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## THE SOCIOMATERIALITY DEBATE REVISITED. THE CONTRIBUTION OF ASSEMBLAGE THEORY

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### The Sociomateriality Debate Revisited. The Contribution of Assemblage Theory

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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 center of IS research. Actor-Network Theory (ANT) has since the middle of the '90s been a popular approach while more recently Critical Realism and, in particular, Agential Realism have received a lot of attention (see e.g. Mingers et al. 2013; Cecez-Kecmanovic et al. 2014). Yet we consider that these theoretical approaches leave what we here call the 'dynamics of socio-material complexities' underexplored. To fill this gap, we will in this paper present and draw upon Gilles Deleuze's process ontology (Deleuze and Guattari 2010) labeled Assemblage Theory<sup>1</sup> (AT), as interpreted and presented by Manuel DeLanda (2002, 2003, 2006, 2010, 2016).

One may argue that certain aspects of the relationships between the technological and the social are shared by all sociomaterial assemblages. However, following Schultze (2017), certain aspects of this relationship has also changed as the variety and characteristics of IT solutions and the social structures they are embedded into have evolved. When the IS research field as well as the IS business domain were established, the focus was on individual information systems and their implementation and use within individual organizations. Over the years, driven by the emergence of new basic technologies like smartphones, (wireless) communication technologies, Internet of Things, cloud technologies, machine learning, etc., the number and variety of IT solutions have been growing dramatically and so have the number and variety of use domains. An important aspect of this change is the growing complexity of the technological as well as the social entities IS research needs to focus on.

These changes have in particular been represented by the emergence and evolution of platform ecosystems and information infrastructures. The emergence and growth of platform ecosystems represents a change from "classic" IS in the sense that it aims primarily to support users' activities, not as employees in organizations, but rather as consumers, patients, or citizens. This change is represented by dating, social media, mobile payment, on-line shopping, marketplaces, hotel and restaurant booking, platforms, etc. Further, platform ecosystems represent a change in terms of their number of users, which in many cases counts millions and sometimes even billions, and in the number of independent developers and development organizations, which also may count several thousands, developing the overall ecosystem in various collaborative arrangements. Finally, while a platform ecosystem, including the platform, the apps, the users, the platform development organization and the app developers, is very complex in themselves, they are actually integrated into and parts of more complex entities. Another example is hotel booking platforms which are integrated with the hotels' booking systems as well as global payment infrastructures; social media platforms are integrated with advertising infrastructures (see below) extended with payment services which are integrated into national and global banking or payment infrastructures, used as a publishing channel, i.e. integrated with newspapers' publishing systems, etc. We see, then, not only the emergence and evolution of platform ecosystems, but also ecosystems of platform ecosystems.

Information infrastructures represent another category of complex sociomaterial assemblages. This concept has been used to research the growing complexity of IS within organizations. This complexity has been growing as the number of information systems in use within organizations has been growing at the same time as they have become increasingly integrated with each other and also integrated with information systems in other organizations. For

<sup>&</sup>lt;sup>1</sup> Assemblage Theory has so far received almost no attention from the IS research community (exceptions are Henningsson and Hanseth 2011; Yeow and Faraj 2014; Rodon and Silva 2015; Sesay et al. 2016).

instance, a regional hospital organization in Norway identified in 2018 more than 5700 different information systems in use (Sigurdsen 2018). When a new Electronic Patient Record system was implemented at one of the hospitals, the absolute minimum number of other solutions it had to be integrated with was decided to be 60. When the new system was up and running, users requested integration with 60 more. Finally, concurrently as the hospitals are sharing information (electronically) with the other hospitals within the regional organization, they are also sharing information with hospitals in other regions, with primary care, and with various national solutions and at the same time projects are ongoing to develop solutions for information sharing with health care institutions within the EU.

Other typical examples of information infrastructures are solutions for sharing information within a business sector like the SWIFT interbanking infrastructure which all banks' core banking solutions are connected to (Scott and Zachariadis, 2012). Another example is the global infrastructure supporting so-called programmatic advertising, i.e. on-line personalized (and algorithmic) advertising (Zuboff, 2015; Alaimo and Kallinikos 2018). This is a global information infrastructure which all on-line publications selling space for advertisements as well advertisers advertising on-line are connected to.

These examples illustrate in our view that complex entities like platform ecosystems and information infrastructures are important "objects of study" for IS research. We need, then, an appropriate ontology supporting such research. In our view there are three important requirements to such an ontology. First of all, understanding the relations between the social and the technological is definitively a crucial issue when researching such entities. Second, platform ecosystems and information infrastructure evolve and grow over long time. What they are at a certain point in time is the result of a long historical process. This implies that when researching such entities, we need an ontology supporting the analysis of how they evolve and grow and become what they are, or where they are moving at a specific point in time. Finally, platform ecosystems and infrastructures like those mentioned above are composed on a huge number of technological and organizational components. These components are composed of a number of smaller components at the same time as they are components of larger assemblages. Accordingly, we need an ontology supporting an analysis of smaller as well as larger components and the relations between a component and the larger whole it is a part of.

We consider the ontologies (or approaches) mentioned above (ANT, AR, and CR) as having limitations regarding our three requirements, while Assemblage Theory has significant strengths in this regard. We will explore this through a case study of the development and evolution of a complex high-tech 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 is based on the practices of multiple disciplines, foremost cardiovascular surgery, cardiology and radiology. The procedure also involves anesthesiologists in addition to a number of nursing specialists and occasionally radiographers. It also involves collaboration between hospital departments, between hospitals, between hospitals and primary care, as well as collaboration between hospitals and vendors of specific TAVI instruments and devices. TAVI also includes a plethora of digital imaging instruments that are used during diagnostic processes and surgery, numerous interconnected information systems for storing, communicating, and analyzing patient information as well as sophisticated image analysis and presentation tools.

Despite sharing many characteristics of information and traditional infrastructures, TAVI is neither a platform ecosystem nor exactly a typical information infrastructure. Yet, it is definitively a complex sociomaterial assemblage and therefore well suited for our purpose with this paper.

### 2. The sociomateriality debate

The study of the relationship between the information systems and their social and organizational context has always been at the center of IS research (Sarker et al. 2019). Since the mid-1990s, Actor-Network Theory (ANT) has been a popular approach, while more recently the focus has been directed towards the concept of sociomateriality and its relations to Karen Barad's (2007) Agential Realism (Cecez-Kecmanovic et al. 2014). This approach has been adopted by a broad range of scholars, but it has also received substantial criticism, in particular from scholars having adopted a Critical Realism perspective (Mutch 2013, Leonardi 2013, Faulkner and Runde 2012), triggering an ongoing debate between these two positions (Scott and Orlikowski 2013, Leonardi et al 2012, Kautz and Jensen 2013, Schultze 2017, Hultin 2019, Faulkner and Runde 2019).

Agential Realism is first of all based on the assumption that entities (people, organizations, technological artifacts) do not have any given determinate boundaries and properties – "they are seen as relational effects, continuously performed in a web of relations" (Cecez-Kecmanovic et al. 2014, p. 811). In Orlikowski's (2007, p 1437) words, "the social and the material are considered to be inextricably related – there is no social that is not also material and there is no material that is not also social," and "people and things only exist in relation to each other (Orlikowski and Scott 2008, p 455). Further, "the social and material are inherently inseparable" – one cannot exist without the other (Barad 2007, p ...; Orlikowski and Scott 2008, p. 456). This relational ontology is by most scholars adopting this sociomateriality approach said to also be based on a process ontology: everything is always in a state of becoming (Barad 2003, 2007; Scott and Orlikowski 2014).

The Agential Realism approach to sociomateriality shares some important assumptions with dominant approaches within practice-based studies (Feldman and Orlikowski 2011). This includes the focus on the performativity of practices and the claim that practices are never stable but "always in a state of becoming" (Chia and Tsoukas 2002). Also, within this research field it is argued that there is a need for putting more effort into the development of process theories of organizations, and doing research based on process ontologies. One stream of "process research" focus on organizational action drawing upon Whitehead's (19..) and Heidegger's philosophy om time and how actors act in the present based of their projections of the future which again are shaped by their past (Hernes 2007, 2014; Introna 2013; Helin et al. 2014). However, within organization studies, there is also a stream of research into "organizational becoming" drawing upon a range of approaches as "sensitizing devised," including Actor-Network Theory, Complexity Theory and Activity Theory (Langley and Tsoukas 2011; Langley et al. 2013). While the first approach focuses on the role of time in individuals' experience of the world, the latter focus on how organizational structures and practices evolves *over* time.

A number of critical remarks have been raised against the Agential Realism based approach to sociomateriality, in particular from a Critical Realist perspective (Mutch 2013; Leonardi 2013; Faulkner and Runde 2012). Two critical issues mentioned are of more practical character: it lacks explanatory power; and it is difficult to operationalize. The latter issue is also subscribed to by those actively drawing upon Agential Realism (Wagner and Newell, ). Two other

remarks are related to its ontological claims and assumptions: it lacks a concept of time; accordingly, it does not support the description or analysis of how change processes are unfolding, and it treats all relations as intrinsic which is not correct. We will here focus on the latter two. The very last point is in particular argued by Faulkner and Runde (2912), using relations between a postman and a dog as an example. A dog and a postman might be tightly entangled at a certain point in time (when the dog is biting the postman), but it is not the case that a dog cannot exist without a postman or that a postman cannot exist without a dog. The relationships between a dog and a postman are, according to Faulkner and Runde (ibid.), not intrinsic, as sociomateriality claims that all relations are, but extrinsic. The relations between husband and wife and employer and employee, however, are intrinsic. Some relations are asymmetric. For instance, rivers may exist without river fishing, while river fishing cannot exist without rivers.

The lack of a concept of time is in particular argued by Mutch (2013) and subscribed to by Leonardi (2013). "Organizations and people's practices exist in time. They unfold and change along a temporal plan. Without a consideration of time, no analyst could explain why practices arise, endure, or change" (ibid. p 67). We see the lack of a concept of time as closely related to the strong claims made about inseparability. Actually, if the elements of a sociomaterial assemblage are inseparable, it is hard to see how it can change. At least, it can only change as a whole because if the elements are inseparable, the assemblage cannot change by removing one element and replace it by another. Accordingly, if the elements of all assemblages are inseparable, there is no change and a concept of time would be redundant. This is a bit paradoxical as most scholars drawing upon Agential Realism are also subscribing to a process metaphysics and claiming that sociomaterial assemblages are always in the state of becoming (Cecez-Kecmanovic 2016). However, these scholars refer to the process metaphysics derived from Whitehead, focusing on the role of the future and the past in an individual's experience of the world, and not one focusing on how the world (organizations, practices) changes over time.<sup>2</sup>

This criticism of the lack of a concept of time and the problematic issues related to the assumption about inseparability is reflected in empirical IS research drawing upon Agential Realism. It is very hard to find any empirical IS research describing or analyzing unfolding change processes. What we find is just the static description of sociomaterial assemblages emphasizing the entanglements of the various elements at specific points in time. A typical example may be Jones (2014) presentation of the introduction of a computer system in a hospital department in UK. He describes the hospital department as a range of entangled organizational and material elements before and after the implementation of the information system. He gives two snapshots of the department at different points in time, but, actually, nothing is said about the process bringing the department from the "initial" to the "final" state. Change is usually only described as an individual making different agential cuts (Schultze 2016).

<sup>&</sup>lt;sup>2</sup> Hultin (2019) says that Mutch's (2013) and Leonardi 's (2013) criticism of Agential Realism for lack of a concept of time is based on a misunderstanding. I rather think she has misunderstood their criticism. She demonstrates how she used Whitehead's process ontology, or concept of time, to reflect upon the previous location (the past) of the organizational unit she was observing help her understand its present. But she did not analyse the process through which the unit was transformed from its previous location to its present. Leonardi and Mutch is criticizing Agential Realism for its lack of a concept of time supporting such transformation processes.

Mazmanian et al.'s (2014) research on the "dynamic reconfiguration in planetary exploration" may look as an exception to this. They are drawing extensively upon the Agential Realism approach and vocabulary when describing the evolution of sociomaterial assemblages triggered, for instance, by the need to replace one software system with a new version and when a software engineer is transferred from one department to another and others need to take the responsibility for the maintenance of software he has developed. But here again, we cannot find that the authors are using any concepts from Agential Realism when describing how change actually happens, only when describing snapshots of sociomaterial assemblages at certain points in time during the change processes.

Agential Realism share important similarities with Actor Network Theory. The latter also has relations as its main focus. However, it does not make any claims about inseparability. Rather the opposite: the focus is on translation processes where actor-networks, which could very well be called sociomaterial assemblages, evolves through processes where new elements are translated and included, or enrolled, into an existing network or how an existing network is changed (i.e. translated) when some of its elements are modified or replaced by others.

Critical Realism departs from Agential Realism in recognizing the potential existence of a reality beyond our knowledge about or conscious experience of it (Bhaskar 1979). In contrast to Agential Realism's assumptions about inseparability, Critical Realism "would argue that the social and the material are indeed separate entities that are put into relationship with one another and come to appear inseparable through human activity over time" (Leonardi 2013, p 69). Further, sociomaterial assemblages evolve in a process where distinct social and material elements are brought together and gradually creating a durable infrastructure – a process Leonardi (ibid.) describes using the metaphor imbrication.

Scholars drawing upon Agential Realism limits themselves to Barad's formulation of this approach. Critical Realism, however, is more of a "living organism" where new contributions are added of which Leonardi's concept of imbrication can be seen as one example. More fundamental, though, is Margret Archer's (1995, 2000) morphogenesis approach (i.e. how form or structure emerges). Based on Bhaskar's original formulation of Critical Realism, she develops an alternative formulation of structuration to that of Giddens (which she finds problematic). In Critical Realism, the concept of mechanism is central to the relationship between structure and action. Mechanisms are real and existing and shape action. They are triggered by specific social structures or contextual factors (Bygstad 2010; Bygstad and Munkvold 2011; Henfridsson and Bygstad 2013). Consistent with Archer's approach, Elder-Vass (2010) has elaborated further on the role and evolution of social structures by focusing on emergence and causality. Further, some Critical Realists have also incorporated Gibson's (1966, 1979) concept of affordances into their approach to describing and analyzing the relations between entities of various kinds (Bygstad et al. 2016).

We will now comment on how the ontologies presented relate to the requirements we put forwards in the introduction. ANT had proved to be a quite powerful approach to describe how social and technological or material elements are entangled into actor-networks as well as how such entangled networks are evolving and have come to be what they are at certain moments. In describing the evolution of such networks, the agency of individual actors, which are actor-networks in themselves, is emphasized – opposed to perspectives where technologies develop or diffuses apparently by themselves (Latour 1987). ANT also has some, although limited, conceptual tools for analyzing relations between parts. An actor-network may be black-boxed to become an actant in a larger network, and an actant in a network,

previously black-boxed, may be opened up again. But ANT does not talk about levels, neither has multi-level analysis been a focused issue in ANT based research.

While both ANT and Agential Realism is based on a relational ontology, Agential Realism appears to be much more "fundamentalist" in this regard, because of the strong claims made about inseparability which all IS researchers drawing upon this approach seem to subscribe to. However, while Agential Realism introduced some new concepts like agential cuts, intraaction, and apparatus, its conceptual vocabulary is more limited than that of ANT. Accordingly, we consider it as less powerful in terms of analytical power and in terms of how easy it is to operationalize. These limitations are particularly striking regarding relations between smaller components and larger wholes, as well as how sociomaterial assemblages evolve over time.

Critical Realism has, at least in Bhaskar's (1979) original version, a rather limited vocabulary for analyzing the relationships between the social and the technological. This weakness, however, have been reduced by adding Gibson's (1968; 1979) concept of affordance to the toolbox. The term "entity" has always been extensively used in Critical Realism based research without defining the term as a theoretical concept. The term is at the centre of Elder-Vass' (2010) analysis of emergence and the causality of social structure. He defines the concept in way that could just as well be called a sociomaterial assemblage. However, he does not say much about his assumptions regarding relations between the technological and the social. On the other hand, Elder-Vass' (ibid.) analysis represents a very rich and powerful approach for analyzing relations between a component and the larger whole it is a part of.

Critical Realism's concept of mechanism offers us a tool for analyzing how complex sociomaterial assemblages evolves.

### 3. Assemblage theory

Manuel DeLanda presents  $AT^3$  as both a (non-essentialist, realist) process ontology and a theory of social complexity. Drawing extensively upon the work of Gilles Deleuze, DeLanda (2000, 2002, 2006, 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 anticipate 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

<sup>&</sup>lt;sup>3</sup> Key AT concepts together with examples from our case are listed in Table 1 towards the end of the case section.

of the [component parts] between which they are established" (DeLanda 2006, p ??). Assemblages emerge from the interactions between their parts; so, the properties and capacities of an assemblage are derived from both the aggregation of the properties of its components and the interactions between those components. These capacities depend on the component's properties but cannot be reduced to them since they involve reference to other interacting entities. How an assemblage's properties and capacities are emerging from interactions between its components DeLanda also calls *upward causality* which also has a top-down aspect: "once an assemblage is in place, it immediately starts acting as a source of limitations and opportunities for its components" (DeLanda 2016, p. 21), what DeLanda calls *downward causality*. DeLanda (2006) advocates complementing this *hierarchical/vertical* view with a *horizontal* one to better account for the complexity of social reality in which entities at different scales such as people, institutional organizations, networks, cities, nations, and so on interact and overlap with one another in various ways. In other words, assemblages can interpenetrate each other; there are relationships which cut across different assemblages.

The concept of assemblage is also related to the "classic" distinctions between an object's form, function and matter (DeLanda 2000; Kallinikos 2012). In short, an object's form and matter are represented by its properties, while its function is represented by its capacities. For instance, a knife has the function to cut meat and wood (but not metal) due to its hardness (determined by its material properties) and its form determining its sharpness. DeLanda also discusses how an object's form emerges from the interactions between its parts at the same time as its form creates opportunities and constrains the evolution of the object's form: "... the spherical form of a soap bubble emerges out of the interactions among its constituent moleculs" at the same time as the spherical form of the bubble enables and constrain its evolution until it bursts (DeLanda 2000, p. 34).

DeLanda defines assemblages 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* ones 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* in which an assemblage becomes involved and that either lead to its *stabilization* or *destabilization*. Stabilization is the process that gives shape and identity to an assemblage. DeLanda describes four kinds of stabilization process: Territorialization, homogenization, coding, and interlocking. Territorialization means that the boundaries between an assemblage and its outside context is becoming more sharp. Homogenization occurs through processes that increase the degree of internal homogeneity among its components, making them more similar. Coding occur through, for instance, formalizing contracts and agreements, writing and approving requirement specifications, passing laws and regulations, etc.; while interlocking takes place when components of an

assemblage are becoming more tightly related and interdependent. Each of these processes there is an opposite de-stabilization process. 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 2005). For instance, a member of a political party can stabilize the party by voting in favor 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 AT 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 trajectories. 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 destabilization 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 Assemblage Theory, we will now briefly compare and contrast Assemblage Theory to the other ontologies popular in IS research. Assemblage Theory has quite a lot in common with Actor Network Theory, but the explicit distinctions between an assemblage's properties and capacities makes, in our view at least, Assemblage Theory a more powerful tool for detailed analysis of how social and technological entities relate. Further, the focus on emergence and downward causality 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 close to how the stabilization processes were 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 analyze the "fluid" character of sociomaterial complexities.

Agential Realism (AR) is demonstrated to be a powerful approach in describing the "entanglements" of social and technological aspects of information systems. However, the concept of capacities to interact makes AT a more powerful tool helping us to describe and analyze in more detail how various entities actually are related or entangled. AR's claim strong claim about inseparability makes Agential Realism, obviously, an "organic theory" of the kind DeLanda rejects. Agential Realism scholars criticize what they call substantialist ontologies and reject altogether that entities or phenomena have properties describing their substance. They critizise one extreme position in order to defend the opposite extreme. The only thing that exist are relations. While Assemblage Theory, as well as Actor-Network Theory, focus primarily on relations, Assemblage Theory also accept that entities have properties. In this way Agential Realism is a rather "fundamentalist" relational ontology compared to the other two.

AT and AR are also dramatically different in their view on the relations between components of larger totalities. Agential Realism provides us with no concepts supporting the analysis of such relations. The same is the case when it comes to the description and analysis of how sociomaterial assemblages evolve 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 – a limitation some scholars (Bygstad et al. 2016) have tried to overcome by adopting Gibson's concept of affordances. Emergence is also central to CR, but its terminology for describing how emergence happens is limited. The concept of entity is extensively used within CR. It can be seen as similar to an assemblage in AT, but it is not defined as a theoretical concept; it is only used in the common sense as an ordinary language term. However, Elder-Vass (2010), drawing upon CR, has extensively discussed emergence and upward and downward causality in relation to entities in a way that is very close DeLanda's. Change within CR is primarily explained as being driven by mechanisms triggered by contextual factors. Yet it lacks concepts enabling a rich analysis of the evolution of assemblages compared to AT.

To summarize: Assemblage Theory shares Critical Realism's realist ontological assumptions that reality may exists and have certain properties independent of humans and social contexts. But it focuses, like Agential Realism and Actor-Network Theory, primarily on relations. While Critical Realism focus on stability (of structures), and Agential Realism sees reality, or phenomena, as always in a state of becoming, without saying anything about how it is becoming, Assemblage Theory sees reality, i.e. assemblages, as involved in a mix of stabilizing and destabilizing processes. All positions mentioned here can be seen as a mix of ontologies and theories. They all make some ontological claims about reality at the same time as they provide us with theoretical constructs and concepts helping us describing and analysing reality. We see Assemblage Theory as different from the others in the sense that it provides us with a more rich and powerful conceptual "toolbox" in terms of the precise definition of the richer concept of assemblage (compared to the simpler and more loosely defined concepts of entity in Critical Realism and actant and actor-network in Actor Network Theory), and the extensive vocabulary to describe how stabilizing and de-stabilizing processes are unfolding and interacting.

### 4. Methodology

The point of departure for this research project was a grant by the Norway Research Council to study the process of innovating, adopting, organizing and developing a radical new technology across different hospitals in Scandinavia. We started our study at the Intervention Centre (IVC) at Oslo University Hospital (Norway) in 2011. Our initial study gave us rich insights into the complex processes of development and adoption that seemed to explain the way TAVI came to be organized and performed at this site (reference omitted). It also appeared that the activities at the centre often were closely connected to activities taking place elsewhere, both in time and space. We therefore started to 'zoom out' (Nicolini 2009; 2012) to trace the connections to the trans-situated practices and make sense of the wider picture. We visited 9 other Scandinavian hospitals, interviewed over 35 key actors (the interviews lasted on average 60 minutes), analyzed documents and observed procedures and some meetings. We also interviewed representatives from the two main TAVI valve equipment companies and attended several national and international TAVI practitioner conferences and events. These latter conferences and events were important as they enabled us to observe and talk to representatives from different hospitals in Scandinavia and different medical

equipment companies, and to develop a better understanding of similarities and differences across sites. A summary of our data is provided in Table 1.

	IVC	Other hospitals	Medical equipment companies
Interviews and	30 formal	Norway: 5 interviews with	4 interviews with key account
field	interviews,	TAVI team in one hospital	managers from 3 medical
conversations	regular field	Sweden: 20 interviews with	equipment companies
	conversations	TAVI teams in five hospitals.	Regular field talks with
	with TAVI team	More to be conducted	company representatives during
		Denmark: 13 interviews with	their visits to IVC and other
		TAVI teams in three hospitals	hospitals. Includes a full day in-
			depth discussion with one of the
			representatives
Observations	Over 120	Norway: Observations at Spring	Attended TAVI Days in 2014
	procedures, in	meeting for Norwegian thoracic	and 2015. (TAVI Days last for
	addition to daily	surgeons (representatives from	two full days and at this event
	fieldwork at the	all hospitals in Norway present).	we also had talks with
	centre and	A seminar organised by a	representatives from all of the
	attendance at	technology provider where all	medical equipment companies
	meetings and	hospitals in Norway doing	delivering products in Sweden).
	seminars	TAVI met together to share	Attended seminars organised by
		experiences. (Apart from Oslo	medical equipment companies in
		the other hospitals only had	two of the hospitals where they
		nurses present)	presented new developments of
		Sweden: Observations of TAVI	their products and clinical
		procedures in one hospital.	results.
		Observations during the TAVI	
		Days 2014 and 2015, which is	
		an annual event where doctors	
		and nurses from all TAVI teams	
		from hospitals in Sweden meet	
		to share their experiences	
		(approx. 80 participants).	
		Denmark: observations of TAVI	
		procedures in two hospitals and	
		observations of TAVI team	
		meetings prior to procedure in	
		one hospital.	
Document	Protocols for the	Protocols, publications,	Clinical data and publications,
analysis	project,	presentations	presentations, product
-	presentations,		brochures, online information
	publications		sources and news clippings on
			companies and their products
Video analysis	Recordings of		- *
, ·	TAVI		
	procedures at		
	the IVC.		
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Table 1:	Summary	of data
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The overall topic of the project was how new technologies trigger changes in existing practices, and also leading to new practices at the intersections of existing ones. The research strategy was exploratory and the primary theoretical framing was Practice Theory. Because

the emergence and evolution of new technologies was so central to TAVI, we followed the debate about sociomateriality. Our analysis proceeded utilizing the established conventions and practicalities of robust interpretive social science (Yanow and Schwartz-Shea 2006). The research team mutually constructed a primary thematic structure. The themes reflected the ongoing concerns of practitioners such as contract negotiations, team relations, technology developments, local, national and international networks of communication, etc.

Once a specific issue started to emerge as a topic of interest, we went back to our data and mined the field notes, interviews and document for relevant clues and meaningful events leading to a range of publications on topics like the changing nature of expertise, the "transsituated" nature of expertise, contradictions as opportunities for innovation, emergent coordination and situated learning, etc. For each topic we were moving continuously between data and literature going through multiple cycles of analysis, and we returned to the field and asked some of the practitioners for further information and feedback on our observations. For each article, the analysis continued well into the writing stage.

The issue addressed in this paper emerged rather late in the project. As we produced papers on a variety, although overlapping and related issues, we became increasingly interesting in developing a more holistic understanding of the TAVI phenomenon. Being familiar with Assemblage Theory, over time we came to see this theory as a powerful approach to capturing the "whole of TAVI." We then, based on the findings presented in the papers already written, started to systematically analyze and describe TAVI and its evolution from this perspective. In doing so, like for other issues we wrote papers about, we went fact to our informants to collect more data to fill in holes in our material in parallel with examining the relevant literature more carefully.

### 5. 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' [20] we will introduce and apply new aspects of AT for each level.

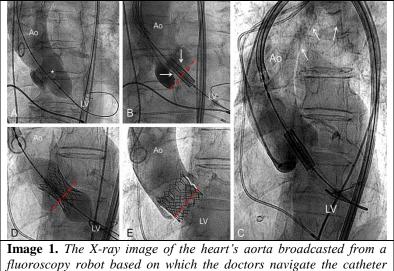
### 5.1 The "core" TAVI assemblage. Properties and capacities

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. TAVI was in the beginning offered only to patients that were not eligible for open surgery and had on average only 50 % chance of surviving unless they are treated within two years. As the TAVI procedure and technologies improved and positive results were achieved, 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<sup>4</sup> (RH) in Oslo, TAVI is performed in a so-called hybrid suite at the hospital's Research and Development department (IVC). This room has various advanced digital x-ray and ultrasound imaging technologies, and other digital instruments linked to numerous monitors placed around the patient's bed and elsewhere in the room. In addition, there are computers for accessing patient records, images from various kinds of imaging instiruments, and other patient data.

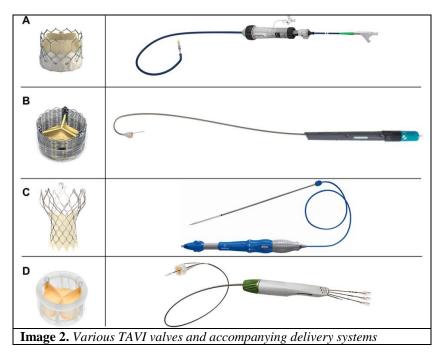
The unique TAVI equipment consists of the replacement valve, catheters and disposable delivery systems for these catheters (see images 1 and 2). Depending on the conditions of the patient, the catheter is inserted through one of four possible access points. The transfemoral TAVI procedure is performed 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. In the beginning a TAVI team typically consists of 2 surgeons, 2(3) interventional cardiologists, an anesthesiologist, anesthetic nurse, echo cardiographer, radiographers, nurses and crimping nurses. As the teams became more experienced and the technology (valves and the other equipment) became more developed, the number of individuals involved in each procedure was reduced.



and position the valve in the aorta

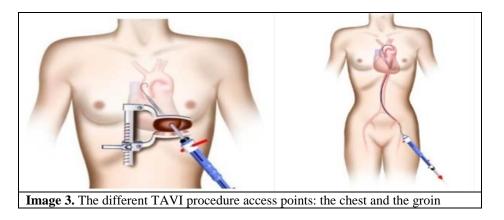
The producers offer valves in different sizes and capabilities, these again with different techniques of handling and operating when inside the patient's body. The choice of valve depends on the patient's physical condition and the diameter of her aorta.

<sup>&</sup>lt;sup>4</sup> Rikshospitalet was in 2009 merged with three other hospitals in Oslo into Oslo University Hospital.



(Wenaweser et al. 2016)

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, the catheter, the patient, the bed, and screen to expressive ones such as a statement made by a doctor or an image on the monitor's screen. There are also nonmaterial 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. Each assemblage has a number of properties. A valve has a certain diameter, a monitor has a certain size, each person involved has certain competencies, etc. And each assemblage has certain capacities to interact with other assemblages. A valve has capacities to interact with a catheter, the aorta where it is position and the heart so that it opens and closes correctly as the heart is beating. The properties of an assemblage are partly a combination of the aggregation of its components' properties, and partly emerging from the interactions between the components. The productivity and the quality of the work of the TAVI team in the surgery theatre, for instance, are emergent properties being a result of the various elements' capacities to interact with each other.



### 5.2 The IT assemblage

In this paper our focus is on the TAVI assemblage as a whole and not specifically on the IT solutions involved. But TAVI is indeed heavily infused by and dependent upon a number of complex solutions. Each of these solutions is interacting with a number of others as well as more or less all non-IT components of the overall TAVI assemblage. We will here briefly summarize the main IT solutions involved and their role. As illustrated by Images 4 and 5, the performance of the TAVI procedure within the surgery theatre is based on a number of IT solutions that the users interact with by means of a huge number of screens and input devices. Most important among these is the digital x-ray video system, including its sophisticated 3D software, which is used for guiding the catheter and positioning of the valve. In addition, the procedure also uses digital ultrasound to control for leakages between the valve and the aorta and a number of more conventional intensive care instruments monitoring the patients' condition. In addition, there are also computers in the surgery theater giving those involved access to various relevant information about the patients like Electronic Patient Record systems and systems for storing and analyzing various kinds of medical images.

IT solutions are also heavily involved and playing crucial roles during the diagnostic and preoperative processes. First of all, TAVI hospitals receive (digital) information about patients potentially eligible for TAVI from the patients' GPs and admitting hospitals. Then they use a number of digital technologies like CT and digital x-ray and ultrasound in combination with image analysis software. The image analysis software is used for identifying, for instance, calcifications in the patients' vascular system and measuring the size of the patients' arteries and aorta. This information is combined with other data about the patients' health conditions to decide if the patient is eligible for TAVI, and, if that is the case, decide which valve and procedure to choose. Some vendors also require that until a hospital has performed a significant number of TAVI procedures, all relevant data (EPR data, CT images with measurements, etc.) about a patient are sent to one of the vendor's competence centres and that decisions are made in collaboration with the vendor's experts. Many hospitals are also sharing information with each other for collaborative learning purposes and giving each other advice about individual patients.

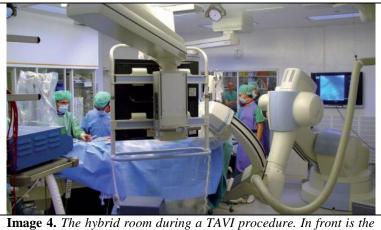
After a TAVI procedure reports are produced and stored in EPR systems, and more detailed data are entered into an information system especially developed to support the follow up of patients and to support the evaluation of TAVI in order to improve practice as well as research on TAVI.

The individual systems mentioned here are interacting with each other in various ways constituting an information infrastructure (Monteiro and Hanseth 1996, Hanseth and Lyytinen 2010; Monteiro et al. 2013) with capacities to interact with the other components of the TAVI in a way making TAVI real. The various systems are, however, only loosely coupled, making the composition of the infrastructure flexible. Most of the systems used are generic tools and not specific for TAVI. Exceptions include databases with specific TAVI related information about TAVI patients (in particular information collected after the procedure) and specialized imaging analysis software. This means that the infrastructure supporting TAVI is independent of how TAVI is performed. It supports TAVI based on an *informating*, and not an automating, strategy in Zuboff's (1998) terms which enable the TAVI hospitals total flexibility in how they want to perform and organize their TAVI related activities. The infrastructure emerges out the various users' selection and combination of IT solutions, a process described by IS scholars as *infrastruturing* (Pipek and Wolf, 2009).

### 5.3 The TAVI assemblage at the surgery theater and hospital level. Stabilizing and destabilizing processes.

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 hybrid room at the hospital's Intervention Centre (IVC). Radiologists also wanted to participate, but the surgeons and cardiologists agreed they should not. Individual members of the TAVI team were selected, and they decided to use valves from Edwards (one of the two producers of TAVI valves and equipment at that time). Next, they attended a course at Edwards' facilities (in Rouen, France) where they trained using simulators.

The first two procedures were carried out on the 16th September 2009. Proctors and other support staff provided by Edwards assisted the first 20 TAVI procedures.<sup>5</sup> The RH team decided to begin with central access procedures (entering the patient's body through their chest, see Image 3) because these were more familiar to them being closer to ordinary openchest surgery.



laparoscopy (live X-ray) robot

Image is the courtesy of IVC, 2014

Becoming ready to start doing TAVI at RH was primarily a process of assembling various components constituting and stabilizing the assemblage required to perform the procedure. 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 negotiations 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.

<sup>&</sup>lt;sup>5</sup> 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 TAVI assemblage was, then, stabilized through territorializations processes like determining where the procedure should be performed (at IVC), who should be involved, which patient should be offered the procedure, and which vendor's valves should be used. The assemblage was also stabilized through coding processes where decisions made at both department, hospital, and regional levels where written down in formal documents and the signed contract with the vendor. Further, the assemblage was stabilized as its components became interdependent and were interlocking each other. Finally, the assemblage was stabilized through homogenization processes, the decision that only central access procedures should be performed being one example.



Image is the courtesy of IVC, 2014

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 purchased 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. Cardiologists examined the patients. 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 that was established to perform the first twenty procedures was de-stabilized and a bit later an expanded assemblage was (re-) stabilized again. The initial assemblage was, for instance, de-stabilized in terms of being de-territorialized and opened up for the inclusion of new valves (and delivery systems) from Medtronic, and for new (i.e. transfemoral) procedures. New organizational structures were also established and included into the expanded assemblage which was re-stabilized, i.e. re-territorialized as the new borders were set and the new and old components were becoming interdependent, i.e. interlocking each other. The new assemblage was also re-stabilized through coding, for instance, by working out and signing the contract division of labour and responsibilities between surgeons and cardiologists.

### 5.4 Further evolution

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

### 5.4.1 Cycles of de- and re-stabilization

Since the early stabilization of the main structure of TAVI at RH, the procedure was undergoing 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 we above 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, crimping the valve and putting it into the catheter, maneuvering 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 destabilized 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 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,<sup>6</sup> being transferred from surgery to cardiology.

### 5.4.2 Interacting processes and thresholds

Having described the evolution of the TAVI assemblage at RH as cycles of de- and restabilization 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, proposing 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 transfermoral 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

<sup>&</sup>lt;sup>6</sup> PCI (Percutaneous coronary intervention) is a non-surgical procedure used to treat narrowing (<u>stenosis</u>) of the <u>coronary arteries</u> of the <u>heart</u> found in <u>coronary artery disease</u>.

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 becoming 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* making the split possible. In such situations, individual de-stabilizing events have no visible effect until the threshold is reached and a small additional event may trigger the change of a large assemblage.

### 5.4.3 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 started their TAVI procedures in a cath lab within the cardiology department. For this reason they began their TAVI activities doing only transfermeral procedures.

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

At Skejby Hospital in Denmark they also started in the cath lab with a team of cardiologists. Here also the very first patient died, in this case during the procedure. However, the TAVI team here drew an almost opposite conclusion of Karolinska. They concluded that TAVI required surgical expertise to be safe, and, accordingly, that surgeons as well as anesthesiologists 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. The 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 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.

### 5.5 National and global TAVI assemblages

### 5.5.1 Multi-level interactions. Upward and downward causality

We will now turn our focus on multi-level interactions and upward and downward causality. In particular, we show how de-stabilization of an assemblage at one level leads to destabilization of the assemblage it is a part of, which may again trigger new de-stabilizations both at higher level assemblages as well as one or more of its components. We will illustrate how this may happens by at looking at parts of the overall TAVI assemblages 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 treated with TAVI. This change has happened as part of a continuous process where the regulatory structures and actual TAVI practices are shaping each other.

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 centers 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 networks 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, also tested valves from Symetis and other producers from 2016. 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 destabilized.

### 5.5.2 Variety: Converging and diverging processes

We have seen how the TAVI assemblage at Skejby and Karolinska evolved along different trajectories, both rather different from the trajectory TAVI evolved along at RH. These examples show how TAVI evolved in a way leading to increased divergence. But we have also seen how the TAVI assemblages at different hospitals evolved towards increased convergence (Francarro and Tarrantini 2016). Convergence of TAVI practices among hospitals happens primarily through collective learning processes. Through such processes various "best practices" emerge. For instance, consensus emerges around how specific procedures should be performed as well as which procedure and valve should be chosen for which patients and the criteria to be used to make such decisions.

TAVI practices among hospitals are diverging, partly due to their different strategies. Two similar hospitals, RH in Oslo and Karolinska – both the most advanced university hospitals in their respective countries – decided to embark on exact opposite strategies. RH decided – due to their position as the most advanced hospital in Norway – that they should work with and learn to master all procedures and all valves available while Karolinska decided to specialize on a minimalistic and streamlined procedure. Over time the differences between these two hospitals increased. For both hospitals their strategies were heavily influenced by available equipment and facilities. RH had a richly equipped hybrid room while Karolinska had not. Further, at Karolinska the distance between the cath labs and the surgery theatres were 800 meters, accordingly bringing a patient to a surgery theatre in case of emergence during the procedure would be very difficult. Accordingly, specializing on patients that could be treated safely in a cath lab was a rather obvious strategy.

TAVI practices are also diverging due to new technologies (valves, catheters, imaging technology, etc.) made available. These new technologies increase the variety among the procedures on how they are performed, and they may fit well with the existing practices at some hospitals by not others. Further, as TAVI is becoming an increasingly popular procedure and used for more and more low risk patients, TAVI is increasingly adopted by new hospitals, among them smaller ones without cardiac surgery departments. The smaller ones have to focus on simpler and safer procedures. In addition, as "late adopters" they also they have to find their position related to "division of labour" among hospitals that have emerged over time.

Key Assemblage Theory	TAVI examples
concepts	
Relations of exteriority,	Relations between surgeon or cardiologist, catheter, valve, live x-ray video
capacities to interact	robot, and patient
Emergence, upward	The properties of TAVI assemblage in the surgery theater in terms of the
causality, emergent	assemblage's capacity to perform safe and efficient TAVI procedures
properties	
Downward causality	How the properties and capacities of the overall TAVI team shape the actions
	of each individual in the surgery theatre
Material roles	The roles played by the bed, the catheter, etc.

Expressive roles	Decisions and agreements, oral instructions, images and other data on monitors
Stabilizing processes	Designing an assemblage so that all components fit together (for instance
	negotiating and deciding who should be members of the TAVI team), learning
	processes
	Territorialization
	Homogenization
	Coding
	Interlocking
De-stabilizing processes	Breakdowns during procedure (cardiac arrest, breaking of a catheter),
	accumulation of knowledge leading to better ways of performing TAVI
	De-territorialization
	De-homogenization
	De-coding
	De-interlocking
Thresholds	Level of knowledge and experience required to split TAVI into one surgical
	and one cardiological at RH
Bifurcations points, critical	Decision to go for a minimalist approach at Karolinska
junctures	
Path-dependency	The evolution of TAVI at Karolinska after deciding to go for the minimalist
	approach

**Table 2:** Key assemblage theory concepts

### 6. Concluding 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 – in particular the increasing sociomaterial complexity we are encountering as we more and more are creating the "Internet of people, data and things." First of all, the concept of assemblage as defined in AT is well suited for describing and analyzing such complexities and their dynamics. We find the distinctions between an assemblage's properties and capacities to interact (or affect and being affected) are simple intuitive and –not the least – powerful in analyzing the relations between elements of different kinds.

TAVI 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. We see these aspects as central to the evolution of TAVI, and, accordingly, the case also demonstrates the validity of the three requirements to an ontology for IS research we pointed out in the introduction section. When looking at our case from the perspective of the three other ontologies we have related Assemblage Theory to, we find that the case confirms our analysis of these ontologies earlier in the paper. We find in particular Agential Realism less helpful. The different elements involved in the TAVI assemblage are certainly entangled, but they are not inseparable. Further, we have difficulties in seeing how any concepts in the Agential Realism "toolbox" can help analyzing the evolution of TAVI. Actor-Network Theory can certainly help us in doing so, but we find Assemblage to be a more powerful process theory than either of these two.

Some 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 they 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' (1994) 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.<sup>7</sup>

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.

In this paper we have argued that AT can be a useful and powerful process ontology for understanding, analyzing 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 analyzing the relations between technological and non-technological (humans, organizations, institutions) and 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. AT sees the components of sociomaterial assemblages not as just entangled and inseparable, but as component can be replaced with another having different capacities and accordingly making the assemblage behave differently. We have in this paper demonstrated how processes are interacting in various ways such as:

<sup>&</sup>lt;sup>7</sup> 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 destabilizing 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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