

IMPACT

Intelligence based iMprovement of Personalized medicine And Clinical workflow support

DELIVERABLE D5.1.1

Definition of workflows and data collection methods for selected clinical workflows



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Deliverable review procedure:

- **2 weeks before due date:** deliverable owner sends deliverable –approved by WP leader– to Project Manager
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable
- **1 week before due date:** co-reviewer provides input to deliverable owner
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer

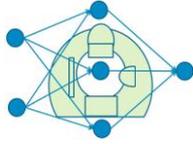


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1 Executive summary

This document describes the definition of workflows and data collection methods of selected clinical use cases that would be used for workflow optimization within the work package.

The work package aims to improve efficiency through workflow optimization by making workflows more standardized, predictable, traceable, reproducible and easy to use. The selected scope is the clinical workflows during percutaneous coronary interventions, liver surgery and brain metastases treatment planning.

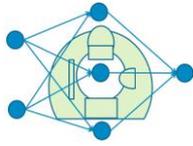
This document provides the overview of selected clinical workflow and the identification of inefficiencies. Different types of data and corresponding collection and analysis are also discussed here.

Lastly, this deliverable gives a foundation in support to other deliverables within the work package.



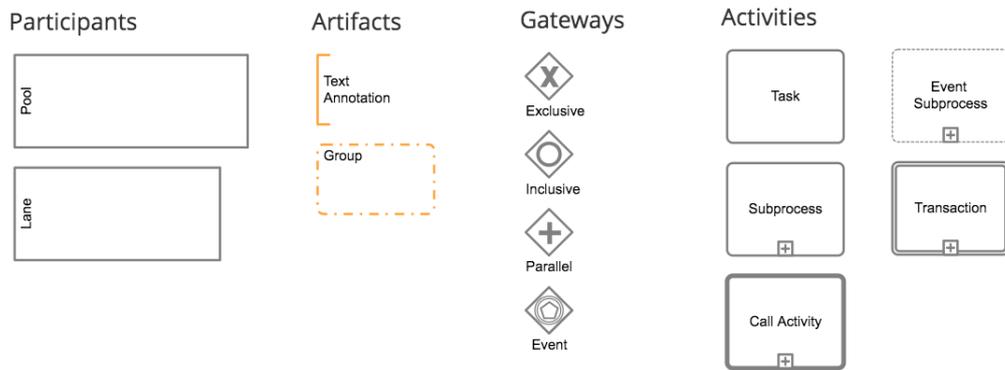
2 Glossary

BPMN	Business Process Model and Notation
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DVH	Dose Volume Histogram
DVI	Digital Visual Interface
EHR	Electronic Health Record
EMR	Electronic Medical Record
FPS	Frame Per Second
HL7	Health Level 7
MIS	Minimally Invasive Surgery
MRI	Magnetic Resonance Imaging
OAR	Organ At Risk
OR	Operating Room
PCI	Percutaneous Coronary Intervention
PoE	Power over Ethernet
QR	Quick Response
RFID	Radio-Frequency Identification
RGB-D	Red Green Blue-Depth
RIS	Radiology Information System
RTLS	Real-Time Locating Systems
SOSU	Social-og Sundhedsassistent (Social and Health Assistant)

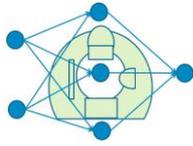


3 Workflow model notation

Workflows are modeled using the standard Business Process Model and Notation (BPMN). The following tables are the graphical representation defined in BPMN.



Type	Start			Intermediate				End
	Normal	Event Subprocess	Event Subprocess non-interrupt	catch	boundary	boundary non-interrupt	throw	
None								
Message								
Conditional								
Signal								
Error								
Escalation								
Termination								



4 Introduction

4.1 Aim of activities

Healthcare is a complex adaptive system given its dynamic and fast changing nature. Factors such as patient safety and economic pressure demand enhanced productivity and reduced cost while hospital service is growing. In healthcare organizations, processes are executed by multidisciplinary teams. These processes demand in-time scheduling and coherent coordination, which influence the level of efficiency in the workflow. Once a patient is being diagnosed, various steps are followed. Figure 1 gives an idea of a very high level workflow for general patient treatment. They are typically step-by-step, i.e. the previous step has to be completed before proceeding to the next step.

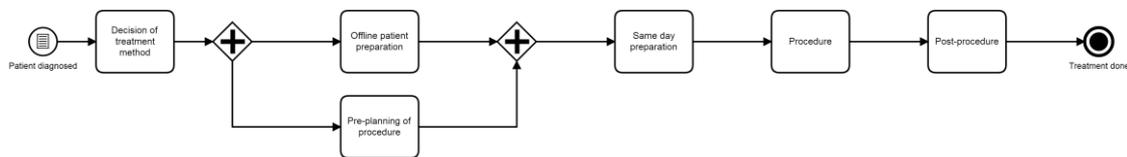


Figure 1: A high level workflow for patient treatment in general case.

Inefficiencies in workflow include tedious, manual and/or repetitive tasks that are present in the operation room, treatment planning, etc. With the technology advancement, appropriate use of new technology could give assistance to reduction in workflow inefficiencies. Sensors, cameras, modern logging systems, new data storage systems and others are potential candidates for redundancy reduction. Latest research and development in machine learning as well uncovers new approaches in data analytics for automation.

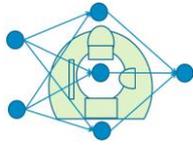
In order to optimize the workflows, they are modeled and decomposed for inefficiencies identification. Data is also collected and analyzed for decision support at various levels in hospitals concerning patients, staffs and equipment. Workflows are thus aimed to be more standardized, predictable, traceable and reproducible through the proper use of data.

Three clinical use cases are selected, namely cardiac, liver and brain. They are being discussed in detail in the following sections.

4.2 Contributors

Several authors contributed to this document. Following partners were responsible for each use case

Cardiac	Philips, NewCompliance
Liver	LUMC
Brain	Elekta, Inovia



5 Use case: Cardiac

Percutaneous coronary interventions

5.1 PCI workflow breakdown

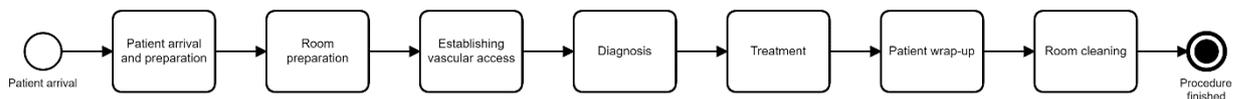


Figure 2: High-level PCI workflow. Detailed descriptions of each block can be found in Section 5.5.

Workflows for Percutaneous coronary intervention (PCI) procedures generally follow the high-level workflow shown in Figure 2. For a detailed breakdown, see 5.5, where the individual workflows for each of these blocks are described according to the five main roles: the patient, cardiologist, sterile nurse, non-sterile nurse and monitoring assistant. Given the large number of steps indicated in these workflows, it is typically difficult to indicate the duration of each step or identify where the workflow might be improved.

5.2 Workflow challenges

Healthcare costs are high and rising (~20% of GDP in USA). There are huge shortages of qualified staff (especially in Europe). Quality is an issue (medical errors are the 3rd leading cause of death in USA). Also, an increasing administrative burden on medical staff is leading to high burnout rates among physicians and nurses. Administrators are struggling to get a hold on costs and quality and are looking at LEAN and Six Sigma methods to improve both.

Interventional procedures are growing rapidly and becoming more specialized in diverse areas of care. PCIs are one of the most common interventional procedures. As the number of these procedures grows, pressure mounts to improve and standardize workflows in order to improve both patient safety and efficiency. Improving and standardizing workflow requires real-time feedback on protocol adherence as well as retro-active data analysis to identify bottle-necks and drive improvement.

5.2.1 Lack of accurate operational data to drive continuous improvement

LEAN and Six Sigma in the healthcare setting rely on accurate and continuous operational and clinical data to drive continuous improvement. Today, in the interventional suite, there are no reliable sources of operational information available. While limited logging is performed by the monitoring and/or sterile nurse, our (Philips Healthcare) workflow studies have shown that this data is often inaccurate and incomplete (as an example, see Figure 3 below).



10% of the RIS records have been excluded from analysis based on missing data or obvious key entry issues

Filter Item	Records Affected (cumulative)	Remaining		Filter setting
		13,635	100%	Total dataset from InfoFlex from January 2014 – June 2016
1	615	13,020	96%	"Room" only A, B, C, D, E (excludes Mobile lab* , Room 10 and Cardiac Theatre and null)
2	320	12,708	93%	"Procedure category" field not filled or "Other"
3	28	12,680	93%	"Time into theatre" between 01-jan-2014 and 31-jun-2016 is not null
4	132	12,548	92%	"Time out of theatre" between 01-jan-2014 and 31-jun-2016 is not null
5	31	12,517	92%	"Needle to skin time" between 01-jan-2014 and 31-jun-2016 is not null
6	8	12,509	92%	"Time procedure completed" between 01-jan-2014 and 31-mar-2016 is not null
7	11	12,498	92%	"Consultant" field not empty
8	45	12,453	91%	"Length of procedure" has to be more than 0 minutes
9	49	12,404	91%	"Length of procedure" has to be less than 24 hours
10	129	12,275	90%	Timestamps per procedure have to be chronological
		1,360	9.97%	of records discarded

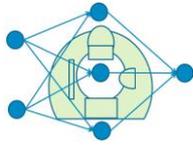
Figure 3: RIS record filters indicate that 10% of RIS data is inaccurate for analysis.

Clinical data required to adhere to patient safety protocols and provide feedback on patient readiness is available but requires time and effort to retrieve from disparate sources reducing its usefulness as a real-time feedback and improvement tool. Subsequent protocol adherence isn't reliably tracked.

Several studies (Reed et al., 2018, Lindsay et al., 2018) suggest operational efficiency and patient safety can in fact be improved through continuous improvement methods and standardization.

5.2.2 Increasing administrative burden leading to staff burnout

In Medscape's 2019 physician survey 44% indicates feeling burned out, 11% feels colloquially depressed and 4% is clinically depressed. The increase of bureaucratic tasks (e.g. charting, paperwork) are named as the top contributors (Figure 4).



What Contributes Most to Your Burnout?

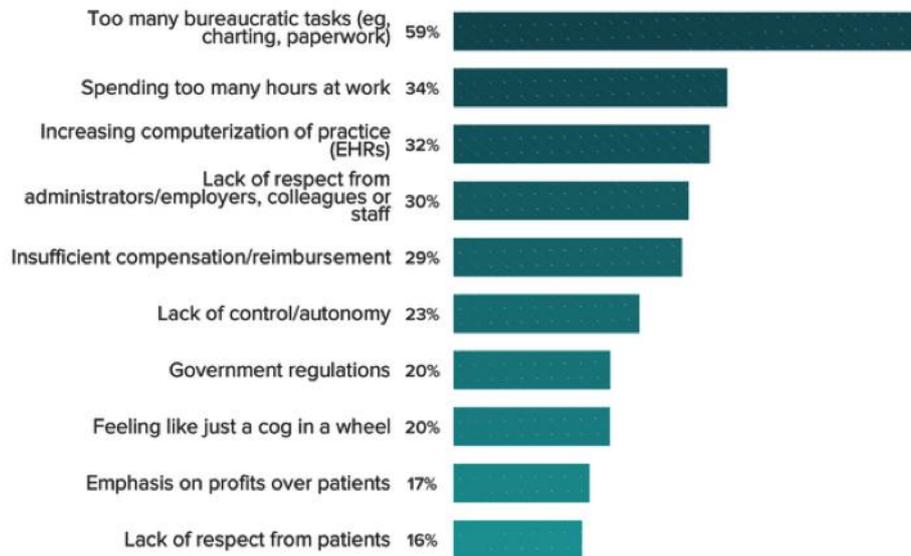


Figure 4: Top contributors to burnout (source: Medscape physician survey 2019).

Bureaucratic tasks for PCI (and other cardiac workflows) include, but are not limited to: charting, reporting, copying information across different devices and systems.

5.3 Data collection methods

- Interventional video gathering leveraging existing video infrastructures (ImageStream & MedinBox)
- Video and X-Ray data gathering through sponsor-initiated studies using a custom built / X-Ray vendor agnostic data gathering device
- EMR and planning data gathering through HL7 interfacing

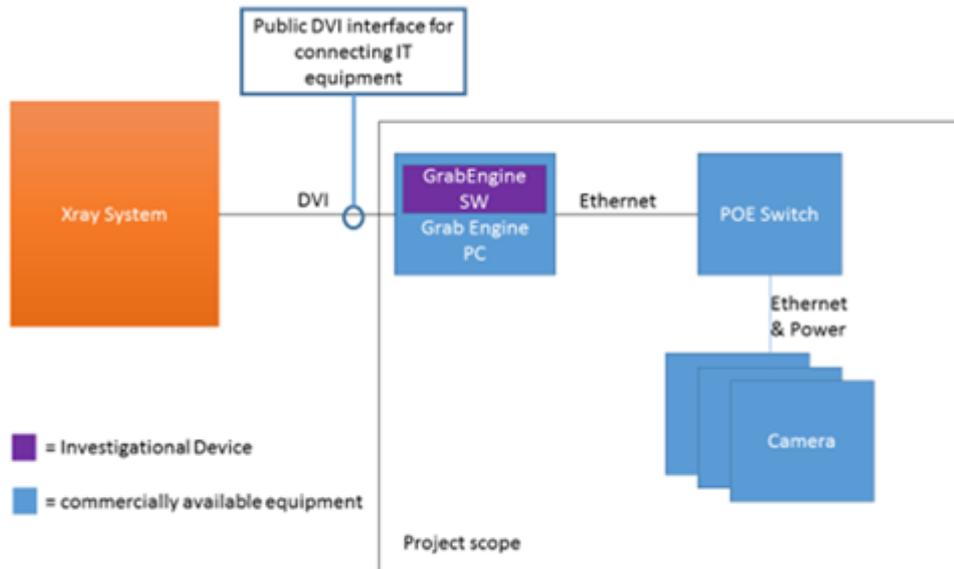
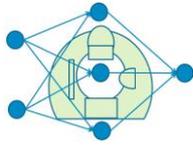


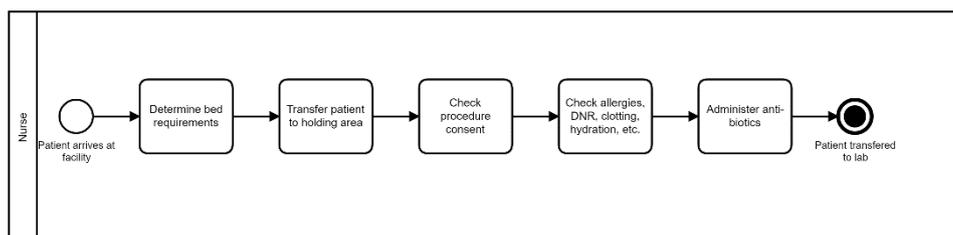
Figure 5: Data gathering device system overview.

5.4 Identification of candidate tasks for automation

- Automatic, continuous and accurate data gathering to enable continuous improvement methods like LEAN and Six Sigma
- Automation of simple and repetitive administrative tasks, like entering patient details, copying information from one screen to the other and looking up data for safety checks
- Automation of charting and/or reporting

5.5 Detailed PCI workflow

This section contains detailed workflow models that correspond to each of the blocks of the high-level PCI workflow of Figure 2. Tasks that may benefit from automation and/or workflow support have been highlighted.



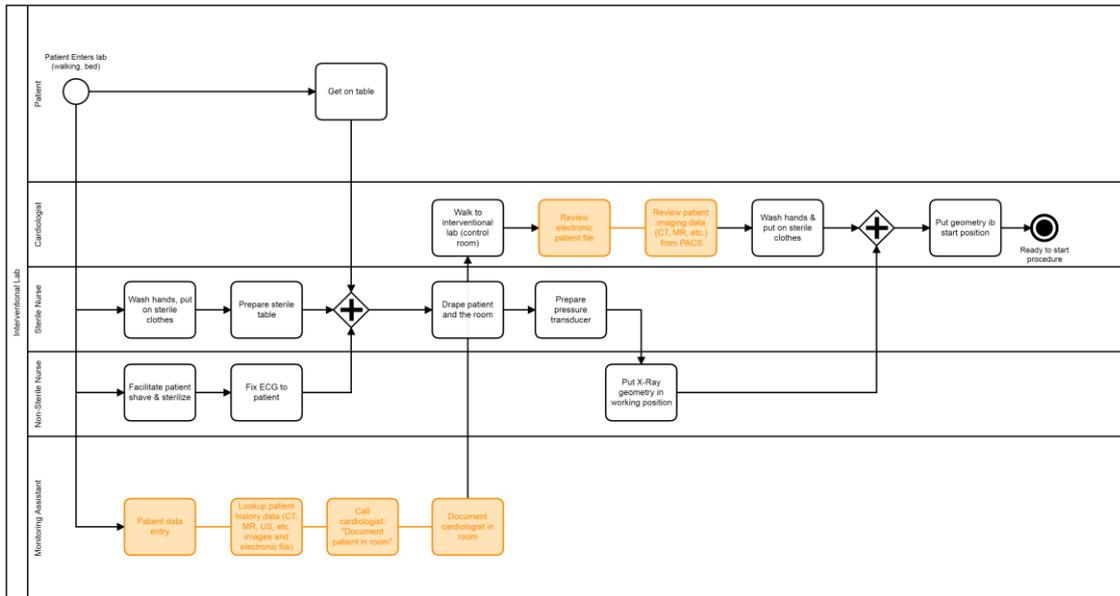
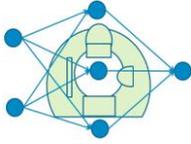


Figure 6: Room & patient prepared

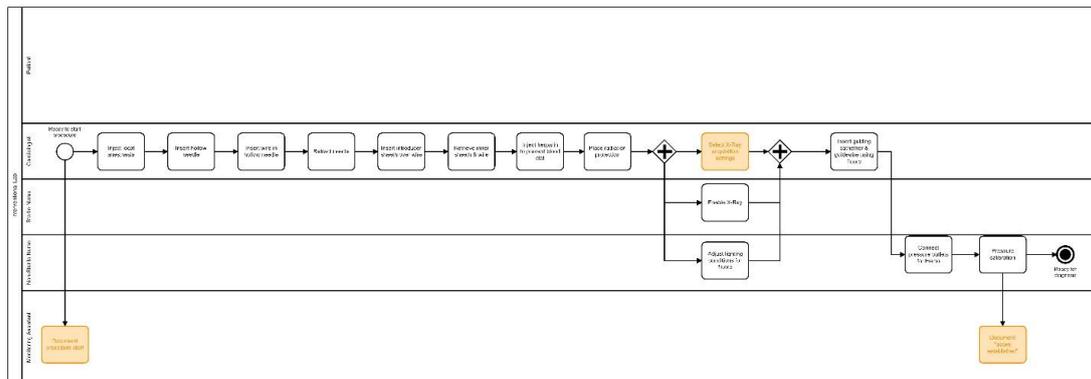


Figure 7: Establish vascular access

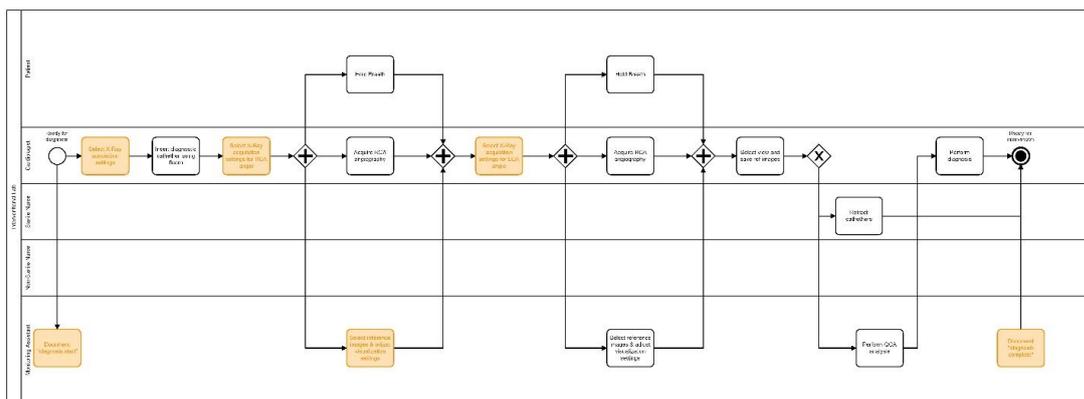


Figure 8: Diagnosis

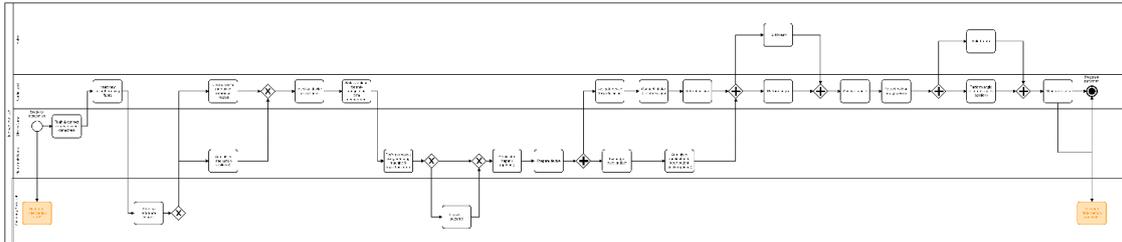
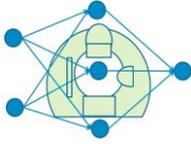


Figure 9: Treatment

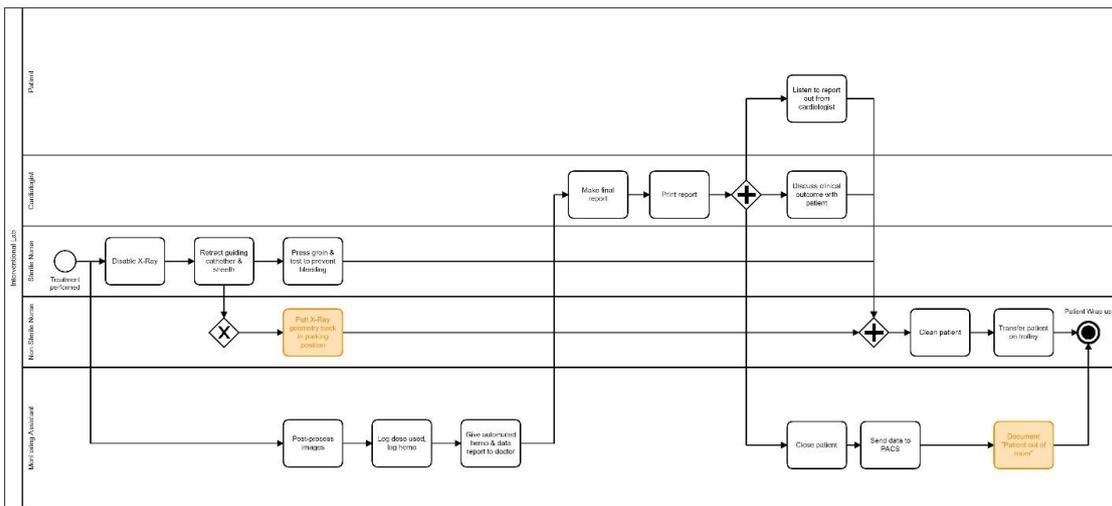


Figure 10: Wrap up

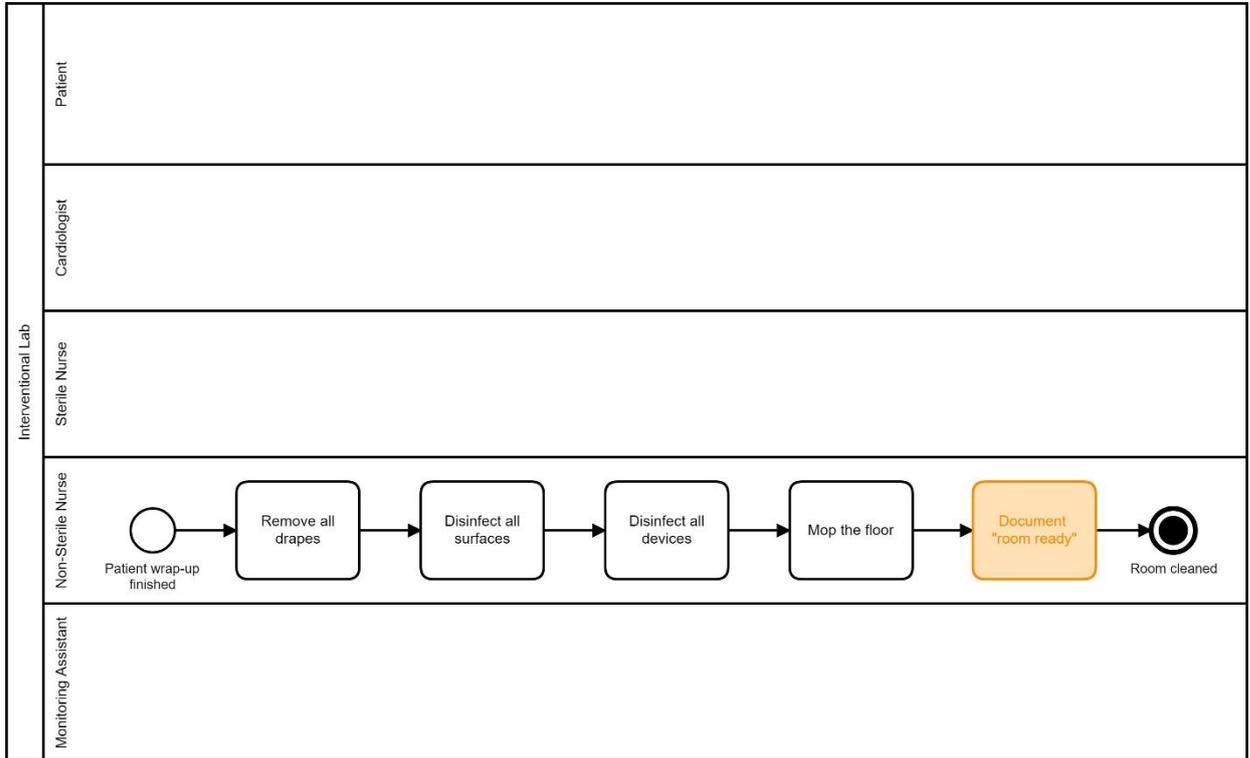
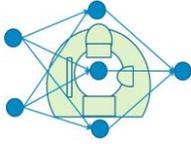
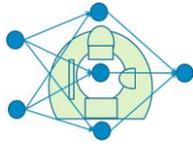


Figure 11: Patient wrap-up



6 Use case: Liver

Liver surgery

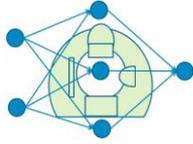
6.1 Introduction

The increase in the number of possible treatments in healthcare, together with the aging of the population puts a lot of pressure on the costs and waiting lists in the healthcare system. To be able to treat as many patients and prevent the costs from rising, one of the options is to improve the workflow efficiency. The Operating Room (OR) is the department with the highest expenses in a hospital, so this is potentially a place to start investigating. To identify potential cost reduction, the workflow needs to be analysed and optimized. As Joerger et al. (2017) describe: *"... for a process to be stable, its workflow outcomes need to stay in a certain range and try to avoid as much as possible outliers. To be able to reach such a goal, systems need measurement systems in order to, first, detect where inefficiencies are and then see if the new system put in place improves something."*

In the technological sector, a shift is taking place where electronics and data play a bigger role, which is called Industry 4.0. This shift is also getting attention in the medical field, as described by Wolf and Scholze (2017). The importance of information about processes is also mentioned by Katić et al. (2015), who write: *"The rise of intra-operative information threatens to outpace our abilities to process it. Context-aware systems, filtering information to automatically adapt to the current needs of the surgeon, are necessary to fully profit from computerized surgery."* In this case, it is suggested that systems need to be developed to support surgeons in the operating room. To do so, these systems need to be aware of the stage of the procedure in order to properly advice and inform the medical personnel.

Context awareness and information are not only important for the quality of surgery but also for its safety. As Padoy (2019) write: *"Disruptions may indeed cause safety issues and a recent study notes that over 129 surgeries observed in the OR, a disruption occurred every 75 seconds. Providing digital information about the current status of the procedure in each operating room would simplify coordination across the different stakeholders."*

Currently the planning of the procedures is made based on duration estimations by surgeons. For their estimation, they use their memory about similar previous cases, the medical condition of the patient and their physical condition. Then, because of delays, medical deviations and other unexpected events, the operation is delayed. The planning has to be adjusted due to these delays. To solve this, e.g. the LUMC medical university hospital of Leiden, has four employees re-adjusting the planning every day. They are continuously on the phone talking to colleagues in the OR. The problem is that this is all done without using any kind of computer system that collects and displays all this information at a centralized location. A system that is aware of the state of the on-going surgical procedures and able to estimate the duration of the individual procedures based on recorded data and patient data would be an ideal situation. Also, other data could be taken into account. For example, how long has the surgeon already been working this day or the past week.



Delays are a huge problem for the planning. Research showed that after examining 5.598 cases 88% of these were delayed. These cases consist of only the first procedures of that day for every operating room. This automatically implies that subsequent surgeries suffer from even larger planning alterations.

6.2 Workflow

To study the workflow, the different steps for a liver surgery have been identified and are shown in the workflow diagram in Figure 12. This figure shows the pre- per- and post-procedural steps for an operation. As mentioned in the introduction, it is important to keep track of the progress of a procedure. Therefore, the procedure has been split up in different phases.

The goal is phase recognition, but for that it is important to determine what phases or steps are important and give useful information about the process. Veen-Berkx (2016) defined a number of phases, ranging from the patient entering the operating room to the patient leaving the operating room as can be seen in Figure 13.

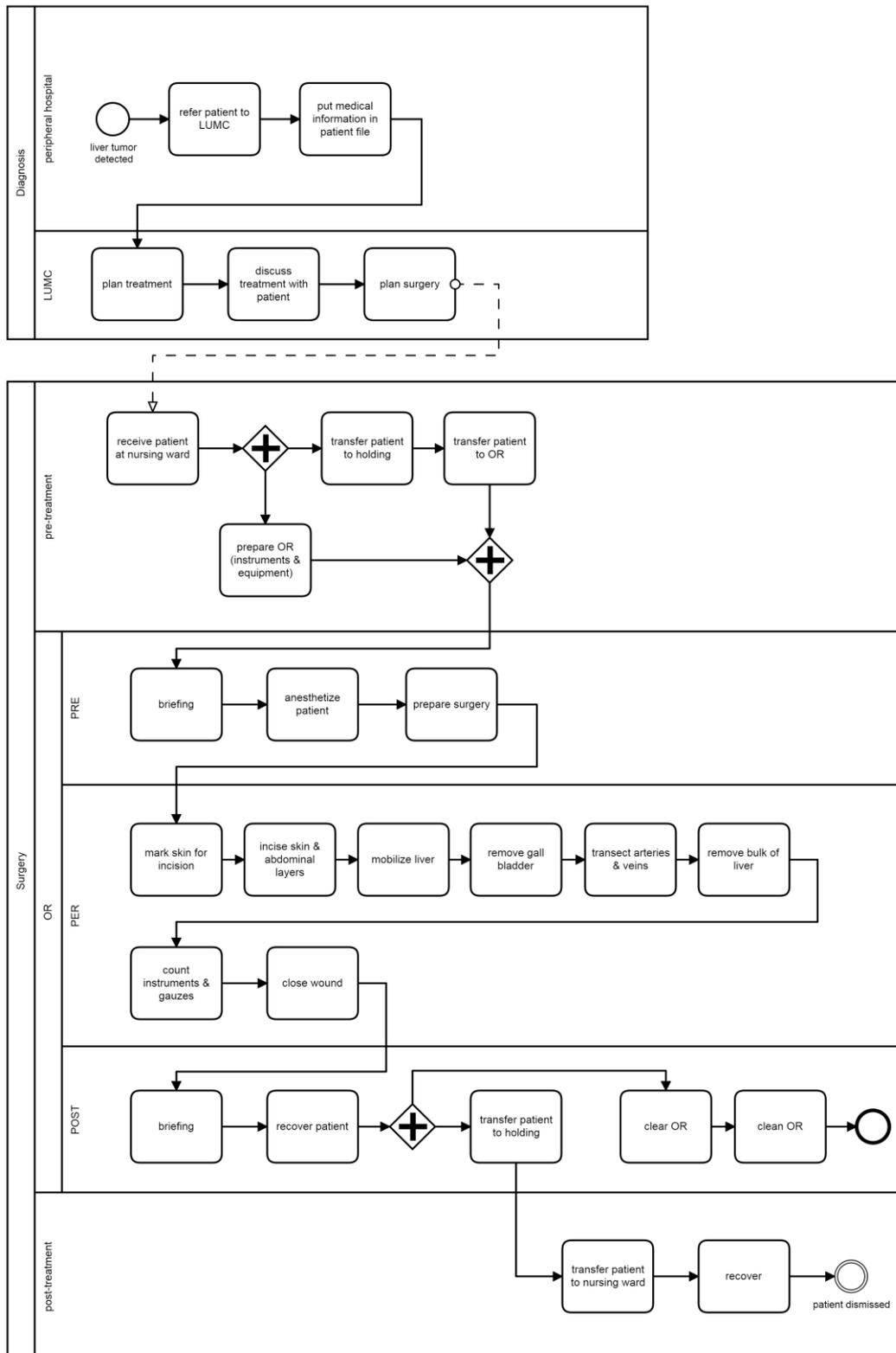


Figure 12: The general workflow of a patient in the pre-, per- and post-operative phase.

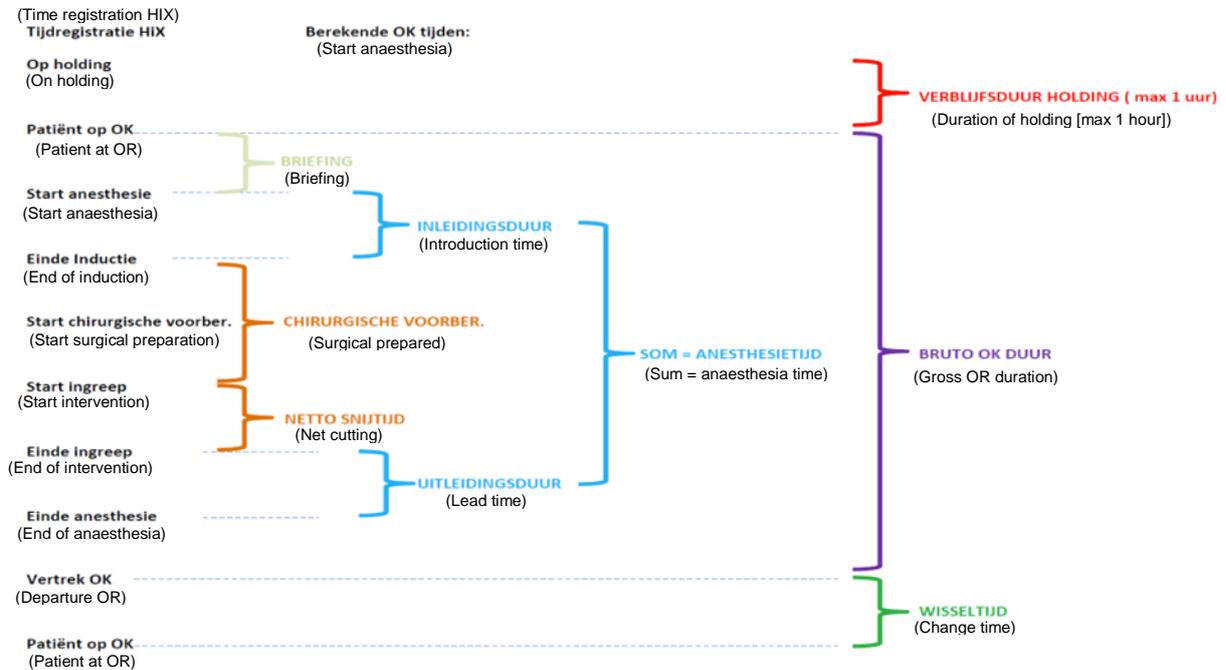
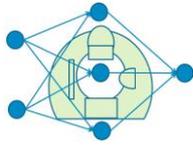


Figure 13: Phases of surgery by Veen-Berkx (2016).

Another example of phases to be recognized is given by Bardram et al. (2011) in Figure 14. This figure shows the activities for a laparoscopic appendectomy. A big part of this overview is applicable to most operations. This is a good overview of the different phases and their accompanying activities. These can be used to find key identifying factors for these activities in order to detect the phases. This overview was generated by recording video in the OR and doing a temporal analysis of the recorded surgeries. Then these videos were transcribed and the specific actions, involved actors and locations inside the OR. The research done by Bardram et al. (2011) brought up different sets of actions and tasks for certain types of surgery. Some types of equipment were used only for specific actions. Also, four important zones (1 Anesthesia table; 2 Anesthesia machine; 3 Operating table; and 4 Operating trolley), were identified, which they describe as specific areas where collections of actions were carried out.

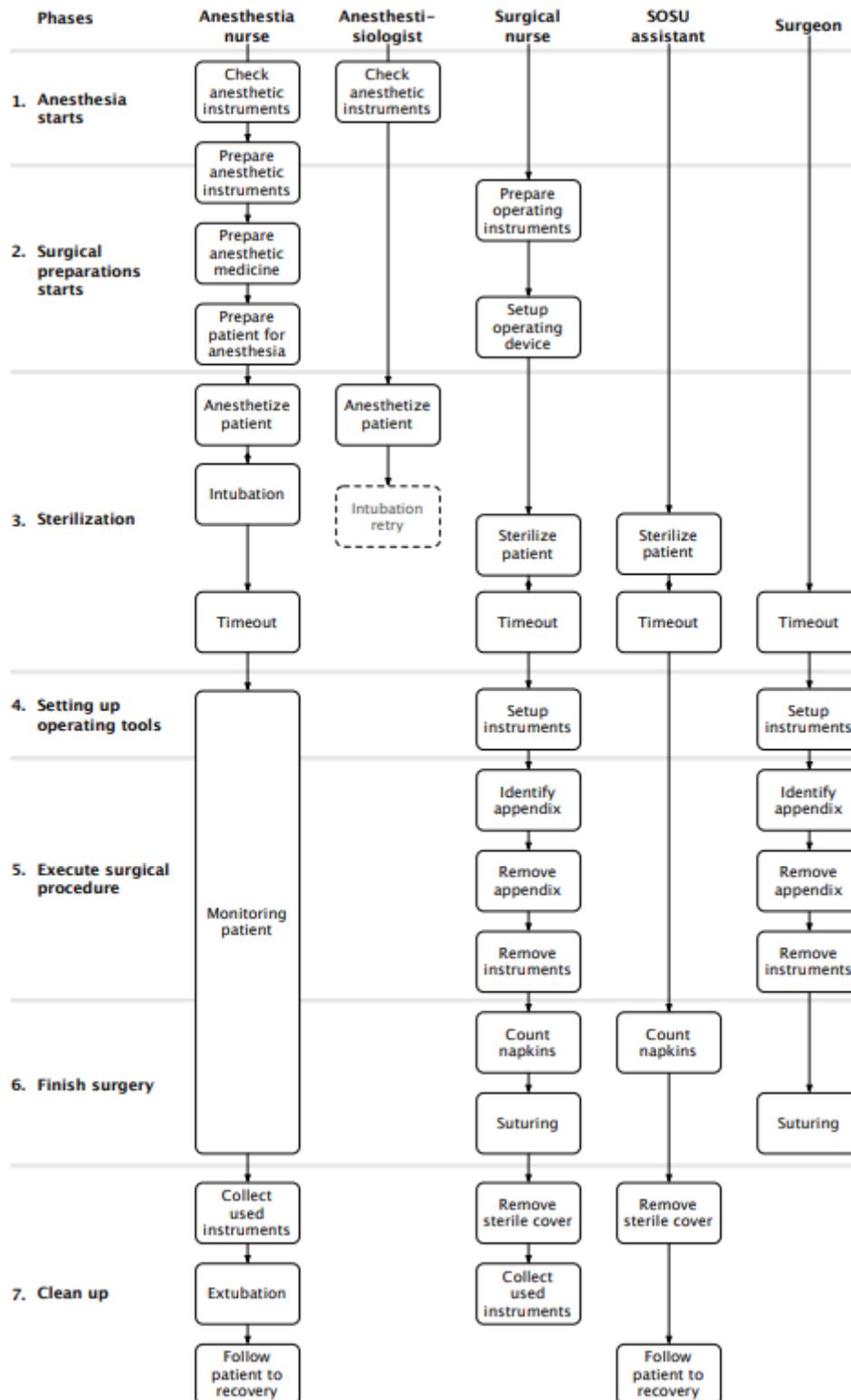
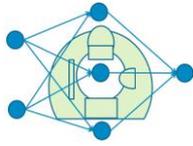


Figure 14: Phases for laparoscopic appendectomy by Bardram et al (2011).



6.2.1 General OR procedure

After talking to multiple people in the hospital ranging from surgeons to OR planners, an overview of the basics steps of the patient trajectory on a day of surgery was made.

- Patient arrives at nursing ward
- Patient is brought to OR department
- Patient is prepared for surgery
- OR is cleaned and set-up for surgery
- Patient is brought to OR
- Patient bed transfer
- Patient anesthetized
- Start surgery
- Surgery specific events
- Count gauzes & instruments
- Patient is recovered from anesthesia
- Patient brought to recovery room
- Patient is brought back to nursing ward

Depending on the type of surgery, thorax or another type of surgery, there is a briefing when the patient is still awake or already anesthetized.

6.3 Phase indicators / features

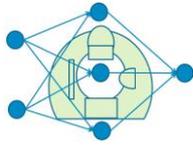
In this section, a set of features of the OR is presented. These features are good indicators to estimate the phase of the surgery.

6.3.1 Movement medical staff

To recognize different phases during operating procedures, it must be known what kind of factors indicate these phases. The movement and the number of people in the operating room can indicate a lot about the phases. When nobody is present, no surgery is being performed. When there are about two to three persons present, the operating room is likely to be cleaned or made ready for surgery. When the operating room is filled with more than 5 people, this can indicate the surgical procedure is active. Furthermore, the movement of the surgeons can also reveal phases within the surgical procedure. It is likely that non-invasive, invasive and MIS surgery, but also suturing can be detected, based on the movement of the surgeon and presence medical staff.

Not only the movement is important, also the area of activity in the operating room is of importance. Bardram et al. (2011) describes a method that uses zones in which specific activities are executed. Like for example the area of the anaesthesiologist, no real surgery will be done here. But when the medical staff is mostly positioned around this area. This can indicate the intubation phase or the end of the surgery where the respiration equipment is removed.

Wang et al. (2018) proposes a method to analyse motion because "The complexity and duration of the motion involved can be used as basis for broad categorization into four kinds namely gesture, action, interaction and group activity." By not only



analysing these properties on their own but altogether, more complex patterns can be detected.

6.3.2 Pose estimation

Pose estimation is one of the many ways to analyse the movement of humans. Urgo et al. (2019) writes: "...the tracking of the human pose has shown a rapid and significant development in the last few years taking advantage of deep learning image recognition methods to estimate the human pose in terms of legs, arms, hands and face." Multiple pose estimation networks exist and their quality keep increasing. These networks make skeletal models based on video recordings. This does not only work for the limbs, but the most recent works also contain the detection of fingers. An example of applied pose estimation can be seen in Figure 15.



Figure 15: MVOR skeletal model.

6.3.3 Equipment

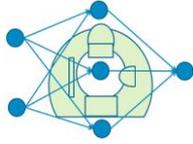
Tracking the presence and use of equipment in the OR is another way to retrieve information about the activities in the operating room. Different procedures depend on different kinds of equipment, but also different phases of procedures can be connected to specific equipment. This is a feature that has been used in earlier research to indicate phases. RFID is a much used technique for this. Later in this chapter the different options of data acquisition will be discussed.

6.3.4 Lighting

The lighting configuration and intensity can give insight into the phase of the procedure as well. The best example is the lights dimming in case of minimally invasive surgery (MIS). But the setup of the surgical lighting can give more specific information on the events going on as well.

6.3.5 Appearance medical staff

The differences in clothing of the medical staff give information on the types of employees that are present in the operating room. Among these are surgeons, operation assistants, nurses, anaesthesiologists, students and other personnel. The biggest difference is between those that perform the actual surgery and those that do not. Those performing the surgery wear long drapes in a slightly lighter colour.



Another thing that can be recognized is when x-ray scans are made inside the operating room. In this case, the medical staff will wear protective lead sheets; these can easily be recognized and used to detect these kinds of events.

Recently, the medical staff in the operating room of the LUMC started to wear name tags on their heads. This takes away the problem of personnel that don't know each other. This improves safety and partly prevents misconception and miscommunication. These name tags have different colours depending on the function. So surgeons, nurses, anaesthesiologists, students and others all have their own colour. These colours can potentially be used to distinguish the roles of individuals during surgery.

6.3.6 Time (frames)

For all these factors goes that not only the recognition or tracking is important but also the aspect of time is important. The time a certain piece of equipment is used or the time a person is spending in a zone gives information that can help determine the current phases.

6.3.7 Quality data set

It must be noted though that each surgeon has their own style and way of working or has had its education at another institution and/or got educated by another person/institution. Furthermore, the type of procedures performed in the LUMC differs from those performed in peripheral hospitals. Most patients present cases that are more complex. This makes that many procedures do not follow a normal pattern. Many procedures are unique. A peripheral hospital could be compared to a factory, where many of the same procedures are performed. This makes it easier for an algorithm to recognize phases, as most indicating factors follow the same pattern and order with quite a similar time line. An academic hospital is more like handcraft. Many surgeries are one of a kind.

On the other hand, all surgeries have the same standard procedure to start up and end the process. But, there are also actions that are not directly related to a certain phase or procedure, like for example the ordering of blood. Extensive blood loss could potentially occur in most of the phases within the cutting time. However, they are more likely to occur during some phases than in others. So this is not entirely correct.

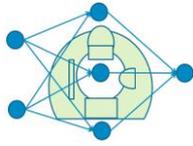
6.3.8 Other indications

Another information source is for example the presence of a surgical blanket on the operating table. As long as this blanket is not present, it is most likely that the surgery has not yet started. As soon as this blanket is detected, the surgery procedure must have been initiated. Then, at the end, the removal of this blanket indicates the end of the procedure. These kinds of information sources seem to be unnecessary with the availability of other more information dense sources, however it might be useful to implement some redundancy into the system in case detection systems fail.

6.4 Data acquisition

6.4.1 Past methodologies

The detection of phases during procedures has been done for quite a while. It can be used to measure the performance of medical personnel for example. In the past, a person would annotate the events while watching a video recording as described by



Aggarwal and Cai (1999) in 1999. This was a lot of work and can only be done post-surgery. Automation would take a lot of work out of hands from medical personnel. This system can be used for other purposes besides checking personnel performance. Such as, the recognition of surgical phases to further optimize the workflow. Nowadays, different kinds of sensor are used mostly to collect data. In this section, several techniques will be listed for the acquisition of data inside the operating room.

6.4.2 Information types

Text annotation

Text annotation is a type of manual data acquisition. Information from processes in the OR have been gathered this way for a long time. In the past, a person would annotate events real-time during surgery. Later this was done based on video recordings. This form of data collection is still used today. For example to analyse communication between medical personnel or to analyse the performance.

Instrument use

Binary information on the use or appearance of equipment in the OR can be gathered. By instruments, we mean tools like forceps and knives.

Equipment data

Equipment data can give more information than just binary data like usage. Electrosurgical devices can be used at different settings and these devices can communicate their settings. But also imaging devices that can be used in a (hybrid) OR can provide data that can be fed to a system that the medical staff uses for analysis.

3D position data

The position of instruments and humans can be tracked and give x, y & z coordinates within a frame defined inside the OR. This way an instrument can be tracked or its movement can be analysed. Movement tracking can reveal more information about the surgery situation.

Video

Humans can extract a lot of information from video recordings. The performance of computers in analysing video material is growing towards the performance of humans in this area.

Audio

The audio in the OR can reveal more information than one might think. The electrosurgical unit makes a noticeable sound when it is used. In addition, communication between medical personnel can be analysed.



6.4.3 Sensors

(Multi-)camera / RGB-D

Recently a data set has been published that uses multiple RGB-D cameras to record procedures in the OR. This data set that has been published in an article written by Srivastav et al. (2018) can be used to test pose estimation algorithms in a medical environment. This MVOR data set uses cameras with a resolution of 640x480 pixels at 20 FPS.

Using a camera setup is very non-intrusive way to get information out of the operating room. A lot of other techniques require more equipment to be installed in the OR or require connection with a lot of different devices. The setup for a camera system only needs about three cameras per room. They are not obstructing the medical staff in any way during surgery. A system that gathers and saves the data can be placed outside the OR.

The necessity of multiple cameras in a setup is clear. But it would be interesting when an algorithm is applicable to different camera set-ups. This is exactly what Kadkhodamohammadi and Padoy (2018) have developed. To do this it is necessary to apply this technique to multiple operating rooms varying in size and shape and with different arrangements of equipment. This way it is also possible to create a larger database. A bigger database will be able to train the model better and thus yield better results.

RFID (RTLS)

In the past, different techniques have been used or are still used. These are mainly focused on tracking instruments. One of the ways to track instruments is by using RFID tags. The downside of this technique is that it has different drawbacks. For example, all instruments need to be equipped with RFID tags. To give an idea how much work and money this would cost: in the LUMC more than 5000 unique instruments are used and they are multiple of most of these instruments. This can become expensive and the RFID tags, although small, can be unpractical. Doctors can be hindered or annoyed by the tags while using the instruments during surgery. The consent of the surgeons is a necessity for such a system to be employed and therefore important.

QR- and barcodes

Another way to track instruments is by using QR codes. A test was done in the LUMC where QR codes were attached to instruments in the form of stickers so that they could be scanned and tracked. However, the proposal of using these was rejected. The safety for the patient could not be guaranteed. The chance of the stickers ending up in a patient, after wear and tear due to use and cleaning, was too high to be deemed safe.

Markers

Visible markers as used in the movie industry can be used to track the three-dimensional position of instruments or humans. However, all the equipment in the OR



and lighting hanging from the ceiling can block the view. Then it is hard to properly track the subjects.

6.5 Current achievements with camera for OR analysis

As mentioned before, to optimize the workflow it is important to have tools to measure and monitor the workflow. Based on a database with reliable measurements, it will be possible to have a better planning of the OR on forehand compared to manual entered durations for certain procedures based upon memorized data. Furthermore, the automatic monitoring of the progress of a procedure allows for the automatic detection of for instance delay in a procedure, which will affect the overall planning of the OR's. Essential is that the acquisition of the parameters is as automatic and non-disruptive as possible.

A camera system would be a good fit for a live phase detection in the OR due to recent developments in artificial intelligence and the non-intrusiveness and low costs of such a system. A more detailed look into current achievements on phase detection inside the OR will follow below, to get insight into what is currently possible. Therefore, not only video analysis systems will be discussed below, but also systems that use different setups.

6.5.1 Video analysis, but not automatic and not live

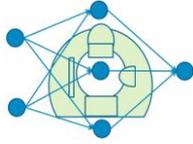
As mentioned before, in the past, surgeries were recorded and afterwards someone would annotate what happened during the operation. This annotation work could then be used for analysis purposes. This technique is still used today. Mainly for the same use case; to analyse human behaviour and human interaction and communication. Many hospitals use this technique. However, the best-known example is the Black Box, which is used in the AMC Amsterdam medical university hospital. They worked together with Theodor Grantcharov and his team; they published an article about this Black Box (Jung and Grantcharov, 2017). The Black Box system works like a black box as used in the aviation industry. A team of medical trained personnel analyses the videos and gives feedback to the medical team that has been recorded.

6.5.2 Video analysis, automatic, but not live

In other applications, computers were used to analyse the video material shot in the operating room instead of humans. However, this analysis is performed post-surgery; therefore, the information is not live. This way it is easier to analyse sequences and segment the video. Whereas in a live situation it is harder to detect events or activities because less information is known at a specific live moment.

6.5.3 Analysis, live, but not with video

Other research reports live analysis, but do not use video data. These systems use a set of different sensors like light intensity, movement or electronic sensors. This kind of data is easier to analyse, as the data comes in binary or as measurable data with a meaning. Whereas video data needs to be processed first, to decompose the occurring activities inside the OR, like the human movements. Only after the data processing this data can be used for analysis. Other examples of non-video analysis include using RFID tags or tracking instruments that are used during surgery through various other techniques like QR codes or markers.

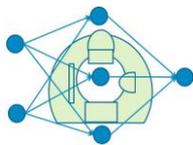


6.5.4 Video analysis, live, but only endoscopic

Detecting phases during surgery is already achieved by using endoscopic video data. The benefit of this video material is that the environment is limited and controlled. There are only so many tools and physiological structures to be detected. Current work can detect individual tools as well as different phases during a procedure. The downside is that only the phase during this endoscopic procedure can be detected. All activities before and after the endoscopic phase cannot be analysed.

6.5.5 Video analysis, automatic, live and whole OR

Given the recent developments in computer vision and machine learning, the goal is to detect phases during surgery with cameras that record a view of the entire OR. As mentioned before, endoscopic video analysis can only detect phases during the cutting time. However, a lot of phases and activities occur outside the endoscopic view and before or after the cutting time. There is no work known that does exactly this in an automatic way and performing live, while recording the whole OR. Therefore, here lies a huge opportunity to push forward the research of automatic phase analysis in the OR in order to improve the workflow. Examples can be better planning, because of an increasing database that is able to train the model better.



7 Use case: Brain

Brain metastases treatment planning

7.1 Introduction

This use case includes the current workflow of the Leksell Gamma Knife (Gamma Knife) radiotherapy treatment planning for patients with multiple brain metastases. The treatment plan is being done within Leksell GammaPlan (GammaPlan). It is then exported to Gamma Knife for radiotherapy treatment using 192 external radiation beams from cobalt 60 according to the treatment plan. The main focus of the workflow here would be the treatment planning performed in GammaPlan as shown in Figure 16.

7.2 GammaPlan Workflow

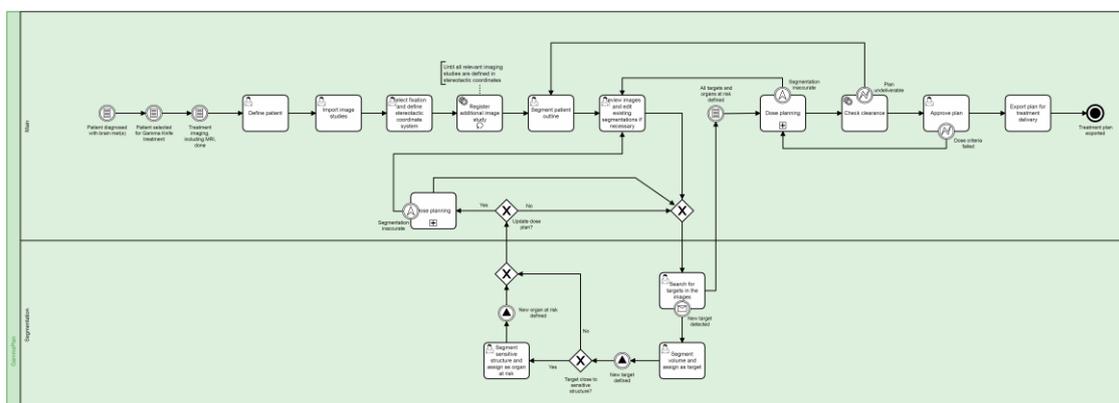


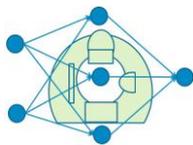
Figure 16: Current workflow of radiotherapy treatment planning for brain metastases in Leksell GammaPlan.

7.2.1 Pre-treatment planning

Treatment imaging will be performed after the patient diagnosed with brain metastases is selected for Gamma Knife treatment. Medical images, including MRI and/or with contrast, are used for treatment planning in GammaPlan. Dependent on the fixation and coregistration method, the patient may need to be scanned with a frame. When patients are prepared for treatment planning, treatment images will be imported as DICOM files to GammaPlan.

7.2.2 Treatment planning

Within GammaPlan, major steps in treatment planning are patient administration, image coordinate registrations, segmentation, dose planning, evaluation and approval.



7.2.3 Patient administration

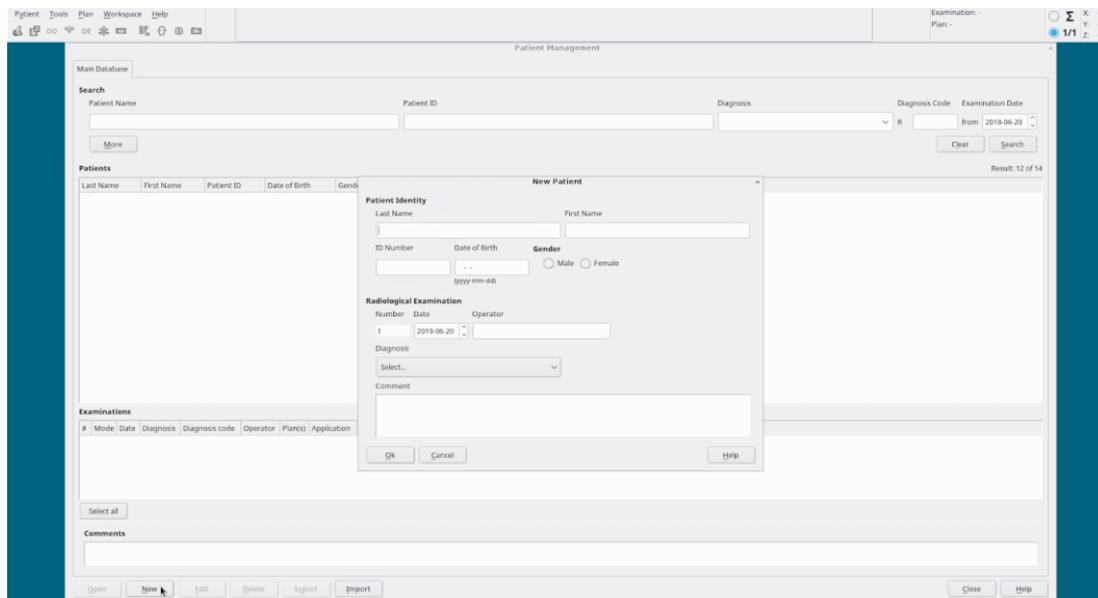


Figure 17: Patient administration page.

Patient identity is filled with patient name, ID number, date of birth and gender. Radiological examination information is also filled in relation to patient. Operator, diagnosis and date of operation are included. This stage is manually processed by the user. This is the initial step in GammaPlan (Figure 17). A patient has to be defined in GammaPlan for treatment planning or follow up.

7.2.4 Image registration

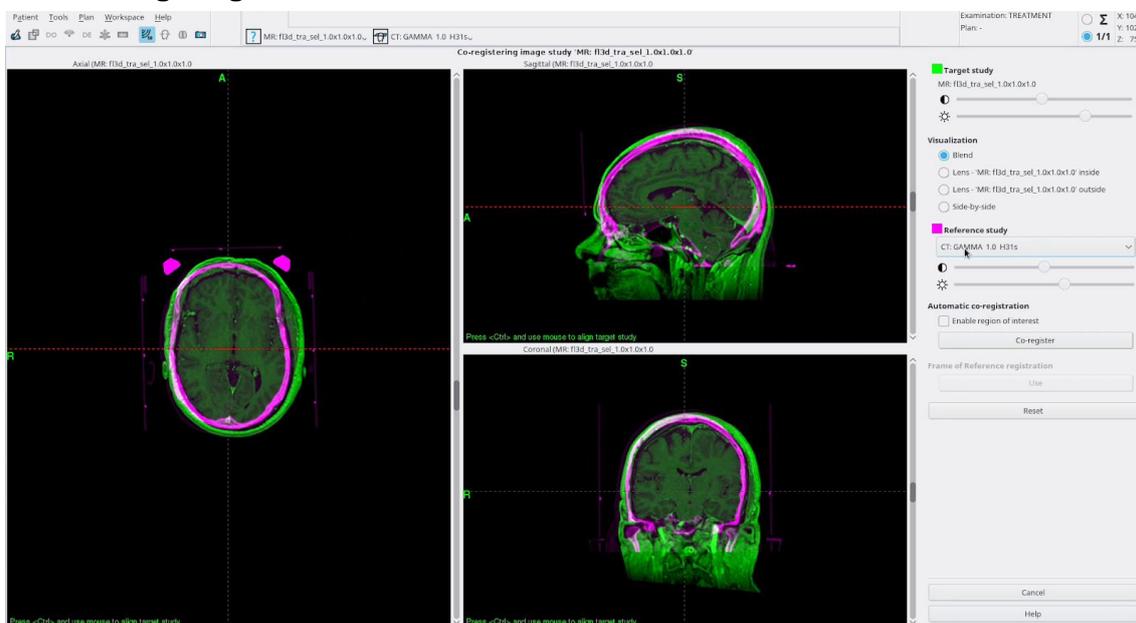
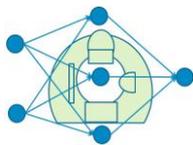


Figure 18: Image registration between a stereotactic defined CT image and a MR image.



After defining the patient, one can import relevant DICOM images for treatment planning (with or without frame). Depending on the choice of the coregistration method, the user will need to select a fixation method and register the images coordinates to the stereotactic coordinate system. For frame-based images, the user needs to define the fiducial markers in the frame for stereotactic coordinate registration. For other relevant imaging studies without fiducial markers, they are coregistered to studies that are defined in the stereotactic coordinates. The registration is a service within GammaPlan as shown in Figure 18. The user needs to click buttons to undergo registration. The skull is also defined at this stage for dose calculation in planning.

7.2.5 Images review

After registration, relevant images are being reviewed to check if the coregistration is accurate between image studies. Followed by the identification of tumor, users would search and identify targets in the images before segmenting them as volumes.

7.2.6 Segmentation

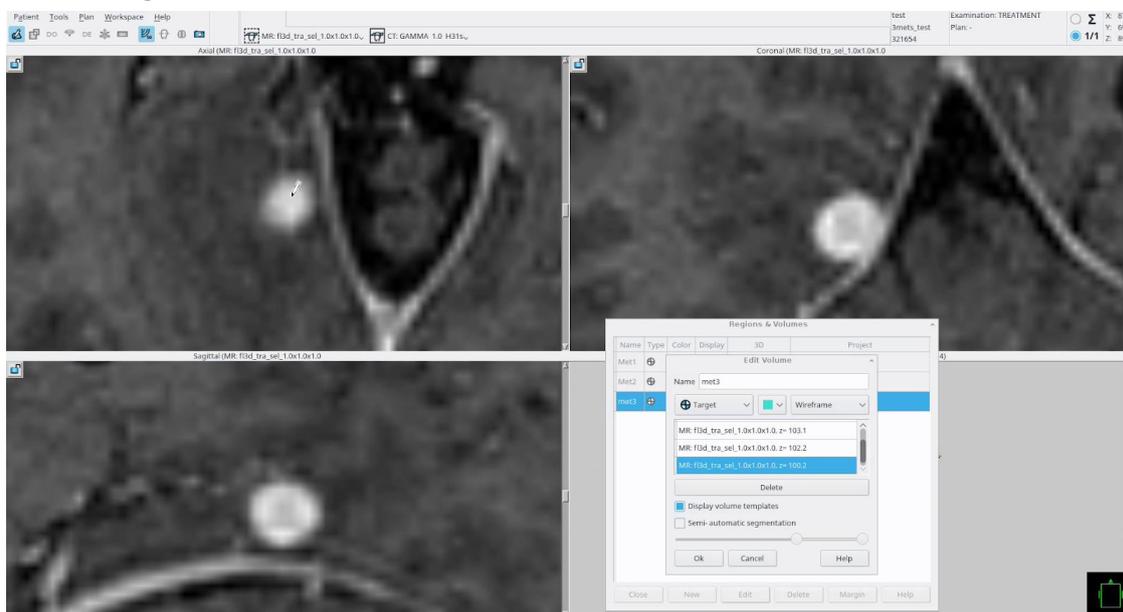
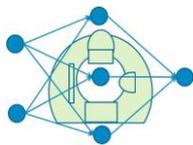


Figure 19: Segmentation tool in GammaPlan for user to delineate volumes of target and/or organ-at-risk.

Targets are segmented through a segmentation tool in GammaPlan (Figure 19), which can be done manually or semi-automatically. Once the metastases are identified, the user will go through one by one, slice by slice to segment the tumors. Segmented volumes are then assigned as targets in a plan which would be used for dose planning and evaluation. It is noted that if the targets are close to sensitive structures such as optical nerve, brain stem, etc., the user will deliberately delineate organs-at-risk (OARs). These structure volumes are then assigned as risks for dose planning and evaluation later. When the segmentation of targets and/or OARs are delineated, the user will proceed to the next step for dose planning. In the dose planning, the metrics for inverse planner and evaluation are calculated based on the definition of



segmentation, it is thus not uncommon that segmentation steps are repeated manually during dose planning for intermediate evaluation with more accurate metrics.

7.2.7 Dose planning

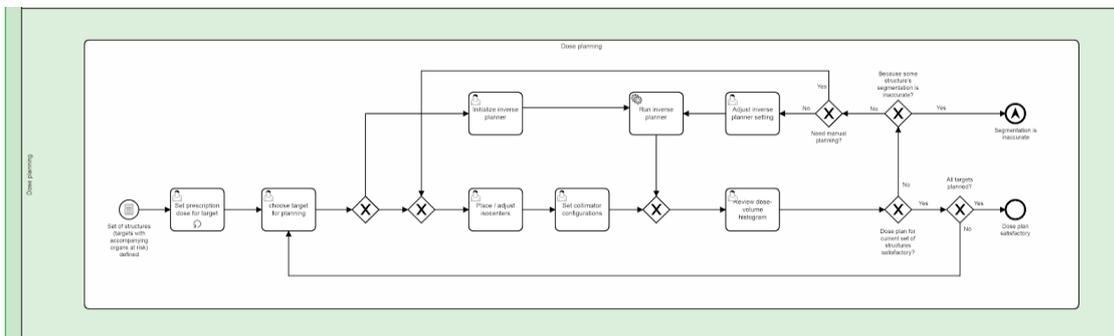


Figure 20: Current workflow for dose planning.

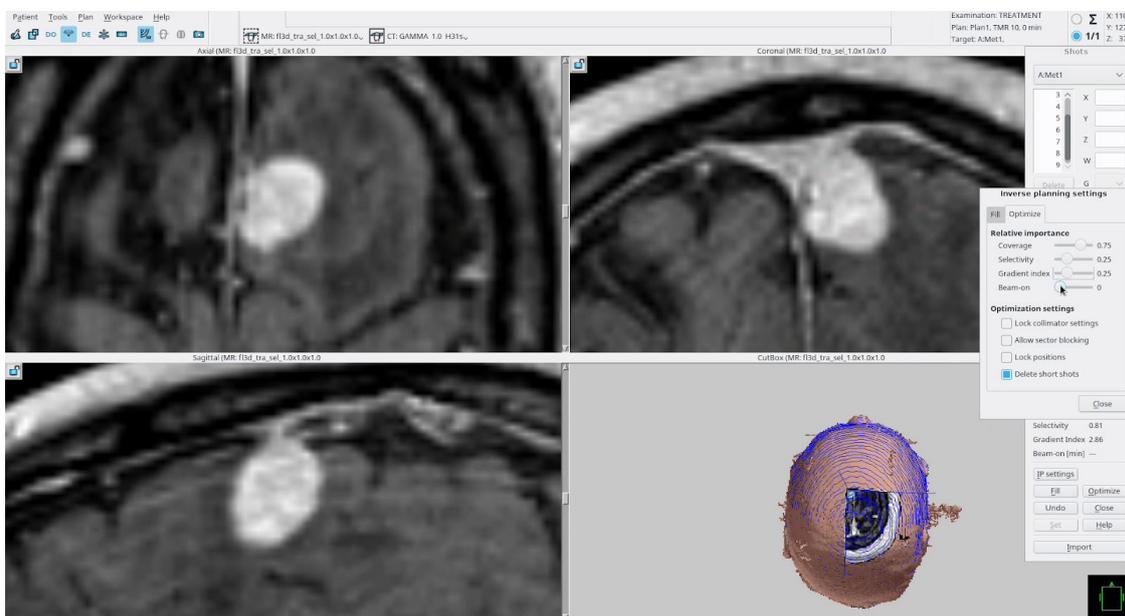


Figure 21: Current inverse planner setup for dose planning service in GammaPlan.

Figure 20 shows the current workflow for dose planning. Having defined volumes as targets and/or OARs, the user will set dose prescriptions for targets. The dose prescription is set manually. The user can perform the dose planning manually or decide to use the inverse planner. For manual dose planning, the user will place isocenters one by one and set their collimator configurations. In order to have a high-quality plan, a wide range of criteria need to be considered and reached. Therefore, during the course of setting, adding or removing isocenters, the user may review the dose volume histogram (DVH), adjust isodose prescription or even change the segmentation volumes. These steps are possibility repeated until the plan is satisfactory. Unlike manual planning, inverse planner (Figure 21) optimizes the dose based on inverse planner settings such as coverage, selectivity, beam-on-time, etc. that are defined by the user. If the plan is unsatisfactory, the user may adjust settings



again and re-run the inverse planner. Otherwise, the user can adjust isocenters manually based on results from inverse planner. For multiple metastases, the user can choose to use either or a combination of both planning methods. When the plan is satisfactory and has met the criteria, the treatment plan will be reviewed with DVH as displayed in Figure 22.

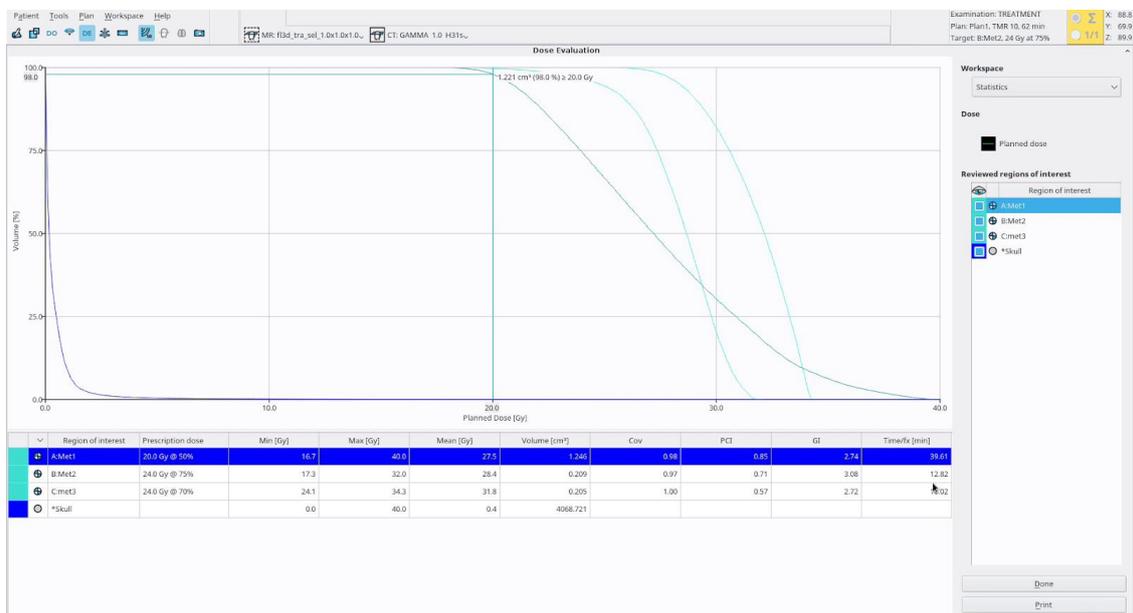
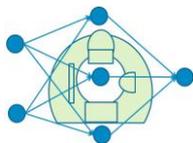


Figure 22: Dose volume histogram for dose plan evaluation.

7.2.8 Clearance check

After final review with DVH, the user needs to check the clearance of the plan to see if it is deliverable. If there are error messages with the clearance, the planner will need to check the plan again.



7.2.9 Plan approval and export

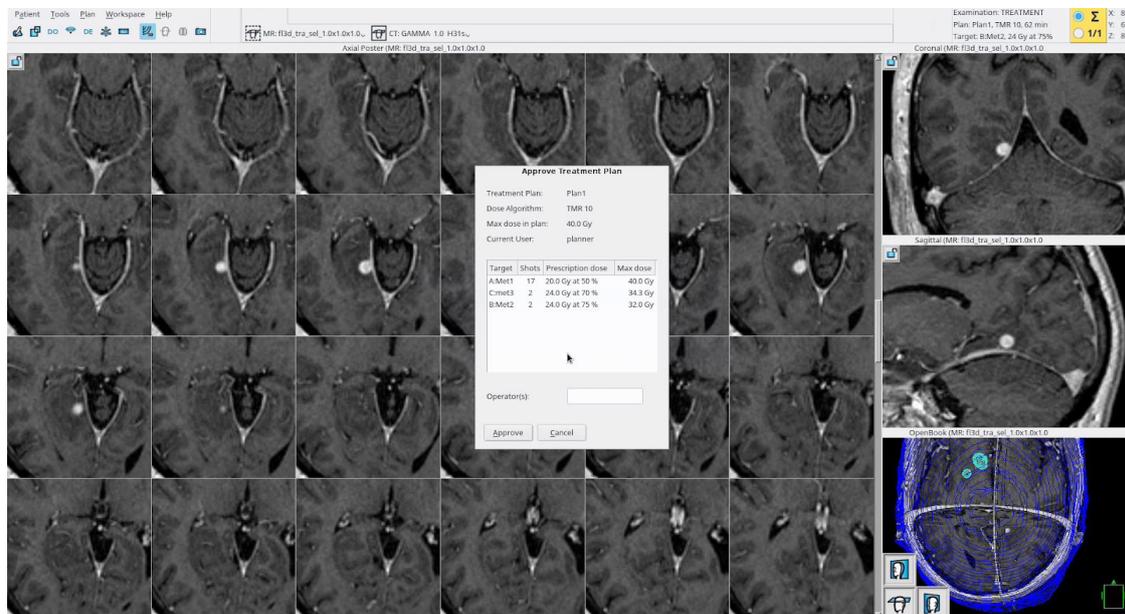


Figure 23: Approval of treatment plan.

If everything is fine, the user can approve the final plan as in Figure 23. If there are error messages, the planner will need to go to the problems and fix them. An approved plan can be exported from GammaPlan to Gamma Knife for treatment.

7.3 Bottleneck identification

Major bottlenecks in the workflow are time-consuming and repetitive steps in rule-driven parts, i.e. segmentation and dose planning. Segmentation is time consuming because targets and OARs could differ in size, shape and contrast, and contrast as well depends on image quality. The accuracy of segmentation is highly dependent on the experience of the user. In spite of using manual or semi-automatic tools, it is still a very tedious step. Simply put, the quality of segmentation is highly demanding in order to achieve certain rules, i.e. evaluation metrics in dose planning.

Time-consuming steps

Dose planning is another time consuming step. Aside from the use of manual planning or inverse planner, a certain level of coverage is required to deliver enough dose to targets while sparing sensitive structures with maximum dose. Depending on the radiotherapy philosophy of the user, there are other important factors that compose a high-quality treatment plan, such as gradient index, beam-on-time, etc. It is, therefore, taking so much time to consider all factors to create a good plan, especially for targets that are close to sensitive structures. When targets are irregular and large in size, it will take even more time to set isocenters and their configurations. In general, dose planning using inverse planner is faster than manual planning especially for irregular targets.

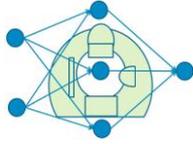


Figure 24 shows a case study of 6 brain metastases. Volumes delineation and dose planning are major parts in duration throughout treatment planning.

Time distribution of a case with 6 brain metastases

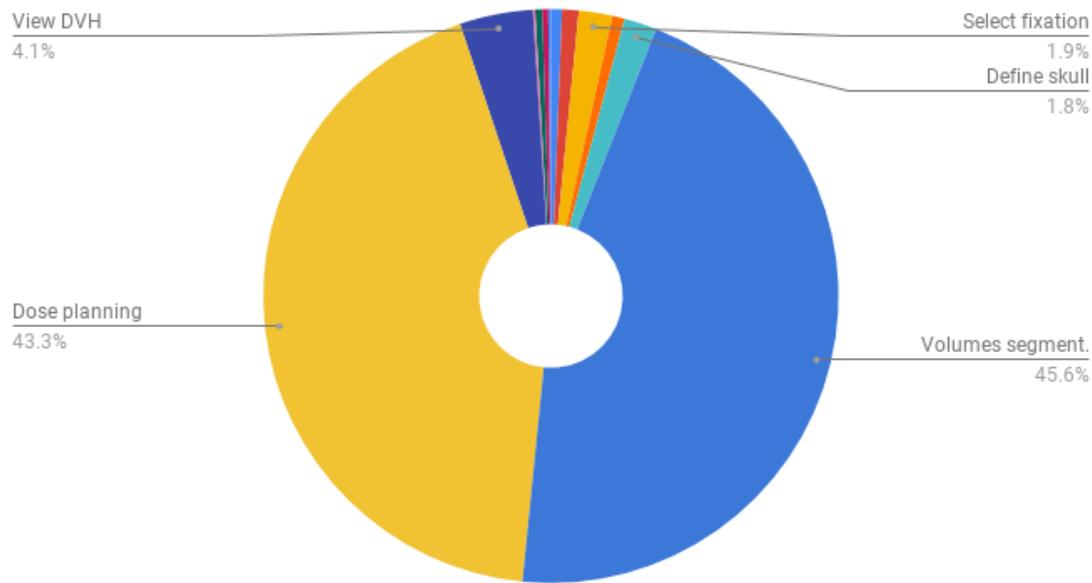
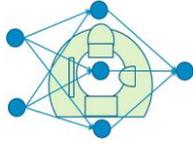


Figure 24: Time distribution of treatment planning in GammaPlan of a case with 6 brain metastases.

Repetitive steps

Repetitions in these two parts also contribute to the bottleneck in the workflow. These procedures are performed per targets and/or OARs and are thus repetitive with multiple metastases. It can be reflected by the fact that the time spent on segmentation and dose planning increases as the number of metastases increases in general, as displayed in Figure 25. Given that there are so many factors affecting the treatment plan, such as tumor irregularities, positions, size and others, time spent on these steps are not linear to the number of metastases. Yet, increased number of metastases means further repetition of these procedures, i.e. more segmentation and dose planning per target. Revision of previous steps leads to additional repetition. For instance, inaccurate segmentation causes incorrect metrics in dose planning. Previous segmentation needs to be reviewed or redone in order to get a better evaluation for dose planning. Inverse planner facilitates the dose planning process, but it still needs to be applied one by one.

Because of the time-consuming nature and repetition in these steps, most time is spent on these steps in the workflow. Allowing automation of segmentation and dose planning for multiple targets and OARs would improve the workflow at the bottleneck.



Time for different tasks

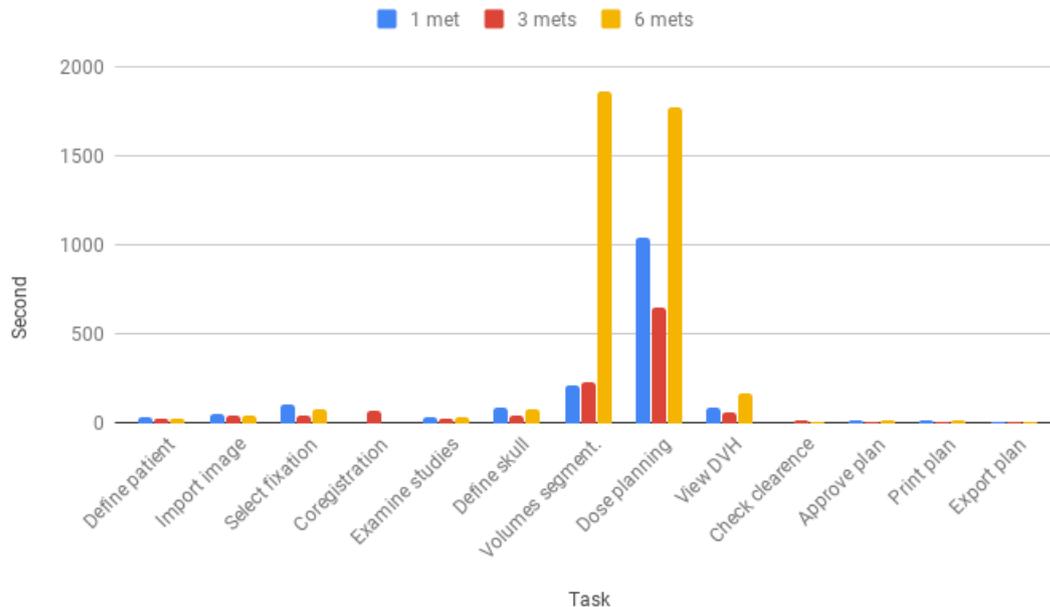


Figure 25: Time (in seconds) for different tasks with different number of brain metastases in GammaPlan. It is worth noticed that the locations of metastases are different in different cases, e.g. some are close to brain stem in the case with 6 metastases.

7.4 Candidate tasks for automation

The bottleneck is composed by tedious manual steps in segmentation, regardless of using the semi-automatic tool, and dose planning, disregarding the use of manual planner or inverse planner. Possible solutions are to replace manual tasks with automatic services and minimize manual intervention in workflow, which lead to increased efficiency.

7.4.1 Segmentation

Recent research shows the possibility of using deep learning to automatically detect and segment brain metastases. Liu et al. (2017), Charron et al. (2018) and Grøvik et al. (2019) used deep convolutional neural networks (Figure 26) to segment multiple metastases in MR images such as T1-weighted and T1-weighted with contrast. Grøvik et al. states that it takes approximately 1 minute for multiple brain metastases auto-segmentation with a full MR brain volume, while having a dice score 0.79. The auto-segmentation algorithm could serve as suggestion for metastases detection or even replacement of manual and semi-automatic segmentation if results are superior. Multiple metastases could be predicted with probability values (Figure 27) and auto-segmented simultaneously. This could reduce time caused by tedious tasks and repetition in relation to manual intervention in segmentation.

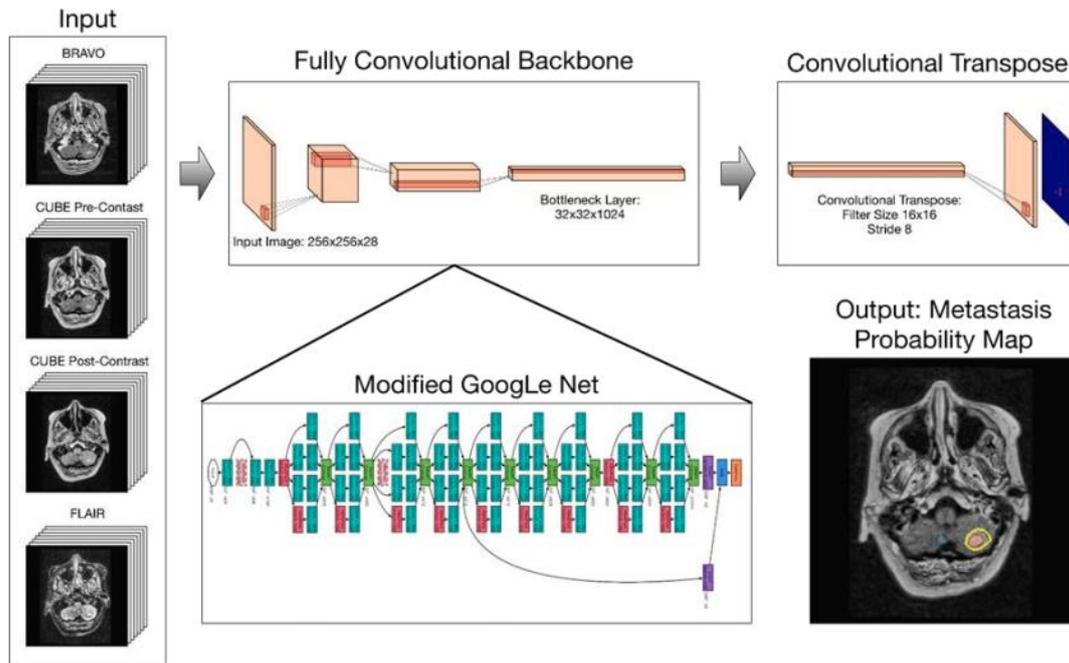
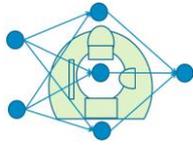


Figure 26: Convolutional neural network used in Grøvik et al. for brain metastases auto-segmentation.

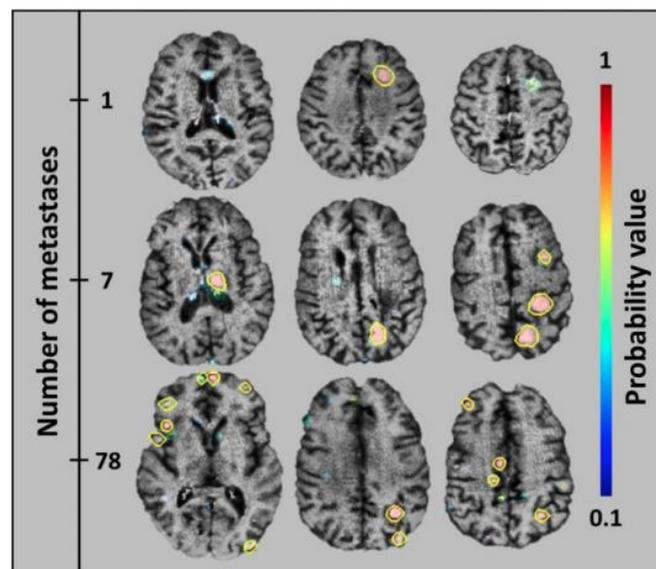
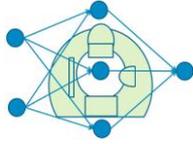


Figure 27: An example of multiple brain metastases prediction with probability values from the deep learning model proposed by Grøvik et al.

7.4.2 Dose planning

The current inverse planner can reduce labour-intensive work in manual dose planning. Yet, it has some limitations such as difficulties in simultaneously managing multiple targets and enforcing criteria such as maximum dose to OARs. Sjölund et al.



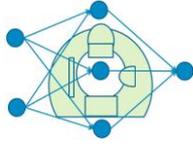
(2019) has proposed an alternative approach to inverse planning in Gamma Knife radiosurgery that could handle multiple targets and OARs at the same time. A better dose planning service allows shorter time to reach the standard for treatment, i.e. the criteria for dose planning. As stated in the paper, the new inverse planning approach runs well under a minute. Besides, the ability of managing multiple targets and handling OARs simultaneously could diminish the repetition in the process.

In short, these candidate tasks can be of potential use for reducing manual intervention and resolving the bottleneck in the workflow.

7.5 Data collection methods

For automatic segmentation, there will be mainly two types of data needed, i.e. data for run-time segmentation and data for training. Data for run-time segmentation is prepared before treatment. T1-weighted and T1-weighted with gadolinium contrast MR images are common treatment images for brain metastases. They are being imported for treatment planning as in the current workflow.

For auto-segmentation using deep learning, a large amount of labelled data is required for training. Data collection includes scanning patients with brain metastases and labelling metastases by experts. MR images may include T1-weighted, T1-weighted with gadolinium contrast or others. Potential data collection may be patient scanning from hospitals or publicly available datasets.



8 References

Reed, G. W., Hantz, S., Cunningham, R., Krishnaswamy, A., Ellis, S. G., Rak, J., & Kapadia, S. R. (2018). Operational efficiency and productivity improvement initiatives in a large cardiac catheterization laboratory. *JACC: Cardiovascular Interventions*, 3472.

Lindsay, A. C., Bishop, J., Harron, K., Davies, S., & Haxby, E. (2018). Use of a safe procedure checklist in the cardiac catheterisation laboratory. *BMJ Open Qual*, 7(3), e000074.

Joerger, G., Rambourg, J., Garbey, M., Conversy, S., and Gaspard-Boulin, H. (2017). Reengineer operating room data acquisition and transmission for improving surgical suite awareness and management. In 2017 IEEE EMBS International Conference on Biomedical & Health Informatics (BHI), pages 205–208. IEEE.

Wolf, B. and Scholze, C. (2017). 'Medicine 4.0': The role of electronics, information technology and microsystems in modern medicine. *Current Directions in Biomedical Engineering*, 3(2):183–186.

Katić, D., Julliard, C., Wekerle, A.-L., Kenngott, H., Müller-Stich, B. P., Dillmann, R., Speidel, S., Jannin, P., and Gibaud, B. (2015). LapOntoSPM: an ontology for laparoscopic surgeries and its application to surgical phase recognition. *International Journal of Computer Assisted Radiology and Surgery*, 10(9):1427–1434.

Padoy, N. (2019). Machine and deep learning for workflow recognition during surgery. *Minimally Invasive Therapy & Allied Technologies* Machine and deep learning for workflow recognition during surgery.

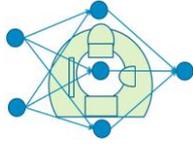
Veen-Berkx, E. v. (2016). Benchmarking operating room performance in Dutch university medical centers.

Bardram, J. E., Doryab, A., Jensen, R. M., Lange, P. M., Nielsen, K. L. G., and Petersen, S. T. (2011). Phase Recognition during Surgical Procedures using Embedded and Body-worn Sensors. In *IEEE International Conference on Pervasive Computing and Communications (PerCom)*, Seattle.

Wang, P., Li, W., Ogunbona, P., Wan, J., and Escalera, S. (2018). RGB-D-based human motion recognition with deep learning: A survey. *Computer Vision and Image Understanding*, 171:118–139.

Urگو, M., Tarabini, M., and Tolio, T. (2019). A human modelling and monitoring approach to support the execution of manufacturing operations. *CIRP Annals*.

Aggarwal, J. K. and Cai, Q. (1999). Human Motion Analysis: A Review. Technical Report 3.



Srivastav, V., Issenhuth, T., Kadkhodamohammadi, A., de Mathelin, M., Gangi, A., and Padoy N. (2018). MVOR: A Multi-view RGB-D Operating Room Dataset for 2D and 3D Human Pose Estimation. ArXiv.

Kadkhodamohammadi, A. and Padoy, N. (2018). A generalizable approach for multi-view 3D human pose regression. ArXiv.

Jung, J. J. and Grantcharov, T. P. (2017). The Operating Room Black Box: A Prospective Observation Study of the Operating Room. *Journal of the American College of Surgeons*, 225(4):S127–S128.

Liu, Y., Stojadinovic, S., Hrycushko, B., Wardak, Z., Lau, S., Lu, W., ... & Nedzi, L. (2017). A deep convolutional neural network-based automatic delineation strategy for multiple brain metastases stereotactic radiosurgery. *PloS one*, 12(10), e0185844.

Charron, O., Lallement, A., Jarnet, D., Noblet, V., Clavier, J. B., & Meyer, P. (2018). Automatic detection and segmentation of brain metastases on multimodal MR images with a deep convolutional neural network. *Computers in biology and medicine*, 95, 43-54.

Grøvik, E., Yi, D., Iv, M., Tong, E., Rubin, D., & Zaharchuk, G. (2019). Deep learning enables automatic detection and segmentation of brain metastases on multisequence MRI. *Journal of Magnetic Resonance Imaging*.

Sjölund, J., Riad, S., Hennix, M., & Nordström, H. (2019). A linear programming approach to inverse planning in Gamma Knife radiosurgery. *Medical physics*, 46(4), 1533-1544.