to a safe treatment.
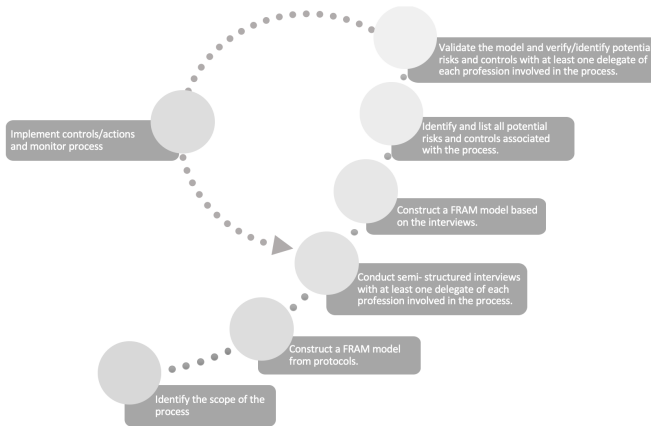
Figure 8.1: Proposed strategy for creating effective controls to monitor and mitigate risks for HollandPTC.

8.3. DISCUSSION

In chapter 6 potential causes for identifying different potential risks with HFMEA compared to FRAM are discussed.

There can be discussed that the proposed strategy shows similarities with the approach proposed by FRAM for conducting a prospective risk-analysis. Indeed, the individual approach towards the involved actors and the graphical strengths of FRAM can be recognised in the strategy as they are identified as a useful and effective approach to reveal how "everyday performance" affects a process [5]. The qualitative approach used in the proposed strategy enables to reconcile the linear- with the systemic view on safety because reducing the complexity of systems is key in this strategy. However, the complexity of "everyday performance" cannot always be reduced and rather needs effective controls to monitor the risks associated with this performance. This strategic objective differs from the objective of FRAM which aims to understand the variability of performance and not the effectiveness of a control.

Another point for discussion is whether a qualitative approach is sufficient to assess the

effectiveness of a control designed to mitigate and/or monitor risk in a process. The use of interviews and observations to gather information on "everyday performance" in a process is partly biased by the interviewer/observer and the willingness of the interviewee to share information. In other words the safety culture and objectives of an organisation have an effect on the outcome of the strategy. Nevertheless, it is believed that having both individual interviews and a validation meeting will counteract this bias. Functional resonance is characterised by the approximate adjustments that people make to counteract performance variability. The identification of the variability with a qualitative approach by conducting interviews is assumed to be sufficient as they experience the variability. Therefore, it is assumed that reviewing the identified potential risks with a qualitative method is sufficient. Designing a quantitative approach for the assessment of risks would require a method to design scenarios for the process under review that allows to capture the effect of coupled activities on risks. This would require quantitative data on the resonance of functions, the safety limits and how resonance aggregates. Only with this data probabilities can be constructed and reliable scenarios can be simulated. Nevertheless, retrieving this data is difficult because safety limits are hard to define.

Additionally, it can be questioned whether the strategy is applicable to assess different processes within HollandPTC or even broader can be used to review processes in different organisations. The impact of the outcome of the proposed strategy is assumed to depend highly on the complexity, time-dependency, number of elements and uncertainty of a case. Nevertheless, it is assumed that applying this strategy for other process will result in an increased understanding of the process and will help to make the process more efficient as FRAM has shown its added value in other high risk settings [5] [41] [50].

It can be challenged whether both prospective risk-analysis that were conducted for this research were truly prospective because the timing differed. The HFMEA was conducted 4 months prior to the start of this thesis. However, no plan-adaptations were conducted when the interviews were held for this research. The cases that were used to validate the process occurred after the interviews. Therefore, it is assumed that the timing had no effect on the results of this research. In addition, the researcher was not biased by the results from HFMEA as they were provided after validating the results found with FRAM.

Lastly, the comparison of the work-as-imagined and work-as-done models and the related potential risks can be questioned. Some of the foreground functions in the work-as-done model seem to be pivotal but were not identified for the work-as-imagined model. This was due to a lack of detailed process knowledge from the author. Nevertheless, the addition of these functions in the work-as-done models ensured that the process was complete.

8.4. RECOMMENDATIONS
In this section we discuss opportunities to improve and continue the research done in this thesis. Furthermore, the case study led to several observations that are presented here as recommendations for HollandPTC.

METHODOLOGY

For the case study, five persons were interviewed to map out the plan-adaptation process. The radiation oncologist was not interviewed due to a busy schedule. Since all the interviewee's had a different role in the organisation a broad perspective was retrieved. Nevertheless, it is advised for other researchers to interview all the healthcare professionals that are involved in the process, because this will improve the validity of the model when it is presented to the team. Moreover, it prevents that a caregiver has to introduce his activities during the validation meeting.

The validation meeting for the case study was set on 2 hours which was rather short and not all healthcare professionals were able to stay for the entire duration of the meeting due to unexpected events. It is recommended to include more participants in the validation meeting. This allows to discuss a wider set of potential risks because it is more likely that all type of caregivers will be represented. Furthermore, raising awareness is likely to be higher among the caregiver, when more healthcare professionals are involved in the risk assessment.

The models were analysed by the researcher by systematically tracking changes between the WAI and WAD model. The WAD model contains 59 activities and even more couplings. Creating a matrix to compare the couplings is error prone. Therefore, it is recommended to create a macro in Excel that automates this process in the future.

The effectiveness of the controls identified with HFMEA for the process were assessed on the set of potential risks identified with FRAM. It is recommended to develop a set of parameters to make the measuring of the effectiveness more transparent.

FUTURE RESEARCH

The strategy presented in this thesis (chapter 7) should be validated on a different case study to verify the correctness. During the case study uncertainties in the strategy should be addressed such as effective groups sizes for the validation meeting and the number of participants for the interviews. Because it is likely that having more participants will reveal more insights regarding the performance variability during "everyday performance". However, the effective group size is expected to be limited. Furthermore, a more strategic and systemic approach for the scenario assembly should be explored.

Measuring safety is still one of the most controversial topics within safety science. The number of adverse events does not reveal how safe a system is and feeling safe in not the same as being safe [18][27]. Nevertheless, the most novel quantitative metrics available to date to measure the effectiveness of controls still rely on counting on how many occasions the control was not effective i.e. resulted in a failure of the system and provide a bimodal answer on effectiveness (yes/no) [56]. No information is generated on how many occasions the control was able to overcome an adverse event by approximate adjustments of the system rather than the use of the control. Furthermore, the coupling of events are not taken into account. Developing safety metrics for measuring the effectiveness of controls that are able to capture these feature of systems are believed to be

highly valuable to asses safety of systems in the future.

Recommendations for HollandPTC

From the case study on plan-adaptation, several new insight were generated. A new set of potential risk were identified for the plan-adaptation process. The critical ones were directly resolved by HollandPTC after the validation meeting. Yet, some of the potential risks required awareness rather than a direct control. It is advised to come up with a strategy to raise awareness for these set of potential risks.

The risk analysis method used in the case study, can also be used for other process at HollandPTC. This might reveal new insights regarding the efficiency and safety of these processes. It is advised to have the interviews conducted by a researcher who is not familiar with the process. This prevents that activities are not told because it is assumed it is known to the researcher.

Finally, logic reasoning remains one of the key components for formulating potential risks after identifying potential hazardous couplings. The experience of those involved, tacit knowledge, is invaluable for this because only little literature is available for proton therapy and the procedures can differ between treatment centres. Therefore, it is recommended to formulate potential risks with many different involved healthcare professionals and to discuss the potential risks with the other facilities in the Netherlands. Additionally, it is advised to promote participation in risk assessments in the organisation. This research showed that by investing little time (approx. 4 hours per caregiver), great insights can be generated regarding the safety and efficiency of process.

8

REFERENCES

[1] https://www.tudelft.nl/2018/tu-delft/opening-hollandptc/. Online, accessed on 31.07.2019.

[2] *IAEA Safety Glossary: 2018 Edition*. Non-serial Publications. INTERNATIONAL ATOMIC ENERGY AGENCY, Vienna, 2019.

[3] Jerry L Barker Jr, Adam S Garden, K Kian Ang, Jennifer C O'Daniel, He Wang, Laurence E Court, William H Morrison, David I Rosenthal, KS Clifford Chao, Susan L Tucker, et al. Quantification of volumetric and geometric changes occurring during fractionated radiotherapy for head-and-neck cancer using an integrated ct/linear accelerator system. *International Journal of Radiation Oncology* Biology* Physics*, 59(4):960–970, 2004.

[4] Ken Catchpole, David M Neyens, James Abernathy, David Allison, Anjali Joseph, and Scott T Reeves. Framework for direct observation of performance and safety in healthcare, 2017.

[5] Robyn Clay-Williams, Jeanette Hounsgaard, and Erik Hollnagel. Where the rubber meets the road: using fram to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implementation Science*, 10(1):125, 2015.

[6] European Comission. 2018 reform of eu data protection rules. `https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en`. Online; accessed on 26.05.2019.

[7] Lynne Coventry and Dawn Branley. Cybersecurity in healthcare: A narrative review of trends, threats and ways forward. *Maturitas*, 113:48–52, 2018.

[8] Nikki L Damen, Marit S de Vos, Marco J Moesker, Jeffrey Braithwaite, Rob AF de Lind van Wijngaarden, Jason Kaplan, Jaap F Hamming, and Robyn Clay-Williams. Preoperative anticoagulation management in everyday clinical practice: an international comparative analysis of work-as-done using the functional resonance analysis method. *Journal of patient safety*, 2019.

[9] N.L.M. Damen. Waarderende procesanalyse met de fram methodiek. *Kwaliteit in zorg*, 6:23–27, 2017.

[10] JA De Bruijn and EF Ten Heuvelhof. Scientific expertise in complex decision-making processes. *Science and public policy*, 26(3):179–184, 1999.

[11] Sidney Dekker, Paul Cilliers, and Jan-Hendrik Hofmeyr. The complexity of failure: Implications of complexity theory for safety investigations. *Safety science*, 49(6):939–945, 2011.

[12] Sidney Dekker, Erik Hollnagel, David Woods, and Richard Cook. Resilience engineering: New directions for measuring and maintaining safety in complex systems. *Lund University School of Aviation*, 2008.

8

[13] Joseph DeRosier, Erik Stalhandske, James P Bagian, and Tina Nudell. Using health care failure mode and effect analysis™: the va national center for patient safety's prospective risk analysis system. *The Joint Commission journal on quality improvement*, 28(5):248–267, 2002.

[14] JA Efstathiou, PJ Gray, and AL Zietman. Proton beam therapy and localised prostate cancer: current status and controversies. *British journal of cancer*, 108(6):1225, 2013.

[15] Bert Enserink, Jan Kwakkel, Pieter Bots, Leon Hermans, Wil Thissen, and Joop Koppenjan. *Policy analysis of multi-actor systems.* Eleven International Publ., 2010.

[16] A Eurocontrol. White paper on resilience engineering for atm. *Report of the Project Resilience Engineering for ATM*, 2009.

[17] Giuliana Faiella, Anam Parand, Bryony Dean Franklin, Prem Chana, Mario Cesarelli, Neville A Stanton, and Nick Sevdalis. Expanding healthcare failure mode and effect analysis: A composite proactive risk analysis approach. *Reliability Engineering & System Safety*, 169:117–126, 2018.

[18] Eric C Ford and Stephanie Terezakis. How safe is safe? risk in radiotherapy. *International Journal of Radiation Oncology• Biology• Physics*, 78(2):321–322, 2010.

[19] Dominique Fortin, Parminder S Basran, Tanya Berrang, David Peterson, and Elaine S Wai. Deformable versus rigid registration of pet/ct images for radiation treatment planning of head and neck and lung cancer patients: a retrospective dosimetric comparison. *Radiation Oncology*, 9(1):50, 2014.

[20] BA Fraass. Impact of complexity and computer control on errors in radiation therapy. *Annals of the ICRP*, 41(3-4):188–196, 2012.

[21] M Giardina, MC Cantone, E Tomarchio, and I Veronese. A review of healthcare failure mode and effects analysis (hfmea) in radiotherapy. *Health physics*, 111(4):317–326, 2016.

[22] Eric K Hansen, M Kara Bucci, Jeanne M Quivey, Vivian Weinberg, and Ping Xia. Repeat ct imaging and replanning during the course of imrt for head-and-neck cancer. *International Journal of Radiation Oncology* Biology* Physics*, 64(2):355–362, 2006.

[23] E. Hollangel. Can we ever imagine how work is done? *Hindsight 25*, pages 10–13, 2017.

[24] E Hollnagel, J Leonhardt, T Licu, and S Shorrock. From safety-i to safety-ii: A white paper. eurocontrol, 2013.

[25] Erik Hollnagel. Risk+ barriers= safety? *Safety science*, 46(2):221–229, 2008.

[26] Erik Hollnagel. The functional resonance analysis method - framsynt. http://functionalresonance.com/onewebmedia/Manual%20ds%201.docx.pdf, 2018. Online; accessed on 02.02.2019.

8

[27] Erik Hollnagel. *Safety-I and safety-II: the past and future of safety management*. CRC press, 2018.

[28] Erik Hollnagel, Jeanette Hounsgaard, and Lacey Colligan. *FRAM-the Functional Resonance Analysis Method: A Handbook for the Practical Use of the Method*. Centre for Quality, Region of Southern Denmark, 2014.

[29] Erik Hollnagel, Robert L Wears, and Jeffrey Braithwaite. From safety-i to safety-ii: a white paper. *The resilient health care net: published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia*, 2015.

[30] Grace Huang, Gaylene Medlam, Justin Lee, Susan Billingsley, Jean-Pierre Bissonnette, Jolie Ringash, Gabrielle Kane, and David C Hodgson. Error in the delivery of radiation therapy: results of a quality assurance review. *International Journal of Radiation Oncology* Biology* Physics*, 61(5):1590–1595, 2005.

[31] Patrick Hudson. Accident causation models, management and the law. *Journal of Risk Research*, 17(6):749–764, 2014.

[32] K Ilicic, SE Combs, and TE Schmid. New insights in the relative radiobiological effectiveness of proton irradiation. *Radiation Oncology*, 13(1):6, 2018.

[33] Satoshi Ishikura. Quality assurance of radiotherapy in cancer treatment: toward improvement of patient safety and quality of care. *Japanese journal of clinical oncology*, 38(11):723–729, 2008.

[34] Linda T Kohn, Janet Corrigan, Molla S Donaldson, et al. *To err is human: building a safer health system*, volume 6. National academy press Washington, DC, 2000.

[35] Aafke C Kraan, Steven van de Water, David N Teguh, Abrahim Al-Mamgani, Tom Madden, Hanne M Kooy, Ben JM Heijmen, and Mischa S Hoogeman. Dose uncertainties in impt for oropharyngeal cancer in the presence of anatomical, range, and setup errors. *International Journal of Radiation Oncology* Biology* Physics*, 87(5):888–896, 2013.

[36] Sarah L Krein, Laura J Damschroder, Christine P Kowalski, Jane Forman, Timothy P Hofer, and Sanjay Saint. The influence of organizational context on quality improvement and patient safety efforts in infection prevention: a multi-center qualitative study. *Social science & medicine*, 71(9):1692–1701, 2010.

[37] Christopher Kurz, Reinoud Nijhuis, Michael Reiner, Ute Ganswindt, Christian Thieke, Claus Belka, Katia Parodi, and Guillaume Landry. Feasibility of automated proton therapy plan adaptation for head and neck tumors using cone beam ct images. *Radiation Oncology*, 11(1):64, 2016.

[38] Johannes A Langendijk, Philippe Lambin, Dirk De Ruysscher, Joachim Widder, Mike Bos, and Marcel Verheij. Selection of patients for radiotherapy with protons aiming at reduction of side effects: the model-based approach. *Radiotherapy and Oncology*, 107(3):267–273, 2013.

8

[39] Nancy Leveson. A new accident model for engineering safer systems. *Safety science*, 42(4):237–270, 2004.

[40] Wei Liu, Steven J Frank, Xiaoqiang Li, Yupeng Li, Peter C Park, Lei Dong, X Ronald Zhu, and Radhe Mohan. Effectiveness of robust optimization in intensity-modulated proton therapy planning for head and neck cancers. *Medical physics*, 40(5):051711, 2013.

[41] Karin Lundblad, Josephine Speziali, Rogier Woltjer, and Jonas Lundberg. Fram as a risk assessment method for nuclear fuel transportation. In *Proceedings of the 4th International Conference Working on Safety*, volume 1, pages 223–1, 2008.

[42] Lawrence B Marks, Kim L Light, Jessica L Hubbs, Debra L Georgas, Ellen L Jones, Melanie C Wright, Christopher G Willett, and Fang Fang Yin. The impact of advanced technologies on treatment deviations in radiation treatment delivery. *International Journal of Radiation Oncology* Biology* Physics*, 69(5):1579–1586, 2007.

[43] SE McGowan, NG Burnet, and AJ Lomax. Treatment planning optimisation in proton therapy. *The British journal of radiology*, 86(1021):20120288–20120288, 2013.

[44] Ian I Mitroff. *Stakeholders of the organizational mind.* Jossey-Bass Inc Pub, 1983.

[45] Birgit Sabine Müller, Marciana Nona Duma, Severin Kampfer, Simeon Nill, Uwe Oelfke, Hans Geinitz, and Jan Jakob Wilkens. Impact of interfractional changes in head and neck cancer patients on the delivered dose in intensity modulated radiotherapy with protons and photons. *Physica Medica*, 31(3):266–272, 2015.

[46] European Commission Directorate General of Energy. General guidelines on risk management in external beam radiotherapy. https://ec.europa.eu/energy/sites/ener/files/documents/RP181web.pdf, 2015. Online; accessed on 26.06.2019.

[47] Harald Paganetti. Range uncertainties in proton therapy and the role of monte carlo simulations. *Physics in Medicine & Biology*, 57(11):R99, 2012.

[48] Riccardo Patriarca, Johan Bergström, Giulio Di Gravio, and Francesco Costantino. Resilience engineering: Current status of the research and future challenges. *Safety Science*, 102:79–100, 2018.

[49] Riccardo Patriarca, Giulio Di Gravio, and Francesco Costantino. A monte carlo evolution of the functional resonance analysis method (fram) to assess performance variability in complex systems. *Safety science*, 91:49–60, 2017.

[50] Riccardo Patriarca, Giulio Di Gravio, and Francesco Costantino. myfram: An open tool support for the functional resonance analysis method. In *2017 2nd International Conference on System Reliability and Safety (ICSRS)*, pages 439–443. IEEE, 2017.

8

[51] Riccardo Patriarca, Andrea Falegnami, Francesco Costantino, and Federico Bilotta. Resilience engineering for socio-technical risk analysis: Application in neurosurgery. *Reliability Engineering & System Safety*, 180:321–335, 2018.

[52] J Reason, E Hollnagel, and J Paries. Revisiting the swiss cheese model of accidents. *Journal of Clinical Engineering*, 27(4):110–115, 2006.

[53] Julie E Reed, Cathy Howe, Cathal Doyle, and Derek Bell. Simple rules for evidence translation in complex systems: a qualitative study. *BMC medicine*, 16(1):92, 2018.

[54] P. Reijnders-Thijssen. Prisma-rt. https://www.prisma-rt.nl/en/goals/. Online accessed ;21.01.2019.

[55] Gill Ringland and Peter Préfacier Schwartz. *Scenario planning: managing for the future*. John Wiley & Sons, 1998.

[56] Alfred Roelen, Robbert van Aalst, Nektarios Karanikas, Steffen Kaspers, Selma Piric, and Robert J de Boer. Effectiveness of risk controls as indicator of safety performance. *AUP Advances*, 1(1):175–189, 2018.

[57] Barbara Rombi, Sabina Vennarini, Lorenzo Vinante, Daniele Ravanelli, and Maurizio Amichetti. Proton radiotherapy for pediatric tumors: review of first clinical results. *Italian journal of pediatrics*, 40(1):74, 2014.

[58] Jesmin Shafiq, Michael Barton, Douglas Noble, Claire Lemer, and Liam J Donaldson. An international review of patient safety measures in radiotherapy practice. *Radiotherapy and Oncology*, 92(1):15–21, 2009.

[59] Xiang Su, Jarkko Hyysalo, Mika Rautiainen, Jukka Riekki, Jaakko Sauvola, Altti Ilari Maarala, Harri Hirvonsalo, Pingjiang Li, and Harri Honko. Privacy as a service: Protecting the individual in healthcare data processing. *Computer*, 49(11):49–59, 2016.

[60] Michael J Taylor, Chris McNicholas, Chris Nicolay, Ara Darzi, Derek Bell, and Julie E Reed. Systematic review of the application of the plan–do–study–act method to improve quality in healthcare. *BMJ Qual Saf*, 23(4):290–298, 2014.

[61] James E Turner. *Atoms, radiation, and radiation protection*. John Wiley & Sons, 2008.

[62] M. van Vulpen. Presentation: Overview proton therapy. 7th ncs lustrum. https://radiationdosimetry.org/files/documents/0000104/291-02-mvv-overviewprotontherapy.pdf, 2017. Online; accessed on 05.03.2019.

[63] Miranda Visser. Risk analysis in a complex socio-technological system. a literature study, 2019. Not published in a journal - written for course BME51010 (2018/2019) at TU Delft.

[64] WHO et al. Radiotherapy risk profile, 2008. Online; accessed on 26.11.2018.

8

[65] MV Williams. Improving patient safety in radiotherapy by learning from near misses, incidents and errors. *The British journal of radiology*, 80(953):297–301, 2007.

[66] Qiuwen Wu, Yuwei Chi, Peter Y Chen, Daniel J Krauss, Di Yan, and Alvaro Martinez. Adaptive replanning strategies accounting for shrinkage in head and neck imrt. *International Journal of Radiation Oncology* Biology* Physics*, 75(3):924–932, 2009.

[67] Robert Yin. Analytic generalization. *Encyclopedia of case study research*, 1:20–22, 2010.

APPENDIX

A
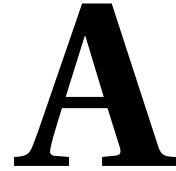
INTERVIEWS

This appendix contains an overview of the interview guidelines and contains a summary of each interview. The notes of the interviews can be made available upon request.

A.1. SET-UP OF THE INTERVIEWS

All participants were invited by e-mail 3 weeks prior to the date of the interview by J. Clarijs. Only a very brief description with the goal and relevance of the interview was provided to the participants.

Brief description: *Hierbij nodig ik jou graag uit voor het onderzoek naar de toepassing van een nieuwe methode om risico's mee te inventariseren.*

1. **Introduction** - 10 min. Introduction of the interviewer, explain the relevance of the study for HollandPTC and how the interview will be conducted and introduction of the interviewee.

2. **Interview questions** - 30/50 min.

   - The interviewer has prepared a start activity from the written procedures. The interviewer verifies whether this is the first activity of the interviewee in the process of plan-adaptation. If the interviewee does not agree with this starting point the interviewer search together with the interviewee for a starting point within the scope of the process of plan-adaptation.

   - When the start activity is identified the interviewer will use the question provided in section A.2 to create semi-guided interview.

   - The interviewer identifies the various activities during the conversation and verifies whether all information is given regarding the 6 aspects for a FRAM.

   - Required time depends on the number of activities the interviewee has.

3. **Closure** - 10 min. The interviewer asks whether there is a topic that has not been discussed but that is relevant according to the interviewee for the scope of the

study. The interviewer invites the interviewee for a follow up; the validation meeting and thanks the interviewee for his/her time.

A.2. Guiding Questions

The following questions were used to guide the semi-structured interviews by the interviewer.

Table A.1: Questions used to guide the semi-structured interviews in Dutch [9]

Aspect	Guided Questions
Input	Waardoor begint de functie?
	Waardoor verandert de functie?
Output	Wat is het resultaat van de functie?
	Informeer je iemand over het resultaat? Zoja, wie?
	Noteer je het resultaat ergens? Zoja, waar en hoe?
Time	Wat is de invloed van tijd op de activiteit?
	Is er een specifieke tijd/moment waarop de activiteit moet worden uitgevoerd?
	Wat gebeurt er onder tijdsdruk? Voer je dan de activiteit anders uit?
Control	Hoe wordt de activiteit gecontroleerd/gemonitord?(richtlijnen, werkafspraken, missie/visie)
	Zijn er formele afspraken of instructies?
	Zijn er specifieke personen, zoals supervisoren, die de activiteit monitoren/controleren?
	Zijn er aspecten die de activiteit beperken, zoals budget?
Precondition	Zijn er voorwaarden waaraan voldaan moet zijn voordat de activiteit kan starten?
	Wat doe je als er niet aan deze voorwaarden zijn voldaan?
Resources	Wat heb je nodig om de activiteit te kunnen uitvoeren?
	Wat gebruik je tijdens het uitvoeren van de activiteit aan menskracht, materiaal, gebouwen, software etc.
	Zijn deze bronnen altijd aanwezig?
	Wat doe je als dit niet aanwezig is?

Table A.2: Questions used to guide the semi-structured interviews in English.

Aspect	Guided Questions
Input	What starts the function?
	What signals that the function can begin?
Output	What is the result or the output of the function ?
	Do you have to contact anyone when the function is finished ?
	Who will use the output of this function?
Time	Is there any time (pressure) related to the function?
	When there is time pressure do you execute the function differently?
Control	Are there any guidelines or any other written instructions in place to control the functions?
	Is the function controlled by a person?
	Are there any values that control the function?
Precondition	Are there any preconditions that needs to be fulfilled?
	What do you do if the preconditions have not been met or are not available?
Resources	Which resources do you need to execute the function?
	Are these resources always available?
	What happens if they are not available?

B

VALIDATION MEETING

B.1. GOAL OF VALIDATION MEETING

The validation meeting was organised to gain insights in the various dynamic couplings, validate the model, discuss opportunities to dampen variability among the couplings and to identify potential risks.

B.2. SET-UP OF VALIDATION MEETING

In order to obtain the desired information from the participants the following setup was designed by the researcher for this meeting:

	Goal	Time
Introduction	Familiarise participants with the method FRAM.	10 min
Identify a Function	Introduce the WAD-model to the participant by having them look for 1 or more activities in the model that match their role as caregiver.	5 min
Casus	Explore the WAD-model further with participants by introducing an imaginary patient and letting the patient flow through the model.	10 min
Potential Risks	Introduce the potential risks that have been found during the analysis of WAI vs WAD by researcher	10 min.
Discussion	Discuss the various risks that have been introduced and the model in depth.	30 min.

B.2.1. Participants

3 weeks in advance a total of seven caregivers were invited for the validation meeting by J. Clarijs. All of the invited participants accepted the invitation but due to unforeseen conditions, only 5 were able to physically attend the meeting. All 5 participants have a different role within the organisation.

Table B.1: Overview of participants that attended the validation meeting.

Role of Caregiver
Medical Physicist
Logistic Planner
Radiotherapy Technologists (Gantry/CT-scan)
Radiotherapy Technologists (Dose planning)
Radiation Oncologist

B.2.2. Tools used

To facilitate the meeting a 10 pages booklet was designed for each participant. The booklet contained: an A3 sized WAD-model, a specification of the various WAD instantiations including guiding text, an overview of the identified functions specified per caregiver and some background information on FRAM.

Next to the booklet, the researcher brought an A0 poster of the WAD-Model printed both in colour and in black-and-white. The coloured poster was placed on the table to facilitate a discussion without having the trouble of participants being distracted by looking into their booklet. The intention of the black-and-white poster was to be able to create a path through the model without being distracted from all the colours. Lastly, a powerpoint was used for the introduction part of the meeting and to introduce the setup for the meeting.

B.3. Reflections on the validation meeting

Prior to the meeting it was clear what the goal of the meeting would be to the researcher. By communicating the goal of the meeting clearly to all the participants during the introduction part of the meeting it was prevented that matters were discussed that were not within the scope of this study. Furthermore, all the participants were open and eager to receive feedback on the process of plan-adaptation through the model. As a result the meeting generated many insights on dynamic couplings, opportunities to dampen performance variability, potential risks and chances for actions regarding the process of plan-adaptation.

The validation meeting was led by the researcher. Some problems and solutions were not directly clear to the researcher as they involved very detailed processes. The participants were therefore asked by the researcher to elaborate on some topics. In some cases elaborating to the researcher on a topic led to new potential risks/ideas/chances. However, it is recommended to have a more process experienced person leading the discussion. This way the researcher is able to listen more actively and relate the discussed

topics better to the model.

Due to unforeseen events 3 participants could not attend the meeting. As a result the medical physicist assistant was not represented during the meeting. However, the activities linked to this role were verified by the medical physicist. Furthermore, due to a tight schedule the participants were only able to attend for an hour instead of 1.5. Therefore, the set-up had to be adjusted by the researcher. The small number of participants allowed the discussion on the risk to still take most of the time. However, a higher number of participants is recommended as it is expected that each participant will have a different view on the process. Therefore, it is thought that more participants (not an unlimited number) will result in a better insight on the potential risks of the process.

Lastly, from participants feedback was received that the model indeed provided new insights into the interdependencies of activities and that it was easy to interpret. Furthermore, the participants were very positive that the model allowed to incorporate many things that were neglected during other risk assessments.

B.4. COUPLINGS MATRIX

The matrix shown on the next page was created to generate insights regarding differences in couplings. All green coloured boxes are couplings that were only present in the WAD model. All green coloured boxes were present in both the WAD and WAI model. These couplings served as input for the design of potential risks.

Design structure matrix (activities C1–C59 as rows; activity codes C8–C56 as columns). Green cells shown as **G**, orange cells shown as **O**.

Activity		C8	C9	C10	C13	C16	C18	C19	C23	C24	C25	C26	C27	C28	C29	C30	C31	C32	C33	C34	C38	C39	C40	C41	C42	C43	C44	C46	C48	C51	C55	C56
To observe anatomical variation	C1	O																														
To have tumour in head/neck region	C2	O				G																										
To prioritise activities	C3	G																														
To have other appointments	C4	G																														
To have a CT_available	C5	G																														
To have staff available	C6	G																														
To have malfunctioning scanner	C7		G																													
To create carepath rCT-scan	C8		G																													
To make a rCT-scan	C9				G																											
To check worklist regularly	C10				G																											
To have other activities	C11			G																												
To prioritise activities	C12			G																												
To Import rCT-scan	C13				O																											
To operate ARIA	C14	O	O		O																			G								
To draw external in rCT-scan	C15					G																										
To merge CT-scans	C16						G	O									G															
To operate RayStation	C17					G																										
To check the merger of CT-scans	C18							G																								
To run a robustness test	C19								O																							
To use a computer	C20							G																								
To adjust script manually	C21							G																								
To have other activities	C22						G																									
To evaluate test results	C23									O	O	O	O			G																
To create carepath plan-adaptation	C27																								O		O					
To check NeoZis	C28																		G											G		G
To have an unfitting mask	C29	O																														
To evaluate OAR/CTV	C30															G			G													
To adapt OAR/CTV	C31																	O														
To create adapted treatment plan	C32																				G	O										
To change masks	C33																															O
	C34																															
To use a template f_all	C35																															
To use QA mode on gantry	C36																	G								G						
To request time required for QA	C37																				G											
To adjust nr. remaining fractions	C38																					G										
To check adapted treatment plan and fractions	C39																					G					G					
To check worklist regularly	C40																							O								
To import adapted treatment plan ARIA	C41																							G	G							
To prepare QA	C42																									O						
To execute QA	C43																	G									G					
To check adapted radiation plan	C44																	O							G	G	G					
To have a gantry available	C45																															
To validate QA results	C46																	O										G				
To prepare gantry	C47																											G				
To analyse QA	C48																												G			
To upload report in ARIA	C49																															
To check numbering of beams	C50																															G
To activate the adapted treatment plan	C51																													G		
	C52																															
To manually calculate total dose	C53																														G	
To use credentials MP	C54																	G														
To perform a dose correction	C55																													O		
To use the adapted treatment plan	C56																															
To check changes made by RTT	C57																															G
To attend morning meeting	C58											G		G				G														G
To use the adapted treatment plan	C59																													O		G

C

HFMEA

The full HFMEA of the process plan-adaptation is available upon request at HollandPTC. Below an executive summary is provided of the process and the potential risks identified with HFMEA.

C.1. GOAL OF HFMEA
The goal of the meeting was to release the clinical adaptive workflow by conducting a prospective risk analysis.

C.2. SET-UP OF MEETING
The meeting was held on 12/12/2018 at HollandPTC and led by a medical physicist. The researcher of this thesis was not involved in this risk-analysis. The HFMEA was conducted in accordance with the NHS report 'A risk matrix for risk managers'. The following risk assessment assumptions were made for conducting the HFMEA. As plan-adaptation is a risk for the patient, a multidisciplinary HFMEA is required.

C.2.1. PARTICIPANTS
A multidisciplinary team was assembled for conducting the HFMEA. The team consisted of:

# of caregivers	Role of Caregiver
4	Radiotherapy Technologists
2	Medical Physicist
1	Radiation Oncologist

C.3. IDENTIFIED POTENTIAL RISKS

All the identified potential risks and their criticalness are depicted below. The function to which the potential risk is related to is used as title. The colours in the upper left corner of each process step indicates the criticality of the risk. The following indicators are used to indicate the severity: red - major event, yellow - moderate event and green - minor event. The potential risks have been ordered to their criticality.

Inschatting risico's	Risico Niveau
Kans op incidenten door complexiteit van handeling/bediening	🟨
Kans op incidenten door gebruiksomgeving	🟨
Kans op fouten door introductie	🟨
Risico voor bedrijfsproces	🟨
Risico voor de patiënt	🟥
Risico ten aanzien van informatieveiligheid/ICT	🟩
Risico door beperkte detecteerbaarheid van/bij onjuist functioneren	🟨
Risico door lage gebruiksfrequentie (door betrokken medewerker)	🟩

Risico niveau	Vervolgstappen
🟩 Laag	Verdere risicoanalyse niet noodzakelijk
🟨 Midden	Risico-analyse light
🟥 Hoog	Multidisciplinaire HFMEA noodzakelijk

RE-OPTIMISATION OF THE TREATMENT PLAN

(Catastrophic)

Process Description	The adapted treatment plan is designed with a template for the full number of fractions. However, the patient has already received a certain number of fractions as treatment has already begun. Therefore, the number of fractions has to be adjusted to meet the remaining number of fractions.
Potential Risk	The adjustment is incorrect; too little or too many fractions remain in the adapted treatment plan. Which causes the treatment plan to be incorrect.
Proposed Action	Adjustment of the fractions should be done by both a radiotherapy technologists and a medical physicist (multi-disciplinary team and 4 eye principle

RIGID REGISTRATION FOR DOSE CALCULATION

Process Description	Rigid registration is required for the dose calculation. During the rigid registration the CT images are aligned with the treatment CT images [19]. This alignment is used to calculated the dose distribution in the volumes.
Potential Risk	⟳ Incorrect decision is taken due to an inaccurate alignment of these images
Proposed Action	Always check the matching manually and give approval for the contours.

DEFORMABLE REGISTRATION FOR CONTOURING.

Process Description	Differences in CT-images due to for example weight- or positional changes complicates the matching of the images. Deformable registration tries to correct for these deviations by matching voxels [19].
Potential Risk	⟳ Incorrect decision is taken due to an inaccurate matching of the voxels of these images.
Proposed Action	Always check the matching manually and give approval for the contours.

SCHEDULING IN ARIA

Process Description	The treatment plan is deactivated when the adapted treatment plan is approved.
Potential Risk	Deactivation of the treatment plan occurs too early. No plan is available at the gantry.
Proposed Action	Timing of deactivation is added to the work instructions.

SCHEDULING ARIA

Process Description	The treatment plan has to be deactivated, when the adapted treatment plan is evaluated and approved.
Potential Risk	Two treatment plans are available at the gantry.
Proposed Action	Timing of deactivation is added to the work instructions.

SCHEDULING ARIA

Process Description	?
Potential Risk	Cluttered administration.
Proposed Action	Add check to checklist of radiotherapy technologist and medical physicist.

SCHEDULING IN ARIA

Process Description	Appointments have to be scheduled in ARIA for administering the fraction. It is possible to schedule 20 appointments while 35 fractions have to be administered and vice versa. Or the patient is not able to make it, which causes a mismatch in fractions-appointments.
Potential Risk	There are too little/many fractions in the adapted treatment plan.
Proposed Action	

GANTRY

Process Description	For some patients it is required to design a new mask. This mask has to be available at the gantry when the adapted treatment plan is used as treatment plan.
Potential Risk	The wrong mask is available at the gantry.
Proposed Action	Update the work instruction moulage with the instruction: the date of the rCT-scan should be written down on the mask during the moulage of the new mask. Furthermore, the 'old' mask should be destroyed when the new mask is put into use.

EVALUATION

Process Description	?
Potential Risk	↻ Labelling of the wrong case which causes a cluttered administration.
Proposed Action	Add the labelling of cases to the checklist of the RTT and MP so it will not be forgotten.

NEW DOSE SPECIFICATION POINT

Process Description	?
Potential Risk	Incorrect dose specification point.
Proposed Action	A check has been incorporated in the checklist of the radiotherapy technologist and medical physicist. Furthermore, the development of a script to prevent this is recommended.

SCHEDULING IN ARIA

Process Description	The dose correction is done after the adapted treatment plan has been evaluated by the medical physicist. During the dose correction, the dose already omitted to the patient is added to the adapted treatment plan.
Potential Risk	There are too little/many fractions in the adapted treatment plan which causes the total dose to be too low/high.
Proposed Action	Add a check to the checklist of the medical physicist and radiotherapy technologist.

DECISION TIME

Process Description	When the CT-images have been matched and a robustness test has been done the radiation oncologist has to decide whether plan-adaptation is required.
Potential Risk	⟳ Variation in decision criteria of radiation oncologists as a result patients are not treated uniformly.
Proposed Action	The treatment guidelines are updated with clear agreements.

SCHEDULING ARIA

Process Description	Multiple iso loc files are available in ARIA.
Potential Risk	Wrong a priori shift.
Proposed Action	Not specified.

RE-OPTIMISATION OF THE TREATMENT PLAN

Process Description	The treatment plan is designed in RayStation. When the plan is approved, the plan has to be imported into ARIA.
Potential Risk	⟳ The plan is not imported correctly into ARIA, which causes the treatment plan to be suboptimal.
Proposed Action	The final treatment plan is evaluated, to detect such mishaps.