Novo Nordisk A/S

# An investigation of how Standard Operating Procedures are practiced in Novo Nordisk DFP Bagsværd

4th Semester Master Thesis

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# Resumé

I Novo Nordisk Bagsværd, afdelingen for Diabetes Finished Products trænes medarbejdere i at kunne producere bl.a. insulin præparater efter gællende standarder inden for Pharma industrien. I dag beror denne træning hovedsageligt på læsning og gennemgang af skrevne procedurer. Disse procedurer bliver nu udfordret af et nyere og mere indlæringsmæssig korrekt koncept, hvor ordene er færre og de reelle kompetencer i højsæde. Dette koncept møder som udgangspunkt modstand fra flere fronter, og denne modstand fungerer som det umiddelbare springpunkt for specialet.

Ved brug af praksisteori bliver det tydeligt, at modstanden er nuancefyldt og kompleks. Dette speciale undersøger hvilke agendaer og forestillinger der ligger i at praktiserer disse procedurer på den nuværende og dermed udelukkende skrevne måde. Ved at interviewe forskellige relevante aktører omkring deres arbejde med og forhold til disse procedurer, åbner der sig en verden af livshistorier og individuelle strategier der lægger sig til måden at praktiserer disse procedurer på. Analysen viser, at samtlige informanter arbejder efter de gællende regler, men at de også alle har opbygget coping-strategier til at kompenserer for det, som de skrevne procedurer ikke efterkommer.

I diskussionen udfordrer jeg potentialet i disse strategier og hvorledes de hver især skaber mere eller mindre værdig indenfor givne arbejdsområder, ligesom det diskuteres hvorvidt den ene strategi er mere værdifuld en andre.

På baggrund af det empiriske materiale har jeg i dette speciale identificeret hvorledes en Standard Procedure kan praktiseres på en nuancefyldt måde, og afslutningsvist hvordan dette spektrum af nuancer kan bidrage til en forståelse for brugen af disse procedurer og ikke mindst deres mangler til videre brug.

## Acknowledgement

# Table of Contents

# Abb.

- ATS: Training Area Supporter

- Compliance / being in compliance: When all SOPs are read and signed for

- EHS: Environment and Health

- FDA: Food and Drug Administration

- ISOtrain: The software system where SOPs are read and signed for

- Past-due: When a SOP has not been read in time

- Shopfloor: The production Floor

- SOP: Stand Operating Procedure

- SOP owner: The employee who has the responsibility to gather the necessary informants in order to construct a new SOP.

- SOP writer: The employee whow writes the document and places it in flow

- SVP: Senior Vice President

- QA: Quality Assurance

- QBIQ: Library for SOPs

## Introduction

*Quick steps are heard through the office. A team leader just rushed in to speak to one of the supporters. It is about an operator in his team who is not allowed access to the gowning room. This is the second time he asks the supporter to enable the access in the system. The supporter cannot help, still. The operator needs to come back in person and correct the typing error on the paper. This paper entails leaning goals and specification on the training he has been through, required to enter the gowning area. The team leader sighs, he pulls up his phone from his pocket as he leaves the open office area.*

*In a different office 12 new employees are gathered. In the office is 12 bouquets of flowers lying in the window. The employees are taking turns in testing their sterile hand wash. Just as when you were a kid and chewed the pink pill at the dentist to check for places you have not brushed, the 12 employees are smeared in glitter lotion to become certified in washing hands according to procedures.*

*On the opposite side of the hall is the Training Factory. A true mock-up of one of the filling lines are installed here. Behind it is a projector turned on, and a screen pulled down. There is nothing on it. At the mock-up an employee holds a bag of capsules. He pours them into the funnel of the machine. The operator looks at the direction of an operator I have seen inside the production, he nods quietly, and the employee throws the empty bag in a trashcan.*

I have since September been inside the gates of the Novo Nordisk Production Site in Bagsværd. The organization is the 7th largest pharmaceutical company worldwide, while they nationally are extremely superior to their competitors. The business began with simply Marie and August Krogh who along with Dr. Hagedorn completed the first successful experiment of extracting insulin from an ox pancreas. The ground-breaking experiment was done in the Villa of Hagedorn in 1922. Since the company has gone through quite the expansion. Currently Novo Nordisk employees nearly 43.000 people in 79 different countries, and they market their products in more than 170 countries (Novonordisk.com, 2019). Along with the expansion and the entering to different world markets,

came regulations and requirements. Some health authorities are tougher to please than others, and the most important one's in a financial perspective are USA and China. These nations come with their own health authorities, just as medicine sold in Denmark has to live up the regulations set by Danish health authorities. FDA inspections are of high importance as USA is the largest market to Novo Nordisk. The American market itself represents a total of roughly 57% of the total value of Novo Nordisk. In comparison the European market represents 22% (NovoNordisk.com 2019b).

When the American health authorities back in 2012 filed a warning letter to Novo Nordisk Bagsværd, it therefore choked the entire organisation. As am employee said: "*they were just about to pull the plug on us*" (Interview 4 with Sanne, may 27th 2019). The findings by FDA were numerous and divided into categories of 1) manufacturing and control of the finished product, 2) the validation of the aseptic fillings process as well as 3) Quality Control laboratories involving sterile testing (Warningletter 2012, p. 2-3). In order to comprehend a productions process, I have inserted a simplified drawing of the different departments that the product goes through from beginning till end.



*Figure 1: Process Flow for insulin production.*

The findings were widely spread throughout the production process. Nearly everything was under attack and the common denominator for many of the findings were lack of standards within documentation as well as operation. An excerpt from the letter thus sounds:

"*We further discussed the need for the firm to develop an SOP[1] addressing the criteria for acceptance of media fills after experiencing a failed media fill[2]. The objectionable conditions are listed below (...)*

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[1] A Standard Operating Procedure for employees to follow closely.

[2] A process simulation, where a liquid is prepared and filled to test whether the aseptic procedures are adequate to prevent contamination during actual drug production (Fda.gov, 2019).

1. *No procedure requiring a review of previous batch production records to detect changes or events which may affect subsequent media fills.*
2. *No procedure describing how to detect minimum levels of contamination; and no training records for personnel performing visual inspections or media fill.*
3. *Not all employees who participate in media fills have been trained in aseptic techniques.*
4. *Not all employees working in the aseptic filling areas have been giving training in the firm's current gowning procedures.*
5. *Gowning procedures do not require personnel to put on sock and shoe covers prior to entering the septic filling room"* (Warning letter 2012).

These points are excerpts of the list of a total of 60 objectionable conditions that the auditors found. All are they in one way or another connected to procedure not followed, or a procedure missing all together. In the time followed by this inspection the number of Standard Operating Procedures, (hereon after referred to as SOPs) increased considerably.

For comprehension I have inserted a picture of a SOP on deviations. It counts 81 pages.
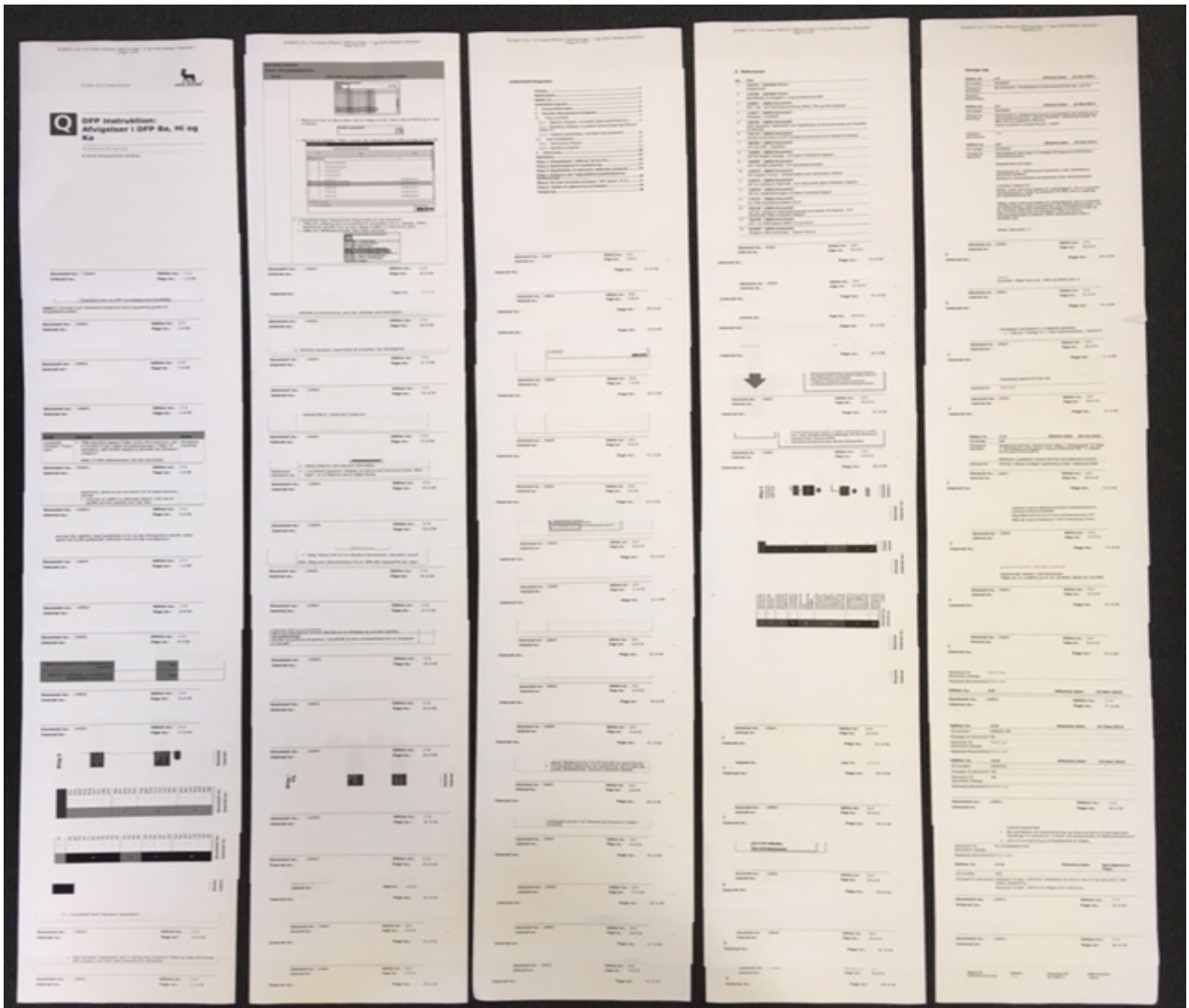
*Figure 2: Deviation SOP.*

Today the health authorities keep a close eye on the organization. Not for the lack of control of procedures and training of staff, but for leaning back in full confidence that a SOP is the correct action to take – at every area at all times. This way of practicing resulted in very long and complex SOPs

When joining a training summit in January 18 this approach towards teaching and training was questioned:

*"There is no need to document analytical training for each individual product analysis when the analytical method for each of these products follows applicable general principles for which training*

*is done. For example, once the analyst has been trained in the general technique of HPLC[3] they could be considered trained to perform HPLC analysis for a broad range of dosage strengths and types*" (Observation 1, Training Summit jan. 20th 2019).

Training for Competence, is a pedagogic tool which is purposed from a corporate stand to help eliminate some of the noise that SOPs create in terms of over processing and frustration caused by long and difficult formulations. I will elaborate on the concept later, however for clarification I can be helpful to know that the concept embraces a number of SOPs, only leaving the fundamental information behind to be documented and taught. Instead of training only relying on reading information, the concept of Training for Competence confronts the poor teaching method and instead tests, games and classroom teaching are of preference.

When viewing the Cone of Learning by Edgar Dale, it is evident that the human mind is less likely to remember things by only reading. Whereas we remember 50% of things we have seen when watching a movie, we only remember 10% of things we have read. Common for the two are, that we are learning passively. When participating in a discussion on a topic or even better simulating an experience we move both to an active level of involvement, while we at the same time get closer to remembering what was both said and done (Dale, 1969).

Taking such a radical turn, conveying to different ways of teaching and thereby practicing the training of staff is a fundamental change to a large organization like Novo Nordisk. I have during the last 9 months slowly begun to learn the world of the pharmaceutical industry, and I have been amazed of how every process, every step, every tool is embraced in some sort of standard operation procedure. I have more than once questioned this rationale, but has along the way begun to understand, that an organization of this size, with this kind of responsibility, you do not implement changes overnight and you do not cut corners. I have the last few months quietly observed the buzz which has been heard around the Site, when talking of Training for Competence, as the concept is currently tested as a pilot project for new employees. I have found this buzz to

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[3] High Pressure/Performance Liquid Chromatography. A well-used technique in the laboratory, used to separate numerous mixtures and identifying the ingredients (Clark, 2019)

result in a division of parties; those who are immediately positive for the change, and those less likely to acknowledge the alteration and the road towards a change in the way SOPs are practiced. Initially I have therefore chosen to investigate which factors are embedded in the different actors, as their willingness towards changing their practices is of such difference.

## Problem Area

This thesis is a multiple case study on how SOPs are practiced as a part of the daily work for employees at Novo Nordisk. The goal of the thesis is not to scrutinize how poor the SOP is in its current form, but to analyse which circumstances are at stake when working with SOPs as a part of your daily routine. By investigating a number of cases in which SOPs are practiced, I intend to search for, not les understand the reasons as for why there exists two camps with each their approach towards Training for Competence, as an alternative to SOPs.

In broad terms, the problem I will attempt to answer is the following:

*What is at stake when practicing SOP's, and what are the factors causing a change of this practice to be of such challenge?*

At a later point, once I have discussed my theoretical resources, I will present a more specific research question.

## Theoretical resources

This paragraph it to present the theoretical recourses on which I draw throughout this report.

My approach towards this field is broadly inspired of theories from techno anthropology and the likes which describes how technology and materiality always lies embedded in a social practice. This means, in broad sense, that I will draw on theories which does not speak of structures and technology in general terms but instead how they unfold in certain surroundings and circumstances. This is the reason as to why I find it obvious to have a more ethnographic approach for studying the field.

With this as my departing point, I will in paragraph below present the specific theories which have particularly inspired me to investigate this case and the materiality embedded in it.

## Specific theoretical framework

In relation to my research question and the field I wish to investigate, I seek for a perspective that can capture the work that surrounds the phenomenon around SOPs. Social Practice Theory takes materials into account as an important factor for what forms the social practice. As mentioned in my introduction SOPs are of great importance in general in Novo Nordisk. I believe that the SOPs constitutes a phenomenon, and that it involves a number of materials such as physical documents and software programs.

I am, at this point not able to point at something, or a series of actions and practises, and argue that these are the cause as to why some employees have one mind-set towards this change, and others a different mind-set. Social Practice theory seeks to understand peoples work and the society they live in through their actions, which is why I find it relevant to apply on this case. Especially more recent Social Practice Theory pursues to approach and understand how one's social life is organized through practices, and maybe more relevant for this thesis, how the normativity in these practices contributes to certain actions. It is within these actions that I see a distinction. Some people act in one way based on the same thing, whereas their colleagues react differently. Could there be specific circumstances at stake, which result in either this thing or the other?

These apparently strong circumstances that certain people practice, in certain situation and because of certain things seem to be different. This phenomenon - SOPs - captures multiple things, however besides the fact that health regulations and bylaws requires a certain level of documentation, the reason for these tendencies are invisible. I therefore seek for a theoretical framework that can embrace this invisibleness and contribute to an understanding of how these tendencies are built. A framework that captures the dynamics that exists between whoever is acting and whatever they are acting with.

Having a Social Practice Theoretical approach means that my starting point is in the actual practice carried out. From there I seek to understand why this individual does what he/she does. What lies embedded in that practice? The approach of Social Practice Theory is not to bring forth a critical

view on different controlling elements and on that notion conclude on the meanings behind it, but instead the understanding of the practice itself: how it changes, prevails and stay the same (Shove et al, 2010, p.2). Practice orientation circulates around the notion that human activity and social structures are *recursively related*:

*"activities are shaped and enabled by structures of rules and meanings, and these structures are, at the same time, reproduced in the flow of human action. This flow is neither conscious, voluntary purpose of human actors, nor the determining force of giving social structures"* (Shove et. all. 2010, p. 2).

Above all, practice exists as both an entity and as a performance. Practice-as-entity revolves around the element which "*consequently figures as an entity that can be spoken about*", whereas practice-as-performance is to be viewed "*through the immediacy of doing, that the pattern provided by the practice-as-an-entity is filled out and reproduced*". As an example Shove et all brings forth the skateboard. Skateboarding exists of a blend of a skateboard, streets/spaces where one can practice the bodily competencies which is needed in order to do skateboarding along with the rules/norms that are tied to the practice of skateboarding. Skateboard thereby exists as an element figuring as an entity which one can speak of, and skateboarding exists as a performance one is doing. Shove et all speaks of a recursive relation between these two practices, meaning that the practice-as-entity structures the practice-as-performance (Ibid p. 15). In the same way I intend to investigate how the practices around SOPs, as a practice happening in a social structure and at the same time being a human activity are a recursively related.

## Social Practice Theory through time

This case study is based on the principals of the most recent development within the landscape of practice theory. I will in this paragraph bring forth the view upon Social Practice Theory as I intend to interpret it and why. I intend to, in short, present the theory by its most significant theorists and elements, on which grounds I place myself and the theoretical framework for this thesis.

| Schatzki (2002) | Warde (2005) | Shove-Pantzar (2005) | Reckwitz (2002b) |
|---|---|---|---|
| Practical understanding | Understandings | Competences | Body |
| | | | Mind |
| | | | The agent |
| | | | Structure/ process |
| Rules | Procedures | | Knowledge |
| Teleo-affective structures | Engagement | Meanings | Discourse/ language |
| | Items of consumption | Products | Things |

*Figure 3: Key elements in the understanding of practices (Gram-Hanssen 2011)*

The chart above is a simplified overview of branches within the framework of Social Practice Theory, and the understanding of what holds a practice together.

Professor Theodore Schatzki describes practical understanding, here being the know-how or routines as previously mentioned, explicit rules and teleo-affective structures as the latter of things that holds a practice together. Schatzki argues that these teleo-affective structures thus imply: "*that the practices are guided by a direction toward and objective that has a substantial meaning for someone*" (Gram-Hanssen, 2010, p. 154). Professor Andreas Reckwitz sidelines with Schatzki as he emphasizes that practice is understood through both body and materiality, however Reckwitz find that mind, agencies and structures are relevant elements as well. Whereas Schatzki focuses on elements holding practices together, Reckwitz focuses on how these chosen core socio theoretical elements that are intertwined in practice theory when comparing to other sociocultural theories. (Shove et al. 2012, p. 23).

Both Warde and Shove-Pantzar seem to have leaned on Schatzki in terms of elements, understanding and naming of them. However, they have reduced the number of elements and then draw on Reckwitz as they include materiality's (products/items of consumption/things). Shove-Pantzar disagrees with Schatzki as they argue that he does not see artefacts, materials and technologies as an integrated part of practices, as disconnected from the practice itself. Though

Shove, Pantzar and Watson distinguish their take on Social Practice Theory from Schatzkis they have also leaned towards him and his definition of a social practice: "*a temporally and spatially dispersed nexus of doings and saying*" (Ibid p. 7). Schatzki thereby argues that practices are not random or in other ways accidental actions, but instead they are a result of tied in a relationship of time and space between those performing the practice.

As the chart shows, Shove et al. speaks of three elements in their book *The Dynamics of Social Practice (2012).* Elements to be understood as when people do things, could be driving, could be working by an SOP, they actively combine the elements of which these practices are made (Shove et al, 2012, p. 14). As the overview shoes, these elements are *materials.* Materials in the sense of physical things, technologies, tangible physical entities and the stuff of which objects are made; *Competences* being skills, know-how and technique and finally *meanings* being symbolic meanings, ideas and aspirations.

The reason for choosing this book, is that it is not simply a theory, it also presents itself as a method for analysing. By breaking a practice down and into elements in order to build them back up, I can get a detailed view into the details of the practice and how these details when joint constitutes a certain practice. It is this method I intend to make use of.

**The definition and understanding of meanings, competences, materials.**

As mentioned Shove, Pantzar and Watson defines social practices as routinized behaviour consisting of the three elements (*meaning, materials, knowledge*), combined in a relationship where the different practices are carried out in time and space. This is the definition of Social Practice Theory and the understanding behind it I intend to use in this thesis. As Shove, Pantxar and Watson has not come up with the definition themselves, I am aware that I also draw on both Schatzki and Reckwitz as mentioned previously. As Shove et al argue themselves, their tree-elements take on Social Practice Theory is an 'even simpler scheme' than thus of Reckwitz (Shove et al 2012, p. 22-23), one I find exactly simple to apply on this case. In the section below I will define the elements before applying them to my empirical findings.

The aspects of 'things' is crucial to Social Practice Theory, as practices are entwined with objects (Shove et al 2012, p. 23). It is thus hard to picture the practice of shopping for groceries without the actual objects of groceries, some sort of payment and potentially a way of caring the groceries from the store and to the kitchen. Materials are thus viewed as a combination of objects, infrastructures, tools, hardware and the body itself (Ibid).

When it comes to competences, there is an obvious distinction between having the knowledge to evaluate a giving action and on the other hand having the skills to actually performing the action. However, Shove et al has taking this into consideration as they "*lump multiple forms of understanding and practical knowledgeability together*" and refer to them as the element om competences (Ibid).

The final element is thus of meaning. According to Schatzki, whatever people do and how they act, their action or practice has a history and a setting such as purposes, emotions, moods and beliefs. Shove et al has chosen meaning as the term to represent "*the social and symbolic significance of participation at any one moment*" (Ibid). It is thus an element of practice and not as something with the status of a driving force or in any other way something that stand outside.

When applying these theoretical elements to my field of research I discover a number of interesting questions to be answered: How is the 'talking' around SOPs? Which concepts are linked to SOPs and which combinations of elements lies in the practice of working with, by and after SOPs?

According to Shove et al. their book: "*takes up the challenge of developing and articulating methods of understanding social order, stability and change in terms that are required and informed by theories of practice*" (2012, p. 4). The answer to this fits very well into the work of this thesis, as I wish to both investigate and understand this social order and the stability that these practices have created. Or more specifically, what kind of social order exists around the working with and by SOP's, and in which way are the element present in the practices around SOPs?

Practice is to be understood as partly something bodily, something concrete and something socially (Ibid). Practice is defined as a way of acting, assuming some sort of regularity or custom. These activities are performed both 'concrete and bodily', most often with the use of some sort of materiality, and is therefore worn or used by individuals (Ibid). At the same time practice is defined as something social. A practice is somewhat organized, it maintains itself and exists based on knowledge that is known to everyone in the community where the practice is exercised. As an

individual you do everyday things in a certain way – you exercise this everyday practice in a certain way, and you do so, due to whatever practice is built in to the thing, the materialistic thing you may use to perform this practice. Whenever I change the sheets in my children's rooms, I most often do it in the same way: I start by removing the dirty sheets, I throw them on the floor and I put on new clean sheets. I stuff the pillow into the pillowcase, whereas I turn the quilt sheets inside out and put it onto the quilt by grabbing two corners first. I do it like that based on how I was thought changing sheets. At the same time there is a reason for even changing sheets in the first place, which lies in the norm that one changes their sheets every once in a while, and I as an individual have taken this norm upon me and chosen to live by it. Me changing sheets is therefore both something social as I perform it in a routinized manner based on some sort of knowledge. At the same time the practice of changing sheets is a way of acting, something I do 'with' my sheets as something materialistic one can argue. As Shove et al. argue, when I change my sheets, I combine the three elements of which this practice is made (Shove et all 2012, p. 13).

Social practices, like changing sheets, are routinized. Some are built into the materialistic object and some comes with the norm of how these objects are used. Common for both is that the practices are not built on deliberate reflections or in other ways results of individual choices taking this, that and the other into consideration whenever done. Instead they are a result of certain circumstances and certain materiality's as mentioned above.

With the use of Practice Theory, I have presented and explained how I see my field of research to be understood and analysed. Besides an analysis of which elements are present and how they are alive, I find it relevant to view how this phenomenon of SOPs is worked with. Is there a specific context in which SOP's are performed? Is there a specific period of timeframe or other dimensional aspects present when practicing SOPs? To grasp these dimensions, I will below present Distributed Cognition as it is explained by Edwin Hutchins.

## Hutchins

Prior to explaining Hutchins specific take on cognition, I will shorty explain the path towards this exact view upon cognitive science and the differences they imply.

In the 1950'ies, the first wave of cognitive science rose as a counter movement towards behaviourism.[4] This wave divides the human being into two: mind and body. From there the human cognition is viewed as the mental link between perceptual input and behavioural output (Boden 2006, p. 485). The mind is here in focus, cognitive qualities as memory and reason, however the first wave did not encounter how these qualities were connected to the human body as a part of the cognitive process. This led to the second wave of cognitive science, beginning in the 70'ies. The significance difference between the two is that, while the first wave of cognitive science is an independent vision to the physical structures happening in the mind, the second wave embraced the fact that the body as an organism was in fact embodied in the cognitive science. The third wave moved beyond this embodiment as it encountered any organism and not solely the body. As an example one could draw on depressions. In modern psychiatry you no longer believe that depressions are solely a mean of biochemical imbalance, instead studies have shown how multiple factors which reach beyond the mental structures can cause the disease. One is genetic vulnerability, medical problems which embraces the whole body, or stressful life events moving beyond the body as an organism of mind and body. Cognition is thereby not centralised to the body but distributed as it is spread beyond the mind, the body and outside world (Hutchins 1995, p. 288).

### *Distributed Cognition, the third wave.*

With the use of distributed cognition, it is possible to investigate how actors make use of each other, and how they make use of technology / materials / recourses in their surroundings, which is what Hutchins does in his book (1995). Unlike the first and second wave of cognition science, the third wave argues that one cannot address the individual alone, since whatever is happening within this individual, it must be viewed as a part of a greater whole (Hutchins 1995, p. 49). One of the great believers of the third wave within cognitive science is the cognitive anthropologist Edwin Hutchins.

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[4] Approach as viewed by Watson: awarding exterior phenomenon's and behaviour which are observable and ignoring non-observable phenomenon's from the internal (Britannica.com, 2019)

Hutchins has done multiple field studies, always taking its starting point in a well-defined task to be solved by a cognitive system, being one or more people and different technologies. (Steffensen, 2016, p. 28). Hutchins sees this system as functional: "*It is a constellation of structures, some of them interval to the human actors, some external, involved in the performance of some invariant task*" (Hutchins 1995b p. 281).

In November 1980, Huchins did a (cognitive-anthropological) field study on-board an American navy ship sailing in the northern pacific (Hutchins 1995 p. xi). Hutchins studied what operators of the ships steam propulsion plan knew and 'how they went about knowing it' (ibid). These studies lead to a demonstration of how the cognitive activity, which is central to the navigation and manoeuvre (of the navy ship), requires a complex network of crew, artefacts and cultural structured practices. Individual actions and practices could be viewed as quite essential for the rest of the teams coordinating actions and practices. These actions and practices, as a whole, leads the team to make short and precise decisions on navigation of the ship. Decisions that the individual could not have come up with on its own. Hutchins argues in his book, as a third wave of cognition science, that cognition is not central or embedded to one's body, it is instead distributed to move beyond it:

"*Human beings are adaptive systems continually producing and exploiting a rich world of cultural structure. In the activities of the navigation team, the reliance on the and the production of structure in the environment are clear. This heavy interaction of internal and external structures suggests that the boundary between inside and outside, or between individual and context, should be softened*" (Ibid p. 288).

Hutchins hereby argue, that to understand cognitive systems, one must investigate and understand the cultural structures around the team as well as its history. As a clarifying example, should we move back to the navy ship, Hutchins argue that in an effort to understand the history of navigation seen form a cognitive perspective, one must embrace the whole suite of navigation instruments through time, required to navigate. Besides these navigation tools, Hutchins furthermore argues that there exist mental tools which the navigators bring forth to solve the task of navigation (1995, p. 113-114).

With his book, Hutchins wants to study human cognition in its natural habitat (e.g. The Wild), as he argues that exactly these surroundings are different from cognition 'in captivity' which refers to laboratory experiments throughout history (Ibid p. 370). Hutchins continues and proposes that one, in order to explore cognition in a different cultural setting than in a laboratory, does a descriptive enterprise.

Figure 3 illustrates any moment in any human practice (Ibid p. 371). I have found this cube quite difficult to grasp, so for clarification I will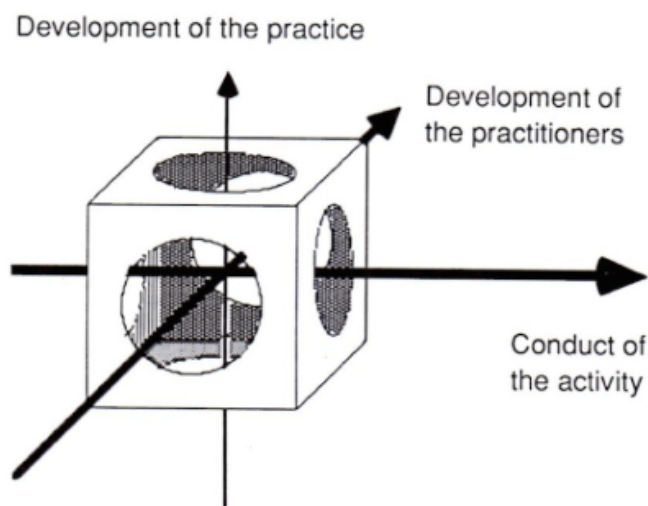 explain with the use of an everyday example from my previous work. When I worked as a midwife I occasionally did ultrasounds. I went to school for three and a half years, which in itself does not educate you to become a sonographer, but it provides me with enough information and practice so that I can scan a pregnant woman to see if her child is head or breach position. My education and thereby the development of me as a practitioner has taken years. I have acquired knowledge on how to feel may way towards the baby's position, just as I have learned to manoeuvre the scanner, the technology behind it and the overall understanding of what I am searching for. Which images represent head, and which image verifies that the baby lies in a breach position? This scan usually takes me a maximum of a few minutes to perform.



Figure 4: A moment of a human practice (Hutchins 1995, p370).

The actual development of the ultrasound practice has been developed through centuries but the ultrasound scan itself is, surely depending on the purpose, done in minutes. The conduct of the activity I perform when scanning has a short history, but the structural elements of the activity being the journal where I note the findings down and the ultrasound scanner itself will live beyond the scan.

The reason for drawing on Hutchins in this thesis, is that, just as Social Practice Theory, it evolves around the everyday world and the practices in it. However, distributed cognition offers a perspective of time and view the practice in a historical context.

As mentioned above both mental and material tools should be studied as they both contribute to the cognitive system. I thus intend to investigate how cognitive activities are distributed and coordinated in cognitive systems across individuals, artefacts, environments and cultural structures as: "*All human societies face cognitive tasks that are beyond the capabilities of any individual member*". (Ibid p. 262). I thereby need to examine the cultural structures in the practice of SOPs and the history around it, just as the cube implies.

**Sum-up**

Through the understanding of these two theories, I have come to realise how human cognition and human practice is the sum of a complex relationship of elements like, meanings, competences materials happening in a giving time in a giving cognitive system. I thereby find myself to have moved beyond the narrower and more psychological explanation as to what encircles the phenomenon around SOP's in Novo Nordisk. As implied earlier, I initially had mental and psychological explanations as to why the SOPs are a live and maintained. Instead I have now come to understand how the answer is to be found in certain circumstances instead. This jumping to conclusions or inaccurately awarding cognitive abilities to something or someone has been articulated by Bruno Latour, in his book Laboratory Life in 1985. The telling goes that Latour, when doing observations in Vest Africa, found how the former anthropological tendency amongst African executives, was to explain phenomenon's based on the 'African mind'. At that time black students found it hard to adjust to modern industrial life. The students faced an accusation in technical schools, regarding their their lack of skills to view tings in three dimensions. The reason for this as it turned out, was to be found in the school system that these boys attended. Here engineer drawings were introduced prior to the student's introduction to any practical work or actual machinery. These students, as they for the most part originated from country districts, had therefore never seen or worked with an engine, and little were they to know about interpreting a drawing of an engine in three dimensions. It was therefore more likely that their lack of experience with drawings

of dimensions and engineering was the answer to their challenges, than a mental deficiency as a result of their 'African mind' (Latour, Woolgar, 1985, p. 274): "*As the study proceeded, the established preference for far-fetched cognitive explanations over simpler social ones became more evident*" (Ibid). Latour emphasizes that researchers should always look for materialistic circumstances and not cognitive explanations. The example with the African students is to underline how, in this case, it was not the "African Mind" causing them to fail interpretation of technical drawings, but "*the lack of appropriate connections required to interpret such drawings*" (Vries, 2016, p. 13). This exact claim is what today is in the heart of Science and Technology Studies, as they argue that "*competence is not something hidden, giving mental entity*" (Ibid).

With this said I have, until now, found myself to have fallen into these far-fetched explanations as to why SOPs are the answer to, what seems to be, most of the questions within the gates of Novo Nordisk. With this deeper understanding of what is embedded in a social practice I find it relevant to qualify the area of the problem that this thesis seeks to investigate.

## Qualified problem area

Based om both Shove et al. and Hutchins I am now aware of how meaning is embedded in practices, as well as individual competences and whatever material the practice may engage with. Likewise, I have understood how a human practice offers both a before and after. Embedded in the practices around SOPs lies a development of the giving practice. Could there be a history to SOPs that I have yet to discover? The same goes for the actor who carries out the practice. Finally, there is a conduct embedded in the activity. Is there a special way to work with SOPs today versus 25 years ago? Staying true to Hutchins cube and the elements of Shove et al,, means that I must investigate these unknown factors. I intend to do so through multiple case studies, which I expect will bring me to a number of cases with which SOPs are thought 'with'. Finally, I intend to assemble these 'thinking's' and cognitive systems into a draft of strategies for how the phenomenon of SOPs should be understood as a way to serve nuances and a deeper understanding of SOPs and the practice around them. My intentions for these solutions are to affect the implementation of a new training setup not based solely on SOPs. I am aware that Novo Nordisk prior to this report had

intended to scrutinize the work with SOPs, however I expect to bring forth more nuanced analysis of the issue to be taking into consideration by the organization.

This investigation is answered through two research questions:

1. How are the elements of *knowledge*, *materials* and *competences* embedded in the practice of SOPs?
2. Compared to Hutchins' Cognitive System, what are the embedded developmental dimensions within a SOP practice?

The first question will answer how the phenomenon of SOPs is manifested in everyday practices. It is important to understand the elements represented in the practices and how there are combined in a relationship, in order to draw a nuanced analysis prior to an implementation of a change leading away from SOPs. The second question I will answer on the basis of my first research question including Hutchins dimensions of time and place of the giving cognitive system.

As I how now qualified the purpose of my research, I will unfold the empirical reflections and methodological approach towards accomplishing it.


## Empirical reflections

As for now I have explained the starting point from where this thesis has its beginning. I have in the prior paragraph argued why I find the Social Practice Theory of practice relevant for both answering this initial wonder of mine, but perhaps of more interests – the underlying reasons behind this answer. What are the practices, norms and routines behind the phenomenon of SOPs?

As my perception of reality revolves around the mentioned theories, it is evident that I percept the world as being socially constructed. It is not an objective arrangement which can be separated from the individuals existing in it, neither is it something only existing in the mind and consciousness of these individuals. It is on the contrary a community which we all are a part of and all create through social interaction. This social interaction I intend to investigate, and I will below unfold the basis of which I have chosen the involved parties.

I believe there to be a number of different situated, material conditions surrounding these SOPs, and my intentions are to investigate a number of these. A number of cases by which these people think 'with' when engaging with SOPs.

## Methodology

The spectrum of SOPs, those who practice it, weather it being the actual writing of the documents, Supporters training staff in the content of SOPs or employees reading SOPs are quite large. In order to in any way approach the field, in a structured way, and thereby pursuing my research question, I need a somewhat limited area of focus, and a concrete method for approaching it.

During my 9th semester I worked with Project Supporters on implementing new initiatives in the production area or reviewing old ones. I therefore have knowledge of some of those involved in the pilot project mentioned previously. I find it relevant and fortunate to participate in their ongoing work which addresses a part of my focus: the elements embedded in SOP practices, how are they ensured when asking employees to change their practices.

Each month new employees are assigned onboarding through four days. During these four days the employees are asked to read (and understand) a number of SOPs preparing them for certain things such as going through the main gates, gowning in the correct order and entering a classified area.

The pilot project runs on one module covering four SOPs. The module is a basic module, meaning that the SOPs consists of basic information meant for every employee no matter their title. The pilot project is launched to deal with this specific module, consisting of four SOPs: SOP 151679: Emergency situation, 129121: Waste Management, 123428 Pest Control, 197563: Access Control. Two SOPs are owned by the same SOP owner, and the last two both have individual owners.

As this pilot project runs independently of my thesis, I have been able to join meetings and become familiar with both the projects itself as well as the actors involved. These actors can be divided into SOP owners, supporters who train and teach in the SOPs and different coordinators. These actors are in each their way in relation to SOPs, and I therefor view them as relevant actors to my thesis. Besides representatives from this group, which I initially found relevant, I have looked towards James Spradley in order to support my choice of informants. What is a 'good informant', and which potential pitfalls should I be aware of? According to Spradley, there are a number of things which

can result in difficulties during an interview but the most common problems is that the researcher fails in finding 'a good informant': "*Someone who can assist the novice ethnographer in learning about what informant's culture while at the same time learning the interviewing skills*" (Spradley2016, p. 46). To ensure this selection I have looked for informants who can let me in on a world of SOPs. A side from SOP owners, and Area Training Supporters I find it relevant to speak to actors with more hands-on knowledge in terms of a SOP being practiced on a machine inside the production for instance. Besides participating in meetings in relation to the pilot project, I intend to handpick actors from those meetings for interviews as well as others of relevance as mentioned. Due to time constrains I will not be able to include the findings of the pilot project in this thesis, however I will feed of the meetings and thereby gain insight on how the enrolment of the new concept is to be implemented and thereby adjust my findings accordingly.

In regards to the forthcoming interviews, I have had reflections on how to process both my approach towards the informants and the empirical material derived from them. These thoughts are processed in the paragraph below.

## Informant and ethics around them

Ethics revolves around what can be viewed as morally acceptable in a research project like this. Is it alright to observe without letting people know, should informants from interviews be anonymised? As a large part of my project is based on interviews, I will shortly reflect upon the ethical implications related to these interviews.

The informants I have chosen to address are based on numerus things. On the Bagsværd Site there are three Area Training Supporters, who's responsibility it is to teach and train employees based on whatever the regulations may be at that giving work area. I find it relevant to speak to a someone with these qualifications and one who's daily routine largely deals with SOPs, as the regulations are anchored in these. One of the Area Training Supporters is very eager on training. This shoves in the way she often volunteers on tasks regarding new employees, students and visitors, and I therefore view her as passionate towards these events and the task that lies in learning and introducing how things are done on Site. In regards to this thesis, I view her as an engaged and knowing informant, one who I found it plausible would set off time to speak to me. Besides this informant, I have

reached out to an operator with many years of experience in hands-on teaching. He has through the years established a process of his own, where he teaches operators to become skilled in several productions related techniques in less time, yet more efficiently than previously. I see this actor as a well-chosen informant to let me in on a more hands-on perspective in relation to SOPs.

As mentioned the new training concept is to be launched on one module covering four SOPs. By participating in meetings, I have established contact to one of the SOP owners. This particular SOP owner happens to have a history with my colleague from a prior project, and I therefor made a decision not to record the meeting, but instead observe and take notes. Ultimately the meeting turned out a success and I felt confident enough to ask the informant for an interview. This time I asked for, and was approved to record the interview as with the other informants.

## *Kvale's 7-step guide towards interview research*

As stated I will through interviews seek to understand which elements of Social Practice Theory are present when people 'do' SOP practices. My personal experience on conducting interview is limited, why I find it necessary to become more familiar with this method prior to conducting an interview guide and reaching out for appointments. This paragraph will unfold my reflections towards the interview guide, and the thoughts behind it.

According to Kvale conversations are the basic mode of human interaction (2007, p. 2). However, whereas spontaneous or at least interview of an everyday conversation may be straight forward, one may very well find himself in limbo when proceeding towards analysing the transcribed data: what was the purpose that the answers were meant to fulfil? On the other hand, a too structured interview seeks to probe the responses the subject may give, which in this case differs from my wish: to understand people's lifeworld, I do not find the in-depth interview adequate in order to gain sufficient knowledge to answer my research question. On a personal note, the in-depth interview calls for experience, at least in order to carry out a successful interview, an experience and skill that I do not impose. However, in between the two mentioned interview forms we find the semi-structured interview. This approach is to Kvale defined as: *"an interview with the purpose of obtaining descriptions of the life world of the interviewee with respect to interpreting the meaning of the described phenomena"* (Ibid p. 8).   This purpose fits well into my research, and I therefore

expect this interview form and the interview guide, to capture important aspects of the social effects and the norms which rules in the field to step forward. I have in the guide carefully selected the questions which I will get back to. This, as a semi-structured interview will leave room for questions to be asked and answered and leave me the responsible to judge whether I should commit fully to the guide, or if follow-up questions will be both informative and appropriate.

When looking towards the actual interview guide, I have done research in order to make sure that the questions asked, also are the questions that are most likely to provide information that can help my answer my research question, and not spontaneous or randomized conversation as mentioned previously.

Kvale offers a seven-step guide towards an interview inquiry, which I find relevant to follow in order to ensure that I embrace some of the standard rules that Kvale argue exists (Ibid p. 33). Kvale emphasizes the fact that the quality of the interview of course rests on the technique of the researcher, and I am here well aware of my potential lack of competences and therefor acknowledge that I should make use of any help I can get, especially as most of my empirical data rests on these interviews. Firstly, Kvale speaks of the purpose of the investigation. This should be well identified and formulated. The way to do this is by answering the questions *Why* – reveals the purpose of the interview. *What* – gathering knowledge of the topic, and *how* – relating to the approach I chose in relations to theory, interview technique and analysis.

The 2nd. Step is the design phase. This phase embraces all seven steps before beginning the actual interview. In short this step can be described as obtaining the intended knowledge including the creation of the interview guide (Ibid p. 35).

3rd step referrers to the actual interview being conducted based on the interview guide from the previous step.

Transcribing the interviews are the 4th step, preparing the data for analysis, leading to the actual analysis representing step 5. This step includes choice of method to analysis, which is naturally based on the purpose of the interviews.

Once the analysis has led to findings, these are to be validated as a part of step 6. This includes viewing the validity, the reliability and the generalizability of the findings. Finally step 7 leads to reporting, referring to the findings presented in a form that lives up to specific criteria and resulting

in a readable form, which in this case equals my thesis. In the paragraph to come I will dive into step 1 and 2, as they are to one's revolving the actual interview. Step 3-7 are the report as it follows, I will not explicitly elaborate on how each step is followed as this is the underlying progress of the thesis, however I will comment on the categories of relevance as it occurs. 3

### *Step 1-2 applied to thesis*

Step 1

The purpose of the report is extracted from the stated research question. When investigating the elements *meaning, competences and materials* I am thus seeking for an understanding of how SOPs are practiced by the different informants chosen. The research purpose therefore requires more structured interviews than for example interviews seeking to investigate a life history such as biographic interview (Ibid p.38).

In regards to the knowledge of this topic, Kvale argues that the *what* involves *"developing a conceptual and theoretical understanding of the phenomena to be investigated in order to establish the base to which new knowledge will be added and integrated"* (Ibid p. 39). Applied to this thesis, the pre-obtained knowledge on the subject to be investigated originates from different platforms. Overall topic of this thesis is built on an interest and wonder on my part. Since September 2018 I have been in Novo Nordisk, more specifically the Bagsværd production Site. I have worked together with project people towards the route of a more agile and simple training of employees[5]. This work has led me into a world of practises where I find there to be as many ways of 'doing' SOPs than there are employees. Many areas of work are based on requirements from health authorities, the government, environment and so forth, and I therefore had an initial expectance of the way training was conducted, was to 'live up' to demands from crucial authorities which Novo Nordisk Bagsværd depends on

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[5] Every employee is trained in everything from correct use of gloves to the more critical area of insulin production like the training of correct handling of machinery and products. All together there are a number of 600 SOPs, Job Description Plans and practical training sessions.

I have now explained the purpose of the interview as well as the knowledge I have obtained in advance on the matter to be investigated. To round up Kvales 1st step, I have in the paragraph above answered *how* I will draw on Social Practice Theory in order to formulate my interview question, just as I below elaborate more on the specific formulation of these. This brings me to step 2.

Step 2

I have designed the interview so that I can interview both SOP owner, Area Training Supporter as well as an actor with hands-on knowledge. The reason for drawing on multiple interviews with different actors within the field of training is to understand the different ways of working and thinking I see when practicing SOPs. In regards to the number of SOP owners and training supporter I will have to investigate, is will have to rely on Kvale's assumption that I will have to "*interview as many subjects you necessary to find out what you need to know*" (Ibid p. 43). As stated I have my area of focus which limits me to three SOP owners however, I will strive to interview the correct number of subject till I have found a foundation for my conclusion. In line with this, I am aware, that too few interviews are unlikely to provide me with generalizations and too many tend to limit the time necessary to conduct a thorough analysis. Giving the timeframe of this thesis I expect a blend of Sop owners, Area Training Supporters and a more hands-on informant to provide me with sufficient data to conclude on the elements and practices present in SOPs.

### *Conducting an interview guide.*

In regards to my interview guide, I once again leaned towards Kvale's argumentation of scripting the interview. I find this of absolute relevance, both as a structure to overcome the interview as a whole, but also as a reminder of what to look for as researcher besides asking questions and paying attention to answers in order to follow up. These additional attentions point I will get back to.

On an overall basic, Kvale makes the argument that the first few minutes of an interview are of great importance. I order to make people comfortable and safe in expressing themselves freely to a stranger which in this case I am. Approaching people fast and yet in depth is not new to me, as I have drawn on the same characteristics as a midwife: establishing good contact by attentive

listening, showing interest and respect towards the person as well as the subject, all with an appearance of calmness, concise and the overall appearance of being in control (Kvale 2007, p. 55).

In terms of *briefing* the subject, meaning setting the stage for the interview, letting the informant in on the purpose for the interview, I have chosen to do so up front. I will naturally ask for permission to tape the interview, and let the informants know that they can ask any questions they might have as we go along. Once the questions have been asked and answered, I will *debrief.* In line with Kvale's thoughts, I find it relevant to both sum-up, providing the informant a chance to comment on the feedback I will provide him/her, but also to assure the informant in the fact that he/she has been very open in terms of own feelings, experiences and so forth. According to Kvale this open talk and ideally safe room to share one's life world can leave the interviewed feeling empty since the information is primarily unidirectional (Ibid 56).

The additional attention point mentioned above are areas to be considered in parallel as these too add meaningful information to the end result(Ibid). These are body language, facial expressions and the like, which obviously will not be transcribe able but yet potentially important for the meaning of the answers. I will after each interview therefor prioritize to note down any immediate impressions that may provide a valuable context for my following analysis.
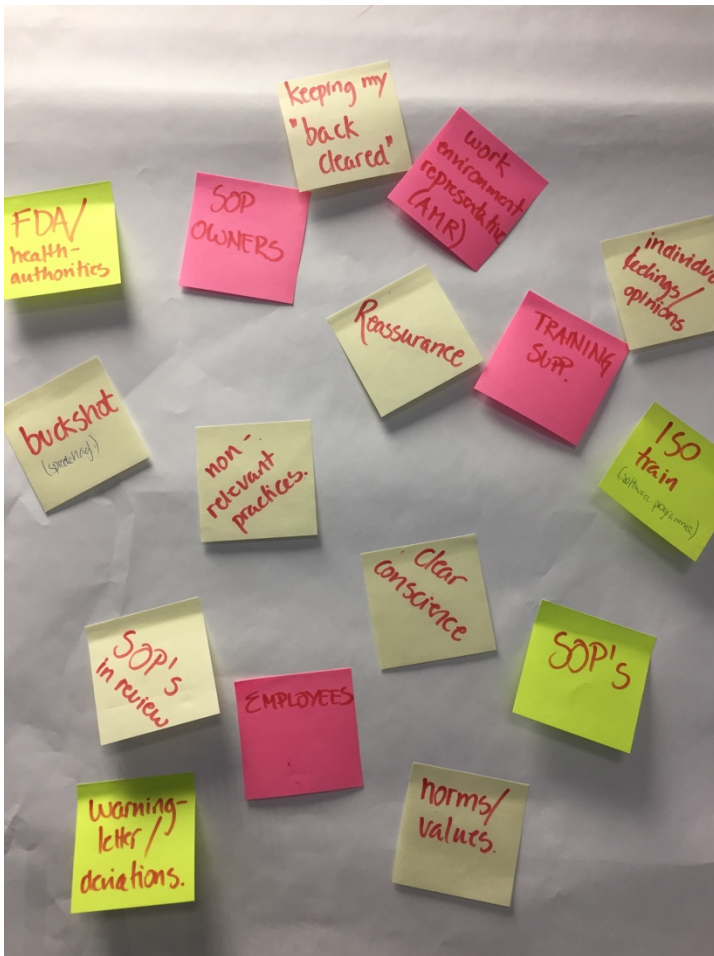
*Figure 5: Messy Map conducted on the premises of Clarke 2003*

The topics to be covered in the interviews are based on my fieldwork as mentioned previously. As a part of working towards a focus of my research, and putting words to my wonder I have conducted a messy map. Inspired by Adele Clarke's Situational Map, I mapped human actors (pink post-its), non-human actors (green), discourses (yellow) as a way towards defining different types of elements which all have in common that they are represented in the field of "training" and the premises behind it[6]. As Clarke argues, the dirty and messy map is "*more or less a brainstorm exercise*" (Clarke 2003, p.87), to keep the resulting elements present, emphasising their meaning as they nourish the field with a key towards understanding and openness.

I did the exercise in two minutes, writing down the elements as they occurred with my research purpose as the header. The map has helped me towards an understanding on what, how and why I should investigate further.

The elements from my messy map has helped me towards conduction my interview guide. According to Kvale the interview guide may very well be structured by chosen topics, in this case some are the elements from my messy map, which helps me think in formulating my questions. Kvale offers the opportunity to conduct two guides: One with the projects thematic research

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[6]Later this perception changed, which I will confront late in the analysis sum-up.

questions, being questions relating to the *what* of the interview, and one guide with interview questions addressing taking both thematic and dynamic – addressing the *how* in the interview - dimensions into account (Brinkman and Kvale, 2015, p. 58). Interview question can quickly become abstract, creating a somewhat distance between me and the informant. Instead I have strived for asking more everyday easy-going language *"providing thematic knowledge and also contribute dynamically to a natural conversation flow"* (Ibid).

### *Construction of an etic question*

At first glance the construction of an interview guide – the construction of questions that would let me into the lived worlds of the informants – seemed straight forward. And yet I find that my first few attempts to an interview guide results in much to closing questions with my preunderstanding and the expectations to their answers permeating the guide. These difficulties have resulted in a detour towards Spradley's guide towards descriptive questions. The first attempts to an interview guide meant that questions and answers were separated in what Spradley would call two different cultural meanings systems, whereas the goal of ethnographic questions is thus to: *"begin with the assumption that the question-answer sequence is a single element in human thinking"* (Spradley p. 79), meaning that the questions I ask draws on my cultural meaning system and the answers comes from the subjects cultural meaning system. This leads to distortion as Spardley argues, and instead I am searching for a question-answer approach that will: *"offer informants a frame and canvas and asking them to paint a word-picture of their experience"* (Ibid). But how does one ask questions that does not give you a standard and potential boring answer, placing the informant in a box that he/she would have to stick to for the rest of the interview? Neither should the questions be coloured by any biased perception of the role that SOPs play, but instead give access to more open and descriptive answers. I found myself struggling quite a bit with the construction of these questions and therefor, as already revealed, looked towards Spradley's take on the ethnographic interview, as he gives a somewhat specific outline to how the researcher can conduct and ask descriptive questions, which according to Spradley: *"forms the backbone of all ethnographic interviews* (ibid*).* In order to ask about routinized activities I as a researcher need to know, that the

informant does in fact carry out this practice. In this case, I have chosen people who I know work with SOPs as mentioned in the paragraph above.

The overall headline – descriptive question – Spradley divides into different categories: Grand-tour Questions, Mini-tour Questions, Example Questions, Experience Questions and Native-language Questions. Each category applies to a certain setting, or cultural scene as Spradley argues, and the answer then again applies to a certain (new) kind or category of descriptive questions.

The Grand-tour questions for the most part take its starting point at a specific location or other aspects such as time, objects, activities or the like. A descriptive question including the aspects of activities could be: *"Could you describe all the different areas of knowledge, departments and equipment you use in the construction of an SOP"?* I would with this question expect a description of substantial features within the cultural scene I am investigating. As I am looking for these routinized practices that the informant may not even be aware of, it would be relevant to draw on 'Typical Grand-tour Questions' like "*could you describe a typical process when constructing a SOP?*", as this asks the informant to generalize and address the patterns that are present in these practices, invisible or not (Ibid). Another Grand-tour question could be that of addressing the most recent practice or event in regards to the cultural scene, asking specifically to the work of the review of SOP X or another specific activity that I as a researcher know takes place. This could be of relevance should one of the SOPs be in need of a review.

Mini-tour Questions are often follow ups to Grand-tour Questions as they address an experience or practice but in much smaller components than the answers to Grand-tour Question. Spradley argues that these follow-ups can be sneaked into any interview, leading to detailed, actual practices (Ibid). In my case I could ask a Grand-tour Question like: "*I have never participated or been in on the work of a SOP, could you describe to me all the things that happen in the construction of a SOP from the moment you find that you need one, through the process and till it's in the system"*? The answer might entail the necessity of other departments joining the work, and I could follow up with a Mini-Tour Question like:" Can *you give me an example of why department X needs to be involved, an example of their role in this work*"?

Native-Language Question are the last of Spradley's categories within descriptive questions. These questions are designed to obtain the language of the native, which tells the informant that I as a researcher want to, and is eager to learn his/her language. This speaks well into Kvale's point of
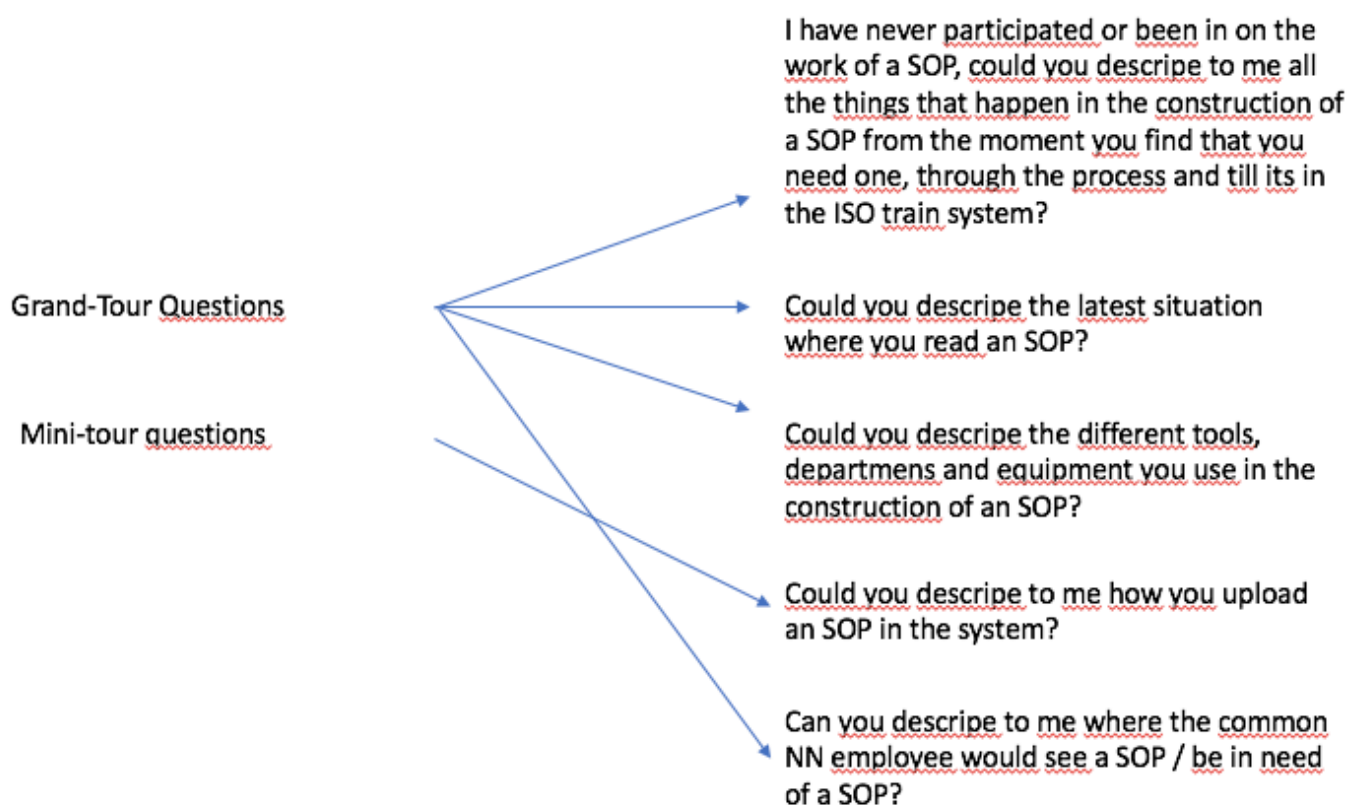
making the informant comfortable as mentioned above, and like Kvale, Spradley suggests that they are woven into the interview in its early beginning (Ibid).

On this basis I have gone through step 1-2 of Kvale's guide, step 3 equals the actual interview just as step 4-7 follows throughout the thesis. Below is the conducted interview guide, which I have worked my way towards through Spradley's guide.

With these question I have been meaning to express cultural ignorance. By placing myself in a position where I now the term of SOB owner exists, but I'm unaware of what it actually involves, I pave the way for the informant to provide me with an ethnographic explanation (Spradley, 1979 p. 61).

### *Table of research & interview questions.*



Grand-Tour Questions

I have never participated or been in on the work of a SOP, could you descripe to me all the things that happen in the construction of a SOP from the moment you find that you need one, through the process and till its in the ISO train system?

Could you descripe the latest situation where you read an SOP?

Mini-tour questions

Could you descripe the different tools, departmens and equipment you use in the construction of an SOP?

Could you descripe to me how you upload an SOP in the system?

Can you descripe to me where the common NN employee would see a SOP / be in need of a SOP?

**Pilot Interview**

I have little experience with interviews and for multiple reasons I conducted a pilot interview. According to Spradley, these 'practice interviews' can *"help reduce the anxiety that all ethnographers experience when they begin interviewing a new informant"* (p 28). My helpful colleague Sofie, both happens to have time to spare in her schedule and has a thorough knowledge of SOP, plus she owns a few herself, why I would presume that she could both answer my questions and contribute to the findings.

To reduce this anxiety that Spradley speaks of, he offers three tasks for the ethnographer to follow: The first task is thus the practice interview. The questions that I asked her are identical to the table of interview questions above. I recorded the interview with her acceptance, brought with me my laptop where I had written down the questions. The 1. question – the grand tour question worked just as such. It opened up to a world that Sofie was familiar with and the question therefore made sense to her (Ibid p. 86):

*I have never participated in an SOP process. Could you describe to me all the usual things that goes on in a typical construction of an SOP from the moment you find that you are in need of an SOP, until it is in the ISOtrain software system?*

ISO train is the software system that embraces the SOPs. If you have not read an SOP it will appear with the text 'missing'. Once you have signed for having read and understood, the text changes to 'taken'. Each SOP is put in ISOtrain with a number of grace days for reading. Should you pass your grace days, the text changes to pass due as a sign of being out of Compliance.

Spradley would categorize this as a Typical Grand Tour Question. It asks the informant to generalize in terms of what is a typical SOP construction, and which things such a construction usually is composed of. Besides the generalization of a SOP process, the question in general encourage Sofie to simply say anything connected to a SOP process. I have stated that I have no knowledge of the topic, and thereby urge her to enlighten me. What happened was, that Sofie started mapping the process. As it turns out, the actual writing process of the SOP is the last thing that takes place. Prior to this step is a number of steps and stakeholders who represent each of their field of importance. To visualize this, Sofie started grouping her hands first at the table on her left, then in the middle and

finally navigating between the different invisible clusters she had made with her index finger. As a part of Spradley's 2nd. task: "*identify in writing the skills you managed well and those that need improvement*", I thought of another specific type of Grand Tour Questions, called the Task-Related Grand Tour Question. Spradley argues that once informant draw or perform a task while answering a Grand Tour Question, it gives the ethnographer the opportunity to ask along the way, just as I did with Sofie as she drew the process on the table. I asked questions like: "*I thought QA[7] weren't active until the end where they accept or decline the finished SOP"*? or "*This person her* (pointing at one invisible cluster she had made, representing the SOP writer), *can he be the same as this person her*? (pointing to another cluster). As a part of Spradley's 2nd. task, I have therefore decided to bring A3 paper and pencils for the next informant to map what has turned out to be more of a stakeholder-process than an administrative process.

Another thing that needs improvement, which I believe can be solved through this mapping tool, Is the fact that I felt a little stressed when Sofie answered. These answers offered multiple opportunities for further investigation, being the Mini-Tour Questions mentioned previously. However, as Spradley argues: "*Because Grand Tour Questions lead to such rich descriptions, it is easy to overlook these new opportunities*" (Ibid p. 48), which is exactly how I felt. In order to not forget and miss these opportunities I started taking notes on the laptop I brought along. This led to however, a feeling of losing the connection to Sofie a little as we sporadically lost eye contact. With pen and paper and the possibility to draw, I think I will have a better chance of remembering these little golden seeds that informant reveal during a Grand Tour Question, and thereby the chance of not missing the opportunity to follow up with a mini tour question.

Other things to improve was the 4th. question. Asking how a SOP is uploaded and made available to employees provided me no descriptive and valuable information, as the process is simply placing the document in a software folder and connecting it the its practical training if any needed. I have therefore deleted this question for the interviews to come.

Though I have written the questions in my interview guide based on Spradleys introduction to an ethnographic interview, I have come to realise that my questions are hybrids of two of more of his categories. My Grand Tour Question opens up for Mini-tour Questions of both a general and task-related sub category, just as Sofies answers gives me knowledge to later use the native language

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[7] [Quality Assurance]

even though the question initially was not designed to obtain this knowledge. I feel comfortable with this strategy; sticking to my interview guide in a way that my Grand Tour Question makes the informant *ramble on and on* as Spradley says (Ibid p. 86), providing me with information on which I base my mini torus questions a long with the predefined questions of my guide.

The pilot interview resulted in 50 min on record, however the actual interview guide was completed after 25. This amount of time suits me very good, as Sofie stated: "*I don't think you get people to set off more than half an hour in their calendar*". As I have approached the informants I have felt good when only asking for 30 min of their time, as I was under the impression that a long term interview would keep some from participating.

I expect the interviews to provide me with a number of cases, with which these selected informants think with. Or put in another way. These cases that I expect to extract in my analysis, they will bring with them a number of explanations towards how people in Novo Nordisk think and view this phenomenon and its practices. As a closing remark the interviews have all been transcribed. This has helped me towards an overview before conducting my analysis which is primarily based on text material, just as I believe gesticulations are of relevance when wanting to communicate a story.

## Analysis

I wish to investigate a phenomenon within work life, and I therefor prioritize to investigate and examine specific situations where this work is being done in a day to day situation. Or put in another way, I want to understand the phenomenon based on the actor's concrete activity and "doings" (Buch 2017, p. 38). The understanding of a phenomenon like SOPs, must therefore be done by understanding how the different actors "do" SOPs.

My analysis is built around different practices where this is done. These practices I have scrutinized my way towards, by mapping and analysing my empirical data. My methods for collection data on SOPs have provided me with extensive material to be investigated. The data supporting my analysis is built on interviews and the transcribed data derived from those, field notes from ethnographic observations and meetings. I have worked with this data within the theoretical framework I have presented.

I have chosen to present my analysis through four stories. Each of the stories below are told by employees of Novo Nordsik Bagsværd. The informant all have different titles and jobs, and yet they all work with, by or are surrounded with SOPs in some shape or form. The stories will provide a contemporary take on SOPs. Together they reflect upon the elements which is embedded in the practices.  My intention for presenting the analysis this way, is that around or on top of the common understanding of an SOP, lies embedded in an individual agenda, practices and reflections on SOPs and how they are being 'done'. These embedded factors may reveal underlying aspects which, if they are taking into consideration, will provide a positive outcome in terms of changing the way SOPs are work with and thought of in terms of implementing a new concept of teaching and training.

**Huub, the Driving Teacher Strategy**

Huub 55, once the youngest driving teacher in all of the Netherlands, today one of Novo Nordisk's greatest assets within training of operators who work the filling line. Huub has been a long for the journey, from expansions in Clayton and Monte Claros to major layoffs in 2018. With a charming accent and a great calmness Huub sets an honour in teaching his operators the finesses of working with insulin production. He does so by his own mental playbook.

For interviewing Huub, I arranged to meet him inside the production site. Huub works on the filling line, filling the insulin into vials or penfills - the holiest of the holy chapels within all of Novo Nordisk.  This requires him to gown in an extremely specified order before beginning his work. This practice alone is described in four SOPs, two e-learnings, a practical training and a security round before entering the area. Should Huub step out to meet me, would require an inexpedient amount of time as he would need to change three times to meet me and go through the gowning procedure yet again when

The production site is divided into classified areas, covering:
CNC (Controlled not classified)
C (supporting clean area max. 100,000 viable/non-viable particles)
B (maximum of 10,000)
A (maximum of 100).

stepping back into the classified area. In order to simplify what is a quite complex process, an employee like HUUB, hired to work in area A/B is approximately two years along the way: first of,

an operator must go through onboarding, practical training in training factory where mock-up machinery is available, courses on hygiene, sterility, behaviour, gowning, and most importantly the daily operational practice of operating on the line, which is only possible during shutdowns maintenance two times a year (costing 1 million DKK pr. day apart from loss of profits), or actual acute breakdowns.

> Before a product can be launched from any production Site, it must be validated. Is the product validated at one Site, it must be validated again when a new Site opens up, despite the machinery being the same.

In 1994, Huub was hired in Novo Nordisk. He was trained by a skilled operator, who took him under her wings. The route towards being a skilled operator at that time was based on job training[8] side by side all the way. Huub compares it to a general craft unlike a supporter function which often works with administrative procedures and not production procedures. He would start in the washing machine and would stay there for three months until the next new employee would need to start learning how to handle the washer. After job training, Huub and however trained him on the line, would 'maybe' take a look at the document connected to the practical training he had just been through. Huub explains how things have changed since he began his journey towards the classified areas: it is "incomparable" to todays practice. Today SOPs are the binding and essential factor in any training. Before even entering the washing machine or any other piece of equipment you must have read and signed a number of SOPs. Throughout the years Huub's experience has brought him to exotic Novo Nordisk production Sites around the world. This has provided him with extensive knowledge on both product validation, but above all the training of operators. Novo Nordisk has a tradition for guiding people on towards new challenges within the organization if wanted, and Huub has for sure become an essential example hereof.

On a regular day Huub teaches operators from 6.30 till 15.05 were the dayshift turns into evening shift. A fixed routine before being licensed to work in classified areas is 42 SOP's. Unlike in the 90'ies, the meaning of hands-on learning has been downgraded so that more people can be trained more efficiently, sooner and faster. The latest "news of the week[9]" is that an operator can take on

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[8] Sidemandsoplæring

[9] The best news is picked and published in a virtual magazine and monitors around the Site.

specific tasks in a classified area after 10 weeks and not 18 moths as previously. To Huub that has a hollow sound, as operators who have yet to become skilled turn in sick or leave the Site all together due to stress and performance anxiety. Huub has his own way of sneaking operators towards the Holy Grail without emphasizing the importance and significance of each single practice performed by any operator and the effects it may have if done incorrectly. His schedule lies safely in his mind, taking the easiest SOPs first. When having taking out the trash[10] in day one or two, new employees have gotten a sense of understanding of the building and where machinery, lockers etc. are placed in relations to each other. Should the line have a breakdown one morning, Huub sees it as an opportunity: "*It's nothing to me or the student. In between the washer and the tunnel we have a silicone tape; it's just like playing with LEGO. You need to unmount it and put it back on… so breakdowns are good. So really.. it's the machine who invites*" (Interview 3 with Huub, may 7th. 2019). This way of working provides new employees with a greater understanding of the tasks to be handled, yet Huub finds it difficult when too many operators are hired at the same time: "*I lose the small talk with them*". An example of small talk could be the review office. Whenever a typing error occurs, the employee causing the error receives a mail to come by the review office. Outside the office is a '60 inches' screen with name and picture of the employee who typed in the error. This kind of information is not SOP described, yet Huub knows from experience that things like this, new employees would like to know.

Being in Compliance means that every SOP is followed.
Thereby the production is run based on the requirements set by health authorities, which have given Novo Nordisk license to operate based on these SOPs.

To Huub everything of importance is therefore not synthesized in a SOP. When viewing the SOPs as an isolated thing, they have the meaning of being in Compliance: "*As a teacher it means that I must be in control of it* (the SOP). *As an operator it means that I'm not in Compliance if I haven't worked in accordance of the SOP. I have to have read it. If I'm in doubt I must look it up*" (Interview 3 with Huub, may 7th 2019). But to Huub teaching new employees are much more

LEAD time: The amount of time from the product is being formulated until it is released for sale by QA.

than the words in a SOP. It is small talk, it is knowing that you will have your picture displayed on the screen outside the review office and letting them know that it is not meant as an exhibition but a way of creating focus on lead

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[10] Taking out the correct trash to the correct trashcan in the correct manner is described by SOPs

time. As it turns out, typing errors causes the LEADTIME to rise. In Bagsværd today the LEADTIME is 39 days. The goal of 2019 is to bring this number below 30[11], as it stalls the products for release. All in all, this creates ground for loss of customers as the competitors are able to deliver products faster than Novo Nordisk. New employees do not know this, they view the picture as distrust and potentially a way of making a joke out of someone's mistake. The meaning to a new employee of having this picture displayed, is radical different than why the reviewers display the picture – as a try of placing focus on bringing down LEADTIME. To Huub these quite undefinable factors are very essential as he argues that: "*you have no idea of these things. It's a little thing, but it's important*" (Interview 3 with Huub, may 7th 2019).

Should we proceed to view the way Huub practices the actual SOPs in his day to day work as a teacher, I find more aspects of interest. For starters the number of students is of significance to Huub. 2-3 people at a time, is what he describes as 'better'. It gives him the opportunity to practice hands-on on the machines. Whenever the teams are bigger than 6-8 people, he 'loses them'. Huub speaks a lot about an order. How things make more sense when they come in a giving order than when in a random order: "*If I ask you to sew a dress, I will expect you to need a recipe to do a good job*" (Interview 3 with Huub, may 7th 2019). The self-constructed playbook of SOPs that Huub

In Bagsværd there are four lines producing insulin products. Each line has a flow which are:
1. Warehouse
2. Wash & Sterilisation of utensils
3. Formulation
4. Filling into vials/penfils
5. Inspection
6. Batch Documentation Quality Control/Assurance

practices is a way of having constructed the right order. When Huub teaches the employees how to take out the trash, it is because he has an agenda. His mental playbook tells him that, when Mads has taking the trash all the way from within classified area B, to non-classified CNC and down the waste gate, he becomes familiar with both areas, people, behaviour *and* the standardized way of removing trash in accordance to the SOP. When Mads then two days later are asked to read SOP on trash, he knows where, what and how the practice around trash is. He knows the order, and he is able to find his way through the story that Huub has told and showed him through his playbook. The opposite shows itself whenever the teams

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[11] Each year the Sites goalset their Must Win Battles. 2019 calls for 1) reduction in LEAD time and 2) a new isolator to become fully ready for production (glopeshare.novonordisk.com//padges/gsresult.aspx?k=dfp+ba+must+win+battles)

are too big. Huub's playbook is practiced backwards as the jobtraining is challenged with too many people. Shoving a piece of tiny equipment to 8 people within a machine is difficult and takes time. Depending on the machine they might not even have granted access that many at a time due to particles. The result of big teams is a practice where the SOPs are in focus, unlike when the 'machine invites'. To Huub this results in 'loosing' the employees. Just like the African boys who were unfamiliar with drawings in 3D, how can an employee *know what I'm talking about if they've never even seen the washing machine. They don't know if it's in class CNC or A/B*." (Interview 3 with Huub, may 7th 2019). I find that practicing the SOPs in the right order and by his own playbook is how Huub finds his job as teaching and training most valuable.

In Bagsværd there is an increased demand for products only produced there. This has meant that all lines have manned up so that the production now runs 24/7, whereas operators only worked daytime in the 90'ies. The increased demand leads to 10+ employees being hired every month creating the difficulties to Huub as mentioned above. However, the increased demand is not the only thing that has changed in relation to how Huub work with SOPs.

In the 90'ies an operator would work more manually. Inspections of the products were by hands and there were no robots installed to do heavy lifting or sorting. In 2018 the Bagsværd Site was giving two robots for Christmas by the current Senior Vice President. These robots come with huge potential but also a complicated and challenging technology. In fact, all the machinery is more technological challenging than when Huub began his career in Novo Nordisk.

The fact that machines and robots each have been developed and implemented in a production like the one in Novo Nordisk Bagsværd obviously changes the conditions that people work under. The advanced technology requires practical training yes, but it also requires software programmes, an understanding of data and all of this has, ever since technology have made its entrance, required some kind of explanation within the SOPs. This has caused the SOPs to become longer and more difficult to understand, they have become advanced unlike previously.

When speaking of the more complex and advanced technology which has made its impact, I find it relevant to view the third element of which constitutes a practice. In the daily practice of Huub this element is more than just the physical machine though this plays a central role. Huub describes how the 'machine invites' to let people learn during acute break downs or when it needs cleaning.

Huubs practices are hereby built around the machine, so that whatever fits the machine, Huub will fit into his playbook of the day. In find no doubt that this materiality (the washing machine, the filling line etc) present in these practices are directly implicated in the conduct and reproduction of Huub's daily life (Shove et al, 2005, p. 44). Besides the machines I find the SOPs to be of relevance when speaking of objects though SOP are analogue. However, the content of some SOPs does, as mentioned describe complex technologies which is embedded in the physical machines. When having heard Huubs story and understood the way he practices these 42 SOP, I have almost come to see the elements embedded within each other. The way he lets the machine decide and yet goes through the SOPs which he keeps in mind. He has no need to look up the number in QBIQ[12], because he knows them by heart. He knows that when he shows a tiny nut in an intricately tunnel (which is only possible because the washing machine lets him), it will tell a part of the story that the operator will later need for having understood the SOP that it relates to. Somehow the meaning of the SOPs and the materialism of the machine merge into one. This is of course only possible due to the knowledgeability of Huub (Shove et al, p. 23). The story I have presented is almost one historical narration of the Dutch boy who one was the youngest driving coach in all of the Netherlands, but who fell in love with a Dane and became an exceptionally good operator who have become outmost skilled within his field of practice. He has become educated through education, but has also literally travelled around the world to both obtain knowledge and to teach it. His mental playbook is an example of how his knowledge has made him successful in the performance of his practice (Ibid). He does not need to bring the SOPs he does not need to let the SOPs be of focus. He can take the machine up on its invitations, and let it lead the way towards what he evaluates as the best way to practice a giving SOP.

This first story leaves us with the understanding that Huub has the strategy of providing new operators with the correct approach to become skilled. He has developed a strategy of his own, dosing the SOPs in the correct order and in the correct way. As a super-user of this strategy, he ensures to compensate for what the SOPs may lack, and thereby educate operators in what he believes is the correct strategy.

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[12] Library for all SOPs

Huub has been a long for an extensive journey with the organization. Not only has he heard the stories from the 'old days', he lived them. Today the SOPs are a representation of a way to develop and educate operators who he takes under his wings. The SOPs are a guideline to Huub, a guideline of which steps he must go through. These steps he carefully weighs with the machinery and his own reflections on what good teaching is.

I should mention that due to the classified area that the interview happened in, I did not bring pen and paper for Huub for use for mapping his answers. I was not under the impression that Huub, compared to Sofie, felt the need for drawing as his answers were less related to different stakeholder, but more of a life story.


**Sanne, the troubleshooter Strategy.**

Sanne 53 started her time in Novo Nordisk as an unskilled operator 19 years ago. Throughout the years she has worked her way out of the production area and into a supporting role where she supports the overall frame of the production. Sanne is a hardworking woman, not afraid to get busy or even dirty. She is known throughout the Site, without haven worked with Sanne, I know her too, and because of that I postponed my interview with her, contacting the other informants and doing their interviews first as I gathered the courage. However, she took me by surprise.

The second story is thus of Sanne. Sanne works in the facility department in Novo Nordisk Bagsværd. Though she is both physically and professionally placed far away from my department, I know her very well. The story goes that Sanne, though she may be the only women in her department, she is the one with the largest knowledge of her field and the strongest pair of arms too.

On a daily basis Sanne works with Facility and EHS[13] support. This department covers tasks like incident reporting, safety rounds within the production Site and more regular facilitating tasks as placing drying cabinets in the locker rooms for when operators come to work all soaked and hang their clothes to dry. When interviewing her, she had just unmounted an old, no longer functional emergency break along with repair of the wall subsequently. This repair is not written in a SOP

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[13] Environment Health Safety

however the overall standard for maintenance of walls and interior does not allow for changes or deviations for the standard.

Sanne has been in Novo Nordisk for 19 years. She began her journey as a temp for operators, and has slowly moved further and further away from the actual production and is today placed in an office in a building next to it. She goes in whenever needed, for instance when unmounting an emergency break. During a common work week Sanne works with SOPs on more levels. Sanne is SOP owner of three SOPs: Q123428 on Pest Control, Q151679 on Emergency Plans and Q129121 on Waste Management. Within the ownership of these SOPs lies a few things. Back when these SOPs were developed, she along with suitable stakeholders having knowledge and work relations on the giving topic, would get together and discuss the content of the SOP. In this context Sanne shares with me how things like the development of SOPs have changed since she began in Novo years ago. Prior to the standardizations and wielding's in 2016-2017, she would check into a hotel with stakeholders of relevance, and work determinedly for 2-4 days on capturing the right SOP:

"(…) *we never do that anymore. Today we achieve agreement through mails you know?.. I can then comment on contents and formulations. It makes the process more.. øh.. it takes up a lot of your time like this, and it makes you pay less attentions because you go back and forth (…) and then you figure out where in the process landscape it belongs.. the QBIQQ-lists[14].. how the setup is.. that what takes up your time"* (Intervier#4).

Along with how the arrangement has changed for the development of the SOPs, so has the content of them. She explains how she occasionally struggles with understanding what they say. Both as an operator in the beginning and still as a facilitating supporter, where one might could argue that the complexity of the administrative tasks is increased compared to when working as an operator. Basically the language is too challenging to her. Sanne describes how she once brought a SOP on LAF[15] to her English teacher she saw due to her difficulties with English. Though the SOP was in Danish, the teacher through in the towel after four lines declaring the formulations and choice of

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[14] QBIQ: Search database for SOPs.
[15] Laboratory Air Flow (stationær arbejdsbænk med udsug)

words 'uncomprehensive'. Instead Sanne prefers SOPs to be more simple and palpable like the one she had just read herself as it turned out in relation to question 2 of the interview guide.

Some SOPs are more complicated than others, and not just the content but the nexus of parties having a say or needing to be heard. As an example Sanne draws on a SOP that needed review as one or more circumstances had changed since it was first developed. The SOP dealt with a ventilator. The ventilator itself is critical equipment, as it runs into a classified area, but the drip tray at the beginning of it is not. The practice embedded in the SOP is therefore not of a critical character, but the equipment embedded in the practice is. Sanne rolls her eyes as she describes how numerous stakeholders therefore often are gathered in order to assemble all the loose ends.

Besides being a SOP owner, she, as well as any other Novo Nordisk employee, must work according to those SOP of relevance to her work. For Sanne this means that she currently has 129 SOPs in 'taken'. This involves anything from sterile hand wash and security rounds to maintenance of specific rooms with certain cooling or suction equipment. Here, the same applies for Sanne as for anybody else, she must be in compliance before beginning her tasks.

During the interview Sanne tells the story of when the FDA did an inspection back in 2012: "*We painted all the chimneys. But only the half which would be visible to the FDA you know? We got their route, and we painted the part of the chimney that they would be able to see, and we left the rest. It was absolute galimathias*" (Interview 4 with Sanne, may 27th 2019). Prior to this inspection the American health authorities had signed a warning letter where they criticized numerous thing from lack of processes being thoroughly described to procedures missing for review of batches, gowning procedures which lacked information on personnel socks and shoe covers and so forth. The result of this warning letters was what Sanne describes as a 'crazy time'. This crazy time placed its mark on the way Sanne would work. After the warning letter her tasks would be to 'close GAPS'. The relevance or complexity was not as important than whether it was described in a procedure or not. The SOP gave QA something to 'show' to

> **Q**uality **A**ssurance as department has the final say and stamp of approval before a product can be ultimately released for sale.

the FDA. The warning letter from 2012 ended up marking the rest of the interview, as it clearly has marked Sanne and her work ever since. Instead of referring to the year of which the letter was

received, the reference is 'since the warning letter'. Whatever we talked about, it was mentioned in accordance to this letter.

A SOP to Sanne is numerous of things. The story with the warning letter showed an employee who is both conceited to her work, and aware of what is at stake when producing products for human injection like insulin: "*after the warning letter everything had to be SOP written, and sometime you would feel that what you did, brought very little value*" (Interview 4 with Sanne, may 27th 2019). Sanne cares whether she writes SOPs or follows SOPs because there is a need for it, or because the entire Site is in a state of 'paralysation' and has begun to close any potential areas of vulnerability with a SOP. Furthermore, Sanne has a great deal of self-respect when it comes to her work as a SOP owner. The fact that Sanne acknowledge that she finds a SOP challenging, let alone brings it to her teacher testifies that she finds it meaningful to create SOPs to which her colleagues can relate and comprehend. The practice that lies in developing a SOP is another situation which leave a mark on the way Sanne practices SOPs in a routinized way. The fact that the negotiations on content etc. have been moved from actual meetings to distant mails Leaving Sanne with a feeling of being less connected to the development of the giving SOP. It interferes with her other tasks during the day as she must go back and forth, and ultimately she pays less attention, which she does not find satisficing. The reason why Sanne may still be successful in contributing and developing SOPs despite the distanced meetings could be that her spectra of knowledge is wide. She has a built-in knowledge around her specific field of expertise, and she carries herself accordingly without blinking. Her time spent on the Site has giving her ballast, and the journey the Site has been on has giving Sanne perspective. This perspective is expressed as competences within her field or work and she has arguments and data to back it up.

This 2nd story illustrates a different take on SOPs. Sanne 'does' SOPs as a mixture of meetings, mail exchange, administrative work on where the SOP should be placed. Her practice around SOPs are interwoven with a number of objects and actions which are necessary for her to 'do' her thing. Sanne is in that sense a trouble-shooter. Whenever there is a fire, she runs to take it out. Sanne was brought up as an operator in Novo Nordisk. Should I repeat her answers to my interview questions in this thesis, would only to the reader generate further questions to be clarified and confusion at

best. Her answers imply, through abbreviations, quick calculations on the price of SOP writing, not to mention her accurate historical recall of the organization, that she as a practitioner has both practical understanding and knowledgeability.

To Sanne the SOPs become a symbol of a battle which was won in the years after the warning letter in 2012. Her exhaustion on the years that followed 2012 was easy to live through during the interview, and it was clear that there at that time were too many fires which needed her attention.

## Helle, the pedagogic strategy.

Helle works in the department of Novo Nordisk where I am based. It is a squid department covering 13 people who have tasks within training, Human Resource support, archive, procurement, business intelligence and projects across the Site. Helle shares her specific field of work with two others. All of them are titled as Area Training Supporters. Prior to Helle's hiring in Novo, she worked as an auditor, doing inspection in hospitals. As a midwife I remember these inspections, they would turn the hospital upside down in its efforts to present good results within different areas. Personally I have therefore often felt that Helle was a little special as we both know of this hospital-universe. She knows something about being 'on the floor', something practitioners know about but supporters have very little knowledge of.

Due to Helle's prior job, I have found it both easy to approach her, just as I found her answers relevant for my thesis. She does not only write and read SOPs, she also teaches them in a quite comprehensive way. For starters there are no limitation as to who Helle trains. It could be the newest mechanical student or it could be the latest CVP who was hired in the summer 2018. Either way, Helle (and the rest of the training supporters), are the ones to have the overall overview, making sure that people are assigned the correct training and are granted access on the basis hereof. Helle also runs the pilot project. This project is limited to

*Training for Competence* encourage for training to evolve from Read and Understand to actual learning. The concept is compared to a driver's license: A combination of different ways of learning makes you competent in driving a car. (traffic rules, classroom, practical training in different road types, weather conditions etc.). So should Novo Nordisk build up its employee's competences; choosing the most effective and efficient training methods.

four SOPs which constitutes a module. This module is a fairly straight forward module as the number of SOPs are limited and the criticality likewise. The pilot project involves training people in their competences and not in reading a SOP.

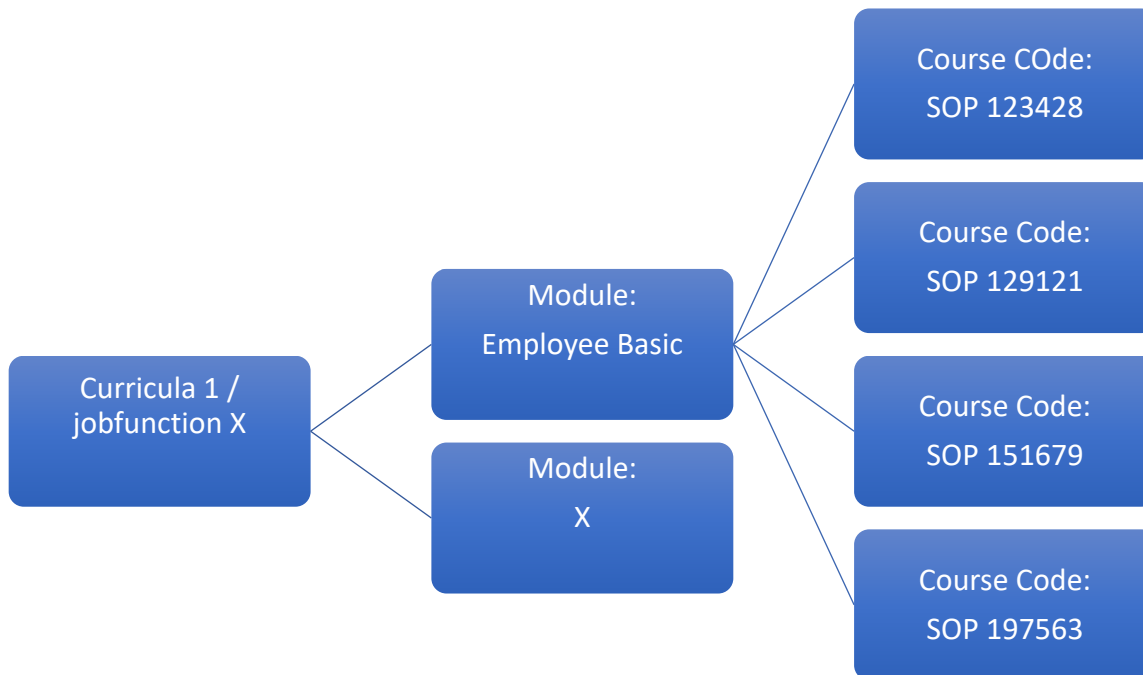To visualize this Road Map, figure 5 shows the setup.



*Figure 6: Road Map to visualise the link between job function and connected SOPs.*

Each curricula consists of a number of modules. Attached to each module is a number of Course Codes which in the end leads to training in the form of a SOP, an e–learning or a practical training always in combination with a SOP. The Road Map is meant to provide a simple and transparent overview where one can couple a job function with a number of SOPs.

As visualised the job function that each employee has, equals a specific amount and extent of modules which covers a number of course codes which in the end is specific SOPs. This Road Map is a lot of Helle's job, which in the end provides her with the knowledge of who should be trained in what. Whereas Huub trains specific operators to become skilled in the filling line, Helle's embraces training in a wider spectrum as she teaches/trains every employee in less specialized SOPs.

Instead of reading only SOPs, the Training for Competence Outline is a document embracing the essential knowledge of the SOPs. These essentials are taught through practical training, tests and games in a combination with more classic training methods like reading and presentation.

The last few month, Helle's daily work has been characterized by Training for Competence, and the extensive planning this requires. I have found her engagement

and loyalty towards her work extensive, which is often shown by late hours and knowledge that embraces broadly beyond her own work area. When the department as a whole fail on a task, Helle often works to set the record straight, and rarely rests until this is done. Presently Helle's days are packed with meetings on conveying SOPs into Training for competence Outlines. This requires explanations and negotiation from early morning till late evening. As an observer in these meeting I have seen how Helle is through the explanation of the concept over and over again. Just as it seems that the agenda have progressed till the actual formulation of the Outline, people (could be SOP owners or stakeholders), return to the concept, not yet fully convinced of its function. In times like this I have found Helle must patience, as she has yet again repeated the foundation and principals of the concept. In these repetitions it has become evident how Helle has been able to draw on her broad knowledge on training

> Shopfloor is the inside of the production site. Every morning an Area Training Supporter visits an area of production as a part of following up on training, spotting needs and in general working on preserving a healthy relationship to operators.

and the administrative structure that lies behind it. Because she knows how the Road Map is built, she also knows the connection and strings between the elements (Job functions, modules, course codes etc.), and how one thing is related to another.

Besides the administrative part of implementing Training for Competence, an area training supporter starts his/her day on shopfloor. As an ATS, Helle has the responsibility of 4 areas within the productions. When a new employee start, Helle tailors a training plan for which SOPs the employee should go through and when. She then follows up on past-due cases and adds SOPs to the training plan as the employee develops. Helle's work is somewhat twofold. Behind the scenes

> Past due: If one does not sign for a SOP within the amount of grace days giving.

Helle administrates structure and coherence between the many hundreds of job functions which are connected to many more SOPs. On stage Helle besides keeping a firm grip in the selection and assignation of SOPs, she teaches them. During my one onboarding course in September 2018, Helle took me, as well as the other new employees through a number of SOPs. As an example she taught us the content of Q139845: Calibration of measuring equipment in DFP Bagsværd. This SOP of 81 pages is about calibration, when it must be done is and how it is handled. Prior to TFC, Onboarding was mostly based on individual SOP reading, beginning from the top of the list. Helle did not teach in this SOP as much as she mentioned that is was difficult and long. She

brought the copies to class and handed them out. Today, after the Onboarding has been through Training for Competence, the essentials of the SOP have been extracted. In a nutshell this means that the 10 lines that describes how 1st what a calibration label looks like, and 2nd if the label looks torn of worn the employee should inform his/her manager to have it replaced. The rest of the SOP is for specialized employee, who will be taught accordingly. Now Helle takes employees from Onborading to the training factory to show them these labels, what it looks like when approved, and what it looks like when not approved. Helle herself does not know the entire content of the SOP, as she says herself:

*"no one can remember the whole thing.. basically we forgot the entire foundation of why we have SOPs in the first place.. it is to.. from those SOPs you get the bigger picture and then you can combine it with practical training so that you achieve the competences necessary"* (Interview 2 with Helle, may 15th 2019).

This quote is the head of the nail as to why implementing TFC is justified. No one can remember 81 pages in details, this specific SOP does in addition contain information on high tech equipment. Just as with Huub's operators and the African students, one cannot read their way towards understanding calibration equipment if they are not familiar with the functionality and purpose of it. I myself had no luck in interpreting my way towards a complete understanding of the SOP. Helle is no different, she sees the gap of competences and works on implementing more simplicity and accurate training. This is evident in the way Helle describes how it, more often than not, is academics writing the SOPs. A SOP described in 100 pages, Helle estimates 2/3rd. to be purely noise and 1/3rd to be of actual relevance to the operator. Recently, in connection to Training for Competence Helle has, on her own initiatives gathered SOP writers, team leaders and operators to, in plenum, talk about the consequences of the complex SOPs: *"it's been nice to see how the leaders are partnering up with the operator, taking on the challenge with the supporter. That's really nice to see.. and I think this is where we can make a difference"* (interview 2 with Helle, may 15th 2019). Helle then goes on to talk about how a part of this process also is to qualify the supporter. Having them to understand the point of adjusting their language and complexity level and thereby adjusting their way of working all together.

During the interview Helle three times answers how it is 'tradition' that have made the SOP's to what they are today. During her own Onboarding three years ago, Helle was overloaded with SOPs, many without relevance to her own area of work. Back the Helle took on the task and challenged the allocation of SOPs. She did so based on her own previous work: "*So.. I come from a position where I was auditor myself, and we would only do something if it was of importance.. (…)I had the impression however, that others had tried the same thing but threw in the towel because they never got through.. *" (Interview 2 with Helle, may 15th 2019).

This story provides an understanding of Helle's work with and around SOPs. When viewing the SOPs alone for what it is – words on a piece of paper, Helle may not interact with it much. But to Helle a SOP is much more than 81 pages of text on calibration. It is a Road Map of the structure behind it. Jobfunctions, modules and course codes. All leading to specific SOPs which are connected to the individual employees and their work. SOPs are, to Helle, especially about providing meaning and a feeling of tangibility for the individual. When she finds the meetings between operators, their leaders and process supporters of great value, it is due to the difference that Helle finds that these meetings make. They are the foundation for knowledge shared across jobs, which according to Helle is 'gold worthy'. There is an obvious catch as LEADTIME may be reduced, but besides that Helle finds that the entire workflow will be based on individual competences and not expecting the impossible of people.

I cannot say for certain that Helle's past as an auditor makes her more confident on deliberately questing procedures she finds unjustifiable, but the answer above tells me that she is a skilled employee, who does not simply work by the procedure, but questions them when she finds it rightful. Unlike Helle, I, when I participated in the same Onboarding programme did not question much. Yet I felt the workload heavy, and quite understandable too. I participated in Onborading with a positive intention, but I lacked the skill or knowledge to understand the practices embedded in the Onboarding. A part of the new training concepts that Helle runs, is exactly to scrutinize some sort of range of competences perceives as necessary for participating in this specific programme. Another competence connected to this is the fact that language is essential. The SOPs are written in Danish, as many operators read danish and danish alone. Yet more and more foreigners apply and

are hired, creating them some obvious difficulties when signing that they have 'read and understood' the giving SOPs formulated in a language they have no knowledge of.

The reason that Helle has even landed where she is - a place where she is comfortable with challenging the tradition of anchoring big and small in a SOP, is thus of her past. Qua her former position as an auditor, Helle brings with her a courage: "*it didn't take me long.. from I started to wonder.. but I can understand why others can't even remotely begin to comprehend to say something*" (Interview 2 with Helle, may 15th 2019). The reasoning is that unless you come with a certain ballast you a likely to be overwhelmed by the amount of knowledge, reading load and Novo Nordisk abbreviations, causing the wonder to stay as just that.

With this 3rd partial analysis I have presented yet a story on how different practices and agenda exists around the phenomenon of SOPs. Though Helle is a training supporter of title, she does not make much use of the SOPs in its physical version. To her SOPs are the result of a Road Map of a larger structural web. Helle would like to have standardized job profiles with connecting SOPs. To Helle, SOPs should provide tangibility and structural coherence between the job you are hired to do, and the practical tasks of you daily performance. Her desirers of creating more structure with the Road Map makes her have strategic ambitions for the Site when it comes to SOPs. In Helle's opinion there is currently an old and inherit system around SOPs, and her practice around SOPs is an attempt of reforming that system. She does so by introducing pedagogic tools for applying practical practice after having read a SOP. To her SOPs are thereby an object towards gradual organizational reforms.

**Sofie, the technical strategy.**

Sofie at 28 works in my department. More often than not people from all over the Site stop by Sofie to ask her something. It may very well be outside her work portfolio and yet she knows the answer. She hardly ever touched the mouse when working but works her way through excel sheets and dashboards solely by the use of hotkeys, and in general, she provides people with more help than they knew, they were in needing.

Sofie is a relatively new educated engineer from 2015. The first two years of her professional life she worked in the Danish dairy group ARLA FOODS, and then later signed with Novo Nordisk.

Sofie represented my pilot interview, however I fund Sofie relevant to interview based on a number of things. For starters Sofie is what I would refer to as the (new) technological generation. She automatically thinks in effective solutions, suggestions for improvement and have learned me the meaning of process confirmation, data visualisation and macros in excel. When I first started my internship, a robot to sample particles was just installed for trial. Within my department is was a well-known joke, that Sofie was never seen as excited as when that robot was delivered to the building. This image of her fits well into who she really is. She is an employee driven by improvements, she lights up when things are done in an innovative and optimized manner, just as she is a little saddened when she does not feel colleagues having pride in their own work. Sofie starts her day with updating different tools which track a number of things. It could be how many employees are in past due on the Site, or a tool she made herself, keeping track of task to be completed within her department each day.

The fact that she works so much with data and technology makes her interesting in terms of the practices around SOPs as these are often manually handled. The SOP in itself is manual in the sense that it is printed, signed and scanned to be archived both physically and digitally. This practice alone Sofie has a hard time not having an opinion of. The other informants may find the practice of writing SOPs as challenging language and with a detail level that is inexpedient, but Sofie's mind-set is different as she thinks of digitally solutions more than anything. The process in itself; printing, signing and scanning the SOP could very well be digitalized. It is not easy, but it is durable. This durability is what drives Sofie. The opportunity for optimisation and improvements.

One of her projects is just that, digitalising the process of signing and archiving the documents. Embedded in this process lies dividing the documents as 'what they are': "*Is it an SOP? There's also supportive guidance, procedures both globally and locally, there's job instructions and there's.. I don't remember how many but there's so many different…*" (Interview#1). Sofie has, tough she has been in Novo Nordisk quite briefly, seem how information as a broad term, have been anchored in a SOP. This confuses her, as the content of an SOP, should come from a need – as also Sanne explained above. However, to Sofie any kind of information, regardless the need, is anchored in a SOP.

As with the other informants, Sofie reads the SOPs assigned to her in order to be in Compliance. With this said, Sofie does not work directly with SOPs. Indirectly however, she is involved with them in a number of ways. Whenever a SOP is changed, the owner of it must decide if all the employees assigned the previous SOP need to read the SOP yet again based on the changes made. Depending on the changes, the owner can demand a revision or he/she can simply replace the now outdated version with the new. To put a few numbers on how often this happens I have done a small survey. The SOP's involved with the pilot project of Training for Competence involves as mentioned four SOPs. These have been changed 18 times all together. All changes but one, were put in revision for everyone the read. Examples for changes could be that the department 'FM Maintenance' was changed to 'Facility Management' throughout the document. It could be a deletion of a paragraph (leaving the remaining document unchanged), combining two paragraphs to one without changing the actual content is another example. The fact that the SOPs are viewed as having 'revision status' rests on a software programme solution. This is where Sofie comes in. She handles new editions of SOPs, assigns people in ISOtrain and dives into the content whenever it requires her expertise within data and software. As an example, Sofie does not own the SOP on door access, but she handles the way we are in control of who has access to what. The overall overview is based on the Road Map mentioned above (Job Function equals specific modules containing specific Course Codes leading to different SOPs). Sofie makes sure that the door access is actual granted, and thereby works more often than not, as the link that closes the gap between ISOtrain (what people are allowed to, based on having read their SOPs), and the actual access whether it being doors, IT access, surveillance TV or others. Sofie's daily work does as implied not involve a lot of SOP handling

> Deviations cause increase in LEADTIME, as a product cannot be released for sale until released from Quality Assurance. Many deviations are caused by operators doing typing errors or missing a field of signing all together.

in the sense of working with the SOP in terms of formulation the content or teaching it. Instead Sofie handles the consequences of the SOP, understood in the sense that for instance this summer, production will close down for maintenance for three weeks. During those weeks 400 craftsmen will enter the Site to work. These 400 men will need training in behaviour and safety among other things, and this training will give them access to enter doors. This is Sofie's job. This job is thus implicated in SOPs, but as a part of its

consequences or function and not its content as such.

To Sofie the consequences of the SOPs are of large significance: *"(…) but the problem is, as soon as the SOP exist and we don't live up to it.. them we're out of Compliance"* (Interview with Sofie, may 10th 2019). Whenever a SOP is created but not followed, it becomes a compliance issue. This leads to a deviation as explained in Helle's story above. The same goes for the other way around. A department may have developed a better and more efficient way of handling a process, but is the SOP has not been updated so that it describes the process, one is still working out of Compliance.

GXP relevance: whenever product quality is involved. Example: SOPs on behaviour inside production are of GXP relevance (do no lean on thing, do not sneeze, do not high-five etc.). SOPs on how to purchase coffee is not of GXP relevance.

In fact, SOPs are initially meant for things/needs that are of GXP relevance, and the rest for a user guidance or a regular job instruction. The initial purpose of the SOPs, we find if we return to the story of Huub. He began his days in Novo Nordisk with job training on the different machines. Back then not much were anchored on paper, which in time opened up for the possibilities that operators were taught differently depending on the colleague who trained them. When producing medicine this is obviously not preferable. This led to the initial need for anchoring a process on paper, which have later been known as a SOP. Instead of keeping the SOPs to processes which can be linked directly to the quality of the products, Novo Nordisk today anchor any process in a SOP.

To Sofie this displacement of needs (processes where the product quality is potentially compromised versus any processes regardless its relevance towards the quality of the products), weighs heavily in her relationship to SOP:

*"(..) and that's what's so funny.. cause most of what it says.. we're for freak sake not born yesterday.. but we are when it comes to Novo Nordisk, because so much of what it says applies for the real world too: Stop the injury, call for help, don't be an idiot.. It's so funny that you.. the first page should at all times just say: the rules that apply outside Novo Nordisk apply inside as well"* (Interview 1 with Sofie, may 10th 2019).

To Sofie this way of over processing is wrong, and it strives against her own beliefs on what SOPs are and what they are meant for. During the interview Sofie would say "I just love it", being obvious

ironic when referring to the way SOP are used around the Site. Each quarter year some SOPs are put in every employees ISOtrain. The content has not changed, but a deviation should always lead to a corrective action, and more often than not, that corrective action is a repetition of the SOP. The same Sop that is. As an example the SOP on not bringing your private phone into classified areas are placed in peoples ISOtrain four times a year, as a consequence of people still bringing their phone. The content of the SOP is untouched, but the frequency of how often it's read is increased. It is this reasoning that Sofie finds challenging, and she finds is hard to legitimize the value of that strategy to a new employee like myself.

Instead of living with the pitfalls existing within SOPs, Sofie works from an understanding that by cultivating the technology, things can be improved. According to Sofie, the SOP practices should be scrutinized for ways to be improved by technology and systems. Instead of adding more sentences to a SOP, or increasing the frequently, Sofie's strategy is to fix the problem all together and not simply work around it.

## Sum-up

With this forth perspective on SOPs, I have presented different ways of practicing SOPs. It provides us with an understanding that SOPs are a fusion of practices to different people. For all four informants they must read and sign for the SOPs put in their ISOtrain. These SOPs are essential for their work understood in the sense, that above all, one cannot work if not if out of Compliance, and Compliance means that one's SOPs are signed for.

Besides this overall demand of being in Compliance, the four informants have different agendas and practices built upon SOPs.

The analysis shows how different actors practice SOPs, with the use of Shove et al. three elements *meaning*, *competences* and *materials*. In fact, all the informants are depending on this three-fold in order to practice SOPs the way they are here practiced. In this organization of SOP practices, I thus see a clear coherence between the theoretical framework and the empirical material of this thesis. What is especially prominent is the fact that all the informants have their own strategy in the way they practice SOPs. This is, in itself noticeably as the way to handle a SOP (as a document) is the

same to everybody: once read, you sign for having read and understood. Simple as that. However, as the analysis also shows there are many different ways of practicing in order to work around and challenge what at the surface seem simple.

Sanne is a trouble shooter. Wherever the fire has broken out, she will go to take it out. Huub's strategy is to provide competent and metor-like teaching, to ensure that the SOPs do not do any harm. His strategy ensure the correct dose of SOPs at the right time for both the machine and the practitioners. Helle teaches as well, but her strategy is more pedagogic. She adds practical training as a mechanism before the SOPs turn into damaged goods. Her strategy can be equating with Huub's though with the twist that Helle has ambitions for the strategy to become an embedded educational tool. Huub has no such desires, he simply strives for the best possible outcome. Sofie too has strategic intentions. She works each day to improve and challenge the way SOPs are practiced from the top down. It is as if Sofie is asking, why yet a sentence is added to a SOP if we know it will not solve the issue. Instead Sofie's strategy leads towards turning everything upside down and look for innovative solutions.

I will later discuss some of these differences and debate if they can actually be viewed as each other's mirrors or on the contrary as each other's contributors.

To follow up on a previous comment to the messy-map from when conducting my interview guide. Initially I looked towards causes to be the reason as for why some were against and some were for changing the practice around SOPs. As I have worked my way through this report, I have instead approached a composed picture of a practice where specific (psychological) causes aren't the reason for people's relationship towards the change within training. I have found it logical, now, to ask questions for further clarification and not causes that needs fixing. I will pursuit this approach further through the four stories already mentioned. The elements of Social Practice Theory are present in every story, but besides these elements I find the perspectives of Hutchins' as well. As these four stories represent different practices that exists on top of the phenomenon of SOPs, I find it relevant to encapsulate them in Hutchins cube of a human practice, as I find that the informants contributes to a SOP practice in each their way. Their stories all have a perspective of time and place within them, a perspective that characterises the way they practice SOPs.

## A moment of a SOP-practice.

Prior to extracting the different dimensions of Hutchin's distributed cognition I find it relevant to illuminate how I see the cognitive system, as the system performing SOP practices. As explained in the theoretical paragraph such a system is formed through the practices carried out in a nexus of cultural structures and historical context in which the practices live. The analysis above provides me with an understanding of the practices linked to working with SOPs. However, to follow the path of Hutchins, these practices should be placed in a context of both history and cultural structures in order to become functional in a cognitive system. I will therefor explain how I, through my time in Novo Nordisk as well as through the gathering of empirical material for this thesis, have gained an understanding of these culture structures that exists, and in which historical context it does so. From the different strategies extracted in the analysis I find a constellation of cultural structures. Each one the informants have their own strategy towards SOP practice, as they all independently express how simply reading a SOP from start to finish is not the best possible way to obtain knowledge. There seem to be somewhat relatively common understanding of this approach not being sufficient, and yet it is the approach used. As already stated, one of the informants explicitly argue that the use of SOPs, a use that indicates that SOPs have become a tool which is commonly used, have become tradition. According to her, there is no doubt that SOPs lies embedded in the way Novo Nordisk practice when it comes to anchoring any kind of information which is needed when producing insulin. This interpretation is supported by Sanne, another informant who have been in the organisation for almost 20 years. During my interview with her she explained a conversation she had with a colleague from QA, as she questioned a SOP put in her ISOtriain about behaviour in a specified building:

Sanne: "*I never go there*"?

QA: "*Well, it's a good thing that you know*"

Sanne: "*But I don't work in that building*"?

QA: "*No but then you know*".

When Sanne performed this scene, I remember how she lifted her arms into the air as saying how argumentation like that is hard to make something of. It is this kind of relatively common understanding that I place in the constellation of cultural structures.

To handle this, the informants have different strategies to cope and thereby different structures embedded in these strategies to support the insufficient approach of reading SOPs. Besides these cultural structures we have previously been confronted with a historic perspective. The warning letter in 2012 had much to say on how SOPs were later practiced. They became a way to 'close gaps'. Herein lies the fact that the need for a new SOP was secondary to the fact that any gap was turned into a need for a SOP. Years before this as explained in the story of Huub, the lack of SOPs led to differentiation in the way things were done on the machines which again led to the birth of the SOP.

The above mentioned dimensions represents the cultural structures and the historical context in which they are performed. The essential of Hutchins' take on cognition was that of viewing the practice as a whole. Thus the practices are not centrally embedded in either Huub or Sofie, but they are distributed to move beyond their body. I have placed the informants and their strategic approaches in the cube, which I will now rationalise.

Huub's job consists mainly of teaching new operators to work the filling line. His strategy is to compensate for the SOPs, by implementing his own approach. When drawing on Hutchins Huub
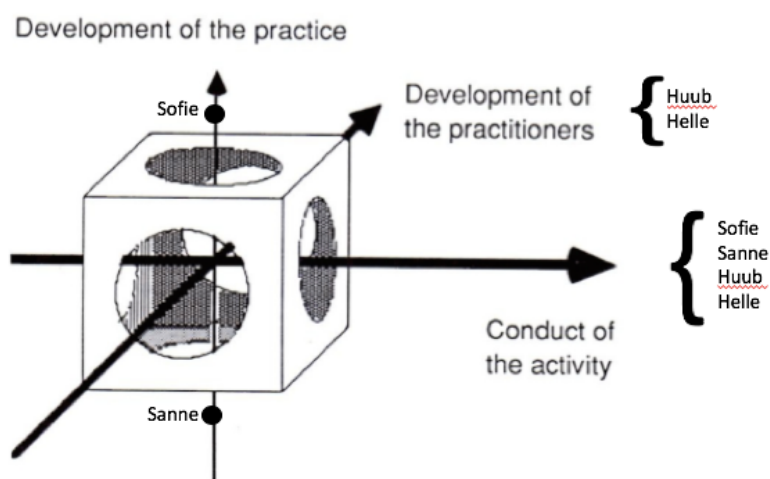


Figure 7: A moment of a human practice (Hutchins 1995, p370).

thereby represents the dimension of developing practitioners. As explained in the paragraph of theoretical recourses the development of a skilled operator takes years. Both new employees and Huub himself has required the necessary skills throughout his entire time at Novo Nordisk and even prior to that as a driving teacher. Besides Huubs own career,

Novo Nordisk as organization has changed when it comes to the development of practitioners. To Huub and other operators the same applies as for the quartermaster on the navy ship – it takes longer to learn how to actual wash the vials before filling them with insulin than it does to actually wash them. I have placed Helle in parallel to Huub in the cube. Her approach and strategy may be different, but she still works with the development of the practitioners. As Helle's has a past which have placed her at the level of competence she is at, I have simply chosen to place them parallel on the arrow, though I am aware that Huub may have had a longer relevant history to have him become this competent.

Sanne I have placed in the dimension that develops the practice. I have knowingly placed her at the bottom part of the arrow, as her strategy of taking out fires is somewhat less progressive than Sofie's. Sanne takes out fires as they occur, but she does not actively engage in developing the next greatest hit within SOPs. Sofie however, is already on her way out of the practice. She deliberately confronts challenges and does not hang on to historical factors in the same way I see Sanne caught in the warning letter from 2012, and what it led to. As they all represent a conduct towards their SOP practices, they are all represented on the horizontal arrow.

When viewing a practice and not the informants take on one, it could be washing the vials, this has developed too. Unlike the practitioners, this development takes centuries. When the insulin production began, there were no autoclave, there were no robots or technological software to work on behalf of the practitioner. Just as there were no SOPs. Instead there was job practice. Job practice slowly turned into SOPs which turned into over processing of SOPs. This arrow, the development of the practice continues as the practices of SOP are not finalized. The SOP is in continuously development, and within a short future I see Training for Competence to be represented as a part of that arrow.

The strategies are different ways of coping with the insufficient SOPs. In the below paragraph I will discuss if they can be combined as one united strategy or if they confront each their kind of SOP-problem. Could there be a situation where one strategy is to prefer from the other, or circumstances where a combination can be of especially good use?

# Discussion

The analysis shows the informants all live by the rules which exists behind the blue gates of Novo Nordisk. It is an organization where everyone is taught to work by the principals[16]: "if it's not written down, it didn't happen" and "if it's not written down correctly, it didn't happen either". The informants of this thesis live up to those principals, but they all find it to be insufficient. To overcome this insufficiency, they have their own ways and strategies to cope. Initially when this report took its starting point I was of the perception that people were divided into two camps: those who were willing to look towards SOPs with a sceptical view and those who were less likely to move beyond writing procedures at all times for any purpose.

Had this been the case, the organization could simply force or fire all those less willing to change their practice around SOPs, in order to level the gap. However, as the analysis has shown it is not a question of those for and those against SOPs, but instead about how things have grown up and around the phenomenon of SOPs. The four informant's present us with each their take on how things has grown up around SOPs. They all have a strategy to cope with them and their insufficiency. Can something be extracted from these four strategies? At first glimpse it is simply a SOP, but the strategies let us know that there is more at stake.

When viewing the different strategies, I find it relevant to discuss if they can work as combinations or if one takes over where the other let's go. If we begin with Sanne's strategy, the trouble-shooter approach. Sanne practices SOPs as a firefighter takes out fires. Whenever there is a fire, whatever it being an emergency break which needs fixing or a chimney that needs painting, she will run to the crime scene and take out the fire. Ones the task is solved, she will return and wait for the next alarm. And this is where I she her in need of a take-over strategy. The way Sanne practices, is a trouble-shooter way of practicing. Her work is not preventive. She will always solve the problem at hand, satisfy her colleagues and that's that. However, her work is not focused on strategically preventing the problem all together. In-stead her practice is frozen in time – she fixes something and returns to her base. This is where the driving-teacher-strategy would come in handy. Huub practices SOPs in a way which guides him through the SOP regime or even away from it all together. Instead of Sanne's one-time fix, Huub works as a superuser to help others navigate in the regime.

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[16] Written principals which new employees are taught during Onboarding.

By dosing the SOPs appropriately, he strives to provide qualified training by not leaving the operators with a pile of SOPs to be read, but instead adjusts the number of SOPs and the content of the SOPs to both the machines and the practitioners. In this way he compensates for what he believes the SOPs are missing, and tries to present the SOPs in a way to prevent them to do harm. It is thus I see Huub and his strategy as a take-over strategy of Sanne's, as Huub actually works to prevents fires all together.

Between Helle and Sofie, I see both how Sofie can take-over from Helle, just as I see potential for their strategies to be combined. Helle's strategy is two-folded. She works, as Huub to provide better training. Helle strives to find pedagogic approaches to support the training. In this way the SOPs make less noise and leave less potential frustration. Embedded in this approach, Helle has, unlike Huub strategic ambitions. With the use of her road map she would like to change the way SOPs are practiced all together. Implementing a well-defined pedagogic concept, she will both train people in a better way and help towards to organization to change it beliefs. If the organization was developed like her Road Map is organized, it would make her job easier in terms of assigning training and SOPs. For this strategic ambition she will need Sofie's strategy to carry her agenda forward. Sofie is always seeking for the next innovative approach with her suggestions for improvement and eternal quest for digitalizing processes and workflows. She is the one of four informants who does not work around the SOPs, but instead towards a better solution all together. Besides Sofie's strategy being the take-over of Helle's, I also find a possible embedded combination of the two. In the future Helle's strategy towards better pedagogic training could very well be combined with technological tools which Sofie represent. If for instance the SOPs were to be improved in a technical manner or making them more logical, Helle would also meet her ambitions for changing the organization and the way it embraces SOPs.

One way of building these combinations further is thus of searching for any specific situations where a specific combination can be of especially use. Could there be a type of situations, or an assembly of circumstances where one combination of strategies is better than the other?

One answer to that could be when engaging with hands-on practice, the operators on different machines, engaging in a variety of practical skills, the merge of Huub and Sanne's strategies would be of preference. These very local and tangible practices, filling the funnel with capsules in the right way, has very little yield of all the innovative possibilities within Sofie's strategy. However, having

the approach of straight-away locating the fire in terms of an empty funnel, for then having had the practical training which provides you with the knowledge of refilling the funnel and thereby taking out the fire, that provides value. I see this combination of strategies to be of use mainly inside production where practical skills like filling a funnel, washing vials or looking for flaws on finished products to be of most value. However, when entering the office of supporters, I find the combination of Helle and Sofie's strategies to take over. This strategy is especially useful when it comes to streamlining, elimination of process errors or in other ways optimization of processes whether it being administrative or systemic. I can picture a scenario where Helle and Sofie join forces in terms of converting all the documentation of a product which is currently in pen-to-paper solution, and converting it digitally. This process would require a great amount of time, recourses and different skills, but when viewing it in a simplified manner, the overall strategy would be thus of Helle and Sofie. The outline would be Sofie developing the system. There will be needs for digital signatures, creating all the templates which are used for typing information, and creating a process for how the digitalized document travels around through the departments, just as the collection of paper today changes hands. Besides a system for anchoring this, it will require some sort of training of people. Once the digital signature is created, how does one create an actual signature? How is the production information typed into the digital template and how should an employee handle the passing and the receiving of the documentation? In such a scenario I see a combination of the pedagogic and technological strategy to be valuable.

Another take would be that of alliances. The strategy of implementing a more pedagogic approach, could as I just stated above make use of the technological strategy. Those two combined can develop better SOPs, but the technological aspect could also provide new and better learning tools. As mentioned in the introduction, our mind is less likely to remember information based on reading. The technological strategy could help provide training material based on approaches that the brain records. It could be a video where the content of a SOP is filmed and presented. It could be a game with multiple choice opportunities to help the employee towards the correct solutions. Parring questions and answers in an intuitive game, creating some sort of excitement amongst the employees, unlike today where they are left alone to read. Such an intuitive and immediate solution is where Sofie's competences become useful to Helle's strategy, and they become allies. If we

follow this scenario, that these strategies join forces, I see the need for a driving teacher to take over the steering wheel from here. If the SOPs are turned into a variety of things, which presents themselves in a pedagogic tool, the driving teacher strategy can be applied from here. The pedagogic tools are to be taught to the employees by a superuser. Though the SOP regime will have changed in compared to prior, the SOPs will still be needing a sort of position in terms of when and where, also in combination with the machines as Huub has built his strategy around.

The last strategy however, I find excluded from the alliance above. The strategy of fixing tasks, practicing the problem that lies right in front of you does not provide any value in the long run. This strategy is the least progressive strategy, and I find it hard to combine it in the alliance made by the remaining.

Should I take the stand of the devil's advocate and argue that a full implementation of Training for Competence will not go through - is there then something to lose? The organization has run on SOPs for years, and so has its employees. I would have to argue, that the practices work as they are. Whenever an employee runs into shortcomings of the SOP, there is a underlying list of contacts. In case of practical difficulties on machinery, Huub would be the correct help to search for. Does one need an easy and correct fix, Sanne is always reliable. These actors complement each other and this without an explicit agreement of who does what. It is because of their individual strategies that the practice of SOPs successful. In an intelligent way Novo Nordisk as organisation lives with this relatively irrational system which in time has grown more and more absurd, but yet it lives through it because there are numerous strategies which smooths the systems towards being more logical whenever the opportunity presents itself.

There are many visions for how to develop and design technology. Traditionally design has been consideration for the users' perspective (Tuuli, 2006, p. 16), whereas Novo Nordisk as this thesis represents, views technology to be designed between practice and organised learning. This form of a re-design process which does not work because people sabotage or in other ways misuse the system of SOPs, but because they chase the opportunities that lies within the system. Many may think that SOPs are something that one is destined to live by, while in-fact this shows that within the system, practitioners are trying to tune in on developing and improving the system as it is.

As I have now discussed different ways to make use of the strategies extracted from the analysis, I will present my concluding remarks for the report.

## Conclusion of research question

In this paragraph I will conclude on the findings of my thesis. I will synthesize significant points from the report and present how the different paragraphs contribute to the problem field of the thesis. Finally, I will conclude how the theoretical framework of Social Practice Theory contributes with knowledge on how SOPs are practices by employees in Novo Nordisk Bagsværd and thereby to answering my research question.

The study shows how SOPs are practiced in numerous ways. Each of the informants have contributed to this thesis which I have told through four stories.

Common for them all is their dependency on having read their SOPs as a foundation for being able to work. They need to do so both in terms of Compliance and in terms of access to both areas and systems.

Besides this dependency, they have all, in time, built a new layer onto the SOP phenomenon. SOPs are not one thing or one way of practicing. Instead it is multiple practices. Had I interviewed four more employees, had I very well been able to tell four more stories on how SOPs are practiced. The theoretical framework has thereby provided me with tools to unfold the phenomenon which is much less simple than first assumed.

The element *material* shows how it is rarely the document in itself that creates or organizes the practice. Instead it is materials in terms of tangible physical entities as a washing machine, the technology that lies embedded in the software programme ISOtrain or the tools that Sanne for instance needs in order to take down an emergency breaks inside the production area. The materials that the informants surround themselves with are obviously depending on which practice they are 'doing'.

The element of *competences* is of great importance in the way the informants practice SOPs as it is very crucial for their actual actions. Had one informant not been a driving teacher in his younger

days, I find it hard to believe that he would have had the educational qualities to be as successful in his job as a mentor as he is today. Or Sofie, who constantly challenges and questions the way things are done, she does so both as it is a part of her generation to be curious, but also because she during her education learned about SOPs and their function, not to mention the techniques it requires to practice SOPs the way she does.

*Meaning* which represents the last element shows how this component is crucial in the way the informants perform their practice. Not in the way they go about it in a practical sense, but what kind of ideas and aspirations they have in relation to it. Probably the most eye catching was Sanne, as she explained how writing SOPs just to close gaps was worthless to her, indicating that whether a practice has a symbolic meaning or not is not irrelevant to her. The four stories shows how meaning is represented as a many things. To Huub the meaning is represented as a map – a carriageway where you learn how to drive. Meaning is embedded in the way SOPs are practiced as a tool towards gradual organizational optimization to Helle, or Sanne – where meaning comes out as a diving save whenever she closes a gap, paints a chimney or takes down an emergency break.

These four stories have finally presented themselves to be four strategies to cope with what a SOP does not entail. To summarize the strategies are here a recapitulation.
Huub has developed his own driving-teacher strategy. He applies it so that the SOPs in their pure form does as little harm as possible. His was of practicing makes him a mentor to new operators, and he estimates which and how the SOPs are to be dosed. In relation to that I see Helle's strategy. Helle's works with training of staff like Huub, yet Helle has ambitions on behalf of the organization in terms of optimization of training in a different way than Huub.
Sofie strives for innovation and constantly challenges the SOPs in their pure form. She works for developing the SOPs and their content through technology and digital solutions. Sanne, the owner of the last strategy practices SOPs as they require her to in a her-and-now context. Though she may never eliminate the problems she faces, she solves them when faced.

Besides the elements from Social Practice Theory, I have portrayed how I see Hutchins' cube as a way to apply a new perspective on the strategies and their growth over time. This portrait does not,

as Social Practice Theory, tell us something about every aspect present at all times, but instead is tells us something about a specific practice, in a specific historical context, entangled in a constellation of cultural structures. On that ground I have placed the four strategies as I see them in relation to these dimensions.

Huub and Helle works in parallel on developing practitioners using each of their strategies. Sofie and Sanne work on developing the materiality and tools, though their strategies are very different. Were Sanne practices SOPs as a trouble shooter, Sofie seeks to optimize her findings, preventing the situation from happening again. In each their way, they all represent some conduct towards their activity, and they are therefore all placed onto the horizontal arrow.

In terms of approaching my problem field, my problem was not undiscovered prior to this thesis. The weaknesses of SOPs are well known to Novo Nordisk, and they also have potential solution in their pipeline. My thesis however, has brought nuances in terms of the shortcoming of SOPs. What lies embedded more than a document to be read and understood? I have through these nuances and perspectives gained a deeper understanding of how SOPs are practiced in an everyday work life. Along with this understanding new questions arises. I see it to be of relevance that DFP Bagsværd if and how they can coexist with these strategies as a way to exploit the resources mentioned in this thesis.

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