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The Dynamics of Complex Sociomaterial Assemblages: The Case of Transcatheter Aortic Valve Implantation

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Abstract:
This paper aims to contribute to our understanding of the sociomaterial complexities of information systems. By applying Gilles Deleuze's process ontology, called Assemblage Theory (AT), as interpreted and presented by Manuel DeLanda, we examine the case of a new high-tech medical procedure called transcatheter aortic valve implantation (TAVI). Complex innovations like TAVI evolve as sociomaterial assemblages whose dynamics are seen as driven by the interaction between various stabilizing and de-stabilizing processes. We argue that AT is a very powerful (process) ontology for researching and theorizing the dynamics of increasingly complex information systems

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1. Introduction

The study of the relationship between the IT systems and their social and organizational context has always been at the centre of IS research. Actor-Network Theory has since the middle of the '90s been a popular approach while more recently Critical Realism and Agential Realism have received a lot of attention (e.g. Mingers et al., 2013 and Cecez-Kecmanovic et al., 2014). Yet we consider that these theoretical approaches leave the dynamics of socio-material assemblages underexplored. To fill this gap we will in this paper present and draw upon Gilles Deleuze's process ontology (Deleuze and Guattari, 1988) labelled Assemblage Theory [1] (AT), as interpreted and presented by Manuel DeLanda (2000, 2002, 2006 and 2010). Our motivation in doing so is the desire to gain a better understanding of what we call sociomaterial complexities. We find this important because of the rapid growth the of the complexity of ICT solutions such as the Internet; the emergence and evolution of platform-based ecologies like those related to iPhone/iOS, Android and Facebook; and the growth in the number of information systems in organizations. In the latter case, several thousands of various information systems can be found in many large organizations, each integrated with a huge number of other systems across organizational and geographical borders. A typical example may be the rapidly ongoing transformation (digitalization, globalization, individualization) of the publishing/media and advertisement sectors (Zuboff, 2015). This makes the understanding of the dynamics of such complex sociomaterial arrangements an urgent issue. These dynamics have been researched under the labels digital and information infrastructures and platform ecologies (see for instance Mol and Law, 1994; Monteiro et al., 2013; and Tiwana, 2015). This research has drawn extensively upon ANT, Complexity Theory, Reflexive Modernization (Hanseth et al., 2006) and recently also Critical Realism (Henfridsson and Bygstad, 2014). John Urry (2003) has argued that sociologists should focus more of their research on issues related to globalization and presents a combination of ANT, Complexity Theory and Reflexive Modernization as an ontological foundation for these under the label "global fluids" and suggests that Internet is the paradigm example of such a fluid. The combination of these three theories/ontologies brings us close to AT. However, we see AT as a more coherent and well integrated (process) ontology that helps us better understand how social and material elements are related in addition to two crucial aspects of complex assemblages: firstly, how complexities emerge from simpler elements where AT enables us to focus on both individual elements and larger totalities, and secondly, the dynamics of the unfolding of complex assemblages over time.

The potential of AT will be explored through a case study of the development and evolution of a complex medical procedure called transcatheter aortic valve implantation (TAVI). TAVI is a minimally invasive procedure for treating patients suffering from aortic stenosis. In this case, the aortic valve is replaced by an artificial one and positioned in a patient's heart/aorta by means of digital imaging instruments and catheters inserted through small incisions at the patient's body. TAVI merges the practices of multiple disciplines, foremost cardiovascular surgery, cardiology and radiology. The procedure also involves anaesthesiologists in addition to a number of nursing specialists and

[1] Assemblage Theory has so far received almost no attention from the IS research community. Exceptions are Henningsson and Hanseth (2011), Yeow and Faraj (2014) and Rodon and Silva (2015)

radiographers or radiologists. TAVI includes a plethora of digital imaging instruments that are used during diagnostic processes and surgery, numerous interconnected information systems for storing and communicating patient information as well as sophisticated image analysis and presentation tools.

2. Assemblage Theory

Manuel DeLanda presents AT as both a process ontology and a theory of social complexity. Drawing extensively upon the work of Gilles Deleuze, DeLanda (2000, 2002, 2006 and 2010) describes Assemblage Theory as contrary to most social theories which he argues are "organic theories" which form their basis around what he terms *"relations of interiority."* In such theories, the component parts of a larger totality are seen as constituted by the very relations they have to other parts of the whole, like the organs that comprise an organism or the different parts of a mechanical watch. DeLanda sees what the philosopher Gilles Deleuze calls assemblages as the main alternative to theories of organic totalities. Assemblages are wholes primarily characterized by *relations of exteriority*. This means that he distinguishes the *properties* defining a given entity from its *capacities* to interact with (or affect and being affected by) other entities. While its properties are given and may be denumerable as a closed list, its capacities are not given – they may go unused if no entity suitable for interaction is available. In this view, the capacities to interact form a potentially open list since there is no way to tell in advance in what way a given entity may interact with innumerable other entities.

Relations of exteriority signify that a component part of an assemblage may be detached from it and plugged into a different assemblage in which its interactions are different. Relations of exteriority also imply that the properties of the component parts can never explain the relations that constitute the whole. That is, "relations do not have as their causes the properties of the [component parts] between which they are established" (DeLanda, 2006) although they may be caused by and *emerges* from the activation of the component's capacities. These capacities do depend on the component's properties but cannot be reduced to them since they involve reference to other interacting entities.

Assemblages are defined along two dimensions. The first dimension describes the variable *roles* that an assemblage's components may play and the second dimension defines variable *processes* in which components become involved.

The roles that components engage in range from purely *material* roles at one end of the continuum to purely *expressive* roles at the other. Thus for example the material components can include individuals, organizations and physical structures such as buildings, networks, computers, and so on. At the other end of the continuum are the expressions about those material entities, which may be expressive or linguistic (e.g., laws, contracts, norms, codes of conduct, rules) and non-linguistic (e.g., bodily expressions, dressing, acts of subordination, the logo of a company, or the design of a smartphone). Most components will at the same time have both material and expressive roles. For instance, an iPhone may play a material role when it is used as a device for communication, but it may also indicate association with a social status (expressive role).

The second dimension refers to the processes of *stabilization* and *destabilization* in which the components become involved. DeLanda discusses some examples of specific processes through which (de-)stabilization takes place. For instance, stabilization may happen through processes that *increase the internal homogeneity* of an assemblage (making the components more equal to each other) or through those which clarify the boundaries between component parts within or outside the assemblage. On the other hand, there are processes of destabilization that transform the assemblage so that it can express new functions, capacities, forms and boundaries. For instance, adopting social networking technologies like Twitter, Facebook or Whatsapp are examples of destabilization processes as they blur the spatial boundaries of social interaction.

Any component of an assemblage may participate in all these processes "by exercising different sets of capacities" (DeLanda, 2006). For instance, a member of a political party can stabilize the party by voting in favour of all its issues while at the same time destabilize the party by engaging in scandalous behaviour.

The combination and interaction of stabilizing and de-stabilizing processes make an assemblage evolve as a continuous process. The dynamics involved in the assemblage's evolution can be explained with many of AT's terms. Drawing upon Complexity Theory, or what DeLanda calls the mathematics of dynamic systems, AT may describe the continuous evolution of an assemblage as *path-dependent*, i.e. that it evolves along certain paths. In other cases, de-stabilizing events may sometimes have no apparent effect until a certain *threshold* ("critical mass") is reached. Sometimes the re-stabilization of an assemblage after its destabilization brings the evolution of the assemblage on a new path, i.e. the de-stabilization becomes a *critical juncture* in the assemblage's evolution. After describing our methodology, we will discuss these phenomena through specific examples in the development of the case of TAVI.

Having presented key concepts of AT, we will now briefly compare and contrast AT to the other ontologies popular in IS research. The conclusions from this discussion are illustrated in table 1 below[2].

AT has quite a lot in common with Actor Network Theory (ANT). An assemblage is quite similar to an Actor-Network, however, the centrality of emergence in AT implies that there is a significant difference between the two approaches when it comes to multi-level interactions and part-whole relations. If we focus on the stabilization of an assemblage only, this will look pretty much the same as how the stabilization of Actor-Networks through enrolment and alignment has been described. Such stabilization was central in the research on the establishment of so-called immutable mobiles during the 1980s and 90s. However, more recent ANT research has focused on more complex, unstable, or overlapping networks. Such networks have been described as characterized by "mutable mobiles" and conceptualized as fluids (Mol and Law, 1994). In our view, however, AT provides us with a richer vocabulary to describe and analyse the "fluid" character of sociomaterial complexities like TAVI and today's ICT solutions more broadly.

Agential Realism (AR) is demonstrated to be a powerful approach in describing the "entanglements" of social and technological aspects of information systems. However, AT and AR are dramatically different in their view on the relations between components

[2] Our discussion of AR and CR is based on how theme are presented and used in IS research, in particular the MISQ Special Issues focusing on each of these (Cecez-Kecmanovic et al., 2014; Mingers et al., 2013) and not of the original writings of Karen Barad and Roy Bhaskar respectively.

of larger totalities. AR claims that components of large wholes are inseparable[3], that is seeing totalities as based exclusively on relations of interiority, while AT considers relations of exteriority primary. Relations of exteriority between components are preconditions for replacing one component with another, i.e. to describe and account for dynamics and change in assemblages. In contrast, the assumption of inseparability implies that AR is applicable only to describing stable assemblages or their structure at a specific moment and not over their course of changes[4]. Further, AR provides us with no concepts to analyse emergence and the multi-level interactions of complex assemblages, nor their unfolding over time.

Critical Realism (CR) assumes that social and technological objects are connected and interact, but does not tell us more about how they actually are or may be connected. Emergence is also central to CR, but its terminology for describing how emergence happens is limited, although its concepts for describing and explaining change are more sophisticated. Change is primarily explained as driven by mechanisms triggered by contextual factors.

Table 1. Comparison of ontologies.

	Assemblage Theory	**Actor-Network Theory**	**Agential Realism**	**Critical Realism**
Sociomateriality	✓✓✓	✓✓✓	✓✓✓	✓
Multiple levels	✓✓✓	✓✓	-	✓
Evolutionary dynamics	✓✓✓	✓	-	✓✓

3. Methodology

Our longitudinal study of TAVI[5] commenced in 2011 and so far spans eight hospitals in Scandinavia (two in Norway, four in Sweden and two in Denmark). Our main site is the Intervention Centre (IVC) at Rikshospitalet (RH) in Oslo. We have observed more than 120 procedures there, each lasting 2-4 hours. We held continuous informal conversations with the practitioners before, during and after the procedures. At the site we conducted over 30 semi-structured interviews of cardiologists, thoracic surgeons, nurses, radiographers, heads of departments and other persons formally and informally involved in TAVI. The key team members have been interviewed several times. The interviews lasted on average 75 minutes, and were complemented by document analysis and some video recordings.

At each of the other sites we interviewed key practitioners performing TAVI and their respective project or department leaders, altogether comprising another 32 interviews lasting on average 60 minutes. At three sites we also observed procedures and/or TAVI

[3] See Faulkner and Runde (2012) for an elaborate discussion on this.
[4] This criticism against AR has been raised, from a Critical Realism perspective, by Alistair Mutch (2013) and Paul Leonardi (2013). We are aware of the fact that Karen Barad mentioned that entities changes through stabilizing and de-stabilizing processes, but have not seen that she has spelled out how this happens, nor has this issue been addressed in IS literature drawing upon AR.
[5] TAVI was invented and tested on pigs in 1989 and on humans from 2002.

meetings. We have also interviewed representatives from the two main technology vendors, had field talks with representatives from another two vendors and attended practitioner conferences.

Data was coded manually and collaboratively by researchers to include the main on-going concerns expressed by practitioners and critical moments of the TAVI project's development. We went through multiple rounds of analysis, discussed interpretations between researchers to compare and appraise our interpretations and to validate our analytical categories. The results were continuously shared with the practitioners to get their feedback.

4. Findings

In this section we will describe the elements involved in the TAVI procedure and how they have evolved and interacted throughout its history. We will begin by describing the core elements involved when an artificial valve is to be inserted into a heart. We zoom out to the establishment and evolution of TAVI at the local level, i.e. at RH and finally we will look at TAVI at national and global levels and the interactions between the levels. As we are 'zooming out' (Nicolini, 2009) we will introduce and apply new aspects of AT for each level.

4.1 The "core" TAVI assemblage

TAVI is a procedure that uses advanced technology to treat aortic stenosis, a heart condition in which the heart's aorta narrows because of increased calcification. This condition reduces blood flow to the heart and over a period of a few years it significantly weakens the heart muscle. It is commonly treated by open-chest surgery. The patients that are offered TAVI are not eligible for open surgery, and have on average only 50% chance of surviving unless they are treated within two years. More recently, the procedure also began being offered to patients as an *alternative* to open-chest surgery.

During the TAVI procedure, the doctors make a small incision in one of the arteries at a specific location on the patient's body through which they insert thin wires and catheters. They navigate the catheters through the patient's circulation system guided by real time digital X-ray videos (fluoroscopy). When the catheter reaches the heart's aortic valve, the doctors position the new valve, release it, and then retract the catheter. If all goes well the patient is out of the hospital in a few days. At Rikshospitalet[6] (RH) in Oslo, TAVI is performed in a hybrid suite at the hospital's Research and Development department (IVC). This room has various advanced digital x-ray, ultrasound imaging technologies, other digital instruments linked to numerous monitors placed around the patient's bed. In addition there are computer for accessing patient records, X-ray images, and other patient data.

[6] Rikshospitalet was in 2009 merged with three other hospitals in Oslo into Oslo University Hospital.

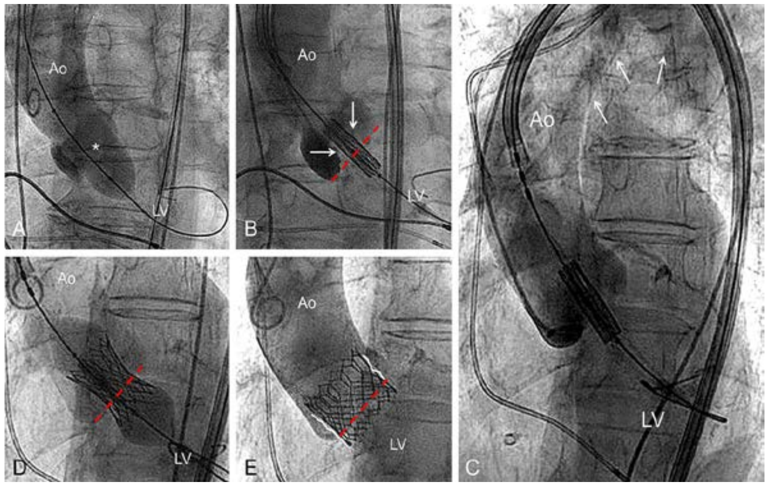

Image 1. The X-ray image of the heart's aorta broadcasted from a fluoroscopy robot.

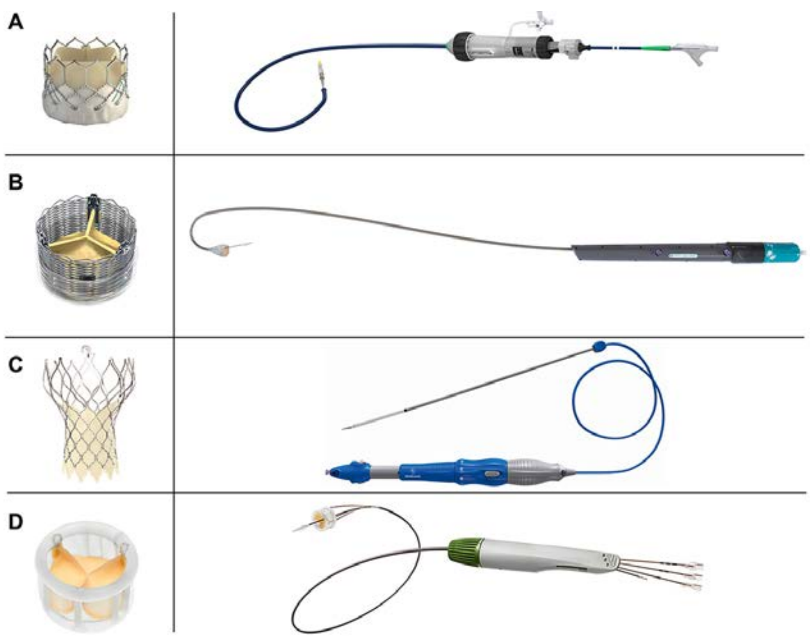

Image 2. Various TAVI valves and accompanying delivery systems (Wenaweser et al., 2016).

The unique TAVI equipment consists of the replacement valve, catheters and disposable delivery systems for these catheters (see images 1 and 2). Depending on the conditions of the patient the catheter is inserted through one of four possible access points. The transfemoral TAVI is performed from the groin (the least invasive) and is generally in the domain of interventional cardiologists (see image 3), whereas the three others (central) are performed via small chest incisions by the surgeons in collaboration with the interventional cardiologists. A TAVI team at typically consists of 2 surgeons, 2(3) interventional cardiologists, an anaesthesiologist, anaesthetic nurse, echo cardiographer, radiographers, nurses and crimping nurses.

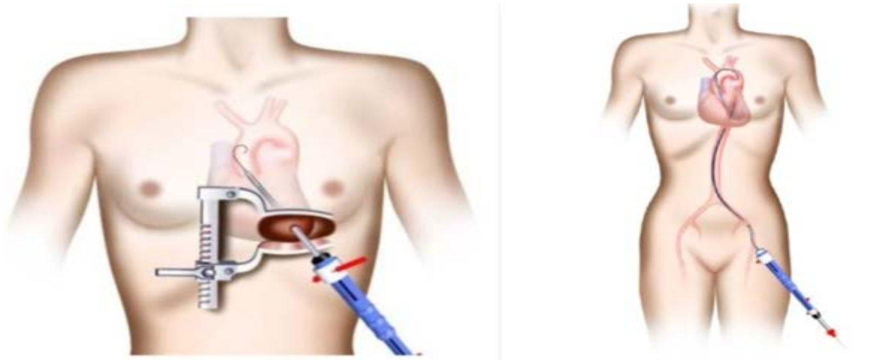

Image 3. The different TAVI procedure access points: the chest and the groin .

The producers offer valves in different sizes and capabilities, these again with different techniques of handling and operating when inside the patient's body. The choice of valve depends on the patient's physical condition.

Image 4. The hybrid room during a TAVI procedure. In front is the laparoscopy (live X-ray) robot. Image is the courtesy of IVC, 2014

When looking at TAVI through the lens of AT we see a number of layers of nested assemblages interacting during a procedure. We find component assemblages ranging from material ones like a valve, patient, or a screen to expressive ones such as a statement made by a doctor or an image on the monitor screen. There are also non-material assemblages like an individual's identity and skills or their decisions. Next to these, we find heterogeneous assemblages in the form of a specific task that is performed such as the positioning of a valve or the entire procedure for inserting a replacement valve. During a TAVI procedure the various assemblages are enacting their capacities to interact with each other. The productivity and the quality of the work of the TAVI team in the surgery theatre cannot, then, be reduced to the properties of the assemblage's components, but is an *emergent property* being a result of the various elements capacities to interact with each other.

Image 5. The TAVI team in action**.** Image is the courtesy of IVC, 2014

4.2 Stabilizing the TAVI assemblage at the surgery and hospital level

Around 2006, different groups of doctors at Rikshospitalet (RH) became knowledgeable about TAVI at scientific conferences and in scientific journals and they considered whether to start at their hospital. By 2007 these groups began discussing in more detail how to start TAVI activities. They contacted their respective regional health authority (HSØ) and began working on funding issues. Cardiologists and surgeons agreed that they should establish a TAVI team where both groups were involved and that TAVI should be performed at the hospital's Intervention Centre's (IVC) hybrid room.

The first two procedures were carried out on the 16th September 2009. At the technology producers' facilities (Edwards, in Rouen, France) they trained using simulators. Proctors and other support staff provided by Edwards assisted the first 20 TAVI procedures at RH. A proctor is a surgeon or an interventional cardiologist who has done at least 50 TAVI procedures. They travel around supervising TAVI practitioners and sharing experiences.

The RH team decided to begin with central access procedures (entering the patient's body through their chest) because these were more familiar to them being so similar to ordinary open-chest surgery.

Becoming ready to start doing TAVI at RH was primarily a process of defining and stabilizing the assemblage required. This happened through the combination of a number of stabilizing processes. Important among these were the process through which the different elements of the assemblage were "designed" or specified (formally or informally). Equally important were the negotiation and decision-making processes among doctors involved, among doctors and managers at the hospital, between the hospital and health authorities (HSØ), and between the hospital and the TAVI vendors. Another important stabilization process was learning – both individual learning through lectures, observation and rehearsing using simulators, as well as collective learning of how to coordinate various activities.

After the first 20 procedures were performed, the focus shifted to establishing TAVI as a regular practice. After a number of central-access procedures they began with transfemoral procedures. The TAVI team wanted to master all available access points and valves to learn under which condition each was most appropriate. Accordingly they eventually purchased the Medtronic valves 9 months after start-up that again included visits to training sites organized by the vendor and supervision of initial procedures by its proctors.

As the number of procedures was growing and the TAVI team's experience increased, more organizational structures were gradually established. Some just emerged; others were based on deliberate decisions. Patients were examined by cardiologists. The heart surgery department received the overall responsibility for TAVI patients. This includes keeping a list of patients being considered for TAVI, informing and coordinating with TAVI team members at IVC, doing the measurements of arteries upon which the decisions about access point and valve size should be made, responsibility for pre-and post-operative procedures including coordination with intensive care units, etc. Meetings in the TAVI team before and after each procedure became regular practice where they discussed how the procedure was conducted, if things could or should have been done differently and more general lessons to be learned. After the first start-up period TAVI procedures were carried out two days a month. The number of patients treated rose from about 10-15 patients in 2009, to about 50 in 2010.

All patients considered for heart surgery are discussed by cardiac surgeons and cardiologists at daily "heart meetings." At these meetings they also discuss potential TAVI patients, which are later discussed in a weekly TAVI meeting with 1-2 interventional cardiologists and 1-2 surgeons. During the summer of 2010 a contract specifying the roles and tasks of surgeons and cardiologists was set up and signed. This contract was re-negotiated in 2012.

During this process, the TAVI assemblage within the surgery theatre was increasingly stabilized at the same time as the larger TAVI assemblage at the hospital was "designed" and stabilized. Design, learning, negotiation, and decision making were also key stabilizing processes here. The specification and signing of the contract between the surgeons and the cardiologists illustrates one important stabilizing process emphasized by DeLanda (2006), namely that of coding.

4.3 Cycles of de- and re-stabilization

Having described the initial stabilization of TAVI at the surgery theatre and hospital level, we will now turn our attention to the following evolution at TAVI and how this happened through a combination and interaction of different stabilizing and de-stabilizing processes.

Since the early stabilization of the main structure of TAVI at RH, the procedure was undergoing a continuous change. For instance, whereas in the beginning a TAVI procedure on average lasted 3-4 hours, this was reduced to 2-3 hours. There has been a change in the choice of access points from central to transfemoral procedures, stabilizing in terms of a 50-50 split. There has also been a steady progression in terms of offering TAVI to patients with lower surgical risks.

The change happened as an outcome of a series of de-stabilizing processes and subsequent re-stabilization where just smaller sub-assemblages of the TAVI assemblage have been modified or replaced by new ones. One important de-stabilizing process has been the entrance into the TAVI market by new vendors offering new valves that RH adopted and used in the treatment of specific groups of patients.

While above we pointed out learning as a stabilizing process, in the evolution of TAVI various learning processes also played a key role as a de-stabilizing force. For example, increased practical experience made the practitioners more skilled in performing the various tasks like preparing the room, manoeuvring the catheter, positioning the valve, etc. The members of the team also became more skilled in coordinating the different activities and tasks in the operation room. Each time, these learning processes caused only very small changes of the TAVI procedure.

The TAVI team also improved their practices based on learning from colleagues doing TAVI at other hospitals in Norway and through international communication in informal networks and presentations at research conferences. They have also improved their work based on hints and suggestions provided by the technology vendors.

Finally, the TAVI team learned and modified their practice based on conclusions drawn from the analysis of data they collected about each patient, such as access point, valve type, degree of leakages between the valve and aorta, patient conditions at certain time intervals after surgery, etc. These data were stored together with other patient data in databases. This learning process has improved their competence and changed their practice regarding critical assessments such as criteria for choice of valve and access point. The change towards more transfemoral procedures and offering TAVI to more low-risk patients are outcomes of this learning. This data analysis also changed the procedure regarding which criteria are used in making decisions about whether a patient is eligible for TAVI or not.

Additionally, the TAVI procedure changed because of conclusions drawn from specific incidents destabilizing the procedure. Such incidents included episodes where the valve inadvertently slipped into the aorta, the collapse of a valve, the breaking of a catheter inside the patient, etc. There have also been occasions of cardiac arrests, which required immediate resuscitations. Incidents such as these lead to an immediate destabilization of the procedure followed by re-stabilization by for example figuring out how to deal with the situation when it happens. This is again followed by discussions and modifications of the procedure to prevent similar incidents and agreeing about how such incidents should be dealt with if they happen again.

Some of the processes mentioned here destabilized only a small part of the overall TAVI assemblage, such as for instance the improvement of individual skills. Other processes de-stabilized larger parts, like for instance the adoption of new valves. Initially, TAVI was offered only to patients diagnosed as inoperable due to extremely high risk for surgery. In this sense, TAVI was a complementary procedure that did not have any direct impact on existing open-chest surgery practices. However as TAVI evolved into a procedure that is also offered to lower risk patients, it de-stabilized the existing open-chest surgery assemblage. It meant that interventional cardiologists and the cardiology department were beginning to take over the treatment of aortic stenosis from surgeons and the surgery department. This was part of a larger movement as the development of other minimal invasive technologies and procedures has caused treatments of other diagnoses, for instance PCI, being transferred from surgery to cardiology.

4.4 Interacting processes and thresholds

Having described the evolution of the TAVI assemblage at RH as cycles of de- and re-stabilization processes, in this section we discuss other *forms of interactions* between different processes.

Over the years, with growing experience and positive outcomes, TAVI became increasingly considered as a regular treatment of aortic stenosis patients. Accordingly the number of patients treated has constantly been growing. In 2015 more than 150 patients were treated at RH and about 300 in total in Norway (Aaberge et al., 2015). During spring 2014 the cardiologists gave an impetus to the reorganization of TAVI activities. Their proposal was that the transfemoral procedures should be performed in their catheter lab in the cardiology department by a small team of 2 cardiologists and 2-3 nurses. This would be a significant improvement regarding costs and productivity. The demand for TAVI treatment reached a level where the hybrid room at IVC had become a bottleneck. Doing TAVI in the cath lab would, then, help increase the hospital's capacity.

After a number of meetings the head of the heart clinic decided to move transfemoral procedures to the cath labs, and the planning of this transfer started. Nurses working in the cardiology department were selected and the radiographer who was coordinating TAVI at IVC instructed the interventional cardiologists about the preparations that had to be done before the procedures.

The cardiology department started with transfemoral TAVI procedures in one of their cath labs in late 2014. Twelve procedures were performed in the first three weeks. A new contract was negotiated specifying that interventional cardiologists were responsible for patients undergoing transfemoral procedures and surgeons responsible for the central access procedures. However, it turned out that the cath lab was also a scarce resource due to the high number of patients waiting for traditional interventional cardiology procedures (like PCI) and an insufficient number of beds in the post-operative care unit. So after some time and discussions, all the procedures were transferred back to the hybrid room at IVC which was now reserved for TAVI two days every week (only one previously) – one day for cardiologists and transfemoral procedures and one for surgeons doing central access procedures.

The split of TAVI into two different assemblages or practices was the outcome of the combination of, or interaction between, a number of destabilizing processes: improved skills, improved technologies, growing demand for TAVI, etc. These processes interacted in different ways. First, they all contributed to the de-stabilization of the procedure, i.e. the de-stabilization appeared as an *accumulated* effect of many processes. Second, some of the processes triggered others, that is, constituted a *chain* or self-reinforcing cycle of de-stabilizing processes. An example of this is that the growing demand for TAVI was (partially) a consequence of the positive outcome of TAVI for patients, improved technology and learning. All of these were making the transfemoral procedure more applicable, next to the fact that transfemoral was a less costly procedure which implied that HSØ could afford paying for more patients.

Third, destabilizing processes were also unfolding in *parallel with the stabilization* of the overall procedure. In particular, the performance of more and more procedures and small improvements were making the procedures faster and smoother. These were leading towards the increased stability of the procedures in terms of making the different steps and elements of the procedure being increasingly taken for granted by all actors involved. So in this case, there was a kind of conflict or "*competition*" between stabilizing and de-stabilizing processes, and the disruption of the procedure and the split happened when the destabilizing processes got "the upper hand" in this "fight."

The disruption of the TAVI procedure was therefore the outcome of a series of stabilizing and de-stabilizing process unfolding over a long time. The disruption happened when the *accumulation of de-stabilizing events* reached the *threshold* (or "critical mass") making the split possible. In such situations, individual de-stabilizing events have no visible effect until the threshold has been reached and a very small additional event may finally trigger the change of a large assemblage.

4.5 Path-dependency and critical junctures

We will now look more carefully at *how assemblages evolve* and how concepts from AT like path-dependency and critical junctures help us in this effort at the same time as we look at how TAVI was performed at other hospitals.

In Scandinavian countries, we see many hospitals where TAVI has evolved and been organized in ways similar to RH. But there are also hospitals where TAVI is organized in a very different way and has been *evolving along very different paths*.

One example of this is Karolinska Hospital in Stockholm. Lacking a hybrid room, Karolinska immediately started their TAVI procedures in a cath lab within the cardiology department. For this reason they began their TAVI activities doing only transfemoral procedures.

Unfortunately the very first patient died after been given full anaesthesia but otherwise before the procedure started. Basis on this they concluded that full anaesthesia represented too high of a risk for very sick and old patients (which all TAVI patients were), and that they should try to perform the procedure with local anaesthesia or sedation only. This requires a simplification of the procedure so it could be performed without for instance a urine catheter, and within only 2-3 hours. These issues in combination brought Karolinska on a "minimalist" specialization path. This included specializing in using valves (and equipment) from one vendor only, using only local anaesthesia and percutaneous techniques.

At Skejby Hospital in Denmark they also started in the cath lab with a team of cardiologists. And here as well the very first patient died, in this case during the procedure. However, the TAVI team here drew an almost opposite conclusion from Karolinska. They concluded that TAVI required surgical expertise to be safe, and, accordingly, that surgeons as well as anaesthesiologists had to be included in the TAVI team. Close collaboration among team members was seen as crucial. They also concluded that TAVI should be performed in a hybrid room and not in a cath lab. At the time, they did not have a hybrid room, but a new hospital was being planned. Their cardiologists engaged in the planning process and pushed for the inclusion of a hybrid room in the new hospital. Moreover, they argued that the hybrid room should be located within the surgery department. This, they believed, would make it easier to achieve the surgeons' long-term commitment to TAVI. This strategy was realized and placed their TAVI procedures on a path very different from the one at Karolinska.

These two cases illustrate two important and related aspects of how assemblages evolve. First, there are certain moments that take the evolution of an assemblage in a certain direction – along a specific path. Such moments are called *critical junctures* (or bifurcation or tipping points). The tragic losses of the first patients at Karolinska and Skejby were clearly such critical junctures. In both cases the conclusions drawn from these incidents had a huge impact on how TAVI has evolved ever since at these hospitals. And when an assemblage starts evolving in a certain direction, like the minimalist that is specialization direction at Karolinska, the evolution along that path becomes progressively stabilized. The future evolution of an assemblage will be increasingly constrained by the path along which it has evolved. It becomes more and more *path-dependent.*

4.6 Multi-level interactions.

In the final section we focus on multi-level interaction. In particular, we show how de-stabilization of an assemblage at one level leads to de-stabilization of larger or higher level assemblages that in turn trigger new de-stabilizations at the lower levels. We look at important parts of the overall TAVI assemblage which are found at national and global levels, in particular at the emergence and evolution of regulatory structures on the national level and technological ones on the global level.

In Norway, the first TAVI procedures were performed in 2008 at Feiring, a small private hospital specializing in interventional cardiology and cardiovascular surgery. At first they performed 12 procedures. Two of their patients passed away shortly after the procedure and the case was brought to the media. An evaluation concluded that Feiring did nothing wrong, but they were nevertheless prompted by the health authorities to bring their activities to a halt. This triggered a larger national discussion about how TAVI activities should be organized and regulated in Norway. The “National Council for Quality and Prioritizations in Healthcare” tried to define TAVI as an experimental procedure. But this failed as it was not accepted by important actors in the sector who continued to pursue TAVI. There was a TAVI start-up in Tromsø University Hospital and a consensus was emerging among cardiologists and cardiac surgeons in Norway to define TAVI as an “emergent treatment” which would nevertheless be performed exclusively at university hospitals. Since then the regulation of TAVI in Norway has been changing continuously, one of the most important changes being in the criteria used for deciding which patients can be operated with TAVI. This change has happened as part of a continuous “structuration” process between the regulatory structures and actual TAVI practices.

There is substantial variation among national TAVI assemblages caused by differences in regulatory and funding frameworks. The way health care is funded in Germany, for example, contributed to an early rapid growth of TAVI there. In contrast, the first hospitals in US started performing TAVI only at the end of 2011 due to very strict regulations regarding approval of new medical technologies and procedures.

TAVI is to a large extent a global activity – it is a global assemblage comprising all national TAVI assemblages. There are international journals, conferences and informal networks where experience and research results related to TAVI are shared. Through these networks the international consensus about many aspects of TAVI at the global level is maintained.

Technology vendors are crucial elements of TAVI. Producers of valves and catheters as well as other supporting technologies operate on a global scale. They have research centres and production facilities distributed globally, and they have sales, training and support staff and facilities close to all their customers. The vendors also organize various events and conferences for all kinds of health care personnel at their customer hospitals and for their network of proctors.

TAVI technology is also continuously changing. The most established vendors, Edwards and Medtronic, are launching new and improved valves regularly as they are also improving their delivery systems and catheter devices. In addition, as patents expire, new vendors are entering the market. RH for instance, is now also using valves from another company called Symetis and has performed trials with 2-3 other producers. New valves offer better results and safer procedures for specific patients. New delivery systems are more convenient to operate and, importantly, the catheters are being made smaller and more usable. Improved delivery systems also reduce the risks of stroke.

In addition to the TAVI-specific technologies, also digital imaging and analysis tools have improved. For instance, improved CT imaging technology has led to CT replacing ultrasound technologies in some of the steps of the diagnostic process, in particular the analysis and measurements of the arteries used for deciding whether a transfemoral procedure is applicable and risks of stroke. More use of CT has also improved the accuracy of the measurements of the size of the aorta. Another example of improved technology is Siemens' development of new software to import 3D CT images into the X-ray robot, which contribute to faster and better positioning of the valve. As such, while evolving from an experimental procedure to a standard procedure for treating aortic stenosis, TAVI becomes increasingly technologically intensive and diverse.

The co-evolution of local TAVI assemblages and the (global) technology is an important example of interaction between assemblages at local and global levels. Based on the experiences and outcomes of implanting various types of valves at the hospitals, for instance, the vendors collect and accumulate data based on which they can identify aspects of their valves they need to improve. When a new and better valve is developed, they have to adapt (i.e. re-stabilize) their production facilities and sales and support assemblages to do this. And when a hospital decides to adopt the new valve, the TAVI assemblage at the hospital is de-stabilized.

5. Discussion

In this section we discuss our research contribution based on the AT analysis of TAVI. We see TAVI as a highly relevant case for discussing the suitability of ontological foundations for IS research. TAVI is clearly a case of high sociomaterial complexity in terms of a dense web of relations between large numbers of different kinds of elements. It exhibits the two aspects of the dynamics we pointed out: the interactions and interdependencies between multiple levels of the case and the "logic" behind how the case is evolving over time. Some, however, may find the case to be primarily about medical instruments and material technologies like the artificial aortic valves and the delivery catheters. These technologies are certainly central to TAVI, but so are the numerous information systems being used during the diagnostic processes and the surgery. Yet others are used to support collaboration between doctors within and across national borders. Many of these systems are also used for the exchange of information between hospitals as related to TAVI patient admission, or are used during the diagnostic processes and planning of the operations. In this way TAVI is a case providing rich illustrations of relations and interdependencies between physical/material and digital objects.

Even though our case narrative does not focus on details of the traditional information systems involved, we do believe that the narrative and our analysis make a contribution related to an important emerging IS research issue: the relations and interactions between technological architecture and governance structures and how these two in combination influence the evolution of the complex sociomaterial assemblages constituting current ICT solutions (Tiwana, 2015; Tiwana et al., 2010; Rodon and Silva, 2015; Grisot et al., 2014). Our application of AT illustrates how specific technological and organizational arrangements emerge at various levels (surgery theatre, hospital, national, global) and how structures at one level shape the evolution at lower levels which again lead to changes at higher levels in a cyclic pattern, i.e. how stabilizing or destabilizing processes at one level trigger stabilizing or destabilizing processes at other levels. This cyclic process is obviously similar to the ideas of structuration in Giddens' terms. However, an important difference is that Giddens only focuses on social structures ("traces on the mind") while AT helps us to theorize the role of technological/material and organizational structures that are involved in such processes. Importantly, it also enables us to theorize and describe in detail how the structuration processes actually take place based on the activation of components' capacities to interact and the mix of stabilizing and de-stabilizing processes this generates[7].

In our view AT has proved to be a powerful tool is disclosing and describing the sociomaterial complexity of TAVI. The concepts of capacities to interact (or affect and being affected) and how the enactment of these capacities generates a set of interacting stabilizing and destabilizing processes give a rich picture and capture central aspects of how a sociomaterial assemblage like TAVI evolves. We consider these aspects of AT, and the differences between AT and the other ontologies mentioned in section 2 they represent, that make AT a powerful instrument for understanding the structuration processes mentioned above and the development of strategies for making such processes evolve in desired directions.

6. Conclusion

In this paper we have argued that AT can be a useful and powerful process ontology for understanding, analysing and theorizing the development, evolution and use of new technologies. We have argued and tried to demonstrate in particular how AT can help us in our research into the overall sociomaterial complexities of current information systems. We see the key contribution that AT can deliver to IS researchers is its concepts for identifying and analysing how sociomaterial assemblages are unfolding through the interactions between various stabilizing and de-stabilizing processes and how these processes are generated through the enactment of the various assemblages' capacities to interact. We have in this paper demonstrated how processes are interacting in various ways such as:

[7] John Urry (2003) criticizes Giddens for overlooking the role of complexity and demonstrates how Complexity Theory strengthens Structuration Theory.

- as sequences or cycles of processes where one stabilizing process triggers a de-stabilizing process which again triggers a stabilizing process, and so on;
- parallel processes, either stabilizing or de-stabilizing, strengthening each other; and
- parallel stabilizing and de-stabilizing processes "competing" with each other.

In addition we have demonstrated how some de-stabilizing processes take place through the accumulation of events (for instance enhanced skills through practice) where the change of the assemblage happens only when a certain threshold is reached. There were on the other hand de-stabilizing processes which were more like instant events such as operations going bad or some technological system breaks down. Sometimes when an assemblage is de-stabilized, it may be re-assembled in a way bringing its evolution on a different path and some de-stabilizing processes can then be seen as being path-creating (Garud et al., 2009).

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