Master's Thesis – master Innovation Sciences

The interplay of the **Sociotechnical imaginaries** and policies of **personalized healthcare** in the Netherlands

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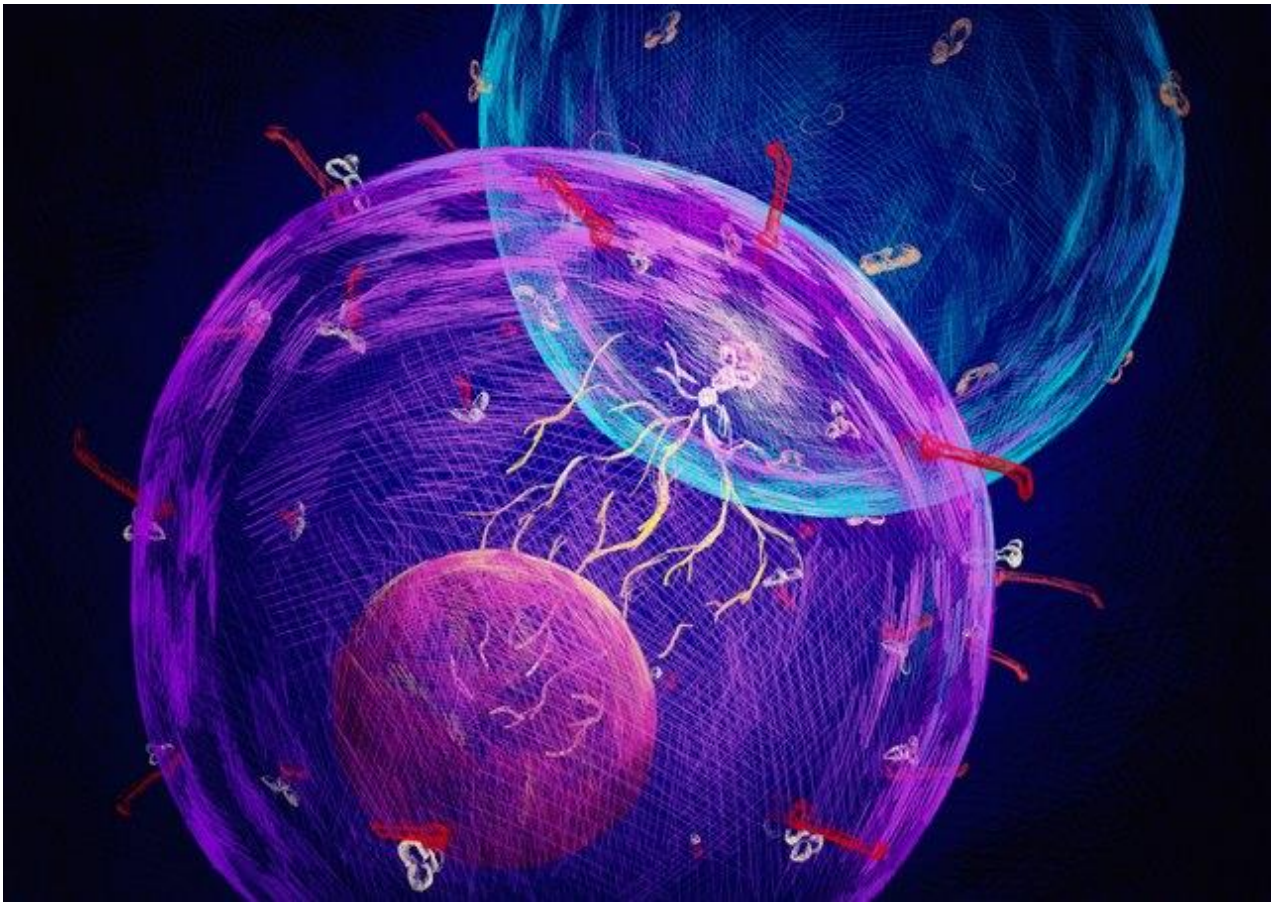

(IMAGE BY: TACHIBANA, 2017)

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Abstract

Introduction

Personalized medicine is a new and fast-rising scientific field in the Netherlands. It is well-established that personalized treatments and drugs are more effective than conventional medicinal practice. This study aims to determine the following: The current collective expectation of personalized medicine, its evolution over time, and the interplay between policy practices and other competing expectations. This is done by the analysis of the Sociotechnical Imaginaries of personalized medicine. This study is carried out to advance theoretical knowledge of Sociotechnical Imaginaries and to help improve policy implementation in the field of personalized medicine. In this context, collective expectations of CAR-T cell therapy, a personalized cancer treatment, are used to represent the concept of personalized medicine in the Netherlands.

Theory

The theory of sociotechnical imaginaries is about the collective expectations of desirable visions of technology in society and their influence on the advances in technology and science. The dimensions of the national sociotechnical imaginaries used in this research are: national needs, solidarity, temporality, competitiveness, risks & benefits.

Methods

To analyze the collective expectations of CAR-T over time and the interplay between policy and competing expectations, interviews with key actors in the CAR-T field have been interviewed about their expectations. In addition, a media framing analysis over the period 2012-2021 of CAR-T cell therapy was performed.

Results

The results show two dominant competing sociotechnical imaginaries in the field of personalized medicine in the Netherlands. These sociotechnical imaginaries are ‘Pharmaceutical Inclusion’ and ‘Academic-driven pharma’. ‘Pharmaceutical Inclusion’ imagines a future with more inclusion, cooperation, and influence of pharmaceutical companies within healthcare and governmental institutions. The ‘Academic-driven pharma’ envisioned a future with academic CAR-T development and production with less pharmaceutical influence in healthcare.

Discussion/Conclusion

An analysis of the results shows the impact the two competing sociotechnical imaginaries have on each other. They frame the competing STI by emphasizing the risks and ignoring its possible benefits. The analysis also shows that the evolution of the STIs is influenced and enabled by policies, just as the policies themselves are influenced by the STIs. On this basis, knowledge of the competing STIs should be considered when designing policies or for substantial discussions on possible technological trajectories.

Contents

Introduction

Personalized medicine (PM) is defined by the Academy of Medical Sciences of the UK (2015) as: "medical decisions, practices, interventions and/or products being tailored to individual patients based on their predicted response or risk of disease". Doctors have incorporated personal information, like disorders of blood relatives, in treatments for decades. However, PM may revolutionize healthcare by using modern knowledge of genetics and molecular biology. This would allow for more precise diagnoses, diagnostics, predictability, and disease course predictions (Goetz & Schork, 2018). PM can make therapies more successful by finding or creating the right treatment for individual patients and improve safety by selecting proper medicine dosages to reduce side effects. People vary significantly in their molecular buildup, and recent studies show this difference is of great importance in medicinal effectiveness (Rehm, 2017). Various upcoming therapies yield significantly better results by focusing on the difference in the molecular buildup of the patients. Three out of four generic cancer treatments are ineffective and might benefit from personalized cancer medicine (Spear, 2001). Personalized cancer treatments, like CAR-T cell treatment, have made promising results in early clinical trials (Tran, 2017). CAR-T cells are white blood cells that originally belong to the patient but have been genetically engineered as cancer therapy (Jackson, 2016). This personalized cancer therapy is increasingly implemented for people with various types of blood cancer (Wang, 2017).

CAR-T cell therapy has its fair share of controversies. The treatment costs over €300.000 per therapy and is currently reimbursed by the Dutch healthcare system (Dutch National Health Care Institute, 2020). This puts tremendous pressure on the national health insurance system. The patients' cells need to be transported to the US for this treatment, where they are genetically modified and sent back. This takes up to six weeks, a time that terminally ill patients often do not have. To combat this, the government gave a 30-million-euro 'Potentially Promising Care' subsidy to the University Medical Center Groningen (UMCG) in 2020 to develop and produce CAR-T cells in the Netherlands (Dutch National Health Care Institute, 2020). The UMCG claims they may be able to produce the therapy cheaper, faster, and with improved quality. The project leader in CAR-T cell production of UMCG, Tom van Meerten, states in an interview in a Dutch newspaper, the Volkskrant (Visser, 2020) that:

> *"There is no government in the world where the government supports academic researchers in providing evidence that they can deliver an innovative treatment that is as good as that of pharmaceutical multinationals."*

This radical new policy aims to incentivize producing complex, innovative pharmaceutical medicine by academic institutions. Shifting a part of the responsibility of pharmaceutical production to academic institutions would be a substantial change, impacting innovation, pharmaceutical companies, universities, the development of the technology, and broader societal assumptions (Barben et al., 2007; Beck, 1992; Guston, 2008). Such a sizable technology policy initiative can thus be seen as an attempt at sectoral reconfiguration.

To study and trace the potential broad-ranging impact of these initiatives, we may turn to analyze **Sociotechnical Imaginaries (STIs)**. In their influential book, Dreamscapes of Modernity, Jasanoff & Kim define STIs as:

> *"Collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understanding of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff et al., 2015a, p. 4).*

The concept of STIs captures the relationship between the development of science and technology, their introduction into society, and societal expectations. Scholars in the Science and Technology Studies field have long described relationships between the development of **science and technology (S&T)** and society (Konrad et al, 2017; Jasanoff, 2004; Dagnino, 2012). That the two strongly impact one another is evident. In terms of the impact of S&T on society, advances in S&T are considered an influential driver of economic and social progress (Gibbons et al. 1994). An example is how the development of the personal computer radically changed our way of communication and information sharing (Jarvenpaa & Staples, 2000). Reversely, the societal response to S&T is an influential factor in technological development. Two prime examples are nuclear power and biotechnology in the 20th century. Both technologies had high expectations and were state supported but faced enormous societal backlash and public resistance in many countries (Felt et al, 2015; Torgersen, 2002; Jasanoff, 2015). This public resistance reduced investments, development, and production in these sectors, resulting in an almost complete stagnation in nuclear power and a severely delayed biotechnical sector (Toke et al, 2021; Qamar et al, 2020).

The theory of STI is based on collective expectations and how these interact with socio-technological development. These collective expectations are subject to change over the years and often compete with other collective expectations within a society (Jasanoff & Kim, 2015). The study of STIs aims to uncover the societal dynamics around innovative technology and its accompanying reconfiguration initiatives (Pfotenhauer & Jasanoff 2017). For example, the CAR-T cell therapy and its 30-million-euro subsidy. Moreover, STIs trace *why* and *how* attempted changes in sociotechnical systems result in successes or failures (Jasanoff, 2015; Hilgartner, 2015). Jasanoff et al. (2015a, p.10) remark that the "mechanics of the interconnections between technoscientific and political practice have not been articulated in detail or systematically", especially not concerning innovations. Tarkkala et al. (2019) have shown that national strategies of PM, are performed by policies and that these policies produce visions that are mutually constitutive with the sociotechnical imaginary (see Jasanoff et al., 2015a, p. 11, 14). Tarkkala et al. (2019) have also shown that this sociotechnical imaginary changes over time together with its policy framing. However, *how* and *why* the STI evolves over the years and its subsequent interplay with policies is still relatively unexplored. This study adds to the theory of sociotechnical imaginaries by showing the interplay of different imaginaries and policy practice over time. Especially the interplay of competing sociotechnical imaginaries on each other and policy implementation. An analysis of the interplay between policy implementation and the evolution of the STI over the years, could reveal the mechanics by how competing STIs influence each other, change over the years, and interact with policy.
This thesis will contribute to the STI theory by showing that competing STIs influence each other's framing and that changing STIs over the years impact policy and practice, while policy and practice simultaneously impact the STIs.

S&T scholars use analyses of the future to trace the role of expectations, or for documenting how integral the future is to social realities (Konrad et al., 2017). Interestingly, by conceptualizing the future as a resource to alter the direction and development of science and technology, desirable

futures can be promoted. STS scholars recently implemented anticipatory practices to alter the direction of nanotechnology with such practices as scenario building or prototyping innovations (Alvial-Palavicino & Konrad, 2019). Knowledge about the evolving and competing STIs of PM and their interplay with policies can raise a discussion about the possible directions of PM. This can prevent or overcome problems and capture not-yet seen opportunities. In the words of Jasanoff (2015, H7. p43):

> *"Without critically examining the nature and workings of the imaginary, attempts to fundamentally reform the governance of science and technology seem doomed to fall short. To make progress, we will need more detailed analyses."*

This data can be used by key players in the PM field to make more informed decisions or implement anticipatory practices. To gather this data, a deeper look into the STIs and their interplay with policies in CAR-T cell therapy are necessary. This will be done by answering the following research question:

What is the interplay between the sociotechnical imaginaries of personalized medicine and the health care policy practices in the Netherlands between 2012-2021?

This research question is supported by the sub-questions:

1. What are the sociotechnical imaginaries of personalized medicine in the Netherlands and how have they developed in the period 2012-2021?

2. What were the primary health care policy changes in personalized medicine in the Netherlands in the period 2012-2021?

These questions are answered by interviews, documentaries, literature, and other media analysis. Data for the documentary, literature, and media analysis has been gathered from the year 2012 to 2021. The year 2012 has been chosen because it is the first year a patient was successfully treated with CAR-T cell therapy (Rosenbaum, 2017).

Theoretical framework

The future is always influential in the present. It plays a role in the decision-making process of individuals and collectives (Beckert, 2016; Vervoort & Gupta, 2018). Societal actors develop tools to render the future actionable: tools such as predictions, models, and scenarios. Policy is based on these predictive tools to achieve this desired future (Bell & Mau, 1971; Polak, 1973; Andersson, 2018; Candy & Dunagan, 2017; Miller, 2018). It is established that the future is performative in the present (Beckert, 2016; Bell & Mau, 1971; Borup et al., 2006; Groves, 2017; Jasanoff & Kim, 2015). However, *how* expectations of the future organize, and design decision making and influence the social system; *how* these visions originate; *why* they are performative; and *who* makes these imaginations performative is not yet fully understood (Oomen, Hoffman & Hajer, 2021). *How* competing STIs impact each other is also not yet known in STI theory. (Gerhold & Brandes, 2021; Konrad et al, 2017; Smith & Tidwell, 2016; Jassanoff, 2015). This paper will try to answer *how* these visions originate, and *how* competing visions within a sector impact each other, and *how* changing STIs influence policies and vice versa.

In Science and Technology Studies (STS), future visions, expectations, and imaginaries are plentiful, and its performativity has been studied extensively. The sociology of expectations focuses on the collective character of expectations and visions in the societal discourse. These collective expectations model the behavior of actors in a society or group. Actors do have individual, diverging expectations, but the broader collective expectations are performative in coordinating, mobilizing, and instructing toward a common goal. Collective expectations act as a common reference point for goals, which can be worked towards. Collective expectations can originate from individuals. By exercising power, building coalitions, and propagating these visions in a society they can be collectively adopted (Jasanoff 2015). When collectively adopted, these visions can instigate the adoption, rejection, or modification of a specific technology. These collective expectations of a technology can manifest themselves as visions. In which the expectations envision an alternate, desirable world in which societal arrangement, governance, or values are revised. Expectations can exist as materialized investments or valuations of a potential new technology. The very act of investing in a technology by an organization reveals and produces commitment towards that technology. Investments like the governmental subsidy and pharmaceutical CAR-T cell factory reveal the materialized collective expectations of CAR-T cell therapy. Collective expectations and visions can be deduced from these investments. To analyze these collective expectations, the concept of Sociotechnical imaginaries can be used.

The concept of Sociotechnical imaginaries has been growing in STS literature lately, as this concept describes how collective imaginations on forms of social life and order, are influencing the development and design of technological projects. Jasanoff & Kim (2015) describe sociotechnical imaginaries as:

> *"Collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understanding of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff et al., 2015a, p. 4).*

STIs note the importance of engrained collective ideas in shaping expectations. Studies have shown how these collective expectations of a desirable vision, legitimate specific technological pathways while inhibiting others (Konrad et al., 2017).

Different collective imaginations can exist within a society, whether coexisting peacefully or in conflict, and these may change over time. The most recent example is the "Brexit" vote in the United Kingdom, where the pro-Brexit and anti-Brexit visions reflect and visualize conflicting imaginaries for the future of Great Britain. These conflicting visions for the place of the UK in the European Union co-existed for years and were not proportionally reflected in mainstream politics (Becker, Fetzer & Novy, 2017). The amount of people with a pro- or anti-Brexit mindset and what a Brexit entails also changes over time (What UK Thinks: EU, n.d.). This example visualizes intra-national competing STIs of a nation that evolves over time. This is emphasized by a recent study by Tarkkala et al., (2019) where Finland's STIs of personalized medicine are analyzed. Tarkkala shows that the dominant STI of Finnish PM shifted from 2005 to 2015 from a focus on the patient to a more economic focus. This study shows that PM is a contested, evolving field regarding STIs. The theory of Sociotechnical imaginaries is an interpretive theory, linking social and STS theory together, about collective beliefs in a society. Sociotechnical imaginaries can give answers to *why* there is a difference in the adoption of collective beliefs and *how* these change over time (Jasanoff, 2015).

Institutions or groups of actors can then facilitate one of these collective imaginations and drive that vision to become the dominant one. When dominant, collective imaginations can guide activities and act as sources of legitimization for a technology. Visions can provide structure and shape expectations of risks and opportunities, as well as attract and encourage investment. Because of this, collective imaginations are an important subject of research for scholars of innovation. An analysis of the collective imaginations existing within a society can provide information and act as a starting point of "techniques of futuring", as described by Oomen, Hoffman & Hajer (2021), in which one actively pursues the development and embedment of a beneficial collective imagination in society. STIs are not neutral and are framed in a very specific way. These different imaginaries can be connected to different actors or interest groups and often have their own "storyline" (Tozer & Klenk, 2018). A storyline is a "condensed statement summarizing complex narratives," and is an effective way to communicate an imaginary (Hajer, 2006; Tozer & Klenk, 2018; Oomen, Hoffman & Hajer 2021). Internally conflicting parts of the imaginary are often let out, while positive notions are deliberately included and emphasized (Skjølsvold, 2014). When emerging technologies are covered in the news media, the issues are framed in specific ways. The news media can set the agenda for how these technologies are understood by framing, topic selection, opinion representation, and visual representation (Luokkanen, Huttunen, & Hildén, 2014; Marks, Kalaitzandonakes, Wilkins, & Zakharova, 2007). The mainstream media is often attracted to stories of new technologies. The representation of novel technologies in the news media tends to be framed around two major dimensions: Benefits and promises; risks and hazards (Luokkanen Huttunen, & Hildén, 2014; Marks Kalaitzandonakes, Wilkins, & Zakharova, 2007; Metag & Marcinkowski, 2014). These two major dimensions, risks, and benefits are key parts of the STI of personalized medicine and are therefore also used as dimensions of STIs in this research.

An STI of a country consists of different dimensions. The five components of national STI's, according to Jasanoff (2015) are: **1) national needs; 2) solidarity; 3) temporality; 4) competitiveness & sustainability; 5) risks & benefits**. These dimensions have been used to uncover the STIs of a nation. Interpretation and interaction with science and technology are not homogenous across nations,

groups, or even between individuals. The acceptance or interpretation of certain ideas is always distinct in different sociopolitical contexts (Jasanoff 2005; Daemmrich 2004; Bernauer 2003; Vogel 1986). Looking at imaginaries from different dimensions will illuminate the acceptance and interpretation of certain imaginaries. In the next paragraph, all components of a national STI are explored.

National needs is a dimension of an STI because the strength of a need of an idea refers to the power of that STI. An STI that better fulfills a need increases the robustness of an STI (Kleinhout-Vliek, 2020). Nations inhabit different social spheres and interpret national needs differently from other nations (Jasanoff, Kim, & Sperling, 2007). In a nation, actors generally share a common imagined future on a problem and a strategy on how to resolve this, like energy, economic, or food security. The way an imaginary envisions overcoming these problems influences its robustness and strength against other STIs (Jasanoff, Kim, & Sperling, 2007). Some scholars argue that nations have frequently wrongly discerned the needs and wants of their own public in technological progress, questioning the dimension of National need in the STI field (Jasanoff, Kim, & Sperling, 2007). Recently, governments have initiated efforts to engage and connect more with the public in technological development, enhancing the dimension within STI theory (Horst, Irwin, Healey & Hagendijk, 2007). Increasing the ability of a society or actors to specify its needs and attribute meaning to these needs enhances the ability of the nation to specify its national needs by conversing with key actors in their respective fields.

Second, the **solidarity** of an STI describes who should be responsible or included and who should not. The solidarity of an STI can be uncovered by asking who belongs, who should be included, and who is responsible. Evidence suggests that differences in ideas of national solidarity and belonging are resulting in differences in the framing of benefits, risks, and socio-political challenges with developing technologies (Winickoff, Sunder Rajan & Kaushik 2005; Jasanoff 2005; Gottweis 1998; Bauer 1997). Linking the differences in national solidarity to risk and benefit framing shows the intertwinement of the dimensions of national STIs. Furthermore, STIs can generate a feeling of solidarity, due to groups of people that feel connected by a shared history, future, and common ideological framework.

Third, **Temporality** refers to the spread of ideas through space and time, that influences the centrality and robustness of ideas. It refers to which futures are desired, which pasts should be abandoned, and which should be reconfigured. The past affects the current STI in the fact that previous successes or horrors alter the imagined futures. Just like how after the second world war German scientists had changed their entire vision of ethical scientific developments as a reaction to their Nazi past (Proctor, 1988). Our vision of a desired future with alternative clean energy sources also sparked different visions of the future (Treffers, Faaij, Spakman & Seebregts, 2005). The spread of the idea through space and time throughout a nation influences the performativity of the STI. Long-held visions of the future are harder to change and social proximity influences adoption (Anderson, 1995). Actors that hold certain visions of the future in places where they can act on these imaginaries, like politicians or large business owners, can influence the performativity of that STI. The history of an idea also heavily influences the adoption of that idea, like the way the US still negatively acts on communism because of the influence of the cold war (Klehr, Haynes & Anderson, 2008).

Fourth, the **Competitiveness and Sustainability** of an STI is about who or what party is ahead, in what respects, what needs to be remedied, what needs to be preserved. A large part of national imaginaries is environmental sustainability and economic advantages. According to Levidow &

Papaioannou, (2013) competitiveness and sustainability are important framing devices and provide a cultural resource for governance to gain policy commitments and R&D funds. Nations like the UK have increasingly prioritized competitiveness and sustainability for innovation policy purposes in fields like energy production and the importance of these dimensions seems to grow over the last decade (Levidow & Papaioannou, 2013). However, the sustainability dimension is mostly used for energy imaginaries. PM is less influenced by the sustainability dimension since it is not inherently seen as substantially wasteful. As is shown in Tarkkala et al., (2019) where PM is mainly framed on its economic prospects and sustainability is not mentioned at all, and this is also the case in other research about PM expectations (Pot et al., 2020; Squassina et al., 2010; Tarkkala et al., 2019). Therefore, only the competitiveness dimension will be analyzed.

Fifth and finally, **Risk & benefits** relate to the perceived contemporary losses or profits, respectively, connected to each STI. It is about who wins or loses in different dimensions and how different STIs frame risks and benefits differently. Evidence suggests that nations indicate the risks and benefits of new technology differently throughout the world (Jasanoff 2005; Daemmrich 2004; Bernauer 2003; Vogel 1986). Risk and benefits are, according to Fischhoff (2013), very important resources in the communication of visions and ideas. It supplies a shared form of understanding and different visions that emphasizes different risks and benefits (Froese & Simon 2016). Proponents of an STI often seem to frame the technology as desirable and good for the public, whereas opponents mainly frame the risks and hazards of these futures (Eaton et al. 2017).

According to the Harvard STS research platform (2015), STIs serves as both the ends of policy and as instruments of legitimation. The relation between STIs and policy has different forms. Konrad & Böhle, (2019) explains that STIs are performative by mobilization, legitimation, guidance, coordination, and sensemaking among innovation policy actors. Konrad & Böhle, (2019) also explains that an STI reflects a common understanding of governance and social order, which influences and envisions certain policy arrangements. As previously mentioned, anticipatory practices or tools that try to give foresight into the future, are commonly used for mobilizing policy making and are often used by innovation actors (Van der Duin, Heger & Schlesinger, 2014). Policy decisions of expenditure on specific technologies and sciences are often decisions framed by STIs (Martins & Mawdsley, 2021). Successful visions are mostly represented in an interesting way, this sways actors to attribute institutional, technological, and material resources in realizing and spreading the STI (Jasanoff, 2015; Martins & Mawdsley, 2021). The investment of these resources in turn influences the STI, by legitimizing and affirming that specific vision of the future. Just like how smart electric grids in Norway were subsidized by the government on a “belief in the future” and then subsequently transformed the STI because of a better understanding of the technology. The transformed STI had a grander future vision and societal role of smart grids in electricity consumption. This policy and subsequent STI transformation impacted new regulations, and this shows how policy shapes the STI and how an STI influences policy. In sum, STIs are important considerations for policy purposes since desirable STIs can be promoted by policies and will eventually shape policies themselves (Jasanoff, 2014), and their relationship is thus a vital topic of study. Policy aimed at socio-technical change in a society is only one part of what influences the STI. Academic researchers, private companies, the public, the media and more, are all actively shaping the STI, and in turn, shaped by the STI.

STI affects policy with each of its dimensions. In new technologies, there is a sense of urgency of international **competition**. The promising societal and economic benefits of a new technology are

often used in an STI and for policy practices (Ulnicane et al., 2021). These are often framed as a **national need** or a potential for international **competitiveness** (Konrad et al, 2017). Policy is heavily influenced by actors by framing the inclusion or exclusion of a certain group. A policy that includes or excludes, reinforces the imaginary of who should or should not be included (Townsend et al., 2020). The group in society that burdens the **responsibility** (**solidarity**) of developing or implementation of a technology can spark social movements that disagree, which in turn can influence policy development and implementation (Barben, Fisher, Selin & Guston, 2008). **Risk and benefits** are commonly used frames by the media or policy actors that heavily influence policy (Nisbet, 2014). Policy, in turn, can acknowledge and legitimize the risk or benefits of a technology and can discourage or attract investments respectively. This shows that the selected dimensions of a national STI all influence and are influenced by policy.

To understand and visualize STIs, a multidisciplinary social science concept, a research method that shares these characteristics should be used. A framing analysis is such a research method. A framing analysis by Schön & Rein (1996) analyzes different framings, it shows how people understand situations and activities. This analysis looks at metaphors, actors, images, messages, and how they frame a specific concept. Framing is, according to Nelson, Clawson, and Oxley (1997, p. 221):

> *"Framing is the process by which a communication source, such as a news organization, defines and constructs a political issue or public controversy"*

Other common frames in the news are: **conflict, economic consequences, human interest, morality,** and **responsibility** (Semetko & Valkenburg, 2000). By looking for these common frames in the news for a specific subject like CAR-T cells, in combination with the components of national STI's (national needs, solidarity, temporality, competitiveness, risks, and benefits), the national STIs of PM can be described.

Method

To answer the first sub-question: *"What are the sociotechnical imaginaries of personalized medicine in the Netherlands and how have they changed in the period 2012-2021?",* a qualitative framing analysis about the development and production of CAR-T cells is performed. For this framing analysis, a broad range of sources has been gathered. These sources consist of 10 interviews, 3 webinars, 1 documentary, and 108 media articles, as is shown in table 2. The data has been coded and analyzed in the dimensions of national STIs and common media frames. The interview participants are shown in Table 1. Interviews have been held with three hematological internists specialized in CAR-T that are all members of the CAR-T tumor board, three employees of a large pharmaceutical company, the founder of a small startup pharmaceutical company, and two academic CAR-T researchers where one is also a member of the CAR-T tumor board.

Table 1

Profession	**CAR-T tumor board**	**Pharmaceutical company**
AMC hematological internist	Yes	-
PMC hematological internist	Yes	-

Radboud UMC hematological internist	Yes	-
UMCG academic CAR-T researcher	No	-
UMCG academic researcher and hematological internist	Yes	-
Manager registration and quality	-	Large, international
Manager market and reimbursement	-	Large, international
Manager governmental affairs and policy relations	-	Large, international
Founder and COO	-	Startup, National

Table 1: Overview of the interview participants and their professions.

These interviews were semi-structured and about 30 to 45 minutes long. The initial questions are based on the dimensions of the national STI (**national needs, solidarity, temporality, competitiveness, risks & benefits**) to accurately reflect the current STI of the Netherlands. Additional questions about CAR-T cell therapy policy practices have been included to get a general view of the most important policy changes and interpretations.

The media analysis includes several different sources of newspapers, television programs, and websites containing information and promotion of CAR-T cells. The type and number of sources used are shown in table 2. The newspaper and article sources concerning CAR-T cells have been gathered from Nexus Uni with the search terms: CAR-T, CAR-T Therapy, CAR T, and Chimeric antigen receptor T cells. Within the parameters, 2012-2021, written in Dutch, removed double articles, and excluded terms that produce non-relevant outcomes. This resulted in 108 articles and provided an extensive collection of news articles about CAR-T technology. Television, documentary, and webinar programs have been found by using google with the search terms: CAR-T cell therapy documentary/webinar/program. The used programs were published on Dutch TV or appeared on a Dutch website between 2012-2021. Programs found were: The documentary “War in the blood”, and the webinars “This is CAR-T”, “KNAW-webinar Gentherapie” and “Toelichting versnelde vergunningprocedure gentherapie 4 februari 2021”.

Table 2

Type	Total	Source/name
Newspaper articles	108	Nexus Uni, collected from various Dutch newspapers
Television program	1	War in the blood
Webinars	3	“This is CAR-T” “KNAW-webinar Gentherapie” “Toelichting versnelde vergunningprocedure gentherapie 4 februari 2021”
Interviews	10	See table 1

Table 2: Type, numbers, and sources of the data used for the analysis.

All gathered data has been collected in NVivo, a qualitative software coding program. The preliminary codes were the dimensions of the national STI combined with common frames in the media, and one extra code for policy changes: **National needs, solidarity, temporality, competitiveness, risks, benefits, conflict, economic consequences, human interest, morality, responsibility**, and **policy practices**. In addition, two more codes emerged from the inductive analysis

called: **phrasing**, and **desired future policy changes**. In which the phrasing and use of certain words were found important to analyze the STI and the desired future policy changes showed their preferred vision of the future. The data collection has been done in accord with the "Algemene Verordening Gegevensbescherming" or AVG (Schermer, 2018). Information about data storage has been provided with clarity and transparency to relevant subjects after consent was agreed upon and recorded. Certain safeguards and security measures compatible with the requirements of the AVG were put into place to protect the privacy of the subjects. Safeguards such as the anonymizing of interview participants and the removal of all directly traceable personal data (patients, mail, profile data, etc.) from interview transcripts. The data is stored in servers of the Faculty of Science of Utrecht University.

To answer the second sub-questions: *What have the primary health care policy changes been in personalized medicine in the Netherlands in the period 2012-2021?* Has been answered by media analysis and interviews. The media has been scanned for mentions of healthcare policies changes regarding PM or CAR-T therapy. The questions about policy practices in interviews have been coded and analyzed. This revealed the most significant policy changes in the period 2012-2021. The analysis will be general since the comparison of STIs with the policy change over the years requires only a general idea of policy changes. In addition, in interviews with CAR-T cell therapy experts, questions about CAR-T cell therapy policy practices have been asked to help answer the main research question.

By analyzing and reflecting on the relationship between the two sub-questions the main research question can be answered. The results from these analyses, from the period 2012-2021, are combined to see the patterns of the changing imaginary of CAR-T cells (personalized medicine) over the years and their influence on and from policies regarding CAR-T technology. This way, it is possible to see the influence of policies on the PM imaginary and the influence of the imaginary on different policies as well as the influence on competing imaginaries.

Results

Timeline

The number of media articles referencing CAR-T therapy has grown steadily over the past 10 years, as seen in figure 1. Beginning in 2012 as the first year CAR-T therapy is introduced in America as a new experimental cancer cure for leukemia. After that in 2015, there was a takeover of the T-Cell producing company Kite, by Celgene for €20 million, framed by an economic magazine called: 'Het Financieele Dagblad' as:

> *"With the deal, Celgene is putting its cards on CAR-T as the most promising cancer treatment."*

Figure 1

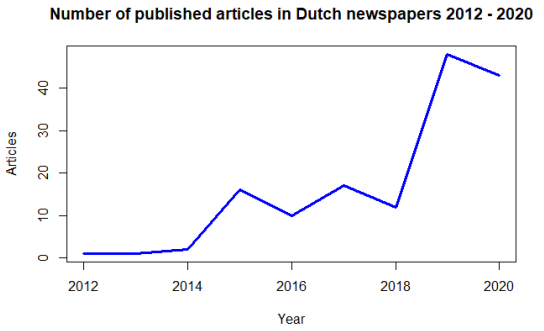

Figure 1: Number of published articles in Dutch newspapers 2012-2020, the year 2021 was left out because the year has not yet ended and is, therefore, an outlier in the data. Source: Own work, data adapted from Nexus Uni

This happened simultaneously with a 1-billion-dollar cooperation between Celgene and Juno Therapeutics in CAR-T cell development. The media framed these takeovers as an enormous boost in the economic trust of CAR-T cell therapy. In 2017 the first two CAR-T products got FDA approval and Kite pharma and Juno therapeutics got taken over by Gilead and Celgene, respectively. Once again establishing the economic trust in CAR-T therapy. In 2018 CAR-T cell therapy got approval from the European Medicines Agency (EMA). After the approval, in 2018, the Dutch National Health Care Institute (ZIN) started discussing the price of CAR-T cell therapy. Dutch healthcare is collective and obligatory, and the ZIN determines the basic health care package. ZIN decides what is included and left out of the basic health care insurance package and negotiates with pharmaceutical companies for a fair price on commercial drugs for treatments within these packages. ZIN finished talks with pharmaceutical companies after 600 days in 2020 when they agreed on the price. The final price for CAR-T cell therapy is secret to the public, however, it is speculated to cost around €330.000 (ANP, 2020). This was framed as far too expensive and a huge burden to taxpayers. Price negotiations happened while a CAR-T tumor board was assembled in 2019 to manage the patient selection process and the new technological developments of CAR-T. In 2020, UMCG received a €30 million subsidy to academically produce CAR-T cells (Visser, 2020). The media frames the academic production of CAR-T cells as a cheaper, faster option with likely improved quality. The media show that UMCG Researchers expect to save €250.000 per patient and emphasize the benefits of the reduced travel time of production within the Netherlands. This framing conflicts with the approval of the CAR-T cell factory of Gilead in the Netherlands. This is mostly framed as a huge benefit to the economy with the addition of 500 jobs and that it is in the national interest to stay a frontrunner in CAR-T technology. In 2021, after pressure from pharmaceutical companies and academics, there was a change in environmental law that reduced the approval of the registration of new CAR-T cell-like products by more than 126 days. Then, just recently in 2021, the long-awaited and speculated CAR-T cell factory that got approval in 2020 is currently under construction. The timeline is shown in figure 2.

Figure 2

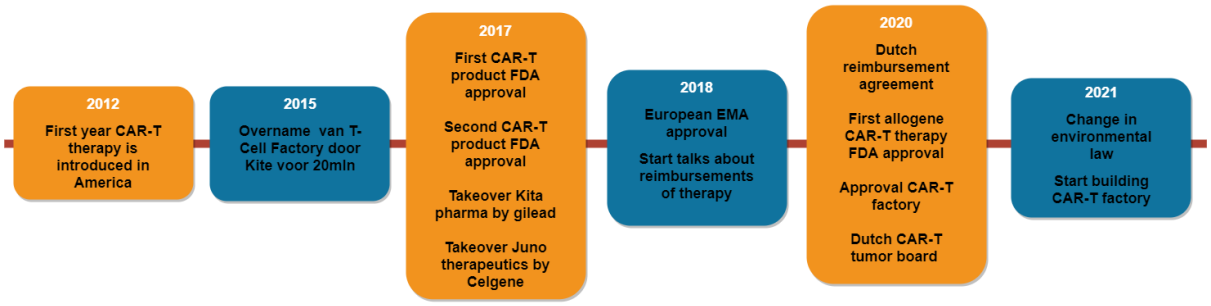

Figure 2: Timeline of CAR-T cell policy practices 2012-2021. Source: Own work

Figure 3

2015	2017	2018
Great results, expansion possibilities, better than alternatives Promising future Economic promise, takeovers Dutch role in research Disease expansion doubts Unreliability of treatment Too expensive	Great results, expansion possibilities Economic promise, takeovers Stock price increase expectation cost decrease allogenic T cells Too expensive Problem with autologous T cells Dangerous Government holding back	Great results, Lots of additional-studies funded, extension possibilities Effective treatment permanent solution economic promise/takeovers necessary Dutch lead in CAR-T Negative side effects Unsure of long term results Lack of production high risk too expensive Approval requires too much time pharma framed evil
2019	**2020**	**2021**
Great results, extension possibilities Effective treatment Lots of takeovers/ economic promise Stockprice increases Dutch production starts/lab announcements High expectations Competition heavy treatment resistence of cancer to treatment yet to be reimbursed in NL expensive high (economic) risk Long wait time complex rules/bureaucracy Foreign depenency requires more time than expected	Upcoming allogene options Promising results Other diseases Pro-point of care New CAR-T factory takeovers humanization of the therapy government subsidies private investments Competition Innefective on a large portion of-patients too expensive Economic downturn Abitrary age restrictions Dissapointing results Risks	Focus on allogene options Promising results More CAR-T products economic investements need for New factory (focus on jobs) Netherlands as a leading cell-therapy focus on reducing costs Expensive high relapse of patients economic downturn Complicated procedures/bureaucracy-problems

Figure 3: The evolution of the media framing over the years 2012-2021, no significant framing was found in the years 2012-2014 and 2016. Source: Own work

Figure 3 shows the evolution of the most portrayed frames by the media. The most recurring frames, portrayed by the media, are the promising future and the expensive costs. This does not change over

the years. In the last two years, the clinical trial results for alternate disease treatment were disappointing. In the last year, the expectations for extension possibilities to other diseases absent in the media. The focus has shifted on allogenic options, in which you use donor cells instead of your own, to improve mass production capabilities. The economic promise is heavily bound to technological developments and bureaucracy. The results of clinical trials on CAR-T cells that reduced the potential to treat other diseases or for efficient mass production negatively affected the economic promise. Just like the complex bureaucracy negatively affected the economic potential of the therapy. However, the negative dimensions are dwarfed by the positive expectations for patients, and the economic potential for corporations, indicated by rapid takeovers of smaller companies. Regular newspapers focused on the potential for patients and commercial newspapers focused mostly on the economic potential and risk of CAR-T technology. In 2018 and 2019, during the startup of the CAR-T tumor board, and even more after the subsidy in 2020, the media increasingly negatively framed the pharmaceutical role in CAR-T therapy. Indicating a rising increase in risk framing when an alternative option was shown.

Academic-driven pharma versus Pharmaceutical Inclusion

Out of the gathered data from interviews with key actors in the CAR-T field. A wide selection of data with different opinions and points of view have been generated. The key actors consisted of three hematological internists specialized in CAR-T that are all members of the CAR-T tumor board, three employees of a large pharmaceutical company, the founder of a small startup pharmaceutical company, and two academic CAR-T researchers.

The analyzed data has shown that there are currently two major STIs of PM coexisting. The two identified STI's, are: "Academic-driven Pharma" and "Pharmaceutical Inclusion". Academic-driven pharma envisions a future with less pharmaceutical meddling and more academic PM production. The Pharmaceutical Inclusion STI envisions a continuation of current practices with more pharmaceutical inclusion and cooperation in hospital and governmental policy discussions. These STIs differ in all the national dimensions of STI's: national needs, solidarity, temporality, competitiveness, risks, and benefits.

The Academic-driven pharma STI mostly concentrate on solidarity with additional important framings in temporality, national need, and risk, and benefits. The Academic-driven pharma STI mainly focuses on responsibility and inclusion. They envision limiting the influence of pharmaceutical companies in hospital practices and shift a part of the responsibility of PM production and development to academic institutions. Actors with this STI want to bring the development of CAR-T cells back to academic institutions. They feel like they should be responsible for the development of CAR-T cells and that the pharmaceutical companies are too involved in current healthcare practices. This is supported by their views on national needs. They desire a cost reduction on the current CAR-T cell therapies and think that this is not going to happen when the development is purely in the hands of pharmaceutical companies. The Academic-driven pharma STI is fixated on improvements in quality, free information flow, and cost reduction as the benefits of an academically driven development of CAR-T cells.

The Pharmaceutical Inclusion STI heavily includes solidarity. Actors with the pharmaceutical focus want pharma to be more included in open communication and want their voices heard in the process of making new regulatory laws. They call for more invitations and inclusion on projects from governmental or academic institutions. This is reinforced by their view on risks and benefits, the

chance of pharmaceutical companies getting a return on their costly monetary investments, depends on future policies and actions of governmental and academic institutions. This STI also includes the dimension of Competitiveness. The Pharmaceutical Inclusion STI feels like they are ahead in the CAR-T field and would like to stay that way. The Pharmaceutical Inclusion STI feels like there is unfair competition from the upcoming academic production. An overview of the dimensions of these competing STIs is shown in table 3. The Academic-driven pharma STI consisted mostly of academics and hematological internists and the Pharmaceutical Inclusion STI consisted mainly of the members of the pharmaceutical companies, with some exceptions.

Table 3

Dimension	Academic-driven pharma	Pharmaceutical Inclusion
national needs	Free information sharing Rare disease treatment Cost reduction	Removal of complicated laws Reduction in reimbursement approval time
Solidarity	less pharmaceutical interference more control over patient selection & drug development (production) cooperation	more inclusion and cooperation in governmental and healthcare institutions (full) cooperation
Temporality	Bring development back to where it came from	Continuation of the current trend
Competitiveness	reduce the influence of pharmaceutical companies	perceive academic research as unfair competition
Risks and benefits	Pharmaceutical influence decreases healthcare quality. Academical production increases patient welfare	Academic production has problems with quality control Pharmaceutical production increases patient welfare

Table 3: Overview of the dimensions of competing STIs within the PM field. Source: Own work

National needs

The National needs dimension encapsulates the way collective visions of the future resolve a problem for a country or society. Different STIs can have different methods to solve societal problems or have different views on the severity of the problem.

The Academic-driven pharma feels like academic development would increase the free flow of scientific information. This will increase transparency and communication and benefit the scientific community. They would like to have CAR-T as a backbone therapy on which they can modify the therapy to other (rare) diseases. Both these things are lacking in current pharmaceutical development according to the Academic-driven pharma.

> *"Pharma does share information but not everything, academical information is freely available for everyone and increases transparency" - PMC hematological internist*

> *"If we are purely dependent on pharmaceutical industry, you can only hope that they find a treatment for rare diseases, the pharmaceutical industry has little interest in rare diseases, but with academic production you can do this" - UMCG hematologist internist*

In the first quote, information-sharing benefits of academic production are expressed and in the second quote, a lack of interest of pharmaceutical companies in orphan diseases is stated, which would be resolved with academic production.

The Academic-driven pharma STI thinks that the current price the national healthcare insurance pays for the current CAR-T cell therapy is too high and would like to reduce the price. The Academic-driven pharma STI thinks that academic development and production would reduce that price significantly.

> *"the price that health insurance pays for car-t therapy is far too expensive" – RadboudUMC internist hematologist*

> *"the consequences of academic production would probably be that costs go down significantly" – AMC internist hematologist*

That the expensive costs for CAR-T cell therapy are the fault of the pharmaceutical development, is supported by the media that frequently frame pharmaceutical companies as greedy, money-hungry entities. As is shown in the following quote:

> *"Half a million euros, for a bag of cells, that reeks of pharmaceutical greed. ... the new treatment could earn the company billions." – De Volkskrant, 2018*

The Pharmaceutical Inclusion STI feels there is too much complex bureaucracy, with outdated, burdensome rules. They frame the field as rapidly changing and complex, resulting in outdated laws. This STI imagines a lack of flexible regulation and a faster reimbursement process as a societal problem hampering innovation.

> *"The complexity and innovativeness of the product makes the reimbursement process longer and more difficult … as a result, those processes also take longer. There should be a trajectory for that and there should be more access for innovative projects." - Pharmaceutical manager, market and reimbursement*

> *"The laws are lagging behind the facts and studies. It is difficult to reach agreement with the government on this. That costs a lot of time... in the Netherlands this is quite complex due to the number of regulations" - Pharmaceutical manager, governmental affairs and policy relations*

These quotes signify the complexity and lengthy process of CAR-T cell development by the Pharmaceutical Inclusion STI. This STI envisions that more inclusion and cooperation of pharmaceutical companies in regulation and policy solves this problem. This STI is supported by the media, stating a need for faster procedures and less complicated regulations.

> *"It is difficult to start clinical research in the Netherlands. That's because we must deal with long and complicated procedures … Acceleration of those procedures is necessary" – ANP, 2021*

In opposition, the Academic-driven pharma STI thinks that because academic institutions do not have to abide by these strict laws, academic production will be cheaper and faster.

> *"(About laws and regulations for pharmaceutical companies) It is crazy complicated in laws and regulations, that's just a shame. And this (going back to academical production) is an excellent first step." – UMCG academic CAR-T researcher*

Policy has probably been influenced by the framing of the high reimbursement costs. Policymakers probably encountered multiple sources complaining about the high costs and the burden for the society of CAR-T cell therapy. This framed a national need for a cheaper alternative. This has been made clear in the media framing analysis in which almost every article presented the high costs as a problem. Researchers and hematologic internists also often noted that the price was one of their biggest concerns. The concurrent subsidization of academic production and development is a reaction to these high costs. This subsidization further established the Academic-driven pharma imaginary by legitimizing the possibility of academic production. This was concluded by researchers and hematologic internists positively reacting to the idea of bringing more responsibility and influence in academic institutions.

The need for better laws and a reduced reimbursement time heavily influenced policy. Since 2013, several requests and letters have been sent to the Dutch House of Representatives over the years, asking for up-to-date laws and a reduced reimbursement time (Schagen & Hospers, 2013; Beintema, 2019). The media also mentioned complex laws, framing it as a reduction in Dutch competitiveness. This pressure caused a legislation proposal and discussion of PM regulations in the Dutch House of Representatives in 2019 with no results (Beintema, 2019). This eventually resulted in the relaxation of environmental law later in 2021 to reduce reimbursement time.

In summary, the competing STIs frame different societal problems to be solved. Academic-driven pharma frames free information sharing, rare disease treatment, and cost reduction as societal problems solved by academic production. The Pharmaceutical Inclusion STI frames the removal of complicated laws and the reduction in reimbursement approval time as societal problems solved by an increase of inclusion and cooperation of pharmaceutical companies. As seen in table 3.

Solidarity

The solidarity dimension is about who should be held responsible and who should be included. It envisions which group within the society should provide a good or activity and who should benefit from it.

The Pharmaceutical Inclusion STI feels that they are getting more excluded from healthcare policies discussions. This STI voices a lack of trust in pharmaceutical companies from governmental and healthcare institutions. They want to keep cooperating and be included more to improve healthcare and implement changes. As is shown in these quotes:

> *"Companies are getting excluded in healthcare improvement. This is mainly about trust, to involve all parties in the conversation would result in better regulation" - Pharmaceutical manager, registration and quality*

> *"The government can bring healthcare and pharma together, and we can remain conversation partners. There are a lot of conversations that are about pharma,*

where pharma is excluded, so we want more inclusion of pharma in conversations. Because it doesn't help to introduce changes this way, you need all parties for that." - Pharmaceutical manager, governmental affairs and policy relations

Some academics had parts of Pharmaceutical Inclusion as an imaginary. However, every academic interviewed believed pharmaceutical companies had too much power and influence in current institutions. There is a prevalent idea of removing power from pharmaceutical companies and bringing it back to academic and professional groups. The main reasons to restore academic control and reduce the pharmaceutical influence are the extremely high price; the decreasing autonomy of hospitals in patient, and medicine selection; and the meager information sharing from pharmaceutical companies. The Academic-driven pharma thinks that academic production will solve these issues.

"if we are completely dependent on the industry for all kinds of various disorders, healthcare will no longer be affordable" - UMCG academic CAR-T researcher

"Ultimately the pharma can decide whether or not a center is suitable for their product … this responsibility should lie with the Dutch Hematologic Association"- AMC internist hematologist

"It is necessary to reduce our dependency on pharmaceutical companies and return the power to the professional groups" - Radboud UMC hematological internist

Contrary, some academics that identified with the pharmaceutical focus do agree fiercely with more collaboration and communication with pharmaceutical companies for expansion purposes. These academics note that the production capacity, supplied by the pharmaceutical industry, is of vital importance. Highlighting that some academics also connect to the pharmaceutical focus.

"I think you need each other, the large infrastructure, studies, and production capacity that pharmaceutical companies provide versus the innovation and knowledge that academia provides" - UMCG academic researcher and hematological internist

The previously mentioned letters to the Dutch House of Representatives and refusal of the government to improve regulation time and complex laws indicate that the cooperation and inclusion of pharmaceutical companies are indeed lacking in policymaking. Better communication with pharmaceutical companies could have improved the pharmaceutical climate in the Netherlands and improved the drug development earlier.

The creation of the CAR-T tumor board was for a part a reaction to the pharmaceutical influence in patient selection. The creation of the CAR-T tumor board connected CAR-T specialists and academics. This, in turn, originated the idea for the academic production and development of CAR-T cells. This way sociotechnical developments influenced the creation and establishment of new visions of the future.

Overall, the Pharmaceutical Inclusion STI relays a feeling of a lack of trust and inclusion in academic and governmental communication. They do not think they have too much power and they feel are portrayed badly and inaccurately. This STI envisions a future with more inclusion in governmental and healthcare institutions. The Academic-driven pharma STI imagines a future with less

pharmaceutical interference and more control over patient selection and drug development. Cooperation was deemed essential by both STIs, only the extent of the cooperation should be limited to production and infrastructure, according to the Academic-driven pharma STI.

Temporality

The temporality dimension contains the impact of the past and what futures should be attained or abandoned. This dimension is about the influence of history and possible futures on society by new technologies.

The desired future of the Academic-driven pharma STI is one rooted in history. The Academic-driven pharma STI has a nostalgic feeling of the time in which drug development was mainly in the hands of academic institutions. They frame academic production not as a way forward, but as a way of going *"back to where it came from"*. As seen in this quote:

> *"I think it's a good first step, if we can get it back … it originated in the academy, we can take it back to the academy" – UMCG researcher*

Pharmaceutical companies refused to comment on academic production, but one might conclude from this refusal that they feel threatened by the rise of the Academic-driven pharma STI. The Pharmaceutical Inclusion STI sees a trend in which healthcare involves more diverse parties in projects and would like that trend to continue.

> *"What I've seen in recent years is that healthcare is trying to involve more and more parties in (policy) conversations, but that's not the case everywhere yet, this would be a good direction" – Pharmaceutical manager, governmental affairs, and policy relations*

The desire for a continuation of this trend is probably based on their desire for less regulation by the Pharmaceutical Inclusion STI. The desire for reconfiguration of the future by Academic-driven pharma is embedded in the former responsibility that academic institutions had. By noting that it is possible, because it already happened in the past, legitimizes the cause of the Academic-driven pharma STI. The policy subsidizing academic production advanced and re-legitimized this vision. Possibly influencing future policies regarding academic production.

In summary, the Academic-driven pharma envisions a nostalgic point in history. While the Pharmaceutical Inclusion STI probably envisions a future with more inclusion and influence for pharmaceutical companies.

Competitiveness

The dimension competitiveness is about who or what party is ahead, in what respects, what needs to be remedied, what needs to be preserved.

The Pharmaceutical Inclusion STI thinks there is unfair competition with the subsidization of academic production. Academic and pharmaceutical research both needs a selective group of patients to test their medicine on. This patient group is limited in the Netherlands and recent

subsidized research competes with pharmaceutical research in this regard. One of their issues is the competition with the number of patients available in the Netherlands.

> *"They also do studies on CAR-T cells in the same hospitals with the same patients that we could treat with our CAR-T cells, in terms of development capacity, it is inconvenient"– Pharmaceutical startup COO*

> *"as far as I'm concerned it's not a level playing field (pharma about Groningen)" – Pharmaceutical startup COO*

Only quotes from the pharmaceutical startup COO can be used since he was the only pharmaceutical actor willing to comment on this subject. These quotes state that academic production in Groningen is unfair competition and that there might be too few patients available for clinical trials if academic production gets more involved. However, since pharmaceutical companies mostly refused to talk about academic production or the €30 million subsidy, one can imagine this policy influenced the competitiveness dimension of the Pharmaceutical Inclusion STI heavily. They probably feel threatened and might lobby against future policies in favor of academic production. Unfortunately, no further conclusions can be made with certainty on the influence of these policies on the Pharmaceutical Inclusion STI since the data is missing.

The Academic-driven pharma STI perceives that the pharmaceutical companies are currently too far ahead. They think their influence is too far-reaching and would like to limit that. Especially in patient selection as mentioned in the solidarity dimension.

In summary, the Pharmaceutical Inclusion STI thinks that academic research is unfair competition and would like to reduce academic clinical CAR-T trials. The Academic-driven pharma STI would like to reduce the influence of pharmaceutical companies in hospitals.

Risks & benefits

The risk & benefits dimensions relate to the perceived contemporary losses or profits, respectively, connected to each STI. It is about possible boons and dangers to society related to STIs.

As is shown in the national needs dimension, Academic-driven pharma thinks that the reimbursement costs of the current CAR-T therapy are too high and that this could be resolved by academic production. To counter the argument of the high reimbursement costs, the Pharmaceutical Inclusion STI argues that the price is fair and corresponds to the high production costs and the extremely high economic risk they face when developing this new therapy. As is shown in the next quote:

> *"I think that (pharmaceutical companies) are currently making a loss on the current CAR-T therapy, even with a price that high" - Pharmaceutical startup COO*

The high economic risk framed by the Pharmaceutical Inclusion STI is confirmed by several articles in economically focused newspapers. As is shown in the following quote:

> *"(CAR-T producing pharmaceutical company) certainly has potential … For the time being, we do not think the ratio between the very high risk and the possible reward is optimal (about stock options)." – Trends, 2018*

In 2019, several business newspapers stated that the risk of developing and producing a complex therapy like CAR-T has extremely high risk. This is reflected in the fluctuating stock prices of Celyad Oncology (a pharmaceutical CAR-T company) over the years as seen in figure 4. Stock prices as high as € 70,95 and low as € 3,43 emphasize the economic risk associated with pharmaceutical CAR-T cell development.

Figure 4

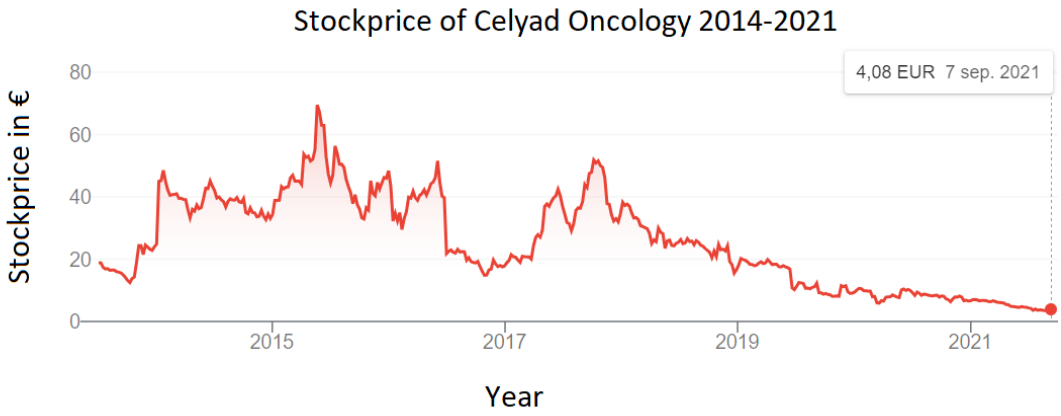

Figure 4: Stock price of Celyad Oncology between 2014-2021, adapted and modified from EURONEXT, 2021.

The Pharmaceutical Inclusion STI argues against the subsidization of the government for academic point of care production and development. They bring up possible risks with quality control and a lack of production capacity with academic production. The Pharmaceutical Inclusion STI simultaneously voices a lack of trust in academic production or refuses to disclose more information.

> *"How can the quality be guaranteed or how can changes in the production process be controlled? With all those variables it is hard to guarantee the safety of the patient with academical production" – Pharmaceutical manager, registration and quality*

> *"I have a lack of confidence ... how are they going to routinely treat thousands of patients, how they're going to do quality assessment" - Pharmaceutical startup COO*

In both quotes, a lack of trust and concerns about production and quality assurance are stated as risks of academic production.

> *"Working days until 11/12 o'clock in the evening to arrange things for a patient is common … it takes a lot of time but is also worth helping patients in this way." - Pharmaceutical manager, registration and quality*

> *"the most important thing is that the patient's interests come first." - Pharmaceutical manager, governmental affairs and policy relations*

These quotes show the framing of the Pharmaceutical Inclusion STI. They promote their position by framing that their number one priority is helping patients, instead of selling their product. They frame their stories with self-sacrifice and strenuous effort to help cure patients. Pharmaceutical

Inclusion STI promotes the idea that inclusion and cooperation with pharmaceutical companies will be in the best interest of patients. However, the Academic-driven pharma STI has a different view as is seen in the next quote:

> *"pharmaceutical involvement in hospital processes is very large... ...the most important thing is that (the product) is sold. We want the very best for the patient, but it is difficult because the selling of as many products as possible often overshadows the patient needs (from the pharmaceutical industry)" - Radboud UMC hematological internist*

This quote shows that the Academic-driven pharma STI, like previously mentioned, mostly feels pharmaceutical companies are too meddling and that this could end in a reduction in patient care quality. The Academic-driven pharma STI feels like the cooperation with pharma is stifled by different end-goals, they feel pharma's first and foremost goal is to sell their product, and not to provide the best care for patients, contrary to pharma's phrasing.

The risks and downsides of pharmaceutical production have suddenly been enlarged and put into perspective by the addition of an alternative. The rise of the Academic-driven pharma STI seems to increase awareness of problems in pharmaceutical production. This is shown by increasing complaints on pharmaceutical costs, interference, and their reluctance to research rare diseases. As is shown in various interviews and media. The recent increase in emphasis on risks, in pharmaceutical production, is enabled by the rise of the Academic-driven pharma STI, which in turn legitimizes the Academic-driven pharma STI. Both STIs are supported by the media. The Academic-driven pharma framing seems to get support from regular newspapers while the Pharmaceutical Inclusion framing seems to be supported by economic newspapers. This shows why the Netherlands seems to support both the new pharmaceutical CAR-T cell factory and at the same time, subsidize academic production. Both STIs have broad support in the media and include influential actors in the CAR-T field.

In summary, these quotes illustrate the framing of different parties on the risks and benefits of their STI. The Pharmaceutical Inclusion STI is framed towards the benefits of patients, provided for by pharmaceutical companies, and towards the risks of quality control that accompany academic production. The Academic-driven pharma STI thinks that the Pharmaceutical Inclusion STI hurts the quality of individual healthcare by their focus on financial gain and that academic production will fix this problem.

Discussion

This thesis analyzed the sociotechnical imaginaries and policy developments of personalized medicine in the Netherlands between 2012-2021 to study the interplay of these two components. This interplay was studied by a media analysis over the period 2012-2021 and interviews with key players within the CAR-T field.

I conclude that there are two dominant sociotechnical imaginaries within the personalized medicine field in the Netherlands. These two dominant imaginaries both centered on how and where

personalized medicine should be developed. I have named them 'Pharmaceutical Inclusion' and 'Academic-driven pharma', respectively. The overview of the two dominant STIs and their visions are shown in table 3. The Collaborative Pharma STI holds a vision of the future with a continuation of pharmaceutical production with more influence and inclusion in policy discussions with governmental and healthcare institutions, resulting in less complicated laws and a reduced reimbursement approval time. The Academic-driven pharma STI holds a vision of the future with academic drug production and development, which would improve information sharing; enable rare disease treatments; reduce treatment costs; reduce the pharmaceutical influence in healthcare; increase patient welfare.

Both STIs strongly feature the solidarity, national needs, and the risks & benefits dimensions. Both imaginaries make one actor primarily responsible for research & development of personalized medicine (responsibility part of the **solidarity** dimension) and frame their imaginary as beneficial for society by solving societal issues (**national needs** dimension). Both imaginaries frame the competing imaginary as a possible reduction in patient care quality while only emphasizing the risks and not acknowledging any benefits of the competing STI (**risk & benefit** dimension). The other dimensions, **temporality**, and **competitiveness** were found to be significantly less influential. The media and interview analysis showed a shift in the common sociotechnical imaginary from the Collaborative Pharma STI to the Academic-driven pharma STI, allowing the second to become more established. This STI was grown from worries over rising costs and inadequate patient care, eventually giving rise to the CAR-T tumor board to combat this, then promoted by the €30 million subsidy to the UMCG, establishing the STI more firmly. The existence of a possible alternative to pharmaceutical production exposed and emphasized the risks and downsides of the pharmaceutical STI. This is supported in risk perception theory, according to Langford (2002), risk perception is increased by the addition of a new option. This also is shown by an increase of negative framings in the media and in a shift of attitude, reported by interviewees.

This analysis shows that the field of PM in the Netherlands is rapidly evolving and that the STIs are actively competing against each other. The changing STIs are affecting policy and practice, shown by the 30-million-euro subsidy for academic production by the UMCG and the environmental law relaxation. These policies, in turn, are affecting the evolution of the STI by legitimizing academic development and production and the settlement of a new pharmaceutical CAR-T factory, as is shown in interviews and media. It shows a fast-rising STI that still needs to prove itself. It also shows the confidence of key actors in this STI that is only mirrored by the doubts raised by key players with conflicting interests. It highlights the influence of policies on collective expectations and vice versa. This study shows the effects of an upsurge of a minor STI on the attitude and perception of the competing, dominant STI.

The interplay between evolving and shifting STIs and policy has been relatively unexplored. This study adds to the theory of sociotechnical imaginaries by showing the interplay of different imaginaries and policy practice over time. Future research could focus on the use of the knowledge gained on these STI's. Previously mentioned anticipatory practices by could be implemented on PM. Practices like scenario building or prototyping innovations (Alvial-Palavicino & Konrad, 2019). The STI and policy change evolution can then be analyzed after a few years of anticipatory practices. These can then be reflected on the results in this study of competing imaginaries to measure the impact of these anticipatory practices more accurately. This way, the impact of anticipatory practices can be

determined. Future research could also focus on the more precise dynamics of the competing STIs and their interplay.

The knowledge of the current situation and evolution of STIs can assist policymakers. Policymakers often have a lack of knowledge on alternative futures and the risks or benefits that resides within that alternative future (Carolan & Hale, 2016). Alternate futures bring different possible interventions and solutions with them. Although, even if the different STIs are known by policymakers, many of the differences and disagreements in those STIs can come from implicit assumptions that the policymakers are not aware of (Vervoort & Gupta, 2018). Which makes it difficult for policymakers to fully understand other STI's. This explains the need for deep analysis and explanation on the current STIs that exist within a nation. This will provide a more varied and reflexive view of different possible futures and how to engage with them (Oomen, Hoffman & Hajer, 2021). Pfotenhauer & Jasanoff (2017) suggest that policymakers should first determine as precisely as possible the deficiencies they seek to address. Then choose the STI which solution best addresses those deficiencies. Then recognize and determine the constituencies that share or oppose that STI. Then connect with these actors and find the accessible political, social, and institutional pathways for attaining these solutions. This way policymakers can recognize what sources they should use. This also lets policymakers draw upon sources of authority for legitimation and get affective engagement of their audience (Oomen, Hoffman & Hajer, 2021). By analyzation of the STIs of personalized medicine from this research, policymakers can now more accurately draw up sources of legitimation, have a more varied view on possible engagement with the future, and better recognize valuable actors. I would recommend policymakers analyze which societal problems they would want to solve. Based on their priorities, they could connect with key actors in STIs that best solve these societal problems. Policymakers should connect with actors in the Pharmaceutical Inclusion STI to revise complex laws to make the Netherlands a more attractive biomedicine country for companies to settle in. These key actors, as shown in this study, are most likely found in pharmaceutical companies. Their knowledge of too complex or redundant laws might be valuable tools for policymakers. If the priority lies with increased free information flow, drug cost reduction, or rare disease treatments, they could connect with key actors within the Academic-driven pharma STI. These key actors are found in the CAR-T tumor board and academic CAR-T researchers. By determining key actors, it becomes easier to legitimize policy, connect valuable actors, and get more affective engagement with their audience. Knowledge of the existence of competing STIs in the PM field is valuable for policymakers to have a more varied view on possible future engagements. Therefore, I would advise analyzing the results of this research before implementing important policies in the field of PM. However, additional investigations into the actual feasibility of these STIs are needed before serious commitment of policymakers.

Strengths & Limitations

This research has been coded, analyzed, and interpreted by only one researcher. Therefore, mistakes and data could have been overlooked or misinterpreted respectively. The data found in interviews overlaps with the data from the media analysis. This increases the reliability and validity of the interpretations. The interviewees all had a thorough knowledge of the subject and were important players in the field. The lack of interviews with policymakers does hurt the interpretation of the intention of the policy. However, this study needed only a brief overview of the biggest policy

changes, which are abundantly found in the media analysis. The interpretation of the policy has been sufficiently resolved by interviews with key actors of CAR-T therapy. Since they actively interpret, influence by consultancy, and work with these policies.

Conclusion

This research aimed to identify the interplay between the sociotechnical imaginaries of personalized medicine and healthcare policy practices in the Netherlands in the past nine years. Based on a quantitative analysis of the current and past sociotechnical imaginaries of personalized medicine, it can be concluded that there are currently two competing sociotechnical imaginaries, identified as 'Pharmaceutical Inclusion' and 'Academic-driven pharma'. These sociotechnical imaginaries envision more pharmaceutical influence and inclusion in healthcare and policymaking (Pharmaceutical Inclusion) or academic drug development and production (Academic-driven pharma). It shows a rise in Academic-driven pharma STI in the last nine years. When analyzed against the policy practices of the last nine years, it shows that the implementation of policy is influenced by, and influences, the evolution of the sociotechnical imaginaries. The results show that the competing imaginaries also influence each other by putting emphasis on risks and ignoring the possible benefits of the competing imaginary. Based on these conclusions, policymakers can benefit from an extensive knowledge of competing STIs to make more informed policy decisions. To better understand the implications of these STIs, follow-up studies can be done in different technological fields to analyze similarities or differences. Further research is needed to determine the relationship between a rising and dominant STI for additional possible effects. This research shows the dynamic interplay between STIs and policy in the Netherlands in a rising technological field.

The use of collective imaginations of new technologies to visualize possible futures is an interesting concept. Investigating how scientific and technological fields are impacted by expectations and visions of sociotechnical change brings about a wealth of knowledge and possible theoretical applications. How the evolution of these visions shape, and are shaped by, key actors and policies, and might eventually shape the direction of research or social change is an important study. A great deal can be learned from the study of sociotechnical imaginaries. Especially in a world where new technologies rise and heavily influence society. The production of complex personalized medical interventions like CAR-T would have seemed unbelievable a few decades ago. This shows that humanity is not limited by its imagination but enabled by it.

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