The Development of a New Procedure in a Hospital:

A case study of how cardiologists and cardiac surgeons respond to the introduction of the new transcatheter aortic valve implantation (TAVI) procedure.

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Acknowledgements

The origin of this thesis came from the first conversation I had with Dr. Erik Fosse at Rikshospitalet, Oslo University Hospital. He asked me the simple question of ‘what are you interested in?’ and as usual I began to list off the many things I liked or wanted to study. It wasn’t until we started discussing my family back in Canada that I spoke about my father having open-heart surgery when I was a little girl. At this time in medicine (1988), even though the cardiac field was experiencing a growth in new methods and procedures, open heart surgery was still quite abrasive for patients. When we started talking about the different techniques that have evolved in the cardiac field since then, Dr. Fosse introduced me to the new method of transcatheter aortic valve implantation (TAVI). It was at that moment I chose the TAVI project for my Master thesis as I felt a special connection to the development of surgical techniques and the idea that this development could continue help other families like mine.

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And many thanks to my friends at school. Cheers for the study room gang!

Med vennligst hilsen,

Kat.
Abbreviations

ANES – anaesthesiologist(s)

CS – cardiac surgeon(s)

CA – cardiologist(s)

IVC – Intervention Centre, Rikshospitalet Oslo University Hospital, Norway

TAVI – transcatheter aortic valve implantation
Abstract

**Background:** Medicine has a strong focus on evidence-based practices. Although, even when evidence helps ease the introduction of new technology, it also creates challenges for medical professionals who are used to traditionally established practices. My study is a case study describing the development of the new transcatheater aortic valve implantation (TAVI). Here, the challenge that has developed is a ‘turf battle’ related to how cardiologist and cardiac surgeons perceive their future role in TAVI. This level of competitiveness is interesting in many ways for it helps illustrate some of the pathways professionals take when undergoing change in their field.

**Methods:** The motivation for this study is to investigate how the TAVI project, a procedure combining cardiac surgery and cardiology, has the potential to mature into a treatment for aortic stenosis. The two main research questions asked were; what kinds of challenges these professionals face with the new minimal invasive procedure and how they are reacting to the uncertainty over ownership in the future. Methods used are interviews with experts in cardiology and cardiac surgery, alongside observations and literature reviews. Here, I will use the theoretical framework of change management with contributions from Kurt Lewin, John Kotter, and W. Warner Burke & George Litwin.

**Results:** The results were the TAVI project is a new, non-inferior alternative to the current standard of care for aortic disease, but this creates apprehension within cardiac surgeons over the possible loss of patients and ownership over the procedure. Nonetheless, experience shows both professions are aware changes in treatment strategies are always underway. The implications are both cardiologists and cardiac surgeons are progressing through a paradigm of change as this new procedure is accepted in the medical community.

**Conclusion:** Indications from informants in this case study have shown that there is a conflict between cardiac surgeons and cardiologists in dealing with who will own the procedure in the future, but the TAVI project is not sufficient enough in size to negatively affect the professional position of cardiologists or cardiac surgeons. On the contrary, the idea of TAVI has expanded the notion of what kind of treatments are available for patients with aortic stenosis and that there is a possibility of a new sub-speciality arising involving new minimal invasive methods.
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1 Introduction

Innovation and change are two separate yet interconnected contributions and motivations to the process of altering something into a new version of its former system or practice. The basic definition of innovation is the introduction of something new or different such as a method or device, while change is to alter, modify, or transform the form, nature, content, or future course of something (Merriam-Webster, 2008). These concepts are relevant for many people in society whether that ‘something’ is information technology, education systems, automotive industries, environmental issues, or common household applications. The health sector is helpful in illustrating the picture innovation and change create throughout society by connecting multiple professions, knowledge, and ideas inside one environment. The main idea of this thesis then is to take the concept of change through innovation and study the challenges CA and CS have with new procedures. This thesis gives in-depth examination as to what challenges they face during this process of change and what their reflections of their own future are under the realm of new minimal invasive techniques. Here, this research project is a case study of how CA and CS are reacting to the new TAVI (transcatheter aortic-valve implantation) procedures.

The theme of the study is the uncertainty surrounding ownership of the TAVI procedure and the future role of CS and CA in the practice. Inside this theme, innovation creates an internal debate among professionals on who will ‘own’ the new TAVI procedure in the future and how they are affected by this uncertainty. Innovation itself has fuelled the debate of being either a ‘linear or a non-linear processes’. The former side of the debate discusses whether innovation starts with empirical research aimed at linking development and performance to technological capabilities, and ends with production and diffusion (Bodin, 2005). It is a comparative perspective and aims at identifying what the ‘best practice’ would be. On the latter side of the debate, as some authors such as Shortell and Kaluzny would support, innovation and change is “not a rational and controllable process, but a complex, uncertain, nonlinear sequence of events and activities” (Shortell and Kaluzny, 2005:384).

Either way, change itself is characterized as a gradual or a dramatic shift from one state of events to another, which produces favourable or conflicting outcomes for the actors involved. The debate of innovation within the literature reflects how the role of innovation impacts the social-
sciences by having to look at innovation from a cross-disciplinary point of view (Fagerberg, 2003). In dealing with TAVI, the primary disciplines having to deal with the change innovation brings are CS and CA. What sorts of challenges that arise within these professions due to this new procedure are dependent on the determinants this innovation carries both to the CS\CA profession and to the OR.

In the past few decades, there is a growing combination of new devices and instruments created from professions not traditionally involved in medicine, such as engineers and physicists (Fosse, 2007). The practice of medicine has been transformed by modern technology, and diagnostic techniques and therapeutic measures that were unheard of in the past but have now become commonplace (Booth, 1985). The growing partnership between advancing physics, engineering, and medical procedures within the health sector is, nevertheless, an interesting area of development because of this continual intertwining of professions. It is similar to the development of economic and social systems by being continually influenced by various different actors involved in the research and practice (Smits, 2001).

To help illustrate this intertwining, the following diagram depicts the pathways between science, technology, and clinical research and practice. They are all different but related activities that generate the means and methods of innovation. Science and technology correspond together, alongside technology and clinical research and practice. The information produced feeds back into science and the loop begins again. In total, the multiple correlations between the three variables strive to both critique and enhance the innovation process. You can see how there is need for a close, harmonious, and creative relationship between scientists, technologists and those involved in the practice of medicine (Booth, 1985) in order to keep the flow of information and influence possible.

(Figure 1. Relation between science, technology, and clinical research and practice. Booth, 1985:268)
The relationship between these categories is also similar to the relationships built between the professionals that are a part of the innovation process. For example, in this study the TAVI project itself is a combination of cardiac surgery, cardiology, radiology, anaesthesiology, and various support staff. The upshot of this is when you integrate these different professions the level of influence is also interconnected with the competitive nature of the professionals. Innovations might become a threat or seen as competing for professional domains (Drazin & Schoonhoven, 1996). The result of this is the new TAVI method is falling victim to a ‘turf war’ over ‘ownership’ of the procedure due to the fact that neither profession knows who will be conducting the method in the future.

This claim to ownership can be described as due to the blurred boundaries technological development creates between traditionally defined professions (Mørk, 2009), which in the case of TAVI the innovation process forces CA and CS to become skilled at each other’s procedures. Incidentally, other concerns arise such as recruitment of future professionals, age factors, and, possibly, the creation of a new sub-speciality merged from the concept of new minimal invasive techniques. As a whole, the TAVI procedure thus produces challenges concerning the future of thoracic surgery on the one hand, and on the other, it assists with the evolution of cardiovascular disease treatment.

The hospital setting itself has both a general and specific importance to society. It provides health services to the population and it combines a variety of knowledge and professions to rapidly develop new innovations in medical procedures (Fosse, 2007). These characteristics continue to press professionals to work collaboratively with new developments in technology to improve services for the patient and pave the way future clinical research and development. This aspect supports the Figure 1 described above. This data demonstrates that technology is an important aspect of both innovation and the medical society.

In a specific context, for professional development and innovations in hospitals, technology plays a key role in this process by collaborating with the professional and challenging their normal routine (Korica and Malloy, 2010). As Booth (1985) cited, the medical field is in a continual transitional period due to the continual interaction and influence technology and science have on clinical research and practice. Clark and Staunton (1989) support this with their
discussion of how innovations can alter work practices by developing new knowledge and work exercises as it is disembedding old ones. This is the middle ground where change happens, where it breaks the barriers of past and present, and is fuelled by the motivation of why change needs to occur.

In a broad context, the set of attributes, beliefs, values, motives, and experiences a person will define themselves in their professional lives (Ibarra, 2000:1) is more or less the process by which people develop an image for themselves by observing others, experimenting with personal changes through trial-and-error learning, and evaluating situations they encounter against their own internal standards (Wirth, 2004). Through this, I will investigate the challenges and changes TAVI innovation fuels within and between cardiologists and cardiac surgeons.

1.2 TAVI in a Work Setting

Table 1 and Figure 2 show the total number of patients who incurred cardiac operations in the years of 2003 – 2009 in Norway. When you look at the progression through the years, there is a slight decrease in amount of operations due to a variety of factors, such as lifestyle and environmental factors\(^1\). The style, however, of how the operations are conducted has begun to change and this is an important factor in both the cardiothoracic field and this study. This ‘style’ is explained as how minimal invasive techniques have been launched in a wide range of situations, for example image guided therapy and interventional radiology. Many departments of the hospital are pressed to integrate traditionally different knowledge, experience, and techniques into clinical procedures and practice. Radiology departments have become producers of substantial numbers of therapeutic procedures, and other specialists like cardiologists, urologists, and vascular surgeons have become users of advanced fluoroscopic or other imaging equipment (Lærum, 2001:81). Now, science, technology, clinical practice and research have combined the techniques of multiple disciplines to develop innovative strategies producing potential advantages and challenges for the actors involved.

\(^1\) This will be discussed to a greater degree in the discussion and analysis chapter.
Statistics Cardiac Surgery in Norway 2003 – 2009

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
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<tbody>
<tr>
<td>Aortic valve</td>
<td>992</td>
<td>1009</td>
<td>1179</td>
<td>1206</td>
<td>1171</td>
<td>1254</td>
<td>1108</td>
</tr>
<tr>
<td>Mitral valve</td>
<td>202</td>
<td>209</td>
<td>261</td>
<td>262</td>
<td>298</td>
<td>283</td>
<td>239</td>
</tr>
<tr>
<td>Tricuspid valve</td>
<td>9</td>
<td>27</td>
<td>27</td>
<td>38</td>
<td>59</td>
<td>61</td>
<td>75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prosthesis or repairs</th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td>619</td>
<td>595</td>
<td>542</td>
<td>499</td>
<td>421</td>
<td>375</td>
<td>334</td>
</tr>
<tr>
<td>Biological</td>
<td>406</td>
<td>573</td>
<td>755</td>
<td>835</td>
<td>815</td>
<td>947</td>
<td>793</td>
</tr>
<tr>
<td>Valve repair</td>
<td>112</td>
<td>133</td>
<td>184</td>
<td>198</td>
<td>297</td>
<td>285</td>
<td>247</td>
</tr>
</tbody>
</table>

(Table 1: Norwegian Medical Association, 2009)

Heart Surgery in Norway. No. of operations per 100,000 inhabitants

(Figure 2: Norwegian Medical Association, 2009)
There is a kind of flexibility in how people design, interpret and use technology. Therefore, technology comes into existence through various actions and is sustained by the ongoing maintenance, adaptation, and context in which it is developed and used (Orlikowski, 1992). When expressing the term ‘technological change’, much research supports the idea that the acceptance of a new technology is a social process, driven by inter-professional negotiations over the role and ownership over the technology (Korica and Malloy, 2010). The concern then behind the technological change and social process that TAVI brings to the thoracic field is the uncertainty over actual ownership of a medical practice due to different yet corresponding disciplines now being able to operate the same procedure.

Here, the technology being created is developed through connecting professions, or heart valve teams. These are a combination of cath-lab/hybrid teams, coronary care teams, and other support staff such as ANES and echo cardiographers (Manoharan, 2010). These traditionally defined specialities are now merging together as TAVI further develops. This is most apparent within the specialities of CS and CA, whom are currently going head to head in this new treatment strategy for aortic stenosis in high risk patients.

The hybrid setting at the Intervention Centre, Rikshospitalet Oslo University Hospital (IVC) is considered a combined treatment room (OR and angiograph rooms) representing a sort of common ground or territory that professionals meet together on equal terms. This common ground can be illustrated by what some organizational researchers refer to as a ‘stage’ or ‘arena’ (Swan, et al., 2002) where medical professionals can act together. These authors have not been a part of the IVC, but their metaphor helps explain how a level networking within an arena is centered on developing close personal contacts with key specialists across the heterogeneous groups in order to enrol good contact and participation (Swan, et al., 2002:489). This is supported by a doctor within the IVC who suggests that the aspect of having such a common ground within a hospital setting can obviously be both simple and hard, but notes that by working hand in hand the professionals hopefully are able to diffuse tensions and ‘collectively own the environment’ (Fosse, 1999). For that reason, arenas for local invention are important because they constantly improvise and the people involved are a source of innovation. The process of innovation then involves actively constructing a conceptual framework, imposing it on the environment, and reflecting on personal interactions (Brown and Duguid, 1991: 53).
Part of this interaction is the relationship between communities of practice (CoPs), as in our case the relationship between two particular communities: cardiac surgeons and cardiologists. A CoP is, according to Lave and Wenger (1991), a group of people who share a domain of interest, craft, and/or a profession, and can evolve either naturally because of the members' common interest, or specifically with the goal of gaining knowledge related to their field. In pursuit of their interest, they share information and resources, and eventually build relationships. The point the authors are trying to make is that these communities are more than just basic interaction between individuals, and develop over time based on shared practices. In the manner of CS and CA, and going beyond CoP's, it is over time that the process of sharing information and experiences that the members learn to also develop themselves personally and professionally, and gain further experience and opportunities from each other (Lesser and Storck, 2001). These experiences relate to how the professionals face challenges of learning new technical language and skills in the workplace.

As the TAVI project requires extensive teamwork and cooperation within this relationship, this new method threatens individual ownership of the procedure: if done through the femoral artery a cardiologist is needed, as compared to if procedure occurs in the chest a surgeon is required. Nevertheless, with the change in aortic valve procedures the cardiologists are present in both scenarios. Henceforth, if it is minimally invasive and a femoral procedure, fewer complications for the patient means that cardiac surgeons risk the potential loss of both the procedure and patient list. In this case study, I will examine how cardiac surgeons and cardiologists respond to both the threat and opportunity brought by this innovation. I will look at how the procedure creates a shared arena of practice that enhances possibilities and difficulties between the connecting professions, and will assess how the new knowledge and technique changes how doctors perceive and preserve their future roles within their cardiology and cardiac surgery.

1.3 Aim and Research Questions

The aim of this study is to investigate how the perceptions of future roles of CA and CS within minimally invasive procedures change due to the level of uncertainty in who will conduct the TAVI procedure. This study will uncover the challenges the new techniques brings and examine the reflections of the CA and CS have on the TAVI project.
My first research question is:

*What challenges do cardiologists and cardiac surgeons face with the introduction of new minimally invasive technology?*

This leads into the second research question of:

*How do cardiologists and cardiac surgeons perceive and react to the uncertainty of ownership over the new TAVI procedure, and thus, the changes that may arise within their profession?*

The first research question focuses on the exact challenges that may arise with the introduction of an innovation on CA and CS. This question is based on new knowledge and learning, future certainty, a possible sub-specialty, and relationships within a professional role. Here, I examine the pressures and influences minimal invasive innovation has on the individual, the specific profession, and the cross-disciplinary environment (in this case, the research and developments within the hybrid OR). During my research and interview process, particular areas I focused on were what it is like to work together with CS and CA, changes in training and education, what working with the technology is like in the hybrid OR and how this affects both the individual and the profession, and how the project changes patient selection.

The second research question further guided my study into examining how CA and CS react to the pressures and influences of new knowledge and roles placed on their profession. Since the new procedure has an uncertain level in regards to ‘ownership’, in this question I looked further into one’s willingness to change and integrate in the face of new developments. During this process, I created a series of questions to ask in the interview process such as what kind and level of uncertainty and fear is created with the new techniques and what kind of impact it has on their impressions of the future. This investigation reflects how professionals perceive and manage the changes created from the TAVI project.

By combining these questions I wanted to have an in-depth analysis of how people respond to the changes occurring in their field - to see what opinions, reflections, behaviours, and relationships developed. This analysis is the combination of both research questions under the theoretical aspect of change management. Described in chapter two, change management theory
highlights both of these questions with a focus on the TAVI project as a case example, however, empirically change management also helps analyze the challenges CS and CA experience.

1.4 Readers Guidance

Throughout the thesis, various perspectives will be presented alongside fundamental concepts and guidelines for medical procedures and change management theory. First, a comprehensive outline of perspectives on change management will be discussed. The next section presents the methodology that has been used in the study. This will also include transferability of the results, ethical considerations, and some limitations of the study. Afterwards, an outline and description of the TAVI project will be presented with an in-depth view of how the procedure is preformed followed by my findings on TAVI and personal observations in the OR.

The final two sections of my analysis and discussion will be divided into several parts. First, I will discuss the research questions separately, and then answer them as a whole through my analysis of the professional collaboration of the TAVI team. This will lead into the paradigm shift TAVI creates within the cardiac field and how it can continue to stimulate the joint venture between CS and CA. In the end, my conclusion will sum up the results of my investigation of CS and CA in the TAVI project with an example of how evidence based medicine and randomized clinical trials help fuel innovation and change within both individuals and organizations. Here, I will include contributions and implications of this study in regards to understanding how change management theory helps people accept new methods that can change traditionally defined practices. This will sum up how CA and CS are interpreting and dealing with competition in their discipline.
2 Theoretical Framework

This study is positioned within the area of research known as change management. Change management gives a framework to how individuals and professional groups examine, prepare for, imitate, and accept new practices. Change management theories enable the exploration of interactions between actors and the processes they go through when experiencing change within their daily routine or thought process.

In the case study of TAVI, change management sheds light on the current interplay between CA and CS as they progress further with learning the TAVI procedure. It helps examine the practical significance to the change of their daily routines, relationship, and professional approaches to the future of this new technique.

In this chapter, I will present three models of change represented by Kurt Lewin, John Kotter, and Burke and Litwin.

2.1 Kurt Lewin and the Three-Stage Model

Starting in the 1930’s, Kurt Lewin developed what is called the Planned Approach to change based on four mutually reinforcing concepts: Field Theory, Group Dynamics, Action Research and the 3-Step model, which are used in combination to bring about effective change. Kurt Lewin (1951) discusses the 3-Step model of change as a comprehensive process that can be different for each individual as they go through the stages. In this model, Lewin illustrates how prior learning can be rejected and replaced by a process that requires ‘unfreezing-change-refreezing’ of earlier behaviour or knowledge.

The first stage represented is called unfreezing, where an individual or group will have to gather information and prepare the necessary arrangements for the change to occur. This is where one would have to initiate a sense of motivation by creating a driving force big enough that it will cause a shift in the mindset of in the individual or group (Schein, 1995; Pettigrew, et al., 1992). Within this stage there are three sub-processes which further describe the relation to motivation for change (Schein, 1996). The first sub-process is if present conditions lead to either dissatisfaction or supports the personal belief that a change needs to occur. It is noted however
that if there is a gap between the initial belief and what needs to be believed in order for change to occur the more likely the new information will be ignored. Burnes (2004) discusses how at this stage Lewin argued ‘that the equilibrium needs to be destabilized (unfrozen) before old behaviour can be discarded (unlearnt) and new behaviour successfully adopted’ (Burnes, 2004: 985).

Schein (1996) adapted Lewin’s theory to include three processes necessary to achieve the first stage: disconfirmation of the validity of the status quo, the induction of guilt or survival anxiety and learning anxiety, and creating psychological safety (Schein, 1996:6; Burnes, 2004). Survival anxiety is described as when previous beliefs are seen as invalid and create concern or apprehension in the individual. This type of fear will arise if the person does not feel they will meet the new goals or standards that have been set (Schein, 1995; Pettigrew, et al., 1992). They will now need to re-learn how to connect and interact with the new environment and those within it. Learning anxiety is characterized by defensiveness and resistance to change due to the trouble of have to unlearn what had been previously accepted. In contrast, Dent and Goldberg (1999) state that there are various characteristics that can lead to a resistance of change, but it is not the change itself they are resisting. People may resist losses such as status, income, or comfort, but they tend to understand and want to embrace the new improvements except for particular obstacles to overcome (Dent and Goldberg, 1999:26). Therefore, help with these aspects can be achieved with regular communication between parties to help connect the new information to something that is cared about (Schein, 1995:3).

In order to move into Lewin’s second stage, change, it is necessary to identify what needs to change. To reduce the level of uncertainty it needs to be understood that the changes are beneficial, and that time and communication are essential. As seen in Figure 2, this is a learning process characterized by adoption and adaptation of new information. Basically, it is a transition that assists any new incoming information such as developing new meanings or concepts, and learning how to absorb and assess new facts. Such a move into this stage also requires a concise view of the new state plus the ability to identify the gap between the present state and that being proposed. Here, individuals or groups start to look for new ways of doing things; a new direction or focus that creates a positive mental change and moves away from former forms of inertia (Tichy, 1983).
The third stage of the process, *refreezing*, is where new behaviours become routine and customary, and change is made permanent. This stage emphasizes the reinforcement of both structural and behavioural change. This atmosphere of learning within a change process can be guided by individuals in leadership roles who have experienced the process personally. They are the ones who learn the technique and then guide the way for others. As Schein (2004) adds to this, organizations can call upon leaders to start evolutionary change processes that are more adaptive. This stage may include developing a new self-concept and identity, and establishing new interpersonal relationships. These characteristics and newfound social bonds can help alleviate some of the pressure of future uncertainty. By establishing new ways and incorporating new changes in daily structure, individuals and groups will be able to identify barriers, launch feedback systems, and keep everyone informed and supported. Burnes (2004) discusses this by how unless group norms and routines are transformed, changes to individual behaviour will not be sustained (Burnes, 2004: 986). In the hospital setting, Lewin’s approach is valuable for short time frames and high work-loads (Suc, Prokosch, and Ganslandt, 2009).

The following figure is a descriptive representation of Lewin’s research:

(Figure 3: Kurt Lewin Three Stage Process of Change management, 1951)
2.2 Burke-Litwin Change Model

W. Warner Burke and George Litwin create their change model around defining and establishing a cause-and-effect relationship between 12 key dimensions that are important to organizational change. Their basic philosophy is that the external environment is the dominant player in change, and that in order for change in structure, practice and system to work, you need to understand the 12 dimensions and the links between them (Burke and Litwin, 1992).

(Figure 4: Burke-Litwin Model of Organizational Performance and Change, 1992)
The figure shown above is an input-throughput-output model with a feedback loop format (Burke and Litwin, 1992: 524). It was built with a theoretical framework and established through the authors practical applications in various organizations and individuals. It can be described as first beginning with the external environment, where key factors that have an impact on the organization should be clearly identified. The second series of elements are the mission and strategy, leadership, and organizational culture. Here, the vision of the organization and strong leadership roles must coordinate with the rules, regulations, customs, principles and values that influence any behaviour apparent in both the individual and organization. The third series encompasses a variety of dimensions. This is where structure of the system should entail general roles, values of both policy and procedure and people involved, as well as specific concerns regarding relationships, responsibilities, knowledge, and motivational triggers. The last dimension engages the individual and overall performance level, and takes into account key areas like productivity, quality, and efficiency. At this point, the feedback loop directly connected to the external system is created and each box of model is united as a collection.

A change in one or more of these ‘boxes’ will eventually have an impact on others (Burke and Litwin, 1992:528). The model was designed this way to make a statement about environmental impact being most important and that leadership, mission, strategy, and culture are more important than structure, management practices, and systems (Burke and Litwin, 1992:529). This model has the ability to navigate potential change in an individual (Goodman, Rousseau, and Church, 2004) and assess effectiveness in the organization (Martins and Coetzee, 2009). I chose to incorporate this model for the authors provide a comprehensive view of how challenges need to be met with a sense of direction, responsibility, and commitment.

2.3 Kotter and the 8 Stage Model

John Kotter, a professor at Harvard Business School, introduced his eight-step change process in "Leading Change" (1995). In his article, Kotter originally described eight ‘errors’ that happen when organizations attempt major changes. He noted that change itself is often understood and wanted, but there are obstacles that prevent performance or completion. Undoubtedly, those obstacles may be in the individual, but Kotter states that such individual resistance is rare. More often than not the obstacle is in the organizational structure or in a ‘performance appraisal
system [that] makes people choose between the new vision and their own self-interest’ (Kotter, 1995: 64).

Kotter created the list of eight errors that can be reversed into an eight stage model to represent attributes associated with a positive direction for change. Before this description, he emphasized two important lessons to be learned from successful cases. One, the process of change will go through a series of phases, and this will require a considerable length of time. Kotter points out that by skipping steps it will only create an illusion of speed and the results will not be as satisfying as they could be. The second lesson in the article is that critical mistakes in any phase can have a dramatically negative impact on both momentum and hard-earned gains (Kotter, 1995: 59).

In the first stage, a sense of urgency surrounding the need to change has to be created. This step is essential because getting a transformation campaign going requires an aggressive approach. Without a high level of motivation, people will not help and the effort will go nowhere (Kotter, 1995: 60). Kotter mentions how good leadership will out rule management positions and transformations will occur. By examining opportunities, developing high levels of communication, and requesting outside support for why change in necessary, the change process will start out honest, open, and prepared. In the second stage, forming a powerful coalition with strong leadership roles will handle the change effectively. By identifying suitable candidates within the team and continually working on team building skills for everyone to eventually become involved, you can ensure an efficient system will grow. In Kotter’s third and fourth stages, creating a vision for change and communicating this vision, will produce various ideas and solutions that shape the overall concept of change and vision of the future. By creating easy lines of communication, clear and well-built strategies, and giving strong directives, those that are supposed to follow the change will be able to make sense of what they are supposed to do. A clear understanding of the project will produce better results, better communication, and be able to address any problems that may arise. In this stage, Kotter in addition states that short-term loses are also acceptable. Sometimes set-backs such as downsizing are a part of the vision (Kotter, 1995: 65).
This leads into the fifth stage of removing obstacles. By this point, the degree of communication and planning will (hopefully) be able to identify any barriers and find solutions. At this time, reviewing and recognizing necessary changes in the planning and implementation of change will help solve residing issues and restore benefits. In this stage, rewarding individuals for their efforts will help maintain the change process. This style of reward system blends into stage six. Here, creating short-term wins motivates both individuals and groups and enables people to feel that their efforts are being noticed. Kotter notes how this is different than ‘hoping’ for short-term wins. ‘The latter is passive, the former is active’ (Kotter, 1995: 67). Stage seven, declaring victory at an appropriate time, depicts how one should avoid premature victory celebrations. Instead of a hasty congratulatory that has the potential to halt progress, each success story should build upon more available opportunities and keep momentum. In this stage, fresh ideas bring continuous improvement.

The final stage, anchoring the changes, makes the new change a part of the individual or organization. This is where efforts to ensure that change has a solid and supportive place will be rewarded with recognition for contributions and effort. As well, plans are still being created to ensure change will not digress or be forgotten. Kotter discusses two important factors in making the change ‘stick’. One, to make a conscious attempt to show people how the new approaches, behaviours, and attitudes have helped improve performance, and two, to ensure the next generation of managers also personify the new approach (Kotter, 1995: 69). It is notes throughout the article that change mainly fails when difficulties are underestimated and weak leaders are in executive positions. Hence, you need to continually inspire change and attract interest while guiding the individuals and groups with capable leadership.

(Figure 5. Kotter and 8 Stage Model, 1995)
2.4 Summing up Change Management

Dent and Goldberg note that both Lewin and Kotter recognize that resistance to change can be in the individual, but can also be found anywhere in the system or in the group as a whole (Dent and Goldberg, 1999). They also noted through a study “Overcoming resistance to Change” by Coch and French (1948) that employee participation, group meetings, and communication resulted in lower resistance and faster recovery. This can be seen throughout Figure 2 with the involvement of people, communication, and data gathering and measurement. In contrast, and in dealing with technological change in particular, Lawrence (1954) states that participation as a device for dealing with resistance to change may lead to trouble (Lawrence, 1954: 50). His article speaks about how the key to resistance is to understand the true nature of it, that it is usually attitudes and social change that create resistance.

To further this, Lewin argued that social settings are constantly changing at a variable rate. Progress depends on where the change is happening, and that change itself is a complex and repetitive learning process. As a whole, the change process involves everyone as a full and equal part (Burnes, 2004: 997), and learning and involvement is key for achieving behavioral change (Burnes, 2004: 996). The challenges that the CS and CA face are related to these characteristics. The fear and uncertainty that is apparent in some of the professionals can be explained by various reasons such as resistance and attitude. Kotter and Schlesinger (2008) note that all people affected by change will experience some sort of emotional turmoil concerning loss and uncertainty, even in changes that appear to be ‘positive’ or ‘rational’ (Kotter and Schlesinger, 2008:42). Their responses can range from passive resistance to aggression, or simple embracement. These authors point out that one major reason people resist change is they think they might lose a sort of value to themselves, they do not understand particular implications, they fear they will not be able to acquire the new skills or behaviours, or they perceive the costs are more than the gains (Kotter and Schlesinger, 2008:43, 44). This can be seen in the process of developing the TAVI project, patient loss, and the level of uncertainty over ownership.
3 Methodology

3.1 Qualitative Methods

The difference between qualitative methods and quantitative methods are that quantitative methods are a quantification of, or a statistical technique used to guide a mathematical approach to data, while a qualitative approach is based on the kind of quality or essential character of something (Kvale, 1996). My two research questions call for a qualitative approach to cover the broad scope of knowledge and information generated from many sources. It is a good strategy to use qualitative methods to reflect upon a hospitals environment of both personal and professional experiences, perspectives, opinions, and available research. Thus, in this study I will use a combination of interviews, participant observations, panel discussions, and document analysis.

I used a qualitative research approach in this study to get a diverse understanding of how medical professionals cope with the challenges of advancing innovations. Since I wanted to see how innovation creates both opportunities and challenges for professionals, I knew that a qualitative method would facilitate finding the ‘essential character’ (Kvale, 1996: 67) in the TAVI situation so that TAVI participants, other health professionals, and external readers would be better able to relate to, learn, and understand the process of change TAVI initiates. For example, in the TAVI project qualitative approaches enable me to study a complex setting through the stories and opinions of experts (CA and CS) who experience life in a hospital first hand. I will be able to study the CA and CS through their personal reflection of the information and events. Therefore, this approach is relevant in this study because I was able to come close to my informants and focus on their experiences of TAVI. I tried to understand and interpret their reactions to changing professional roles, the relationships between professionals, the future outlook of their career, and, potentially, how these impressions and opinions changed over time.

Qualitative research itself is a systematic collection, organization, and interpretation of textual material derived from observations, individual or group based interviews, documents, and previous literature (Feiring, 2011). Eberle and Maeder (2011) examine how these multiple methods of data gathering help represent knowledge about the social world through personal and organizational behaviour and outcomes. This knowledge can be uncertain such as you cannot
always know if it was the most rational decision or if it was interpreted in the right way depending on the knowledge and context of the situation. The aim then is to provide a valid inference to the research at hand.

3.2 Research Design

There are four components to qualitative research that helped design my study. The first component is the research question. I formed two sets of questions that were applicable to the TAVI project and contributed to the framework of scholarly research. One set was the questions I asked within my thesis and the other were the questions I asked during the interview process. I posed all of my questions in a way where my techniques both produced a theory of how CS and CA manage change and how they saw their future as a result of such change. Because my questions were situated within the context of uncertainty and professional development, I tried to find the most relevant questions to ask since I wanted each question to be important to both the informant and other health professionals, and relatable to someone working in another profession. I also wanted these questions to contribute to someone’s personal understanding of the change process they may be going through. Maybe my questions were something they were also asking themselves or others? Possibly these questions fuelled further questions and thoughts on the matter? Or, and potentially, my research questions could contribute to further research.

Forming these two sets of questions helped me design and connect my investigations to my theoretical framework. Theory is the second component to qualitative methods and is important because it helps the research, participant, and reader to understand and interpret the data with precision and concreteness. Based on my own experience with the TAVI project I had undergone a series of changes within my theory chapter. As time passed and I gathered more and more information I began to understand the change CS and CA were going through and gradually began to interpret the material. I passed through different theories before I settled on the final framework of change management because this was the framework that to the largest extent helped me in understanding and explaining the topic under investigation. This experience alone says that data and theory need to match in order to produce a result that actual answers the initial research question. Indeed, there are complications to this back and forth process of figuring out whether a study is deemed deductive or inductive, but overall, the most important thing about
theory is that it needs to guide the research, refine the research question, and say something about the implications of the data.

Another component that needs to be consistent throughout a study is the method of data collection. The first process I went through was asking how I was going to generate my data. Since data needs a level of systematic assembly so it can be considered internally valid, I knew my data needed to come from trusted sources. Interviewing both sides of the TAVI project, using past and present documents supplied from the IVC, and researching prior change management experiences enabled me to gather data that helped interpret the change CS and CA were currently experiencing. This process facilitated the de-contextualization and re-contextualization of the data I received in a relative context to investigating the uncertainty over ownership of the TAVI procedure.

Recontextualization is the method of lifting the matter (in my case, the reflections and opinions of TAVI and procedural ownership) out of the complexities of the day-to-day workings (Silverman, 2006) of the hospital. Here, focusing on and interpreting the findings were key to sifting through the various comments and critiques of TAVI and how CA and CS were reacting. Then, to understand this data I recontextualized the findings in order to find patterns and understand why the data was what it was. Here, my process of focus helped me determine how to use my data in a valid and useful way that not only gave my findings substance but also guided my research into the next category of analysis and discussion of the material.

This leads into the last component of the use of data. In qualitative studies data is not to be generalizable or representative, but to be transferrable to other situations by giving best answers and ensure people the interpretation of the event is if anything adequately applied to the setting (Coffey and Atkinson, 1996). Since the data is selected intentionally, for example in my own methods of pin-pointing specific members of the medical community to give their opinion and reflection of TAVI, the use of the data is integral to explaining how the event in question is explored, represented, and theorized. All of this is done in a manner to minimize bias and uncertainty by making the research procedures explicit and the researcher as an active participant of the research process itself. I was an example of this process by interviewing those involved and not involved in TAVI and experiencing first hand a TAVI procedure in the operating theatre.
Although one or two experiences cannot explain an entire phenomenon, it can give someone an idea of what it would be like to be present in other OR situations.

### 3.3 Case Study

A case study is defined as an in-depth investigation, either descriptive or explanatory, that tries to explore causation in order to find underlying principles (Chambliss and Schutt, 2006; Kvale, 1996). It is well suited when you want to investigate “a contemporary phenomenon within its real-life context, especially where the boundaries between phenomenon and context are not clearly evident” (Yin, 1994:13). In other words, it is a conceptual analysis of a particular situation various characteristics and actors involved.

Since the goal of this project is to contribute to our understanding of how different groups/individuals respond to change and how they foresee their future among a level of present uncertainty, I will focus on how the future of cardiac surgery is uncertain due to the present advancement of minimally invasive procedures. As so, a case study enables me to research how people within the cardiac field feel about the rising challenge of different established guilds competing for ownership of this particular practice and the patients involved.

An ideal setting for having a case study is the IVC, where there is a combination of medical and technical professions involved in the development and research of new medical technologies and procedures. The IVC is also an ideal setting because it mixes a broad range of professions within the health field such as nursing, radiologists, cardiologists, anaesthesiologists, surgeons, and support staff. As mentioned previously, it has become a common territory for multiple professions to work together and create new methods of health care delivery.

### 3.4 Interviews

The purpose of doing interviews was to explore the hospital setting through the experience of those who work within it. It has been estimated that 90 percent of all social science investigations involve interviews (Briggs, 1986). I wanted to explore deeper meanings and understandings of change, and professional influence and interest, and be open to immediate responses and reflections. Interviews normally generate large amounts of data and enable follow-
up questions and clarification (Kvale, 1996), so this provided me with a large scope of information and material plus personal experiences to compliment my theoretical and findings chapters.

I was able to interview 10 informants within the IVC. This included four CS and three CA, alongside three ANES. I chose those who were involved directly and those not involved at all because I wanted to be able to understand not only the entire picture of how the TAVI project influences the internal structure, organization, and future outlook of professional roles within the health field. I aimed each interview to be for one hour and preferably done at the IVC. Interviews for less than one hour were greatly accepted as I was aware time is of the essence for many doctors. I was also open to a more public environment if the informant would feel more comfortable, such as going for coffee. One interview did occur within this environment and lasted for about an hour.

The idea of involving both participating doctors and others is to look into who is most impacted by the new changes and how they can or will influence the advancement of the procedure. The selection of informants came from the TAVI team at the IVC, alongside different departments such as the heart and lung clinic, thoracic surgery, anaesthesiology, and cardiology. The head of each department took part in the selection of the informants. Here, I was engaged in the ‘gatekeeper’ process with the heads of the departments. This is described as a metaphorical term where one person controls access to something, such as the flow of information, or contact with elite informants within an organization (Parsons, et al., 1993).

In my case, I needed to contact doctors both involved and not involved in the TAVI project through the internal system at Rikshospitalet. This is where I needed the help of other professionals in assisting with gaining access to people who would be good candidates for an interview (and who, in turn, would accept me as an interviewer). In the end, the process itself of contacting the informants was quite an adventure. I was not used to the internal paging system (combined with the fear of putting myself out there to ask for an interview), so when I received the list of potential informants I basically started calling at the top of the list. I was able to book all of my ANES appointments in one day and thought ‘wow, this is easy’. Little did I know that was going to be the only easy part I would experience. Booking the appointments for the CA was
a bit harder, and the CS were the most difficult to arrange due to their sporadic availability. Unfortunately for me, this extremely interesting study I was conducting involved extremely busy professionals.

My initial timeline for the interview process slowly declined as I tried to find various strategies in contacting the doctors. On one occasion I actually considered sitting outside their office until they had to eventually meet me, and on two different occasions I had contacted the informants as they were in the middle of operations. By the second time this happened, I went home and started laughing about how they would still ask for my name and number to call me back. All I could imagine was a doctor in the middle of life threatening surgery and me, a Masters student, on the phone asking for an interview. In the end, I was able to achieve 8 out of a possible 12 interviews on my original list, and was given two more contacts at a later date. I wish I was able to talk with more CA; however I needed to finalize my interviews to start the analysis and discussion of the study.

For proper referencing and translation, I recorded and transcribed the interviews. Two interviews were not recorded due to consent not being given for recording. Instead I took hand-written notes which entailed both positive and negative side effects. One, I felt as though I was trying to write down as much information as I could while the interview was in progress. I felt as though I might miss out on important details or write down the wrong information. This took some attention away from possible questions I could ask or maintaining eye contact with the informants. I also hosted the interviews in English, although if the informant would like they could respond in Norwegian if they needed to express properly the terms the wanted to use. The reasons I wanted to have such an option available were so results of the study are as trustworthy as possible and without any barriers to my own research process.

As mentioned, the main approach I had in my interviews was the idea of being open and responsive. I wanted this approach so the informant could react to the topic how they would normally under any other circumstance, especially since I am an outsider to the CS and CA field. I used an open-ended interview format so that the responses are genuine and organic in nature. As well, I made sure the informant knew I planned to keep their identity anonymous in order to protect their responses. I used a semi-structured interview process (Kvale, 2009). With this I had
a platform of questions pre-planned and approved by my supervisors which cover six different topic: the professionals background, working within the hybrid OR, TAVI research and organization, the TAVI project and the concept of minimal invasive procedures, procedural ownership, and the future of the profession TAVI. I chose these topics because I felt they would be able to cover the largest range of reflection, professional opinion, and personal thought on the matters of TAVI, how they felt TAVI was progressing, and their impression of how TAVI will impact the future of CS and CA.

Over the development of the study and as I progressed with the interviews, I began to see how the initial platform I had created needed to become flexible. For example, after the second and third interview I started to realize some questions were more relevant than others, and in some cases, the questions were entirely not relevant at all. For instance, I had initially asked questions pertaining to the idea of working together in the hybrid OR room. However, these professionals have been working in the OR together for some time so such a question did not produce much response or results. I then focused on other more pertinent questions related to how they were managing the change TAVI brought to their profession and how they were simply working as a team. Other questions were also emphasized such as would they prefer the idea of TAVI being in the hybrid OR compared to the cath-lab and the idea of a new speciality emerging. Even though some of the questions began to reach a level of saturation, I liked seeing the trend in responses and was able to compare them to each other. It was interesting to see what each speciality said about the project and their ideas of the future.

3.5 Document Analysis

The main sources of information I used were annual reports generated by the IVC from the years of 2007 – 2009 (Annual Reports, 2007-09), previous Master and PhD thesis from students who studied at the IVC, and literature produced on the TAVI procedures and cardiac heart disease valve replacement. This IVC generated data is useful when analyzing the change that has occurred over the years, as well as helping guide my own research. I also searched on the theoretical aspects of organization and change management. These sources focused on the discussion of change management and the interaction within and between groups of people within hospitals and the medical community. Combined, these documents contribute not only to
my understanding of innovation and change within cross-disciplinary environments in the hospital setting, but it also helps readers who are not a part of the hospital setting to see how change management can be useful in other organizations.

For literary searches, I used the academic sources of PubMed, JStor, Medline, Ovid Medline, BestPractice BMJ, Web of Science, and the University of Oslo library system BIBSYS between the months of October, 2010 and April, 2011. I used two sets of key words for my project. One set to cover the theory of change management and the aspect of organization development for hospitals\professionals, and another set to investigate the medical procedures of TAVI and aortic valve disease and replacement. My search words consisted of change management, technology change management, organizational management, hospital technology, hospital management, relationship between doctors, doctors’ professional roles, and, TAVI, aortic valve disease, aortic valve replacement, surgical activity, PARTNER study, and surgical replacement. I felt that I would need to have two sets of search criteria in order to encompass the entire idea of change within the medical field and how TAVI is truly impacting CS and CA. This proved helpful in the results section of my study when I began to find links between the literature produced by other researchers and my own observations and interviews at the IVC.

3.6 Observations

It was suggested that I should be present in the hybrid OR during a TAVI procedure to get a good feel for how the CS and CA work together. Observations are a way to understand and interpret the phenomena that I would normally not experience through reading literature on TAVI or the collaboration of CA and CS. Participant observations can be described as having five characteristics. One, it is a way for a researcher to establish a direct relationship with what he or she is studying. Two, it is within the context of the phenomena. Three, the researcher is able to physically participate in the normal routine of the participants. Four, it is a means to learn the underlying meaning of behaviours (Gobo, G, 2011). And lastly, it is a naturalistic approach helps a researcher see the reality from the participants’ eyes (Mørk, 2009). I agreed with these authors that participant observation is a distinctive research strategy useful for my study, which stresses the theoretical basis that develops from a particular tradition and history (such as the CS and CA whom have two different backgrounds).
3.7 Panel Discussions and the Internet

Throughout the course of my research, I watched a lot of panel discussions on TAVI. This was very useful for me because the TAVI project (and the highly awaited PARTNER trial) is a new development around the world. Various physicians and specialists would gather and comment, debate, and focus on specific topics concerning TAVI as the project was on-going. I preferred to listen to these for I was able to understand not only the medical concepts and environment of CA and CS, but the surrounding concerns. I felt this was necessary in order to grasp the entire conception and development of TAVI and how minimal invasive techniques are impacting these specialities.

It was also nice to see some of the authors of the articles I was reviewing. This aspect put a face to the words I was learning and referencing, and I felt that it added to my TAVI study becoming more of a true project. The panel discussions were available on the internet and I gradually chose one specific site, www.theheart.org, since the same authors who published article I was reading about were also shown in the discussions. As a medium for communication, the internet provides a source of transmission of information and interaction with others (Markham, A.N., 2011). It reaches out to communities and provides a means for displaying experiences and connecting to other social networks. At first I was a bit apprehensive to include the aspect of including ‘internet research’ in my masters’ thesis and only wanted to keep with peer reviewed articles. But, as my study progressed, I have to admit by watching these panel discussions I understood more about the TAVI project as a whole than if I had not participated in the site. I felt like I gradually comprehended more than just the dilemma of procedural ownership between CS and CA.

The challenges in using this material for explaining my case study is that the information is not peer-reviewed, can contain thoughts that reflect opinions and experiences of other professional environments that are not the IVC, and may refer to questions that are not relevant to the case study. It is also presented in a public media format, which may contain a sense of altered opinions. In other words, the professionals being interviewed may change their opinion because they are being publically interviewed, thereby there is a chance they are giving false reflections of the situation. Even though, I still used some of the discussion since I am not directly involved
in the thoracic field and needed to learn about general on-goings of the project. The discussions then are relevant for the research questions in helping define the challenges of the TAVI project on a broad scale, and also what others in the international medical community think of the new procedure and its effect on the CS and CA.

3.8 Ethical Challenges

Even though the main results of the study are to see the reactions to technology, change, and re-organization of the medical professions of CA and CS, there can still be potential misunderstandings from the results of my study. Therefore, I need to be aware of the level of confidentiality and trust in my study for the protection of my informants. Confidentiality and protection is important because I am interviewing a close-knit group of doctors who work in this project together on a continual basis, and after my study is complete they are the ones who will have to continue working together. So, if by chance a part of my study is not very favourable to someone it could initiate a level of social\individual harm, mistrust, or misinterpretation. Because I want to have a truly good, qualitative study even if the results are not completely positive, I will need to leave a footprint of trust and reliability through confidentiality.

The 1991 International Guidelines for Ethical Review of Epidemiological Studies states that research may involve collecting and storing data relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress. Consequently, this means that I needed to arrange for protecting the confidentiality of my data. For example, omitting information that might lead to the identification of the individuals I interviewed, limiting access to the data, giving the information I received a level of confidentiality, and destroying the data after finalization of the study.

To ensure trustworthiness I established certain rules and regulations within my procedures regarding confidentially of the informants. Trustworthiness is defined as having three characteristics; credibility, dependability, and transferability. Credibility concerns the focus of the study, selection of context and participants, and approach to gathering data. Choosing participants with experience increases the possibility of shedding light on the research question from a variety of aspects (Polit and Hungler, 1999). Dependability is the degree to which data change over time and alterations made in the researcher’s decisions during the analysis process.
On one side, it is important to ask the same questions for all the participants. On the other, interviewing and observing is an evolving process during which new insights into the phenomenon of study emerge and influence follow-up questions or narrow the focus of the interview (Lincoln and Guba, 1985). Trustworthiness also includes transferability, which refers to the extent to which aspects of the findings could be transferred to other settings or groups. This is different than generalizability, where conclusions from a sample population hold true for whole populations given specific conditions (Chambliss and Shutt, 2010). To facilitate transferability in my study, it was valuable for me to have a clear and distinct description of the culture and context of the IVC, selection and characteristics of CA, CS, and ANES, and my data collection and process of analysis.

When I first sat down to chat with each informant, I gave a verbal description of the case study, discussed what type of professionals I would be interviewing and the timeline of the study, and expressed my limited experience in interviewing. Next, I asked if it was okay to record the interview and informed them that I would be transcribing the interview and only my supervisors and I would have access to the material. In addition, I assured all recorded material was to be destroyed after the study was finalized. I took hand-written notes for the informants that did not want to be recorded. As well, each person was informed they were able to withdraw from the interview at any time without question and would be able to read the results before publication of my study. No informants chose to leave the interview early and many were interested in reading the results of the study.

I received help from my supervisors during the interview and analysis process to ensure that one; my procedures are in line with all ethical requirements regarding confidentiality, and two, I am properly interpreting and analyzing the material. This was important because using the data improperly could damage an individual’s well-being through social discrimination, as well as their employability and insurability in the workplace. The Declaration of Helsinki (2000) paragraph 21 states that “researchers have to protect the integrity of the person in that every precaution should be taken to respect the privacy of the subject, the confidentiality of the information and to minimize the impact of the study on the subject’s physical and mental integrity”. Since research is aimed at gaining knowledge about the nature of a group of people rather than the individuals in question, there is a double-sided reason for developing these
methods in my study. 1) Participation was voluntary; therefore, abuse of the information collected could deter people from participating in future studies on this matter. 2) By having a system in place to protect the privacy of the subjects it ensures that other researchers have a pool of subjects available to continue studying this phenomenon or others concerning these groups of people.

Within my interview platform, I asked for personal reflection, interpretation, and experience surrounding the current project and their interpretation of other co-workers around them. This needed to be assessed from an ethical point of view because I was recording personal opinions that have the possibility to create both positive and negative emotional responses from fellow community members. Therefore, with the consequences of the harm that could come from disregarding a fair level of beneficence (where the risk of harm to a subject should be the least possible) I needed to be aware of the open and intimate environment that an interview can produce. For example, in one interview I needed to re-assure at both the beginning and end of the interview that I would be keeping a high level of confidentiality for this informant was concerned about being identified.

Kvale and Brinkman (2009) mention how a researcher needs to be aware of the possible consequences not only for the informants, but also for the community. In my study, the community I dealt with is the specific team the new TAVI project is comprised of, plus other medical professionals that work within the hospital. Here, I needed a deep understanding of the idea that the informants themselves can disclose information they may later regret they mentioned in the interview. Since there is the possibility the personal opinion given during the interviews could alter and/or negatively impact the workplace scenario after my study, I needed to consider the social after-effects for the informants.

3.9 Analysis

In the beginning, I had left room for the study to grow and develop in case new information or analysis arised, and at the end of the study I realized this was a good decision. Since my analysis was an on-going process I wanted to use my theoretical concepts as a guide. Other theories had contemplated were professional identity, power, politics, and professional interest and influence. This proved to encompass more than was allotted for a Masters Thesis project so I simplified to
change management to obtain a crisp view of the TAVI project. I chose change management to be the most reliable to my results and properly reflected the process CS and CA were undertaking.

Throughout the interview process, I spoke with Dr. Fosse about my general impressions and he helped guide me around the details of the cardiothoracic field, and the opinions and interpretations of the professionals. After I had completed the transcriptions I had constructed an Excel style matrix of the results. This chart was based on results from both the interview guide and other questions that had developed throughout the interview process. These consisted of roughly 20 sub-categories revolving around seven main topics. The main topics I concluded were: activity level within the TAVI project, relationship between the professions, personal impression and professional opinion of TAVI, experience of working in the OR, the practical nature of TAVI (including patient selection and transfemoral\transapical approaches), current and future outlook of TAVI, and change management (including how the professionals were handling the change and factors affecting personal development throughout the TAVI project).

Following this process, I made concise summaries for each of the results from the three professions. This was then compared to the information I had analyzed in the literature. I discussed the results and summaries in a meeting with two of my supervisors, Terje and Bjørn, for proper analysis and how to proceed further. This is where I introduced the theoretical aspect of change management and integrated it into the results. By using this mixture of document analysis and interview matrix I was able to form a complex, yet clear understanding of TAVI and the challenges of change management.

3.10 Limitations of the Study

King, Keohane, and Verba (1994) describe how there are four characteristics of scientific research. First, the goal of inference, where you need to not just collect information but interpret it within a context of transferring empirical data to something that gives understanding and meaning. Second, public procedures, where research must be explicit and codified so the scholarly community can judge the results and replicate my research. The third characteristic is how the content is the method, where the methods of research and the validity of the results will depend on the rules created during the research process. The fourth characteristic is that the
research has the potential for *uncertain conclusions* in a contextual manner, because by definition inference is an imperfect process. These four characteristics describe my research for the TAVI project in a sort of linear, yet web-like fashion, each one independent and forthcoming, but dependant on each other for support and guidance. For example, when discussing ‘content and method’ I created certain rules for myself such as I interviewing both those that are involved and not involved directly to TAVI and speaking with at least one other professional who worked closely with CS and CA (ANES were chosen for this category).

As discussed in the ethical consideration section, limitations means that researchers such as myself need to be aware of the surroundings and consider all aspects of impact on the participants both personal and environmental. With the TAVI project, I aim the results to be able to represent the competitiveness that has arose from the introduction of the TAVI project and the challenges that have been produces not only with the new procedure but with the new minimal invasive techniques within the hospital setting. Miller and Glassner (2011:133) note that research cannot provide the mirror reflection of the social world, but it can provide access to the meanings people attribute to their experiences and social world. Limitations of this study would thus include transferability of the results cultures in and outside of the hospital setting, and towards experience of other professionals who are involved in innovation and change within their own organization.

Other limitations I experienced are the fact my case study has a limited amount of interviews (10), and only within three different disciplines (CS, CA, and ANES). A more complete set of professionals, such as those stemming from the support staff would have been able to give a more detailed view of the scenario. For example, working in the OR before and after the TAVI project, or other experiences in the hospital. Adding to this limitation is the length of the interviews. The interviews were fairly short (30 min to one hour) compared to other qualitative studies I have reviewed, and no follow-up interviews were completed due to time constrictions. I addressed this by using the matrix analyses to capitalize on the information I did receive, and compared this to the literature and panel discussions I reviewed.

Another limitation is the amount of observations conducted. I only participated in two observations conducted in the same day. This means that one another day the situation in the OR
could have been different. A proper ethnographical research study over a longer period of time concerning more observations would have been able to give a larger, more comprehensive view of the TAVI challenges and be able to represent the reflections of the professionals in a more in-depth manner. Unfortunately, this case study was not able to include such time and length of study. To compensate for this, I conclude that I will not be drawing generalizations from this case study and can only apply for a level of transferability of the results. Therefore, I understand that my study may not represent other professional opinions.

A third limitation is I, as a qualitative researcher, may have influenced the behaviour in the OR room and in the interviews with my physical presence. Other researchers with different backgrounds in medicine or organizational experience may end up with different results based on the reaction to their presence\non-presence in the same situation. I address this specific issue with a challenge for other researchers to conduct further research on the issue of future uncertainty in CS and CA. In other words, I give the idea of contrasting results a high level of curiosity since the TAVI project is new and has a lot of future research ahead.
4 Situating the TAVI Project

Aortic surgery is performed through two types of procedures: aortic valve repair and aortic valve replacement. Aortic valve repair deals with six different procedures: commissurotomy, valvuloplasty, reshaping, decalcification, repair of structural support, and patching (Otto and Bonow, 2007). Aortic valve replacement deals with two different procedures: biological and mechanical (Chiam and Ruiz, 2009). Biological aortic valve replacement uses materials such as animal tissues or human donated heart tissues with no fear of blood clotting. The method has a lifetime of 10 years. In children and younger ages, these valves break down quicker, so biological valve replacement is often used in elderly patients. As for mechanical valve replacement, this procedure uses valves made of plastic, carbon or metal materials, and are often used for their long-lasting life span. However, after the replacement, patients have to take anticoagulants for the rest of their lives to prevent blood clots around the device.

From the patients’ perspective, aortic valve disease, aortic valve regurgitation, and aortic valve stenosis are the three primary reasons that a person would have to undergo aortic valve surgery. Usually, the patient suffers from aortic stenosis, which is a common disorder particular among elderly patients where the aortic valve undergoes degeneration and calcification as part of the aging process (Alberta Health Services, 2010). In severe cases, this causes a narrowing of the outflow tract of the left ventricle, which restricts blood flow and results on chest pain, dizziness, and symptoms of heart failure (shortness of breath and extreme fatigue). Treatment with aortic
valve surgery depends upon its nature. ‘Mild’ is where a doctor may prescribe life style changes, ‘moderate’ is where antibiotics are prescribed and it is advised to avoid fatiguing work like sprinting or weight lifting (Fullerton and Harken, 2008). Once it falls into a ‘serious’ category, aortic valve surgery is recommended. It is this category that if the patient is deemed ‘non-operable’, or too high risk for conventional open-heart valve replacement surgery, they can then become a candidate for TAVI (Leon, et al., 2010).

The introduction of radiology-guided interventions for the treatment of vascular and cardiac disease makes it possible to treat serious diseases in the angio-laboratory. While cardiac and vascular surgery is performed in the ORs by surgeons, the radiology guided interventional procedures are traditionally performed in the cath-labs by radiologists or CA, thereby reducing the number of patients in need for open surgery. During the last decade in so-called hybrid labs, performance in the ORs has been with integrated high-end angiographic equipment where both surgery and angiographic intervention is more common. In the hybrid lab at the IVC, CA, and CS are now establishing the new minimal invasive technique for aortic valve replacement, or TAVI.

TAVI has two transcatheter systems available in Europe and can be used for clinical practice: the Core Valve Revalving System (Medtronics, Minneapolis, USA) and the Edwards SAPIEN tissue heart valve (Edwards Life-science, Irvine, California, USA) (Linke, Walther, and Schuler, 2010). The main difference between the two systems is the EDWARDS system owns a majority of the transapical procedures while Core Valve has the leading position in transfemoral delivery. Core Valve uses a dumbbell-shaped balloon for the valvuoplasty due to its advantage of conforming to the anatomical structure and providing greater stability in the beating heart than the cylinder-shaped balloon used by Edwards.

The TAVI device made out of cow tissue strengthened by a stainless steel stent. A balloon is employed to dilate the valve opening prior to placement of the prosthesis. This procedure is what surgeons refer to as preparing the ‘landing zone’ (Latsios, et al., 2010). The patients malfunctioning aortic valve is pushed out of the way and replaced by the TAVI device. There are two choices where the patient can receive the device, either through the femoral artery or through an incision in the left side of the chest below the nipple (Yan, et al., 2010). The patient will
receive either of these pathways depending on the co-morbidities of the patient and the conditions of the transfemoral route in the patient (Johansson, et al., 2011).

These valves can be inserted through the femoral artery, or transapically through the heart via a small thoracotomy. A cardiologist can perform this arterial approach alone and the transapical approach requires a surgeon. When applied to the selection of the patient group, the TAVI procedure is best suited for elderly patients considered inoperable or having a higher risk for conventional surgery (Linke, Walther, and Schuler, 2010:513). The IVC in particular uses the Edwards SAPIEN transcatheter heart valve is an investigational device, which is placed through
either a transfemoral (RetroFlex 3 Transfemoral Delivery System) or transapical (Ascendra Transapical Delivery System) approach. The Edwards SAPIEN valve is currently being evaluated in the treatment of patients with severe calcification aortic stenosis. I was informed by one of the professionals on the TAVI team that the IVC chose to use this method on the basis of Edwards Lifesciences directing its technology more towards the transapical route, as compared to Core Valve which focuses on the transfemoral procedures.

Figure 10: CoreValve (retrieved http://www.medtronic.com/corevalve/ous/system.html; 2011-03-14)

This different approach to treating patients with severe aortic stenosis may create a level of uncertainty to the “ownership” of the procedure due to involving two different actors in the medical procedure – CS for the transapical approach and CA for the transfemoral. It is seen that
if this procedure become simple enough to occur in the hands of the CA or radiologist it has the potential to disappear from the work of the CS. For that reason, the IVC is a good case study because it is a ‘hybrid’ setting where multiple professions work together in one environment fused together through technology but divided between the guarantee of the future.
5 Findings

5.1 Readers Guidance

The TAVI project was initially started to provide an alternative to non-operable patients who would normally not have a treatment option. It is a minimal invasive technique basically developed to give elderly patients with aortic stenosis a few more years of life. A reason why development in the field of minimal invasive techniques is interesting is if the new procedures are practiced enough where it can be used for a wider range of patients, it may threaten the demand for surgical services. As the need for surgery decreases, the need for surgeons no longer becomes apparent. For example, surgical services have been decreasing in Norway (refer to graph 1 in chapter 1) so minimal invasive procedures have the potential to occupy these services.

TAVI procedures have the potential to change two things; the idea of aortic valve surgery and the role of the professional who does it. It can make a dramatic impact on the patient as they have the ability to demand minimal invasive procedures. The following chapter is a compilation of my findings from the interview and literature on the idea of minimal invasive techniques, TAVI, and the impact these have on CA and CS in both relationship and professional responsibilities.

5.2 Responses to TAVI

As one informant put the idea of TAVI:

My first reaction is that that was science fiction (laughs). Because it seemed impossible to me...you can really implant a valve into this crater of calcium? But obviously it succeeds, so I have completely changed my mind (Informant 2).

This illustrates the transformation of an initial perception into acceptance through time and experience. While informants discussed this concept, others talked about the different roles CA and CS could develop out of the procedural change. For instance, with CS many had mentioned the change in training and skill set CS would have to undergo if they were to be a part of the project in the future:

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For the CS it is quite a different procedure than surgery...they are will to take on the opportunity of learning (Informant 6).

I think that for many years there has been some change in treatment strategy for cardiac surgery. Change from more surgery to intervention for coronary heart disease. So I think there is a feeling of threat for thoracic surgeons, they have to adapt to another strategy for the future (Informant 1).

In the example concerning the disciple of CA, since they were used to working with the catheters anyways the discussion was more or less about advancing their position with the project and securing ownership of the procedure in the future. This does not exclude the idea of becoming a more surgical approached CA:

When it comes to the TAVI project I think the CA are happy because they see a future for themselves, because sooner or later they will adopt the whole procedure and make it a CA procedure (Informant 2).

Although, some had mentioned that there is the possibility that both CS and CA would have to change and out of TAVI a new sub-specialty could emerge:

I think we have to develop a kind of third arm. We have the surgeons on one arm, the CA on the other arm, a kind of other hand. I think we really should have one with some expertise with both. I see this as a conjoined effort and I see this as a new kind of interventionist surgeon or a more surgical cardiologist (Informant 5).

This means any traditional boundaries originally set between CS and CA disciples are blurred as the TAVI team learns to work together and develop new behaviours to make the TAVI project succeed:

I think we are going more and more together in hybrid procedures. When we discuss, it’s about something we can do together. That is the future. That is my personal opinion. I think the CA will know ... can’t operate, but CS have more problems in realizing they need to gain more experience in using catheters. But this is the first time we have really worked together like this and I think it is a good experience (Informant 4).
The TAVI project particularly comes into effect when these individuals see and feel the impact the TAVI team is making on the CS and CA specialties. Opinions on TAVI can be seen in both a positive and negative light:

I don’t see much of an antagonism to our daily work in this thing evolving. In fact, I think we should welcome that and seriously embark on developing these procedures to see what they are worth and if they can offer patients less invasive and safer or as safe procedures (Informant 5).

If they prove what they say they will do it will completely change the whole field of valve surgery...CA have reacted with enthusiasm because they see this as a new field for themselves. The CS for the first year or two were seriously skeptic because they had looked at this as possible and had a sort of hang up on the complications and not the possibilities. The last year or two this has shifted completely as TAVI is seen as a solution to those patients we have no other solution for...now they see this as a good tool (Informant 2).

Building upon the feelings of future uncertainty between CS and CA, while some mention TAVI in a positive manner, others had discussed how TAVI also brings an unwelcoming change:

...in the future this will compete with open surgery and CS fear that of course. You have some conservative colleagues that hate this (...) and that is normal (Informant 4).

You get a little bit in a defensive position, it’s expected...Yes, I think some people are against this project. I think that a lot of people get in this defense position against changes that in a way make activities in the future unsure. I’m not sure if I’m able to explain it...it’s a normal reaction (Informant 1).

This fear and conservatism is defined by the unknown results that surround TAVI:

At the moment it’s not a threat for anybody, and I don’t think perhaps people have taken it into themselves in a proper manner because I think it will be quite big. And I expect the resistance will be much bigger in the future. So I think it’s kind of a sorrow process...I don’t think the surgeons in the hospital would like [to advance TAVI]. I think the group participating in the TAVI project would like to do it, but I think everyone is waiting for the big study in the cohort\(^2\) (Informant 1)

...I think of a song by Van Morrison; ‘Professional Jealousy’ (laugh). It’s not how I see it, but in this case as this is a little bit of undefined land, a little bit like if you get your hands\(^2\) This is a reference made to the PARTNER study currently underway in the United States, with release of the second cohort in 2011.

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on the land rights. So it’s the same amount of positioning. I’m not sure if it should be
done by the pure CA or the pure CS. I see it as we have to take a step back and get more
and see what this kind of treatment from expertise has from both parts make this work
(Informant 5).

In the end, the aspect of having TAVI as a solution for a population who would otherwise have
no treatment available encourages many to feel that the results of the procedure are what matter
most. What is most important is how the professionals can work together with the new technique
to provide and improve such services:

I know that by new techniques there will always be a little competing in who is doing
what...I know from hearing that there can be some small fights and conflicts maybe in the
future in who is going to do this...this should be a work done by all the professions. I see
no need in having a conflict about it there (Informant 8).

I think that if it is to be a successful project than people need to respect each other. And
that’s not always the case between surgeons and interventional cardiologists today. Half
of them are competitive (Informant 1).

This means that even though there are mixed responses to the change created, the change itself is
present and identifiable and should not be the main concern behind TAVI; it should be the results
of the procedure and if TAVI is a suitable enough tool for treating elderly patients with aortic
stenosis. So far, all of this has been seen within the TAVI team itself in various ways. The
experiences described to me by several informants depict how the TAVI team is working well
and growing together, and helping launch a new side to the profession amidst tension of future
roles. The experience of new interpersonal relationships is relevant for members involved in the
project:

It is a positive challenge because I can learn to see how they work together, think, and get
to know them. In the early days you just met at 3:15pm to discuss problems...and [there]
was a solution. But now we work together, and go abroad together and go to courses
together and eat together. So now I have [their] phone numbers on my cell phone. So I
think it is very positive (Informant 4).
This is supported by other responses that CS and CA have a nice experience working together even though they are considered ‘different persons’. One reflection I had discussed throughout this study was the level of natural leadership the CS have and how this is a strong influence in the fight for ownership over TAVI.

The first procedure with the transapical approach where the surgeons have a natural way of being leaders. I think it is more difficult for the surgeons to be assistants in the transfemoral approach (Informant 4).

CS, among many other health practitioners, like tradition and following best practices (Ledlow, et al. 2007). Leadership, then, has to be a collaborative environment that integrates ideas, promotes and emphasizes motivation, and raises morality as change occurs (VanVactor, 2011).

I think that [the role of a leader] in this project is to start it up, to get it to go, get the initial experience, patient selection and so on, and think that in a few years younger people will get into this and [the leader] is standing behind and leading the way (Informant 1).

Through good levels, styles, and commitment of those in leadership roles, the new CS or CA can adopt the methods created from the TAVI project and welcome the future. As the definition of procedural roles become clearer the uncertainty over ownership of the procedure will extinguish, although it is mentioned how the CS would like to maintain their leadership capabilities in this project.

5.3 Response to TAVI in the OR

5.3.1 First Operation

Observations are useful in this study because I was able to view how the CS and CA respond to the new procedures and each other in the operating room. Through both operations it was highly seen how everyone worked together. Each member was an active part of the whole process and intent on learning and doing to the best of their ability. The level of co-operation was to a great
degree pleasant and their collaboration with different disciplines was highly professional. There was a definite feeling of leadership coming from the CS. One CA had noted this as well and mentioned how during the transfemoral approach the leadership comes from the CA side.

In the month of March 2011, I participated in two TAVI operations at the IVC. In laymen’s terms, this was probably the coolest experience I have ever had. I arrived at the IVC around 8:30 in the morning. The doctors and staff had begun preparations around 8am and the procedure was supposed to start at 9am. When I had arrived, I dressed in green scrubs and shoes, and stuffed a camera in my pocket just in case. I was very eager to experience my first operation. As I came in the operating theatre one of the CS had informed me that the patient was extremely ill and might not survive. The patient was a 90-year old female and was about to undergo a transapical procedure. A small feeling of depression had sunk in and took over my overt excitement...my first TAVI procedure might not happen.

Fortunately, the staff at the IVC was able to work with the patient and the procedure continued. It was exciting to stand in the room with so many people and machines. In the beginning there was about 10-15 people, including CA, CS, ANES, support staff, and other observers like me. During the peak time of the operation, there were 20 people present, and at the end, this number dropped back down to 10. For myself, I felt a little out of place at first. I did not know where I was allowed to stand and was afraid to touch anything around the room. Luckily, after a while curiosity got the best of me and I started moving around looking at all the machines, computers, wires and whatever people were doing. I rather felt like a kid in a candy store, eyes wide open and ready to take in the delicious sweets. I slowly began to feel comfortable and was able to relax and enjoy the fresh experience.

When the procedure began, I quickly realized what Hollywood had left out of their films - the smell and smoke of cauterized flesh as the surgeons opened the chest cavity. It sounds distasteful when in written down in words but I would like to express how this was the actual moment I realized a real surgical procedure was happening. After the main incision, what was most interesting was to see the migration of people within the room. Slowly but surely the observers moved to where the action was happening and started bobbing about trying to find various positions in order to get a good look over the surgeons shoulders. I myself have to admit I forgot
about being a ‘TAVI observer’ and was attracted to the aspect of seeing a live beating heart. I soon become one of the moving observers and found a spot close to the operating table.

After some time I settled more within the theatre and began to observe my surroundings. I noticed how this procedure really is in its infancy, a training phase for everyone. In the corner of the room, there was a table with several support staff working with the TAVI device itself and filling catheter devices for use later on. Here, one staff member was instructing several others and they were having many discussions about the devices. In the computer room, there was another IVC member who was in training. There were many nurses moving about making sure things were ready for use, put away after use, cleaning materials disposing of waste, etc. Then there were others in the area in case of an emergency. I noticed how the groupings of people matched what one informant had mentioned in the interviews:

We come in and like to huddle in our groups (laugh) (Informant 9)

Being in the OR was a good experience because I was able to put a real experience next to what I was told in the interviews. It was interesting to note the placement of the professions. It was exactly what I was told in one interview

I think we have to develop kind of a third arm. We have the surgeons on one arm and the CA on the other arm, a kind of other hand. I think we should really have one with some expertise with both (...). Some complications will be surgical in nature and some will need a conversion to conventional surgery. I see this as a conjoined effort and I see this as a new kind of interventionist surgeon or more surgical approached cardiologist. (Informant 5).

By the end of the procedure, the atmosphere was good and the TAVI procedure was a success. I stood by and observed the final closure of the chest cavity. Here, I was quite taken aback at the surgeon’s skill. I could really see the expertise in the hand movements of the surgeons. The fingers moved with grace with large tweezers and tiny rounded needles, sewing together the incision of the chest. It was hard to believe where only a few moments ago a live heart was exposed, and now laid a nice, simple line. As this was happening I remembered one comment in an interview concerning the actual practice of surgical procedures in order to achieve good results:
If you want to be good at any procedure you need to do them a fair number of times. It’s just like playing Beethoven’s sonata. If you are doing it once every six months it’s not worth while listening to (laugh). Compared if you played it two or three hours a day it makes you…I mean, it’s so much tactical things. You need to be doing the procedures, handling them, and so we have to evolve specially to these procedures (Informant 5).

This comment reflects how the high standards and skills of the surgeons are due the actual practice of surgery. In the operating room, I fully understood how a decrease of operations could affect such skill and why this would worry some professionals.

I think what may worry some surgeons is in order to have a level of expertise...you need a very experienced set of surgeons, and for them to be experienced you need a certain amount of surgeries...if you rip the basic material you need to be a trained surgeon from underneath the surgical gloves you end up with results so poor that surgery itself will be a risk procedure...

...people know the results they can expect in expert hands and they go for nothing less...of course when you take the cub bear from the lioness she wakes up (laughs) (Informant 5).

5.3.2 Second Operation

The second operation was in the afternoon of the same day, at 1:30pm. The patient was an 86-year old female and undergoing a transapical procedure. During the procedure there was not as many observers and the room was more quite than the morning. At the peak of the procedure there were 16-17 people and at the lowest point 8. This made for more of an intimate and interactive session and again the support staff was confident in their own process as well. I was able to stand closer to the patient and chat a bit more with the CS and CA. One of the extra CS who was there for emergency purposes inquired into my own presence. When I mentioned I was a Masters student in health economics he laughed and asked if I was counting supplies. I was then able to chat a bit about my study and how I was there to observe the interaction between the CS and CA. Everyone started laughing and asked how they were doing so far, giving each other praise and making fun of the other profession at the same time. The general spirit of the room was pleasant and I could tell the team worked well together. In this moment, I watched how a team was working together and there was no level of animosity between the professions. It
seemed strange how through this moment of strong communication and team work there was going to be an after-party of discussion about ownership and the future of TAVI:

Yes, they [think about it] a lot. They talk about it a lot, at least at every meeting, and after a glass of beer (laugh). So, there is some kind of fear and uncertainty at least, for CS who are 50 years or older there can still have something for us to do before we retire, but for the other ones who are not deeply involved in the TAVI project there is a bit of uncertainty about ordinary procedures. So, there are both expectations and fear. It depends on where you stand in age and interest (Informant 2).

I was able to get a bit of up-close instruction on the catheter part of the procedure from the CA performing that day. Similar to watching the CS in the morning I was also able to see the skill involved in being a CA. Again, it was nicer to be in the room without so many people for I am not sure the experience would have happened if there were too many people in the OR. One informant had mentioned this in the interviews as well:

It's too overcrowded. The TAVI OR per se, I don’t like to stay in the OR because there are too many people in there because it is a new project. We are few but we are working very good together, but I think there are just too many coming are coming in just to watch what you are doing. This is a problem we have (Informant 4).

5.4 Development of New Sub-Specialty

The development of a new sub specialty was one of the main questions talked about in my interviews. I had read about this in various pieces of literature and listened to the idea in panel debates, but it was after I had observed the two operations I understood how the two disciplines could merge and create other sub-specialties. The TAVI team worked well together and learned where and when to anticipate each others next move. An interesting note however, was everyone I interviewed was competitive as to who would do the procedure, but oddly enough they were open to having another person to it. Or in other words, the idea of have a sub-specialty arising from the process. In total, all ANES, CA and CS feel that if this new sub-specialty were to arise the reason for development would have to encompass more than just the TAVI project and will probably aim in the direction of a CA due to the use of catheters:
It’s a long way to go because it’s not up to us; it is up to the health department more or less to create a new specialty. I think it will take years. Only to create a new specialty only for the TAVI project is meaningless. You need a much wider group of patients (…) but there is a lot of talk about the new intervention specialty (Informant 2).

Since the use of catheters is prevalent, this merge or development can have an influence on the learning path of a CS. They will have to learn new methods and techniques in order to evolve with the procedures being developed:

Once [this treatment] is shown to be better or as good as conventional, I’m sure there will be surgical types that during their education can sort of be bi-lingual, have catheter training as well as surgery. But that raises the question of whether it should be a new type of specialty that masters both (Informant 3).

These two statements reflect how many informants agree that the influence minimal invasive procedures have on medicine today raises awareness that individuals are able to cross professional boundaries and learn different techniques traditionally operated by other specialties. This is slowly becoming accepted as compared to how in the past if you belonged to one specialty you were warmly not welcomed in another.³ Now, CS are pressed to learn interventional procedures to keep up with vascular treatment (Informant 9). Such as training in the cath-lab, intensive care unit, and learning echocardiography/radiology techniques (Informant 10). Although, this can inflict a kind of fear within CA if CS learn their techniques and are able to enter their natural domain. This emphasized the competitive nature between CS and CA.

It was mentioned by several informants that anyone currently within in the field would have time to retire before a new sub-specialty arises out of TAVI. This means the development of a new sub-specialty would more likely effect the recruitment of new professionals to CA, CS, or INT surgery/cardiology then current staff members. It was mentioned that if a sub-specialty was to emerge there would be a few extra challenges for the CS. “They must learn other ways of doing things” (Informant 10) because “it would change the rules for CS – they would have to know

³ I had roughly three or four discussions with cross-trained professionals and they all mentioned how at times they were questioned by their colleagues about ‘where they belonged’ in specialities.
about the cath-lab imaging to meet the new specialty, and this could create more opposition in the cath-lab” (Informant 9). This can be explained through one comment that “basically we are all conservative and a bit skeptical of new things impinging or encroaching on our area” (Informant 5).

One panel discussion⁴ I watched on what the future hold for the TAVI project asked a similar question to my study: who will be doing this procedure in the future? The respondents commented on how the heart-valve team is a completely integrated program for pre and post care. Nonetheless, as more experience is gained in the procedure this multi-disciplinary team structure created for TAVI could devolve into a single specialty.

5.5 Summary of Findings

After spending the day in the OR I gained more knowledge about how CS and CA worked as a team, grasped the concept of how there are challenges to learning new the new procedure, and understood how the future can be uncertain over ownership of the procedure. First, the team had a high level of communication both verbally and physically. Second, there was a lot of mixing of technical knowledge and practice that concerned multiple professions. In this case, someone operating in the room, whether they are a CS, CA, or support staff, would have to know the language, speed, and delivery of the procedure. This leads into the last summary, ownership of the procedure. At this point in the observations you can see how it is unclear in who will be mainly performing the procedure and who will be assisting. Both the CS and the CA have a vital role in the TAVI project and there is definite potential in developing TAVI into a broad based technique. This idea was initially discussed in the interviews and one main solution was the development of a sub-specialty that encompasses both CS and CA roles.

There are generally mixed results that come from the two different professions of CA and CS, and mostly from those not directly involved in the TAVI project. It is here my study found the most interesting and controversial results. The CA are the most optimistic about the new procedures and have the most interest in the future of the project – mainly if TAVI becomes a

CA dominated procedure. On the other hand, CS remains the most skeptical and awaits the long-term results on TAVI and it is applicability for use in patients other than the high-risk group. Due to previous bad experiences with the off-pump coronary by-pass procedures, the CS are most concerned with the quality of the work TAVI and its team has to offer rather than the demand from either the patients for a minimal invasive procedure or the market industry. Therefore, the CS thinks this should remain in the hands of the CS due to safety and skill level. The CA knows this style of thinking is apparent in CS and CS do not like the change that is happening (and the fact that CS want to own the procedure). Conversely, they also see patient demand for minimal invasive procedures as something that should be applicable in the decision-making process.

Either way, CA feels that CS will have to manage both the uncontrolled developments in technology and patient demand on the same level. Since the CA has expertise in the use of catheter-based procedures, they see TAVI as an opportunity not only for them but for patient as well. One informant had mention of how patients are a population that should be treated and not necessarily ‘owned’:

From a professional point of view, it is not quite ethical to be looking at patients as something you own (...). We should be open minded in evolving procedures that are safe and beneficial. Patients have to be the ultimate goal in the results. Any kind of jealously - on behalf of the procedures that you used to do that may be taken away from you, sort of numbers. (Informant 5).

One disagreement found between CS and CA is the aspect of where the TAVI procedure should take place and reflects the same concerns about safety I noted in the paragraph above. On one side, you have the CA who would prefer for the procedure to take place in the cath-lab and become a CA procedure. On the other, you have the CS who feels that TAVI should remain in the hybrid lab due to safety concerns and should remain a CS procedure due to the high quality surgical care CS can offer. These concerns are based on complications that TAVI has yet to solve and the high level of quality of care standard surgical valve replacement can offer a patient with severe aortic disease.

These two aspects reflect how CS and CA opinions differ in regards to ownership over the TAVI procedure. They may have good collaboration while working with TAVI project, but the CS and
CA feel differently about who will actually put their name to the procedure. The patient always comes first in both the CS and CA eyes, however for differing reasons with substantial concerns. This was the biggest conflict I encountered during my research, and it was explained to me that the CS exercise more of a stronger responsibility for the patient. This reflection is highly noted in their responses of how much time is spent on each patient before, during, and after cardiac procedures. CS reflected that CA ‘get the fun part of the procedure’ and not the actual responsibility of the patient. The CA on the other hand recognize that the CS think they are ‘stealing’ the patients and acknowledge that there is a state of uncertainty in the CS over the ownership of the procedure and fear of patient loss.

[If TAVI booms] there is going to be an earthquake in our specialty. That is our daily life, the valve surgery, and so if you take that away from us, I don’t know how this will look in 10 years. You will have to remove 1/3 of the cardiac surgeons (Informant 2).

On the contrary, when I was putting together the results section of this study I was able to have an interesting conversation with the professor and doctor at Rikshospitalet Jan L. Svennevig who presented the Norwegian Medical Association graphs for the years of 2003 – 2009. In our correspondence, I asked about the impact TAVI could have on the patient numbers for CS and he brought up several thoughts worth mentioning. One was how the decrease in cardiac operations in Norway are most likely due to a change in lifestyle behaviours, such as the decrease in smoking and an increase in the general health of the population rather than minimal invasive techniques. ‘I’m convinced that the population is getting healthier due to changes in smoking habits (reduction from 52 to 23% within a few years) and nutrition’. For instance, the impact these changes make in an individuals’ life affect the level of heart infarctions in a general population. Svennevig discussed that since heart infarctions have had a significant reduction in the number of deaths there will also be a decline in the number of heart operations. This can be a strong explanation for the decrease in the need for cardiac surgery.

The second thought of Svennevig’s I found interesting was if TAVI could have the potential to influence the remainder of operations that did occur. He commented on how the project would probably not cause a statistically significant decrease in total cardiac operations due to the small size of the project and the high expenses. Although, since aortic valve repair (AVR) does not
exceed the age of 90, and the population of elderly is increasing, TAVI does have the potential to include more high risk patients and extend the indications of AVR. Svennevig’s comments on how many other surgical services are necessary in various departments, from paediatrics to complicated valve surgery, were supported by one of my informants during the interview process when I inquired into the same questions:

Of course [cardiac surgeons] don’t like that the volume of cardiac surgery is going down, but in this country you need big changes before you reduce the number of cardiac surgeons (...) so in this hospital we have the paediatrics case (...) and transplantation. So we haven’t felt much of the reduction, a little bit, but this hospital is doing most of the cases the other centres in Norway will not do (Informant 7).

This informant knew that if TAVI’s outcome was similar to conventional surgery patients might prefer the new method, however even though it may be ‘a parallel process with many patients there are more things to do that exchanging one valve’ (Informant 7). For reasons such as this, the concern over the loss of patient numbers can then be replaced by optimism with the aspect that surgeons can offer high quality services other than aortic valve replacement.
6 Analysis and Discussion

6.1 Analysis of Research Question 1

My first research question was:

What challenges do cardiologists and cardiac surgeons face with the introduction of new minimally invasive technology?

To answer this question, the interview process connects with the literature on how when change happens in a pragmatic fashion, multiple venues are opened. Since changing the idea of aortic valve surgery is connected to the change in the procedural roles of CS and CA and vice versa, the professionals involved must learn a variety of new techniques and this creates challenges for all actors. For example, new mechanisms in OR that combine CA and CS techniques imply that each specialty must learn procedures that were traditionally considered ‘CS’ or ‘CA’. A second example is patient criteria and selection. A challenge for the CS is accepting that criteria changes and the CS and CA now have to work closer together in the decision-making process and provide solutions to problems as a team. This means that CS might have to accept patient losses and procedural changes. For example, the idea of having to learn catheter based procedures in order to maintain patient numbers, or, learning how to conduct entirely new methods of thoracic surgery such as when CS went through the development of cardiopulmonary bypass, heart-lung machines, or the current minimal invasive techniques (Fosse, 2009). On the other hand, the CA would have to accept changes in their own field such as recognizing they need more patient responsibility if they are to fully take on the TAVI project, or even learn surgical techniques.

This research question is apparent in the beginning of my paper with Booth’s (1985) feedback loop of how medicine, technology and scientific research influence each other. Booth’s description of the continual pathways between science, technology, and clinical research and practice show a desire for constant development. When analyzing this aspect next to the current progress of TAVI and the evolution of the CS and CA disciplines, it means that some professionals will have to change their traditional paradigm of thinking as individual specialties and incorporate the new methods of practice into one specialty in order to accommodate new needs and demands of both the medical profession and the patient. This arise out of the idea that
innovation and change fuel each other through the circular pathways of learning, experimenting, experiencing, reviewing, and reinstating evidence-based practice.

As mentioned, the CS may have to learn an entirely new method of treating aortic disease with catheters, or the CA may have to learn how to use a more surgical approach to achieve their results. Either way, this level of change can create fear of having to learn new methods and hesitancy to how they are going to learn them, but it also brings a kind of brightness to a new development within a discipline. This style of change and fear of change is in relation to Kotter’s 8-Stages of change management. Here, the CS and the CA would have to undergo several steps in order to overcome the obstacles TAVI produces and achieve desired results. For instance, the need for a procedure to accommodate a patient population that cannot be otherwise treated and the aspiration for the TAVI project to be that procedure creates a connection to the first four stages; urgency, leadership, vision, and communication. These stages help create clear strategies and strong commitments to both the professionals and the procedures.

The next three stages of removing obstacles and rewarding improvement shows that those involved in and with the TAVI heart team understand that change and innovation brings challenges, but that these can be addressed and overcome with positive reinforcement. The last stage anchoring the changes is something that has to be confirmed within the future. Since TAVI is a relatively new project and further studies are needed, stabilizing the changes within both CA and CS will have to be determined through more research and evidence. Although, experience and knowledge learned throughout the process can still be taken into consideration even if the TAVI project does not succeed.

As mentioned before, a third challenge is within the CA in having to learn CS techniques. For instance, it was mentioned how in CA TAVI has the potential to bring a bit of excitement to the field:

I think that people have been through a period of ten years now or something in CA where not much has happened, where the first new big change is the TAVI procedures. And I think everyone is feeling that big thing. Something is happening again (Informant 1).
This feeling of ‘something big happening’ compliments the first stage of Lewin's 3-Stage change theory; unfreezing. It discussed as the initial motivation to change behaviour. This motivation may consist of adding new behaviour to an already establish routine or removing some of the existing factors that maintain prior behaviours. In the case of the TAVI, this is two-sided. On one side, the TAVI procedure itself is an initial motivation for change. The CA see this as something new they can learn that is exciting and might bring added possibilities and patients.

On the other side, it is also the break in the professional barriers of CA and CS, which is Lewin’s second stage of change. Here both the CS and CA will have to undergo by adopting and adapting new information and techniques in both minimal invasive methods and the TAVI procedure. By looking for new ways of doing things, the disciplines change with the innovation presented by and to them, and consequently a new direction is taken for both professionals. As a result, the third stage of refreezing has a possibility of being implemented if the TAVI procedure is fully accepted in the medical community. At this stage, routines, behaviours, and opinions will emphasize the new structure the TAVI innovation has brought to CS and CA, and barriers between the disciplines will blur as the challenges dividing the professions are prevailed over.

In regards to the innovation and technology change challenges, even though CA and CS are in the middle of the change management process dealing with minimal invasive techniques, change management theory can be seen as a structured approach to this research question. It enables other people and organizations to move from one state of knowledge to another, or therein to a desired future state. This is in order to semi-anticipate the conditions and outcomes of the new procedures. This is important for CA and CS as they are involved in the new TAVI procedures, and as a result, the changes that happen within the project affect not only challenges to changing their medical knowledge, training, and experience but also their definition of their own profession. TAVI procedures have the ability to change the role of the CS or CA in the future, and this includes where they work and with whom.
6.2 Analysis of Research Question 2

My second research question was:

_How do cardiologists and cardiac surgeons perceive and react to the uncertainty of ownership over the new procedure, and thus, the changes that may arise within their profession?_

After researching several theorists, I have come to recognize change management as an organizational and psychological process aimed at helping people embrace change within their professional environment. Of course this process can have both positive and negative outlooks as some people may or may not accept change adamantly, yet interestingly enough, this is where the core of my TAVI research began. Since TAVI has an uncertain future, varying responses such as excitement, fear, actions of preparedness, or simple laid-back optimism is shared among CS, CA and support staff during TAVI’s process of development.

First, to describe the uncertainty of the future, in Schein’s adaptation of Lewin’s change management theory, survival anxiety can cause change but it may not be sufficient to stimulate change if learning anxiety has a strong presence within the situation. To elaborate, this is apparent in the TAVI procedures for many CS and CA individuals have especially spent a lot of time learning the traditional material and have a personal connection to their speciality. Unfortunately, this also induces learning anxiety which can create further stratagems of denial, scapegoating, manoeuvring, and bargaining. For example, the uncertainty felt by the CS and the reactions felt by both the CS and CA rest on the idea of unknown results of the new procedures. Complimenting the state of change, uncertainty is characterized by security of the present conditions and feelings of the unknown:

_I think basically we are kind of conservative, maybe because we know what we are doing, we know what we can do, we see uncertainties about these new procedures and we may also maybe mess up kind of surgical procedures that may be done in the future...I think we’d probably have mixed feelings from that point of view basically because we don’t know really the long term results from these procedures... we are a bit reluctant yet (Informant 5)._
Expanding on this concept, I will bring in the Burke-Litwin model as a response to the uncertainty produced through TAVI. It could be used as a guide to facilitate thinking about the components involved in change management and how to rise above anxiety. The model is emphasizes that key factors such as organizational culture and mission and strategy statements are important in assessing the situation and engaging both the individual and the organization. This is accompanied by understanding and recognizing the elements of individual skills and tasks, needs and values, and motivation. When applying this to the TAVI team and associates, any kind of anxiety that would naturally bring uncertainty or fear for the future can be aided with leadership and management practices.

Nonetheless, since it is agreed that the TAVI procedure has a place in the future, it may inevitably mean that CS and CA will have to go through some sort of change process. Some or much of their prior knowledge about their speciality, daily routines, future role in the procedure, or future professional replacements is in contest with their new speciality, daily routines, future role in the procedure, or future professional replacements.

The reality behind who will own the TAVI procedure will be dependent on what kind of results about TAVI emerge from randomization studies. Will this procedure be able to compete with conventional surgery? If so, will CA be able to grasp hold of the technique and call it their own? Or, will CS have to learn new methods and skills in order to hold on to TAVI? These questions are bundled together through a style of hesitation due to prior positive and negative experiences of new technologies in the medical field. These statements in the literature were supported in the interviews. For example, in remarks made about the off-pump coronary by-pass procedure that were based more or less on an idea that unfortunately did not work well in practice:

In many ways there are procedures, and in thoracic surgery as well, that have been industry driven to some extent and some procedures that have been herald as the new thing has kind of fallen on their face. As for example to that is the off-pump procedures, where ‘if you’re not doing off-pump you’re not a man anymore’. Now it’s hardly spoken of. It has drawn its crowd, a few people but not many numbers now. But of course to have the long term follow-up for these procedures, it may have an impact where you have to change direction or add to have improvement to procedures, or otherwise you have to go back to the old procedures if they don’t work out as expected (Informant 5).
This is supported by another informant who mentions how technology succeeds when it is created for a purpose that needs a solution:

There is no antagonism against TAVI. It has not been the same for other minimal invasive procedures, like the off-pump coronary by-pass surgery that was introduced here 10 years ago. It was a lot of antagonism from colleagues, at least the CS because it tried to solve a problem that was not there. When it comes to TAVI there is a big problem, it should be solved (Informant 2; with support from Informant 10).

Or, if the actual treatment of disease changes the technology as well:

There has always been a change in treatment of disease which has always been very big things, and after a couple of years no one is performing it (Informant 8).

Basically, these quotes innately describe what has been said in the literature at how the aspect of having to change is known by the actors involved but having to change is difficult due to a level of uncertainty. In the example of TAVI, this is past experience with new technology that fails, or knowing who will be doing the procedure and if it will create a large enough effect on their professional role. On the flip side, the recognition of necessary growth and change forms when individuals and organizations know that they need to change in order to keep the producing what they are involved in:

Where they are doing cardiac surgery, they are in a way of acquiring new technology skills all the time. They go to courses and learn new ways of doing valve repairs, it’s not like they are doing the same surgery they have been doing for 30 years. The field is in constant motion so I don’t think this has been a very big challenge compared to valve repair and development (Informant 7).

This is seen in all three of the change management models, such as Lewin’s motivation in Stage one, Kotter acknowledging the urgency around the need to change, or Burke-Litwin’s feedback loop involving the external environment and individual and organization performance. My analysis of these would be that I see the constant motion in CS and CA as both mental and physical, where learning is a double-sided process because the CS and CA have to integrate the new methods and skills into their practice and have to internalize the professional changes. The
emphasis then is that the person in the present state sees what it could be like in the future state and desire to be there. Thus, they move forward with particular activities that help make the change happen, such as imitation of role models or leaders, or exploring personal changes through trial-and-error learning.

6.3 Discussion on Collaboration

Beyond the competition for TAVI, everyone I interviewed thought that the TAVI team as a whole has good collaboration.

At first, there were (as expected) small fights as to who would do what and when, but as everyone established their roles (...), the collaboration between the members of TAVI became a fine co-operation where [members] are invaluable to the team (Informant 3).

Statements such as this one were common throughout the interviews, pieces of literature I read, and news videos from other countries I had come across while researching TAVI. The basic notion is that CS and CA work well together and people on the TAVI team can cooperate well enough to achieve successful results in the procedure. The models of change management presented in the literature discuss how communication and cooperation among all parties are essential to progressing from one state of change to another. For example, Lewin mentions this in stage two and Kotter in stages three and four. One thought I have on this is the idea that because the team is has a small size it makes communication, cooperation, and developing personal connections easier. You get to know the people around you and establish a relationship with them. As one informant put it;

You respect them and get to know their strengths and weaknesses (...). We can eat lunch together and I have some of their numbers on my cell phone (...). (Informant 4).

Comments like this lead me to think that the success of a procedure and the kind of role either a CS or CA would have in TAVI could potentially be influenced by how the team works together in the first place. When I was in the hybrid lab observing the TAVI procedure, whether or not there was any underlying emotions of ‘he stole, she’s stealing, why won’t they just let it go’ I felt
there was a strong sense of professionalism and respect for each member present. This is where the TAVI team has the capability to change not only the future path of the procedure, but the paradigm of who owns the treatment of aortic stenosis and the CS versus the CA competiveness.

To explain, since CS maintains the standard treatment for aortic valve disease (Tamburino, et al., 2010) they are usually maintain core consultation authority in the TAVI procedure. Nonetheless, they have to share the procedure with the CA. As such, this heart team produces not only results but a style of relationship despite outside community member’s thoughts and opinions on the project. Thus, the team moves an acceptance of the procedure and style of cooperation in a new direction. The continuation of this coexistence is founded on whether or not the results can be comparable to, and if not exceed, the current procedures results. As Tamburino, et al. (2010) put it:

Will the two traditional competitors live together in peace forever, as the wolf and the lamb of Isaiah's scripture? In other words: is this coexistence founded on a solid, lasting basis or is it just a prelude to relaxation of the indications for TAVI? (...) A paradigm shift for the treatment of aortic stenosis requires time and comparative high-quality data.

Tamburino et al. (2010) quoted a series of verses from the Bible that represents their thoughts on whether or not CS and CA can really work together, such as being the wolf and the lamb. For some time the idea of a paradigm shift crossed my mind, and when I had read this article they also spoke about the TAVI project being a paradigm shift for these disciplines. The ‘uncertainty’ and ‘optimism’, the ‘fear’ and ‘jealousy’ that arises from both professions until they know their exact roles in the process are the result of what is occurring due to the shift change. Regardless of the uncertainty and competitiveness between CS and CA, many people feel this project is a good idea and will become an available option for those patients who cannot undergo conventional surgery. Even though there was a recognition that the number of cardiovascular surgeries have been decreasing, the majority of informants recognized that there will still be a need for surgery. Other common remarks were that new minimal invasive technology and development is a basic part of the cardiac discipline and that change is inevitable – older professionals will have to accept this and younger professionals will have to learn this.

This remark was in relation to the recruitment and education for up and coming CS:
The older guys don’t care, they will retire before the boom comes, they are saved by the bell. For the younger ones who are not interested in TAVI see this as a fear for the future because the patients will disappear. (…) so the smartest of them will grab the TAVI project and become a part of it. (Informant 2)
6.4 Concluding Remarks

The main aim of this case study was to shed light on the turf battle that has arisen over the new transcatheter aortic valve implantation procedure. The two research questions examined the challenges minimal invasive techniques bring to cardiac surgeons and cardiologists, and also investigated how TAVI produces uncertainty about ownership of the procedure in the future. The data produced was from several sources of participant observations, and interviews generated from the Intervention Centre, Rikshospitalet Oslo University Hospital, international panel discussions, and literature surrounding change management theory and information of the cardiothoracic field. This data was analyzed with qualitative methods concerning transferability of the results and limitations to qualitative methods such as personal influence in the OR during operation observations and in the interview process itself.

The main findings were that there is a general expectation of the TAVI project will hold a place in the future and that the cardiac surgeons and cardiologists will need to adapt to the new procedure. Some conservative professionals are sitting back with a high level of uncertainty over the loss of patients and the change happening within their profession, while others are excited for the new development of international studies such as the PARTNER trail (2011). Even though there is a high level of competition among cardiac surgeons and cardiologists, each discipline knows their field is in constant motion and any level of regret or fear needs to be met with a level of acknowledgement of change.

These finding relate to the theoretical contributions of change management. The theorists of Lewin, Kotter, and Burke-Litwin were used as a guide to the theoretical framework. Their models helped produce an understanding the process of change by discussing the various aspects of individual and organizational motivation, leadership, adaptation, and eventually the desire to accept change. This means that the collaboration of the TAVI multi-disciplinary team and its leaders are key to producing successful and sustainable results. When connecting the result of the interviews to the theoretical contribution of change management, Swan et al. (2002:486) illustrates what happens within a hospital and its effects on the professionals working there:

“There was quite a lot of resistance (...) to this method because it is a method that directly competes with (...) what they do. Also they are trained as surgeons and it is difficult to
embrace the multi-disciplinary approach when they have been used to being in charge of everything. There is a feeling that they will lose control over the patients which makes them not very responsive at first”.

Professionals in this example tend to adopt a defensive stance “if we don’t start doing this we are going to have these patients taken away from us. We are not going to have any participation at all” (pp. 487). This indicates that there is recognition of necessary change and growth. The implications of this study are that the cardiac surgeons feel as though they may lose ownership of TAVI, but in accordance with past experience in new innovations being introduced to the thoracic field, the surgeons have the capability of learning other techniques. For instance, with minimal invasive procedures they could learn how to use catheters. Other implications are that the cardiologists could learn surgical techniques and TAVI will become a part of their domain. This would imply that cardiologists are willing to take on the full extent of the TAVI project and patients.

Limitations of the research were that this case study was small and only held during a short period of time. Therefore further research is highly suggested.

**6.5 Avenues for Further Research**

While I was conducting this thesis, a large randomization study named PARTNER (Placement of AoRTic TraNscathetER) was being completed in 26 centres across the United States (22), Canada (3), and Germany (1) by Edward Life Sciences (2011). The PARTNER Trial is the world's first randomized clinical trial of a TAVI and studied the Edwards SAPIEN valve in both operable (Cohort A) and inoperable (Cohort B) patients with severe aortic stenosis. In September 2010, The New England Journal of Medicine published data on Cohort B, showing it successfully met the primary endpoints of all-cause mortality and mortality plus repeat hospitalization. Cohort A’s one-year clinical outcomes were presented on Sunday, April 3, at the American College of Cardiology's (ACC) 60th Annual Scientific Session & Expo in New Orleans, Los Angeles, USA. The results here were that TAVI met primary end points, demonstrating that the procedure is ‘non-inferior’ in terms of all-cause mortality when compared to traditional aortic valve replacement (Wood, 2011).
Now that TAVI is deemed a non-inferior alternative to conventional surgery (Woods, April 3, 2011) it changes the perception of aortic stenosis treatment, which impacts the importance of TAVI in the future by increasing the importance of who is going to own the procedure. Cardiac surgeons and cardiologists who are a part of the TAVI team see the opportunity for applying the treatment to a wider patient group (Leon, et al., 2010; Buchbinder, et al., 2011). This means there is going to be a greater conflicting interest in who is going to treat these patients in the future. The idea of expanding the device to less risky population has the potential to further increase competition alongside other matters:

It’s quite an interesting turmoil we are in and of course vested interests will come in here in several parts. The industry certainly, because they are producing the products we are putting in, and of course they have a huge amount of money involving these projects (…), then of course the question is who should be doing them (Informant 5).

The introduction of new minimally invasive technologies and techniques in a hospital setting, and how cardiologists and cardiac surgeons perceive and react to the uncertainty of ownership over the new procedure, challenges traditional boundaries of cardiologists and cardiac surgeons. Further research on the progress of TAVI and how cardiologists and cardiac surgeons perceive not only their future within the project but minimal invasive procedures is an interesting avenue to take. Possibilities are studying cardiologists and cardiac surgeons in two separate categories and see how each field develops, researching further into their reflections on medical treatment involving minimal invasive procedures. Building upon this, other avenues of research could be to follow the possibility of a sub-specialty. This would entail commentaries from both cardiologists and cardiac surgeons’ disciplines, plus recruitment from future medical students.

My overall response is that a large amount of support is needed during TAVI’s development for both cardiologists and cardiac surgeons. The process of uncertainty over how and when to change in the appropriate direction can be facilitated with familiarity and experience of the OR procedures and process (Schachner, et al., 2009). Altogether, everyone agreed TAVI has at least some place in the future.
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