Video-based assessment of communication during cardiopulmonary bypass

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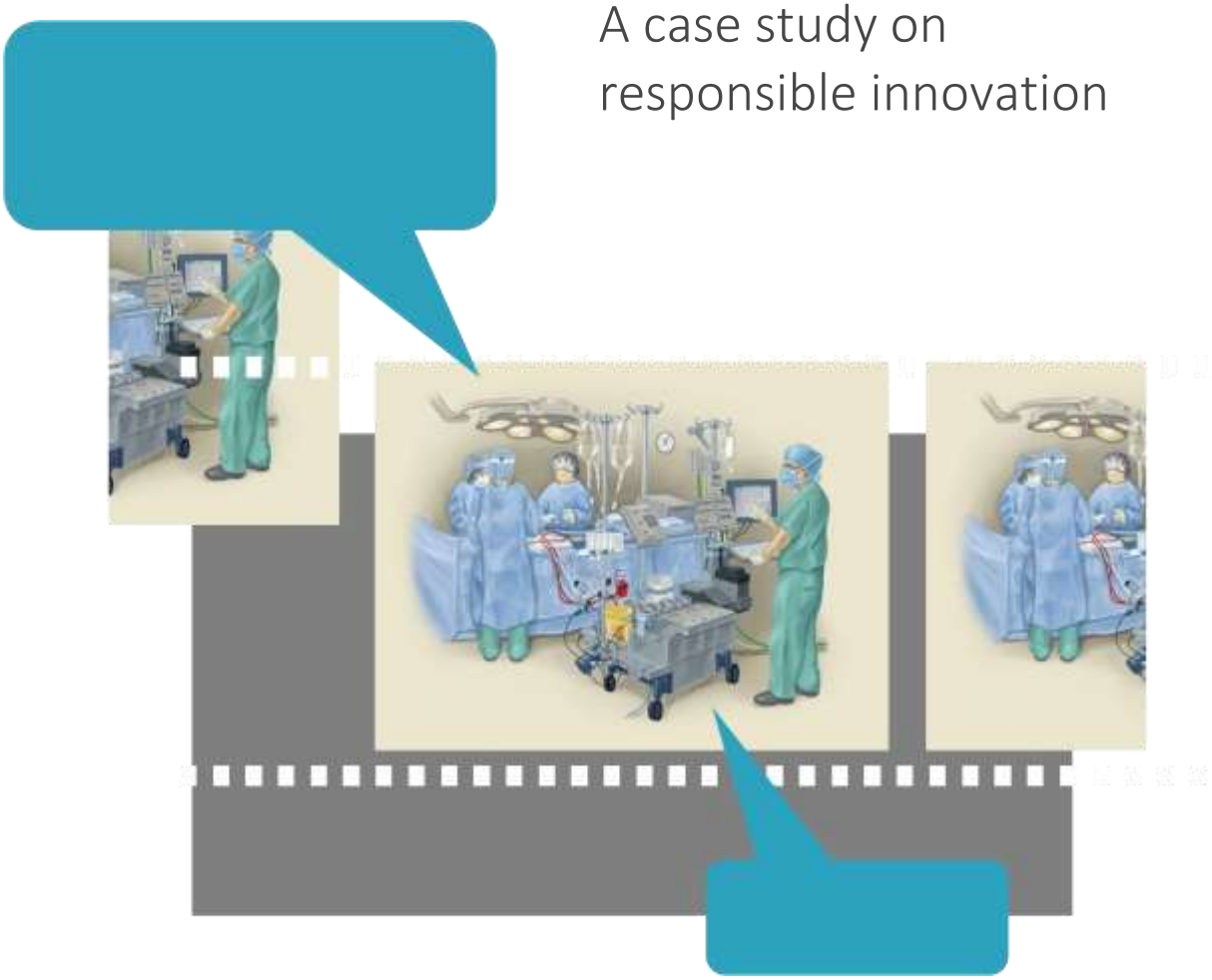
A case study on responsible innovation



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Graduation report in partial fulfillment of the requirements for the degrees of Master of Science in Science Communication at the faculty of Applied Sciences and Master of Science in Biomedical Engineering at the faculty of Mechanical, Maritime and Materials Engineering at the Delft University of Technology.

Graduation report

Video-based assessment of communication during cardiopulmonary bypass

&

A case study on responsible innovation

by

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June 24, 2016

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Preface

I remember chatting with a friend and going, 'I guess this would be the dream project of *any* mechanical engineer'. My friend, a mechanical engineer herself, responded with hysterical laughter.

Indeed, this project may be an unusual choice for a student with a Bachelor degree in mechanical engineering, because it centers on communication and innovation. However, it wasn't unusual for me. In fact, there are very few projects in which I could have put my various backgrounds to such good use. This project allowed me to study the use of a piece of high-tech equipment in a medical setting, and in this way combined my interests in engineering, communication and medical sciences. Not only did I study an interdisciplinary environment, I also engaged in one during my own graduation project. And I loved every part of it.

This report is written for partial fulfillment of two master degrees. Part A1 and A2 are written for the master Science Communication, whereas Part B is written for the master Biomedical Engineering. In the General introduction and General discussion, the integration of both parts is addressed.

I would like to thank my supervisors for their unceasing support and inspiration. Steven, who was there from the beginning and taught me to approach difficult times with humor and pragmatism. Jenny, who welcomed me when I had nothing to offer and was so insightful to recommend this project to me. Araz, who was available day and night and introduced me to his colleagues. Caroline, who was probably the most involved second supervisor anyone ever had and always found the right critical questions to ask and kind words to say. All of you showed faith in me and left no chance unused to motivate me. I appreciate this greatly.

Furthermore, I would like to thank John for sharing his experiences with DORA during an interview we had two years ago. Without either of us realizing it back then, you made this project possible by sparking my interest in the use of video recordings.

Finally, I would like to thank all personnel at the thorax surgery department at the LUMC for their kind cooperation. I would like to thank Sabrina in particular, who showed great commitment and contributed immensely to the surgical aspects of this project. Together you made this project possible, together we opened up the black box of an operating room.

Aafke Fraaije, Delft
May 31, 2016

Summary

The goal of this thesis was twofold. The goal of part A was to formulate recommendations on the use of video recordings in observation of medical specialists during surgery. To this end first a theoretical framework was developed on Responsible Research and Innovation (Part A1) and then this framework was applied in a case study at the Leids Universitair Medical Center (LUMC) (Part A2). In Part B of this report, video recordings were used to develop a quality standard for the verbal interactions of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. The integration of part A and B is addressed in the General discussion. Each of these parts is summarized below.

Part A1

A theoretical framework on Responsible Research and Innovation

Although few would argue for *ir*responsible innovation, Responsible Research and Innovation (RRI) lacks definition and clarity. This hampers its implementation. Multiple studies attempted to develop a coherent definition of RRI (e.g. (Kupper et al. 2015; Wickson & Carew 2014; Owen, Stilgoe, et al. 2013), but their similarities and differences had not yet been reviewed.

The goal of Part A1 of this thesis was to develop a framework on RRI qualifiers based on a systematic literature review and so facilitate its implementation. Since the meaning of RRI is formally negotiated in both academia and policy, documents of both worlds were reviewed. Only the normative and theoretical literature was included.

As a result of this review, qualifiers for both responsible processes as well as products were identified. Responsible products were defined as relevant for society, market competitive and high scientific quality. Responsible processes were described as transparent, inclusive, reflexive, anticipatory and responsive. Each of these dimensions was further specified in terms of its rationale and implementation. Any interactions between those dimensions were explicated and visualized (see Figure 4).

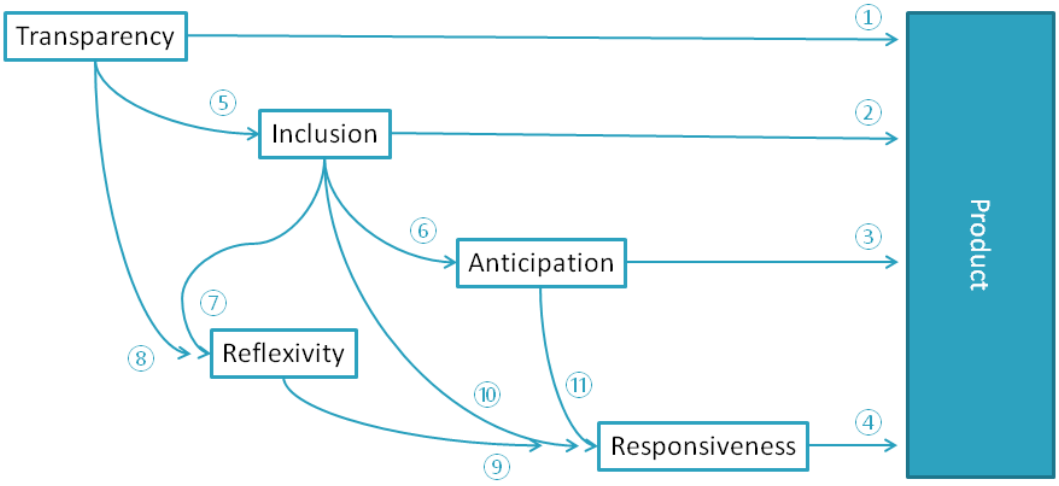

Figure 1 Theoretical interactions between RRI dimensions as described in the reviewed literature. All theoretical interactions represent positive relationships, e.g. transparency was thought to support inclusion. The dimensions and interactions ① to ⑪ are discussed in detail in Part A1 of this thesis.

Part A2

Case study: application of the framework on Responsible Research and Innovation

The LUMC uses video recordings to observe medical specialists during surgery (see Part B for an analysis based on these observations). Video recordings cannot be used without permission of the patient and staff, because their use touches on primary ethical and social aspects in healthcare. The literature provides limited insights on the appropriate conditions of use as well as the steps that should be taken to arrive at those agreements.

The goal of Part A2 of this thesis was to formulate recommendations on the use of video recordings in operating team research. First the framework developed in Part A1 was used to develop a set of events that could potentially support Responsible Research and Innovation. Then a reconstruction of these events during the case study was made based on document analysis and interviews with researchers and operating room personnel. The reconstruction was then used to assess to what extent the use of video recordings in this case study adheres to the RRI framework.

> *Transparency* There were significant attempts to be transparent, but a lack of transparency about potential risks caused a staff member to refrain from participation.
>
> *Inclusion* A diverse audience was included, but operating room personnel was mainly involved for instrumental reasons and only after the IRB protocol had been approved. Patients did not inform the product in any way.
>
> *Reflexivity* Many activities allowed for reflexivity, but operating staff's concerns were sometimes ill understood by the researchers and the researchers misjudged to have completely satisfied the stakeholders with a revision of the IRB protocol in June 2015.
>
> *Anticipation* Especially during the inception phase a wide variety of alternative conditions of use, potentially problematic societal impacts and desirable impacts were identified. Interactions with stakeholders also provided plenty of alternatives and impacts, but these were hardly on time to be meaningful.
>
> *Responsiveness* The IRB protocol was revised a few times during the first phase of implementation, but was only changed once after that. The changes to the IRB protocol on June 6, 2015 were substantial, informed by societal perspectives and swift.
>
> *General process qualifiers* The RRI dimensions were thoroughly coupled, especially through stakeholder interactions which could simultaneously allow for transparency, inclusion, reflexivity and anticipation.
>
> *Product* Although both operating room team members considered the project societally relevant, they would find it more relevant if they could review their own recordings with a safety expert. The project was only sufficiently ethical acceptable for one of the two operating room team members to consent. The operating room team members suggest that the recordings would be more ethically acceptable if those observed could access the images and if the images were stored for a shorter period of time. The act of recording surgeries may become more ethically acceptable over time as personnel becomes less distracted by it.

The results indicate that indeed some conditions of use can balance scientific interests with the interests of operating staff. Recommendations for the responsible use and implementation of video cameras are presented in the discussion chapter.

Part B

Communication during cardiopulmonary bypass procedures

During cardiopulmonary bypass (CPB) the function of heart and lungs is taken over by a heart-lung machine. This allows the heart to be still, so that it can be operated on during open-heart surgery. CPB is performed by a team of perfusionists, surgeons and anesthesiologists, who operate the heart-lung machine, perform the surgical procedure and manage the patient's sleep and pain levels respectively. Coordination during cardiopulmonary bypass is essential, but sensitive to failure. Standardization of communication practices could increase resilience to these failures.

The goal of Part B of this study therefore was to develop a quality standard for the verbal interactions of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. To this end, a list of events critical to verbalize and a set of quality criteria per verbal exchange were developed based on a systematic literature review, observations and interviews with specialists. The quality standard was then applied to six cardiopulmonary bypass procedures.

Three quality criteria were defined: purposefulness, consistency and breakdown resilience. The results include:

> *Purposefulness* Events that practitioners did not agree about were verbalized less often than those that were unanimously scored critical: conflicting events were verbalized in only 3.5 out of 6 cases whereas other critical events were verbalized in 5.1 cases.
>
> *Consistency* Almost half of all critical events were initiated by different sub-teams and one third of critical events were verbalized with different exchange types.
>
> *Breakdown resilience* Open loops and insubstantive call-backs were used regularly for a selection of critical events. Only a few exchanges were directed at a specific team member by name.

The results indicate a highly inconsistent communication pattern across cases. Inconsistencies often indicated an uncertainty about the distribution of roles (which events can be performed independently and which should await instruction) or a poor understanding of each other's tasks, therefore indicating significant room for improvement.

General discussion

In this thesis, video cameras were both a topic investigation (part A) as well as an instrument of research (Part B). The advantages, limitations and conditions of such integration are discussed here.

The *advantage* of such integration, is that it provides insights into how video cameras can be used. Part A showed for example that reviewing the video recordings with operating room staff could have improved the scientific rigor of the analysis in Part B, as well their societal relevance and ethical acceptability. A *limitation* with regard to integration was that part A could not be used to design Part B, because the video cameras were already installed when Part B was performed. A *condition* of the integration is that the researcher is mindful of his dual role with regard to stakeholders; to elicit the full range of social and ethical objections of staff, it was essential to interview them as a neutral 'reporter' rather than as a member of the research team.

The premise in part A was that the use of video recordings can contribute to patient safety. To that end, recommendations for the responsible implementation and use of video cameras in operating room research were formulated. In Part B of this study, the analysis of six recorded cardiopulmonary procedures indeed supported patient safety. This thesis shows therefore that the use of video cameras in operating team research can indeed contribute to patient safety and that there are responsible ways to implement and use them. The hope is that with the results of this thesis, video cameras can be used more often and more responsibly in future operating team research.

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PART B. COMMUNICATION DURING CARDIOPULMONARY BYPASS

General introduction

In this chapter the research project is introduced. Special attention is paid to the integration of the three parts of this thesis (A1, A2 and B).

Making open heart surgery safer

During cardiopulmonary bypass (CPB) procedures, the function of heart and lungs is taken over by a heart-lung machine. This allows the heart to be still, so that it can be operated on during open-heart surgery. The procedure is performed by a multidisciplinary team of perfusionists, surgeons and anesthesiologists who operate the heart-lung machine, perform the surgical procedure and manage the patient's sleep and pain levels respectively.

The coordination of these activities between team members is essential during CPB, because they depend on each another. For example, the perfusionist should administer a solution to arrest the heart as soon as the surgeon has placed a clamp on the aorta.

Any coordination is challenged however, because the perfusionist cannot see the surgical site and the surgeon cannot see the perfusionist. Therefore, most information is shared verbally. Unfortunately, verbal communication is susceptible to failure; it was reported as both the most common type of minor failure as well as a feature in most major adverse events during cardiac surgery (Catchpole et al. 2007; Catchpole et al. 2006).

A mechanism that could allow for these failures is communication inconsistency. This was found to be a problem in general surgery (Lingard et al. 2004) but also specifically in cardiopulmonary bypass (Santos et al. 2012). Standardization of communication practices could therefore reduce the number of communication failures per surgery.

Research goals

Improving communication practices in operating rooms can save lives. The aim of this study was to open up the black box of the operating room and to formulate recommendations on the communication practice of operating staff. To this end, three research goals were formulated.

A quality standard for communication during cardiopulmonary bypass

A quality standard that to inform the standardization of communication practices is currently lacking. Quality standards used to evaluate the effectiveness of interventions in the field of cardiopulmonary bypass lack the depth necessary to standardize current communication practices.

That is why one goal of this study was to develop a quality standard for the verbal interactions of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. To this end, a list of events critical to verbalize and a set of quality criteria per verbal exchange were developed based on a systematic literature review, observations and interviews with specialists. The quality standard was then applied to six cardiopulmonary bypass procedures. The results of this study are described in Part B of this report.

Recommendations for use of video recordings in operating rooms

In this study, video recordings were used to develop and apply the quality standard. Video recordings are an increasingly popular tool to study teamwork, as they provide a scientific rigor that cannot be obtained through mere unrecorded observation (Mackenzie & Xiao 2011).

Video recordings cannot be used without question however, because their use touches on primary ethical and social aspects in healthcare. (Henrickson et al. 2013, p.1123) for example wrote that although "ideally" videotapes would be collected and analyzed, recording such tapes posed such "significant challenges with regard to confidentiality and liability" that they finally chose not to. Others reported various constraints

with regard to the use of video recordings and a generally unwelcoming attitude of the staff towards their study (Catchpole et al. 2007). Also the Leiden University Medical Center (LUMC), the medical institution from which case-studies were analyzed during this research project, encountered several issues regarding the use of video recordings; it took four years to obtain the staff's support and other resources necessary to install the video cameras.

The main challenges at the LUMC were about establishing a set of conditions under which the recordings could be accessed, stored and used. Yet, literature provides no insights on either an appropriate set of conditions or the steps that should be taken to arrive at those agreements. The one study that does provide guidelines on implementing video cameras in surgery rooms only recommends to "comply with all legal requirements", "ensure privacy and confidentiality related to participant identity preservation" and to obtain "legal consent" (Asan & Montague 2014).

Due to this lack of guidelines in the literature, the second goal of this study is to formulate recommendations for the use of video cameras as a means to study communication behavior of medical specialists in the operating room. The implementation process and conditions of use as established at the LUMC provide a case study to this end. The results of the case study are presented in Part A2 of this report.

A framework on Responsible Research and Innovation

In order to identify relevant aspects of the case study, a framework on Responsible Research and Innovation was developed. In short, Responsible Research and Innovation concerns "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)*"* (Von Schomberg 2011b). As such, Responsible Research and Innovation could provide insights in the conditions under which cameras are implemented ('innovation process') and used ('marketable product') so that they are (ethically) acceptable, sustainable and desirable according to the actors involved. In this case, the video cameras are an innovative research method that should be implemented responsibly. Yet the various existing frameworks on Responsible Research and Innovation, such as (Owen, Stilgoe, et al. 2013; Kupper et al. 2015), were of limited depth and contained contradictions. Therefore, a third goal of this study was to develop a theoretical framework for responsible research and innovation. To this end a systematic literature review was performed. The results of this study are presented in Part A1 of this report.

Structure of this report

The results of Part A1 were used to inform Part A2. Yet the lessons learned in Part A were *not* used to inform Part B, because the video cameras were already implemented and installed before the study in Part B took place. To create a logical flow in the report, first part A and then Part B is presented. The former is summarized in the table below.

Part	Research goal	
A1	Develop a theoretical framework on Responsible Research and Innovation processes and products	p. 2
A2	Apply the theoretical framework on Responsible Research and Innovation in a case study at the LUMC to formulate recommendations for the implementation and use of video recordings in operating team research	p. 3333
B	Use video recordings to evaluate the communication performance of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures at the LUMC	p. 78

PART A1.

A THEORETICAL FRAMEWORK ON RESPONSIBLE RESEARCH AND INNOVATION

1 Introduction

In this part of this thesis (Part A1) a framework on Responsible Research and Innovation (RRI) is developed. In the next part, the framework on RRI is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. Together, these parts are used to formulate recommendations on the use of video recordings in observation of medical specialists during surgery.

In this chapter the research problem (1.1) and research objective (1.2) and approach (1.3) of Part A1 are introduced. This chapter closes with a short overview of how the remainder of Part A1 is structured (1.4).

1.1 Research problem

An often cited working definition of Responsible Research and Innovation (RRI) by (Von Schomberg 2011a, p.9) reads:

> RRI is a transparent, interactive process in which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technologies advances in our society).

In theory therefore, responsible research and innovation balances scientific, economic and societal interests and delivers products that are societally desirable.

In practice however, Responsible Research and Innovation (RRI) lacks definition and clarity. Or as (Owen, Stilgoe, et al. 2013) put it: "few would argue for *ir*responsible research and innovation". In an introduction to a recent book on Responsible Innovation, (Koops 2015) identified a wide range of definitions on responsible innovation and concluded that although it is a popular term in science and policy, "it is by no means clear what exactly the term refers to, nor how responsible innovation, once we know what is meant by this, can or should be approached" (p. 2).

A lack of clarity on what good quality RRI entails, forms one of the barriers to the implementation of RRI. Or as (Jong et al. 2015) put it: "If [R]RI is to be effective as a guiding principle in science, there needs to be a greater, common understanding of what it means in terms of concepts and methodologies."

Specifically, a lack of clarity on how RRI qualities *relate* to one another forms a barrier to implementation of RRI. Several studies have emphasized that RRI should be performed in an integrative manner. (Stilgoe et al. 2013, p.1573) for example states that "[RRI dimensions] do not float freely but must connect as an integrated whole". (Stilgoe et al. 2013) also acknowledges however that some RRI dimensions may reinforce each other whereas others may conflict:

> [RRI] dimensions may in practice be mutually reinforcing. For example, increased reflexivity may lead to greater inclusion or vice versa. But…these dimensions may also be in tension with one another and may generate new conflicts. Anticipation can encourage wider participation, but… it may be resisted by scientists seeking to protect their autonomy, or prior commitments to particular trajectories.").

As such it is essential for an integrative implementation of RRI that not only RRI qualities are defined but also that the mutual relationships between those RRI qualities are explicated.

Indeed, multiple studies have called for a coherent definition of RRI and its criteria. In a report commissioned by the European Commission to describe the current state of art on RRI in Europe, an expert group called for a coherent framework of RRI criteria:

> "The key objective of EU action should be **to develop a coherent approach** among the EU Member States that defines processes, instruments and criteria for RRI that encourage researchers and innovative firms to consider ethical concerns and address societal needs. **A framework for the operationalization of RRI entails (a) defining criteria for RRI**, (b) defining processes for a successful application of RRI, and (c) Defining instruments to encourage RRI." (Jacob et al. 2013, p.4)

In recent years many studies have answered to such calls for clarity, by developing RRI frameworks and assessment rubrics, e.g. (Kupper et al. 2015; Wickson & Carew 2014; Owen, Stilgoe, et al. 2013). While these studies share overlapping features that suggest a set of core characteristics, they also contain various contradictions. Whereas (Kupper et al. 2015) for example called for 'Openness and Transparency' and (Wickson & Carew 2014) called for 'Honest and Accountable' research, (Stilgoe et al. 2013) did not include either of these dimensions. The similarities and differences between existing RRI frameworks have not been systematically reviewed to date. (Wickson & Carew 2014) suggested that if criteria can be identified that are shared across studies, these may be central to the emerging concept of RRI.

Overall, it seems that although few would argue for irresponsible research and innovation, RRI lacks definition and clarity. Since many studies have recently reported RRI criteria, a systematic review of the literature may provide RRI criteria that are central to the concept of RRI.

1.2 Research objective

This study aims to establish a framework of RRI qualifiers based on a systematic review of the literature.

A framework in this context is an overview of qualifiers and the relationships between those qualifiers, whereby a qualifier is anything that a researcher or innovator can do to support responsible processes or products. The objective therefore is to develop an overview of what signifies good quality RRI and how these qualities are thought to support each other. Such a framework may be used to facilitate the integrative implementation of RRI by providing clarity on 'what good quality RRI looks like' (Wickson & Carew 2014) and on what activities should be performed together.

1.3 Research approach

A systematic review is performed to provide qualifiers central to RRI. Since the meaning of RRI is formally negotiated in both academia and policy, documents from both worlds are included. Since the goal is to develop qualifiers, only normative documents are included. Since the goal is to develop a framework on the general ideas about RRI, only the theoretical literature is included.

Both qualifiers for responsible processes as well as products are developed. This distinction was based on the afore mentioned definition of RRI by (Von Schomberg 2011a), who distinguished between 'the innovation process' and 'its marketable products'. In this study, a RRI process is defined as an activity that a researcher or innovator can perform to support RRI. A RRI product is defined as the outcome of such research or innovation activities, including academic findings and marketable products.

Qualifiers for responsible processes are further specified along several process dimensions. These dimensions are partially adopted from one of the first and most influential studies to develop a RRI framework (Stilgoe et al. 2013). (Stilgoe et al. 2013) suggested that four process dimensions (inclusion, reflexivity, anticipation, and responsiveness) together support RRI as a means to "take care of the future through collective stewardship of science and innovation in the present" (p. 1570). In this study, these four process dimensions form the grounds to further specify process qualifiers in an inductive manner.

Finally, this review also set out to explicate the theoretical interactions between those process dimensions. To this end the rationale of each process dimension, the reason to perform the activity in the light of RRI, is explicated and visualized.

1.4 Outline of Part A1

In the next chapter, the review methodology is described. Subsequently the results of the literature review are presented in a framework (see p. 15). The framework is summarized in section 3.3 Framework summary, p. 26. Finally Part A1 closes with a Discussion chapter on the value and limitations of the framework and the systematic review (see p. 29).

2 Methodology

In this part of this thesis (Part A1) a framework on Responsible Research and Innovation (RRI) is developed based on a systematic review of the literature.

In the previous chapter the review was introduced, providing backgrounds to the research problem and research objective. In this chapter the methodology of the review is described. Three steps were taken: First, any documents that could be relevant to the study were sought (2.1). Then of these, only the relevant documents were selected (2.2). Finally the documents were systematically analyzed to deliver a set of qualifiers on RRI products and processes (2.3). Each of these steps is described below.

2.1 Seeking relevant documents

To obtain an overview of RRI qualifiers, a review of academic and policy documents was performed. Various types of academic and policy documents informed the literature review.

For one, all chapters from the book Responsible Innovation – Managing the responsible emergence of science and innovation in society were included (Owen, Bessant, et al. 2013). This was the first book on Responsible Innovation and the book summarizes the first academic thoughts on and attempts at its practice.

Furthermore all chapters from the proceedings Responsible Innovation 1: Innovative Solutions for Global Issues (Hoven et al. 2014) and Responsible Innovation 2: Concepts, Approaches and Applications (Koops et al. 2015) were included. These volumes are based upon work that was originally presented at the First and respectively Second International Conference on Responsible Innovation, hosted by the Dutch Organization for Scientific Research (NWO) in 2011 and 2012. The conferences brought together the results of research projects under the NWO Research Program "Responsible Innovation" (Maatschappelijk Verantwoord Innoveren) as well as international research projects.

Also all Workplan 1 (WP1) and Workplan 5 (WP5) deliverables from the European research project RRI Tools (see www.rritools.eu) were included for review. Funded under the European Framework Programme FP7 (2007-2013), RRI Tools intends to develop a set of digital resources to implement RRI under Horizon 2020. WP1 deliverables concern a widely supported definition of RRI, an analysis of the implementation of RRI in Europe and an analysis of RRI best practices and standards. Amongst others, WP5 deliverables concern the production of criteria and indicators to evaluate RRI aspects. Although largely unfinished at the time of reference (October 14, 2015), RRI Tools' deliverables represent the view of 26 European research institutes and are therefore deemed sufficiently relevant for inclusion. Work under the RRI Tools project continues until 2016.

In addition all peer-reviewed, original research articles and reviews published in the Journal of Responsible Innovation were included. The journal was first published in 2014 and publishes 3 issues per year. Five issues were published at the time of reference (September 11, 2015).

Lastly also policy documents, representing Dutch and European guidelines on RRI, were included for review. For this review the following publications were included: a governmental publication on Dutch research policy (Anon 2014b), the call for proposals by NWO for their funding program "Responsible Innovation" (Anon 2014a) and the European Work Program 2014-2015 for Horizon 2020 (Anon 2015).

These sources were complemented with a database search on Scopus, ScienceDirect and Google Scholar. The titles and abstracts of peer-reviewed articles and reviews were searched for combinations of "Responsible Research and Innovation" or "Responsible Innovation" and "indicators", "criteria", "requirements" (search performed on September 15, 2015). Furthermore potentially relevant documents were identified through examination of the reference lists of the initial source base and added accordingly.

2.2 Selecting relevant documents

These documents were reviewed based on their titles and abstracts (or the introduction when an abstract was missing). In addition to being about the goals of and recommendations for RRI, the document had to do one of the following:

- elaborate on the concept of RRI based on rhetorical arguments (rhetorical study)
- evaluate an innovation or innovation process according to RRI standards (evaluation study)
- evaluate or propose a method to support RRI processes (intervention study)
- put RRI to practice (action research)
- review the literature on RRI (literature review)
- or describe policy guidelines for RRI practice (policy document)
- be of a normative rather than descriptive nature, so that normative goals and recommendations could be derived from it
- concern European or American research practice, so as to exclude goals and recommendations unique to RRI in developing countries
- and be written in Dutch or English

Based on these criteria, a total of 38 academic documents and 6 policy documents were included for review.

2.3 Analyzing documents

Both an inductive and deductive approach were applied. Qualifiers were first divided across process and product dimensions, following the suggestions of (Von Schomberg 2011b). Process qualifiers were then grouped according to the dimensions described in (Owen, Stilgoe, et al. 2013) and (Owen, Stilgoe, et al. 2013), namely inclusion, reflectivity, anticipation and responsiveness. Together these dimensions formed the grounds to further specify the qualifiers in an inductive manner.

Qualifiers were coded in a closed as well as open manner, meaning that the initial set of signifiers were based on the original definitions of (Owen, Stilgoe, et al. 2013) and later expanded iteratively during coding (for examples, see Table 1).

Table 1 Examples of signifiers in coded text per process dimension

	Original definition (Owen, Stilgoe, et al. 2013)	**Examples** in coded documents
Inclusion	"inclusively opening up visions, purposes, questions, and dilemmas to broad, collective deliberation through processes of dialogue, engagement, and debate, inviting and listening to wider perspectives from publics and diverse stakeholders"	• 'to engage', 'to incorporate', 'to adopt', 'to integrate', 'to include' or 'to broaden' • in combination with 'stakeholders', 'stakeholder values', 'social/ethical values', 'perspectives', or simply 'the public', • through 'deliberation', 'discussion', 'debate' or 'dialogue'
Reflexivity	"reflecting on underlying purposes, motivations, and potential impacts, what is known…and what is not known; associated uncertainties, risks, areas of ignorance, assumptions, questions, and dilemmas"	• 'to reflect', 'to gain understanding', 'to challenge', or 'to reorient' • in combination with 'own role', 'assumptions', 'limitations', 'motivations', 'underlying values' or 'drivers'
Anticipation	"describing and analyzing those intended and potentially unintended impacts that might arise, be these economic, social, environmental, or otherwise"	• 'to anticipate', 'to predict', 'to imagine', 'foresight' • in combination with 'consequences', 'impacts', 'outcomes' or more generally 'the future'

Responsiveness	"… to both set the direction and influence the subsequent trajectory and pace of innovation"	• 'to respond', 'to adapt', 'to implement', 'to act'

Table 2 shows the results of the initial coding analysis. It shows what qualifiers were associated with RRI and what dimension they were attributed to. For example to 'Diversify values' was associated with RRI and attributed to Inclusion in various sources, namely (Sykes & Macnaghten 2013; Eden et al. 2013; Blok 2014; Jacob et al. 2013).

Table 2 Results of initial coding: qualifiers per RRI dimension.

RRI dimension	Qualifier	Sources
Inclusion	Diversify values	(Sykes & Macnaghten 2013; Eden et al. 2013; Blok 2014; Jacob et al. 2013)
	Diversify expertise	(Flipse et al. 2013; Stahl 2013; Jacob et al. 2013)
	Democratize RD decisions	(Stahl 2013; Flipse et al. 2013; Von Schomberg 2011b; Sutcliffe 2011; Blok 2014; Sykes & Macnaghten 2013)
	Command public support for potential outcomes	(Flipse et al. 2013; Zwart et al. 2014; Sutcliffe 2011)
	Define desirable outcome (relates to anticipation)	(Owen et al. 2012; Flipse et al. 2013; Blok 2014; Sykes & Macnaghten 2013)
	Identify and clarify social-ethical impacts (relates to anticipation)	(Anon 2014b; Jacob et al. 2013; Sykes & Macnaghten 2013)
	Diversify alternatives (relates to anticipation)	(Jacob et al. 2013; Sykes & Macnaghten 2013; Sutcliffe 2011; Blok 2014)
	Assess social desirability of alternatives and outcome (relates to anticipation)	(Jacob et al. 2013)
	Expand capacity for change (relates to responsiveness)	(Flipse et al. 2013; Anon 2014b; Owen et al. 2012; Blok 2014; Jacob et al. 2013)
	Contribute to social desirability of outcome (relates to product)	(Stahl 2013; Flipse et al. 2013; Anon 2014b; Blok & Lemmens 2015; Anon 2015; Owen et al. 2012)
	Contribute to scientific quality of outcome (relates to product)	(Anon 2014b; Flipse et al. 2013; Anon 2015)
	Command public support for potential outcomes (relates to inclusion)	(Sykes & Macnaghten 2013)
Reflexivity	Recognize socio-ethical and science-based drivers in RD decisions	(Flipse et al. 2013; Schuurbiers 2011; Jacob et al. 2013; Sykes & Macnaghten 2013; Stahl 2013; Wynne 2011)
	Challenge drivers in RD decisions	(Schuurbiers 2011; Wynne 2011)
	Enhance transparency of decision-making process	(Flipse et al. 2013; Sykes & Macnaghten 2013; Wynne 2011)
	Assess social desirability of alternatives and outcome (relates to anticipation)	(Eden et al. 2013)
	Identify and clarify socio-ethical impacts (relates to anticipation)	(Stahl 2013; Flipse et al. 2013; Schuurbiers 2011; Wynne 2011; Jacob et al. 2013)
	Expand capacity for change	(Schuurbiers 2011; Wynne 2011)
Anticipation	Diversify perspectives (relates to inclusion)	(Jacob et al. 2013)
	Recognize drivers for decision making in R&D (relates to reflexivity)	(Owen et al. 2012; Owen, Stilgoe, et al. 2013)
	Define desirable outcome	(Owen et al. 2012; Zwart et al. 2014; Von Schomberg 2013)
	Identify and clarify socio-ethical impacts	(Anon 2014a; Stilgoe et al. 2013; Stahl 2013; Owen et al. 2012; Von Schomberg 2013; Sutcliffe 2011; Jong et al. 2015; Owen, Stilgoe, et al. 2013)
	Diversify alternatives (relates to anticipation)	(Jacob et al. 2013; Stilgoe et al. 2013; Owen, Stilgoe, et al. 2013)
	Assess social desirability of alternatives and outcome	(Owen et al. 2012; Zwart et al. 2014; Von Schomberg 2013)
	Expand capacity for change	(Stilgoe et al. 2013; Nordmann 2014; Sutcliffe 2011; Jong et al. 2015)
	Contribute to social desirability of outcome	(Stahl 2013; Jacob et al. 2013; Stilgoe et al. 2013)

	(relates to product)	
Responsiveness	Influence the innovation trajectory towards more desirable outcomes	(Stilgoe et al. 2013; Jacob et al. 2013; Sutcliffe 2011; Owen, Stilgoe, et al. 2013)
Product	Socially desirable	(Wickson & Carew 2014; Jacob et al. 2013; Anon 2014b; Von Schomberg 2011b; Stahl 2013; Zwart et al. 2014; Von Schomberg 2013; Sutcliffe 2011; Anon 2014a; Jong et al. 2015; Owen, Stilgoe, et al. 2013)
	(Ethically) acceptable	(Jacob et al. 2013; Jong et al. 2015; Von Schomberg 2013)
	Scientifically high-quality	(Anon 2014b; Wickson & Carew 2014; Jong et al. 2015)
	Market competitive	(Wickson & Carew 2014; Zwart et al. 2014; Anon 2014a; Von Schomberg 2013)

After initial coding, two observations informed the development of the final framework. Firstly, the qualifiers after initial coding were of different abstraction levels. For example 'Define desirable outcome' was a more concrete claim than 'Expand capacity for change'. For this reason, the goals were organized according to their abstraction level. This analysis caused *activities*, such as 'Define desirable outcome' to separate from *goals*, such as 'Expand capacity for change'. The results of this analysis are shown in Figure 2.

Also, various qualifiers appeared in more than one process dimension (see Figure 3). In-depth review of the 'double' qualifiers showed that in each case, one dimension was thought to support the other. Define desirable outcome for example, appeared in both inclusion and anticipation. It appeared in anticipation because it was considered a critical element of anticipatory processes. It appeared in inclusion, because inclusive processes were thought to support this anticipatory activity, leading to a better and more relevant definition of desirable outcomes.

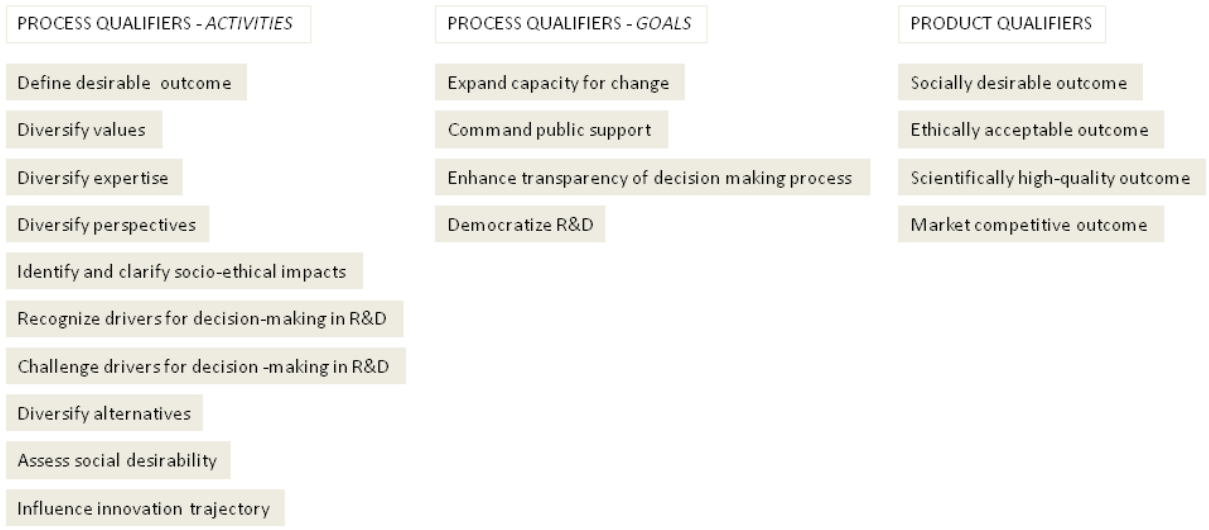


Figure 2 The initial process qualifiers were of different abstraction levels, distinguishing between *activities* (left) and *goals* (middle).

Figure 3 Various qualifiers in the initial codes (left) were associated with more than one RRI dimension (right).

Together these two steps of analysis resulted in a presentation of qualifiers whereby qualifiers pertaining to the *rationale* and the *implementation* of a dimension were separated. The *rationale* of a dimension referred to any reasons that a researcher or innovator may have to apply this dimension. This included the qualifiers that were grouped under *goals* above, and any qualifiers that were thought to support another RRI dimension. The *implementation* of a dimension referred to any aspects of a dimension that were thought to determine its success, including the qualifiers that were grouped under *activities* above.

3 Framework

The goal of this literature review was to find factors that indicate quality in responsible processes and products (qualifiers) and as such establish a framework on responsible research and innovation. In this chapter the results of the literature review are presented.

The results are presented in two sections: first the qualifiers of RRI products and then the qualifiers of RRI processes are described. Qualifiers at the product level describe the desired outcomes of responsible research and innovation, including academic findings as well as marketable products. Qualifiers at the process level describe what type of research and innovation processes precede these outcomes and how these processes should be implemented in practice.

The section on responsible processes is furthermore presented in five sub-sections, each pertaining to one of the responsible process dimensions, including transparency, inclusion, reflexivity, anticipation and responsiveness. Each process dimension is discussed with regard to the reasons that a researcher may have to use this dimension (rationale) as well as the factors thought to determine its success (implementation). Under rationale also any ways in which the corresponding process dimension is thought to influence other dimensions is discussed. For an overview of these interactions, see Figure 4.

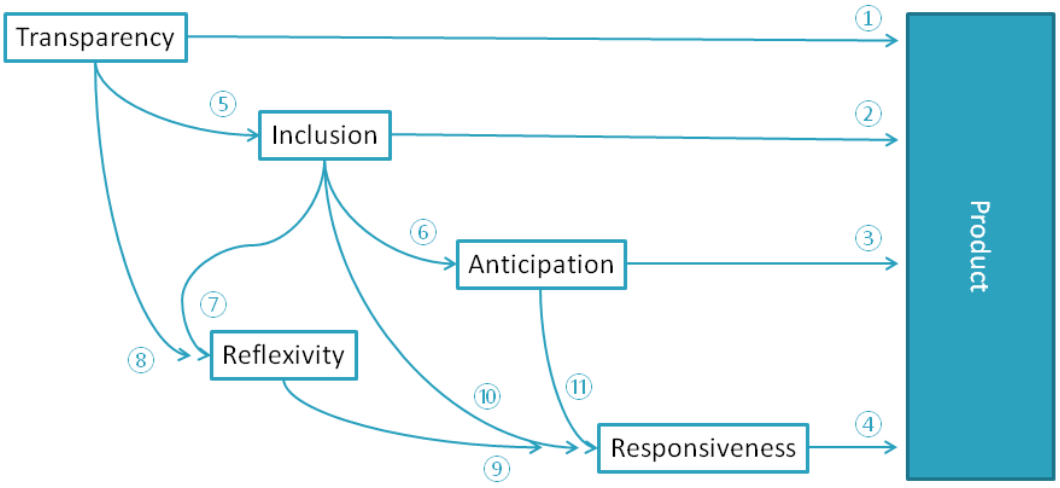


Figure 4 Theoretical interactions between RRI dimensions as described in the reviewed literature. All theoretical interactions presented in this overview are positive relationships, e.g. transparency was thought to support inclusion. Interactions ① to ⑪ are discussed under the rationales of the corresponding process dimension in the text below, e.g. ⑤ is described under Transparency.

3.1 Responsible products

Qualifiers at the product level concern the outcomes of research and innovation, including its academic findings as well as the marketable products. Three product qualifiers are mentioned in the literature: societal relevance, market competitiveness and scientific quality.

3.1.1 Societal relevance

All sources stress that a product can only be responsible if it pays a relevant contribution to society. It seems that the societal relevance of a product is determined by both the social relevance of its impacts as well as the usability of its form.

Relevant impacts

Responsible impacts are relevant to society in one way or another. These impacts are described as 'socially desirable' (Von Schomberg 2013; Klaassen et al. 2014; Kupper et al. 2015; Stahl 2013), aligning with 'societal challenges' (Jacob et al. 2013), taking into account 'societal objectives' (Von Schomberg 2014) or contributing to the 'public or collective good' (Jong et al. 2015). Overall then, responsible products should have impacts relevant for society.

The resolution of a wide range of issues may contribute to society. (Jong et al. 2015) reviewed that responsible impacts may be ethical, social, societal, environmental, scientific, health, legal, cultural and political. Especially the resolution of social issues and the contribution to sustainable development receive much emphasis in the literature and are addressed below.

Resolution of social issues Responsible products may help resolve social issues. Social issues are usually defined in terms of values or norms. The Dutch program for responsible innovation for example calls for projects that focus on supporting justice, equality and autonomy (Anon 2014a). At a European level the Treaty of the European Union is often cited (Jacob et al. 2013; Von Schomberg 2014; Von Schomberg 2013; Zwart et al. 2014), which reads "[The European Union] shall combat social exclusion and discrimination, and shall promote social justice and protection, equality between women and men, solidarity between generations and protection of the rights of the child", as cited in (Von Schomberg 2014).

Contribution to sustainable development Sustainable innovation is generally considered responsible innovation (although this needn't be true the other way around). In contrast to the WWF, which focuses on the environmental aspects of sustainability (Owen, Stilgoe, et al. 2013), the RRI literature emphasizes that sustainable innovation should balance environmental with social and economic interests (Von Schomberg 2013; Sutcliffe 2011; Jacob et al. 2013; Koops 2015; Von Schomberg 2014). The EU Treaty for example stresses that the sustainable development of Europe is based on 'balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment' (Von Schomberg 2014).

Usable forms

Even the most socially relevant products cannot achieve its goals if they are not used. Therefore the literature stresses that a responsible product should not only aim for certain impacts, but also be presented in a usable form. The literature reports that in order to be used, a product needs to be ethically acceptable, sufficiently concrete and in order to be viable in current market economies also market competitive.

Ethically acceptable Multiple sources stress that a product is more likely to be properly embedded in society if it is ethically acceptable. Very generally this means that research and innovation outcomes should comply with fundamental rights such as the right for privacy (Jacob et al. 2013; Koops 2015; Von Schomberg 2014; Von Schomberg 2013; Klaassen et al. 2014; Kupper et al. 2015). Safety norms regarding human health and the environment are also regularly mentioned in this light (Von Schomberg 2013; Zwart et al. 2014; Jacob et al. 2013; Von Schomberg 2014).

Although widely accepted, human rights lack specificity and need to be translated into more applicable norms (Stahl 2013). (Stahl 2013) mentioned several more specific norms which may be appropriate for RRI, such the UNESCO Draft Code of Ethics for the Information Society. This for example includes a code on how every person irrespective of where they live, their gender, education, religion, social status should 'be able to benefit from the Internet'. What codes are relevant in a specific case should be discussed per case.

Concrete products The outcomes of research and innovation should also be sufficiently concrete in order to be embedded in society. It is in this light that (Wickson & Carew 2014) calls for the delivery of 'a successful solution' over 'the creation of decontextualized knowledge'. A similar call is made by the Dutch program for responsible innovation, which requires a research project to make concrete contributions to innovation (Anon 2014a).

Viable in market economy (Von Schomberg 2013) stated that although responsible innovation should go *beyond* market competitiveness, competitiveness remains a necessity for the viability of responsible products in current market economies. In other words, in his view a socially relevant product cannot achieve its goals if it does not sell, because it will not be used.

3.1.2 Market competitiveness

In contrast to (Von Schomberg 2013), who sees viability in the current market economy as a precondition for social relevance, others see market competitiveness as a goal of responsible innovation on itself. In this view, responsible products should strengthen the (inter)national economy and make research funding more efficient. This seems to have been the primary drive of the European Commission to institute RRI at a European level. An evaluative report issued by the European Commission for example described the motives for instituting RRI as follows: "there are many examples in which the outcomes of research has been contested in society, because societal impacts and ethical aspects have not adequately been taken into consideration in the development of innovation. In many cases, the related research funding is wasted… RRI has the potential to make research and innovation investments more efficient, while at the same time focusing on global societal challenges" (Jacob et al. 2013, p.16). Indeed the report by (Jacob et al. 2013) calls for socially relevant outcomes, but only as a stepping stone towards more efficient research funding. These motivations later are summarized by (Zwart et al. 2014), who wrote: 'Inclusion of ethics beforehand, it seems, will lead to less contestation of innovations afterwards'.

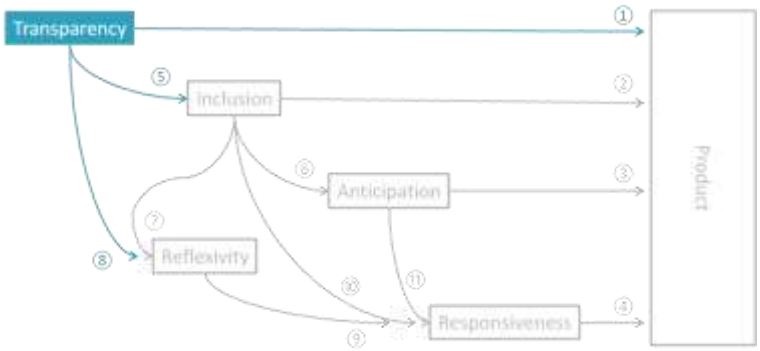
3.1.3 Scientific quality

According to the (Anon 2014b), the promise of scientifically high-quality outcomes is one of the primary drives of the Dutch government to promote Responsible Research and Innovation. The view that responsible research should also lead to scientifically high-quality research is shared by (Wickson & Carew 2014), who included various indicators of scientific quality in their framework for responsible research (repeatability, reliability, novelty and elegance).

3.2 Responsible processes

Qualifiers at the process level describe the processes that precede research and innovation products. The qualifiers may apply to any research or innovation process phase, including proposal writing, designing, validating and submitting research results. Essentially a responsible process was thought to support the delivery of responsible products through responsible decision-making.

Five process dimensions were found to contribute to the delivery of responsible products: transparency, inclusion, reflexivity, transparency and responsiveness. Below each of those process dimensions is described. For each process dimension, an overview of the reasons to apply it (rationale) and the strategies to implement it (implementation) is given. Some recommendations regarding the implementation of responsible processes concern more than one dimension, and are therefore summarized under general recommendations at the bottom of this section.



3.2.1 Transparency

Activities that contribute to process transparency, communicate the bases of decisions and the distribution of the responsibilities to external publics.

Rationale

(Stilgoe et al. 2013) did not include Transparency as one of the process dimensions in RRI. This is because (Stilgoe et al. 2013) defined process dimensions that support the responsiveness or "collective stewardship" of innovation, and therewith focusing on *forward*-looking responsibility; how can decisions can be taken such that they lead to 'better' decisions? Transparency is mainly a *backward*-looking aspect of responsibility – providing justification and clarity on decisions that were taken already – and does therefore not contribute to the quality of those decisions. As such, transparency cannot contribute to responsiveness directly.

Indeed the literature did not suggest that transparency can support responsiveness directly. However, Transparency was still added as a fifth process dimension, because it was found to support other process dimensions and so support responsiveness indirectly. Transparency is thought to support inclusive and reflexive processes and so contribute to responsiveness indirectly. Transparency supports inclusive processes ⑤, because it is a requirement for meaningful dialogue (Sykes & Macnaghten 2013; Kupper et al. 2015) and trust between stakeholders (Kupper et al. 2015). Transparency can also support reflexive processes ⑧, because being open about the bases of decisions allows others to challenge those bases (Wynne 2011).

Furthermore, transparency was found to support the delivery of responsible products ①, because it can help to gain public support for research and innovation products (Sutcliffe 2011; Sykes & Macnaghten 2013) and so support the *usability* and *market competitiveness* of a product.

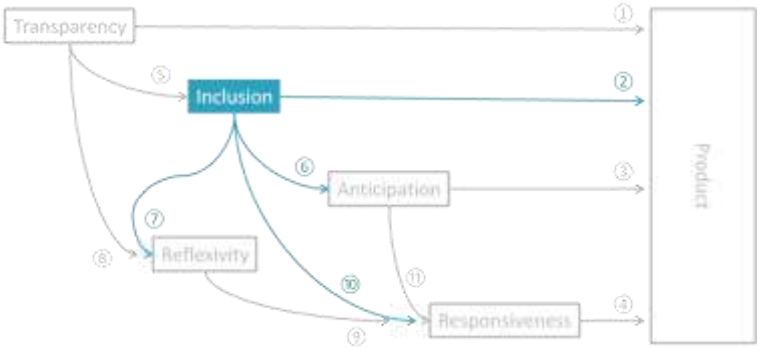
Implementation

In its most general sense, the normative literature asks researchers and innovators to be open about the drivers behind their decisions, or 'the key commitments driving and structuring science' (Wynne 2011). Specifically, the literature emphasizes a transparency about the assessment criteria used, the role of stakeholders involved and any limitations that the researchers may experience with regard to transparency.

Transparent about assessment criteria Transparency asks researchers and innovators to be open towards stakeholders about the assessment criteria that they use for their decisions. In the literature this is referred to as 'the values which underpin their work' (Sykes & Macnaghten 2013) or 'the social and ethical bases of R&D decisions' (Flipse et al. 2013). Overall it seems that and innovators are asked to communicate what advantages caused them to prefer one solution over another.

Transparency about the role of stakeholders Furthermore researchers and innovators are asked to be open about the role of stakeholders involved. This includes transparency about what stakeholder groups are involved in the decision-making process (Kupper et al. 2015; Grunwald 2011) and what is done with their input (Kupper et al. 2015).

Transparency about limitations Yet full transparency about these drivers is not always possible – intellectual property rights may prevent innovators from sharing the bases of their decisions. In this case (Kupper et al. 2015) recommends innovators to be transparent about their limitations in this respect.



3.2.2 Inclusion

Essentially, inclusive processes take in the societal aspects of an innovation. The most frequently described way to take in those societal aspects, is to engage with stakeholders. Any way to include stakeholders is referred to from here on as an 'inclusion activity'.

Of all dimensions, inclusion receives most emphasis in the RRI literature. The literature describes many different reasons for being inclusive (rationale) and refers to a wide variety of processes as 'inclusive' (implementation).

Rationale

Most importantly, inclusiveness is thought to contribute to more responsible outcomes. Three types of inclusiveness can be distinguished in this light: inclusion can be used to (1) gain public support for a product, (2) learn from (experience) experts, and (3) share responsibilities for solving a societal issue with stakeholders. Each of these are discussed below.

Gain public support This first type of inclusion primarily gets stakeholders involved and enthusiastic about the product and is in no way geared towards improving the product itself as a result of this interaction. (Sutcliffe 2011) for example proposed that under Responsible Research and Innovation citizens should perhaps be seen as co-creators of innovation to get 'the buy-in' of customers right at the start. Since public support contributes to both *market competitiveness* and *usability by society*, which are both product qualifiers of responsible research and innovation, inclusion for public support can be a means to responsible outcomes. Note however that this type of inclusion does not require the innovator to respond to societal perspectives and is therefore not necessarily *responsive*.

Learn from experts The second type of inclusion helps to reveal social and ethical aspects so as to inform decision-making during product development. Stakeholders are seen as experience experts, whose opinion is valued and used to improve the product. In this type of inclusion, the expertise of the research group is diversified (Jacob et al. 2013; Kupper et al. 2015), not only leading to a richer discussion (Flipse et al. 2013), but also to 'better' decisions (Stahl 2013).

As an enriching and informative experience, this type of inclusion is thought to support each of the other responsible processes. Through inclusion, the purpose of and drivers behind research and innovation may be discussed (Von Schomberg 2013; Blok 2014) and so inclusion may contribute to *reflexivity* ⑦. Inclusion of stakeholders can also help to identify risks (Jacob et al. 2013; Sykes & Macnaghten 2013; Anon 2014b) and new possible routes to desired impacts (Blok 2014; Jacob et al. 2013; Sutcliffe 2011), and so support *anticipatory* processes ⑥. Yet inclusive processes are also thought to support *responsiveness* ⑩ directly. Innovators may incorporate societal aspects in the development process by adjusting research projects to the needs and concerns of civilians and stakeholders (Anon 2014b) or more precisely, by using these considerations as 'non-functional' design requirements (Jacob et al. 2013). Stakeholder dialogue may support responsiveness by helping to 'keep various options open', to prevent 'innovation lock-in and path dependency' and to enhance corrigibility (Blok 2014). According to (Anon 2014a), inclusion is not responsible unless a direct relationship with responsiveness can be shown.

Through these processes, but also directly, this type of inclusion is finally thought to contribute to more responsible products ②. For one, products are thought to become more *relevant to society* through this type of inclusion: 'engaged research is more likely to become socially accepted, relevant to policy and environmentally friendly' (Flipse et al. 2013) and 'the incorporation of societal voices in R&I will lead to relevant applications of science' (Klaassen et al. 2014) because inclusive deliberation opens up opportunities for science and innovation to be 'directed towards socially – desirable ends' (Owen et al. 2012). Furthermore, inclusion is thought to lead to products that are more *usable by society,* meaning that they are more widely accepted: 'the inclusion of stakeholders is necessary to facilitate the shaping of widely supported designs' (Correljé et al. 2015). Finally this type of inclusion is also thought to support the *scientific quality* of products. According to various policy documents, collaboration with citizens, users and scientists from other disciplines contributes to the scientific quality of outcomes (Anon 2015; Anon 2014a; Anon 2014b). Indeed (Flipse et al. 2013) found evidence that the inclusion of social and ethical aspects can enrich the process of scientific investigation through benefitting research planning, stimulating the researcher's creativity and helping to set better research goals.

Share responsibilities with stakeholders The third type of inclusion serves to distribute the responsibilities for solving a societal challenge among stakeholders. In this type of inclusion there is no single innovator or researcher who includes or involves others – the group operates as a cross-disciplinary and inter-organizational team to solve a societal challenge at a systems level. This is described in the literature as 'societal actors become co-responsible' (Von Schomberg 2013), stakeholders become 'mutually responsive' (Von Schomberg 2013; Von Schomberg 2011b) and publics become 'engaged' (Kupper et al. 2015; Klaassen et al. 2014). This type is based on the idea that true societal challenges, such as social inequality and global warming, are wicked and can therefore not be solved by a single stakeholder (Blok & Lemmens 2015). Wicked challenges by definition require the collaboration of multiple stakeholders in order to be solved. Or, as (Klaassen et al. 2014) put it: the 'responsibility for our future is shared by all people and institutions affected by and involved in research and innovation practices'. This type of inclusion supports responsible research and innovation because it aims to deliver products that are in every sense *relevant to society* ②.

All three types of inclusion intend to contribute to responsible products in one way or another. Yet the RRI literature reports also a fourth, completely different reason for being inclusive. Both the Dutch call for RRI proposals and the main framework for RRI stress that researchers and innovators may have normative reasons for inclusion (Owen, Stilgoe, et al. 2013; Anon 2014a; Sykes & Macnaghten 2013), meaning that inclusion can be simply *the right thing to do*. In this context, studies stress that governments have a 'moral responsibility' (Sutcliffe 2011) and citizens have 'the right' to be involved (Flipse et al. 2013). Similar to transparency, this type of inclusion does not necessarily contribute to responsible products, but is seen as a responsible act in its own right.

Implementation

Inclusion can only drive responsiveness effectively, when it elicits meaningful contributions and allows the product or process to change in response to it. Qualifiers for both of these aspects are listed below. First, qualifiers to elicit meaningful contributions are listed.

Include many, diverse and fundamentally different stakeholders For inclusion to effectively inform responsiveness, it is essential that the relevant societal voices are heard. Stakeholders should be the 'right publics' (Kupper et al. 2015) and represent 'all relevant views' (Balkema & Pols 2015; Anon 2014a). This means selection of stakeholders should be sensitive to specific contextual factors (Correljé et al. 2015; Flipse et al. 2013). Therefore some simple approaches were mentioned in the literature to make sure the relevant voices are heard.

The simplest and crudest way to make sure all relevant voices are heard, is to include *many* perspectives or persons. (Kupper et al. 2015) for example, prompts to include many perspectives and participants.

A somewhat more advanced method, is to include a *diverse* set of stakeholders. According to (Stilgoe et al. 2013; Sykes & Macnaghten 2013), diversity is a criterion for meaningful dialogue. In the literature this is reported as a variety of stakeholder groups that should be engaged (Kupper et al. 2015), a range of stakeholders that should be included (Wickson & Carew 2014) or the wide configuration of deliberation in general (Owen, Stilgoe, et al. 2013).

Fundamentally different stakeholders can furthermore enhance self-criticism and social learning (Blok 2014). Cross-disciplinary inclusion may compose such fundamental differences; (Von Schomberg 2013) asks for a multidisciplinary approach and (Kupper et al. 2015) prompts researchers to move beyond engagement with stakeholders to include members of the wider public (transdisciplinary approach). Most specific are the criteria of (Wickson & Carew 2014), who prefer transdisciplinary over interdisciplinary, interdisciplinary over multidisciplinary and multidisciplinary over monodisciplinary practices.

Inform stakeholder prior to inclusion Prior to any inclusion activity, all stakeholders should be properly informed about the issue at hand, because 'societal actors can only appraise technological developments if they know about them first' (Flipse et al. 2013). It could furthermore support trust between stakeholders (Kupper et al. 2015) and so contribute to a meaningful dialogue (Sykes & Macnaghten 2013; Kupper et al. 2015). This also relates to the dimension Transparency, whereby researchers are transparent about the drivers of decisions taken.

Frame discussion together with stakeholders At the beginning of any inclusion activity, the stakeholders should be involved to frame the discussion together. In this way a broad spectrum of issues is defined (Sykes & Macnaghten 2013), which prevents important topics from remaining undiscussed as well as empowering stakeholders in the process. (Stilgoe et al. 2013) emphasizes that these frames do not only have to concern characteristics of the product, but that they may also concern the participation process itself. This view is shared by (Kupper et al. 2015), who suggests that also research methods should be a topic of conversation: 'As complex issues might call for new methods or a synthesis of methods used in different disciplines, methodologies should be topic of deliberation within the practice.'

Empower stakeholders to contribute In order to act as effective drivers of learning, stakeholders should able to contribute to the discussion, meaning that all stakeholders should feel 'empowered' to challenge directions of research and innovation (Kupper et al. 2015). Therefore power differences between parties should be compensated for so as to 'create a level playing field' (Balkema & Pols 2015) in which stakeholders feel free to express themselves and stakeholders should be trained to make meaningful contributions. Furthermore researchers should support participants to develop their arguments and claims (Sykes & Macnaghten 2013), to make scientific contributions (Kupper et al. 2015) or to make 'rational arguments' (Balkema & Pols 2015).

Besides making sure that the stakeholders make meaningful contributions, the researcher should make sure he is adequately equipped to use the contributions and to allow the product or process to change in response to them. Below three of such qualifiers are listed.

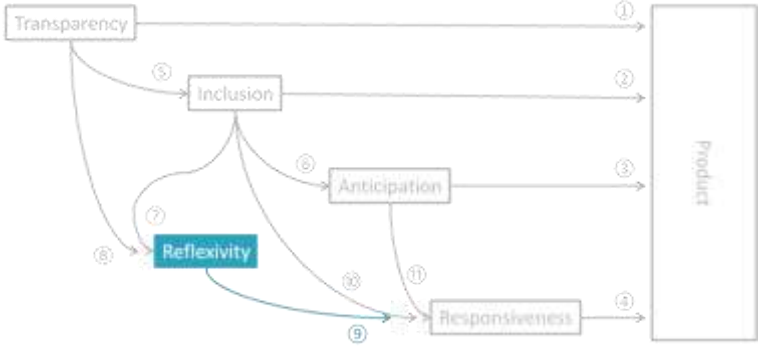
Include stakeholders from the outset Policy documents generally emphasize that inclusion should be performed 'from the outset' (Anon 2014a) and 'at an early stage' (Jacob et al. 2013; Anon 2014b). The rationale for this approach is pragmatic – the earlier the stage of development, the more 'degrees of freedom' available to change the direction of a new development (Flipse et al. 2013) and the longer the part of the trajectory that can still benefit from its results (Kupper et al. 2015). In the most extreme case, this means that stakeholders are included in the definition of the research objectives and priorities (Von Schomberg 2013).

Indeed, according to (Stilgoe et al. 2013) and (Sykes & Macnaghten 2013), the earliness of inclusion is a measure of dialogue intensity and as such a way to support learning processes between those involved. Furthermore in a research process studied in (Hoven 2014), the results of an analysis of societal aspects are delivered 'at such a late stage in the development of the issues that it could no longer usefully be employed

to make a difference.' When inclusion is used to support anticipation however, the preferred earliness of inclusive activities should be balanced with the correct timing of anticipatory activities (see Anticipation, p. 23).

Include for normative or substantive reasons If the product is to improve as a result of inclusion, researchers or innovators should have only normative or substantive reasons to do it (Owen, Stilgoe, et al. 2013; Anon 2014a; Sykes & Macnaghten 2013). The idea is that researchers with an instrumental reason to involve stakeholders cannot be receptive towards feedback because it was never their intention to change the product in response to the feedback. This means that inclusion aimed at gaining public support (inclusion type 1) is inclusion for instrumental reasons and considered least responsible of all inclusion types.

Be receptive towards feedback Furthermore, during a discussion, the researcher should have a receptive attitude towards learning, because 'only because stakeholders can hear the voice of the other and can take the perspective of the other, they can become mutual responsive' (Blok & Lemmens 2015). (Blok 2014) goes further to state that that the primary goal of dialogue in RRI should be to become critical towards "ourselves, i.e. towards our own interests and value frames" rather than to "self-express" in order to convince others. Also (Sykes & Macnaghten 2013) lists openness as one of its criteria for stakeholder dialogue, meaning that 'plural views' can be articulated and issues can be 'redefined', and (Wickson & Carew 2014) prefers the 'active' encouragement of mutual learning over simply being 'open' to mutual learning or even being 'defensive in the face of counter-views or stakeholder questions'.



3.2.3 Reflexivity

Reflexive processes help a research or innovator to recognize what factors determine decision-making in the research and innovation process and to understand the social and ethical effects of those decisions.

Rationale

Reflexivity is never mentioned to deliver responsible products directly, only through increased responsiveness ⑨. An increased understanding of the factors that influence decision-making is thought to help prevent researchers and innovators from pursuing problematic influencing factors. In other words, reflection can affect 'R&D practice, feeding back into on-going research practices' (Flipse et al. 2013) and shape 'technological trajectories' (Schuurbiers 2011) when the reproduction of 'problematic underlying ethical, social and political commitments of the science' (Wynne 2011) is prevented.

Implementation

Reflexive processes should help a researcher or innovator to recognize what factors influenced his or her own decision-making and to challenge those drivers accordingly. Furthermore the researcher or innovator may gain a deeper understanding of the social and ethical implications of his actions.

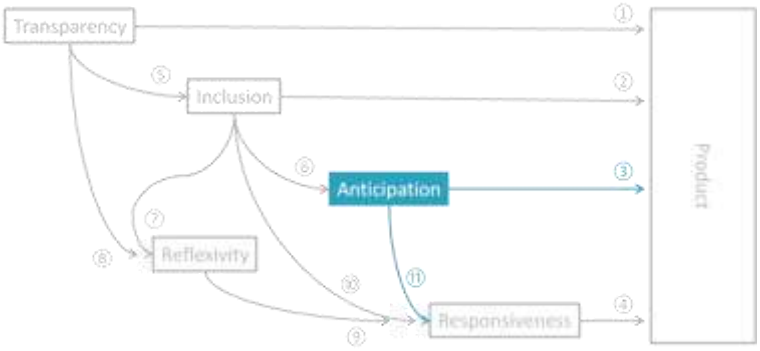
Recognize own drivers Reflexive processes should help the researcher or innovator to recognize the factors that influence his or her own decisions. According to the literature there are three types of factors that a researcher can learn to recognize. For one, the researcher should recognize how his or her own personal

values can affect decision-making. These are referred to as 'their own ethical, political or social assumptions' (Jacob et al. 2013), 'the values which underpin their work' (Sykes & Macnaghten 2013), the 'social and ethical bases for R&D decisions' (Flipse et al. 2013) or the 'value-based socio-ethical premises that drive research' (Schuurbiers 2011). Next to their personal values, researchers should learn how scientific norms influence their decisions. These norms are referred to as 'the assumptions of research' (Stahl 2013), 'the methodological norms of the research culture, and the epistemological and ontological assumptions upon which science is founded' (Schuurbiers 2011) or 'the public justifications of science as impartial and innocently curiosity-motivated' (Wynne 2011). Thirdly also the 'institutional and contextual limitations' of the research should be identified (Wickson & Carew 2014).

Challenge drivers Reflexive processes do not contribute to responsiveness if the researcher or innovator does not question and *challenge* the drivers identified. This is indicated by the emphasis on a critical attitude in reflexivity, for example in (Schuurbiers 2011) 'to critically reflect', in (Anon 2014a) 'to question', in (Wynne 2011) 'to challenge' or most explicitly in (Wickson & Carew 2014) 'with an effort to improve upon these conditions'. Being open (transparent) about the bases of decisions allows others to challenge those bases (Wynne 2011) and can therefore support reflexivity.

Gain understanding of how product impacts society Reflexivity should furthermore help a researcher to understand the impacts of the product on society. In the literature this is referred to as 'to understand ethical issues' (Stahl 2013), to gain understanding of 'social and ethical context' (Flipse et al. 2013) or to understand 'what shapes society in the name of science' (Wynne 2011). The difference with inclusive and anticipatory activities is that these reflexivity activities focus on gaining an understanding of, rather than only identifying societal issues.

Gain understanding of how framing impacts the inclusion process Yet researchers should not only reflect on how their products impact society, they should also reflect on how they themselves impact the inclusion process. (Jacob et al. 2013) for example emphasizes that through reflexivity, researchers should learn to recognize the importance of 'framing issues, problems and the suggested solutions' in public dialogue.



3.2.4 Anticipation

During decision-making, anticipatory processes provide an overview of the choices available through an exploration of impacts and alternative routes to those impacts.

Rationale

The wide exploration of impacts and alternative routes is thought to support responsiveness ⑪, for a solid overview of choices supports the making of responsible decisions. In the words of (Jong et al. 2015), anticipating potential impacts helps to 'intervene on the basis of this acquired knowledge in the design stage'. (Sutcliffe 2011) emphasizes that anticipation should help to 'respond quickly to changing knowledge and circumstances'. (Nordmann 2014) stresses that 'innovation processes could be steered to either bring about or prevent what is suggested by the various… scenarios of the future' and that it should 'promote a regime of vigilance'.

Anticipation is also thought to contribute to responsible products directly ③, for it is thought to result in products that are more ethically acceptable (see product qualifier *usably by society*, part I) as they are more resilient (Stilgoe et al. 2013) and socially robust (Jacob et al. 2013).

Implementation

Anticipatory processes help researchers and innovators to identify the societal impacts of innovation as well as the alternative routes towards and from those impacts.

Identify societal impacts Where reflexive processes aim to gain a deeper understanding of impacts, anticipatory processes simply help to identify them. By asking 'what if...?' (Owen et al. 2012; Owen, Stilgoe, et al. 2013) anticipatory processes help to identify impacts that may otherwise 'remain uncovered and little discussed' (Owen, Stilgoe, et al. 2013).

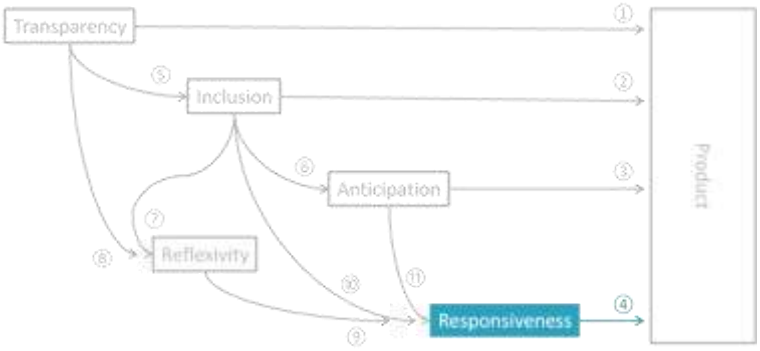
Although the impacts explored should have a societal focus, the impacts explored can include social (Sutcliffe 2011), environmental (Owen, Stilgoe, et al. 2013; Sutcliffe 2011; Kupper et al. 2015), ethical (Sutcliffe 2011; Anon 2014a) as well as economic (Kupper et al. 2015) aspects.

Define desirable societal impacts Although it may be tempting to assume that anticipatory activities only support responsible research and innovation as long as potential *negative* impacts (i.e. risks) are identified with them, quite a few studies stress that anticipation should be used to identify potential *positive* impacts (i.e. desirable outcomes) as well. The range scenarios explored should be intended as well as unintended and desirable as well as problematic (Owen, Stilgoe, et al. 2013; Kupper et al. 2015; Wickson & Carew 2014; Sutcliffe 2011). It is for this reason that (Wickson & Carew 2014) values 'a range of positive and negative future scenarios' (exemplary practice) over 'a singular optimistic prognosis for future project outcomes' (routine).

In this view, the key to Responsible research and innovation is to see the ethical and moral aspects of innovation as an inspiration rather than as an obstacle. In the words of (Owen et al. 2012): '[Responsible innovation] seeks to consider not only what we do *not* want science and innovation to do… but what we *do* want it to do.' Also key RRI advocate Von Schomberg seems inclined to this viewpoint. In (Zwart et al. 2014) he is quoted saying: "What's new about RRI is that we no longer see the ethical aspects of new technologies as constraints, as restrictions. Instead, we look at the aims of technology development. Which positive contributions do you wish to obtain from research and innovation?" According to (Zwart et al. 2014), this positive attitude is implemented by asking what would be the right impacts and the right processes towards those impacts, rather than what impacts should be avoided. Overall it seems that the broader range of scenarios is explored, the better.

Identify alternatives routes Furthermore, anticipation aims to identify alternative routes to and from these impacts. In the literature this process is referred to as 'to think through various possibilities' (Jacob et al. 2013), 'to explore other pathways to other impacts' (Owen, Stilgoe, et al. 2013), to reveal 'new opportunities' (Stilgoe et al. 2013), to 'conceive of… a variety of R&D trajectories' (Nordmann 2014), to 'think through various options' (Kupper et al. 2015), or to assess and prioritize opportunities (Sutcliffe 2011). To seek alternative routes then, means to seek alternatives to current research activities with the intention of reaching alternative products.

Choose timing wisely The correct timing of anticipatory activities is not apparent from the literature. When anticipatory activities are carried out too early, the possible impacts of technology may still be difficult to predict and 'choke off' potentially beneficial technologies (Flipse et al. 2013). Carried out too late, and the anticipatory activities may no longer influence the development process. The general recommendation is therefore to 'well-time' anticipatory processes, so that they are early enough to be constructive but late enough to be meaningful (Stilgoe et al. 2013; Kupper et al. 2015).



3.2.5 Responsiveness

Responsive processes describe the making of responsible decisions in research and innovation.

Rationale

The main rationale for responsiveness is to support the delivery of responsible products ④. In this sense, responsiveness supports responsible decision-making: 'the making of decisions that are likely to promote desirable states' (Stahl et al. 2013) or simply the making of 'better decisions' (Stahl 2013), thus leading to better products.

Implementation

According to the literature, any substantial change to the research product or process is responsible when it responds to societal perspectives as they emerge.

Respond to societal perspectives Responsible processes respond to the social and ethical aspects of innovation. The information that responsible processes should respond to are described as 'societal needs' (Von Schomberg 2013), 'the views, perspectives, and framings of others – publics, stakeholders' (Owen, Stilgoe, et al. 2013), 'societal and ethical implications' (Anon 2014a), 'public values' (Jacob et al. 2013), 'perspectives, views and norms' (Stilgoe et al. 2013), 'stakeholder's needs/interests/values/perceptions' and 'contextual changes (e.g., results by competing R&I groups; judicial changes, etc.)' (Kupper et al. 2015). Very generally this shows that a responsible process should respond to the norms, values and views of the public at large and its stakeholders specifically.

Respond to changing perspectives Yet values, norms and views change constantly. They are described as 'a changing information environment' (Owen, Stilgoe, et al. 2013). Therefore the researchers and innovators should respond to new knowledge as it emerges (Stilgoe et al. 2013; Kupper et al. 2015), 'when the evidence of harm is uncovered' (Sutcliffe 2011) or 'when it becomes apparent that the current developments do not match societal needs or are ethically contested' (Jacob et al. 2013). This means the response should be swift.

One way to increase flexibility is to repeat decision-making activities several times throughout the process. The repetition of both anticipatory and reflexive activities are emphasized by (Wickson & Carew 2014). To bring out potential societal impacts as they emerge, (Wickson & Carew 2014) ask researchers to carry out future scanning or future scanning (anticipatory) activities 'at various points' throughout the research process (exemplary practice) rather than at 'limited points' (good) or at one point (routine). Furthermore (Wickson & Carew 2014) suggests exemplary reflexive practice involves 'periodic' reflection, while great practice involves 'occasional' and good practice involves 'one-off or ad hoc' reflection.

Respond with substance A response is only considered responsible when it has a substantial effect on the research and innovation process. Responsible responses have 'a material influence on the direction and trajectory of innovation itself' (Owen, Stilgoe, et al. 2013), adjusting courses (Stilgoe et al. 2013), changing directions (Sutcliffe 2011), redirecting the innovation process (Anon 2014a), changing the direction or

shape of innovation (Jacob et al. 2013) or changing the '(methods in) the course of the research and innovation practice' (Kupper et al. 2015).

One way to enhance substantive capacity, is to consider societal values into account as non-functional requirements alongside the already existing functional requirements of the system (such as storage capacity, bandwidth, etc.) (Hoven 2014). Another way to enhance substantive capacity is to design the research or innovation process such that it allows changes to happen at set times. In this way avenues are created for responses to materialize. In the words of (Wickson & Carew 2014) there should be 'clear avenues for embedding responses' to anticipatory activities and the 'evidence of potential to adapt' in response to feedback.

3.2.6 General recommendations for implementation

Some recommendations regarding the implementation of responsible process concern more than one dimension, and are therefore summarized here.

Couple inclusive, reflexive and anticipatory activities Responsible decisions can only follow from a preparatory process consisting of both inclusive, reflexive as well as anticipatory activities. These processes should be coupled and integrated (Owen, Stilgoe, et al. 2013; Owen et al. 2012), meaning that one process should be used to inform another and vice versa.

Repeat reflexive and anticipatory activities Both anticipatory and reflexive activities should be repeated throughout the RRI process (Wickson & Carew 2014). To bring out potential societal impacts as they emerge, (Wickson & Carew 2014) ask researchers to carry out future scanning or future scanning (anticipatory) activities 'at various points' throughout the research process (exemplary practice) rather than at 'limited points' (good) or at one point (routine). Furthermore (Wickson & Carew 2014) suggests exemplary reflexive practice involves 'periodic' reflection, while great practice involves 'occasional' and good practice involves 'one-off or ad hoc' reflection.

Apply formal methods Several studies stress the use of existing, formal methods for they offer a certain rigor and robustness. They are mentioned specifically in the context of anticipatory processes, where they support systematic thinking and overall resilience (Stilgoe et al. 2013; Wickson & Carew 2014), and reflexive processes, where they support a structured, analytic and explicit review of underlying drivers (Stahl 2013; Wickson & Carew 2014). Formal methods mentioned in the literature to support reflexivity and/or anticipation include: midstream modulation, technology assessment (TA), foresight activities, constructive TA, value-sensitive design (VSD), scenario planning, real-time TA, participatory TA, integrative TA, TA in social context.

Combine different methods Furthermore, the methods should be used in combination so as to prevent the 'technological determinism' (Stilgoe et al. 2013) that a single method may provoke when applied too narrowly. The scale of methodological diversity for responsible research suggested by (Wickson & Carew 2014) ranges from an 'integrative method' (exemplary practice) to 'a wide range of methods' (great), 'some level of methodological diversity' (good) and finally 'mono-methodological' research (routine).

3.3 Framework summary

The normative, theoretical literature described both product and process qualifiers. This review distinguished between five process dimensions of RRI (transparency, inclusion, reflexivity, anticipation and responsiveness) and three product qualifiers (societal relevance, market competitiveness and scientific quality) (see Table 3 for an overview of these qualifiers).

Furthermore this review explicated the interactions between RRI dimensions. Both transparency, inclusive, anticipatory and responsive processes were thought to contribute to the delivery of responsible products directly. The literature expected that inclusive, reflexive, as well as anticipatory processes should inform responsiveness. Inclusion was thought to support reflexivity and anticipation, while in turn transparency is

thought to support inclusive and reflexive processes. An overview of these interactions is shown in Figure 5.

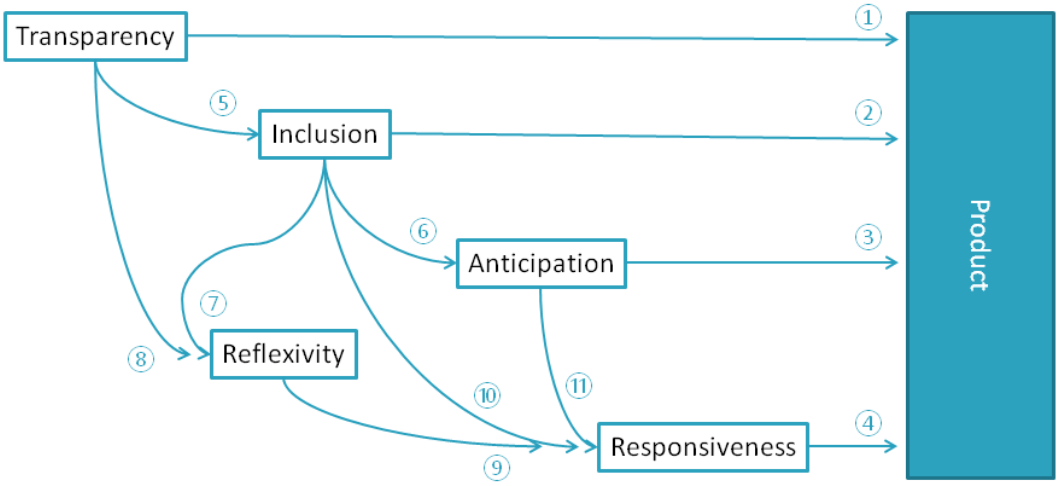


Figure 5 Theoretical interactions between RRI dimensions as described in the reviewed literature. All theoretical interactions presented in this overview are positive relationships, e.g. transparency was thought to support inclusion. Interactions ① to ⑪ are discussed under the rationales of the corresponding process dimension in the previous chapter, e.g. ⑤ is described under Transparency.

Table 3 Process and product qualifiers thought to support responsible research and innovation per RRI dimension.

Dimension	Qualifiers
Transparency - communicates the bases of decisions and the distribution of the responsibilities to external publics.	• Be transparent about assessment criteria • Be transparent about the role of stakeholders • Be transparent about any limitations with regard to transparency
Inclusion - takes in the societal aspects of an innovation, through e.g. stakeholder engagement.	Elicit meaningful contributions: • Include many, diverse and fundamentally different stakeholders • Inform stakeholders prior to inclusion • Frame discussion together with stakeholders • Empower stakeholders to contribute Allow product and process changes to occur in response to those contributions: • Include stakeholders from the outset • Include stakeholders for normative or substantive (rather than instrumental) reasons • Retain a receptive attitude to feedback
Reflexivity - helps a researcher to understand the social and ethical aspects of an innovation.	• Recognize how personal values, scientific norms and institutional limitations drive a decision • Challenge those drivers • Gain an understanding of how the product impacts society • Gain an understanding of how framing affects the inclusion activities
Anticipation - provides an overview of possible impacts and their alternatives.	• Define desirable societal (social, environmental, ethical and economic) impacts • Identify problematic societal impacts • Identify alternative routes to those impacts • Choose a both constructive and meaningful time to anticipate
Responsiveness – describes the making of responsible	• Respond to societal perspectives • Respond swiftly to changing perspectives

decisions in research and innovation.	• Respond with substance
General recommendations for RRI processes	• Combine inclusive, reflexive, anticipatory activities • Repeat inclusive, reflexive, anticipatory activities throughout the process • Apply formal methods • Combine various methods
Product - the outcomes of research and innovation, including its academic findings as well as its marketable products.	Societally relevant • Aims to make societal (social, sustainability) contributions • Meets relevant ethical norms • Is sufficiently concrete so that it can be used in practice • Competes in current market economies Profitable Scientifically high-quality

4 Discussion

The goal of this study was to develop a theoretical framework on Responsible Research and Innovation (RRI) based on a systematic review of the literature. In this chapter, the framework (4.1) and the systematic review (4.2) are discussed. The chapter closes with a short conclusion (4.3), summarizing the above.

4.1 Discussion of framework

The goal was to develop a theoretical framework of qualifiers central to RRI by identifying characteristics that were shared across academic and policy documents. Although the reviewed documents differed greatly in terms of terminology, orientation, depth and emphasis, finally three product and five process dimensions could be defined, indicating that indeed these documents shared some core characteristics. Perhaps indeed, "there will likely be more than one flavor of RRI" (Stahl 2013), but in this study a common ground across RRI studies and policy documents was found in terms of RRI qualifiers and dimensions.

A framework of such widely supported RRI qualifiers may support implementation of RRI by providing clarity on 'what good quality RRI looks like' (Wickson & Carew 2014). According to (Wickson & Carew 2014), such clarity supports research funding bodies that need to select RRI research proposals and researchers and innovators who need to articulate their capacity to undertake toward RRI or who want to improve the performance of their work. In Part A2 of this thesis, this framework is applied in a case study to help formulate recommendations for the practical implementation of RRI.

Next to developing a set of qualifiers, this review explicated and visualized what interactions the normative, theoretical literature expects between RRI dimensions. This is an answer to (Stilgoe et al. 2013), who emphasized that dimensions should be carried out together in an integrative manner and that dimensions could reinforce each other. Explicating the theoretical interactions facilitates the implementation of RRI, because it shows which dimensions should be carried out together, and furthermore allows each interaction to be tested and discussed.

Below the two most important findings with regard to the framework are discussed.

4.1.1 'Transparency' as a fifth process dimension of RRI

In contrast to (Stilgoe et al. 2013), who informed the original framework, transparency was defined as a fifth dimension of RRI processes. In this framework, transparency was defined as any activity that communicates information about the assessment criteria and the distribution of responsibilities within the research team to external publics.

(Stilgoe et al. 2013) did not include transparency as a process dimension of RRI, because they defined RRI as a 'collective stewardship of the future' and therewith only as a forward-looking responsibility. With this definition, every RRI dimension has to inform future decisions (responses) of the research team. Since transparency is a one-way communication process, it can provide justification and clarity on decisions that have already been taken, but can hardly inform new decisions on the part of the research team.

This literature review included transparency as a fifth dimension of RRI, because it was found to support the delivery of responsible products. It can help to gain their public support and so contribute to product usability and competitiveness. Furthermore transparency was found to support other process dimensions and so support responsiveness indirectly, which is in line with other frameworks such as (Kupper et al. 2015). For these reasons, the framework developed in this study included transparency as a process dimension of RRI.

4.1.2 'Responsiveness' can be bypassed

Three process dimensions were found to contribute to the delivery of responsible directly and so bypassed 'responsiveness' (interactions 1 – 3, see Figure 6). In this study, responsiveness was defined as the making of

substantial changes in response to societal perspectives. As such, these interactions do not improve product characteristics, but only improve the public perception of a product. In other words, they can contribute to the usability and competiveness of a product that is already responsible, but cannot *create* a responsible product. These are serious considerations, especially since (Owen, Stilgoe, et al. 2013) described responsiveness as 'key' to RRI and (Owen, Stilgoe, et al. 2013; Anon 2014a; Sykes & Macnaghten 2013) considered any 'instrumental' reasons to include stakeholders (such as to improve the perception of a product) per definition not responsible.

It seems that a direct interaction with product qualities puts transparency, inclusion and anticipation at risk of being used as short-cuts – ways to produce responsible products without having to actually change the product in response to societal perspectives. Further research should investigate to what extent such short-cuts can be considered responsible.

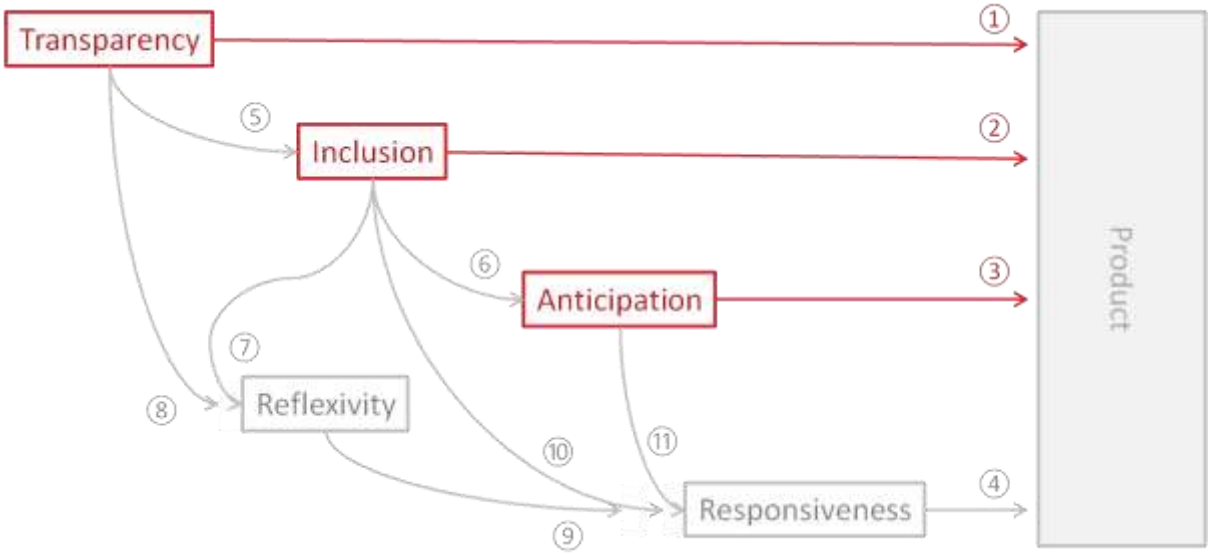


Figure 6 Transparency, inclusion and anticipation were considered qualifiers of RRI partially because they were thought to contribute to the delivery of responsible products (interactions 1 – 3). This puts them at risk of being used as short-cuts; ways to produce responsible products without having to change the product in response to societal perspectives (responsiveness).

4.2 Discussion of the systematic literature review

A systematic literature also deals with limitations. Two limitations of this review are discussed below.

4.2.1 Only theoretical workings of RRI reviewed

This study did not include empirical evidence on the workings of RRI. Empirical studies could have provided more concrete indicators of quality and insights in the 'real' rather than the 'theoretical' workings of RRI. Empirical studies were excluded because the theoretical literature was already greatly divergent and sometimes contradicted itself. The result is that the framework as established here only provides insights on the theoretical workings of RRI. The framework should be applied in case studies to indicate whether the theoretical workings of RRI as presented here are feasible in practice.

A point of attention could be to elicit which dimensions conflict with each other in practice. This study only explicated how RRI dimensions can support each other, because only qualifiers (qualities) of RRI were reviewed. Application of this framework in case studies should indicate what dimensions conflict with each other.

4.2.2 Only 'responsive' RRI considered

Another limitation of this study regards the scope of the qualifiers developed. By only including qualifiers that contributes to responsiveness and the delivery of responsible products, this literature review excluded a set of qualifiers that may contribute to RRI in other ways. For example, the literature referred to transparency as a qualifier of RRI, because it clarifies decisions and makes them more understandable for external publics (Flipse

et al. 2013). Although this does not contribute to 'better decisions' being taken per se, it can be described as a part of proper research ethics and therefore arguably be defined as rationale of RRI. Similarly, the literature reported inclusion to contribute to RRI not only substantively (contributing to responsiveness and responsible products), but also normatively. It was described as simply the right thing to do and therefore considered a responsible act in its own right.

This suggests that there may be two sides to RRI. On one side, RRI should lead to 'better' decisions (Stahl 2013) and 'better' products. On the other side, RRI should meet the moral obligations of research and innovation to justify decisions and involve stakeholders. Perhaps this shows that RRI should be both Responsive as well as Justified (see Figure 7). In this study, only qualifiers for Responsive RRI were included.

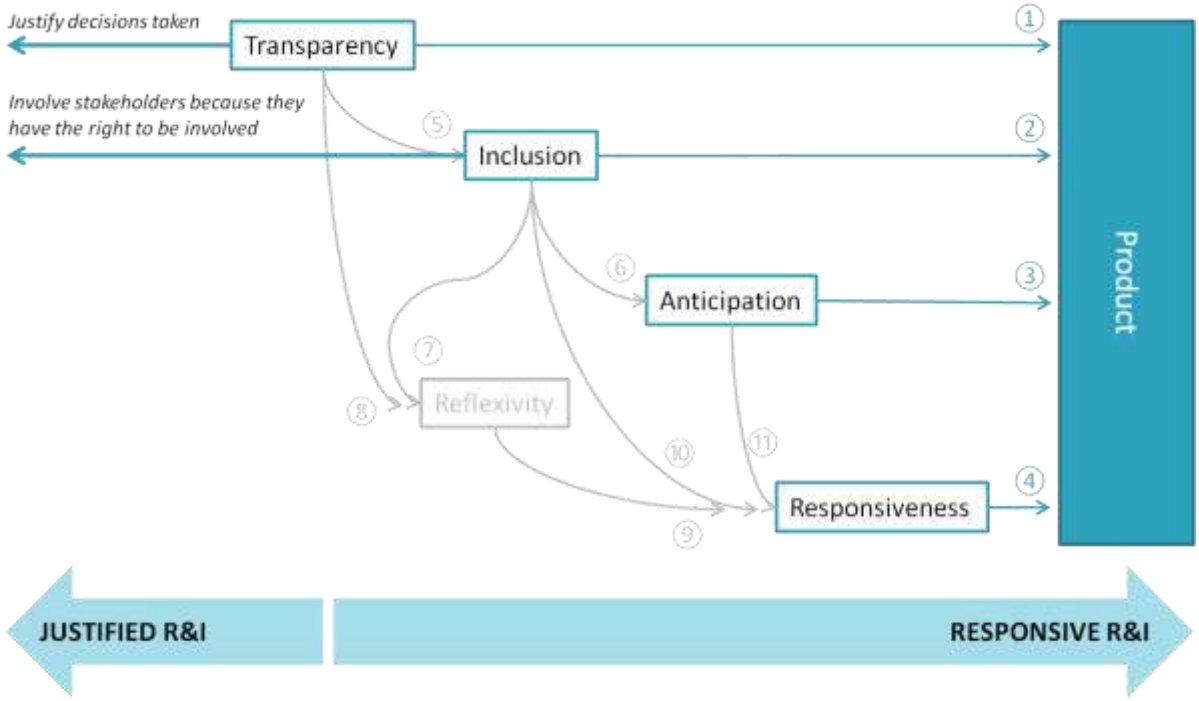


Figure 7 The literature suggests that there are two sides to RRI: on one side, RRI should meet the moral obligations of any researcher or innovator to justify decision and involve the public at large ('justified' research and innovation). On the other side, RRI should lead to better decisions being taken and finally better products being produced ('responsive' research and innovation). In this study, only qualifiers for 'responsive' research and innovation were developed.

4.3 Conclusions

Overall, this review developed a set of widely supported qualifiers that may be central to the concept of responsive RRI. Furthermore any interactions between RRI dimensions as described in the literature were explicated and visualized. Further research should investigate the extent of the applicability of this theoretical framework in practice.

PART A2.

CASE STUDY: APPLICATION OF THE RESPONSIBLE RESEARCH AND INNOVATION FRAMEWORK

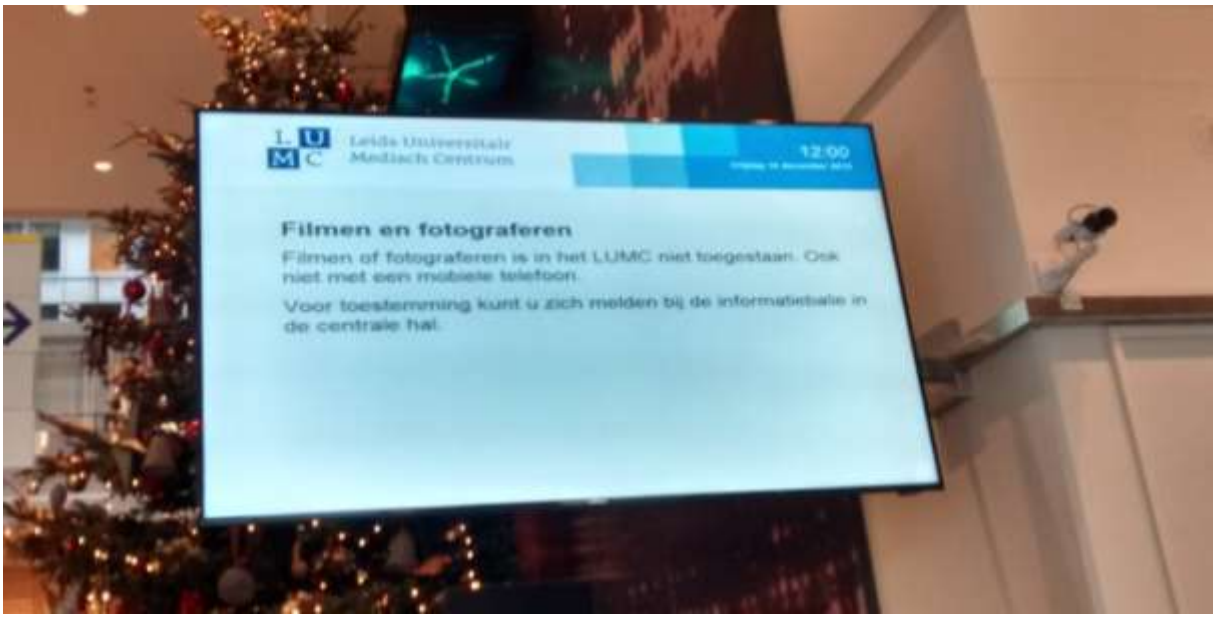


Figure 8 In this part of this thesis, the RRI framework is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. This is an image taken at the site of the case study, indicating that visitors cannot make any video recordings at this hospital. Right next to it is a security camera of the hospital itself. This illustrates the complex ethical context of the use of video recordings in a hospital.

1 Introduction

In the previous part of this thesis (Part A1) a framework on Responsible Research and Innovation (RRI) was developed. In this part of this thesis, the RRI framework is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. Finally in Part B of this thesis, video recordings are used to study communication during cardiac surgery.

In this chapter the case study is introduced, presenting the research problem (1.1), research objective (1.2), research questions (1.3), research approach (1.4), a definition of key terms and scope (1.4) and an outline of Part A2 (1.6).

1.1 Research problem

Video recordings are an increasingly popular tool to study teamwork, as they provide a scientific rigor that cannot be obtained through mere unrecorded observation (Mackenzie & Xiao 2011). Video recordings can be reviewed multiple times, which allows the observation of multiple simultaneous activities. This is especially convenient for observation of large teams such as in cardiac surgery (Catchpole et al. 2007; Catchpole et al. 2008). Furthermore video recordings provide a wider context to a communication process than audio transcripts alone, allowing for a deeper understanding of the data (Hazlehurst et al. 2007).

An added advantage is that the video data can be reviewed with those observed. This not only provides the researchers with an in-depth understanding of the observations (ElBardissi et al. 2007; Catchpole et al. 2007; Wadhera et al. 2010; Carthey et al. 2001; Hazlehurst et al. 2007), it also provides clinicians with direct feedback on their practice (Yanes et al. 2015; Xiao et al. 2007). In this way, video-based research can contribute to patient safety directly.

Video recordings cannot be used without question however, because their use touches on primary ethical aspects in healthcare. In the Netherlands any recording that 'reveals incidental findings and complications' should be included in a patient's medical records, because the findings could inform further treatment of the patient (Blaauw et al. 2014). This allows patients to use the recordings in malpractice claims. This could put professionals both to an advantage as well as disadvantage, since video recordings provide 'little room to argue about the circumstances' (Joo et al. 2016). Furthermore the privacy rights of patients should be protected and safety risks (such as distraction of the surgical team and interference with surgical equipment) should be minimized. This shows that scientific, social and ethical aspects should be balanced when video recordings are used for research in operating rooms.

Under what conditions the video cameras should be used however is unclear. It is also unclear how researchers should establish those conditions and if they should for example include stakeholders in the process. The one study that provides guidelines on the implementation of video cameras only recommends to "comply with all legal requirements", "ensure privacy and confidentiality related to participant identity preservation" and to obtain "legal consent" (Asan & Montague 2014). (Catchpole et al. 2007) generally recommends to 'negotiate' the conditions with operating room staff.

The lack of clarity about the implementation and use of video recordings currently constrains their use in research and hence their potential to improve patient safety. (Henrickson et al. 2013, p.1123) for example wrote that although "ideally" videotapes would be collected and analyzed, recording such tapes posed such "significant challenges with regard to confidentiality and liability" that they finally chose not to. Others reported various constraints with regard to the use of video recordings. In (Catchpole et al. 2007) the use of the video recordings was limited to the observing researcher alone and only a portion of the original study sample was included. The authors attributed these constraints to 'the constraints imposed by the ethics committees and the consent process of staff' and a generally unwelcoming attitude of the staff towards the study. To the author's knowledge, there is no study on how operating room personnel perceives video-based research and under what conditions they find the recordings acceptable.

Overall, video-based research can make significant contributions to patient safety in the operating room. It is clear that scientific interests should be balanced with the interests of patients and operating room personnel, but what conditions of use sufficiently 'balance' these interests and how those conditions should come about is not clear. A lack of clarity on these matters currently hampers the use of video observation in research and therefore limits its contributions to patient safety.

1.2 Research objective

The goal of this study is to formulate recommendations on the *implementation* and *use* of video cameras in *operating team research* by applying a theoretical framework on *Responsible Research and Innovation* (RRI) in a *case study* at the Leids Universitair Medisch Centrum (LUMC). Key terms (in italics) are defined below.

In this study, *implementation* is referred to as the steps that a researcher takes to develop the conditions of use, for example by engaging with stakeholders. *Use* is referred to as the set of conditions under which the video recordings may be used, accessed and stored. *Operating team research* is referred to as any study that tries to analyze team processes in the operating room in order to inform patient safety improvements. As such, this study aims to facilitate the future use of video cameras in operating room research and so support patient safety improvements.

A theoretical framework on *RRI* is applied, because it can offer insights on how video cameras should be implemented and used. An often cited definition of RRI reads that it is

> "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)" (Von Schomberg 2011b).

Therefore RRI provides insights in the conditions under which video cameras should be implemented ('innovation process') and used ('marketable product'), so that they are ethically acceptable and desirable according to the actors involved. This makes video cameras an innovative research method that should be implemented and used responsibly.

A *case study* approach is applied, because a case study can provide detailed insights on how video cameras are currently implemented and used in practice. At the academic hospital under investigation, video recordings were used to study communication practices during cardiac surgery. The hospital encountered several issues during implementation of the video cameras, requiring four years from first inception to first use. One of the key challenges was to obtain the staff's support and to agree on conditions under which the recordings could be accessed, stored and used. This case can therefore provide relevant insights on the implementation and use of video cameras in practice.

1.3 Research questions

If application of a theoretical framework on RRI is to inform recommendations on the implementation and use of video recordings in operating team research, the following question should be answered:

Main research question. To what extent do the implementation and use of video cameras at the LUMC meet qualifiers for RRI processes and products?

(a) What qualifiers does the literature prescribe for RRI processes and products?
(b) What events allowed for RRI qualifiers during the implementation of video cameras at the LUMC?
(c) Under what conditions were the video cameras used at the LUMC?

Sub question (a) results in a set of RRI qualifiers for processes and products. Sub questions (b) and (c) result in a reconstruction of the implementation process and the conditions of use respectively. The RRI qualifiers developed for sub question (a) are then applied to reconstructions developed for sub questions (b) and (c) to

evaluate to what extent the implementation and use of video cameras at the LUMC meet the RRI qualifiers (main question).

1.4 Research approach

Sub question (a) was answered based on a literature review, which was described in Part A1 of this thesis in detail (starting p. 2). The results are summarized for convenience in the methodology section of this part of this thesis (p. 43).

Sub question (b) is answered based on two in-depth interviews with the lead investigator and supported with evidence from project documents. The implementation process is reconstructed from first inception in 2011 until first use in July 2015. Any event that can potentially support RRI process qualifiers is included in the reconstruction (see methodology section for an overview of these events).

Sub question (c) is answered based on a document analysis of the research protocol that was submitted and approved by the institutional review board (IRB). This document contains all conditions of use.

The main research question is then answered based on an evaluation of the implementation process (b) and the conditions of use (c) with regard to the RRI qualifiers. To this end, semi-structured interviews with two researchers and two operating room staff members were held about one key event in the implementation process.

The answer to the main research question is then used to formulate recommendations on the responsible implementation and use of video cameras in operating room research. If for example a RRI qualifier wasn't met and operating staff perceived this as problematic, the RRI qualifier is adopted as a recommendation for the use of video cameras in operating team research. If a lack of a RRI qualifier is *not* perceived as problematic by operating room staff and researchers have no ambitions to meet this qualifier, then this particular qualifier may not apply in this case study and this reflects on the theoretical framework itself.

1.5 Outline of Part A2

The answers to the research questions are described in the following sections of this report:

Main research question. To what extent do the implementation and use of video cameras at the LUMC meet RRI qualifiers for processes and products?	Results, p. 57
(a) What qualifiers does the literature prescribe for RRI processes and products?	Methodology section, p. 43 (described in detail in Part A1 of this thesis, starting p. 2)
(b) What events allowed for RRI qualifiers during the implementation of video cameras at the LUMC?	Process reconstruction, p. 47
(c) Under what conditions were the video cameras used at the LUMC?	Product reconstruction, p. 55

2 Methodology

In this part of the thesis, a framework on Responsible Research and Innovation (RRI) is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication practices during cardiac surgery. The goal of this study is to formulate recommendations on the use of video recordings in observation of medical specialists during surgery and to provide insights on the practicality of the RRI framework.

In the previous chapter the case study was introduced, providing backgrounds to the research problem, research objective and research questions. In this chapter the methodology of the case study is described, first describing how the case study was reconstructed and then how this reconstruction was used to analyze the case study with regard to RRI.

The chapter starts with a definition of key terms (2.1). Then the reconstruction of the implementation process is described. The implementation process was reconstructed at two different levers. First the whole implementation process was reconstructed based on interviews with the lead investigator and document analysis (2.2). Subsequently one event was analyzed in detail based on interviews with two researchers and two members of the operating room staff (2.3). The product was reconstructed based on document analysis and observations of the site (2.4). These reconstructions were then evaluated with regard to the RRI framework (2.5) and recommendations for implementation and use of video cameras for operating team research were formulated (2.6).

2.1 Definition of key terms

In order to apply the theoretical framework, RRI concepts are linked to specific aspects of the case study. Theoretical terms from the RRI literature and their case study equivalent are presented in Table 4.

Table 4 Theoretical terms from the RRI literature and their case study equivalent.

RRI framework (if applicable)	**Case study equivalent**
Research or innovation process	**Implementation process** Implementation of the video cameras in the operating room from inception in 2011 to first use in 2015.
Research or innovation product	**Conditions of use as described in the IRB protocol** Conditions of use as described in the IRB protocol filed in 2015.
Researchers / innovators	**Research team** All those formally involved in the project according to the IRB protocol, including the principal investigator (#R1), his promoters and co-promoters (including #R2).
The public at large / society	**Actors** Anyone who is involved in the project in any way, including Stakeholders, Providers and Advisors.
Stakeholders	**Stakeholders** Anyone who has a stake in the research project, including Research subjects and Authorities of approval.
End-users / customers	**Research subjects** Anyone who has had to consent to be recorded, including operating room personnel and patients. Also including the two critical participants (#S1 and #S2).
	Authorities of approval Those who grant permission to perform the project and therefore carry responsibility for its outcomes, including the institutional boards of approval (institutional review board, works council, board of directors) and the department directors (operating room management, thorax surgery director, division director).

	Providers Those who constrain the project by providing and/or limiting resources (suppliers, funders).
	Advisors Those who advise or inspire the researcher team without any authority to make changes to the product, including advisors (quality advisors, legal advisors), researchers from partner institutes, members of the focus group, executors (the infrastructure department).

2.2 Building a reconstruction of the implementation process

In this case study, the research or innovation process was defined by the implementation process of the video cameras. Therefore this process was reconstructed from first inception in 2011 to first use in 2015.

First the types of events that could be relevant to RRI were selected and then the lead investigator was interviewed to reconstruct these events.

2.2.1 Select relevant types of events

To include events in the reconstruction of the implementation process that are relevant to RRI, the RRI framework was used to select such events. A process dimension key to RRI is so-called 'responsiveness', whereby a 'response' refers to any substantial changes made to the research product in response to societal perspectives. Since in this case study the research product is referred to as the conditions of use as described in the IRB protocol, changes to that protocol are seen as a potential act of responsiveness.

Furthermore any event that could potentially inform such an act of responsiveness was reconstructed. According to RRI, responsiveness should be preceded by acts of transparency, inclusion, reflexivity and anticipation. For each of these dimensions, any event that could potentially support this dimension was made (see Appendix, p. 141). Most events could support various dimensions at the same time, so that finally seven types of events were included in the reconstruction, whereby each event was indicated with a symbol (see Table 5).

Table 5 List of events that were included in the reconstruction and the RRI dimension that could potentaill support.

Event	Potential RRI process dimension
Interaction within the research team (during team meetings or through other communications) ●	• Reflexivity • Anticipation
Interaction with actors, including stakeholders ● (operating room personnel, patients and authorities of approval) and other actors (including providers ● and advisors ●)	• Transparency • Inclusion • Reflexivity • Anticipation
Investigation of stakeholder perspectives without interacting with them (individual inclusion) ●	• Inclusion
Reflection on impacts of product or process without interacting with actors (individual reflection) ♥	• Reflexivity
Application of formal method to increase reflexivity or anticipation ▲	• Reflexivity • Anticipation
Perform pilot study to test the product ♦	• Reflexivity • Anticipation
Revision of the IRB protocol ★	• Responsiveness

To include details about each event that are relevant to RRI, the RRI framework was used to list such details (see Table 6). If for example an event allowed for transparency, a description of the event had to include details about who received the information and what information was shared. If the event also allowed for inclusion, furthermore the communication means and setting of the event was reconstructed. Some details about inclusion and reflexivity only applied if a communication partner was involved in the activity.

Table 6 List of details included in the reconstruction based on RRI qualifiers.

RRI process dimension	Event details
Transparency	• Who received the information • What information was shared
Inclusion	• Who was included in the interaction (if applicable) • With what communication means were they included (if applicable) • In what setting were they included (if applicable)
Reflexivity	• Who informed the reflection (if applicable) • What was the reflection about
Anticipation	• Who proposed the potential impact or alternative • What impact or alternative was proposed
Responsiveness	• What aspects of the product were changed

2.2.2 Reconstruct events with lead investigator

The process was reconstructed during two in-depth, semi-structured interviews with the lead investigator (from here on referred to as #R1). The focus was not the exact dates but on the sequence of these events, so as to understand how the various events informed each other (a qualifier of RRI). During the first session, the major timeline was reconstructed. During a second session previous details were checked and final details were added. The first session took 3 hours, the second session took 1 hour. Both sessions were fully audio recorded to allow for the recovery of details later if necessary.

To help the interviewee remember the sequence and details of the events, the implementation process was visualized during the interview. To this end the interviewee was asked to draw a timeline on two sheets of A1 paper and to divide the implementation process into two phases (before and after funding was secured). Subsequently the principal investigator was asked to complete a preliminary map of actors involved (see Figure 10). The principal investigator was then asked to map moments of interaction with each of these actors on the timeline with a sticky note (event type B). Subsequently also the other event types were mapped on the timeline. The session was closed with an open question to add any missing events.

To further support the visualization of the events, sticky note colors were used to indicate the type of event (with different colors for interaction with members of the research team, research subjects, bodies of approval within the institution, other internal parties and other external parties). Event details were written on the sticky notes (see Figure 9). See Appendix p. 143 for full interview protocol.

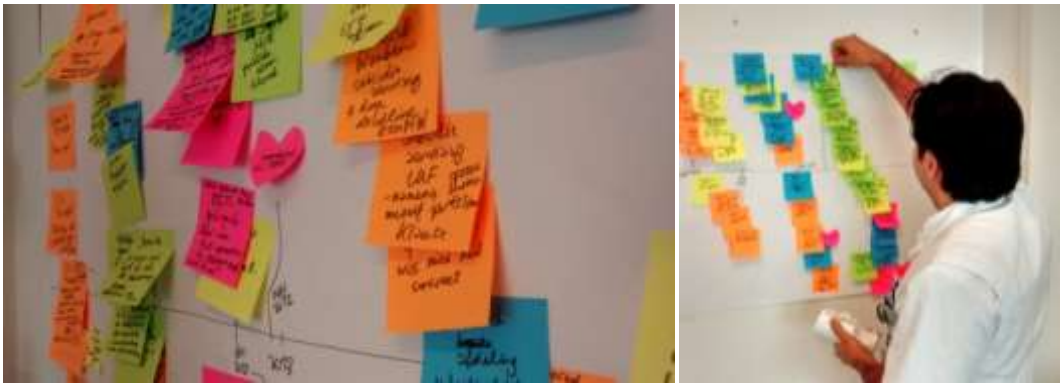


Figure 9 Impression of the reconstructed timeline after the first reconstruction interview.

To further help the interviewee remember the sequence and details of events, the interviewee was supported with guiding questions from the interviewer. These questions were informed by a year of participant-observation as a member of the research team (see Part B of this thesis for the results of those efforts) and analysis of project documents (including emails, presentations, drawings, earlier versions of the research protocols). These also informed the preliminary map of actors (see Figure 10).

The reconstruction of the product and processes were sent to the principal investigator for validation and a second interview based a similar approach was held to fill any remaining gaps.

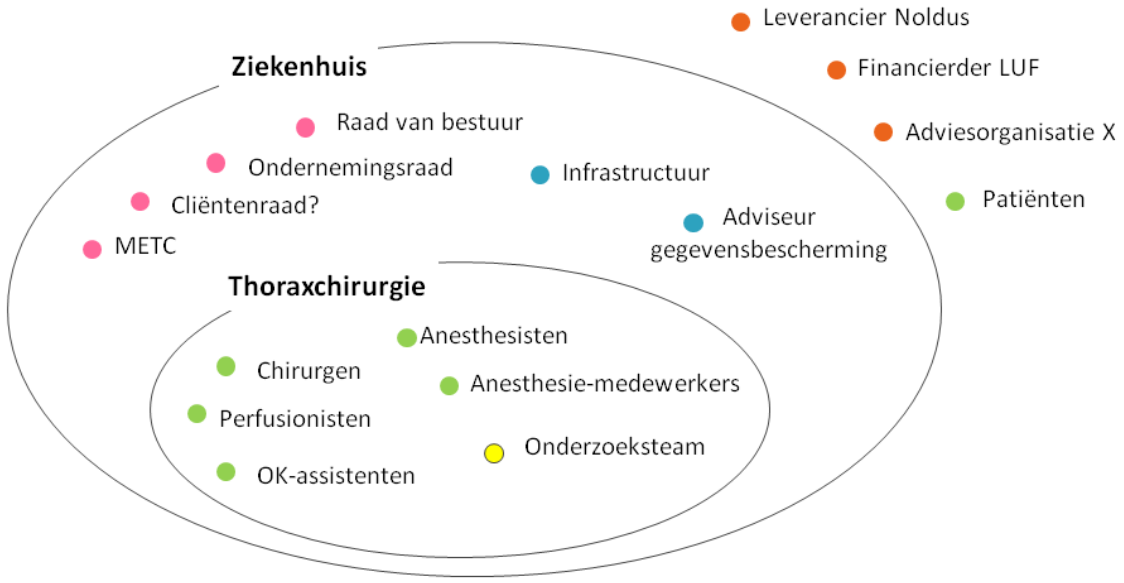


Figure 10 Preliminary map of actors that the interviewee completed during the first reconstruction interview (in Dutch).

2.3 In-depth analysis of one key event

After reconstruction of the whole implementation process, one event was selected for in-depth analysis. A process dimension key to RRI is so-called 'responsiveness', whereby a 'response' refers to any substantial changes made to the research product in response to societal perspectives. According to the RRI framework, a response should be preceded by certain responsible processes and contribute to the delivery of responsible products. Therefore analysis of one response could provide insights into what extent the case study meets RRI criteria.

This section first describes the selection of a single response and then the in-depth analysis of this event based on interviews with two researchers and two members of the operating room staff.

2.3.1 Selection of key event

One 'response' was selected for in-depth analysis. Since in this case study the research product is referred to as a set of conditions of use as described in the IRB protocol, changes to that protocol are seen as a potential act of responsiveness.

Analysis of the implementation process at macro scale showed that the IRB protocol changed three times. The first time was long ago and at this time the protocol was still taking shape. The second only contained technical details about the camera set-up. The third was the most recent of all three (and therefore most likely to be remembered by stakeholders) and was a result of competing interests of those involved. Therefore the third change was selected for reconstruction at a micro scale.

The event selected was a 'response' of the research team, whereby the IRB protocol was revised in response to criticism expressed by several research subjects. Analysis of this event could show to what extent responsible processes informed this response and to what extent this response contributed to the delivery of more responsible conditions of use.

To prevent tunnel vision, selection of this event was performed during a creative session with peers (experts in science communication but not informed about the details of the case). The session took roughly 2 hours. The attendants were provided with a schematic diagram of the preliminary RRI model, a schematic diagram of the implementation process and an overview of the product's conditions of use.

Figure 11 Impression of the creative session with peers

2.3.2 In-depth analysis of key event

To analyze this event in detail, semi-structured interview with stakeholders were held. Two researchers involved in the revision of the IRB protocol (#R1 and #R2) and two members of the operating room staff who had expressed their criticism (#S1 and #S2) were interviewed. The following interview questions played a central role in the interviews:

- Why did the research subjects express this critique?
- Why did the research team respond with a change to the IRB protocol?
- To what extent did this response satisfy the critical research subjects?

For the complete interview protocol, please refer to the Appendix, p. 145.

Each interview took 20 to 50 minutes, depending on how much time the interviewee had for the interview. During each interview written notes were made and each interview was fully recorded. The audio recordings were furthermore fully transcribed with f4transkript[1] and summarized using descriptive codes in NVivo 10 for Windows © QSR International Pty Ltd.[2] One recording was lost due to technical difficulties and therefore analyzed only on the basis of written notes.

2.4 Building a reconstruction of the final product

The conditions of use were obtained from the final institutional review board (IRB) protocol, filed in June 2015 by the research team. This protocol includes a description of the project's ambitions as well as consent forms and letters to potential research subjects. Similar to the reconstruction of the implementation process, also the reconstruction of the product was based on the RRI framework. Since the RRI framework contains qualifiers on societal relevance, market competitiveness and scientific quality, the product reconstruction includes the following product aspects:

- The societal contributions it aims to make
- The economic contributions it aims to make (in terms of revenue)
- The scientific contributions it aims to make
- The ethical norms it explicitly adheres to
- To concreteness of the product (idea / product)

These were then used the evaluate the product with regard to RRI qualifiers (see 2.5 Evaluating the reconstructions).

2.5 Evaluating the reconstructions with regard to the RRI framework

The reconstruction of the implementation process and the product were used to evaluate the case study with regard to RRI qualifiers, which were presented in Part A1 and are repeated here (see Table 7).

[1] https://www.audiotranskription.de/
[2] http://www.qsrinternational.com/

Table 7 Process and product qualifiers thought to support responsible research and innovation.

Transparency	• Be transparent about assessment criteria • Be transparent about the role of stakeholders • Be transparent about any limitations with regard to transparency
Inclusion	Elicit meaningful contributions: • Include many, diverse and fundamentally different stakeholders • Inform stakeholders prior to inclusion • Frame discussion together with stakeholders • Empower stakeholders to contribute Allow product and process changes to occur in response to those contributions: • Include stakeholders from the outset • Include stakeholders for normative or substantive (rather than instrumental) reasons • Retain a receptive attitude to feedback
Reflexivity	• Recognize how personal values, scientific norms and institutional limitations drive a decision • Challenge those drivers • Gain an understanding of how the product impacts society • Gain an understanding of how framing affects the inclusion activities
Anticipation	• Define desirable societal (social, environmental, ethical and economic) impacts • Identify problematic societal impacts • Identify alternative routes to those impacts • Choose a both constructive and meaningful time to anticipate
Responsiveness	• Respond to societal perspectives • Respond swiftly to changing perspectives • Respond with substance
General process recommendations	• Combine inclusive, reflexive, anticipatory activities • Repeat inclusive, reflexive, anticipatory activities throughout the process • Apply formal methods • Combine various methods
Product	• Aims to make societal (social, sustainability) contributions • Meets relevant ethical norms • Is sufficiently concrete so that it can be used in practice • Competes in current market economies • Returns on investments • Scientifically high-quality

2.6 Formulating recommendations for implementation and use

The reconstruction was evaluated based on the RRI qualifiers with two goals in mind. On one hand, the analysis was to provide insights on recommendations for use of video recordings in operating rooms. On the other hand, the results were used to provide insights on the practicality of the RRI framework.

To distinguish between results that reflected on the case study and that reflected on the RRI framework, various situations can be identified. Two possible scenarios can inform recommendations for implementation and use as follows:

A. A RRI qualifier wasn't met, the researchers had no ambition to meet this RRI qualifier and operating room staff did not perceive a lack of this RRI qualifier as problematic. This indicates that the RRI qualifier may not apply to this case study.
B. A RRI qualifier wasn't met, but the researchers had significant intentions to meet this RRI qualifier and operating staff perceived a lack of this RRI qualifier as a barrier. This indicates that the RRI qualifier

should be adopted as a recommendation for the use of video cameras in operating team research, but that practical context factors may hinder its performance.

Together these types of situations helped to distinguish between results that should inform recommendation for use of video recordings in operating rooms and provide insights on the practicality of the RRI framework.

3 Case study reconstruction

In this part of the thesis a framework on Responsible Research and Innovation (RRI) is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. The goal of this study is to formulate recommendations on the use of video recordings in observation of medical specialists during surgery and to provide insights on the practicality of the RRI framework.

In the previous chapter the methodology of the case study was described, explaining how a reconstruction was used to analyze the case. In this chapter that reconstruction is presented, first describing a reconstruction of the implementation process (3.1) and then of the research product (3.3).

3.1 Reconstruction of the implementation process

This section describes the implementation process of video cameras at the LUMC to study communication during cardiac surgery from first inception in 2011 until first use in 2015. The reconstruction was based on two interviews with the lead investigator and document analysis. The events are grouped into 8 distinct activities (sometimes performed in parallel), and each activity is described chronologically.

In the text, each event is accompanied with a symbol indicating its event type. In the methodology section six types of event were defined. *Interactions with actors*, both within and outside of the research team, are indicated with a bullet of the corresponding color (see Figure 12 for an overview of these actors and their color). Interactions within the research team for example are indicated with a yellow bullet (●) . *Investigation of stakeholder perspectives without interaction* are indicated with a grey bullet (●).*Pilot studies* are indicated with a diamond (♦). *Alterations of the research product* are indicated with a red star (★). Two types of events, i*ndividual reflections* on the impact of the research product or process and *the application of formal methods* to support reflexivity or anticipation, did not occur.

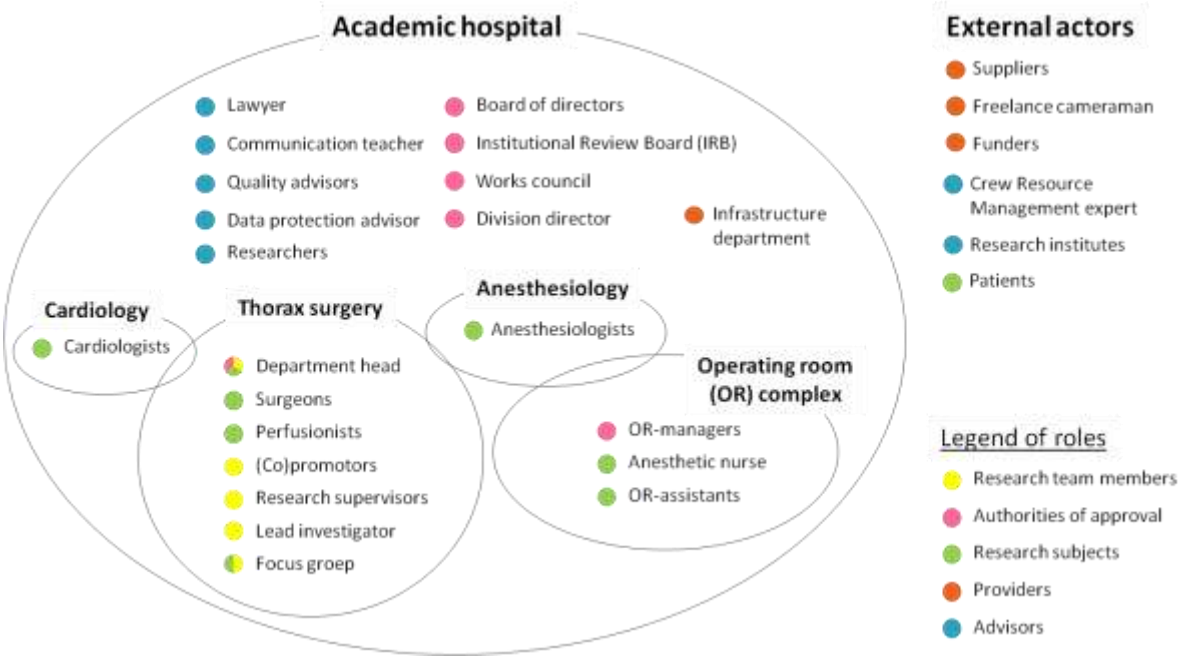


Figure 12 Actors involved during the implementation of video cameras at the LUMC. For a specific definition of the roles mentioned in the legend, please refer to section 2.1 Definition of key terms , p. 39.

The lead investigator is from here on referred to as #R1, whereas his co-promoter is referred to as #R2 and two members of the operating room staff are referred to as #S1 and #S2.

3.1.1 Inception

The lead investigator (#R1) informally speaks with his department head about his desire to do research on communication and patient safety.

April 4, 2011. #R1 writes first research protocol draft (no video recordings are mentioned).

July 5, 2011. #R1 meets with department head to discuss the project plans. The department head sets up a meeting with a research group from a partner research institute who has experience with this type of research.

August 4, 2011. #R1 meets with the acquainted researcher from the partner research group.

November 10, 2011. #R1 works on project plan (still no mention of video recordings).

March 1, 2012. #R1 meets with the professor of the partner research group. From this meeting, #R1 takes away the following: (1) video analysis is the most objective research method to study communication and patient safety, (2) Supplier A can provide satisfying video analysis tools, (3) any relevant legal frameworks are summarized in (C. Blaauw, 2013) and (4) any video recordings made for the purpose of studying teamwork are legally not patient-related, discarding a whole set of legal restrictions.

August 2011 – January 2012. #R1 meets with the division's quality advisor to discuss the project plans. This was at the time of Eyeworks @VUmc, so that the meetings were about how to prevent such a disaster at the LUMC.

March 5, 2012. #R1 meets with an external Crew Resource Management expert. During this meeting the CRM experts show the main research a video recording from a CRM training. #R1 learns that video is a good method to record communication processes which can be replayed several times and therefore you can note many different aspects/people of the same surgery.

Later #R1 is further inspired by the department head, who is also involved in international surgical trainings for mitral valve replacements. Those trainings are recorded and streamed live so that congress members / students can follow the surgery live. The recordings were supposes to record only technical skills, but the audio recordings include conversations between team members. From this recording, #R1 learns that video is an excellent method to record communication during real-life cases (rather than simulated cases such as those during CRM training). Later #R1 says that 'he himself has never had to grant permission to be recorded for those events'.

May 9, 2012. #R1 meets a researcher from the other department, who provides him with their video recording protocol. In their protocol, the surgeons carry the microphones on their face. This will inspires #R1 to take a similar approach and to request Supplier A for such a microphone (June 25, 2013). Later #R1 believes these aspects of the approach to be undesirable, because the microphone can distract the surgeon and because several team members regularly leave the opearing room or change diensten during surgery and the microphone would have to be changed every time. Also, in this protocol, the recordings are sent to another institute for analysis. #R1 decides not to take such an approach, because the recordings can be lost or intercepted during the transmission.

September 9, 2012. #R1 meets with a university teacher in public speaking skills. She shows #R1 that she uses video recordings to give feedback to her students about their own communication skills. #R1 learns that video recordings are an effective instrument to give feedback on communication skills.

The acquainted researcher meets with other researchers from external institutes who also used video cameras to record surgical processes. In this way #R1 learns about a project in which a film crew was used to record communication exchanges between operating room personnel and other hospital departments.

Also, #R1 meets a researchers from another department who has experience with research on patient safety in the operating room ● and the department head of the quality institute within the hospital ●. The two researchers give recommendations regarding the contents of the research, and advise to further specify the aims and research method. Also the quality advisors emphasize that the recordings should be stored up until 15 years after they were made so that the researcher in question would be able to answer to research fraud investigations.

3.1.2 Pilot study (1)

In a research meeting, one of the research supervisors ● recommends to pilot the use of video cameras and suggests to work together with a certain freelance cameraman.

March 30, 2012. #R1 rewrites the project plan for the pilot study (no mention of video recordings) ★.

#R1 performs a pilot study ♦ with the freelance cameraman ●. The photographer is present during surgery and uses a handheld camera to record interactions between operating room team members. #R1 is unsatisfied with the pilot study procedure because (1) the photographer records single interactions rather than the operating team as a whole, (2) the camera is in the way and there are many cables running across the floor which can both compromise patient safety and (3) the whole set-up is clearly visible to anyone in the operating room, which can influence the communication behavior of those observed.

Figure 13 Screenshots from recorded images of first pilot. One of the standalone microphones is visible on the left image next to the operating table.

3.1.3 Apply for board approval

September 2012. Before seeking approval from the institutional review board (IRB) (medisch ethische toetsingscommissie), #R1 and one of his supervisors meet with a member of the IRB ● and a legal advisor ●. During this meeting, #R1 learns four things. (1) If a medical incident is accidentally recorded, the recordings become part of the medical records of the patient and therefore can be used in court against the caregivers. (2) Approval from the IRB is not legally required for this type of research, because the research does not concern patients directly (geen patientgebonden onderzoek). #R1 decides to request a declaration of no objection (verklaring van geen bezwaar) from the IRB nonetheless, because he desires to publish the results of the study in academic journals. (3) The application should address how the identity of the participants is protected. (4) Video cameras have been used to record surgical process before by another research group at the same hospital. #R1 is recommended to meet with this research group.

#R1 writes a draft IRB application. #R1 sends the draft to one of his supervisors ● and the division's quality advisor ●. #R1 asks these advisors for their feedback on the application's content, but neither makes substantial changes; the application is only reviewed in terms of language.

October 4, 2012. #R1 meets with the works council (ondernemingsraad) ● to discuss the IRB application. A series of meetings and email exchanges follows. From these exchanges, #R1 learns "what it means for an individual to be recorded in the public domain" and accordingly makes the following changes to the application: (1) anyone who appears on camera should be asked for their consent, (2) participants should be notified of upcoming recordings in advance and (3) signs outside of the operating room should remind participants of any ongoing observations. With these changes, permission from the works council is granted.

It is around this time that #R1 familiarizes himself with the matter of participant privacy. He reads about how security agencies tap civilian phones without their consent. From this experience #R1 asks himself: why does the public let security agencies tap its phones while OR-personnel does not consent an academic investigation in the operating room? The researcher answers for himself that this must be because civilians (1) are not aware of the observations that security agencies make and (2) feel that they have nothing to hide. #R1 wonders what it is that operating room personnel has to hide that makes them want to avoid being recorded.

#R1 further familiarizes himself with the matter of participant privacy by reading publications from philosopher John Stuart Mill about the liberty of the individual. From this he learns that recording people in a work environment is different from recording them at home, because at home 'you can say anything' while in the public domain you're being watched.

October 22, 2012. Approval from the works council is obtained.

November 6, 2012. #R1 visits the secretary of the board of directors to inform them about the PhD project.

#R1 submits the application to the IRB and the board of directors (November 2012). Six weeks later permission from these parties is granted (December 2012).

#R1 meets with the new operating room manager, who disregards all agreements with the former operating manager. The new operating room manager demands to see consent forms from everyone involved before each observation.

#R1 meets with the division director. #R1 asks for his support and emphasizes that if the operating room manager has to approve every recording, the manager will also obtain the responsibilities of the IRB and board of directors. In response, the division director meets with the operating room manager and the manager grants permission to proceed.

3.1.4 Pilot study (2)

#R1 wants to conduct another pilot study and meets with the operating room manager. The operating room manager says to have no objections against the pilot study as long as no cameras are attached to the walls of the operating room (since this would compromise patient safety).

In the same period a research intern from the partner research institute compares two suppliers (Suppliers A and B) of video analysis software programs and recommends to use Supplier A due to its ease of use.

The research intern emphasizes that permission should be obtained from all participants about the pilot study. The department head says no such thing is required for a pilot study.

#R1 selects and rent four standalone video cameras from Supplier A for the pilot study. The approach differs from the first pilot study in the sense that more cameras are used to create more overview of the surgery, and that no film crew is present during surgery.

#R1 then informs the participants about the coming pilot study. To this end, #R1 personally meets with patients who are going to be recorded and sends all personnel working at the operating room complex for cardiothoracic surgery (including surgeons, anesthesiologists, operating room assistants, nurse anesthetists and perfusionists) an informative email. Also, #R1 invites the same personnel for an informative presentation at the operating room complex. The atmosphere at the presentation is informal and festive; the presentation is held after working hours, attendance is voluntary and #R1 provides the attendees with snacks. The presentation is mainly attended by nurse anesthetists and operating room assistants, some perfusionists and one anesthesiologist. At this meeting, the attendees raise the following concerns with regard to the use of video cameras: (1) the storage period of one year is long, (2) the analysis of video recordings is time-consuming and may therefore not be a desirable approach, (3) perhaps the video recordings should be stored at a lawyer's office, (4) the participants would like access to the images (to which #R1 responds that he can't allow that because he also has to protect the privacy of the other participants), (5) it is unpractical to ask for permission from the

participating personnel before each individual observation. Instead, the attendees recommend to ask permission from all operating room personnel at once before the start of the study.

June 21, 2013. #R1 writes to those employees who work in the operating room at the time of recording individually and asks for their consent 🟢. He writes that 'logistically, the employees will not experience any problems, because the camera is already turned on when the patient enters the operating room' and that 'the recordings will be removed after analysis' and 'can only be accessed by authorized personnel'. Also, #R1 emphasizes that the participants are well-protected ('I want to highlight your rights: the video recordings cannot be used to challenge the performance of operating room personnel'), and that anyone has the right to refrain from participation ('It's absolutely no problem if you do not want to be recorded, just let me know in advance').

#R1 proceeds with the pilot study and four surgeries are recorded ♦. From the pilot study, #R1 learns the following: (1) the four cameras take up space, which makes the room feel smaller, (2) the cameras are clearly visible and may influence the behavior of the personnel observed, (3) #R1 cannot be sure whether he correctly cleaned the cameras and cables, because there is no protocol for cleaning these materials.

Figure 14 Two screenshots from recorded images of second pilot. One of the video cameras is visible on the right image in the corner of the operating room.

3.1.5 Apply for funding

Funding is needed to acquire the video cameras. #R1 seeks help with the funding application and meets with the judicial subsidy department of the hospital 🔵. No help is provided because the department says to support much larger applications only. December 6, 2012. #R1 contacts a commercial mediation agency to help with the funding applications, yet the agency is found too expensive and contact is ended 🔵.

January 22, 2013. Together with a partner research institute 🔵, #R1 writes an application for a subsidy from a public funder (Funder A). The subsidy is not awarded. #R1 personally writes an application for a subsidy from another public funder (Funder B). The subsidy is not awarded.

September 2013. To try and turn the tide, the department head recommends to ask #R2 to join the project as a daily supervisor and co-promoter 🟡. Daily supervisor and co-promoter (#R2) joins the project.

November 2013. Together with #R2, #R1 writes a new subsidy application. Subsidy is not awarded. January 2014. Together with two of his supervisors 🟡, #R1 meets with two researchers from the partner institute 🔵 to write a second application for Funder A. Again the subsidy is not awarded. Together another application is written for Funder C. Still, no funding is awarded.

August 2014. Together with #R2 🟡, #R1 applies for a subsidy from Funder B 🟠 for a second time. This time, the subsidy of 25,000 euro is awarded. With this funding the video cameras and additional materials can be acquired.

July 2014. Shortly before the lasts subsidy was applied for, #R1 meets with the supplier (Supplier A) . September 2014. #R1 visit the supplier (Supplier A) to discuss the possibilities. The supplier offers two types of video cameras: a dome camera and a steerable camera. The dome camera provides an overview of the whole operating room from one static perspective. With a steerable camera, the observer can follow team members manually and zoom in on interesting aspects. Also, the supplier offers to blur the faces of the recorded individuals.

3.1.6 Install recording system

#R1 speaks with the department head to emphasize that dome cameras (which are attached to the operating room walls) rather than standalone cameras need to be used for the study, because they (1) do not require any cables to lay around in the operating room, which could compromise sterility, (2) are hardly visible to the participants, so that natural communication behavior is observed, (3) do not get in the way, which could compromise safety, (4) provide a broad overview of the operating room and (5) are much cheaper.

#R1 meets with operating room manager and the medical operating room manager . Both grant permission to proceed with the installation of cameras as long as no holes are drilled in the operating room walls, because this could compromise the sterility of the room. They also recommend to have a look at another operating room in which cameras are currently installed.

#R1 speaks with the division director to ask who he needs to settle the issue with . The division director says he should settle it with the operating room management directly.

December 3, 2014. #R1 organizes a meeting with the operating room manager , the medical operating room manager , and the department head . During this meeting the department head asks the operating room management to allow the attachment of dome cameras to the operating room walls. This time, the operating room management grants permission to do so. According to #R1, the operating room management just 'needed to hear it from the department head'.

#R1 opts for two dome cameras on both sides of the operating room. He does not order the blurring feature because he is afraid this would hinder analysis of the recordings. Furthermore, the supplier is asked to combine these images with those from the video camera which is already present in the operating room.

#R1 meets with a member of the infrastructure department and a quality advisor to design the final set-up. Infrastructure has detailed questions about the cameras. January 20, 2015. #R1 brings the infrastructure department in direct contact with the supplier so that they can finish the design together. March 2015. Infrastructure and the supplier email with each other and #R1 to discuss the final set-up. Infrastructure makes a sketch that shows where the cameras should be placed and where the cables should be laid.

April 24, 2015. Infrastructure pre-drills the holes in the operating room walls and lays the cables . The supplier installs the cameras . Infrastructure hires a commercial party to measure the electromagnetic interference between the cameras, cables and other operating room equipment. The commercial party advises to make some changes to minimize interference, which infrastructure performs.

The camera cables do not completely fill up the holes that were drilled in the operating room walls. This is an issue with regard to sterility, because it allows air to pass along the cables. The supplier makes a second visit to the hospital to install connectors that completely fill up the space between the cables and the holes so that air can no longer pass between the operating room interior and exterior.

3.1.7 Seek participant consent

#R1 sends an email to all operating room personnel , explaining the consent procedure and providing them with the consent form.

#R1 asks permission from the operating room manager to present the study at one of the weekly staff meetings for general nurse anesthetists, operating room assistants and operating room managers.

April 7, 2015. #R1 holds a presentation at the staff meeting 🟢. 120 staff members attend the presentation (of whom most also work at the thorax surgery department). At the presentation, #R1 explains the objective of the study and the terms and conditions of participation. Among other things, #R1 emphasizes that (1) all personnel has the right to refrain from participation, (2) surgeries performed by personnel who did not consent will not be recorded, but recordings are not disregarded when a team member that did not consent temporarily joins the team during the procedure, (3) recordings are randomized so that the results are anonymous, (4) only standard surgeries are included to limit risk of recording an incident, (5) recordings will be announced outside of the operating room an per mail in advance. The presentation takes 10 minutes in total.

#R1 gives a presentation to surgeons 🟢 during one of the daily patient transfer meetings. #R1 explains 'why video' and repeats that the recordings are no part of the medical records and that analysis is anonymous. The presentation takes 15 minutes. One of the attendees wants to know why revision surgeries are not included in the study. #R1 responds by saying that for now this study focuses on a common and fairly well-standardized procedures (coronary artery bypass grafts and aortic valve replacements) from which general lessons may be learned that may apply to other procedures as well. One of the attendees asks whether he'll also record medical incidents.

Figure 15 Two slides from the presentation for operating room personnel

One of the members of the focus group (an anesthesiologist) 🟡 visits #R1 and reports that her colleagues have questions about the study.

May 5, 2015. #R1 organizes a meeting with anesthesiologists 🟢 to answer these questions. The presentation takes place at the operating room complex at lunch time. Only two or three anesthesiologists attend the presentation. The attendees say to find this meeting unnecessary, because they already know everything they need to know. The meeting takes only a few minutes.

#R1 sends an email to cardiologists to ask for their consent 🟢.

July 7, 2015. #R1 arranges a meeting with the perfusionists 🟢, who are also his direct colleagues. The meeting takes place at the operating room complex on a normal workday and takes 15 minutes. All perfusionists attend. During this meeting, one of the attendees objects against the storage period of one year.

Before the each recording, #R1 meets with the patient 🟢 who he wants to record. During these meetings, the researcher emphasizes that (1) the study does not negatively affect patient safety and that (2) the patient will not be recognizable in the image. During an observed meeting with a patient, the patient expresses questions about (1) whether he will be on television (no), (2) whether others have consented (yes) and (3) whether he can access the recordings (no, because the researcher also has to protect the identity of those taking care of the patient).

3.1.8 Renew application for board approval

May 2015. While a part of the operating personnel has already given its consent, two anesthesiologists (#S1 and #S2) 🟢 expressed their concerns with regard to the use of video recordings in the project. One of them had

already consented at the time (#S1), the other hadn't (#S2). The concerns regarded the unintended use of the video cameras and the operating room team members demanded a letter from the board of directors that forbade such unintended use. The focus group member from anesthesiology expresses her disbelief towards #R1.

#R1 discusses the issue with the department head. #R1 discusses the possibility of such a letter with the works council, who send him to a legal advisor. The legal advisor emphasizes that 'necessity has no law' (nood breekt wet), which means that even *if* the board of directors were to write such a letter, the recordings can still be used in court in the case of a medical incident. The legal advisor recommends #R1 to meet with a hospital privacy functionary.

#R1 meets with a hospital privacy functionary. The privacy functionary takes two weeks to discuss the matter with her colleagues. Finally the privacy functionary recommends against a letter from the board of directors, because indeed necessity has no law and a letter may invoke the curiosity of the board of directors. Instead, the legal advisor recommends to alter the patient consent letter so that patients explicitly consent to exclude the recordings from their medical records and cannot make any claims on the recordings.

Finally, the research team decides to change the IRB protocol. The researchers respond for three reasons: they find this criticism useful, they feel greatly dependent on the opinion of these two anesthesiologists and they were planning to make small changes to the IRB protocol anyway.

The researchers do not demand a letter from the board of directors however. Instead, the patient letter (which is part of the IRB protocol) is altered, now explicitly stating that patients cannot retrieve the recordings after surgery. In the original IRB protocol (filed November 2012), the patient consent letter included the following information about their access to the recordings.

> <quote removed to protect privacy of interviewees>

In the new patient letter (filed June 2015), the patient consent letter explicitly states that the recordings will not be included in the medical records.

> <quote removed to protect privacy of interviewees>

#R1 discusses the potential changes with the IRB. #R1 emphasizes that the changes will not have any negative consequences on privacy and only provides an extra clarification with regard to the privacy protection of the patient.

June 3, 2015. #R1 contacts the anesthesiologist from the focus group to inform her of the upcoming changes to the IRB protocol.

June 6, 2015. The alterations to the patient consent letter are made and a renewed IRB application is applied for. The renewed application is approved by the IRB. Later, #S1 says to be satisfied with this response, because he felt taken seriously, but #S2 is not satisfied because it didn't provide him with the assurances that he had asked for. Nevertheless both operating room team members finally consented to take part in the project. Finally 106 staff members explicitly consent, 1 staff members do not consent and it is unclear how many staff members do not hand in a consent form. All patients (8 in total) consent.

The first recording takes place on July 1, 2015. The implementation process is summarized in a schematic diagram (see Figure 16).

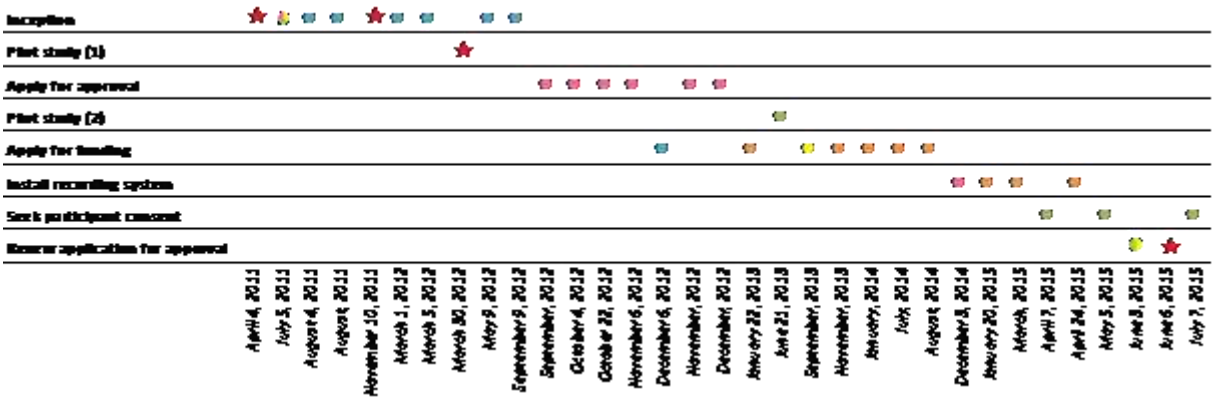


Figure 16 Schematic overview of the sequence of events during implementation of video cameras at the case study. Symbols indicate the type of event: ● interaction with advisors, ● interaction with authorities of approval, ● interaction with providers, ● interaction with study participants, ● interaction within the research team, ★ alteration of the conditions of use. Note that only events with a specific date were included in this overview.

3.2 Reconstruction of the product

The implementation process resulted in the following conditions of use as presented in the IRB protocol and based on observations of the site:

Use	• Recordings are used for the analysis of non-verbal and verbal communication between caregivers and for the analysis of non-technical skills of caregivers. The protocol emphasizes that the recordings shall not be used to discuss nor challenge the competency of individual caregivers during surgery, neither to investigate the technical skills of those caregivers. • The use of video cameras for this project is authorized by the medical ethics review board, the board of directors and the works council • The composition of the operating team is randomized • Recordings are processed anonymously • In total ten open-heart surgeries are recorded
Access	• The recordings are not part of the medical records • Patients sign to make no claims on any video recordings • The recordings are stored on a computer and in a room which only authorized personnel can access
Storage	• The recordings are stored up until 1 year after analysis • The recordings are stored on a computer outside of the operating room
Recording set-up	• 3 cameras are used, including 2 cameras attached to the walls of the operating room and 1 camera focused on the surgical site • 3 microphones are used, each attached to existing infrastructure in the operating room • The video cameras cannot zoom

With these conditions of use, the protocol explicitly states to adhere to national law. The research project complies with the medical treatment act (wet op de geneeskundige behandelingsovereenkomst, WGBO) and the personal data protection act (wet bescherming persoonsgegevens,WBP) (see Appendix, p. 147 for the meaning of these laws).

Furthermore the protocol emphasizes that this project can only be successful if errors are not reprimanded. The IRB protocol indicates that ‘in order to improve a health care process’ it is essential that ‘operating room personnel feels sufficiently safe to report hazardous situations and their own mistakes’. According to the IRB protocol this requires a ‘concrete signal from the executives’ that error reports will be used to improve quality of care and are not reprimanded.

4 Results

In this part of the thesis a framework on Responsible Research and Innovation (RRI) is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. The goal of this study is to formulate recommendations on the use of video recordings in observation of medical specialists during surgery and to provide insights on the practicality of the RRI framework.

In the previous chapter the case study was reconstructed, describing the implementation process of the video cameras and the conditions of use that this process finally resulted in. In this chapter, this reconstruction is used to identify RRI qualifiers.

The results are discussed per RRI dimension. Per dimension, first the RRI potential is determined based on the reconstruction of the case, and then the extent to which this potential is fulfilled according to researchers and operating room staff is described. To this end two researchers and two operating room staff members were interviewed.

To remind the reader of the theoretical framework that informed the results, each section starts with a definition of the RRI dimension and an overview of the RRI qualifiers (as defined in Part A1 of this thesis, see framework summary p. 26). Process dimensions also start with a list of events that were thought to potentially support these qualifiers (as defined in the methodology chapter of this part of the thesis, see p. 40).

Any sub-conclusions are emphasized in **bold**.

4.1 Transparency

Dimension	Qualifiers according to RRI literature
Transparency - communicates the bases of decisions and the distribution of the responsibilities to external publics.	• Be transparent about assessment criteria • Be transparent about the role of stakeholders • Be transparent about any limitations with regard to transparency

4.1.1 Potential for transparency based on the reconstruction

The RRI framework defines transparency as a one-way communication process towards 'external' publics, whereby external publics are all those actors who are not part of the research team. **Interaction with actors,** including stakeholders (operating room personnel ●, patients ● and authorities of approval ●) and other actors (including providers ● and advisors ●), were therefore thought to allow for transparency.

The researchers organized many interactions with actors, thereby showing great transparency potential to all sorts of publics. The transparency potential was determined per type of public. Of all publics, the IRB protocol states a particular ambition to be transparent towards operating room personnel and patients, because this can help to obtain their permission. Indeed, the researchers organized many interactions with operating room personnel. The researchers held presentations, spoke with them informally and installed a focus group to communicate with them. This indicates great transparency potential towards *operating room personnel*. There was only one event in which the researcher communicated with patients and none in which he interacted with patient interest groups however. This indicates limited transparency potential towards *patients*. Furthermore, the IRB protocol was not accessible to external publics and no new articles were published about the study. This indicates a lack of transparency potential towards *the greater public*.

There is no evidence of the researchers being transparent about the role of the stakeholders in decision-making or the researchers' limitations with regard to transparency (such as intellectual property rights), but the researchers may have been transparent about assessment criteria. The presentation to operating room personnel during a staff

meeting (during the phase ‘seek participant consent) the researcher explains that the recordings are randomized ‘so that the results are anonymous’ and that only standard surgeries are included ‘to limit risk of recording an incident’. This indicates that the researchers may have been transparent about assessment criteria to some extent.

4.1.2 Perception of transparency according to stakeholders

Both researchers felt that they organized many interactions with stakeholders and therefore were very transparent. When asked, #R1 even says that next time he would be *less* transparent because it only elicited ‘meddling’ from operating staff.

<quote removed to protect privacy of interviewees>

This indicates that the according to the researchers, they could not have been more transparent.

The staff however perceived a lack of transparency. #S2 felt that the potential risks of the project were not being communicated to him. Clearly the study was not *without* risk, because otherwise he wouldn’t have had to consent.

<quote removed to protect privacy of interviewees>

<quote removed to protect privacy of interviewees>

Also #S1 perceived risks that the researchers didn’t communicate, but instead of making him suspicious, #S1 thought the researchers just hadn’t thought of those risks yet. That is why #S1 wanted to inform the researchers about those risks and expressed his concerns.

#S2’s fears about the potential risks of the project were further fueled by a lack of information about the study design, including the study’s length, included participants and objectives. The study design had changed several times and #S2 got confused about the details.

<quote removed to protect privacy of interviewees>

Finally these considerations caused him to refrain from participation. There is reason to assume that #S2 might have agreed with the purpose of the project if he was better informed, because during our interview he finds that our conversation refines his opinion about the purpose of the project:

<quote removed to protect privacy of interviewees>

This indicates that the researchers were insufficiently transparent about the purpose and about the potential risks to #S1 and #S2. This caused #S1 and #S2 to refrain from participation and express their concerns.

There is indeed evidence that #S1 and #S2 were less well informed about the study than other stakeholders, because they were from the anesthesiology department, rather than the thorax surgery department, which led the investigation. #R1 says to have had less informal interaction with them.

<quote removed to protect privacy of interviewees>

Furthermore the first focus group member with this specific stakeholder group may not have informed the anesthesiologists well.

<quote removed to protect privacy of interviewees>

Furthermore #R1 and #R2 suspect that the anesthesiologists were more vigilant about the potential risks than other stakeholders because the study was not initiated by their department.

<quote removed to protect privacy of interviewees>

This indicates that an organizational structure (such as departments) can hinder transparency and that researchers should be extra careful to communicate potential risks to stakeholders from other departments.

Analysis of the key event also shows a lack of direct interaction between #S2 and #R1 limited the researcher's capacity to be transparent. #S2 was the first to raise concerns. He raised his concerns during a work meeting with his direct colleagues. His concerns 'triggered' others, after which the focus group member went up to #R1 to discuss the concerns. This provided #R1 with little idea of what concerns were discussed within the group and little capacity to respond to them.

<quote removed to protect privacy of interviewees>

This indicates that direct interaction between the concerned staff and the researcher might have allowed the researchers to be transparent about the risks perceived.

4.2 Inclusion

Dimension	Qualifiers according to RRI literature
Inclusion - takes in the societal aspects of an innovation, through e.g. stakeholder engagement.	Elicit meaningful contributions: • Include many, diverse and fundamentally different stakeholders • Inform stakeholders prior to inclusion • Frame discussion together with stakeholders • Empower stakeholders to contribute Allow product and process changes to occur in response to those contributions: • Include stakeholders from the outset • Include stakeholders for normative or substantive (rather than instrumental) reasons • Retain a receptive attitude to feedback

4.2.1 Potential for inclusion based on the reconstruction

Inclusion was defined as any activity that elicits contributions from external actors. Therefore two events, **Interaction with actors,** including stakeholders (operating room personnel ●, patients ● and authorities of approval ●) and other actors (including providers ● and advisors ●) and **Investigation of stakeholder perspectives** without interacting with them (individual inclusion) ●, were thought to allowed for inclusion.

There are two key qualifiers of inclusion, the potential to elicit meaningful contributios and the potential to inform product changes based on those contributions. Each is discussed below.

Potential to elicit meaningful contributions

The researchers organized many interactions with actors, thereby showing great inclusion potential. The actors involved were of a very diverse nature, including suppliers, advisors, authorities of approval, operating room personnel and patients. Since also actors from outside of the hospital were involved, fundamentally different stakeholders were involved, indicating great inclusive potential.

The inclusion activities showed some potential to elicit meaningful contributions. Although there is no evidence of stakeholders being sent any project documents prior to formal inclusion activities, the researchers regularly spoke with stakeholders informally in hallways and during coffee breaks so that they were could have been adequately informed nonetheless.

Also power differences between stakeholders and researchers were compensated, because the lead investigator usually presented alone for an audience of many (at least ten) stakeholders. Furthermore the stakeholders were always of the same as, or even of a higher hierarchical level than the lead investigator (e.g. surgeons versus a

perfusionist), therewith further empowering stakeholders to contribute. Perhaps accidentally, power differences between various stakeholder groups were compensated for because each stakeholder group was met with separately, one specialism after the other.

Several factors limited stakeholders to make meaningful contributions. The formal inclusion activities were not framed together with stakeholders, because the meetings always begun with a presentation. A big limitation also, was the short duration of these meetings. Each formal meeting took only between 5 and 15 minutes, therewith limiting the possible depth of the discussions.

Potential to make product changes in response to stakeholder contributions

The RRI framework lists three inclusion types, of which type 2 and 3 are considered most responsible. In the case study there was potential for all three inclusion types. There was indication for type 1 (whereby stakeholders are involved to create support for a product), because the IRB protocol stated that stakeholders should be involved to create support.

> <quote removed to protect privacy of interviewees>

There was also indication for type 2 (whereby stakeholders are asked to contribute their experience and knowledge to a project), because operating room teams are experience experts on the topic of investigation (communication in the operating room) and therefore could have contributed to its analysis substantively.

> <quote removed to protect privacy of interviewees>

There was indication for type 3 (whereby researchers and stakeholders frame, analyze and solve a complex challenge together), because the aim of the project was to improve surgical safety and therefore required operating room staff to implement its outcomes. #R1 emphasizes that since the project is about improving surgical safety, operating room staff is responsible for the implementation of the outcomes of the study.

> <quote removed to protect privacy of interviewees>

In practice however, the inclusion activities only allowed for type 1 inclusion, which limited stakeholder contributions to improve the product. Both #R1 and #R2 stress that the presentations with stakeholders were intended to inform and convince, rather than to gain stakeholder input.

> <quote removed to protect privacy of interviewees>

Also the focus group was mainly used to create support for the project rather than to gain input from stakeholders.

> <quote removed to protect privacy of interviewees>

Furthermore these activities only took place *after* the IRB protocol had been approved and so stakeholders could not contribute to the contents or objectives of the study. Before the IRB protocol was filed for the first time, operating room personnel was only involved through the works council. Most personnel was not involved directly until full permission from the approval boards and full funding had been obtained. Patients were not involved once before the final IRB protocol was submitted and therefore had to chance to influence the conditions of use. The late timing of these meetings severely limited the potential for stakeholders to inform product changes.

4.2.2 Perception of inclusion according to stakeholders

The researchers generally feel that they organized many inclusion activities and involved many actors. Therefore #R1 feels that there were plenty of opportunities for #S1 to express his criticism earlier:

> <quote removed to protect privacy of interviewees>

In particular, #R1 feels the critical participants should have come to the informative presentations about the coming project. The research team organized two group meetings for these particular subjects. The first was held right before the pilot study and was open to all participants. The second was held right before the actual study and was organized for this group of participants specifically. According to #R1, neither meeting was attended by any of the two critical subjects. Indeed neither subject says even to remember any such meeting.

<quote removed to protect privacy of interviewees>

<quote removed to protect privacy of interviewees>

#S1 indicates that he would have liked to interact with the researchers earlier in the process, because it would have allowed him to express his criticism and refine his opinion about the project. **This indicates that the concerns of #S1 and #S2 might have surfaced earlier if they had joined the organized inclusion activities.**

The critical participants provide two possible explanations for their absence. One of the research subjects emphasizes that medical specialists can rarely attend *any* group meeting and that this is an issue for him in general.

<quote removed to protect privacy of interviewees>

Yet a busy schedule has always limited medical specialists and they still manage to attend some of the group meetings that they prioritize. #S1 suggests that also a sense of *urgency* was lacking among the potential research subjects. #S1 explains that it wasn't until #S2 started to point out a critical issue with regard to the research protocol, that the sense of urgency was raised among his peers:

<quote removed to protect privacy of interviewees>

This indicates that operating staff did not feel inclined to join inclusion activities, because they did not perceive the meetings as urgent or important until the very end.

Another qualifier of inclusion in RRI is the attitude of researchers to feedback. The response of #R2 to the criticism shows that she maintained a receptive attitude to the feedback from #S1 and #S2, because she was eager to improve the research protocol with their input,

<quote removed to protect privacy of interviewees>

While #R1 found their criticism unhelpful. Partially because of the way the criticism was expressed,

<quote removed to protect privacy of interviewees>

And also because he felt that the focus group members are no more experts in this field than he is.

<quote removed to protect privacy of interviewees>

Mostly however, #R1 just didn't understand why the research subjects were so concerned. For one, #R1 felt that he had already taken care of the risks that they perceived. The protocol already stated that the images could only be used to evaluate communication performance in a research setting, and that the technical parts of the procedure would not be recorded.

<quote removed to protect privacy of interviewees>

<quote removed to protect privacy of interviewees>

And #R1 didn't understand why the approval from the board of directors, the IRB and the works council were not enough to gain their trust.

<quote removed to protect privacy of interviewees>

These stories indicate that whilst #R2 was receptive to the feedback, #R1 didn't understand the feedback and may even have felt threatened by it. When asked, #R2 explains that it was different for her, because she was not the lead investigator and heard everything from second hand (from #R1). Also #R2 had only just joined the project, and may have felt less responsible for the IRB protocol that was being criticized. **This indicates that the way feedback is perceived by researchers varies from person to person and may relate to the specific responsibilities of the researcher within a project.**

4.3 Reflexivity

Dimension	Qualifiers according to the RRI literature
Reflexivity - helps a researcher to understand the social and ethical aspects of an innovation.	• Recognize how personal values, scientific norms and institutional limitations drive a decision • Challenge those drivers • Gain an understanding of how the product impacts society • Gain an understanding of how framing affects the inclusion activities

4.3.1 Potential for reflexivity based on reconstruction

Reflexivity processes were defined as activities that could help researchers understand the social and ethical aspects of innovation. As such the following events were thought to allow for reflexivity: **Interaction within the research team** (during team meetings or through other communications) ●, **Interaction with actors,** including stakeholders (operating room personnel ●, patients ● and authorities of approval ●) and other actors (including providers ● and advisors ●), **Reflection on impacts of product or process** without interacting with actors (individual reflection), **Application of formal method** to increase reflexivity or anticipation and **Perform pilot study** to test the product ♦.

Although two event types that could have supported reflexivity were not performed (individual reflection and application of formal method to support reflexivity), the remaining event types occurred so often that a large number of events could support reflexivity, allowing for great reflexive potential in the implementation process.

Two similar events in the reconstruction show both examples of great and limited reflexivity. When the researchers were applying for board approval, the meetings with the works council taught #R1 'what it means for an individual to be recorded in the public domain'. This indicates great understanding of stakeholder perspectives and therefore of the qualifier 'to gain understanding of how product impacts society'. When shortly after #R1 investigated stakeholder perspectives without interacting with them, this only increased his incomprehension about why stakeholders do not want to be recorded: it made #R1 wonder what operating room personnel 'has to hide'.

Comparison of the two events suggests that direct interaction with stakeholders can lead to reflexivity, whereas a lack of direct interaction does not necessarily contribute to reflexivity.

4.3.2 Perception of reflexivity

Analysis of the key event shows that a lack of direct interaction between #S2 and #R1 might have limited #R1's understanding of #S2's concerns. #S2 was the first to raise his concerns. He raised his concerns during a work meeting with his direct colleagues. His concerns 'triggered' others, after which his direct colleague, #S1, decided to demand a letter from the board of directors, stating that the recordings would not be used in a legal case against operating room staff. #R1 was informed about this demand through the focus group member, providing #R1 with little idea of what concerns were discussed within the subject group and little capacity to obtain an understanding of them.

<quote removed to protect privacy of interviewees>

This indicates that #R1 may have obtained a better understanding of stakeholder perspectives if he had had direct interaction with the concerned stakeholder.

Reflexivity was usually intertwined with other RRI dimensions. Therefore some examples of reflexivity and a lack of reflexivity are mentioned here, with references to their analysis in other RRI dimensions.

- While both researchers believe to have responded sufficiently to the criticism of the research subjects, #S2 did not perceive the response as such (see Responsiveness, p. 64). The fact that the researchers were not aware of this discrepancy shows a limited understanding of stakeholder perspectives. #S1 on the other hand felt fully understood by the researchers, indicating great reflexivity.
- Both researchers acknowledged the importance of protecting the recordings from being used for unintended parties, which is line with the perceived risks of #S1 and #S2 (see Product, p. 66). This indicates a reflexivity within the researchers to understand the impacts of their product on stakeholders .
- #R2 believed that anesthesiologists needed to understand the purpose of the project in order to consent in participation. Indeed, #S1 consented (even in the light of his own criticism) because he recognized the importance of the project, and #S2 did *not* consent because he did *not* recognize the importance of the project (see Product, p. 66). This agreement between #R2 and the research subjects shows a thorough understanding stakeholder values and hence reflexivity.

4.4 Anticipation

Dimension	Qualifiers according to the RRI literature
Anticipation - provides an overview of possible impacts and their alternatives.	• Define desirable societal (social, environmental, ethical and economic) impacts • Identify problematic societal impacts • Identify alternative routes to those impacts • Choose a both constructive and meaningful time to anticipate

4.4.1 Potential for anticipation based on reconstruction

In this study, anticipation was defined as the identification of alternative impacts and alternative routes to those impacts. As such, the following four events were thought to support anticipation: **Interaction within the research team** (during team meetings or through other communications) ●, **Interaction with actors,** including stakeholders (operating room personnel ●, patients ● and authorities of approval ●) and other actors (including providers ● and advisors ●), **Application of formal method** to increase reflexivity or anticipation, and **Perform pilot study** to test the product ♦.

Although one event type that could have supported anticipation was not performed (application of a formal method to support anticipation), the remaining event types occurred so often that a large number of events could have support anticipation, allowing for great anticipatory potential in the implementation process.

The use of video recordings was never reconsidered after the researchers learned about video recordings as 'the most objective research method to study communication and patient safety' from other researchers in March 2012. **This indicates limited anticipation, because only limited alternatives to video recording were considered.**

During inception, the specific conditions of use however were repeatedly reconsidered, showing great indication of anticipation. During this first and most influential period, the researchers spoke with many advisors (researchers from other institutes, researchers from other departments and communication experts). Together these advisors suggested a wide variety of alternative conditions of use (about the consent process, position of the microphone and recording system), potentially problematic societal impacts (what if the recordings are lost, personnel gets distracted or the hospital is humiliated) and desirable impacts (recordings can be replayed to analyze simultaneous processes and are an effective instrument to give feedback on communication practices).

Also during other meetings with stakeholders, impacts and alternative routes were suggested, showing great anticipation potential.

Although every interaction with stakeholders provided new alternatives and potential societal impacts, stakeholders were only involved after the first IRB protocol had been filed. **The timing of interactions with stakeholders was therefore too late to be meaningful.**

4.4.2 Perception of anticipation according to stakeholders

The fact that #S1 and #S2 felt the need to express the risks that they perceived at the end of the implementation process, shows that they felt potentially problematic societal impacts had not been accounted for properly (see Transparency, p. 57 for these quotes). The fact that the researchers made a change to the IRB protocol in response to these concerns indicates that indeed these risks had not been accounted for completely. **Analysis of this key event therefore indicates that anticipation *until* this response was not entirely effective.**

4.5 Responsiveness

Dimension	Qualifiers according to RRI literature
Responsiveness - makes responsible decisions in research and innovation.	• Respond to societal perspectives • Respond swiftly to changing perspectives • Respond with substance

4.5.1 Potential for responsiveness based on reconstruction

Responsiveness in this study is defined as the making of decisions. Therefore **Revisions of the IRB protocol** ★ are considered events that could potentially harbor responsiveness.

The IRB protocol was only revised a few times, therefore indicating limited responsiveness. Most revisions occurred at the beginning of the implementation process, during inception and application for board approval, suggesting responsiveness was limited after the first protocol was filed in November 2012.

Analysis of the key event (**Revision of the IRB protocol** ★, June 2015) indicates full responsiveness. Changes were made to the research protocol (and therefore substantial), those changes were made in response to the criticism of stakeholders (and therefore in response to societal perspectives) and made within a month of the first criticisms (and therefore swift).

4.5.2 Perception of responsiveness according to stakeholders

For the researchers the response (**Revision of the IRB protocol** ★, June 2015) was a dual experience. It caused another project delay in an already lengthy project and generally demoralized #R1.

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The researchers made the change to the IRB protocol nevertheless, for three reasons. In part, the researchers responded because they felt it could improve the research protocol significantly.

> <quote removed to protect privacy of interviewees>

Also #R1 explains that the project was greatly dependent on the opinion of these few research subjects because they could influence others and so impede the study.

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And finally the opportunity arose, #R2 explains, because #R2 had joined the project since the previous IRB protocol was filed and the patient letter needed to be updated anyway. **This indicates that two mechanisms facilitated the response: the researchers perceived to be greatly reliant on operating staff and there was an opportunity to change the IRB protocol.**

Although both researchers acknowledge that this change was not what the research subjects demanded, the researchers believe that it satisfies the research subjects because it is deals with their underlying concerns.

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Indeed #S1 found the response sufficiently satisfactory, because he felt taken seriously and because the risks he had perceived earlier were adequately mitigated with this response.

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#S2 however did not find the response satisfactory, because with it, he did not receive the assurances that he desired.

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This indicates that although the response met all RRI qualifiers, it only partially satisfied the stakeholders whose perspectives it was a response to.

4.6 General process qualifiers

General qualifiers for RRI processes	• Combine inclusive, reflexive, anticipatory activities • Repeat inclusive, reflexive, anticipatory activities throughout the process • Apply formal methods to support reflexivity and anticipation • Combine various methods

4.6.1 Potential for general process qualifiers

The RRI dimensions were thoroughly coupled, especially through stakeholder interactions which could simultaneously allow for transparency, inclusion, reflexivity and anticipation. Two examples from the reconstruction illustrate these couplings.

- One event shows how inclusion can support reflexivity and responsiveness. In the period that he was applying for board approval, #R1 repeatedly met with the works council (inclusion). According to #R1, those meetings taught him ‘what it means for an individual to be recorded in the public domain’, as such showing a great understanding of stakeholder perspectives (reflexivity). Furthermore he used this experience to make changes to the IRB application (responsiveness). As such this is an example of how inclusion can inform reflexivity and hence responsiveness.
- Inclusion repeatedly supported anticipation. During an informative meeting with stakeholders for example (inclusion) during the second pilot study, stakeholders anticipate potentially negative impacts by expressing their concerns about the storage of the recordings and provide desirable impacts by expressing the desire to watch and learn from their own recordings (anticipation).

Especially in terms of inclusion, many different methods were combined (informal interaction, formal sessions and indirect inclusion through a focus group).

No formal methods to support reflexivity or anticipation were applied.

4.7 Product

Product - the outcomes of research and innovation, including its academic findings as well as its marketable products.	Societal relevance • Aims to make societal (social, sustainability) contributions • Meets relevant ethical norms • Is sufficiently concrete so that it can be used in practice • Competes in current market economies Market competitive (returns on investments) Scientifically high-quality

4.7.1 Potential for product qualifiers based on reconstruction

Societal objectives

According to the protocol, the main goal of this research project was to improve patient safety within cardiac surgery and therefore to make societal contributions. The project specifically aims to decrease 'the chance of avoidable damage' (p. 7) to patients. According to the protocol, video recordings allow a detailed and objective analysis of communication errors, which are a main contributor to avoidable patient damage, and therefore contribute to the improvement of patient safety during cardiac surgery. Furthermore the protocol suggests that the results can be used in a broader initiative to improve safety practices at the thorax surgery department by providing 'insights that allow operating room personnel to recognize unsafe situations and mistakes'.

Economical objectives

In the protocol, the researchers express no desire to commercialize the product and therefore the product cannot compete in current market economies.

Scientific objectives

In the protocol, the researchers express a desire to publish the results of the project in academic journals. The protocol mentions various ways in which the use of audio and video recordings increases the scientific value of the results:

- Audio and video recordings are the 'leading objective method' (p. 8) to assess the quality of communication during surgery
- Video recordings can provide a broad context to the data recorded, so that analysis of this patterns is more valid than that of audio recordings alone
- Remote observation with audio and video recording devices prevents bias because it does not disturb the communication process as much as a human observer present in the operating room

Also the protocol emphasizes that multiple studies have shown the value of audio and of video recordings during the evaluation of medical procedures.

4.7.2 Perception of product according to stakeholders

The section below discusses to what extent operating room team members found the project to fulfill the RRI qualifiers of societal relevance and ethical acceptability. A first indication of such perception, is that many stakeholders consented. Finally 107 staff members explicitly consented, 1 staff member did not consent and it is unclear how many staff members do not hand in a consent form. All patients (8 in total) consented. The large number of participants indicates that many stakeholders perceived the product as socially relevant and ethically acceptable. The question is however why these stakeholders consented. Did sufficient societal relevance and ethical acceptability indeed cause them to participate? Under what conditions would they find the project most societally relevant and ethically acceptable?

Societal relevance

It seems indeed that both operating room team members perceived the project as societally relevant because it can contribute to patient safety. This caused #S1 to consent,

<quote removed to protect privacy of interviewees>

And although #S2 initially did not consent because he did not recognize the purpose of the project as societally relevant

<quote removed to protect privacy of interviewees>

Also #S2 recognized that video recordings can contribute to patient safety during our interview.

<quote removed to protect privacy of interviewees>

This indicates that although both operating room team members recognize a societal relevance, it was only sufficient for one of the two to make him take part in the project. One condition for societal relevance is mentioned by both #S1 and #S2.

Allow personnel to review recordings with expert A major condition for the societal relevance for both #S1 and #S2 is that operating room team members can learn from their own mistakes by reviewing the video recordings with an expert.

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This is not possible under the current conditions of use because the recordings can only be reviewed by the researchers. This indicates that the project would be more relevant for operating room team members if operating room personnel could review the recordings themselves, together with an expert on patient safety.

Ethical acceptability

It seems that the operating room team members perceived the project as partially ethically acceptable. The ethical acceptability of the project was sufficient for #S1 to consent after his criticism was used to improve the IRB protocol,

<quote removed to protect privacy of interviewees>

But #S2 did *not* find the project ethically acceptable. In the contrary, the ethical acceptability of the project was initially a barrier for him to consent,

<quote removed to protect privacy of interviewees>

And #S2 refrained from participation until practical reasons caused him to consent.

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This indicates that only one out of two operating room team members perceived the project as sufficiently ethically acceptable to consent. Various conditions can determine the ethical acceptability of video recordings for operating room personnel. Each of those conditions are discussed below.

Prevent unintended use Both #S1 and #S2 emphasize that the recordings should not be used for the other ends than the study.

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According to #S1 and #S2, this means that the recordings should not be used (1) by an employer to rebuke poor functioning, (2) by the Health Care Inspectorate (IGZ) in the case of a medical incident, because that would be

unfair compared to incidents that are *not* video recorded and (3) by patients, because that could cause misunderstandings since patients are usually not familiar with the daily practice of an operating room. This is in agreement with the conditions of use, which state that the video recordings can only be used for research ends and specifically not to rebuke poor functioning of employees.

Make recordings accessible to those observed Maximum ethical acceptability for the operating room team members is therefore attained if the recordings are only accessible to those who are recorded:

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Or, if that's not possible, observed personnel likes to be present when the recordings are reviewed, so that he can explain their actions.

<quote removed to protect privacy of interviewees>

This is not in agreement with the conditions of use, because the video recordings can only be accessed by the researchers.

Limit storage duration If the recordings are accessible to other audiences, the ethical acceptability for operating room team members is increased when the recordings are stored for a short time:

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For #S1 the storage period of the recordings in this project (of one year) was sufficiently short to take part in the project, but for #S2 this is too long. #S2 sees the time necessary for analysis of the data as a major holdup for quick removal.

<quote removed to protect privacy of interviewees>

This shows that the conditions of use are not in line with the wishes of one of the operating room team members.

Appropriate safety culture Furthermore the ethical acceptability of the video recordings for operating room personnel is determined by whether the hospital culture allows employees can discuss their own mistakes with their supervisors without being reprimanded.

<quote removed to protect privacy of interviewees>

Indeed the IRB protocol indicates that this such be possible and that executives should give a 'concrete signal' that recorded mistakes shall not be reprimanded.

Allow personnel to accustom to recordings Furthermore #S2 mentions that the ethical acceptability of video recordings in an operating room increases over time, as operating room personnel becomes more accustomed to the recordings and is less distracted by it during surgery.

<quote removed to protect privacy of interviewees>

This indicates that the ethical acceptability of this project low (because it is still new for operating room personnel) but might increase over time.

Overall, the video recordings in this project were sufficiently ethically acceptable to take part in the project for one of the two operating room team members. The ethical acceptability of the use of video recordings for operating room personnel could be increased if the video recordings were stored for a shorter period of time (for example by shortening the time necessary for analysis) and accessible to those observed. Furthermore the ethical acceptability of the video recordings may increase over time as personnel becomes more accustomed to them.

5 Conclusions

In this part of the thesis a framework on Responsible Research and Innovation (RRI) is applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery. The goal of this study is to formulate recommendations on the use of video recordings in observation of medical specialists during surgery and to provide insights on the practicality of the RRI framework.

In this chapter the sub questions and the main research question of this study are answered. The main question was to what extent the implementation and the conditions of use (research product) of the video cameras at the LUMC meet RRI qualifiers of processes and products. The study was guided by four sub questions: (a) What qualifiers of RRI processes and products does the literature prescribe? (b) What events (research process) preceded responses in general during the whole implementation of the video cameras? (c) What conditions of use were finally agreed upon?

Below, first the sub questions are answered and then the main question is answered.

5.1 Answers to the sub questions

This study was guided by four sub questions: (a) What qualifiers of RRI processes and products does the literature prescribe? (b) What events (research process) preceded responses in general during the whole implementation of the video cameras? (c) What conditions of use were finally agreed upon? Together these sub questions resulted in a set of qualifiers for RRI processes and products and a reconstruction of the case study on which these qualifiers could be applied to answer the main research question.

Sub questions (a) to (c) are answered below. Sub question (a) was already answered in Part A1 of this thesis, but its results are repeated here for convenience.

(a) What qualifiers of RRI processes and products does the literature prescribe?

The normative, theoretical literature on RRI describes both product and process qualifiers. The framework distinguished between five process dimensions (transparency, inclusion, reflexivity, anticipation and responsiveness) and a product dimension of RRI, each which had its own set of qualifiers (see Table 3 for an overview of these qualifiers).

Furthermore the framework explicated the interactions between RRI dimensions as they were proposed in the literature. Both transparency, inclusive, anticipatory and responsive processes were thought to contribute to the delivery of responsible products directly. Furthermore inclusive, reflexive, as well as anticipatory processes were thought to inform responsiveness and inclusion was thought to support reflexivity and anticipation. In turn transparency was thought to support inclusive and reflexive processes (see Figure 5 for an overview of these interactions).

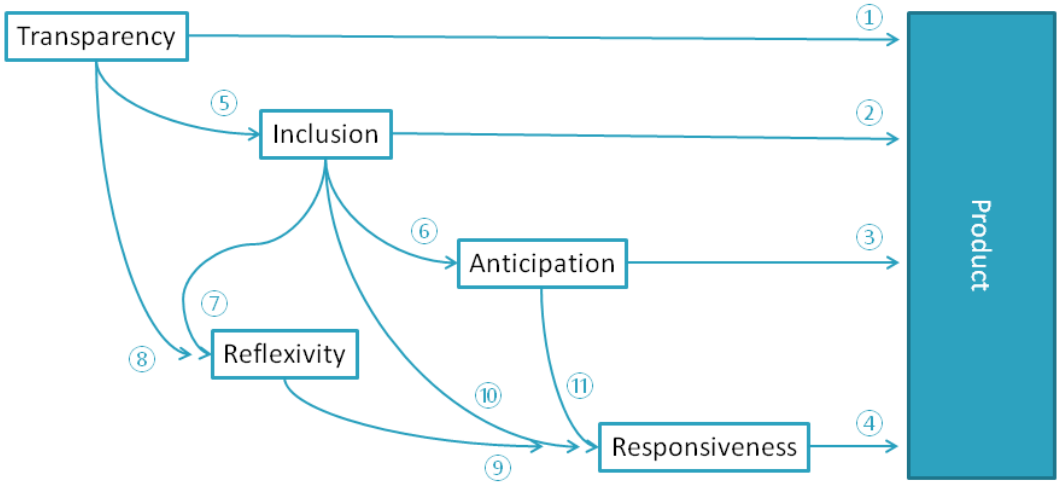

Figure 17 Theoretical interactions between RRI dimensions as described in the reviewed literature. All theoretical interactions presented in this overview are positive relationships, e.g. transparency was thought to support inclusion. Interactions ① to ⑪ are discussed under the rationales of the corresponding process dimension in chapter 1 Framework in Part A1 of this thesis, starting p. 15.

Table 8 Process and product qualifiers thought to support responsible research and innovation per RRI dimension. This summary was also presented in section 3.3 Framework summary in Part A1 of this thesis, starting p. 26.

Dimension	Qualifiers
Transparency - communicates the bases of decisions and the distribution of the responsibilities to external publics.	• Be transparent about assessment criteria • Be transparent about the role of stakeholders • Be transparent about any limitations with regard to transparency
Inclusion - takes in the societal aspects of an innovation, through e.g. stakeholder engagement.	Elicit meaningful contributions: • Include many, diverse and fundamentally different stakeholders • Inform stakeholders prior to inclusion • Frame discussion together with stakeholders • Empower stakeholders to contribute Allow product and process changes to occur in response to those contributions: • Include stakeholders from the outset • Include stakeholders for normative or substantive (rather than instrumental) reasons • Retain a receptive attitude to feedback
Reflexivity - helps a researcher to understand the social and ethical aspects of an innovation.	• Recognize how personal values, scientific norms and institutional limitations drive a decision • Challenge those drivers • Gain an understanding of how the product impacts society • Gain an understanding of how framing affects the inclusion activities
Anticipation - provides an overview of possible impacts and their alternatives.	• Define desirable societal (social, environmental, ethical and economic) impacts • Identify problematic societal impacts • Identify alternative routes to those impacts • Choose a both constructive and meaningful time to anticipate
Responsiveness - makes responsible decisions in research and innovation.	• Respond to societal perspectives • Respond swiftly to changing perspectives • Respond with substance
General	• Combine inclusive, reflexive, anticipatory activities

recommendations for RRI processes	• Repeat inclusive, reflexive, anticipatory activities throughout the process • Apply formal methods • Combine various methods
Product - the outcomes of research and innovation, including its academic findings as well as its marketable products.	Societal relevance • Aims to make societal (social, sustainability) contributions • Meets relevant ethical norms • Is sufficiently concrete so that it can be used in practice • Competes in current market economies Market competiveness (returns on investments) Scientifically high-quality

(b) What events informed responses in general during the whole implementation process of the video cameras?

Four types of events were found to inform a 'response', whereby a 'response' was defined as a change to the research protocol that was submitted to the Institutional Review Board (IRB), since this protocol contained a description of the conditions of use and therefore determined the research product.

The types of events that were found to inform responses included: interaction within the research team (allowing for reflexivity and anticipation), interaction with other actors (allowing for transparency, inclusion, reflexivity and anticipation), investigation of stakeholder perspectives without interaction (indicating inclusion) and the performance of a pilot study to test the product (allowing for reflexivity and anticipation). Two types of events did not occur during implementation (apply formal methods to support reflexivity or anticipation and individual reflection).

These events were mapped on a timeline from first inception in 2011 until first use in 2015. Eight distinct activities were identified, including Inception, Pilot study (1), Apply for board approval, Pilot study (2), Apply for funding, Install recording system, Seek participant consent, Renewing application for board approval, which were partially performed in parallel (see Figure 18).

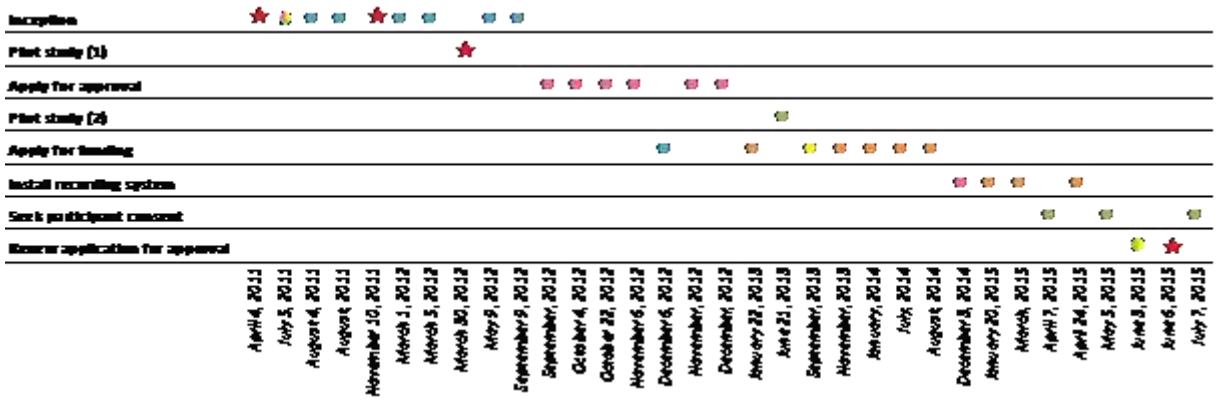

Figure 18 Schematic overview of the sequence of events during implementation of video cameras in the case study. Symbols indicate the type of event: ● interaction with advisors, ● interaction with authorities of approval, ● interaction with providers, ● interaction with study participants, ● interaction within the research team, ★ alteration of the conditions of use. Note that only events with a specific date were included in this overview.

(c) What conditions of use were finally agreed upon?

The conditions of use concerned the use of the video recordings, their set-up, access and storage. Together they described a system to record communication behavior of medical specialists during cardiac surgery. Main conditions of use included: the recordings could only be accessed by research personnel, was not part of the medical records of the patient and was not retrievable by the patient. The recordings were stored up until one year after analysis.

5.2 Answer to the main research question

The main question was to what extent the implementation process and the conditions of use of the video cameras at the LUMC met qualifiers of RRI processes and products. To that end, the implementation process as described under sub question (b) and the conditions of use as described under sub question (c) were analyzed with regard to the qualifiers presented under sub question (a). Two researchers (#R1 and #R2) and two operating staff members (#S1 and #S2) were interviewed to that end.

An evaluation of each of the RRI dimensions (process transparency, inclusion, reflexivity, anticipation, responsiveness, general process qualifiers, and product) is summarized below.

5.2.1 Transparency

Analysis of the implementation process showed great initiative on the side of the researchers to be transparent towards operating room personnel: presentations were held, a focus group was installed and the researchers spoke with operating room personnel informally. Indeed both researchers felt that they were very transparent. #R1 even indicates that next time he would be *less* transparent because it 'caused operating staff to meddle'.

Yet a lack of transparency about the purpose and about the potential risks of the project caused #S1 and #S2 to refrain from participation and express their concerns. Analysis of the key event shows that the organizational structure (such as departments) and indirect communication (through a focus group member) with #S1 and #S2 may have hindered transparency. Furthermore #S1 and #S2 may have perceived more risks to begin with, because the research project did not come from their department.

5.2.2 Inclusion

The researchers organized many inclusion activities and involved many actors. Analysis of the key event shows that #S1 and #S2 did not attend the activities however and that their concerns might have surfaced earlier if they would have attended. Further analysis indicates that operating staff did not feel inclined to join inclusion activities, because they did not perceive the meetings as urgent until #S1 spoke about the risks that he perceived.

The RRI framework lists three inclusion types, of which type 2 and 3 are considered most responsible. In the case study there was potential for all three inclusion types. In practice however, the inclusion activities only allowed for type 1 inclusion, which limited stakeholder contributions to improve the product. Furthermore these activities only took place after the IRB protocol had been approved and so stakeholders could not contribute to the contents or objectives of the study.

Both researchers perceived the criticism of #S1 and #S2 very differently, indicating that the way feedback is received varies from person to person and relates to the specific responsibilities of the researcher within a project.

5.2.3 Reflexivity

Reflexivity was usually intertwined with other RRI dimensions and therefore a large number of events could support reflexivity. Comparison of the two events in the implementation process suggests that direct interaction with stakeholders lead to reflexivity, whereas a lack of direct interaction did not necessarily contribute to reflexivity. Indeed, analysis of the key event indicates that #R1 understanding of the stakeholder's concerns was limited by his inability to speak with #S1 directly.

5.2.4 Anticipation

Alternatives to the use of video recording were hardly considered, but the specific conditions of use were repeatedly reconsidered, especially during the first phase of implementation. Interactions with stakeholders also contributed to anticipation, but their timing was too late to be meaningful. Analysis of the key event shows that although unplanned, anticipation could finally lead to responsiveness. It also indicates however that anticipation *until then* had not been entirely effective.

5.2.5 Responsiveness

Analysis of the key event (**Revision of the IRB protocol** ★, June 2015) indicates full responsiveness. Changes were made to the research protocol (and therefore substantial), those changes were made in response to the criticism of stakeholders (and therefore in response to societal perspectives) and made within a month of the first criticisms (and therefore swift). Interviews with operating staff showed however that it only partially satisfied the stakeholders whose perspectives it was a response to.

Further analysis showed that the researchers performed the response for three reasons. In part, the researchers responded because they felt it could improve the research protocol significantly. Furthermore they were greatly dependent on the opinions of these few staff members because they could influence others and so impede the study. And finally the opportunity arose, because #R2 had recently joined the project and the IRB protocol had to be updated anyway.

5.2.6 General process qualifiers

The RRI dimensions were thoroughly coupled, especially through stakeholder interactions which could simultaneously allow for transparency, inclusion, reflexivity and anticipation. Especially in terms of inclusion, many different methods were combined (informal interaction, formal sessions and indirect inclusion through a focus group). No formal methods were applied to support reflexivity or anticipation.

5.2.7 Product

Both operating room team members recognized the societal relevance of the project, although it would be more relevant to operating room team staff if they could review their own recordings with a safety expert.

The project was only sufficiently ethical acceptable for one of the two operating room team members to consent (the other consented only for practical reasons). The operating room team members suggest that the recordings would be more ethically acceptable if those observed could access the images and if the images were stored for a shorter period of time. Both staff members suggest the act of recording surgeries may become more ethically acceptable over time as personnel becomes less distracted by it.

The researchers express no desire to commercialize the product in the IRB protocol and it can therefore not compete in current market economies.

In terms of scientific quality, the protocol emphasizes that video recordings can increase the scientific rigor of the results, because they are the ‘leading objective method’ to analyze communication during surgery, provide a broad context to the data and prevent bias because they do not disturb the surgical process as much as a human.

6 Discussion

The goal of this study was to formulate recommendation on the responsible implementation and use of video cameras in operating team research. To that end, a framework on Responsible Research and Innovation (RRI) was applied in a case study at the Leiden University Medical Centre (LUMC), where video recordings were used to study communication during cardiac surgery.

In the previous chapter the main research question was addressed, indicating to what extent the case study met RRI qualifiers according to researchers and operating room staff. In this chapter the results are used to formulate recommendations on the responsible implementation and use of video cameras in operating team research.

First the results are used to formulate recommendations for the responsible implementation and use of video recordings in operating team research (6.1). Secondly the results are used to reflect on the RRI framework (6.2). Finally the limitations of the case study methodology are discussed (6.3) and the chapter closes with a few closing remarks on future research.(6.4)

6.1 Recommendations for the responsible implementation and use of video cameras in operating team research

The premise of this study was that video-based operating team research can make significant contributions to patient safety in the operating room. This study sought to find out whether its scientific interests can balanced with the interests of operating room personnel in set of responsible conditions of use and based on a responsible implementation process.

The results suggest that indeed that the conditions of use determine the societal relevance and ethical acceptability of the product according to operating room staff. Therefore recommendations for the responsible use of video cameras in operating team research should address the conditions of use (see Box 1, p. 78).

Furthermore the results suggested that indeed (a lack of) RRI qualifiers played a role in the implementation process of video cameras in this case study. Therefore also recommendations for the responsible implementation of video cameras in operating team research should be included (see Box 1, p. 78).

6.2 Discussion of RRI framework

In this study, a theoretical framework on RRI was applied in case study. What does this mean for the framework itself? Three insights are presented below: (1) responsiveness is not necessarily an indication of RRI, but a response can point to RRI potential, (2) RRI should not only emphasize that stakeholders should be included, but also that stakeholders should be allowed to *refrain* from inclusion, (3) ‘bypassing’ responsiveness to increase the popularity of a product directly can be responsible as long as the product already meets RRI qualifiers.

6.2.1 A methodology to assess RRI

The stakeholders were interviewed about a change that was made to IRB protocol in June 2015. This response met all RRI qualifiers, because it was substantial, swift and a response to societal perspectives. The interviews showed however that these qualifiers do not signify RRI per se. If societal perspectives for example are wrongly understood by researchers, these can lead to changes that no one was asking for. In this case study for example, #S2 was not satisfied with the changes because they didn’t provide ‘the assurances’ that he was asking for, while the researchers believed to have completely fulfilled his needs.

Furthermore, a response that is to the advantage of one stakeholder group may negatively affect another. The change to the IRB protocol in this case study for example limited patient access to the recordings. Therefore *not* changing the product may also indicate RRI, as long as it is a well-informed and balanced consideration of various societal perspectives. This is line with the vision that research or innovation can only be responsible if it

couples various RRI dimensions. Overall, the qualifiers for responsiveness as defined in Part A1 cannot indicate RRI on itself.

What responsiveness *can* indicate however – and for which it was used in this study – is RRI *potential*. The methodology that was developed in this study was based on the following logic: any substantial changes to a product indicate that a response has taken place. RRI prescribes that a response should be informed by transparent, inclusive, reflective and anticipatory processes and that it should contribute to a product that is a societally relevant and ethically acceptable. Therefore, if analysis centers on what processes preceded the response and what product value this response resulted in, the results can indicate to what extent a research or innovation is responsible. In other words, a response can point to interesting aspects of an innovation process (RRI potential) and so facilitate its analysis.

6.2.2 Extended framework: allow stakeholders to *refrain* from inclusion

Currently the framework only states that stakeholders *should* be included in RRI. Analysis of this case study suggests that stakeholders should also have the opportunity to *refrain* from inclusion.

The researchers in the case study were keen to give operating room staff the opportunity to refrain from participation. This is clear from the IRB protocol,

> <quote removed to protect privacy of interviewees>

As well as an email to operating room staff on June 21, 2013:

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Both operating room team members said to appreciate this capacity to refrain from participation.

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In practice however, stakeholders in the case study could hardly refrain from participation for two reasons. For one, there was great desire among operating room personnel to support their colleague,

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Which is both an indication of a social, collegial atmosphere at the thorax surgery department as well as an indication of a social pressure to participate in the study. Secondly, operating room staff could hardly refrain from participation for practical reasons. The crucial factor for #S2 to take part in the project, was that he had already committed to a patient whose surgery was going to be recorded (see quote p. 67).

These mechanisms made it difficult for operating staff to refrain from participation. At the same time, the researchers also couldn't *let* operating room staff refrain from participation, because any declining team members could raise questions and 'trigger' others. This was the fear of #R1 when #S1 expressed his criticism (see quote p. 64).

As a result, the researchers took care to meet the needs of two critical staff members, even though the IRB protocol had already been approved and most operating room staff had already consented to take part in the study. Since the project was not equally reliant on patients (because they were individuals who could not singlehandedly impede the study), such pressure to obtain unanimous support from operating staff can put patients at a disadvantage.

Overall, the pressure to obtain unanimous support from operating staff both deprives staff from their right to refrain from participation and can put patients at a disadvantage. Arguably these are indications of irresponsible innovation. The RRI framework currently provides no qualifier on this aspect however. Therefore the framework should be extended. Currently the framework only states that stakeholders should be included in RRI. Perhaps a inclusion qualifier should be added stating that RRI should also provide stakeholders with the opportunity to *refrain* from inclusion.

6.2.3 Short-cuts can be responsible

In the discussion of the theoretical framework (in Part A1 of this thesis), interactions 1 – 3 were discussed, because they allow transparency, inclusion and anticipation to 'bypass' responsiveness. These were described as short-cuts: ways to increase the popularity of a product without having to improve the product itself. In Part A1, the question was raised to what extent these short-cuts can be called 'responsible'.

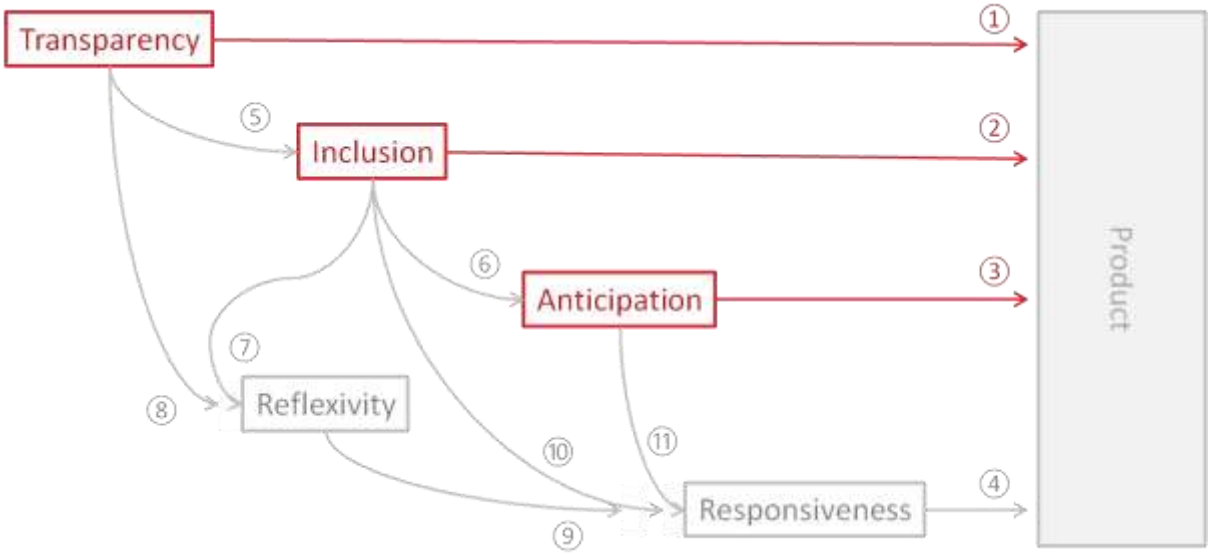


Figure 19 Transparency, inclusion and anticipation were considered qualifiers of RRI partially because they can contribute to the delivery of responsible products directly (interactions 1 – 3). This puts them at risk of being used as short-cuts; ways to produce responsible products without having to change the product in response to societal perspectives (responsiveness).

In this case study, transparency and inclusion were repeatedly used to create support for the product (interactions 1 and 2). The fact that these interactions can make a project more RRI is illustrated by staff member #S2. #S2 missed these activities and was ill informed about the project and its intentions, causing him to refrain from participation.

<quote removed to protect privacy of interviewees>

Seeing how #S2 refined his opinion about the purpose of the project during our interview however, it seems that #S2 didn't necessarily disagree with the project, but just wasn't informed about it properly (see quote p. 58).

Therefore, transparency about the product might have increased its popularity within #S2, even without changing anything about the product through responsiveness. It seems indeed that interactions (1-3) can be used responsibly, as long as they are used to provide clarity on a product that already meets RRI qualifiers.

6.3 Limitations of case study methodology

In this study, a case study methodology was applied with several limitations.

A major limitation of this study is that the perceptions of patients were not considered; only researchers and operating room team members were interviewed. Patients may have other perceptions of what conditions are

ethically acceptable than operating room staff, because they have other interests. The recommendations formulated in this study therefore are only responsible with regard to researchers and operating room staff.

Another limitation of this study is that only two operating room staff members were interviewed. These team members may not represent the views of the entire operating room staff. Reconstruction of the case study shows however that these were the only staff members of a roughly 100 person department who expressed criticism during implementation. Since the recommendations formulated in this study were based on these most critical views, the recommendations are likely to satisfy also the rest of the staff.

A third limitation of this study is that the implementation process under investigation took place one year before this study was performed. It is therefore possible that some details of the case were not reconstructed. This especially hampered the assessment of transparency and inclusion, because these contain qualifiers about very specific details of an event (for example whether researchers were transparent about assessment criteria, explaining *why* they took a certain decision).

6.4 Closing remarks

This single case study showed with the RRI framework, interesting mechanisms are laid bare with regard to the responsible implementation and use of video cameras in operating team research. Further research should therefore continue to perform multiple of such case studies to indicate which elements of this case study are representative for a wider sample. Cases could be located in the Netherlands as well as abroad to indicate the effects of legal frameworks in these mechanisms.

A premise of this study was that video cameras can improve patient safety through operating team research. In part of B of this study, video cameras are applied in a study on communication during cardiac surgery. The discussion of part B addresses whether video cameras can indeed improve patient safety in operating team research.

Box 1 Recommendations for the responsible use and implementation of video cameras in operating team research (addressed to researchers performing operating team research).

Responsible use

- **Review the recordings together with staff.** This increases the societal relevance and ethical acceptability of the recordings for staff, because it allows them to learn from the recordings and to have some power of the analysis of the recordings.
- **Start small.** An explorative study is less societally relevant for operating room staff. A pilot study with only a few number of recordings and participants allows you to develop a rigid study design with clear study objectives. Furthermore the ethical acceptability of video cameras may increase over time as team members become accustomed to them. A pilot study may help staff to become accustomed to the cameras. Thirdly, if only a limited number of staff members are involved, there is no need to obtain unanimous support from staff, which allows staff members to refrain from participation (see Discussion of RRI framework above).
- **Automate (parts of) analysis** to shorten the storage period. The storage period determines the risk of unintended use. A barrier for a short storage period in operating team research is the analysis of the recordings, which can take significant amounts of time. By automating (parts of) the analysis, storage duration is minimized.

Responsible implementation

- **Organize interactions with actors.** Use these to couple RRI dimensions by using them to inform stakeholders (transparency), obtain their feedback (inclusion and anticipation) and gain an understanding of their perspectives (reflexivity).
- In operating team research, make sure to **involve operating room staff before the first institutional review board (IRB) protocol is filed**. Operating room staff is responsible for the implementation of the outcomes of the study, therefore inclusion type 3 is warranted. Inclusion in the first phases of implementation allows you to develop research objectives together (indication of type 3 inclusion).
- Rather than organizing a large number of interactions with actors to increase transparency, make **sure to be transparent about the risks of the project for the stakeholders**. Explain why their consent needs

to obtained. This shows stakeholders which risks you have already considered. Furthermore it may create some level of urgency, which can facilitate inclusion because it can motivate stakeholders to join inclusion activities. Also it allows you to respond to questions directly (see also next point).

- **Make sure to speak directly with stakeholders**. This increases your understanding of their concerns. (reflexivity) and allows you to respond to questions directly, preventing their concerns from spreading across the department.

PART B.

COMMUNICATION DURING CARDIOPULMONARY BYPASS

1 Introduction

In the previous part of this thesis (part A), the implementation and use of video recordings in operating team research was analyzed. In this part of this thesis (Part B), video recordings are used in a study on communication during cardiac surgery at the Leiden University Medical Center (LUMC).

In this chapter the study is introduced, providing backgrounds to the research problem (1.1), presenting the research problem (1.2), the research objective (1.3), the research questions (1.4), the research approach (1.5) and an outline of the remainder of Part B (1.6).

1.1 Research background

During cardiopulmonary bypass (CPB) the function of heart and lungs is taken over by a heart-lung machine, so that the heart is still and can be operated on. A heart-lung machine mainly consists of a reservoir to collect deoxygenated blood, a pump to achieve systematic blood flow and an oxygenator to re-oxygenate the blood (see Figure 20).

CPB is an essential procedure in a wide variety of open-heart surgeries, including coronary artery bypass grafts and aortic valve replacements. 17,293 open-heart surgeries were performed in the Netherlands in 2012 and this number has been reasonably stable for the past five years (Vaartjes et al. 2013, p.28). The LUMC is one of 16 institutions performing open-heart surgeries in the Netherlands and performs 20 – 25 open-heart surgeries per week[3].

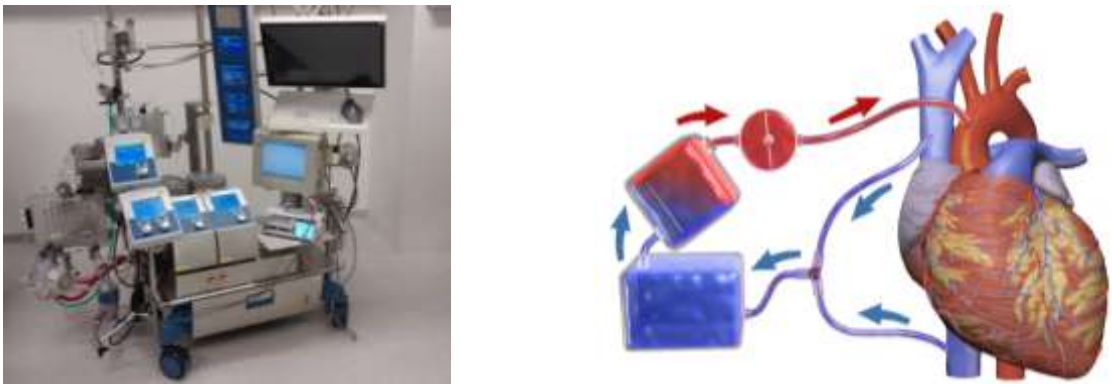


Figure 20 The heart-lung machine. On the left, a typical heart-lung machine used at the Leiden University Medical Center. On the right, a schematic diagram of the heart-lung machine. Deoxygenated blood flows into a reservoir, is oxygenated and pumped back into the body.

Figure 21 The team members who perform cardiopulmonary bypass together, from left to right: (a) the perfusionist, (b) surgeons, and (c) anesthesiologist.

CPB is mainly performed by a multidisciplinary team of perfusionists, surgeons and anesthesiologists. The perfusionists operates the heart-lung machine while the surgeon performs the surgical procedure and the anesthetist manages the patient's sleep and pain levels (see Figure 21). Together with supporting staff, these

[3] Estimate of senior clinical perfusionist Araz Abbas.

make up a large surgical team of eight persons in total, working in ever-changing compositions. The thorax surgery department at the LUMC employs roughly 10 perfusionists, 10 cardiac surgeons, 10 anesthesiologist and nearly 100 nurses and other supporting staff.

1.2 Research problem

The coordination of activities between team members is essential during cardiopulmonary bypass, but sensitive to failure. It is essential, because the activities greatly depend on each another. For example, the perfusionist should administer a solution to arrest the heart as soon as the surgeon has placed a clamp on the aorta. The handbook on the conduct of cardiopulmonary bypass described the importance of these team members functioning in concert as 'without equal in the practice of medicine' (Kurusz et al. 2000, chap.27).

Any coordination is challenged however, because the perfusionist cannot see the surgical site and the surgeon cannot see the perfusionist (see Figure 22). Therefore, most information is shared verbally. Verbal communication is susceptible to failure however: it was reported as both the most common type of minor failure as well as a feature in most major adverse events during cardiac surgery (Catchpole et al. 2007; Catchpole et al. 2006). Especially communication between the perfusionist and surgeon is critical because "there is no other layer of defense for this interaction… if misunderstanding occurs" (Santos et al. 2012, p.6).

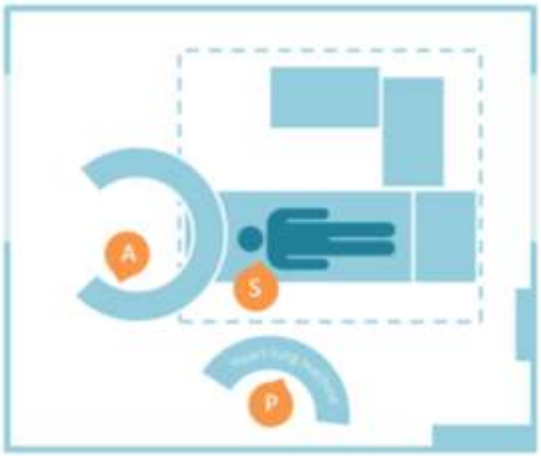


Figure 22 Schematic map of the operating room. Position of the perfusionist (P), surgeon (S) and anesthesiologist (A) in the operating room are indicated in orange. Note that they can hardly see each other's face and are therefore forced to coordinate their actions verbally.

The mechanism that allows for communication failure, is communication inconsistency. Communication was found to be highly inconsistent in general surgery (Lingard et al. 2004) as well as in cardiac surgery. (Santos et al. 2012) observed that during cardiac surgery 'there was an evident lack of systematization and homogeneity of communication between different team members in terms of time and in form of content. The same information was given in different ways at different times, even by the same person.' Standardization of communication practices could reduce the number of communication failures per surgery.

Many have therefore attempted to standardize communication during cardiopulmonary bypass. The literature reports the development of communication protocols (Wadhera, 2010), preoperative briefings (Henrickson et al. 2013) as well as team trainings (Fouilloux, 2014; Hicks, 2011; Melchior, 2012; Sistino, 2011). Furthermore assistive devices were developed to compensate for a *lack* of communication consistency (Parush, 2011). The LUMC is currently planning to build a new heart lung centre, providing ample opportunity to contribute to any of these developments.

A coherent definition of communication quality to inform such standardizations is lacking however. This is illustrated by the wide range of definitions used for communication failure. (Parush et al., 2011) for example includes any verbal sequence that is theoretically susceptible to breakdown, whereas (Wong et al., 2007) only includes those sequences that actually broke down and lead to an adverse event. One study did attempt to develop a communication standard for the verbal interactions of perfusionists (Melchior et al. 2012), but this

standard was targeted at perfusionists in training and lacked sensitivity when it was applied to experienced perfusionists.

Overall, coordination during cardiopulmonary bypass is essential but sensitive to failure. Standardization of verbal communication could reduce failure, but a coherent definition of communication quality to inform such standardizations is currently lacking.

1.3 Research objective

The goal of this study was to contribute to the *standardization of communication practices* by developing a *quality standard* for the critical *verbal exchanges* between surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. Each of the key terms (in italics) are defined below.

Standardization of communication practices could be achieved with a wide range of interventions, including communication protocols, preoperative briefings and team trainings. The *quality standard* developed in this study is composed of two elements: a list of critical events to verbalize and a set of quality criteria describing the way in which these events should be verbalized. In this study, a *verbal exchange* is a verbal interaction about one event between two or three sub teams, and may include several verbal sequences (e.g. first a question and then an answer).

The goal of this study therefore is to develop a list of events critical to verbalize and a set of quality criteria to assess the verbalization of these events with. Such a quality standard may inform the development of interventions such as communication protocols and team trainings and so help to standardize communication practices during cardiopulmonary bypass.

1.4 Research question

If the communication quality standard developed in this study is to inform intervention development, the following research question should be answered:

Main research question. To what extent do critical verbal exchanges between surgeons, anesthetists and perfusionists during cardiopulmonary bypass at the LUMC currently meet theoretical quality criteria?

Sub questions.

a) What quality criteria does the literature on communication during cardiopulmonary bypass recommend with regard to a critical verbal exchange?
b) What events are recurrently verbalized during cardiopulmonary bypass procedures?
c) Which of these are critical to verbalize according to surgeons, anesthetists and perfusionists?

An answer to sub question (a) results in a set of theoretical quality criteria. An answer to sub question (b) results in a list of events that *can* be verbalized during cardiopulmonary bypass at this institution. Answer to sub question (c) results in a list of events that *should* be verbalized during cardiopulmonary bypass at this institution. Applying the quality criteria from question (a) to the way that critical events are currently verbalized (c) results in an assessment of critical verbal exchanges between surgeons, anesthetist and perfusionists during cardiopulmonary bypass at the LUMC (main research question).

1.5 Research approach

Sub question (a) is answered based on a systematic review of the literature on communication during cardiopulmonary bypass. This review is presented elsewhere (see enclosed Literature review, May 2016). For convenience, the results are summarized and repeated in this thesis (see chapter 1

Theoretical background, p. 89).

Sub question (b) is answered based on the analysis of six video recorded cardiopulmonary bypass procedures. The analysis results in a list of events that *can* be verbalized during cardiopulmonary bypass at this institution.

Sub question (c) is answered based on interviews with practitioners. Two surgeons, two anesthetists and two perfusionists indicate whether they find an event critical to verbalize or not during a round of structured interviews. Any disagreements are resolved through a focus group session. Together the interviews and focus group session result in a list of events that specialists at this institution find critical to verbalize.

The main question then is answered by applying the quality criteria from (a) to the verbalization of critical events (c) in the same six recordings that were used to inform the initial list of events. The results provided both insights on the current quality of verbal interaction at this institution as well as the applicability of the communication quality criteria. The research process is summarized in Figure 23.

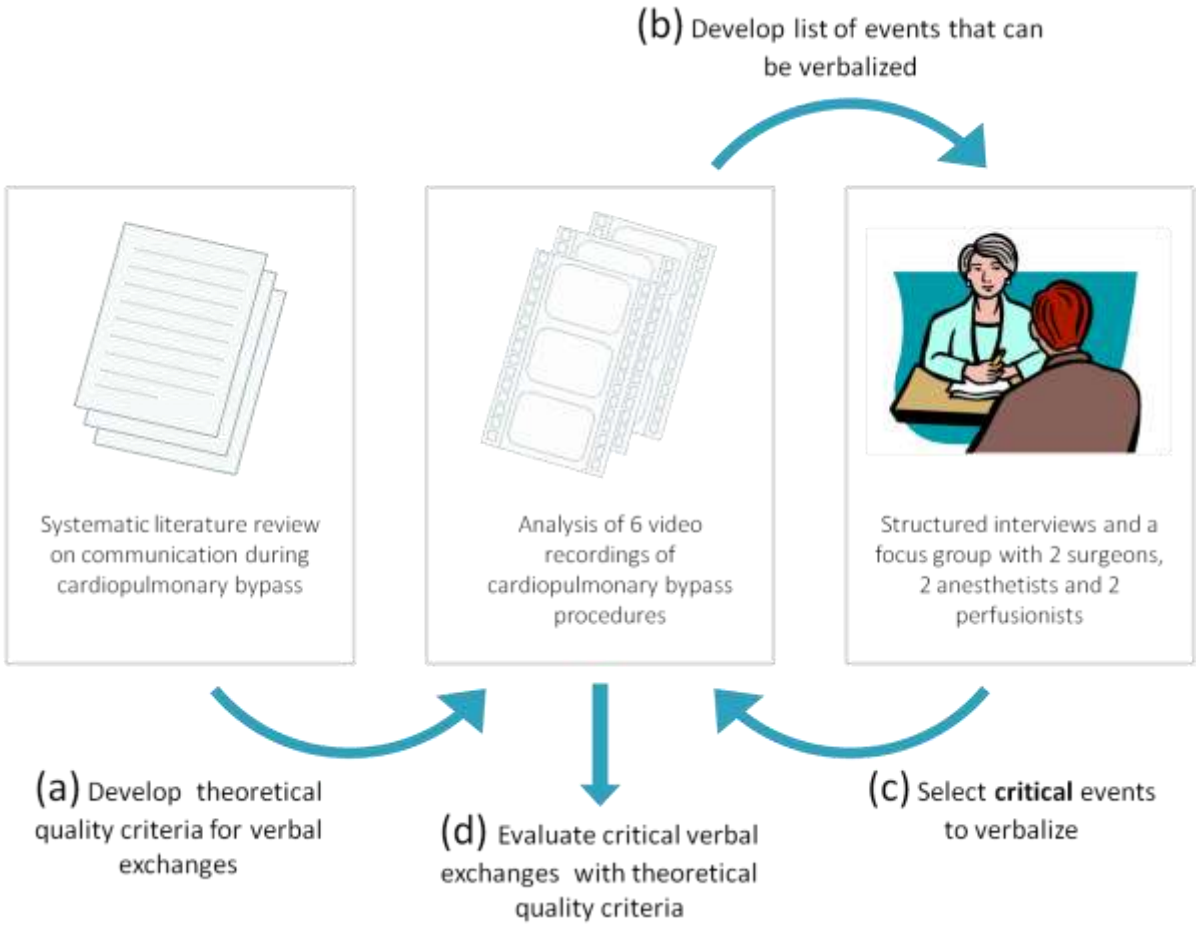


Figure 23 Summary of the research process. A systematic literature review was performed to develop a set of quality criteria. Video analysis of six recorded observations resulted in a list of events that could be verbalized during cardiopulmonary bypass. Of these, surgeons, anesthetists and perfusionists selected events *critical* to verbalize. Together, the list of critical events and the set of quality criteria composed the communication standard. The standard was applied to the same recordings that were used to develop the set of events so as to provide insights on the current quality of verbal interaction at this institution as well as on the applicability of the communication standard.

1.6 Outline of Part B

The answers to the research questions are presented in the following sections of this report:

Main research question. To what extent do critical verbal exchanges between surgeons, anesthetists and perfusionists during cardiopulmonary bypass at the LUMC currently meet theoretical quality criteria?	Results, starting p. 104

a) What quality criteria does the literature on communication during cardiopulmonary bypass recommend with regard to a critical verbal exchange?	Theoretical background, starting p.90
b) What events are recurrently verbalized during cardiopulmonary bypass procedures?	Results section 4.2.1 Recurring events, p. 103
c) Which of these are critical to verbalize according to surgeons, anesthetists and perfusionists?	Results section 4.2.2 Critical events p. 104

2 Theoretical background

In this part of this thesis, video recordings are used to develop a quality standard for the verbal interactions of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. In the previous chapter, the research problem and research approach were introduced. In this chapter, the theoretical background to this approach is presented.

First the definition of a single verbal exchange is presented and then theoretical quality criteria for such an exchange are listed. The results presented here were obtained through a systematic review of the literature on communication during cardiopulmonary bypass, which is presented elsewhere (see Literature review May 16, 2016).

2.1 Definition of a single verbal exchange

Studies that tried to categorize communication failures repeatedly mentioned their lack of consistency as a major limitation (Lingard et al. 2004; Hu et al. 2012; Halverson et al. 2011). The consistency of a verbal exchange-based study greatly relies on its definition of a single verbal exchange. Therefore in this study, a method was sought to define a single verbal exchange reliably.

In this study, each verbal exchange was characterized with respect to its exchange type. These types were adopted from (Hazlehurst et al. 2007), who observed that all communication exchanges during cardiopulmonary bypass fall into one of six distinct categories: Direction, Goal-sharing, Status, Alert, Explanation and Problem-solving. As such, a *verbal exchange* in this study is a verbal interaction about one event between two or three sub teams, and may include several verbal sequences (e.g. first a question and then an answer). The exchanges were applied mutually exclusively (meaning that one sequence was never part of two different exchanges) and comprehensively (meaning that all sequences were attributed to an exchange) to further increase reliability.

The exchange types of (Hazlehurst et al. 2007) were adopted, because (Hazlehurst et al. 2007) provides a theoretical framework that related each of its exchange types to team situation awareness (see Table 9). Since team situation awareness is an important condition for the coordination of tasks in teams, classification according to these verbal exchange types was thought to provide insights into the failure mechanisms of coordination during cardiopulmonary bypass. Furthermore (Hazlehurst et al. 2007) described each exchange type in detail, so that they could be applied validly and reliably.

Table 9 Examples of verbal exchanges and their contribution to Team Situation Awareness (TSA) as published in (Hazlehurst et al. 2007). S – surgeon, P – perfusionist

Verbal exchange type	Example	Contribution to TSA
Direction—command an action that seeks to transition the activity system to a new state	S: Flush cardioplegia P: Flushing	(1) directly determine the current state of the system
Status—create shared understandings about the current state	S: Clamp is on.	(2) reflect and create understandings of the current state of the system
Alert—convey abnormal or surprising information about the current state	S: Fibrillating	
Explanation—create a rationale for the current state	S: Let's go to 750. She's got a good arrest, ventricle's empty. You can see it on the echo, that empty ventricle, it's not distending	
Goal sharing—create expectation of a desired future state	P: Is that going to be our next dose, or will it be cold?	(3) establish expectations about future states of the system
Problem solving—reason toward a more complete understanding of the current state	A series of turns that include alerts, explanations, directions, status reports, and goal sharing.	

2.2 Qualities of a single verbal exchange

The literature reports a wide variety of indicators that may be used to assess the quality of a verbal exchange. This review grouped those indicators in four verbal exchange qualities: breakdown resilience, purposefulness and consistency (see Figure 24). Each of those qualities is discussed in more detail below. The aspect of accuracy is only relevant in an educational setting and since a professional setting is under investigation here, accuracy is not further discussed here.

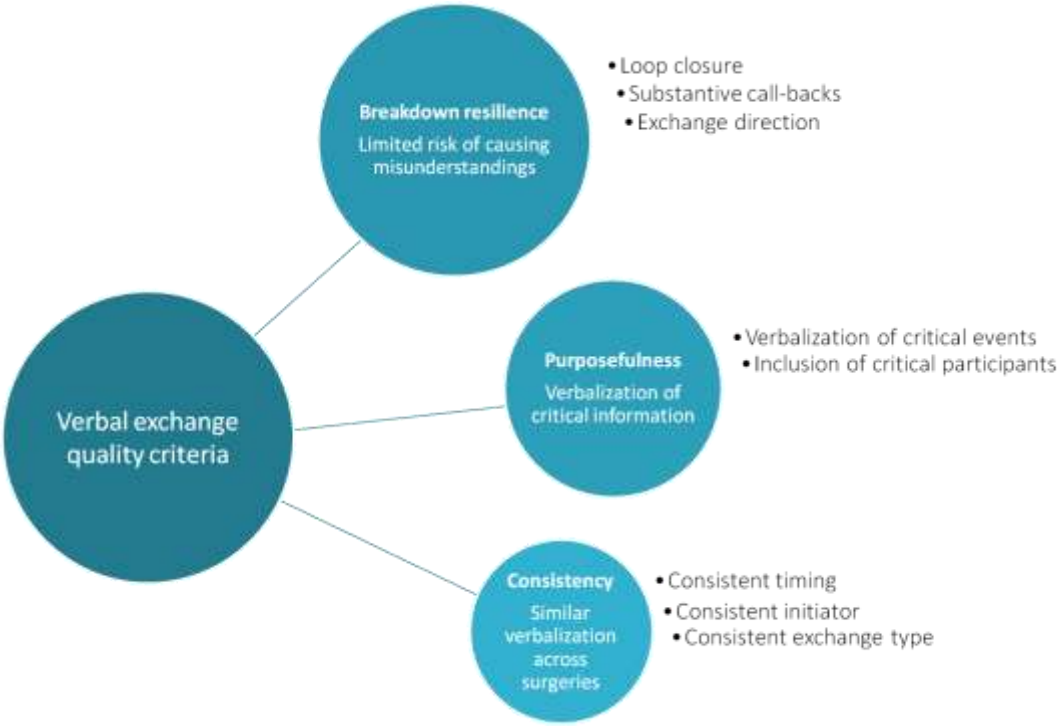


Figure 24 Overview of the qualities of a verbal exchange reported in the literature.

2.2.1 Breakdown resilience

In the literature, resilience verbal exchanges were thought to limit risk of causing misunderstandings and so optimize team situation awareness (Parush et al. 2011). In this study, three aspects of a verbal exchange were considered to affect its breakdown resilience: loop type, call-back type and whether an exchange is directed towards a specific team-member (direction).

Loop type Several reports stressed the importance of loop closure in communication (Catchpole et al. 2008; Santos et al. 2012; Parush et al. 2011; Wadhera et al. 2010; Weller & Boyd 2014; Kurusz et al. 2000). The studies applied different definitions of loop closure however. This study distinguishes between three types: open-loop, call-back and closed-loop communication. In *open-loop communication* a sender initiates a sequence but receives no feedback. In *call-back communication* the initial sender obtains feedback from the receiver (Wadhera et al. 2010) and in *closed-loop communication* the initial sender also replies to that feedback (Santos et al. 2012; Parush et al. 2011) (see for a schematic representation of these three models Figure 25).

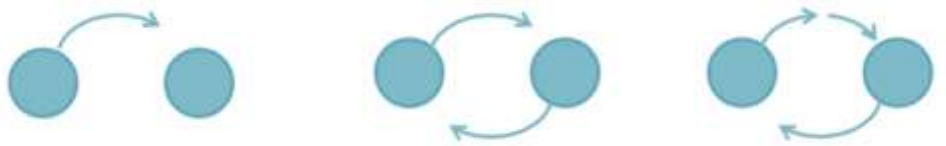


Figure 25 (a) open-loop communication (b) call-back communication (c) closed-loop communication

It seems that loop closure is an ordinal variable which can be attained at three different levels with varying degrees of susceptibility to breakdown. Open-loop communication is referred to as the most susceptible to

breakdown, whereas call-back is more resilient. (Kurusz et al. 2000, chap.27) wrote for example that 'all instructions or announcements should be followed by an acknowledgment from the person to whom it was directed. In this manner, errors of omission will be minimized and the surgical procedure can proceed expediently.' Closed-loop exchanges are regarded most resilient with regard to communication breakdown (Parush et al. 2011), because the initiator double checks the call-back to insure his message was received as intended.

Call-back type An aspect of a verbal exchange that was not mentioned in the literature but considered an indication of verbal exchange resilience in this study anyway, was call-back type.

This study distinguishes between two call-back types: substantive and insubstantive call-backs. Whereas insubstantive call-backs were defined as giving no other information other than affirmation (e.g. 'yes', 'ok', etc.), substantive call-backs were defined as containing content. These could for example be repeated instructions.

In this study, substantive call-backs were considered more resilient to breakdown than insubstantive call-backs, because they give the initiator more information about how the information was received.

Direction (Parush et al. 2011) hypothesized that communicating towards no one in particular provides opportunity for information loss and therefore stated that exchanges should be properly directed towards a specific team member. According to the observations of (Santos et al. 2012) this technique is especially relevant when team members cannot make eye contact:

> *"Another detected communication strategy was calling the receiver's name at the beginning of an utterance to avoid doubts about the audience. This was usually the case with surgeons who usually did not stop looking at the patient chest when talking to their colleagues, or the perfusionist who had the heart-lung machine in front of him and so was not able to look directly at his team mates."* (Santos et al. 2012)

2.2.2 Consistency

On the basis of a quantitative observational study of cardiopulmonary bypass procedures (Santos et al. 2012) concluded : 'There was an evident lack of systematization and homogeneity of communication between different team members in terms of time and in form of content. The same information was given in different ways at different times, even by the same person.'

The implication is that inconsistent communication is more likely to be misunderstood or forgotten than consistent communication. This claim is also supported by (Wadhera et al. 2010) who attempted to standardize communication practices.

The literature lacks insights on what aspects of a verbal exchange need to be consistent in order to improve breakdown resilience is needed. Inspired by the quote from (Santos et al. 2012), in this study the following three aspects of consistency are considered: consistency of timing, initiator and exchange type.

2.2.3 Purposefulness

Some events are more critical to communicate than others. For the effective and safe coordination of cardiopulmonary bypass activities, it is essential that at least the most critical information is verbalized.

A definition of such 'critical information' is provided by handbooks such as (Kurusz et al. 2000). According to (Kurusz et al. 2000, chap.27), perfusionists should communicate anything that can affect decisions on anesthesia to the anesthesiologist, such as 'fluid additions to the cardiopulmonary bypass circuit'. On his turn, the anesthesiologist should communicate anything that can 'affect the conduct of cardiopulmonary bypass' to the perfusionist, such as 'administration of a vasodilator that can alter the circulating volume of blood and cardiopulmonary bypass reservoir level'. Both anesthesiologist and perfusionist should communicate abnormal

conditions to the surgeon so that the surgeon can stay focused on the surgical site. Some abnormal conditions should be immediately communicated because they potentially jeopardize patient well-being (e.g. 'increased cardiopulmonary bypass arterial line pressure; sustained decreased venous drainage; nonfunctioning vent or sucker', etc.). Other abnormal conditions are also potentially damaging but less acute and can wait until an appropriate time presents itself (e.g. 'elevated serum potassium; lower than expected hemoglobin or hematocrit; higher than expected fluid volume requirements', etc.). Finally, the surgeon should alert the perfusionist when he is displacing the unarrested heart because 'surgical manipulations of the heart or major vessels may affect cardiopulmonary bypass' and instruct the perfusionist to momentarily decrease systematic blood flow to lower pressure in the aorta before applying the aortic cross-clamp.

Yet this general definition of 'critical information to verbalize' still leaves plenty of room for interpretation. This is illustrated by the way studies provide examples of successful and less successful exchanges, indirectly indicating what they consider to be 'critical information to verbalize'. Examples of successful verbalization in (Galvan et al. 2005): 'verbal sequences to go on, maintain, and come off bypass; verbal sequences to give heparin, protamine, and blood products'. Example of unsuccessful verbalization in (Henrickson et al. 2013): 'the surgeon not being informed that heparin was administered'. Examples of unsuccessful verbalization in (Wadhera et al. 2010): 'the perfusionist turning on the left ventricular vent when the surgeon wanted it off, the surgeon removing the crossclamp without informing the perfusionists, or initiation of re-warming without a shared understanding.

All in all there seems a general consensus about what is the *most* critical information to verbalize, but it is possible that studies and institutions hold different views about the details. For the application of this quality indicator it is essential therefore that a clear definition of what is 'critical information to verbalize' is provided. In this study therefore, specialists are asked to rate a list of items with regard to their criticalness to verbalize.

3 Methodology

In this part of this thesis, video recordings are used to develop a quality standard for the verbal interactions of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. In the previous chapter, the theoretical background to the research approach was described. In this chapter, the methodology of the study is described in four steps, analogous to the research questions.

First a set of quality criteria was developed based on a systematic literature review. The quality concepts were already introduced in the previous chapter. In this chapter their operationalization for the assessment of verbal exchanges is presented (3.1). Secondly, a list of events critical to verbalize was developed. To this end first a set of events that *could* be verbalized during cardiopulmonary bypass procedures was defined based on the analysis of six video recordings (3.2). Subsequently surgeons, anesthetists and perfusionists determined the criticalness of each of these events based on interviews and a focus group session (3.3). Finally the communication standard was applied to the same video recordings that were used to develop the list of critical events (3.4). Each of the four steps is described below.

3.1 Define quality criteria

Based on a literature review, qualities of communication were listed (for an in-depth discussion of these qualities see section 2.2 Qualities of a single verbal exchange, p. 90). Each quality was operationalized for the evaluation of critical events (see Table 10).

Table 10 Operationalization table. List of communication qualities and their corresponding measured aspects.

Communication quality	Quality aspect	Measured aspect	Measurement range	Source
Purposefulness	Verbalization of critical events	Number of cases a critical event was verbalized in	(1-6)	(Wadhera, 2010)
	Involvement of critical participants	Number of critical participants verbally present (as sender or receiver) per event	(1-3)	
Consistency	Consistent timing	Number of different surgical phases a critical event was verbalized in	(1-5)	(Santos, 2012)
	Consistent initiators	Number of different sub-teams that initiated an exchange about a critical event	(1-3)	(Santos, 2012)
	Consistent exchange types	Number of different exchange types used to verbalize a critical event	(1-6)	
Resilience to breakdown	Closed loop exchanges	Loop type	(open loop, call-back or closed loop)	(Catchpole, 2008; Kurusz, 2000; Parush, 2011; Santos, 2012; Wadhera, 2010; Weller & Boyd, 2014)
	Substantive call-backs	Call-back type	(insubstantive or substantive)	
	Directed exchanges	Whether an exchange is directed towards a specific team member with name	(undirected or directed)	(Parush, 2011)

3.2 Develop list of recurring events based on video analysis

The video recordings informed both the development of a list of events that could be verbalized during cardiopulmonary bypass as well as allow the evaluation of these cardiopulmonary bypass procedures according

to the communication standard. In the first case, the following steps were taken: record surgeries (3.2.1), transcribe any verbal coordination sequences relevant the procedure (3.2.2), group sequences into exchanges (3.2.3), group exchanges into recurring events (3.2.4). Each of these steps is described below.

3.2.1 Record surgeries

To record the surgeries, three video cameras and three microphones were used. The video cameras were set-up at different angles so as to provide an overview of the surgical process (see Figure 26). Two video cameras recorded the surgical procedure from two sides of the operating room, providing an overview of the surgical process as a whole, and one video camera was pointed at the surgical site to recorded the technical details of the surgical process. The microphones were attached to either walls or appliances present in the operating room, using one microphone for every sub-team.

Only one type of surgery was recorded, because the activities related to cardiopulmonary bypass can differ across surgery types. In this study, only coronary artery bypass grafting (CABG) surgeries were recorded, which is a type of surgery that improves blood flow to the heart muscle by creating a bypass around any blockages in the coronary arteries. This type of surgery was chosen because it is performed regularly at this institution (10 to 11 times per week), thereby providing ample opportunity for recording.

Of each surgery, the type of bypass graft (mammary arteries, veins, etc.) was documented, because this can influence the order of surgical steps taken and therefore the order of verbal sequences uttered. A venous graft for example necessitates an additional anastomosis on the proximal side of the graft (because it, unlike the other grafts, is taken from the leg and therefore is not naturally attached to the aorta on one side), thereby changing the time at which the aortic root needle is removed (because the vein is attached to the hole of the aortic root needle).

Figure 26 Picture of the video recording set-up. Two video cameras recorded the surgical procedure from two sides of the operating room, providing an overview of the surgical process as a whole. One video camera (not shown) was pointed at the surgical site and recorded the technical details of the surgical process.

Permission to record the surgeries was obtained from the institutional review board, works council and board of directors. Several safety measures were taken to safeguard the rights of those observed. Prior to recording, consent was obtained from all team members present and from the patient involved. During recording all personnel was made aware of the recordings with a sign (saying ‘recording in progress’) next to the operating room entrance points. All data was analyzed anonymously, only authorized researchers had access to the images and all images were destroyed within one year of analysis.

With a background in biomedical engineering and communication sciences, the main observer was trained in the specifics of cardiopulmonary bypass procedures over the course of six months through regular discussions with

specialists, the observation of five cardiac surgeries and the study of a handbook on cardiopulmonary bypass procedures (Kurusz et al. 2000).

3.2.2 Transcribe verbal coordination sequences

All verbal sequences relevant to the cardiopulmonary bypass procedure were transcribed, recording *at which time*, *what sub-team* uttered *which words*. Verbal sequences were considered relevant if they:

- Concerned the coordination of the cardiopulmonary bypass procedure
- Were uttered by a member of the surgical, anesthetic or perfusionist sub-team
- Directed at one of the other two sub-teams (excluding communication within sub-teams or with other sub-teams, and not distinguishing between members of a specific sub-team)

Sequences were defined such that each new sequence was either uttered by a new sub-team, or was part of a new exchange (see 3.2.3).

Initially only those surgical stages that were relevant either to initiation or weaning of the heart-lung machine were transcribed. To this end the surgery was divided into five surgical phases based on certain surgical events that occurred in every surgery and were marked based on video images of the surgical site (see Appendix, p. 151 for example images and Table 11 for the definition of phases). The definition of surgical phases was loosely based on the critical stages defined by (Wadhera et al. 2010). The definition of surgical events was chosen such that each event could occur during any of the CABG surgeries (using any type of graft).

If the list of events proved incomplete after the sequences were grouped into exchanges and events (see 3.2.3 and 3.2.4), also the adjoining surgical stages were reviewed for transcription. Of all those times that cardioplegia was administered per surgery, only the first time was reviewed, because cardioplegia is given an irregular number of times per surgery.

All relevant verbal sequences were transcribed with Noldus Observer XT © 2015 Noldus Information Technology, which allowed the review of the three video recordings in parallel (see Figure 27 for an example screenshot).

Table 11 Definition of five distinct surgical phases according to various surgical events.

Surgical event		Surgical phase
I.	Opening (first video image)	Preparation
II.	Incise skin	
III.	Apply mammaria retractor to spread chest	
IV.	Incise heart sac	
V.	Divide arterial and venous lines	Initiation of heart-lung machine
VI.	Insert arterial cannule (arterial cannulation)	
VII.	Connect arterial line to arterial cannule	
VIII.	Insert venous cannule (venous cannulation)	
IX.	Connect venous line to venous cannule	
X.	Insert root needle	
XI.	Place aortic cross-clamp	Clamp-time (main surgery)
XII.	Remove aortic cross-clamp	Weaning from heart-lung machine
XIII.	Remove aortic root needle	
XIV.	Remove venous cannule (venous decannulation)	
XV.	Remove arterial cannule (arterial decannulation)	Finish
XVI.	Ending (last video image)	

Figure 27 Example screenshot from software package Noldus Observer XT © 2015 Noldus Obsever Technology. Image source: http://www.noldus.com/.

3.2.3 Group sequences into exchanges

After transcription, all verbal sequences were grouped into verbal exchanges. An exchange could range any number of sequences, including one single sequence or as many as six or seven. Exchanges were defined according to their exchange type as described by (Hazlehurst et al. 2007) (see section 2.1 Definition of a single verbal exchange , p. 89).

In order to define a verbal exchange reliably, the exchange types were applied mutually exclusively (meaning that one sequence was never part of two different exchanges) and comprehensively (meaning that all sequences were grouped under an exchange). As such, a few adjustments were made to the exchange types as defined by (Hazlehurst et al. 2007) :

- **Problem solving** was defined as a separate exchange rather than a combination of exchanges as Halzehurst propose. Staying close the Hazlehurst's original definition ('steering towards a more complete understanding of the current state'), it contained all those exchanges that allowed a sub-team to propose / suggest a solution to an existing issue.
- **Permission** was added, defined as: request approval to further transition the activity system to a new state

For a complete list of exchange types applied, see Table 12 below.

Table 12 Definition of exchange types, adapted from (Hazlehurst et al. 2007).

Direction	"Command an action that seeks to transition the activity system to a new state"
Goal sharing	"Create expectation of a desired future state"
Status	"Create shared understandings about the current state (often initiated by request for information aka question)"
Alert	"Convey abnormal or surprising information about the current state (similar to status exchange but are generated by events that create a perceived deviation from the expected or desired system state. As such the information can imply consideration of a deviation from the expected actions to be taken)"
Explanation	"Create a rationale for the current state"
Problem solving	Steer toward a more complete understanding of the current state (altered)
Permission	Request approval to further transition the activity system to a new state (added)

3.2.4 Group exchanges into events

Exchanges were then grouped into events. This approach is similar to (Parush et al. 2011), who aggregated 'all sequences of shared situation-related information' into 'unique, non-overlapping and non-repeating information items' such as 'Heparin Requested, Heparin Administered, etc.'.

The events were defined iteratively. A first set of events was defined by an interdisciplinary team of specialists, including a perfusionists, thorax surgeon and anesthesiologist. Events were defined such that they could be verbalized with one single exchange, so that a event that was consistently verbalized with more than one exchange per surgery, was split into several sub-events. Events were phrased such that they held no information about what sub-team should initiate the exchange, or with what type of exchange the event should be communicated. Agreement on the definition of events was reached through recurring, individual discussions with specialists (both perfusionists, thorax surgeons and anesthesiologists).

3.2.5 Define recurring events

After grouping all exchanges in an event, the number of cases the event was verbalized in was measured. If the event occurred in at least two surgeries, it was defined as a recurring event and therefore presented to the specialists as an item that could be verbalized during cardiopulmonary bypass.

3.3 Define critical events with specialists

Based on the list of recurring events developed through video analysis, a set of critical events was developed with specialists. To this end specialists were interviewed and subsequently a focus group was held to resolve any disagreements.

3.3.1 Structured interviews

Six specialists (two from each sub-team) were asked to rate the criticalness of each of the events developed through video analysis. First, the interviewee rated all events on the list either as critical or non-critical. Then, the interviewee was asked to explain why this event was (non)critical for their specialism. Finally, the interviewee was asked whether he or she missed any events on the list. Any new items were added to the list in between interviews so as to maintain a complete set of events for every interview. Each second interviewee within the same specialism was confronted with any differences between answers, so as to establish a preliminary consensus between raters.

Each interview took 1 hour. To save time, one specialist (a surgeon) was not interviewed, but recorded her answers digitally. During the interview, notes were made on the interview form. Audio recordings were made and referred to when necessary during analysis. All interviewees were sent a summary of their answers and asked to correct any misunderstandings. See Appendix p. 154 for full interview protocol and p. 155 for interview form.

3.3.2 Focus group

A structured focus group was held to reach consensus about the criticalness of events and sub-teams involved. In addition to the specialists who had been interviewed earlier, also the department head from the thorax surgery department was present. As such, all three specialisms were represented during the focus group.

Prior to the focus group, all those invited were informed about the interview results (who rated what event as critical). During the focus group, the criticalness of events and sub-teams involved were discussed one by one. If the interview results contained conflicts about the criticalness of the event or sub-teams involved, a proposition was made (as to whether this event should be critical and whom it should be critical for) to guide the discussion.

The focus group took 1,5 hours in total. Again, audio recordings were made and referred to when necessary during analysis.

3.4 Apply quality criteria to critical exchanges in video recordings

Finally the communication criteria were applied to the same video recordings that were used to develop the list of critical events. The outcomes were both used to provide insights on the current quality of verbal interaction at this institution as well as the applicability of the communication standard itself.

In the analysis therefore, special attention was paid to explaining a high or low score on the communication standard. Two factors were hypothesized to have an effect on communication quality and their effect was always considered first:

- the number of sub-teams involved in a verbal exchange (2 or 3)
- whether the specialists initially disagreed on whether the item was critical to verbalize or not

After considering those two effects, analysis focused on trying to explain the score of the critical events that were particularly low-quality according to this communication standard. The explanations mainly drew from the discussions with specialists and the video analysis.

4 Results

In this part of this thesis, video recordings are used to develop a quality standard for the verbal interaction of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures.

In the previous chapter the methodology of the study was described, describing first how a communication standard was developed based on a set of theoretical quality criteria and a list of events critical to verbalize according to practitioners, and then how this communication standard was applied to six recorded cardiopulmonary bypass procedures.

In this chapter the results of that study are presented. First the recorded sample is described in terms of recorded surgeries, surgical phases, sequences and exchange types (4.1). Thereafter the list of events critical to verbalize according to practitioners is presented (4.2). Subsequently the evaluation of six cardiopulmonary bypass procedures according to the three quality criteria (purposefulness, consistency, breakdown resilience) is presented per criterion (4.3).

4.1 Sample description

In the following section the recorded sample is described. First the recorded surgeries are described in terms of graft type, staff type and duration. Then the verbal sequences are described in terms of their total number, their distribution across five surgical phases and their distribution across three participating sub-teams. Subsequently the exchange types that these sequences were group into are described. The section closes with a description of events that were uttered more than once in the video recordings (recurring events), a set of events that were considered critical by the specialists (critical events) and a set of events about which the specialists initially did not agree in terms of criticalness (conflicting events).

4.1.1 Surgeries recorded

In total 8 CABG surgeries were recorded, all showing good patient outcome. The surgeries recorded show a wide variety of graft types used (for an overview, see Table 13). Two recordings were discarded due to lacking audio quality (marked with an X). During these surgeries the radio was turned on in the operating room, making it impossible to transcribe and analyze the verbal sequences reliably.

Table 13 Surgeries recorded and their corresponding graft types.

Case	Graft type used
#1	LIMA RIMA
#2	LIMA vein
#3	LIMA RIMA
X	LIMA RIMA GEA
X	LIMA RIMA
#4	LIMA vein
#5	LIMA RIMA
#6	LIMA RIMA vein

LIMA: left internal mammary artery; RIMA: right internal mammary artery; vein: vein taken from patient's leg; GEA: gastroepiploic artery

In the six surgeries selected for analysis, a total of 5 different perfusionists, 6 different surgeons and 6 different anesthesiologists were observed. This is a random sample of a small thorax surgery department of in total 10 perfusionists, 10 thorax surgeons and 9 thoracic-anesthesiologists.

4.1.2 Surgical phases

All recorded surgeries took between 3 hours and 43 minutes (case #3) and 6 hours and 39 minutes (case #6). On average the recorded surgeries took 4 hours and 54 minutes. The surgical events were used to divide the surgeries into five phases. Most cardiopulmonary bypass activities are performed during Initiation and Weaning.

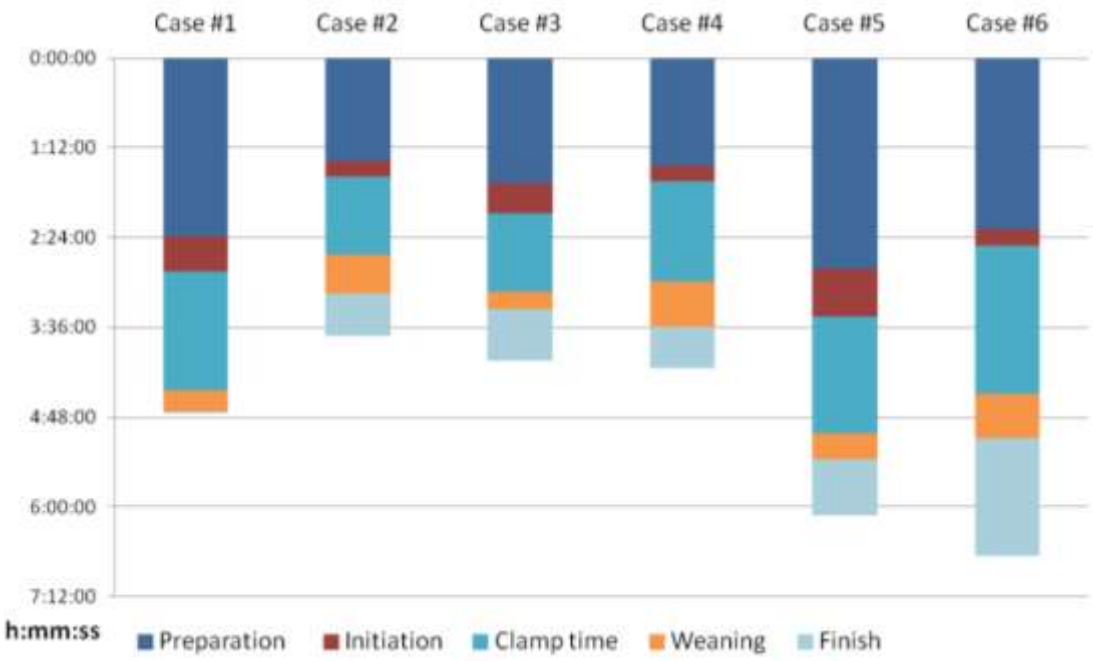


Figure 28 Duration of five distinct surgical phases (Preparation, Initiation, Clamp time, Weaning and Finish) across six recorded surgeries (case #1 to #6).

Initiation took 22 minutes ± 10 on average, and Weaning 26 ± 9 minutes, together accounting for roughly 16% of total surgery duration time. Cases with a venous graft (#2, #4 and #6) took twice as long to 'wean' than the other cases (averagely 34 minutes instead of 17 minutes) because a proximal anastomosis was made during this phase.

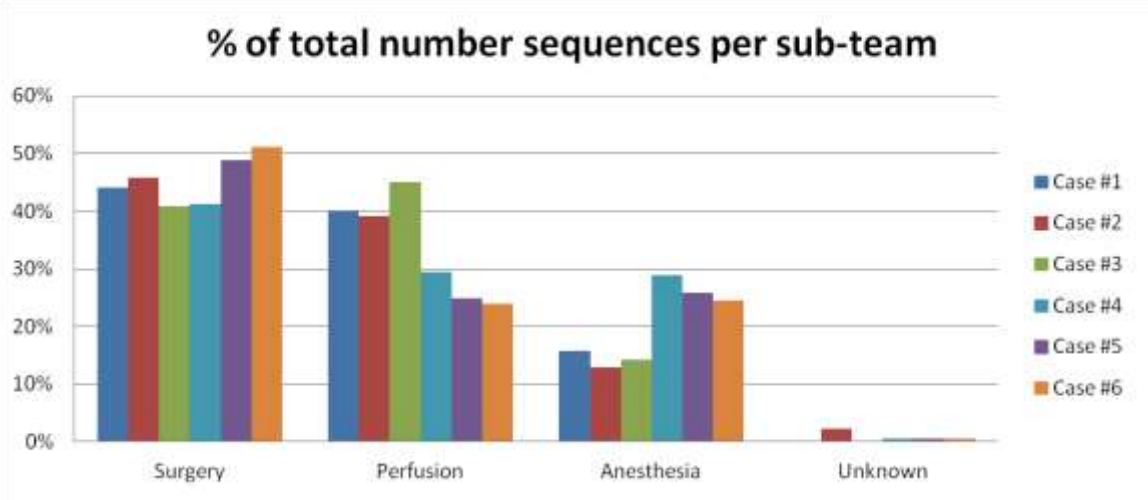
The most variable phase in terms of duration was Finish, which took anywhere in between 1 minute (case #1) and 1 hour and 34 minutes (case #6). Case #1 showed such a short Finish duration time, because the recording was stopped after the last cardiopulmonary bypass event was performed, but before the surgery was finished. Case #6 showed such a long Finish phase, because during this phase the patient had to go on bypass again to repair a leakage.

Noteworthy were also case #5, which took longer because it was used to train a cardiac surgeon trainee, and case #6, which took almost 2 hours to Clamp because *three* rather than two grafts were implemented.

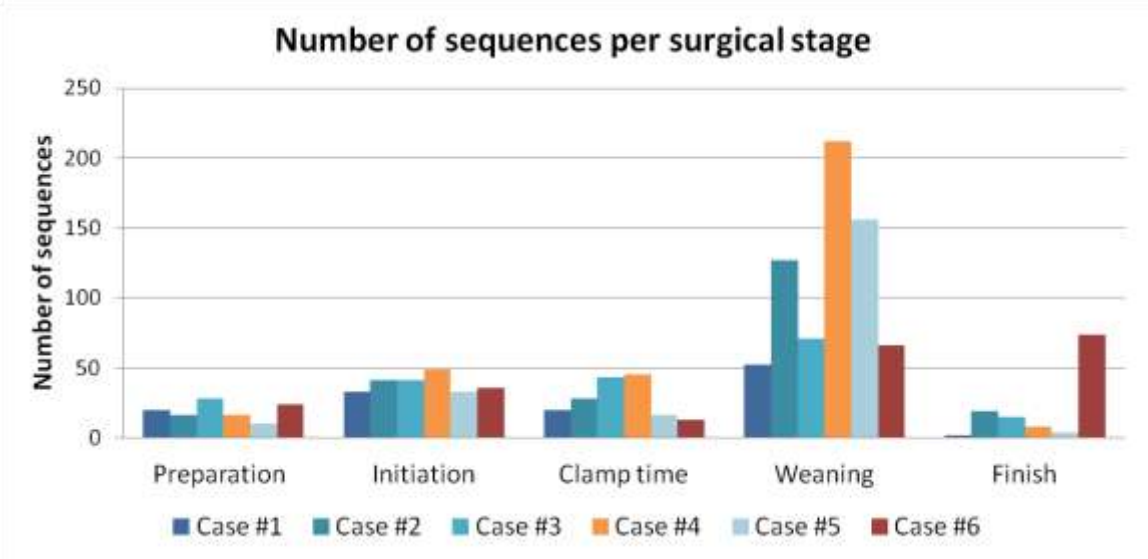
Phase	Average duration (h:mm:ss)	St. deviation (h:mm:s)	St. deviation (%)
Preparation	1:59:44	0:29:37	25
Initiation	0:21:38	0:09:30	44
Clamp time	1:25:30	0:19:42	23
Weaning	0:25:42	0:08:58	35
Finish	0:41:42	0:27:26	66

4.1.3 Sequences transcribed

Across all surgeries, a total number of 1314 sequences were transcribed, resulting in an average of 219 ±41 sequences per surgery. The surgical sub-team consistently uttered most sequences per surgery (on average 99 ±25 seq/surgery), the perfusionist uttered almost as many sequences per surgery (72 ±20) and the anesthetist was least verbally present during all communications about the cardiopulmonary bypass procedure (47 ±25). In total 9 sequences could not be attributed to any of the three sub-teams.



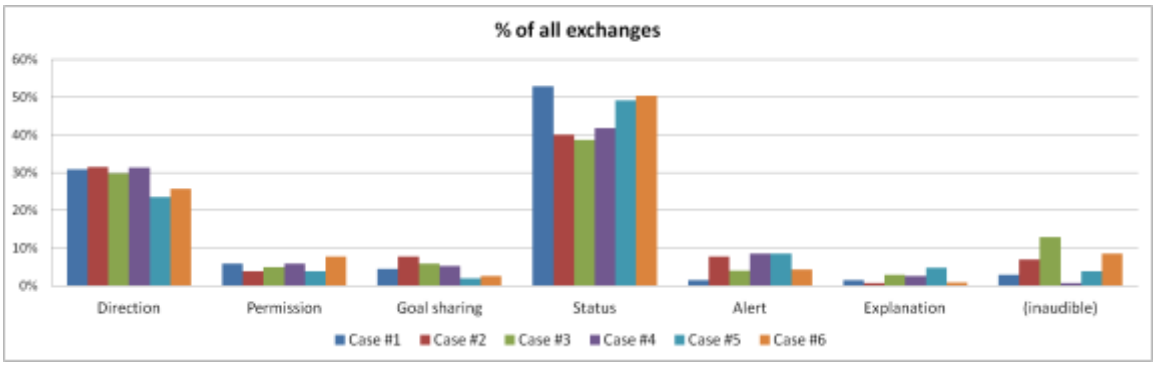
Most sequences related to cardiopulmonary bypass were uttered between cross-clamp removal and arterial decannulation (Weaning): on average 114 ±57 sequences. The least number of sequences related to cardiopulmonary bypass were uttered before dividing of the arterial and venous lines (Preparation), on average 19 ±6 sequences. Case #6 shows a large number of sequences during Finish, because during this phase the patient had to go on bypass again to repair a leakage.

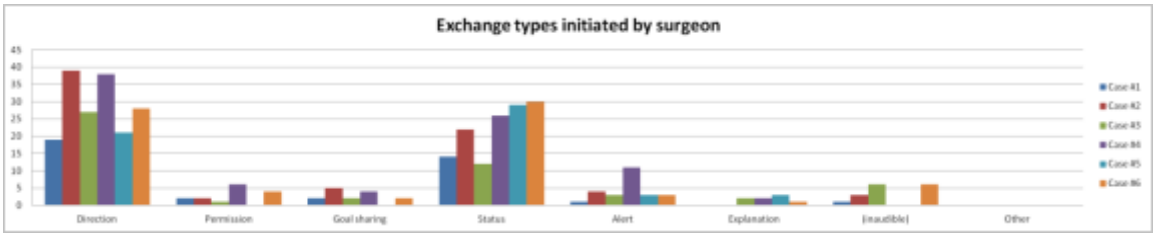


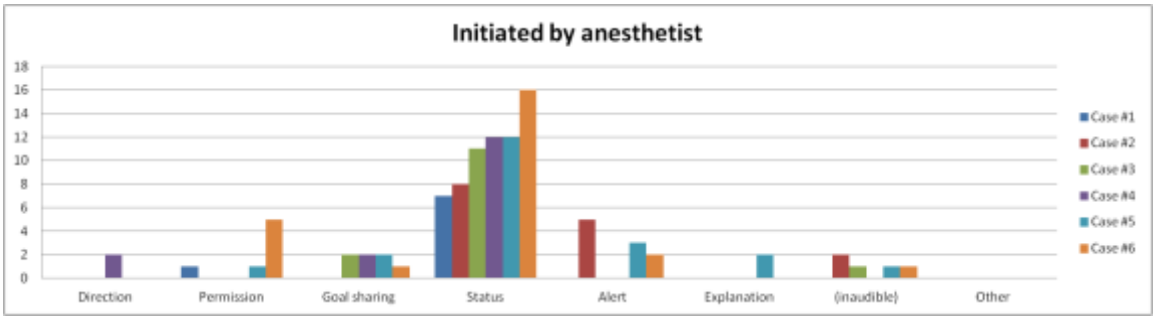
4.1.4 Exchange types

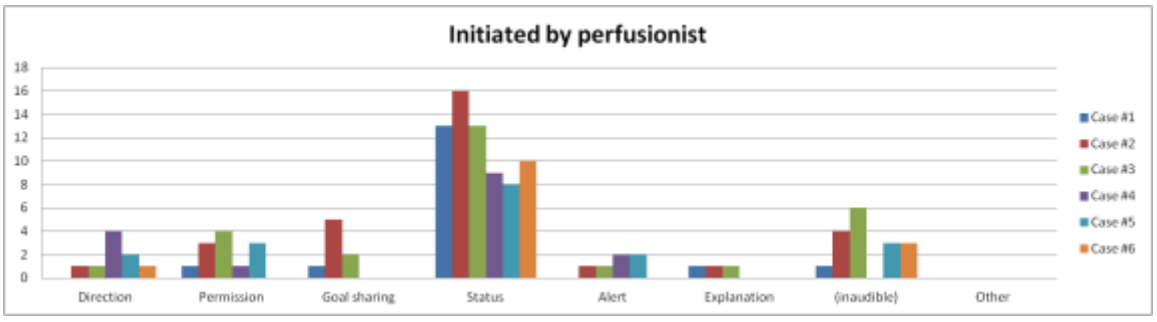
The sequences were grouped into a total of 674 exchanges, resulting in an average of 113 ±26 exchanges per surgery and 1.96 sequences per exchange.

By far the most popular exchange types were Status (50 ±10 per surgery) and Direction (33 ±9). Status exchanges were initiated by all sub-teams, whereas Direction exchanges were initiated mostly by surgical sub-teams.









Similar to the distribution of sequences, most exchanges were initiated by the surgical sub-team: 58% of all exchanges were initiated by the surgical sub-team (66 ±17 exchanges per surgery). Although the perfusionists also uttered a large number of sequences, perfusionists *initiated* only a small number of exchanges: only 19% of all exchanges were initiated by perfusionists (21 ±7 exchanges per surgery). Another 11% of all exchanges were initiated by anesthetists (12 ±3 exchanges per surgery).

Of each exchange type an example is shown in Table 14.

Table 14 Examples of each exchange type, taken from transcript.

Exchange type	Description	Example excerpt from transcription	
Direction	Command an action that seeks to transition the activity system to a new state	Surgery Anesthesia	And the heparin may be administered Yes
Goal sharing	Create expectation of a desired future state	Surgery	Then we can start cannulation
Status	Create shared understandings about the current state (often	Surgery	Heparin was administered two

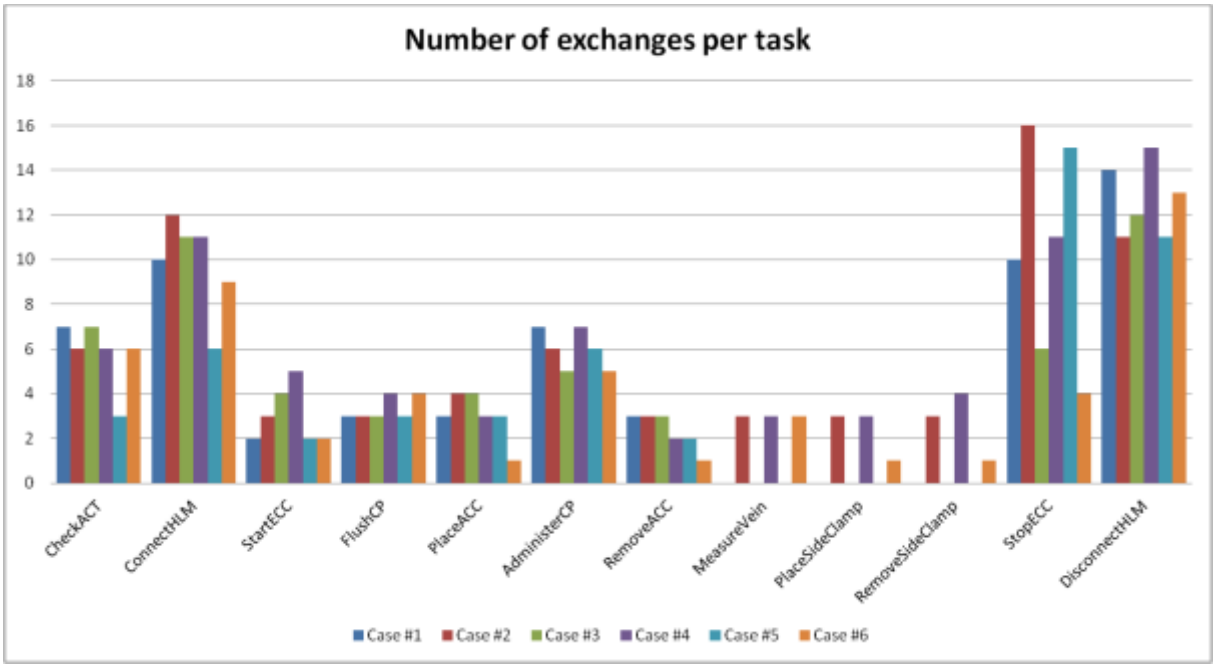
	initiated by request for information aka question)		minutes ago right, [anesthetist]?
		Anesthesia	Two and a half minutes, yes
		Surgery	Oh, two and a half
Alert	Convey abnormal or surprising information about the current state	Surgery	The blood is too runny
Explanation	Create a rationale for the current state	Perfusion	But I really had to, for full flow…
		Surgery	Yes I believe you, that's not the point, but I'm just thinking, it's a lot
		Perfusion	Yes
Problem solving	Steer toward a more complete understanding of the current state	Perfusion	Perhaps we should try the cell-saver
Permission	Request approval to further transition the activity system to a new state	Surgery	Can I start clamping?
		Perfusion	Yes

4.2 Critical events to verbalize

A combination of video analysis, interviews and focus groups was used to define a set of events (events) critical to verbalize. First a set of recurring events was defined based on video analysis. Then specialists added to this list and defined the criticalness of each of the events.

4.2.1 Recurring events

As a result of the video analysis, 68 events were defined. These were selected because they were verbalized in at least two of the surgeries recorded. The events were aggregated into groups of events, ordering them chronologically where possible, to make the set more manageable (Check ACT, Connect heart-lung machine, Start extracorporeal circulation, Flush cardioplegia, Place aortic cross-clamp, Administer cardioplegia, Remove aortic cross-clamp, Measure venous graft length, Place aortic side-clamp, Remove aortic side-clamp, Stop extracorporeal circulation and Disconnect heart-lung machine). For a list of all 68 events, see the interview form in the Appendix, p. 155.



In total 232 exchanges did not match any of the recurring events and were aggregated under 'Other events'. Furthermore 46 exchanges remained inaudible and the meaning of 34 exchanges remained unknown (even after

review with multiple specialists). In total the set of 68 recurring events contained 58% of all exchanges transcribed.

4.2.2 Critical events

The set of recurring events was used to define a set of critical events through interviews and a focus group with specialists. 11 events were added to the list as a result of the interviews, making a total of 79 events. Of these, 64 events were considered critical to verbalize as a result of the focus group. It is the quality of these critical events that is evaluated in the remainder of this chapter.

In order to analyze the quality of these events, also their critical participants were defined (sub-teams essential to include in the exchange). Of the 64 critical events, 21 were considered critical by three sub-teams and 43 were considered critical by two sub-teams. These sub-teams are from here on referred to as the critical participants of an exchange.

The criticalness of some events was found subject to certain boundary conditions. Out of 64 critical events, 13 were considered critical only under specific conditions, from here on referred to as *conditionally* critical events. Examples of those conditions included: * Only critical when the RIMA is passed through; ** Only critical if the corresponding activity is performed; *** Only critical if flow was turned down before; **** Only critical if the cardioplegia has not been given again before this time; ***** Only critical if the artificial breathing was adjusted or turned off before.

The remaining 15 events were considered uncritical to verbalize. This occurred only if the specialists agreed that non-verbalization of an event could not harm the patient in any way. Examples of such uncritical events included 'Pass the lines' and 'Fill the heart'. See Appendix p. 167 for an overview of critical, uncritical and conditionally critical events.

4.2.3 Conflicting events

Although finally consensus was achieved on the criticalness of all events through means of the focus group, the interviews initially resulted in disagreements about the criticalness of 25 events. These conflicts play a key role in the further analysis of communication quality in the remainder of this chapter and therefore are discussed in detail here.

Two types of conflict occurred. One type of conflict arose when the two specialists within one sub-team did not agree with each other about the criticalness of an event (intradisciplinary conflict). The surgical sub-team for example did not agree whether or not the verbalization of 'Start retrograde autologous priming' was critical for them.

The second type of conflict arose when an event was missing a 'conversation partner'; in these cases only one sub-team said to find this exchange critical, or a sub-team said to find this exchange critical for another sub-team who in fact did *not* find this exchange critical (interdisciplinary conflicts). The surgeons for example said to find 'Clamp removed from venous cannule' critical for perfusionists unanimously, whilst both perfusionists said to do nothing with this information.

As mentioned before, all conflicts were finally resolved through means of the focus group. Yet the fact that these conflicts initially occurred is used in the analysis of communication quality in the remainder of this chapter. For an overview of conflicting events see Appendix p. 162.

4.3 Purposeful communication

In the remainder of this chapter, the quality of communication during cardiopulmonary bypass procedures at the LUMC is evaluated. To this end, the way that critical events were verbalized across the six video recordings is assessed according to three communication quality criteria. The set of critical events was defined through the means of structured interviews and a focus group (for a discussion of these events, please refer to section 4.2.2 Critical events , p. 104) and the quality criteria were based on a systematic literature review (for an in-depth discussion of these qualities, please refer to section 2.2 Qualities of a single verbal exchange, p. 90). Note that

the results presented below do not provide any data on the six critical events that were added as a result of the interviews or focus group, because the video analysis was performed before the interviews took place.

Below, the evaluation of communication quality is discussed per quality criterion: purposefulness, consistency and breakdown resilience. In this section, the purposefulness of communication is evaluated. The purposefulness of communication refers both to the verbalization of critical events as well as the involvement of critical participants in an exchange. Both of those aspects are discussed below.

4.3.1 Verbalization of critical events

One aspect of purposeful communication, is the extent to which critical events are verbalized. To assess this aspect, the number of exchanges uttered per critical event was measured per case, a number of zero indicating a lack of purposefulness (see for results Table 15).

Critical events that were not verbalized in a certain case were color coded. Light yellow events were considered critical by 2 sub-teams whereas light red events were considered critical by 3 sub-teams. Note that the criticalness of exchanges marked with an asterisk (*) was subject to boundary conditions and therefore these events were not highlighted (since it is unknown whether these boundary conditions are met).

Table 15 Number of exchanges verbalized per critical event and per recorded case. A lack of verbalization is marked in light yellow when the event was deemed critical for 2 sub-teams, and light red when it was considered critical for 3 sub-teams. The criticalness of exchanges marked with an asterisk (*) is subject to certain boundary conditions and therefore these exchanges were not highlighted.

	Number of exchanges per case					
Event	**#1**	**#2**	**#3**	**#4**	**#5**	**#6**
Administer heparin	1	1	1	1	1	1
Heparine circulating	1	1	2	2	1	2
Heparine circulating 2 minutes*	1	.	.	.	.	.
Activated clotting time (ACT) started	.	.	1	1	.	1
ACT is sufficient for cannulation (>300)	1	.	.	.	.	1
ACT is sufficient for extracorporeal circulation (>400)	2	3	2	1	.	1
Test suction	2	1	2	1	1	.
Suction is adequate	.	1	1	1	1	3
Divide the arterial and venous line	1	1	1	1	.	3
Prepare for cannulation	.	2	1	.	.	.
Arterial cannule has been inserted	1	4	2	3	1	1
Clamp removed from arterial cannule	1	.	1	1	1	1
Sufficient pulsation and line pressure	1	1	1	1	1	1
Permission to start retrograde autologous priming (RAP)	1	.	.	.	.	.
Start RAP*	.	.	1	1	.	.
RAP is complete*	1	.	.	.	.	.
Clamp removed from venous cannule	1	1	.	1	1	.
Start ECC	1	1	1	2	1	.
Full flow achieved	1	1	1	1	.	1
(Do not) adjust artificial breathing	.	1	2	2	1	1
Flush cardioplegia	1	1	1	2	1	.
Stop flushing	1	1	1	1	1	1
Low flow*	1	1	2	2	1	.
Aortic cross-clamp placed	1	2	1	1	1	1
Normal flow*	1	1	1	.	1	.
Start cardioplegia	1	1	1	1	1	1

Pressure in root is adequate	.	1	2	1	1	.
Flow is adequate	1	.	1	.	.	.
Hart is still	.	.	.	.	1	.
Cardioplegia circulating for 2 minutes	1	1	1	.	1	1
Stop cardioplegia	1	1	1	1	1	1
Suck yellow	2	1	1	4	1	2
Low flow*	1	1	1	.	1	.
Aortic cross-clamp removed	1	1	1	1	1	1
Normal flow*	1	1	1	1	.	.
Low flow*	.	1	.	1	.	.
Aortic side-clamp placed*	.	1	.	1	.	1
Normal flow*	.	1	.	1	.	.
Low flow*	.	1	.	1	.	.
Aortic side-clamp removed*	.	1	.	1	.	1
Normal flow*	.	1	.	1	.	.
Continue artificial breathing*	1	.	1	.	2	.
Generate cardiac output	1	1	.	3	3	1
Permission to reduce flow	1	.	.	.	1	.
Artificial breathing is on	1	1	1	1	.	1
Heart rhythm is adequate	.	.	.	2	1	.
Heart function is adequate	2	1	.	1	2	.
Heart filling is adequate	.	3	.	.	1	.
Reduce flow	1	2	2	1	3	2
ECC at 1 liter index	1	1	.	1	1	.
ECC at 1/2 liter index	1	1	1	1	1	.
Stop ECC	1	5	1	2	1	.
Administer protamine	2	2	1	1	1	2
Root needle removed	1	1	.	1	.	.
Venous cannule removed	.	2	1	1	1	1
Withdraw blood from venous line	1	.	1	1	1	.
Protamine at 1/3	1	1	1	.	2	2
Stop blue suction	1	.	1	1	1	.
Blood volume left in pump	1	1	1	.	.	.
Empty pump	2	1	1	.	.	.
Pump is empty	1	1	1	2	1	1
Arterial cannule removed	.	.	1	1	.	.
Protamine complete	1	.	1	1	1	1
Table movements*	.	.	.	7	3	3
Hemodynamically compromising manipulation of the heart*	1	2	.	3	1	2

On average, the unconditional critical events (events without an asterisk) were verbalized in 4.4 out of 6 cases. Events about which the criticalness was not unanimous during the interviews (conflicting events) were verbalized less often than the events about which the sub-teams agreed (3.5 versus 5.1 cases on average). As such, it seems that intra- and interdisciplinary conflicts about the criticalness of an event may cause a critical event to be less consistently verbalized. Events critical for 2 sub-teams were verbalized slightly more frequently than events critical for 3 sub-teams (4.7 rather than 4.2 cases on average), indicating these are more consistently verbalized.

4.3.2 Involvement of critical participants

To further assess the purposefulness of communication, the involvement of critical participants was assessed. To this end, the total number of exchanges that a sub-team was involved in (either as sender or receiver across six surgeries) was listed per event. These numbers were compared against the criticalness of that event according to the corresponding sub-team. As such, a lack of verbal presence in a critical event suggested the exclusion of a critical participant (see Table 16).

The exclusion of critical participants in events considered critical by 2 sub-teams were highlighted in light yellow, whereas those deemed critical by 3 sub-teams were highlighted in light red. The verbal presence of a sub-team that said to not find this event critical, was highlighted in blue. Again note that the six critical events added as a result of the interviews were not evaluated here.

Table 16 The total number of exchanges in which a sub-team was verbally present (either as a sender or receiver in a total of six surgeries) per event, compared against the criticalness of that event according to the corresponding sub-team. Sub-teams that considered an event critical but were not verbally present in the exchanges about that event in any of the surgeries were highlighted (light yellow for events critical for 2 sub-teams, light red for 3 sub-teams). If a sub-team was verbally present in an exchange that they did not consider critical, this was highlighted in blue.

	Sum of exchanges per sub-team		
Event	**Surgery**	**Anesthesia**	**Perfusion**
Administer heparin	6	5	.
Heparine circulating	3	9	.
Heparine circulating 2 minutes*	2	1	.
Activated clotting time (ACT) started	.	3	.
ACT is sufficient for cannulation (>300)	2	.	2
ACT is sufficient for extracorporeal circulation (>400)	6	7	2
Test suction	7	.	7
Suction is adequate	7	.	6
Divide the arterial and venous line	8	.	5
Prepare for cannulation	3	.	.
Arterial cannule has been inserted	12	.	7
Clamp removed from arterial cannule	5	.	4
Sufficient pulsation and line pressure	5	.	5
Permission to start retrograde autologous priming (RAP)	.	1	1
Start RAP*	2	.	2
RAP is complete*	1	.	1
Clamp removed from venous cannule	4	.	2
Start ECC	5	.	7
Full flow achieved	3	3	7
(Do not) adjust artificial breathing	11	7	1
Flush cardioplegia	9	.	7
Stop flushing	7	.	6
Low flow*	6	.	7
Aortic cross-clamp placed	7	.	6
Normal flow*	4	.	4
Start cardioplegia	6	.	6
Pressure in root is adequate	6	.	4
Flow is adequate	2	.	3
Hart is still	1	.	1
Cardioplegia circulating for 2 minutes	4	.	5

Stop cardioplegia	5	.	5
Suck yellow	14	.	11
Low flow*	5	.	4
Aortic cross-clamp removed	6	.	3
Normal flow*	4	.	4
Low flow*	2	.	2
Aortic side-clamp placed*	3	.	1
Normal flow*	2	.	2
Low flow*	2	.	2
Aortic side-clamp removed*	3	.	1
Normal flow*	2	.	2
Continue artificial breathing*	3	4	.
Generate cardiac output	14	2	12
Permission to reduce flow	2	2	.
Artificial breathing is on	4	5	5
Heart rhythm is adequate	4	2	.
Heart function is adequate	6	4	.
Heart filling is adequate	4	3	1
Reduce flow	14	5	12
ECC at 1 liter index	1	2	5
ECC at 1/2 liter index	2	4	6
Stop ECC	8	5	11
Administer protamine	8	8	.
Root needle removed	3	.	3
Venous cannule removed	6	.	2
Withdraw blood from venous line	4	.	4
Protamine at 1/3	3	8	.
Stop blue suction	5	.	6
Blood volume left in pump	4	1	4
Empty pump	3	.	4
Pump is empty	8	4	9
Arterial cannule removed	2	.	2
Protamine complete	4	5	1
Table movements*	2	17	11
Hemodynamically compromising manipulation of the heart*	8	4	2

First of all, the results indicate that the sub-teams were not usually present in exchanges that they themselves did not consider critical. This only happened in 3 instances and two of those may have been coincidental, since they contained only one single exchange. The third instance is more interesting because it concerns 5 exchanges. In this instance, surgeons were involved in an exchange about Turn blue suction off, whereas none of the surgeons considered this event critical for their specialism. Further investigation shows that the surgeons only got involved when they themselves instructed to turn the blue suction off before the protamine was at 1/3 (instead of *after*, as is usually the case). Probably the surgeons did not consider this possibility when they assessed the criticalness of this event with regard to their specialism.

The results furthermore indicate that critical participants are regularly excluded: in 35 instances one of the critical sub-teams was not verbally present. This is a significant amount, considering that these numbers already represent the sub-team's presence across six surgeries *in total*. The anesthetists were most often verbally absent

(26 out of 35 instances), and the events in which it happened were usually critical for 3 sub-teams (32 out of 35 instances).

What these results show more than anything, is that there is a difference between *finding* an event critical to verbalize and actually *being involved* in the verbalization of that event. Each of the sub-teams considered a large number of events critical to verbalize (surgery 62, anesthetists 52 and perfusionists 61 out of 65 events). This doesn't mean however that they also considered themselves critical communication partners. Several interviewees emphasized that they wanted others to verbalize an event so that they could listen in. This may be true especially for anesthetists, who often want to know when to expect a certain event and therefore listen in to conversations between the perfusionist and surgeon. As such an absence of a critical participant may not indicate a lack of purposefulness unless the various communication roles (e.g. initiator, replier, listener) of the participants are accounted for.

4.4 Consistent communication

The consistency of communication refers to to what extent a specific event is verbalized in the same manner across surgeries. A consistent communication process is thought to limit risks of error.

In this section, the consistency of three exchanges aspects is discussed: timing, initiating sub-team and exchange type. Each of these aspects is discussed below.

4.4.1 Consistency of timing

One aspect of communication consistency, is the consistency of timing: to what extent is a critical event always verbalized in the same surgical phase?

The surgical events were initially used to divide the surgical process into 14 different phases. The critical events occurred in 12 of those; none of the critical events were verbalized before the mammaria retractor appeared. 20 out of 65 critical events were verbalized in at least two different surgical phases, each of those indicating a lack of consistency. These exchange were not particularly critical for three sub-teams rather than two, or more conflicting than the other exchanges. See Appendix p. 170 for an overview of these results.

To get an understanding of why these events were verbalized in multiple phases, the phases were aggregated into five larger surgical phases (for a description of these phases, see Surgeries recorded, p. 99). In this way a smaller selection of inconsistent exchanges was obtained and this allowed their detailed analysis.

When the surgical phases were lumped into five surgical phases, only 8 events were verbalized in more than one phase (see table on the next page). Two of those events are performed multiple times throughout the surgery (Table movements and Hemodynamically compromising manipulation of the heart) so that their consistent timing is not expected nor desired. Another 2 events concerned updates about the administration of protamine, which is indeed a long and patient-dependent process and runs parallel to any surgical steps. Yet the remaining 4 events concerned the very events that were used to divide the process into surgical phases (Divide arterial and venous lines, Low flow before aortic cross-clamp is placed, Aortic cross-clamp is placed, Aortic cross-clamp is removed).

This suggests that there is little consistency in whether these events are verbalized before or after the surgical event has taken place. In one case the surgeon may announce the placement of the aortic cross-clamp beforehand and in the next he may only confirm its placement afterwards. One of the surgeons indeed reported in one of the interviews that he never knows whether to verbalize the placement of the aortic cross-clamp before or after placement. Such inconsistencies indicate a lack of knowledge within the sending sub-teams with regard to the informational needs of the receiving party.

Dialogue between the sending and receiving parties should be able to clear up such misunderstandings. During the focus group session for example, it turned out that above all, perfusionists need to know when the clamp is placed *completely*, because he can already see for himself roughly when the surgeon is about to place the clamp and only *complete* placement of the clamp allows him to continue with the next steps. Therefore dialogue

between sending and receiving sub-teams should be able to clear up whether a critical event should be announced before, confirmed after, or both of those.

Event	Preparation	Initiation	Clamp-time	Weaning	Finish	**Number of surgical phases**
	Number of exchanges per phase					
Administer heparin	6	.	.	.	.	**1**
Heparine circulating	9	.	.	.	.	**1**
Heparine circulating 2 minutes*	1	.	.	.	.	**1**
Activated clotting time (ACT) started	3	.	.	.	.	**1**
ACT is sufficient for cannulation (>300)	.	2	.	.	.	**1**
ACT is sufficient for extracorporeal circulation (>400)	9	.	.	.	.	**1**
Test suction	7	.	.	.	.	**1**
Suction is adequate	7	.	.	.	.	**1**
Divide the arterial and venous line	6	1	.	.	.	**2**
Prepare for cannulation	.	3	.	.	.	**1**
Arterial cannule has been inserted	.	12	.	.	.	**1**
Clamp removed from arterial cannule	.	5	.	.	.	**1**
Sufficient pulsation and line pressure	.	7	.	.	.	**1**
Permission to start retrograde autologous priming (RAP)	.	1	.	.	.	**1**
Start RAP*	.	2	.	.	.	**1**
RAP is complete*	.	1	.	.	.	**1**
Clamp removed from venous cannule	.	4	.	.	.	**1**
Start ECC	.	6	.	.	.	**1**
Full flow achieved	.	5	.	.	.	**1**
(Do not) adjust artificial breathing	.	7	.	.	.	**1**
Flush cardioplegia	.	6	.	.	.	**1**
Stop flushing	.	6	.	.	.	**1**
Low flow*	.	6	1	.	.	**2**
Aortic cross-clamp placed	.	1	6	.	.	**2**
Normal flow*	.	.	4	.	.	**1**
Start cardioplegia	.	.	6	.	.	**1**
Pressure in root is adequate	.	.	5	.	.	**1**
Flow is adequate	.	.	2	.	.	**1**
Hart is still	.	.	1	.	.	**1**
Cardioplegia circulating for 2 minutes	.	.	5	.	.	**1**
Stop cardioplegia	.	.	6	.	.	**1**
Suck yellow	.	.	11	.	.	**1**
Low flow*	.	.	4	.	.	**1**
Aortic cross-clamp removed	.	.	2	4	.	**2**
Normal flow*	.	.	.	4	.	**1**
Low flow*	.	.	.	2	.	**1**
Aortic side-clamp placed*	.	.	.	3	.	**1**
Normal flow*	.	.	.	2	.	**1**

Low flow*	.	.	.	2	.	**1**
Aortic side-clamp removed*	.	.	.	3	.	**1**
Normal flow*	.	.	.	2	.	**1**
Continue artificial breathing*	.	.	.	4	.	**1**
Generate cardiac output	.	.	.	9	.	**1**
Permission to reduce flow	.	.	.	2	.	**1**
Artificial breathing is on	.	.	.	5	.	**1**
Heart rhythm is adequate	.	.	.	3	.	**1**
Heart function is adequate	.	.	.	6	.	**1**
Heart filling is adequate	.	.	.	4	.	**1**
Reduce flow	.	.	.	11	.	**1**
ECC at 1 liter index	.	.	.	4	.	**1**
ECC at 1/2 liter index	.	.	.	5	.	**1**
Stop ECC	.	.	.	1.	.	**1**
Administer protamine	.	.	.	8	.	**1**
Root needle removed	.	.	.	3	.	**1**
Venous cannule removed	.	.	.	6	.	**1**
Withdraw blood from venous line	.	.	.	4	.	**1**
Protamine at 1/3	.	.	.	6	1	**2**
Stop blue suction	.	.	.	4	.	**1**
Blood volume left in pump	.	.	.	3	.	**1**
Empty pump	.	.	.	4	.	**1**
Pump is empty	.	.	.	7	.	**1**
Arterial cannule removed	.	.	.	.	2	**1**
Protamine complete	.	.	.	1	4	**2**
Table movements*	.	.	.	11	2	**2**
Hemodynamically compromising manipulation of the heart*	1	2	.	3	3	**4**

4.4.2 Consistency of exchange initiator

A second aspect of communication consistency, is to what extent the same sub-team always initiates the exchange about a certain critical event.

Almost half of all critical events (30 out of 65) were initiated by two or three different sub-teams (see appendix p. 172 for an overview of these results). These events did not stand out from the other events in terms of criticalness or conflicts about criticalness. To obtain an understanding of why these events were verbalized in consistently, the remainder of this section zoom in on the 2 events that were initiated by three different sub-teams: ACT sufficient for perfusion and Artificial breathing complete.

ACT sufficiency is initiated by multiple sub-teams because it is (inadvertently) verbalized multiple times per surgery. The surgeons and perfusionists often check the ACT while the anesthetists already acknowledged its sufficiency before. The interviews and focus group showed that when the anesthetist announces the ACT, the surgeons and perfusionists are often consumed by other activities. Also one of the surgeons explained during the focus group that the sufficiency of ACT is such a common exchange that she doesn't feel alerted by it and instantly forgets that it happened. This example shows that a lack of capacity to listen attentively to an exchange may cause an exchange to be verbalized inconsistently in terms of exchange initiator.

Dialogue between the sending and receiving sub-teams may be able to clear up how the exchange can be designed such that the information is absorbed effectively, for example by timing the exchange more appropriately or presenting the information in a different way.

With regard to the completion of artificial breathing, the interviewees emphasized that there is no professional or institutional protocol with regard to the artificial breathing procedure, because the scientific evidence on what is the best procedure is inconclusive. Therefore the way that patients are supported with artificial breathing during surgery is dependent on the personal preferences and habits of the surgeon and anesthetist. Perhaps as a result of this, it is unclear whether and when the artificial breathing should be turned back on and who should instruct the anesthetist to do so. The risk of such inconsistency is illustrated by the verbalization of this event in case #4:

Perfusion	Breathing is on?
Surgery	Breathing is complete?
Anesthesia	We'll start artificial breathing
Surgery	Ok

This example shows that although the perfusionist proficiently remembered to check whether artificial breathing is complete before reducing blood flow levels, the question itself indicates that the artificial breathing should have been turned on at this point already. The response from the anesthetist shows that this is not the case. In another recording the anesthetist was never instructed to turn the artificial breathing machine on, but simply reports its completion later. These inconsistencies indicate a risk of failure, which perhaps could be combated with a clear allocation of roles (who is responsible for the initiation of this event).

Overall the results indicate that many critical events are regularly initiated by different sub-teams. Although this is a sign that sub-teams currently help and check each other, it also shows that there is significant room for improvement in terms of the attention for a critical exchange as well as the allocation of roles with regard to the verbalization of an exchange.

4.4.3 Consistency of exchange type

A third aspect of communication consistency, is the extent to which the same exchange type is used to verbalize a critical event.

42 out of 65 critical events were consistently verbalized with the same exchange type (see Appendix for an overview of these results, p. 174). Most of these were Status (28 events) and Direction exchanges (11 events), 2 events were consistently verbalized with Goal sharing exchanges (Prepare for cannulation and Start retrograde autologous priming) and 1 event was consistently verbalized with Permission exchanges (Permission to start retrograde autologous priming).

If the exchange types that were used only once are disregarded, a pattern emerges among the inconsistent events in which especially Status, Direction and Permission types take turns: events that are verbalized with multiple different types either combine Status and Direction exchanges (7 in total), Direction and Permission exchanges (3), Status and Permission exchanges (1, Divide the arterial and venous line), or Direction, Status and Permission exchanges (1, Stop ECC).

These inconsistencies indicate a lack of clarity about whether activities can be performed independently or not, because a critical event is both being instructed (Direction), carried out independently (Status) as well as carried out on own initiative but with permission from other party (Permission). These differences are illustrated in an example of Start perfusion, which is Directed by the surgeon in one half of the surgeries and carried out by the perfusionist independently in the other half (compare examples below).

Table 17 Two examples of the same critical event (Start perfusion) that is verbalized with two different exchange types (Status and Direction). S, surgery; P, perfusion.

Example case #1

S	Ok, venous is open	Status
P	Ok, start flow	Status

Example case #5

S	Clamps are removed	Status
P	Ok	
S	On bypass	Direction
P	On bypass	

Dialogue between the sending and receiving sub-teams may be able to clear up whether activities can be performed independently or not. The large number of consistently verbalized events indicates that it is possible to agree on one single exchange type per event.

4.5 Resilient communication

A third indicator of communication is breakdown resilience. An exchange is susceptible to breakdown if one of its sequences can be misinterpreted. Three aspects of verbal exchanges were thought to limit risk of such misinterpretation and assessed here: exchange loop type, call-back type and direction. The assessment of critical exchanges with regard to each of those aspects is discussed below.

4.5.1 Loop type of critical events

A major aspect of breakdown resilience, is exchange loop type. In this study four different loop types were distinguished and each was associated with a different level of susceptibility to breakdown.

The first loop type is referred to as Open loops: exchanges without call-back. Per definition these exchanges only involve one sub-team (the initiators). This type is considered most susceptible to breakdown. The second loop type is referred to as Call-backs: exchanges with call-back from one or two-subteams. This type is considered less susceptible to breakdown than Open loops, but not as resilient as the third type. The third loop type is referred to as Closed loops: exchanges wherein the initiator fully 'closes' the exchange loop with a final call after the receiver gave a call-back. This type is most considered most resilient to breakdown. Also a fourth loop type was defined, named Series, in which more sequences between two or three sub-teams were exchanged than in any of the other loops. The literature is inconclusive as to whether these exchanges are susceptible to breakdown and are therefore considered neither susceptible nor resilient to breakdown until further investigation proves otherwise. See Table 18 for examples of each of these loop types.

Table 18 Examples of Open loop, Call-back, Closed and Series types per number of sub-teams involved. Note that open loops are only communicated by 1 sub-team. S, surgeon; A, anesthetist; P, perfusionist.

	2 sub-teams		3 sub-teams	
Open loop	A	Protamine is at one third		
Call-back	S	Heparine may be administered	P	And the pump is empty
	A	Heparine administered	A	Yes
			S	Good
Closed loop	S	How much do you have [perfusionists]?	P	Breathing is also (...)?
	P	About 100	S	Yes sure
	S	Oh, ok	A	Yes
			P	Ok
Series	S	[Anesthetist], should I stay here, because the pressure is 75	P	Off bypass
	A	Stay there?	A	Yes, I heard you
	S	At half a liter, or… Do you agree that it's going to fast?	S	Off bypass?
	A	No, fine, let's go off bypass (…)	A	Yes
	S	Yes	S	Wonderful

Open loop, Call-back, Closed loop and Series exchanges surmised respectively 27% (91 exchanges), 60% (202) and 8% (26), 5% (18) of all 336 critical exchanges (see Figure 29). In only 18 of those were three different sub-teams verbally present in the same exchange. As such, most critical exchanges were communicated with a call-back between two sub-teams (190) or with an open loop exchange (91).

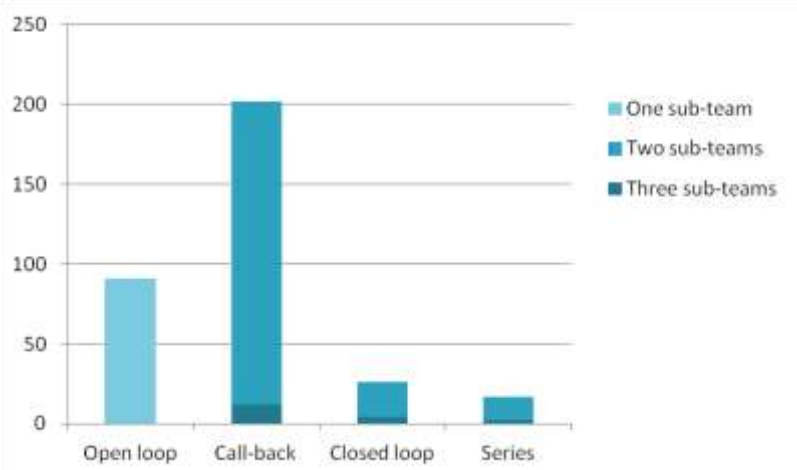


Figure 29 Number of critical exchanges per loop type and number of sub-teams involved.

To evaluate the susceptibility to breakdown, first the susceptibility to breakdown of Series exchanges is explored below. Subsequently the Open loop exchanges are analyzed.

Series exchanges

Most Series (10 out of 18) were 'double' loops between two sub-teams of four sequences in total.

Surgery	You can quit blue [suction] by the way
Perfusion	Yes?
Surgery	Yes
Perfusion	Ok, blue stops

As such, Series between two sub-teams perhaps indicate a lack of efficiency, but there is no indication of an increased susceptibility to breakdown.

In all three Series that occurred between three sub-teams, one sub-team 'mediated' an exchange between the other two other parties by either prompting an exchange (see example in Consistency of exchange initiator, p. 111), or transmitting the result of an exchange to a third party (see Series example for 3 sub-teams in **Table 18**, wherein the anesthetist mediates an exchange between the perfusionist and surgeon). Since in all these exchanges mediation of a third party was necessary, it seems that Series between 3 sub-teams are the result of an exchange in which critical participants were initially excluded. As such, Series between 3 sub-teams are not considered an indication of breakdown susceptibility, but an indication of a lack of purposefulness.

Open loop exchanges

As such the main question remains why critical events were verbalized with an Open loop. The remainder of this section zoom in on the 2 events that were consistently communicated with an Open loop: ACT is running and Prepare for arterial cannulation.

First of all, the specialists did initially not agree on the criticalness of both these events. This indicates that perhaps the perceived criticalness of these events was not unanimous among the observed surgical team, which may have caused them to remain silent in response to the initial sequence.

Furthermore the exchange types of both these critical exchanges may have put them at risk of Open loop communication: most Open loop exchanges were either Status (71) or Direction (14) exchanges, thereby compromising almost 40% of all critical Status exchanges and a selection of all critical Direction exchanges. Only a few Open loop exchanges were Explanation (3) and Goal sharing exchanges (3), but these did compromise all critical Explanation exchanges and 20% of all Goal sharing exchanges (see **Figure 30**). Indeed the two events that were consistently verbalized with an Open loop exchange were also consistently verbalized with a Status (ACT is running) and a Goal sharing (Prepare for arterial cannulation) exchange.

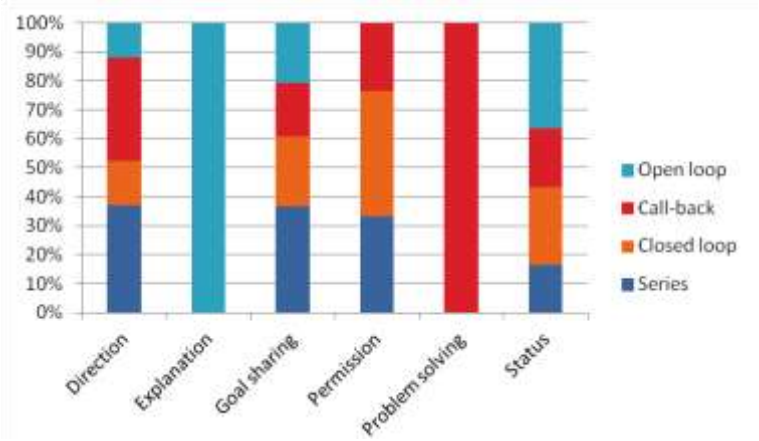


Figure 30 The distribution of Loop types across Exchange types, showing among other things that all critical Explanation exchanges were Open loops (total 3 exchanges) and a large part of Status exchanges were Open loop (total 71).

As such, critical events that were consistently communicated with a Status, Goal sharing or Direction exchange may be at increased risk of breakdown (none of the critical events was consistently communicated with an Explanation). For a list of these events please refer to Consistency of exchange type, p. 112.

These results indicate that agreement about the criticalness of events could help to minimize the number of Open loops per surgery. The focus group session showed that such agreement can be attained. Further implementation of these results should show whether such agreement alone is sufficient to lower the number of Open loops per surgery.

Furthermore the results suggest that certain exchange types are at risk of Open loop communication. Perhaps communication training could help to combat the intuitive response of operating room staff to leave Status and Goal sharing exchanges without call-back.

4.5.2 Call-back type of critical events

If an exchange is call-backed, a second indication of breakdown resilience, is the content of that call-back. Call-backs can either be substantive (containing information about what information was received, for example by repeating the initial sequence) or insubstantive (containing at most affirmative information). Substantive were considered more resilient to breakdown than insubstantive call-backs. For a list of utterances that were defined as insubstantive, see **Box 2**.

Box 2 Call-backs defined as insubstantive.

- Yes
- Okay
- Yep
- Yes that's OK
- Yes, I will do that
- Okay thank you
- Beautiful
- I think that's good
- Yes fine
- Yes, much better already
- Yes this is fine
- Yes, that's possible
- Yup, good
- Yes, we'll do
- Thank you
- Mmm (approvingly)
- Go ahead
- Certainly
- Yes, definitely
- Sounds good
- No
- Yes?
- That is beautiful
- Yes, nice
- I will
- Well ...
- Yes, you can
- We'll do
- Yes, all right
- Yup
- Alright
- Right
- Yes I will
- OK nice

Almost half of all call-backs in Call-back, Closed loop and Series exchanges were categorized as insubstantive (110 out of 245 exchanges).

4 events were consistently call-backed insubstantively, but these were not verbalized more than twice in total anyways. The remainder of this section focuses on the analysis of 10 critical events that were call-backed insubstantively more often than substantively. An analysis of those events suggested three possible reasons for surgical teams to use an insubstantive call-back rather than a substantive call-back. .

A first reason to use insubstantive call-backs more often than substantive call-backs may be disciplinary conflicts about the criticalness of the event. The two surgeons in the interviews for example did not agree on the criticalness of 'ACT is sufficient for perfusion' for their specialism. Perhaps this caused them to reply more insubstantively.

Other critical events may simply not be appropriate to call-back substantively. Some of the events concern instructions that cannot be performed immediately. In these cases an insubstantive call-back may be a way to acknowledge the instruction without giving the false impression that the instruction has already been carried out. An example of an event in which this may be the case includes the administration of heparin. The surgeon instructs the anesthetist to administer heparin, which is commonly replied to with a simple 'yes'. Later the anesthetists gives a status update that the heparin is circulating. In this way both a direct acknowledgement of the instruction and the precise timing of administration are communicated.

Other events are often communicated together with another event and therefore not easily call-backed substantively. The fact that the cardioplegia is fully administered for example, is often answered with a new instruction (to stop administering cardioplegia). As such, events that are often verbalized quickly after another may be call-backed less substantively.

4.5.3 Directed exchanges

The third aspect of breakdown resilience considered in this study, is a sense of direction. Directed exchanges were directed at a specific team member with the use of that person's name and considered more resilient to breakdown than undirected exchanges.

Only 22 out of 336 critical exchanges were directed at a specific team member by name. This number is so low that it challenges the importance of directed exchange with regard to breakdown resilience. An excerpt from case #4 illustrates however that Direction can significantly improve the resilience of an exchange (see Table 19). After four Open loop Alerts, a directed exchange was the first to elicit a call-back from the perfusionist. Indeed only 1 out of 22 directed critical exchanges were Open loops. It seems therefore that directed exchanges can significantly contribute to breakdown resilience by enforcing a call-back from the receiver.

Table 19 Excerpt from transcript #4, showing the relevance of directed exchanges of directing an exchanges at a specific team member.

Speaker	Sequence	Exchange type
Surgery	Turn yellow [suction] on	Direction
Perfusion	Yes	
Surgery	Yellow is not on, yellow is not on	Alert
Surgery	Yellow is blowing	Alert
Surgery	Suck yellow	Direction
Surgery	It's not sucking	Alert
Surgery	Not sucking [perfusionist]	Alert
Perfusion	Ok	
Surgery	You know, we're just pumping air into the heart	Explanation
Surgery	It's still not ok	Alert
Surgery	It's not sucking well	Alert
Surgery	Now it's better	Status

Some sub-teams seem to make use of this mechanism more often than others. Most Directed exchanges were initiated by surgeons (17), some by perfusionists (4) and one by anesthetist (1). Most Directed exchanges were directed at the perfusionist (13), some at the anesthetist (7) and some at the surgeon (2). Surgeons may be more likely to direct exchanges because they communicate with a wide range of staff members and perfusionists may be likely receivers of a directed exchange because of their obstructed behind the heart-lung machine. Yet this distribution may also relate to the personal preferences and habits of the initiators: in this study, two speakers (surgeons in case #1 and case #4) alone were responsible for directing a total of 6 and 8 exchanges respectively.

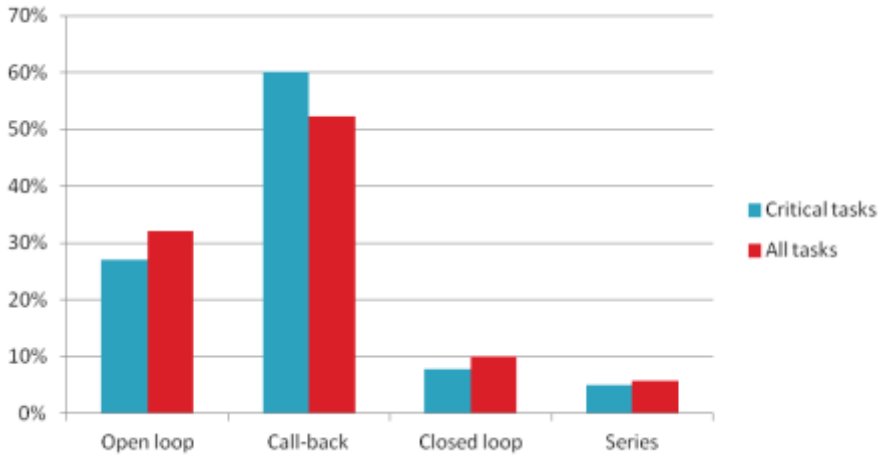
Furthermore some events may be more suitable for direction than others. Some events were directed repeatedly (Test suction, Generate output, Decrease flow and Volume left in pump) whereas other events were not directed once. A great many factors may cause one event to be directed more often than others - perhaps directed exchanges are used when perfusionists are consumed by other events, when the surgeon communicates with a wide range of personnel or when the timing of an events is highly variable. Furthermore one of the interviewees explained that she cannot use names to direct her status updates about ACT sufficiency because she has to direct it at two sub-teams at the same time, suggesting that exchanges critical for 3 sub-teams are not suitable for direction.

To summarize: only a few number of exchanges are currently Directed. The results showed that Directing exchanges can enforce a call-back in critical exchanges, a communication tool that surgeons seem to use more often than others. Furthermore the results indicated that Directing exchanges may be a habit that can be acquired, although it may not be suitable for exchanges in which three sub-teams need to be involved.

4.5.4 Resilience of critical events compared to Other events

In the previous sections, the verbalization of critical events was evaluated. In this paragraph, the verbalization of Other events is compared with the verbalization of critical events to see whether event criticalness affects their resilience to breakdown.

Loop types of critical events were similar to those of other events, although a slightly larger part of the critical events was verbalized with call-backs compared to All events (60% of critical events and 52% of all events) and a slightly smaller part was verbalized with open loops (27% of critical events and 32% of all events). Also the distribution of call-backs was fairly similar, although the lack of open loops in critical events was compensated for with insubstantive call-backs rather than substantive call-backs. Furthermore the distribution of directed exchanges of critical events was similar to that of all events; it only emphasizes the pattern of the surgeon as the main sender and the perfusionist as the main receiver of directed exchanges (see Table 20).



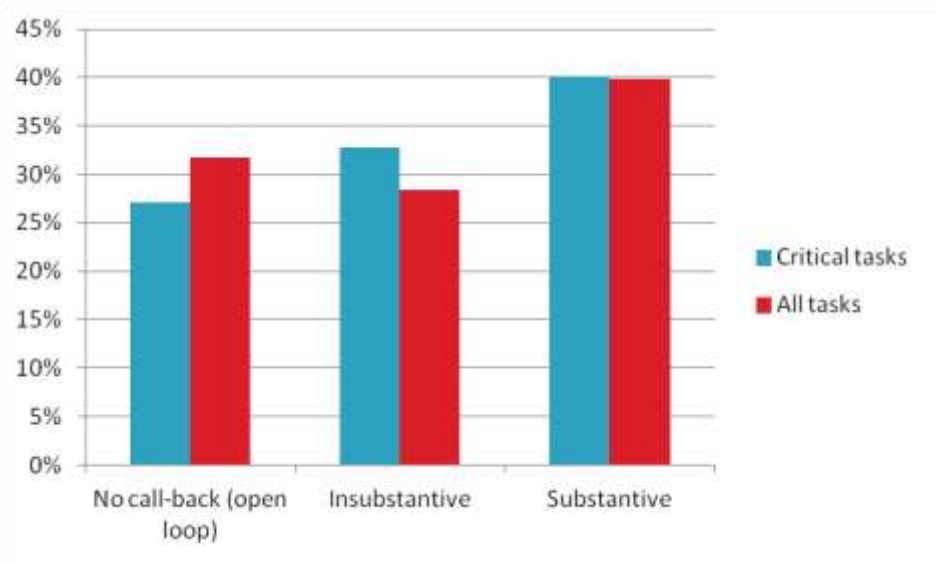


Table 20 Number of directed exchanges per sender and receiver (including all exchanges rather than only critical events).

		At surgeons	At anesthetists	At perfusionists	Total
Directed by	**Surgery**	.	4	20	24
	Anesthesia	4	.	5	9
	Perfusion	1	5	.	6
	Total	5	9	25	

5 Conclusion

In this part of this thesis, video recordings were used to develop a quality standard for the verbal interaction of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures. In the previous chapter the results of this study were presented. In this chapter the research questions are answered based on those results.

The main question was to what extent the critical verbal interactions between surgeons, anesthetists and perfusionists during cardiopulmonary bypass at the LUMC meet communication quality criteria. The sub questions included (a) what quality criteria does the literature on communication during cardiopulmonary bypass recommend with regard to a critical verbal exchange, (b) what events are recurrently verbalized during cardiopulmonary bypass procedures, (c) which of these are critical to verbalize according to surgeons, anesthetists and perfusionists. The quality criteria (a) were then applied to verbalization of critical events (c) in six recorded cardiopulmonary bypass procedures to answer the main research question.

Below, first the answers to the sub questions are described and then the main research question is answered.

5.1 Answers to the sub questions

The sub questions included (a) what quality criteria does the literature on communication during cardiopulmonary bypass recommend with regard to a critical verbal exchange, (b) what events are recurrently verbalized during cardiopulmonary bypass procedures, (c) which of these are critical to verbalize according to surgeons, anesthetists and perfusionists. Each of these is answered below

(a) What quality criteria does the literature on communication during cardiopulmonary bypass recommend with regard to a critical verbal exchange?

Three criteria were defined based on a systematic literature review. Three quality criteria were defined: purposefulness, consistency and breakdown resilience. Purposefulness was defined as the verbalization of critical events as well as the inclusion of critical participants in such an exchange. Consistency was defined as a consistency of timing, initiating sub-team and exchange type of a critical verbal exchange across surgical cases. Breakdown resilience was defined in terms of loop closure (open, call-back or closed loop communication), call-back type (insubstantive or substantive call-backs) and exchange direction (directed by name or not). These criteria are graphically summarized in Figure 24.

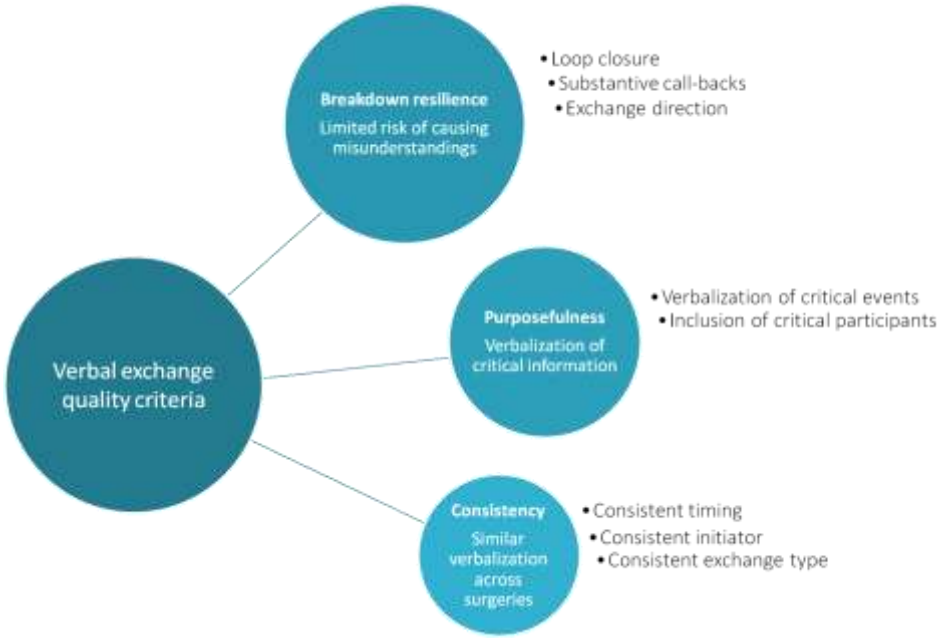


Figure 31 Overview of quality criteria per verbal exchange based on a systematic literature review.

(b) What events are recurrently verbalized during cardiopulmonary bypass procedures?

68 events were verbalized in at least two out of six recorded cardiopulmonary bypass procedures. The exchanges were aggregated into groups of events, ordering them chronologically where possible (Check ACT, Connect heart-lung machine, Start extracorporeal circulation, Flush cardioplegia, Place aortic cross-clamp, Administer cardioplegia, Remove aortic cross-clamp, Measure venous graft length, Place aortic side-clamp, Remove aortic side-clamp, Stop extracorporeal circulation and Disconnect heart-lung machine). In total the set of 68 recurring events contained 58% of all exchanges transcribed. For a list of all 68 events, see the interview form in the Appendix p. 155.

(c) Which of these are critical to verbalize according to surgeons, anesthetists and perfusionists?

The set of recurring events was used to define a set of critical events through interviews and a focus group with specialists. 11 events were added to the list as a result of the interviews, making a total of 79 events. Of these, 64 events were considered critical to verbalize as a result of the focus group.

Of the 64 critical events, 21 were considered critical by three sub-teams and 43 were considered critical by two sub-teams. These sub-teams are from here on referred to as the critical participants of an exchange.

Out of 64 critical events, 13 were considered critical only under specific conditions, from here on referred to as *conditionally* critical events. Examples of such conditions include: only critical when the RIMA is passed through; only critical if the cardioplegia has not been given again before this time; only critical if the artificial breathing was adjusted or turned off before; etc.

15 out of 79 events were considered uncritical to verbalize. This occurred only if the specialists agreed that non-verbalization of an event could not harm the patient in any way. Examples of such uncritical events included ‘Pass the lines’ and ‘Fill the heart’. See Appendix for an overview of critical, uncritical and conditionally critical events, p. 158.

5.2 Answer to the main research question

The main question was to what extent the critical verbal interactions between surgeons, anesthetists and perfusionists during cardiopulmonary bypass at the LUMC meet communication quality criteria. Below the results are described per communication quality criterion. For a list of the corresponding data per event, please refer to Results summary, p. 176 in the Appendix.

5.2.1 Purposefulness

Purposefulness was measured in terms of verbalization of critical events, as well as the inclusion of critical participants. Unconditional, critical events were only verbalized in 4.4 out of 6 cases on average, indicating significant room for improvement. Whether a critical event is verbalized or not may be mainly determined by the congruence of specialists on the criticalness of that event: conflicting events were verbalized in 3.5 cases on average, whereas non-conflicting events were verbalized in 5.1 cases on average.

Especially anesthetists are regularly absent from exchanges about an event that they consider critical. Rather than an indication of a lack of purposefulness, this may indicate that anesthetists are often listeners, rather than initiators or repliers in critical exchanges. Further investigation into the roles of the various sub-teams with regard to the verbalization of an event is necessary if the involvement of critical participants is to be used as an indicator of communication purposefulness.

5.2.2 Consistency

Consistency of communication was assessed in terms of timing, initiator and exchange type consistency. In terms of timing consistency, some critical events were verbalized both before and after the surgical event had taken place, possibly causing confusion among the receiving sub-teams.

In terms of initiators, almost half of all critical events was initiated by two or three different sub-teams, indicating that exchanges are initiated at unsuitable times and that the responsibilities for an exchange (who is the sender, who is the receiver) were not allocated clearly.

In terms of exchange type, one third of all events was verbalized with multiple exchange types (especially alternating between Direction, Status and Permission types), indicating that there is uncertainty about which events can be performed independently and which should await instruction.

5.2.3 Breakdown resilience

Three aspects of verbal exchanges were assessed with regard to breakdown resilience: exchange loop type, call-back type and direction. In terms of loop type, it seems that certain exchange types are more often verbalized with an Open loop than others. Especially exchanges of Status and Goal sharing are at risk, and Direction types to a lesser extent. This is relevant because many events are consistently verbalized with one exchange type. Also interdisciplinary conflicts about the relevance of verbalization could make exchanges more likely to be communicated with an Open loop.

In terms of call-back type, it seems that three possible mechanisms could be at play. Again, interdisciplinary conflicts about the criticalness of an event may cause team members to cause insubstantive call-back. Also some events may simply not be appropriate to call-back substantively. These concern especially events that cannot be performed immediately and those that are are often communicated together with another event.

Only a few number of exchanges are currently Directed. The results showed that Directing exchanges can enforce a call-back in critical exchanges, a communication tool that surgeons seem to use more often than others. Furthermore the results indicated that Directing exchanges may be a habit that can be acquired, although it may not be suitable for exchanges in which three sub-teams need to be involved.

7 Discussion

In this part of this thesis, video recordings were used to develop a quality standard for the verbal interaction of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures.

In the previous chapter the answers to the research questions were presented. In this chapter the significance of those results is discussed. First this study's approach to developing an adaptive communication quality standard (7.1) and quality improvement (7.2) are discussed. Subsequently the limitations of the study are addressed (7.3) and suggestions for future research are made, including a communication protocol and other interventions that the results of this study may contribute to (7.4) The chapter closes with a few closing remarks on the future of communication during cardiopulmonary bypass (7.5).

7.1 An adaptive quality standard

In this study, a quality standard for the verbal interaction of surgeons, anesthetists and perfusionists during cardiopulmonary bypass procedures was developed. Essential to the approach, was a list of events that critical to verbalize. The idea to consider only critical exchanges, was inspired by (Wadhera et al. 2010). (Wadhera et al. 2010) considered all 'non-verbalizations of critical events' an indication of communication failure. (Wadhera et al. 2010) did not include a list of critical events to verbalize however. Also others studies only provided mere examples of such critical events, e.g. (Galvan et al. 2005; Henrickson et al. 2013).

A challenge with regard to the development of such a list of critical events, is the complexity of a surgical procedure. Each institution may hold its own perspective on what events are critical to verbalize. Specialists may prefer a wide range of different approaches to the same event and furthermore unforeseen events may occur during surgery.

To meet these challenges, the list of events critical to verbalize in this study was developed based on existing practices. Analysis of six recorded cardiopulmonary bypass procedures informed rich discussions with operating room personnel. Not only did this make the assessment of 'verbalization of critical events' as suggested by (Wadhera et al. 2010) repeatable and reliable, it also provided results that are inherently aligned with the specific way of working at this institution and so allows for individual differences between practitioners and unforeseen events during surgery.

7.2 An approach to quality improvement

The approach in this study also provided insights for quality improvement.

The approach in this study was inspired by (Parush et al. 2011), who also used observations to define a set of events and asked practitioners to rate their criticalness. The approach was modified in one critical respect however, which increased the depth of its results significantly and allowed this study to directly inform improvements in patient safety.

(Parush et al. 2011) defined 52 events based on observations of cardiopulmonary bypass procedures and asked surgeons, anesthesiologists and perfusionists to rate the criticalness of each of these items on a scale from 1 to 7. (Parush et al. 2011) found 'a high agreement between all raters' (p. 482), which caused them to average the scores and differentiate between three priority groups (high, medium and low). As such, any event that scored consistently high ended up in the high priority group and any event that scored consistently low ended up in the low priority group. The medium priority group however contained two types of events: events that were consistently scored as medium-critical as well as those that showed great differences in perceived criticalness.

Similar to (Parush et al. 2011), in this study some events was found highly critical by all raters, such as 'placement of the aortic cross clamp'. One third of all events however showed great differences in terms of perceived criticalness, both within and between specialisms. Rather than averaging those scores to create a medium-priority group, any differences were addressed during a focus group session. Not only did this approach

result in a definition of criticalness that was supported by all practitioners involved, it also exposed important underlying mechanisms, contributed to a mutual understanding between practitioners an triggered initiatives for quality improvement. Each of these three advantages is illustrated below.

Expose underlying mechanisms Discussion of events about which the perceived criticalness differed between disciplines exposed underlying mechanisms that could inform intervention development. An event about which the perceived criticalness conflicted between disciplines for example, was the activated clotting time (ACT) test. Observations showed that while surgeons usually call-back the initial statement of anesthesiologists, they often request it again later, as if they didn't register it the first time. The interviews showed that anesthesiologists found this event extremely critical, whereas surgeons did not find this event critical. Discussion of this event during the focus group session showed that this event is usually verbalized at an inconvenient time for surgeons – when this event is verbalized, surgeons are usually occupied with other events. As such surgeons would rather not have this verbal exchange and therefore rated it as uncritical to verbalize.

During the discussion however, anesthesiologists and surgeons agreed that this verbal exchange *does* present critical information to surgeons. The practitioners referred to an incident in which the surgeon did not obtain this information, with adverse results. Therefore questions were raised about whether this information could be presented to the surgeons in a different way or at a different time. As such, discussion of differences in perceived criticalness can expose important underlying mechanisms that hamper patient safety.

Contribute to mutual understanding Discussion of events about which the perceived criticalness differed between disciplines contributed to mutual understanding between specialists. In the case about the ACT test for example, anesthesiologists learned that surgeons are not indifferent to their statement about the ACT test, but simply occupied with other events. This might help them in future events to seek a convenient time to communicate the ACT results.

Trigger initiatives for quality improvement Discussion of events about which the perceived criticalness differed between disciplines also triggered initiatives for quality improvement. There were many conflicts about the perceived criticalness of events during 'going from bypass', including those about artificial breathing, heart filling, volume, etc. Addressing these conflicts resulted in the initiative of anesthesiologists to develop a protocol for this part of the procedure. As such, addressing conflicts about the perceived criticalness of the verbalization of an event can therefore directly contribute to quality improvement.

7.3 Limitations

Several limitations applied. Although transcriptions of the recordings were discussed with practitioners, the recordings themselves were only viewed by the researchers. Viewing video observations with practitioners can increase the validity of the data (ElBardissi et al. 2007; Catchpole et al. 2007; Wadhera et al. 2010; Carthey et al. 2001; Hazlehurst et al. 2007) and provide clinicians with direct feedback on their practice (Yanes et al. 2015; Xiao et al. 2007). In this way, video-based research can contribute to patient safety directly. The conditions under which the video recordings are used should be renegotiated with operating room personnel and patients to allow for operating room personnel to watch their own recordings (see also Part A2 of this thesis).

Since this was an observational study, the Hawthorne effect may have occurred, whereby the observation instrument influences the processes observed. In other words, the video cameras may have caused operating room personnel to behave differently. The effect was minimized, because the recording equipment was small and placed unobtrusively in the operating room. However operating room personnel was reminded of the recordings with a sign directly outside of the operating room for ethical reasons. Also, personnel regularly commented on the cameras in a jokingly fashion, indicating that the cameras were not easily forgotten. If the Hawthorne effect occurred, this study is likely to present an overestimate of the quality of communication.

Sometimes limitations of this study indirectly indicated a lack of communication quality. For example, events concerning anticoagulation at the beginning of surgery were difficult to locate because their timing varied greatly. This is not only hampered quality assessment, it also indicates that team members have to cope with a highly consistent communication in this respect. Furthermore 10% of verbal exchanges were characterized as

‘inaudible’. This not only introduces an uncertainty to the data, it also questions whether it possible for team members to hear all verbal exchanges in an operating room. Furthermore two out of eight recordings could not used in this study due to inadequate audio quality. In these cases the radio was turned on, which made it impossible to transcribe verbal exchanges between operating team members based on the audio recordings. Team members may experience a similar disadvantage from operating room radios.

7.4 Future research

Future research can center on various aspects of this standard. Future research may focus on validating the reliability of the method (7.4.1), extending the quality criteria used (7.4.2), and increasing the depth of the communication standard by focusing on individuals rather than sub-teams (7.4.3).

Furthermore the results of this approach can be used to develop interventions to standardize communication practices. Recommendations for a communication protocol (7.4.4), process support tool (7.4.5) and a surgical black box (7.4.6) are discussed.

7.4.1 Test inter-rater reliability of analysis

The reliability of a verbal exchange-based study greatly relies on its definition of a single verbal exchange. Studies that tried to categorize communication failures repeatedly mentioned their lack of consistency as a major limitation (Lingard et al. 2004; Hu et al. 2012; Halverson et al. 2011).Therefore in this study, a method was sought to define a single verbal exchange reliably.

By defining a set of exchange types based on the theoretical framework of (Hazlehurst et al. 2007), a method was proposed to increase the reliable categorization of sequences into exchanges. The exchange types of (Hazlehurst et al. 2007) were adopted, because (Hazlehurst et al. 2007) related each of its exchange types to team situation awareness and because they described each exchange type in detail, so that they could be applied validly and reliably. The exchanges were applied mutually exclusively (meaning that one sequence was never part of two different exchanges) and comprehensively (meaning that all sequences were attributed to an exchange) to further increase reliability. One exchange type was added (Permission) to account for all verbal exchanges. Further research should show whether this method indeed provides reliable results, first by testing its inter-rater reliability.

7.4.2 Extend quality criteria

For the first time a systematic literature review was used to develop a set of theoretical quality criteria. In other studies, quality criteria were based on theoretical models of communication (Parush et al. 2011) or on practitioners’ experience, e.g. (Wadhera et al. 2010; Melchior et al. 2012). The advantage of using a systematic literature review in the field of communication during cardiopulmonary bypass to develop quality criteria, is that the criteria are inevitably suitable to the verbal exchanges of interest and that they provide a structured overview of the current knowledge in this field.

The literature review showed that the field was relatively young however and that the knowledge on this topic was of a limited evidence level (see enclosed Literature review, May 2016). The quality criteria used in this study therefore only provide a first estimate of total communication quality. Arguably experience from other high risk industries such as aviation can be used to extend the set of theoretical quality criteria presented in this study. Perhaps also practitioners may be interviewed to develop new quality criteria.

7.4.3 Develop standard for individuals rather than sub-teams

In this study, verbal sequences were only attributed to sub teams, not to individuals within those sub teams. Interviews and video analysis showed that especially within the *surgical* sub team it is sometimes unclear who is supposed to instruct the anesthesiologist or respond to a comment from the perfusionists. This occurred especially when a cardiac surgical trainee was being trained or when a scrub nurse intervened. Future studies could distinguish between individuals to also allow standardization of these practices.

7.4.4 Develop a communication protocol

In this study, only coronary artery bypass graft (CABG) surgeries were considered. CABG surgeries are performed most often and is generally considered one of the most standardized procedures of all cardiac surgeries. Nonetheless huge variations in communication were observed across surgeries and only 58% of all communications occurred in more than one surgery. This emphasizes that communication in the operating room is highly inconsistent.

To standardize communication practice, a communication protocol may be developed. Some events were always verbalized in the same manner. These may encompass the beginning of a communication protocol. Practitioners could design the rest of the protocol.

The results of this study could inform such a process in the following way. A first protocol based on the results of this study is presented in Table 21 (see Appendix p. 179 for whole protocol). Critical events are listed in the way that they were currently verbalized, if verbalized consistently. Inconsistently verbalized events were left blank. Practitioners can indicate whether this protocol matches their practice and further fill in the gaps. The result would constitute an institution-specific communication protocol, based on an analysis of existing practices.

Table 21 Example protocol, containing only surgical phases, initiators and exchange types for critical events that were consistently verbalized in six cardiopulmonary bypass procedures. Gaps therefore indicate that this critical event was inconsistently verbalized throughout the six procedures.

Critical event	Surgical phase	Initiator	Exchange type
Administer heparin	Preparation	Surgery	Direction
Heparine circulating	Preparation		Status
Heparine circulating 2 minutes*	Preparation	Surgery	Status
Activated clotting time (ACT) started	Preparation	Anesthesia	Status
ACT is sufficient for cannulation (>300)	Initiation	Surgery	Status
ACT is sufficient for extracorporeal circulation (>400)	Preparation		Status
Test suction	Preparation		
…	…	..	..

7.4.5 Develop process support tool

A challenge for the implementation of communication protocols, is that an existing communication practice is hard to change. The communication protocol that (Wadhera et al. 2010) developed for example only reduced the number of communication failures as long as the protocol was present (on paper) in the operating room. Long term results were not identified, but the authors emphasized ‘there was a ‘tremendous pull’ towards the state that existed before the intervention and ‘true change’ was generally gradual.

Technological process support tools may support such changes, for example an augmentative communication display such as in (Parush et al. 2011). A process support could remind operating room teams to verbalize a certain event and so help to increase the number of times that a critical event is verbalized for example. Furthermore a process support tool could automatically reduce disturbances during highly critical events. During these events, a process support tool could for example automatically turn down the radio and warn anyone that tries to enter or contact the operating room that a highly critical event is taking place.

The results could inform such developments in various ways. First of all the results indicate what events are deemed highly critical, for example because they were perceived as critical events in this study by all three sub-teams. An example is placement of the aortic cross-clamp. Furthermore what events should be included in such a support tool may follow from the reasons that specialists said to have for finding an exchange critical to verbalize. The interviews with specialists showed for example that some events are only verbalized to keep each other informed about the surgical progress. These events could be automatically displayed and so ‘provide the critical situation information to all OR team members in a continuous manner, and thus minimize the harmful outcomes of communication breakdown and information loss’ (Parush et al. 2011).

7.4.6 Automate analysis to develop surgical black box

Currently several institutions are developing a surgical black box, a monitoring system that automatically tracks surgical performance based on patient data and video recordings (Gambadauro & Magos 2012; Guerlain et al. 2004; Guerlain et al. 2005). The LUMC is currently building a new heart-lung centre and whishes to implement a surgical black box in the new operating rooms.

If the assessment of communication quality based on the quality standard in this study could be automated, it could be implemented in a surgical black box. A first step would be to complement the video and audio recordings with patient data. Examples of such patient data include blood flow, blood pressure, oxygen pressure, activated clotting time, etc. Analysis of patient data in combination with video and audio recordings can provide insights into how communication and teamwork influence surgical performance.

7.5 The future of communication during cardiopulmonary bypass

As perfusion techniques develop, communication practices between perfusionist and surgeon are likely to grow accordingly. Two important trends are likely to change the practice of communication during cardiopulmonary bypass. An important trend is to try and perform 'bloodless' open heart surgery –surgery without the use of transfusion blood. It is thought to minimize the risks of cardiopulmonary bypass and sometimes desired by patients due to religious beliefs. (Olshove et al. 2010) and (Byrne et al. 2001) suggested that bloodless perfusion techniques may pose extra challenges for teamwork and communication as an multidisciplinary effort is required to conserve blood during open heart surgery.

Another recent development in cardiac surgery is that of minimally invasive heart surgery. During minimally invasive heart surgery, cardiopulmonary bypass is not required, meaning that the perfusionist and the heart-lung machine are on standby during the procedure. This situation may pose new communication challenges to surgeon and perfusionist however when emergency initiation of the CPB pump is required (Fernandes et al. 2015).

With ever-changing surgical and perfusion techniques, communication practices are under constant change. This study explored how a quality standard can be developed that is sensitive to these changes and can grow accordingly. By monitoring communication practices with this standard therefore, new developments can flourish without jeopardizing patient safety.

GENERAL DISCUSSION

In this thesis, video cameras were both a topic investigation as well as an instrument of research. In part A video cameras were the topic of investigation, because their implementation and use in operating team research was investigated. In Part B, video cameras were an instrument of research, because they were used to develop a quality standard for the verbal exchanges between surgeons, anesthetists and perfusionists during cardiopulmonary bypass. Below the advantages, conditions and limitations of such integration in one thesis are discussed. The chapter closes with a few closing remarks (on the next page).

Advantage of integration

The advantage of studying the social and ethical context of a research instrument, is that it provides insights on how the instrument can or should be used. A limitation of the study in Part B was for example, that the video recordings were not reviewed with clinicians to protect the privacy of those recorded (patients and personnel). According to the literature, reviewing the recordings with clinicians would have contributed to the validity of the data and provided clinicians with feedback on their practice. According to the literature this could have contributed to patient safety.

The interviews with operating room staff in Part A2 showed that staff would find the use of video recordings *more* relevant and *more* ethically acceptable if they could review their own recordings with an expert on patient safety (as long as staff members feel safe to discuss their practice with colleagues and supervisors). This suggests that reviewing the video recordings with operating room staff could not only have improved the scientific rigor of their analysis, but could also have contributed to the societal relevance and ethical acceptability of their use. As such, investigating the social and ethical context of a research instrument can increase its scientific as well as its societal value.

Limitation with regard to integration

A limitation of this study was that the recommendations formulated in part A of this study were not used to design the conditions of use in Part B of this study. When Part B was performed, the cameras were already installed and permission was already obtained from the institutional review board (IRB). Also most participants had already consented by that time. As such the recommendations of part A could not be used to design the conditions under which the cameras were used in Part B.

If the recommendations of part A could have been used to design the conditions under which the cameras were used in Part B, the integration of both studies would have been stronger. Also the afore mentioned advantages of integration indicate that the use of video cameras in Part B might have been more scientifically rigorous, more relevant and ethically acceptable according to operating room staff.

Condition for integration

A researcher who tries to investigate the social and ethical context of his research instruments should be mindful of his dual role with regard to stakeholders; the first role is the role of the ‘researcher’, who tries to find out how video recordings can be used to produce scientifically sound evidence. The second role is the role of the ‘reporter’, who tries to find out what social and ethical objections stakeholders might have. It is essential to distinguish between these two roles when interviewing stakeholders, because the researcher and the reporter have different incentives and therefore ask different questions. To elicit the full range of social and ethical objections that staff members experience, it was essential in this study to interview staff as a neutral ‘reporter’ rather than as a member of the research team.

The sometimes lengthy interviews and the depth of their answers indicate that staff members indeed took me into their confidence. I believe my position as an outsider (a person from outside of the hospital) was an advantage in this respect. Furthermore because being able to say that the social and ethical context of video cameras was the focus of my study elicited a forthcoming attitude from the stakeholders. Finally my role as a science communicator also allowed me to ask open questions without prejudice. The question was ‘how do you perceive the use of video cameras’ rather than ‘how can we justify the use video cameras’. These three factors supported the depth of the interviews with operating room personnel and so my contributed to my understanding of the social and ethical context of the video cameras.

Closing remarks

In part A, recommendations for the responsible implementation and use of video cameras in operating room research were formulated. The premise of part A of this study was that the use of video recordings can contribute to patient safety. In Part B of this study, the analysis of six recorded cardiopulmonary procedures indeed supported improvements in patient safety in two ways. One, it provided insights with which interventions such as communication protocols and process support tools can be developed. Two, it informed rich discussion with clinicians, who then showed increased mutual understanding of each other's practice and took initiative to improve patient safety.

This thesis shows therefore that the use of video cameras in operating team research can indeed contribute to patient safety and that there are responsible ways to implement and use them. The hope is that with the results of this thesis, video cameras can be used more often and more responsibly in future operating team research.

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APPENDICES PART A

Operationalizing RRI qualifiers for case study (in Dutch)

	Dimension	Operationalization
Responsible processes	**Transparantie** Het informeren van stakeholders over de drijvende krachten achter een beslissing	Hoe, wie wat, waar, wanneer **transparantie** heeft plaatsgevonden doordat: • de onderzoekers stakeholders hebben geïnformeerd over de redenen voor een product- of procesgerelateerde beslissing (via email, werkoverleg, onderzoeksmiddag, etc.) • de onderzoekers stakeholders hebben geïnformeerd over genomen of nog te nemen onderzoeksstappen (via email, werkoverleg, onderzoeksmiddag, etc.)
	Inclusie Het betrekken van maatschappelijke perspectieven	Hoe, wie wat, waar, wanneer **inclusie** heeft plaatsgevonden doordat: • de onderzoekers zich van maatschappelijke perspectieven op de hoogte hebben gesteld (door deze op te zoeken, af te leiden, in te vullen) • stakeholders hun perspectief op het product of de onderzoeksstappen hebben geuit via direct contact met de onderzoekers (bijv. door email, focusgroep, etc.)
	Reflectie Het besef van hoe individuele waarden, wetenschappelijke normen en institutionele beperkingen de onderzoeksstappen beïnvloeden en het besef van hoe het product de maatschappij beïnvloedt	Hoe, wie wat, waar, wanneer **reflectie** heeft plaatsgevonden doordat: • formele (wetenschappelijke) methoden gebruikt zijn • de onderzoekers elkaar feedback hebben gegeven tijdens formele of informele ontmoetingen • de onderzoekers elkaar feedback hebben gegeven door elkaars werk te verbeteren of aan te vullen. Voorbeelden van zulk werk: subsidieaanvragen, deelnemersbrieven, onderzoeksplannen, etc. • de onderzoekers feedback hebben gekregen van stakeholders op het product of de onderzoeksstappen* • individuele reflectie heeft plaatsgevonden
	Anticipatie De identificatie van gewenste en ongewenste gevolgen van het product op de maatschappij en de identificatie van alternatieven voor het product en de onderzoeksstappen	Hoe, wie wat, waar, wanneer **anticipatie** heeft plaatsgevonden doordat • formele (wetenschappelijke) methoden gebruikt zijn • onderzoekers mogelijke gevolgen en alternatieven aan elkaar hebben voorgesteld tijdens formele of informele ontmoetingen • stakeholders de onderzoekers op de hoogte hebben gesteld van tot nog toe onbekende mogelijke gevolgen en alternatieven
	Responsiviteit Het aanpassen van het onderzoeksplan of het product in reactie op veranderende maatschappelijke perspectieven	Hoe, wie, wat, waar, wanneer **responsiviteit** heeft plaatsgevonden doordat aanpassingen zijn gemaakt aan: • het proces (bijv. nieuwe stakeholder groep betrokken) • het product (bijv. nieuwe METC aanvraag)
Responsible products	**Maatschappelijke waarde** Maatschappelijke waarde van het	Wat is/zijn • de maatschappelijke doelstelling van het product • de normen waaraan het product voldoet (conditions of use) • het stadium van ontwikkeling van het product (kennis vs.

	product in termen van maatschappelijke relevantie en bruikbaarheid	tastbaar product)
	Economische waarde	• de economische doelstelling van het product
	Wetenschappelijke waarde	• de wetenschappelijke doelstelling van het product

Interview protocol implementation reconstruction (in Dutch)

Participant: lead investigator (#R1)
Duration: ca. 2u
Pupose: reconstrction implementation process from first inception to first use

Introductie

Gaan vandaag het proces (volgorde van activiteiten en betrokken) in kaart brengen dat leidde tot de in gebruik name van de videocamera's. Ik heb natuurlijk al veel van je gehoord het afgelopen jaar, dus willen vooral mijn beeld completeren. We gaan ons concentreren op feiten, dus ik wil vooral weten wanneer wat gebeurd is. De focus ligt op volgorde van activiteiten, niet op de exacte datum.

- Mag ik ons gesprek opnemen met een audiorecorder of filmcamera?

Proces opdelen in fasen

We beginnen met het opdelen van het proces in twee fasen. Daarvoor moet ik drie dingen weten:

- Begin. Wanneer was eerste officiële projectvergadering? Wat was de aanleiding daartoe?
- Eind. De eerste opname was in juli 2015, correct?
- Wat was het moment waarop je zeker wist: die videocamera's gaan er komen? Ik dacht zelf aan het moment waarop je de financiering rond had. Wanneer was dat precies?

Het proces is nu opgedeeld in twee fasen: aanloop (begin-financiering), uitwerking (financiering-einde). Voor beide fasen gebruiken we een apart flip-overvel.

In kaart brengen van betrokkenen

Dit is een overzicht van de betrokken (laat schematisch diagram van netwerk zien van Onderzoekers, Deelnemers, Goedkeuringscommissies, overige Interne partijen en Externe partijen).

- Klopt dit beeld? Wie mist er nog?
- In het bijzonder:
    - Heb je ook de cliëntenraad betrokken?
    - Wie zat er tijdens dit proces officieel in het 'onderzoeksteam'? Sabrina?
    - Wie is de externe partij die infrastructuur heeft ingezet?
    - Zijn er nog meer mensen zoals Klautz die een dubbelrol vervullen? (bijv. onderzoeker en deelnemer)

In kaart brengen van belangrijke onderzoeksstappen

Contact met betrokkenen

Nu weten we met welke groepen je allemaal contact hebt gehad gedurende het proces. Nu wil ik weten wanneer je met de betrokken contact hebt gehad en op welke manier dat contact verliep.

- Wanneer heb je met deze mensen contact gehad? Vergeet niet het contact met de afdeling als geheel. Contact met eigen onderzoeksleden en met de MEC komt later. *Markeer contactmomenten op de tijdslijn met een ■ voor Deelnemers (waaronder OK-personeel en patiënten), een ■ voor Goedkeuringscommissies, een ■ voor andere Interne partijen en een ■ voor Externe partijen.*
- Hoe verliep het contact, heb je met ze afgesproken of alleen per email? Wie waren er nog meer bij?
- Waar gingen deze contactmomenten over? Was het voornamelijk informeren, vragen om mee te denken, of anders?
- Heb je je nog op andere manieren laten informeren over het perspectief van de betrokkenen dan door middel van direct contact? Bijv. door een website te bezoeken, in te lezen, etc. *Markeer met kleur.*

Contact met andere onderzoekers

We hebben t nu gehad over contact met betrokken maar ik wil ook weten - wanneer heb je met je eigen onderzoeksteam gesproken? We hadden t al gehad over de eerste projectvergadering.

- Hebben er nog meer van zulke vergaderingen plaatsgevonden? *Markeer met een op ■ tijdslijn.*
- Heb je nog op indivudele basis met de onderzoekers afgesproken? *Markeer met een op ■ tijdslijn.*
- Wat is er op die momenten ongeveer besproken? Waren het voortgangsgesprekken of werden er belangrijke besluiten genomen?

Product- en procesaanpassingen

Het derde punt dat ik op de tijdslijn wil zetten is wanneer je je plannen voor het onderzoek of de camera's hebt gewijzigd. Een belangrijk onderdeel daarvan is wanneer je de METC voorstellen hebt ingediend.

- Wanneer METC proposal ingediend? *Markeer met ■ op tijdslijn.*
- Wat heb je ongeveer gewijzigd?

Daarnaast heb je misschien op andere momenten je plannen aangepast. Ik weet bijvoorbeeld dat je hier de manier waarop de camera's staan opgesteld hebt aangepast.

- Hebben er nog meer van dit soort aanpassingen aan de afspraken rondom de camera's plaatsgevonden? Wat paste je aan? *Markeer met ♥ op tijdslijn.*
- Kan je nog momenten herinneren waarop je de onderzoeksplannen (stappen, het proces zelf) hebt aangepast? *Markeer met ♥ op de tijdslijn.*

Moment van individuele reflectie

Laatste vraag gaat over een eventueel moment van individuele reflectie.

- Heb je ergens in dit hele proces een 'aha-erlebnis' moment gehad? Dat je dacht 'nu begrijp ik hoe de vork in de steel zit'? Waar ging dit over? *Markeer met een ★ op tijdslijn.*

Totaalbeeld

Als het goed is hebben we nu een overzicht gekregen van hele proces.

- Mis je nog een belangrijk moment?

In-depth interview protocol with stakeholders (in Dutch)

Participants: researchers (#R1, #R2) and research subjects (#S1 and #S2)
Duration: ca. 30 minutes
Purpose: find out why was IRB protocol revised June 2015

Bedanken deelname

Introductie onderzoeker

Introductie onderzoek

Het gebruik van videocamera's voor niet patiëntgebonden onderzoek wordt steeds populairder in Nederland en erbuiten. Zoals u weet heeft onderzoeker #R1 afgelopen jaar ook videocamera's gebruikt voor zijn onderzoek.

Dit interview gaat over de aanpassing die #R1 heeft ingediend bij de METC rond juni 2015. Het is een mooi voorbeeld van een onderzoeker die de wensen van zijn deelnemers probeert tegemoet te komen, waarvan andere onderzoekers (die ook videocamera's willen gebruiken voor onderzoek op de operatiekamer) mogelijk kunnen leren. Daarom wil ik u een paar vragen stellen over hoe deze protocolwijziging tot stand is gekomen. Het interview zal ongeveer 30 minuten in beslag nemen.

Sommige van de volgende vragen kunt u misschien uitgebreider beantwoorden dan andere, afhankelijk van uw eigen rol in het proces. Dat is prima; beantwoord de vragen vanuit uw eigen perspectief en in zoverre u dat mogelijk acht.

Toestemming vragen om gesprek op te nemen

Interviewvragen

- Kunt u beginnen door uzelf voor te stellen en eigen uw rol bij het onderzoeksproject van Araz te beschrijven?
- In juni 2015 is er een protocolwijziging ingediend. Wat was volgens u de aanleiding tot de protocolwijzing?
    - Welke bezwaren werden er geuit?
    - Op welke manier raakte u van deze bezwaren op de hoogte?
    - In hoeverre had u deze bezwaren aan zien komen?
    - Evt. Hoe verklaart u dat de wens om het protocol aan te passen juist uit de hoek van de anesthesiologie kwam?
    - Wat hadden de onderzoekers volgens u kunnen doen om te voorkomen dat de protocolwijziging nodig was?
- In hoeverre waren de onderzoekers gedwongen om deze aanpassing te maken?
    - Wat was er gebeurd als de onderzoekers deze aanpassing niet hadden gemaakt?
    - Welke andere oplossingen heeft u overwogen?
    - Wat zou u nu anders doen?
- In hoeverre bent u van mening dat de onderzoekers met deze aanpassing de deelnemers tegemoet zijn komen?
- Tot slot: uiteindelijk heeft een groot aantal deelnemers toestemming gegeven om gefilmd te filmen. Wat heeft hen daartoe aangezet denkt u?
- Is er nog iets anders dat u kwijt wilt?

Afsluiting

Nogmaals hartelijk bedankt voor uw deelname. Ik zal u deze week een samenvatting van ons gesprek sturen zodat u kunt controleren of ik u goed begrepen heb.

Als er toch dingen onduidelijk blijken, zou ik dan op een later moment nogmaals mogen contacteren?

National law on video recording in the operating room

Recording video in the Netherlands is strictly regulated by law. The relevant implications of these laws as specified in the guidelines for video registration published by the national association of hospitals [4] are summarized in Table 22.

Table 22 Ruling national laws.

Law	Specifics
Combination of **Wet op Geneeskundige Behandelingsovereenkomst** (WGBO) and **Wet Bescherming Persoonsgegevens** (WBP)	Since the camera's are used to improve quality of care, the two acts together prescribe the following: **Participant consent** • Participants (including any patients, caregivers and visitors) give their permission to be recorded • Participants give permission to the researchers to *view* the recordings. • Participants are well-informed about what data and with what purpose the data is recorded before any permission to record the surgery is granted **Access to recordings** • The recordings are not passed on to third parties, unless the clients give explicit permission to do so • Professional secrecy • Provision of good care (WGBO) • Anyone who is recorded has the right to know what data is recorded (article 35, WBP) **Legal grounds to make recordings** • Necessity criterion: Since medical patient data is recorded (WBP, art 21), the recordings need to be critical for the improvement of patient care. • Necessity criterion: before any videos are recorded, all other less intrusive methods need to be excluded • The recordings can only be used for the purpose specified. • Only data that is relevant for the purpose as specified in the consent form can be recorded. Any additional data cannot be recorded. **Storage of recordings** • The data is stored as long as is necessary for the purpose specified (in this case until the recordings are fully analyzed and discussed). • This period needs to as short as possible. • This period needs to be agreed upon and documented before the recordings are made. • If the recorded procedure was performed according to professional standards, the recording is destroyed directly after the storage period. If a medical error was accidentally recorded, the recordings may be relevant for the further medical treatment of the patient and the patient may want to view and/or use the recording in a procedure against the caregiver. In this case the recording is part of the medical file and is stored up until 15 years after it was made (7:454 paragraph 3 CC) or until the ongoing legal case has closed. • Any recordings that are made to improve quality stored longer than 24 hours need to be submitted to the Dutch data protection authority (College Bescherming Persoonsgegevens, CBP).

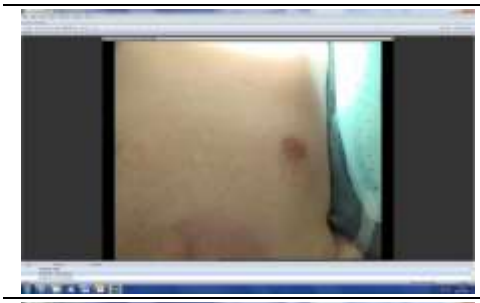
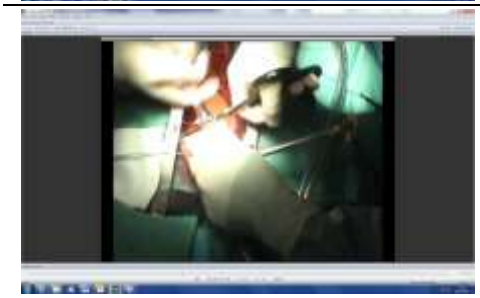
[4] Vereniging van ziekenhuizen NVZ cameratoezicht (pdf), accessed 13 april 2016

Wet Medezeggeschap Clienten Zorginstellingen (WMCZ)	When the recordings can affect patients, the clients participation in healthcare act (WMCZ) applies. This act demands an written recommendation from the institution's client council (cliëntenraad). According to the WMCZ the board of directors (raad van bestuur) cannot deviate from this recommendation. The WMCZ act did not apply in this case case study, because when the study started, the act did not exist yet. The LUMC installed a client council on Wednesday September 10, 2014[5].
Wet op Ondernemingsraden (WOR)	According to the works council act (WOR) the works council (ondernemingsraad) has to the give permission to consent.

[5] https://www.lumc.nl/over-het-lumc/nieuws/2014/september/lumc-heeft-eigen-clientenraad/

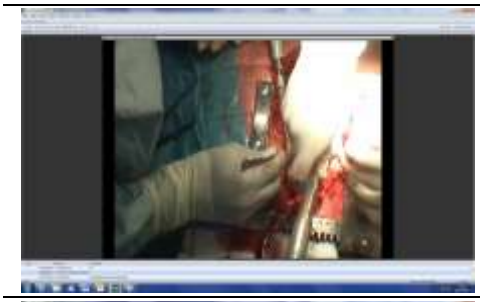
APPENDICES PART B

Images of surgical events used to partition the surgical process

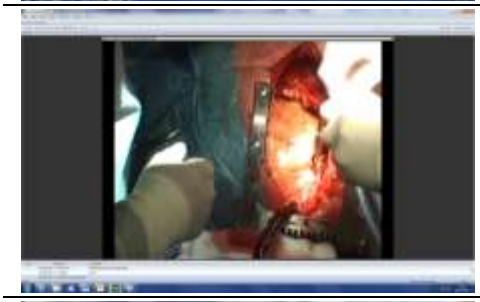
Example video image of the surgical site	Corresponding surgical event.
	I. Opening (first video image)
	II. Incise skin
	III. Apply mammaria retractor to spread chest
	IV. Incise heart sac
	V. Divide arterial and venous lines

VI. Insert arterial cannule (arterial cannulation)

VII. Connect arterial line to arterial cannule



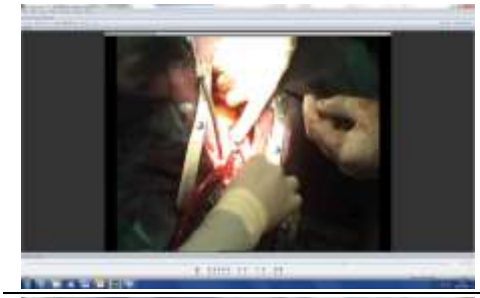
VIII. Insert venous cannule (venous cannulation)



IX. Connect venous line to venous cannule

X. Insert root needle

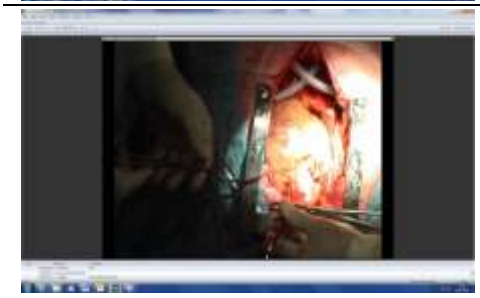
XI. Place aortic cross-clamp



XII. Remove aortic cross-clamp

XIII. Remove aortic root needle

XIV. Remove venous cannule (venous decannulation)



XV. Remove arterial cannule (arterial decannulation)

Structured interview protocol (in Dutch)

Interview protocol

1. Deelnemer bedanken voor deelname
2. Mezelf introduceren
3. Onderzoek introduceren
4. Deelnemer vragen om kritische uitwisselingen te markeren op het formulier
5. Per gemarkeerde uitwisseling vragen *waarom* deze uitwisseling kritisch is – wat zou er gebeuren als deze uitwisseling niet zou plaatsvinden? Aantekeningen maken op formulier.
6. Per gemarkeerde uitwisseling vragen *hoe* deze uitwisseling eruit moet zien: wie moet het zeggen (*sender)*, tegen wie (*receiver)*, en op welk moment (*timing*).
   Van elke gemarkeerde uitwisseling laat ik hen een voorbeeld zien. Dit zorgt ervoor dat alle deelnemers aan hetzelfde denken bij deze uitwisseling, en prikkelt de deelnemer om na te denken over voorwaarden voor succesvolle uitwisseling.
7. Nogmaals bedanken voor deelname
8. Vragen om deel te nemen aan vervolg (focusgroep)

Structured interview form (in Dutch)

Welke verbale uitwisselingen zijn kritisch voor het operatieproces?
Markeer kritische uitwisselingen met een kruis (x) in de eerste kolom. De laatste kolom biedt ruimte voor uitleg.

X	**I. Reguleren van antistolling**	Ruimte voor uitleg
	Geef heparine	
	Heparine circuleert	
	Heparine circuleert 2 minuten	
	ACT is ingezet	
	ACT is adequaat (>400)	
	II. Canulatie	
	Geef de slangen aan	
	Test de zuigers	
	Zuigers werken adequaat	
	Splitsen van de arteriële en veneuze slang	
	Arteriële canulatie	
	Klem is verwijderd van arteriële canule	
	Voldoende pulsaties en lijndrukken	
	Start retrograad autoloog primen (RAP)	
	RAP is volledig	
	Veneuze canulatie	
	Klem is verwijderd van veneuze canule	
	III. Starten perfusie	
	Start perfusie	
	Volle flow bereikt	
	Zet beademing uit	
	IV. Flushen van de cardioplegie	
	Flush cardioplegie	
	Stop met flushen	
	Zuigen aan geel	
	V. Plaatsen van de aortaklem	

	Lage flow	
	Aortaklem is geplaatst	
	Flow weer op	
	VI. Toedienen van de cardioplegie	
	Stop zuigen aan geel	
	Start cardioplegie	
	Druk is goed	
	Hart ligt stil	
	Cardioplegie is volledig	
	Stop met toedienen cardioplegie	
	Zuigen aan geel	
	VII. Verwijderen van de aortaklem	
	Lage flow	
	Aortaklem is af	
	Flow weer op	
	In het geval van een veneuze graft: opmeten van graft	
	Vul het hart	
	Maak het hart leeg	
	VIII. Stoppen perfusie	
	Hervat beademing	
	Beademing is volledig	
	Laat output maken	
	Ritme is goed	
	Vulling is voldoende	
	Verminder flow	
	Perfusie op 1 liter index	
	Perfusie op 1/2 liter index	
	Stop perfusie	
	IX. Decanulatie	
	Stop met zuigen aan geel	
	Plaats klem op plegie (perfusionist)	

	Rootnaald is verwijderd	
	Plaats klem op veneuze canule	
	Verwijder veneuze canule	
	Neem overgebleven bloed in veneuze slang terug	
	Geef protamine	
	Protamine op 1/3	
	Protamine is volledig	
	Plaats klem op arteriële canule	
	Verwijder arteriële canule	
	Neem overgebleven bloed in arteriële slang terug	
	Stop blauwe zuiger	
	Maak pomp leeg	
	Pomp is volledig leeg	
	Andere uitwisselingen	
	Tafel in vulstand	
	Tafel in nulstand	
	Tafel in trendelenburgstand	
	Blauwe zuiger aan	
	Manipulatie aan het hart	
	Papaverine op de mammaria	
	Sample wordt genomen	

Interview results (in Dutch)

Legenda:

★	Uitwisselingen waar een conflict over bestaat
Oranje vlakken	Conflicterend interviewantwoorden
~~Lichtgrijze vlakken~~	Uitwisselingen die niet kritisch zijn om te verbaliseren
Donkergrijze vlakken	Incompleet interview (uitwisseling is pas later toegevoegd)

We zullen in ieder geval alle uitwisselingen met een★ bespreken tijdens de focusgroep.

		Kritisch bevonden ja / nee					
		Chirurgie		*Anesthesie*		*Perfusie*	
	Reguleren van antistolling	RL	SS	JW	SN	AA	LL
	Geef heparine	X	X	X	X		
	Heparine circuleert	X	X	X	X		
★	Heparine circuleert 2 minuten (bij doornemen mammaria)	X	X				
★	ACT is ingezet			X	X	X	X
★	Blauwe zuiger is aan (ACT>300)					X	X
★	ACT is adequaat (>400)		X	X	X	X	X
	Canulatie						
	~~Geef de slangen aan~~ (moet wel gezegd worden, maar heeft geen gevolgen voor de patiënt als het vergeten wordt)	X	X		X	X	X
	Test de zuigers	X	X			X	X
	Zuigers werken adequaat	X	X			X	X
	Splitsen van de arteriële en veneuze slang	X	X			X	X
★	We *gaan* arterieel canuleren		X	X		X	
★	Arteriële canulatie		X	X	X		X
	Klem is verwijderd van arteriële canule	X	X			X	X
	Voldoende pulsaties en lijndrukken	X	X	X	X	X	X
	Kunnen we retrograad autoloog gaan primen?		X	X	X	X	X
★	Start retrograad autoloog primen (alleen bij uitvoeren RAP)		X	X	X	X	X
★	RAP is volledig (alleen bij uitvoeren RAP)				X	X	X
★	Veneuze canulatie				X		
★	Klem is verwijderd van veneuze canule	X	X				
	Starten perfusie						
	Start perfusie	X	X	X	X	X	X
	~~Temperatuur aangeven~~ (wordt tijdens briefing al besproken)						

	Volle flow bereikt	X	X	X	X	X	X
	Pas beademing aan (alleen als S dat nodig vindt)	X	X	X	X		
	Flushen van de cardioplegie						
	Flush cardioplegie	X	X			X	X
	Stop met flushen	X	X			X	X
	Zuigen aan geel (alleen als S dat nodig vindt)	X	X			X	X
	Stop zuigen aan geel (alleen als S dat nodig vindt)	X	X			X	X
	Plaatsen van de aortaklem						
	Lage flow (alleen als S dat nodig vindt)	X	X	X	X	X	X
	Aortaklem is geplaatst	X	X	X	X	X	X
	Flow weer op (alleen als S dat nodig vindt)	X	X	X	X	X	X
	Toedienen van de cardioplegie						
★	Start cardioplegie	X	X		X	X	X
★	Druk is goed		X		X	X	X
★	Hart ligt stil					X	
	Cardioplegie zit er 2 minuten in	X	X			X	X
	Stop toedienen cardioplegie	X	X			X	X
	Zuigen aan geel	X	X			X	X
	Plegietijd is 15 minuten (alleen als plegie nog niet opnieuw is toegediend voor die tijd)	X	X			X	
	Plegietijd is 20 minuten (alleen als plegie nog niet opnieuw is toegediend voor die tijd)	X	X			X	
	Verwijderen van de aortaklem						
	Lage flow (alleen als S dat nodig vindt)	X	X	X	X	X	X
	Aortaklem is af	X	X	X	X	X	X
	Flow weer op (alleen als S dat nodig vindt)	X	X	X	X	X	X
	In het geval van een veneuze graft: opmeten van graft						
	~~Vul het hart~~ (moet wel gezegd worden, maar heeft geen gevolgen als het vergeten wordt)					X	X
	~~Maak het hart leeg~~ (moet wel gezegd worden, maar heeft geen gevolgen als het vergeten wordt)					X	X
	Stoppen perfusie						
	Hervat beademing (alleen als beademing hiervoor is uitgezet of aangepast)	X	X	X	X	X	X
	Beademing is volledig			X	X	X	X
★	Ritme is goed			X			

★	Hartfunctie is goed			X			
★	Temperatuur is goed			X	X		X
★	Laat output maken			X	X	X	X
★	Vulling is voldoende			X		X	X
	Kunnen we flow minderen?	X	X	X		X	
	Verminder flow	X	X	X	X	X	X
★	Perfusie op 1 liter index		X	X	X	X	X
★	Perfusie op 1/2 liter index		X	X	X	X	X
	Stop perfusie	X	X	X	X	X	X
	Decanulatie						
★	Plaats klem op veneuze canule	X		X	X		
★	Verwijder veneuze canule		X	X	X	X	X
	Neem overgebleven bloed in veneuze slang terug	X	X	X	X	X	X
★	Stop met zuigen aan geel			X		X	
	~~Plaats klem op plegie~~ (geen gevolgen voor de patiënt als het vergeten wordt)			X			
★	Rootnaald is verwijderd	X	X	X		X	X
	Geef protamine	X	X	X	X	X	X
	Protamine loopt	X	X			X	
	Protamine op 1/3	X	X	X	X	X	X
	Stop blauwe zuiger			X	X	X	X
★	Hoeveel heb je nog in de pomp?	X	X	X	X	X	
★	Maak pomp leeg	X	X	X		X	X
	Pomp is volledig leeg	X	X	X	X	X	X
★	Plaats klem op arteriële canule	X		X	X	X	X
★	Verwijder arteriële canule		X	X	X	X	X
★	Neem overgebleven bloed in arteriële slang terug			X			X
★	Protamine is volledig			X	X	X	
	Andere uitwisselingen						
	~~Tafel in vulstand~~ (moet wel gezegd worden, maar heeft geen gevolgen als het vergeten wordt)				X	X	X
	~~Tafel in nulstand~~ (moet wel gezegd worden, maar heeft geen gevolgen als het vergeten wordt)				X	X	X
	~~Tafel in trendelenburgstand~~ (moet wel gezegd worden, maar heeft geen gevolgen als het vergeten wordt)				X	X	X
	Tafels op / neer		X		X	X	X

★	Manipulatie aan het hart		X	X	X	X	X
★	Papaverine op de mammaria	X	X	X	X	X	
	Nitroprusside op de mammaria		X	X	X	X	
★	Sample wordt genomen		X	X	X	X	X

Focus group results (in Dutch)

~~Doorgestreept~~ Uncritical event

X New X, resulting in consensus about this event

X removed, resulting in consensus about this event

	Kritisch bevonden ja / nee						
	Chirurgie		*Anesthesie*		*Perfusie*		
Reguleren van antistolling	RL	SS	JW	SN	AA	LL	Aantekeningen focusgroep
Geef heparine	X	X	X	X			
Heparine circuleert	X	X	X	X			Dan weet de chirurg ook: vanaf hier nog 2 minuten wachten
Heparine circuleert 2 minuten *	X	X	X	X			Wist anesthesie niet, is handig als chirurg even aangeeft dat ze willen worden gewaarschuwd na 2 minuten en dat anesthesie na 2 minuten aangeeft
ACT is ingezet			X	X	X	X	
Blauwe zuiger is aan (ACT>300) / ACT is adequaat voor canulatie	X	X			X	X	Vaak reageert de operatieassistent. Wordt nu weinig gezegd.
ACT is adequaat (>400) / ACT is adequaat voor perfusie	X	X	X	X	X	X	Je luistert ook niet meer als het elke keer adequaat is. Bent als perfusionist/chirurg ook met andere dingen bezig. De waarde 400 hebben we in dit instituut afgesproken, kan ergens anders anders zijn. Moet wel hier worden gecomuniceerd omdat het anders te laat is als ACT *niet* voldoende is.
Canulatie							
~~Geef de slangen aan~~							Inderdaad geen indicatie van kwaliteit, want wordt toch altijd gezegd.
Test de zuigers	X	X			X	X	
Zuigers werken adequaat	X	X			X	X	
Splitsen van de arteriële en veneuze slang	X	X			X	X	
We gaan **voorbereiden op** arterieel canuleren	X	X	X	X	X	X	Handig als chirurg dit aangeeft als hij beursnaden gaat zetten, zodat A en P genoeg tijd hebben om voor te bereiden.
Arteriële canulatie	X	X	X	X	X	X	Handig om iedereen alert te maken want is kritisch moment.
Klem is verwijderd van arteriële canule	X	X			X	X	

Voldoende pulsaties en lijndrukken	X	X	X	X	X	X	
Kunnen we retrograad autoloog gaan primen?	X	X	X	X	X	X	
Start retrograad autoloog primen (RAP) **	X	X	X	X	X	X	Handig om ook chirurg te informeren want heeft hemodynamische consequenties
RAP is volledig **			X	X	X	X	
~~Veneuze canulatie~~							Vrijwel nooit een gevaarlijk moment en A kan het zelf zien
~~Klem is verwijderd van veneuze canule~~							
Starten perfusie							
Start perfusie	X	X	X	X	X	X	
Temperatuur aangeven	X	X			X	X	Moet standaard worden aangegeven bij starten perfusie. Perfusionist zegt nu vaak terug dat hij normotherm oid draait.
Volle flow bereikt	X	X	X	X	X	X	
Pas beademing (niet) aan	X	X	X	X			Nu geen protocol voor beademing
Flushen van de cardioplegie							
Flush cardioplegie	X	X			X	X	
Stop met flushen	X	X			X	X	
~~Zuigen aan geel ***~~	X	X			X	X	Zouden chirurgen niet moeten doen, zijn al een aantal incidenten mee geweest. Geen indicatie van communicatiekwaliteit maar van operatieve kwaliteit.
~~Stop zuigen aan geel ***~~	X	X			X	X	Zie zuigen aan geel.
Plaatsen van de aortaklem							
Lage flow ***	X	X	X	X	X	X	
Aortaklem is geplaatst	X	X	X	X	X	X	
Flow weer op ***	X	X	X	X	X	X	
Toedienen van de cardioplegie							
Start cardioplegie	X	X	X	X	X	X	
Druk in wortel is goed	X	X			X	X	
Hoeveelheid plegie flow	X	X			X	X	
Hart ligt stil / ECG is vlak	X	X	X	X	X	X	Zou perfusionist moeten zeggen want die is al met cardioplegie bezig. In theorie hoef je hierna geen plegie

							meer te geven (de eerste keer), maar dat is nu eenmaal afgesproken tot tenminste 2 minuten. Signaal dat plegie gestopt kan worden.
Cardioplegie zit er 2 minuten in	X	X			X	X	
Stop toedienen cardioplegie	X	X			X	X	
Zuigen aan geel	X	X			X	X	
Plegietijd is 15 minuten ****	X	X	X	X	X	X	
Plegietijd is 20 minuten ****	X	X	X	X	X	X	
Verwijderen van de aortaklem							
Lage flow ***	X	X	X	X	X	X	
Aortaklem is af	X	X	X	X	X	X	
Flow weer op ***	X	X	X	X	X	X	
In het geval van een veneuze graft: opmeten van graft							
~~Vul het hart~~ ***							
~~Maak het hart leeg ***~~							
Stoppen perfusie							
Hervat beademing *****	X	X	X	X	X	X	
Laat output maken	X	X	X	X	X	X	
Kunnen we flow minderen?	X	X	X	X	X	X	Lijstje hieronder vooral fijn als je in opleiding bent, voor ervaren chirurgen waarschijnlijk minder van belang. In het algemeen voordeel van expliciet lijstje benoemen dat je niet één persoon verantwoordelijk maakt om het te checken (wat ook een risico is) voor deze belangrijke en risicovolle operatiestap.
Beademing is volledig	X	X	X	X	X	X	Antwoord op ‘kunnen we flow minderen’. Is meestal één keer goed
Ritme is goed	X	X	X	X	X	X	Antwoord op ‘kunnen we flow minderen’. Is meestal één keer goed
Hartfunctie is goed	X	X	X	X	X	X	Antwoord op ‘kunnen we flow minderen’. Is iets dat kan veranderen tijdens de procedure
Temperatuur is goed	X	X	X	X	X	X	Antwoord op ‘kunnen we flow minderen’. Is meestal één keer goed
Vulling is voldoende	X	X	X	X	X	X	Antwoord op ‘kunnen we

							flow minderen’
Verminder flow / van perfusie gaan	X	X	X	X	X	X	
Perfusie op 1 liter index	X	X	X	X	X	X	
Perfusie op 1/2 liter index	X	X	X	X	X	X	
Stop perfusie	X	X	X	X	X	X	
Decanulatie							
Geef protamine	X	X	X	X	X	X	
Protamine loopt	X	X			X		Niet handeling aan gekoppeld zoals bij heparine
~~Stop met zuigen aan geel~~							Niet belangrijk, kan ook zonder stoppen met zuigen wel de rootnaald verwijderen
~~Plaats klem op plegie~~							Geen gevolgen voor patiënt
Rootnaald is verwijderd	X	X	X	X	X	X	Belangrijk voor anesthesia want kan niet meer ontluchten en waar de naald uit gaat onstaat een gat in en vat, altijd relevant.
~~Plaats klem op veneuze canule ***~~							Niet alle chirurgen klemmen en voor anesthesie belangrijker dat ze weten wanneer veneus eruit *is*.
Veneuze canule is verwijderd	X	X	X	X	X	X	Belangrijk voor anesthesie en perfusie om te weten
Neem overgebleven bloed in veneuze slang terug	X	X	X	X	X	X	Belangrijk om te communiceren, want anders halen ze klem eraf en is pomp nog niet helemaal uit.
Protamine op 1/3	X	X	X	X	X	X	
Stop blauwe zuiger			X	X	X	X	
Hoeveel heb je nog in de pomp?	X	X	X	X	X	X	Belangrijk omdat A en S willen meedenken over ruimte voor vulling. S weet wanneer dit handig is, dus hij begint erover.
Maak pomp leeg	X	X	X	X	X	X	Meestal wordt moment door chirurg bepaald, dus die vraagt ook hoeveel er nog inzit
Pomp is volledig leeg	X	X	X	X	X	X	
~~Plaats klem op arteriële canule~~							
Arteriële canule is verwijderd	X	X	X	X	X	X	
~~Neem overgebleven bloed in arteriële slang terug~~ ******							Wordt niet altijd gedaan, patiënt ervaart geen negatieve gevolgen als je het niet zegt, maar chirurg kan wel onder bloed komen te zitten.

Protamine is volledig	X	X	X	X	X	X	Voor chirurgie belangrijk om inschatting te maken van de stolling
Andere uitwisselingen							
Tafel in vulstand	X	X	X	X	X	X	Kan ook alle tafelbewegingen samennemen, want meningen verschillen er niet over. P > A kan niet vergeten worden, maar A > S moet wel echt gezegd worden
Tafel in nulstand	X	X	X	X	X	X	P > A kan niet vergeten worden, maar A > S moet wel echt gezegd worden
Tafel in trendelenburgstand	X	X	X	X	X	X	P > A kan niet vergeten worden, maar A > S moet wel echt gezegd worden
Tafels op / neer	X	X	X	X	X	X	P > A kan niet vergeten worden, maar A > S moet wel echt gezegd worden
Hemodynamisch compromitterende manipulatie aan het hart	X	X	X	X	X	X	
~~Papaverine op de mammaria~~	X	X	X	X			Heeft niks met op / van perfusie gaan te maken.
~~Nitroprusside op de mammaria~~		X	X	X			Nu nog één chirurg die het gebruikt. Moet eigenlijk niet meer gebruikt worden.
~~Sample wordt genomen~~		X	X	X	X	X	Belangrijk áls tijdens perfusie van de lijn wordt genomen, maar dit gebeurt niet vaak

* Alleen kritisch bij doornemen van de mammaria (**alleen bij RIMA, niet bij LIMA vene**); ** Alleen kritisch bij uitvoeren RAP; *** Alleen kritisch als S de bijbehorende handeling uitvoert; **** Alleen kritisch als de plegie hiervoor niet al opnieuw gegeven is; ***** Alleen kritisch als de beademing hiervoor is uitgezet of aangepast; ****** Alleen kritisch als bloed uit arteriële slang wordt teruggenomen;

Critical events and their corresponding critical participants

Regulate anticoagulation	Critical for surgical sub-team	Critical for anesthetic sub-team	Critical for perfusion sub-team	Critical for two or three sub-teams
Adminster heparin	X	X		
Heparine circulating	X	X		
Heparine circulating 2 minutes	X	X		*
Activated clotting time (ACT) started		X	X	
ACT is sufficient for canulation (>300) / blue suction is on	X		X	
ACT is sufficient for extracorporeal circulation (>400)	X	X	X	
Canulation				
Test suction	X		X	
Suction is adequate	X		X	
Divide the arterial and venous line	X		X	
Prepare for canulation	X	X	X	
Arterial canule has been inserted	X	X	X	
Clamp removed from arterial canule	X		X	
Sufficient pulsation and line pressure	X	X	X	
Permission to start retrograde autologous priming (RAP)	X	X	X	
Start RAP	X	X	X	**
RAP is complete		X	X	**
Clamp removed from venous cannule	X		X	
Start extracorporeal circulation (ECC)				
Start ECC	X	X	X	
Indicate ECC temperature	X		X	
Full flow achieved	X	X	X	
(Do not) adjust artificial breathing	X	X		
Flush cardioplegia				
Flush cardioplegia	X		X	
Stop flushing	X		X	

Place aortic cross-clamp				
Low flow	X	X	X	**
Aortic cross-clamp placed	X	X	X	
Normal flow	X	X	X	***
Administer cardioplegia				
Start cardioplegia	X	X	X	
Pressure in root is adequate	X		X	
Flow is adequate	X		X	
Hart is still	X	X	X	
Cardioplegia circulating for 2 minutes	X		X	
Stop cardioplegia	X		X	
Suck yellow	X		X	
Last cardioplegia administered 15 minutes ago	X	X	X	****
Last cardioplegia administered 20 minutes ago	X	X	X	****
Remove aortic cross-clamp				
Low flow	X	X	X	**
Aortic cross-clamp removed	X	X	X	
Normal flow	X	X	X	***
Stop ECC				
Continue artificial breathing	X	X	X	*****
Make output	X	X	X	
Permission to reduce flow	X	X	X	
Artificial breathing is on	X	X	X	
Heart rhythm is adequate	X	X	X	
Heart function is adequate	X	X	X	
Heart filling is adequate	X	X	X	
Patient body temperature is adequate	X	X	X	
Reduce flow / stop ECC	X	X	X	
ECC at 1 liter index	X	X	X	
ECC at 1/2 liter index	X	X	X	
Stop ECC	X	X	X	
Decanulation				

Administer protamine	X	X	X	
Root neelde removed	X	X	X	
Venous canule removed	X	X	X	
Withdraw blood from venous line	X	X	X	
Protamine at 1/3	X	X	X	
Stop blue suction		X	X	
Blood volume left in pump	X	X	X	
Empty pump	X	X	X	
Pomp is completely empty	X	X	X	
Arterial canule removed	X	X	X	
Protamine complete	X	X	X	
Andere uitwisselingen				
Table movements	X	X	X	**
Hemodynamically compromising manipulation of the heart	X	X	X	**
Sample taken from anesthetic line during ECC	X	X	X	**

* Only critical when the RIMA is passed through; ** Only critical if the corresponding activity is performed; *** Only critical if flow was turned down before; **** Only critical if the cardioplegia has not been given again before this time; ***** Only critical if the artificial breathing was adjusted or turned off before;

Consistency of exchange timing

Number of exchanges per surgical phase (sum across six surgeries). Total number of different surgical phases in the last column, numbers over 1 indicating an inconsistency.

Event	Mammaria retractor appears	First incision pericard	Divide arterial and venous lines	Arterial cannule inserted	Arterial line connected	Venous cannule inserted	Venous line connected	Root needle inserted	Cross-clamp placed	Cross-clamp removed	Venous decannulation	Arterial decannulation	**Number of different surgical phases**
Administer heparin	5	1	.	.	.	.	.	.	.	.	.	.	**2**
Heparine circulating	7	2	.	.	.	.	.	.	.	.	.	.	**2**
Heparine circulating 2 minutes*	1	.	.	.	.	.	.	.	.	.	.	.	**1**
Activated clotting time (ACT) started	1	2	.	.	.	.	.	.	.	.	.	.	**2**
ACT is sufficient for cannulation (>300)	.	.	2	.	.	.	.	.	.	.	.	.	**1**
ACT is sufficient for extracorporeal circulation (>400)	4	5	.	.	.	.	.	.	.	.	.	.	**2**
Test suction	.	7	.	.	.	.	.	.	.	.	.	.	**1**
Suction is adequate	.	7	.	.	.	.	.	.	.	.	.	.	**1**
Divide the arterial and venous line	.	6	1	.	.	.	.	.	.	.	.	.	**2**
Prepare for cannulation	.	.	3	.	.	.	.	.	.	.	.	.	**1**
Arterial cannule has been inserted	.	.	.	10	2	.	.	.	.	.	.	.	**2**
Clamp removed from arterial cannule	.	.	.	.	5	.	.	.	.	.	.	.	**1**
Sufficient pulsation and line pressure	.	.	.	.	6	.	.	.	.	.	.	.	**1**
Permission to start retrograde autologous priming (RAP)	.	.	.	.	1	.	.	.	.	.	.	.	**1**
Start RAP*	.	.	.	1	1	.	.	.	.	.	.	.	**2**
RAP is complete*	.	.	.	.	.	1	.	.	.	.	.	.	**1**
Clamp removed from venous cannule	.	.	.	.	.	.	4	.	.	.	.	.	**1**
Start ECC	.	.	.	.	.	.	6	.	.	.	.	.	**1**
Full flow achieved	.	.	.	.	.	.	4	1	.	.	.	.	**2**
(Do not) adjust artificial breathing	.	.	.	.	.	.	5	2	.	.	.	.	**2**
Flush cardioplegia	.	.	.	.	.	.	.	6	.	.	.	.	**1**
Stop flushing	.	.	.	.	.	.	.	6	.	.	.	.	**1**
Low flow*	.	.	.	.	.	.	.	6	1	.	.	.	**2**
Aortic cross-clamp placed	.	.	.	.	.	.	.	1	6	.	.	.	**2**
Normal flow*	.	.	.	.	.	.	.	.	4	.	.	.	**1**
Start cardioplegia	.	.	.	.	.	.	.	.	6	.	.	.	**1**
Pressure in root is adequate	.	.	.	.	.	.	.	.	5	.	.	.	**1**
Flow is adequate	.	.	.	.	.	.	.	.	2	.	.	.	**1**

Hart is still	.	.	.	.	.	.	.	.	1	.	.	.	**1**
Cardioplegia circulating for 2 minutes	.	.	.	.	.	.	.	.	5	.	.	.	**1**
Stop cardioplegia	.	.	.	.	.	.	.	.	6	.	.	.	**1**
Suck yellow	.	.	.	.	.	.	.	.	11	.	.	.	**1**
Low flow*	.	.	.	.	.	.	.	.	4	.	.	.	**1**
Aortic cross-clamp removed	.	.	.	.	.	.	.	.	2	4	.	.	**2**
Normal flow*	.	.	.	.	.	.	.	.	.	4	.	.	**1**
Low flow*	.	.	.	.	.	.	.	.	.	2	.	.	**1**
Aortic side-clamp placed*	.	.	.	.	.	.	.	.	.	3	.	.	**1**
Normal flow*	.	.	.	.	.	.	.	.	.	2	.	.	**1**
Low flow*	.	.	.	.	.	.	.	.	.	2	.	.	**1**
Aortic side-clamp removed*	.	.	.	.	.	.	.	.	.	3	.	.	**1**
Normal flow*	.	.	.	.	.	.	.	.	.	2	.	.	**1**
Continue artificial breathing*	.	.	.	.	.	.	.	.	.	4	.	.	**1**
Generate cardiac output	.	.	.	.	.	.	.	.	.	9	.	.	**1**
Permission to reduce flow	.	.	.	.	.	.	.	.	.	2	.	.	**1**
Artificial breathing is on	.	.	.	.	.	.	.	.	.	5	.	.	**1**
Heart rhythm is adequate	.	.	.	.	.	.	.	.	.	2	1	.	**2**
Heart function is adequate	.	.	.	.	.	.	.	.	.	5	1	.	**2**
Heart filling is adequate	.	.	.	.	.	.	.	.	.	3	1	.	**2**
Reduce flow	.	.	.	.	.	.	.	.	.	11	.	.	**1**
ECC at 1 liter index	.	.	.	.	.	.	.	.	.	4	.	.	**1**
ECC at 1/2 liter index	.	.	.	.	.	.	.	.	.	5	.	.	**1**
Stop ECC	.	.	.	.	.	.	.	.	.	10	.	.	**1**
Administer protamine	.	.	.	.	.	.	.	.	.	.	9	.	**1**
Root needle removed	.	.	.	.	.	.	.	.	.	3	.	.	**1**
Venous cannule removed	.	.	.	.	.	.	.	.	.	2	4	.	**2**
Withdraw blood from venous line	.	.	.	.	.	.	.	.	.	.	4	.	**1**
Protamine at 1/3	.	.	.	.	.	.	.	.	.	.	6	1	**2**
Stop blue suction	.	.	.	.	.	.	.	.	.	.	4	.	**1**
Blood volume left in pump	.	.	.	.	.	.	.	.	.	.	3	.	**1**
Empty pump	.	.	.	.	.	.	.	.	.	.	4	.	**1**
Pump is empty	.	.	.	.	.	.	.	.	.	.	7	.	**1**
Arterial cannule removed	.	.	.	.	.	.	.	.	.	.	.	2	**1**
Protamine complete	.	.	.	.	.	.	.	.	.	.	1	4	**2**
Table movements*	.	.	.	.	.	.	.	.	.	2	9	2	**3**
Hemodynamically compromising manipulation of the heart*	.	1	.	.	.	.	2	.	.	2	1	3	**5**

Consistency of initiators

Number of exchanges per initiating sub-team. Total number of different initiators in the last column, numbers over 1 indicating an inconsistency.

Event	Surgery	Anesthesia	Perfusion	Number of different initiators
Administer heparin	6	.	.	1
Heparine circulating	3	6	.	2
Heparine circulating 2 minutes*	1	.	.	1
Activated clotting time (ACT) started	.	3	.	1
ACT is sufficient for cannulation (>300)	2	.	.	1
ACT is sufficient for extracorporeal circulation (>400)	2	6	1	3
Test suction	6	.	1	2
Suction is adequate	4	.	3	2
Divide the arterial and venous line	7	.	.	1
Prepare for cannulation	3	.	.	1
Arterial cannule has been inserted	11	.	1	2
Clamp removed from arterial cannule	5	.	.	1
Sufficient pulsation and line pressure	4	.	3	2
Permission to start retrograde autologous priming (RAP)	.	.	1	1
Start RAP*	1	.	1	2
RAP is complete*	.	.	1	1
Clamp removed from venous cannule	4	.	.	1
Start ECC	4	.	2	2
Full flow achieved	.	1	4	2
(Do not) adjust artificial breathing	6	1	.	2
Flush cardioplegia	6	.	.	1
Stop flushing	6	.	.	1
Low flow*	6	.	1	2
Aortic cross-clamp placed	7	.	.	1
Normal flow*	4	.	.	1
Start cardioplegia	6	.	.	1
Pressure in root is adequate	4	.	1	2
Flow is adequate	1	.	1	2
Hart is still	.	.	1	1
Cardioplegia circulating for 2 minutes	.	.	5	1
Stop cardioplegia	3	.	3	2
Suck yellow	10	.	1	2
Low flow*	4	.	.	1
Aortic cross-clamp removed	6	.	.	1
Normal flow*	4	.	.	1
Low flow*	2	.	.	1

Aortic side-clamp placed*	3	.	.	**1**
Normal flow*	2	.	.	**1**
Low flow*	2	.	.	**1**
Aortic side-clamp removed*	3	.	.	**1**
Normal flow*	2	.	.	**1**
Continue artificial breathing*	3	1	.	**2**
Generate cardiac output	8	.	1	**2**
Permission to reduce flow	.	2	.	**1**
Artificial breathing is on	1	1	3	**3**
Heart rhythm is adequate	2	1	.	**2**
Heart function is adequate	4	2	.	**2**
Heart filling is adequate	3	1	.	**2**
Reduce flow	7	.	4	**2**
ECC at 1 liter index	.	.	4	**1**
ECC at 1/2 liter index	.	.	5	**1**
Stop ECC	3	.	7	**2**
Administer protamine	5	3	.	**2**
Root needle removed	3	.	.	**1**
Venous cannule removed	6	.	.	**1**
Withdraw blood from venous line	4	.	.	**1**
Protamine at 1/3	.	7	.	**1**
Stop blue suction	3	.	1	**2**
Blood volume left in pump	2	.	1	**2**
Empty pump	2	.	2	**2**
Pump is empty	1	.	5	**2**
Arterial cannule removed	2	.	.	**1**
Protamine complete	.	5	.	**1**
Table movements*	.	8	5	**2**
Hemodynamically compromising manipulation of the heart*	7	2	.	**2**

Consistency of exchange types

Number of exchanges per exchange type (sum across six surgeries). The consistency of exchange type is indicated with the number of different exchange types used (last column), number over 1 indicating an inconsistency. .

Event	Direction	Goal sharing	Status	Explanation	Problem solving	Permission	Number of different types
Administer heparin	6	.	.	.	.	.	1
Heparine circulating	.	.	9	.	.	.	1
Heparine circulating 2 minutes*	.	.	1	.	.	.	1
Activated clotting time (ACT) started	.	.	3	.	.	.	1
ACT is sufficient for cannulation (>300)	.	.	2	.	.	.	1
ACT is sufficient for extracorporeal circulation (>400)	.	.	9	.	.	.	1
Test suction	4	.	3	.	.	.	2
Suction is adequate	.	.	7	.	.	.	1
Divide the arterial and venous line	.	.	2	.	.	5	2
Prepare for cannulation	.	3	.	.	.	.	1
Arterial cannule has been inserted	10	.	1	1	.	.	3
Clamp removed from arterial cannule	.	.	4	.	.	1	2
Sufficient pulsation and line pressure	.	.	7	.	.	.	1
Permission to start retrograde autologous priming (RAP)	.	.	.	.	.	1	1
Start RAP*	.	2	.	.	.	.	1
RAP is complete*	.	.	1	.	.	.	1
Clamp removed from venous cannule	.	.	4	.	.	.	1
Start ECC	3	.	3	.	.	.	2
Full flow achieved	.	.	5	.	.	.	1
(Do not) adjust artificial breathing	5	1	1	.	.	.	3
Flush cardioplegia	5	.	1	.	.	.	2
Stop flushing	6	.	.	.	.	.	1
Low flow*	6	.	1	.	.	.	2
Aortic cross-clamp placed	.	1	6	.	.	.	2
Normal flow*	4	.	.	.	.	.	1
Start cardioplegia	6	.	.	.	.	.	1
Pressure in root is adequate	.	.	4	.	.	.	1
Flow is adequate	.	.	2	.	.	.	1
Hart is still	.	.	1	.	.	.	1
Cardioplegia circulating for 2 minutes	.	.	5	.	.	.	1
Stop cardioplegia	3	.	3	.	.	.	2

Suck yellow	7	1	3	.	.	.	**3**
Low flow*	4	.	.	.	.	.	**1**
Aortic cross-clamp removed	.	.	6	.	.	.	**1**
Normal flow*	4	.	.	.	.	.	**1**
Low flow*	2	.	.	.	.	.	**1**
Aortic side-clamp placed*	.	.	3	.	.	.	**1**
Normal flow*	2	.	.	.	.	.	**1**
Low flow*	2	.	.	.	.	.	**1**
Aortic side-clamp removed*	.	.	3	.	.	.	**1**
Normal flow*	2	.	.	.	.	.	**1**
Continue artificial breathing*	2	.	2	.	.	.	**2**
Generate cardiac output	5	.	1	.	.	3	**3**
Permission to reduce flow	.	.	.	.	1	1	**2**
Artificial breathing is on	.	.	5	.	.	.	**1**
Heart rhythm is adequate	.	.	3	.	.	.	**1**
Heart function is adequate	.	.	6	.	.	.	**1**
Heart filling is adequate	.	.	4	.	.	.	**1**
Reduce flow	4	.	1	.	.	6	**3**
ECC at 1 liter index	.	.	4	.	.	.	**1**
ECC at 1/2 liter index	.	.	5	.	.	.	**1**
Stop ECC	3	1	3	.	.	3	**4**
Administer protamine	4	.	1	.	.	3	**3**
Root needle removed	1	1	1	.	.	.	**3**
Venous cannule removed	2	.	4	.	.	.	**2**
Withdraw blood from venous line	4	.	.	.	.	.	**1**
Protamine at 1/3	.	.	7	.	.	.	**1**
Stop blue suction	3	.	1	.	.	.	**2**
Blood volume left in pump	.	.	3	.	.	.	**1**
Empty pump	2	.	1	1	.	.	**3**
Pump is empty	.	.	7	.	.	.	**1**
Arterial cannule removed	.	.	2	.	.	.	**1**
Protamine complete	.	.	5	.	.	.	**1**
Table movements*	5	1	7	.	.	.	**3**
Hemodynamically compromising manipulation of the heart*	1	.	7	1	.	.	**3**

Results summary

Critical event	Number of critical sub-teams	Conflicts about criticalness of event y/n	Total number of exchanges	Portion of cases this event wasn't verbalized in	Portion of uninvolved critical participants	Portion of Open loop exchanges	Portion insubstantive call-backs	Portion of undirected exchanges	Number of different surgical phases (out of 5 in total)	Number of different exchange types (out of 6 in total)	Number of different initiators (out of 3 in total)	Sum of different phases, exchange types and initiators*
Administer heparin	2		6	0,00	0,00	0,17	0,80	1,00	1	1	1	0
Heparine circulating	2		9	0,00	0,00	0,67	0,33	1,00	1	1	2	1
Heparine circulating 2 minutes*	2	Y	1	0,83	0,00	0,00	0,00	0,00	1	1	1	0
Activated clotting time (ACT) started	2	Y	3	0,50	0,50	1,00	0,00	1,00	1	1	1	0
ACT is sufficient for cannulation (>300)	2	Y	2	0,67	0,00	0,00	0,00	1,00	1	1	1	0
ACT is sufficient for extracorporeal circulation (>400)	3	Y	9	0,17	0,00	0,33	0,83	1,00	1	1	3	2
Test suction	2		7	0,17	0,00	0,29	0,60	0,71	1	2	2	2
Suction is adequate	2		7	0,17	0,00	0,43	0,50	1,00	1	1	2	1
Divide the arterial and venous line	2		7	0,17	0,00	0,29	0,80	1,00	2	2	1	2
Prepare for cannulation	3	Y	3	0,67	0,67	1,00	0,00	1,00	1	1	1	0
Arterial cannule has been inserted	3	Y	12	0,00	0,33	0,42	0,43	0,92	1	3	2	3
Clamp removed from arterial cannule	2		5	0,17	0,00	0,20	1,00	1,00	1	2	1	1
Sufficient pulsation and line pressure	3		6	0,00	0,33	0,33	0,50	1,00	1	1	2	1
Permission to start retrograde autologous priming (RAP)	3		1	0,83	0,33	0,00	1,00	1,00	1	1	1	0
Start RAP*	3	Y	2	0,67	0,33	0,00	1,00	0,50	1	1	2	1
RAP is complete*	2	Y	1	0,83	0,50	0,00	1,00	1,00	1	1	1	0
Clamp removed from venous cannule	2	Y	4	0,33	0,00	0,50	1,00	1,00	1	1	1	0
Start ECC	3		6	0,17	0,33	0,33	0,50	1,00	1	2	2	2
Full flow achieved	3		5	0,17	0,00	0,20	0,50	1,00	1	1	2	1
(Do not) adjust artificial breathing	2		7	0,17	0,00	0,14	0,17	1,00	1	3	2	3
Flush cardioplegia	2		6	0,17	0,00	0,00	0,33	0,83	1	2	1	1
Stop flushing	2		6	0,00	0,00	0,00	0,00	1,00	1	1	1	0

Low flow*	3		7	0,17	0,33	0,14	0,17	1,00	2	2	2	3
Aortic cross-clamp placed	3		7	0,00	0,33	0,14	0,33	1,00	2	2	1	2
Normal flow*	3		4	0,33	0,33	0,00	0,00	1,00	1	1	1	0
Start cardioplegia	3	Y	6	0,00	0,33	0,17	0,40	1,00	1	1	1	0
Pressure in root is adequate	2	Y	5	0,33	0,00	0,40	0,67	1,00	1	1	2	1
Flow is adequate	2	Y	2	0,67	0,00	0,00	0,50	1,00	1	1	2	1
Hart is still	3	Y	1	0,83	0,33	0,00	1,00	1,00	1	1	1	0
Cardioplegia circulating for 2 minutes	2		5	0,17	0,00	0,20	0,75	1,00	1	1	1	0
Stop cardioplegia	2		6	0,00	0,00	0,33	0,00	1,00	1	2	2	2
Suck yellow	2		11	0,00	0,00	0,09	0,40	1,00	1	3	2	3
Low flow*	3		4	0,33	0,33	0,00	0,00	1,00	1	1	1	0
Aortic cross-clamp removed	3		6	0,00	0,33	0,50	0,33	1,00	2	1	1	1
Normal flow*	3		4	0,33	0,33	0,00	0,25	1,00	1	1	1	0
Low flow*	3		2	0,67	0,33	0,00	0,00	1,00	1	1	1	0
Aortic side-clamp placed*	3		3	0,50	0,33	0,67	1,00	1,00	1	1	1	0
Normal flow*	3		2	0,67	0,33	0,00	0,00	1,00	1	1	1	0
Low flow*	3		2	0,67	0,33	0,00	0,00	1,00	1	1	1	0
Aortic side-clamp removed*	3		3	0,50	0,33	0,67	0,00	1,00	1	1	1	0
Normal flow*	3		2	0,67	0,33	0,00	0,00	1,00	1	1	1	0
Continue artificial breathing*	3		4	0,50	0,33	0,25	1,00	0,75	1	2	2	2
Generate cardiac output	3	Y	9	0,17	0,00	0,11	0,50	0,56	1	3	2	3
Permission to reduce flow	3		2	0,67	0,33	0,00	0,50	1,00	1	2	1	1
Artificial breathing is on	3		5	0,17	0,00	0,00	0,40	1,00	1	1	3	2
Heart rhythm is adequate	3	Y	3	0,67	0,33	0,67	1,00	1,00	1	1	2	1
Heart function is adequate	3	Y	6	0,33	0,33	0,83	0,00	1,00	1	1	2	1
Heart filling is adequate	3	Y	4	0,67	0,00	0,25	0,33	1,00	1	1	2	1
Reduce flow	3		11	0,00	0,00	0,09	0,20	0,73	1	3	2	3
ECC at 1 liter index	3	Y	4	0,33	0,00	0,50	1,00	1,00	1	1	1	0
ECC at 1/2 liter index	3	Y	5	0,17	0,00	0,00	0,20	1,00	1	1	1	0
Stop ECC	3		10	0,17	0,00	0,10	0,33	0,90	1	4	2	4

Administer protamine	3		9	0,00	0,33	0,22	0,43	1,00	1	3	2	3
Root needle removed	3	Y	3	0,50	0,33	0,00	0,67	0,67	1	3	1	2
Venous cannule removed	3	Y	6	0,17	0,33	0,67	1,00	1,00	1	2	1	1
Withdraw blood from venous line	3		4	0,33	0,33	0,00	0,25	1,00	1	1	1	0
Protamine at 1/3	3		7	0,17	0,33	0,57	1,00	1,00	2	1	1	1
Stop blue suction	2		4	0,33	0,50	0,25	0,33	1,00	1	2	2	2
Blood volume left in pump	3	Y	3	0,50	0,00	0,00	0,33	0,33	1	1	2	1
Empty pump	3	Y	4	0,50	0,33	0,25	0,67	1,00	1	3	2	3
Pump is empty	3		7	0,00	0,00	0,14	0,67	0,86	1	1	2	1
Arterial cannule removed	3	Y	2	0,67	0,33	0,00	0,50	1,00	1	1	1	0
Protamine complete	3	Y	5	0,17	0,00	0,20	1,00	1,00	2	1	1	1
Table movements*	3		13	0,50	0,00	0,38	0,38	0,92	2	3	2	4
Hemodynamically compromising manipulation of the heart*	3		9	0,17	0,00	0,56	0,75	1,00	4	3	2	6

First communication protocol

Design of a first communication protocol for cardiopulmonary bypass procedures, based on the way that they are currently verbalized. The critical events are listed with the surgical phase, initiating sub-team and exchange type that they were consistently verbalized with in the recorded surgeries. Inconsistently verbalized events are left blank.

Event	Surgical phase	Initiator	Exchange type
Administer heparin	Preparation	Surgery	Direction
Heparine circulating	Preparation		Status
Heparine circulating 2 minutes*	Preparation	Surgery	Status
Activated clotting time (ACT) started	Preparation	Anesthesia	Status
ACT is sufficient for cannulation (>300)	Initiation	Surgery	Status
ACT is sufficient for extracorporeal circulation (>400)	Preparation		Status
Test suction	Preparation		
Suction is adequate	Preparation		Status
Divide the arterial and venous line		Surgery	
Prepare for cannulation	Initiation	Surgery	Goal sharing
Arterial cannule has been inserted	Initiation		
Clamp removed from arterial cannule	Initiation	Surgery	
Sufficient pulsation and line pressure	Initiation		Status
Permission to start retrograde autologous priming (RAP)	Initiation	Perfusion	Permission
Start RAP*	Initiation	Goal sharing	
RAP is complete*	Initiation	Perfusion	Status
Clamp removed from venous cannule	Initiation	Surgery	Status
Start ECC	Initiation		
Full flow achieved	Initiation		Status
(Do not) adjust artificial breathing	Initiation		
Flush cardioplegia	Initiation	Surgery	
Stop flushing	Initiation	Surgery	Direction
Low flow*			
Aortic cross-clamp placed		Surgery	
Normal flow*	Clamp-time	Surgery	Direction
Start cardioplegia	Clamp-time	Surgery	Direction
Pressure in root is adequate	Clamp-time		Status
Flow is adequate	Clamp-time		Status
Hart is still	Clamp-time	Perfusion	Status
Cardioplegia circulating for 2 minutes	Clamp-time	Perfusion	Status
Stop cardioplegia	Clamp-time		
Suck yellow	Clamp-time		
Low flow*	Clamp-time	Surgery	Direction
Aortic cross-clamp removed		Surgery	Status
Normal flow*	Weaning	Surgery	Direction
Low flow*	Weaning	Surgery	Direction
Aortic side-clamp placed*	Weaning	Surgery	Status
Normal flow*	Weaning	Surgery	Direction
Low flow*	Weaning	Surgery	Direction

Aortic side-clamp removed*	Weaning	Surgery	Status
Normal flow*	Weaning	Surgery	Direction
Continue artificial breathing*	Weaning		
Generate cardiac output	Weaning		
Permission to reduce flow	Weaning	Anesthesia	
Artificial breathing is on	Weaning		Status
Heart rhythm is adequate	Weaning		Status
Heart function is adequate	Weaning		Status
Heart filling is adequate	Weaning		Status
Reduce flow	Weaning		
ECC at 1 liter index	Weaning	Perfusion	Status
ECC at 1/2 liter index	Weaning	Perfusion	Status
Stop ECC	Weaning		
Administer protamine	Weaning		
Root needle removed	Weaning	Surgery	
Venous cannule removed	Weaning	Surgery	
Withdraw blood from venous line	Weaning	Surgery	Direction
Protamine at 1/3		Anesthesia	Status
Stop blue suction	Weaning		
Blood volume left in pump	Weaning		Status
Empty pump	Weaning		
Pump is empty	Weaning		Status
Arterial cannule removed	Finish	Surgery	Status
Protamine complete		Anesthesia	Status
Table movements*			
Hemodynamically compromising manipulation of the heart*			