

The creation of the European Health Emergency preparedness and Response Authority (HERA)

A comparative case study of the health preparedness in the
European Union before and after the COVID-19 pandemic
outbreak

Josefin Stenquist

Abstract

The last two decades have been marked by pandemics, epidemics, and outbreaks of infectious diseases. They have highlighted the challenges and flaws the EU has been standing in front of regarding public health emergency preparedness. Public health officials and scholars have presented the need for more developed coordination, cohesion, and communication between the Member States and the EU and its institutions, but without any major changes made. Two years after the COVID-19 pandemic outbreak appeared, the European Health Emergency preparedness and Response Authority (HERA) was created. The puzzle of this thesis is therefore based on the question of why any similar authority did not exist before the COVID-19 outbreak. The findings indicate how changes within the public health policy in the EU have been difficult for several reasons. The Member States did not want to relinquish their sovereignty and autonomy over health, which affected the cohesion and therefore the coordination within crisis preparedness. The thesis demonstrated how the path dependence in health policy was difficult to break, to change the institutions, and hence create anything similar to HERA. What made institutional change difficult pre-COVID-19 could be described as these infectious disease outbreaks were not strong enough to change the robust path dependence.

Key words: public health policy, crisis preparedness, infectious diseases, historical institutionalism, exogenous shock

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Abbreviations

CDC – Centers for Disease Control and Prevention

EC – European Commission

EVD – Ebola virus disease

ECDC – European Centre for Disease Prevention and Control

EMA – European Medicines Agency

ECPP - European Civil Protection Pool

EU – European Union

EWRS - The Early Warning Response System

CPM – Civil Protection Mechanism

HERA – European Health Emergency preparedness and Response Authority

HSC – The Health Security Committee

HI – Historical institutionalism

H1N1 (H1N1pdm09 virus) – Swine Flu

MS – Member State

SARS –Severe acute respiratory syndrome

SARS-CoV-2 – COVID-19 pandemic

WHO – World Health Organization

WHO/Europe – WHO Regional Office for Europe

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1 Introduction

During the twenty-first century, the world has been hit by several epidemics and pandemics, and Europe and the European Union (EU) have not been spared from these outbreaks. The outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 (WHO) challenged the European Union and the governments of the member states (Elbe, et al, 2014, p 441). This was followed by the avian flu called H5N1 from 2003 to 2017 (ECDC, 2022) and the swine flu H1N1 in 2009 (WHO), which led to a strengthened strategy in terms of pandemic planning such as surveillance, vaccines, and public interventions in the EU (Martin and Conceil, 2012, pp 1094-1095). In Greece, Plasmodium vivax malaria and West Nile Virus were found whereas Portugal suffered from cases of dengue fever (Földes, 2016, p 81). This was shadowed by the outbreak of Ebola in 2014 which brought the importance of cross-border preparedness to the table (ibid).

This demonstrates how the EU faced numerous situations where infectious diseases could have been a potential threat to the Union. Researchers and public health officials urged the Member States to enforce national legislation for pandemic preparedness to better prepare the member states for a potential pandemic (Speakman et al, 2017). Scholars also presented how the EU and its Member States needed to improve the communication and coordination with each other in terms of pandemic preparation, as well as the coherence and divergence of the pandemic preparedness plans (Droogers et al, 2018; Holmberg and Lundgren, 2016). Pressure to take the threats of infectious diseases more seriously also came from international organizations such as WHO and ECDC (ECDC 2017, WHO 2013).

The research and pressure from scholars and international organizations considering a coherent crisis preparedness could have paved the way for a developed crisis preparedness authority ready to fight a potential pandemic, but this was however never the case. Soon after the COVID-19 pandemic hit, the authority European Health Emergency preparedness and Response Authority (HERA) was created. Even though the COVID-19 and its outbreak were something new of its kind, this does not explain how a crisis preparedness institution such as HERA was not already present, considering the repeated pressures from scholars and public health officials. This leads to the research question of the paper: *Why did HERA not exist before the COVID-19 pandemic outbreak?*

To be able to answer the research question, the material is investigated through a perspective of historical institutionalism and exogenous shocks, and path dependence. The infectious diseases work as exogenous shocks and independent

variables in order to find out how their strength affects the following path dependence leading to institutional change or not. HERA is hence working as a dependent variable and is indicating the institutional change in the two cases. Case 1 is covering the years 2003-2019 which is based on the year in which SARS had its outbreak until the year when the COVID-19 pandemic outbreak began. Case 2 is covering the years as the COVID-19 pandemic outbreak began until the creation of HERA and thus 2019-2021. This proceeds through a comparative case study in combination with process tracing.

The analysis indicates that although the exogenous shocks in case one was rather strong and had the capability of changing the institution to some extent, they were not strong enough for any institutional change such as HERA. Instead, they developed and extended existing institutions and added authorities and decisions as well. The problem of coordination and cohesion between the member states and the institutions was however still remaining after the changes were made, which highlighted the complexity of the public health policy and the shared responses between the Member States and their strong autonomy and the EU and its institutions.

Scholars and international organizations kept informing the Member States about these challenges but without any major response.

The analysis further indicates that when the COVID-19 pandemic outbreak hit, it seemed like the attitude amongst EU citizens had changed, and they were willing to give up some of their autonomy in favor of a coordinated and coherent approach to tackle the pandemic. One could hence argue for how the COVID-19 pandemic outbreak was an exogenous shock strong enough to change the path dependence and institutional change and create HERA.

2 Background

The background provides an overview of the crisis preparedness mechanisms available before the COVID-19 pandemic outbreak crossed the EU. Since the system of mechanisms and organizations is complex and includes several actors, this thesis focuses on the Health Threat Decision, The Health Security Committee (HSC), and the Civil Protection Mechanism (CPM), which could be considered the most relevant ones for this thesis, after inspiration from the paper by Brooks and Greyer from 2020. The background is of relevance since it is providing a broader understanding of the different tools and mechanisms available for the EU regarding cross-border health threats and crisis preparedness. Those are important to address in order to understand what capacity the EU had to tackle health threats before the outbreak of COVID-19 was present. A background is furthermore an important tool in trying to explain the challenges the EU was standing in front of during the COVID-19 outbreak and trying to explain why HERA was not created before 2019 and the COVID-19 outbreak.

2.1 Crisis preparedness in the EU before the creation of HERA

This section is summing up the organizations that operated as crisis preparedness institutions before the COVID-19 outbreak. Since there are many actors involved and the scope of this thesis is rather limited with the timeframe and space, there will be a selection of the institutions of relevance for the thesis. The chosen authorities are picked from the years 2003-2019 which is the first case I will analyze in this thesis. The year 2003 is selected after the outbreak of SARS in 2003 which led to the founding of the ECDC in 2005. To be able to choose the most relevant institutions within this timeline I used inspiration from the paper written by Brooks and Geyer in 2020.

Brook and Geyer are presenting the two major institutions used when the COVID-19 pandemic outbreak hit: The Health Threats Decision and the Civil Protection Mechanism (CPM) (Brooks and Geyer 2020, p 1059). These authorities are now going to be introduced, together with the health security Committee (HSC) who all worked with crisis preparedness and planning as the COVID-19 pandemic was entering the European borders.

2.1.1 The Health Threat Decision

The Health Threats Decision which is called “decisions on serious cross-border threats to health and repealing Decision No 2119/98/EC” (European Parliament and the Council, 2013) is a framework that was created in 2013 as a response to the outbreak of the Swine Flu (Brooks and Geyer 2020, p 1059). It consists of measurements such as article 4 including “preparedness and response planning”, article 6 “epidemiological surveillance”, and article 8 which is covering “early warning and response” (European Parliament and the Council, 2013). It also operates with procedures such as article 12 – “recognition of emergency situations” and article 16 “protection of personal data” (ibid), to mention some of the articles included in the Health Threats Decision. The decision was hence created to strengthen the cross-border cooperation between the member states and the EU’s institutions in case of a new infectious disease threat (ibid).

The decision is integrated with other authorities such as the Health Security Committee (HSC), the Civil Protection Mechanism (CPM), and the European Centre for Disease Prevention and Control (ECDC) which will be elaborated on further in the next sections. These authorities are of importance in order to understand the crisis preparedness mechanisms in the EU and their limitations, to be able to understand the creation of the HERA.

2.1.2 The Health Security Committee (HSC)

To get a broader understanding of crisis preparedness, the institutions and their functions will now be further elaborated on and explained, starting with the HSC. The Commission is describing the HSC as a committee assigned to “reinforce the coordination and sharing of best practice and information on national preparedness activities” (European Commission, 1).

The MS are coordinating their national crisis preparedness plans and decisions in the setting of HSC when a threat could be a cross-border issue that would affect the other Member States as well (European Commission, 1). They are also cooperating in cases where the threats are considered to be of emergence worldwide in accordance with the so-called International Health Regulations (IHR). The IHR is a regulation for the WHO’s Member States where all EU Member States are included and is requiring the nations to report upon health threats that could be a danger from a cross-border perspective (WHO). Besides the previously mentioned activities, the HSC is also making sure that the general communication towards health workers is consistent and consequent throughout the different member states (ibid).

The committee is working on a few prioritized tasks, and these include the following: “detection and communication, threat and risk assessment, preparedness, scientific advice, crisis management and testing of plans and

cooperation” (European Commission, 2). To give more concrete examples of how this is being proceeded, the committee can mobilize experts and help the MS by sharing their thoughts through the systems of communications (ibid). Within the risk valuation, they are gathering information on possible dangerous situations and are furthermore distributing the information to Member States and their domestic authorities (ibid).

Examples of previous situations where the committee operated include the H1N1 pandemic and the volcano ash clouds that happened in 2009 respective 2010. Both happenings were risks for the health and required meetings and coordination between the Member States to be able to tackle the situation in the best possible way (ibid). The HSC is hence a central organization in terms of a health threat since it coordinates the MS and coordinates the next steps that are necessary to make in order to decrease the damage. The procedures of the HSC during the COVID-19 pandemic and its outbreak will be further explained more in-depth in the thesis, but first, the other crisis preparedness institutions will be addressed, and the next one is the CPM.

2.1.3 The Civil Protection Mechanism (CPM)

The Civil Protection Mechanism is an organ that is working with civic safety in order to develop the crisis preparedness and prevention as well as responding to events that could be of dangerous character (European Commission, 2022 a). The organization consists of the Member States in the European Union and six other states: Norway, Montenegro, Iceland, Serbia, North Macedonia and Turkey (ibid). The mechanism can be applied in situations where any of the MS faces a crisis situation or threat that is not possible to defeat alone, and external help is needed. In those cases, the CPM can be called in (ibid).

The CPM is useful in terms of coordination and efficiency. In situations where member states are in need of assistance, they do not need to contact several different actors and risk doing double work. Instead, the CPM provides experts and the help that is needed for the specific situation (European Commission, 2022 a). There are several examples of situations where the CPM has operated such as the several fires around Europe, the war in Ukraine, and the COVID-19 pandemic (ibid). The latter includes both in a European sense and an international setting (European Commission, 2022 a).

In terms of crisis preparedness measurements which are of high importance in this thesis, the mechanisms have certain responsibilities which include “coordinate disaster preparedness and prevention activities of national authorities and contribute to the exchange of best practices” (ibid). The CPM is providing exercises for preparing for disasters for actors of the Member states such as experts (European Commission, 2022 a). Those are necessary in order for the EU to have cohesion in tackling threats around the EU (ibid).

The European Commission is highlighting how it is sometimes more efficient to have a general crisis preparedness approach for the EU instead of each domestic Member State and their authorities struggling with the upcoming threats alone (European Commission, 2022 a). To do so, they need to get an overview of the potential threats and endorse research in the field of disaster preparedness (ibid). The next subsection is presenting another highly relevant agency concerning cross-border health threats and crisis preparedness in the EU: the ECDC.

2.1.4 ECDC

The ECDC was created in 2005 as a response to the outbreak of SARS in 2003 as well as the threats of bioterrorism (Greer et al, 2020, p 58). It is an EU agency, and it is working on the prevention of infectious diseases (ECDC). Surveillance, data collection, and analysis as well as health preparedness are some of the measurements and tasks being performed by the organization (ECDC; European Union). They are also providing experts and advice and working with assessments and reports in public health and the area of infectious diseases (ibid). The ECDC will be mentioned throughout the thesis and is relevant to understanding the bigger picture of the crisis preparedness planning, coordination, and surveillance in public health in the EU.

To sum up, the background section has shown the main mechanisms used by the EU in terms of a pandemic, epidemic, or infectious disease outbreak before the COVID-19 pandemic outbreak crossed Europe. These institutions are all having different competencies and legal powers and consist of dissimilar actors. They are being shown and acknowledged in order to get a broader understanding of the possible tools the EU had to tackle a pandemic. This is useful when trying to investigate why the EU created HERA after the pandemic and not beforehand, and what possible flaws the EU had in terms of crisis preparedness in the public health policy.

2.2 Crisis preparedness post-COVID-19 outbreak

This section is presenting crisis preparedness in the EU regarding public health after the COVID-19 pandemic outbreak. The creation of HERA will be stated as well as its main tasks. After the presentation of HERA, the literature review will be shown to further understand the previous research within the field of public health and crisis preparedness and what challenges that has been appearing.

2.2.1 The creation of the European Health Emergency preparedness and Response Authority (HERA)

HERA was created on the 16th of September 2021 in response to the challenges faced by the EU during the pandemic (European Parliament Research Service 2022; European Commission, 2020). The creation of HERA took place in the context of the ECDC's increased mandate and the strengthening of the EMA (Council of the European Union, 2021), which were all measures implemented after the COVID-19 pandemic outbreak. This section is focusing on HERA and its role and mission. It is also presenting why such an organ was necessary as well as the challenges the EU was facing as the outbreak appeared.

As the COVID-19 pandemic outbreak spread across Europe, it became clear that the EU's crisis preparedness had flaws and needed to be developed in order to act quickly and coherently in an efficient way (European Commission, 2020). The coordination and coherence were two factors in particular that needed to be strengthened within pandemic planning, both between the Member States and the EU and its institutions (ibid, p 4). The different approaches and discrepancies are taken by the MS in terms of how to isolate and use masks to spread dissatisfaction and skepticism among citizens in the EU (ibid, p 5). In terms of the medical stockpile, vaccines, and personal protective equipment (PPE) the supply was insufficient (ibid, 8). The national crisis preparedness plans of the Member States were incoherent and sometimes also inadequate (ibid, 12). This has been demonstrated and presented by several scholars and international organizations throughout the years, which is shown in the literature review below. Furthermore, the underdeveloped national plans in combination with an uncoordinated approach from the EU led to an incoherent and uncoordinated approach to the pandemic response (ibid).

In order to answer these challenges, HERA was created. A new organ was needed in order to cope with the problem of the lack of coordination and cohesion between the member states as well as between the institutions and international organizations of cooperation. HERA is going to work both with crisis preparedness and response measures during ongoing health crises (European Commission, 2021 b). As for the crisis preparedness part, HERA is going to strengthen the collaboration and coordination with stakeholders involved such as the Member States health authorities and the global associates before the crisis actually appears.

The authority will work with assessing potential health threats as well as promoting and encouraging research in the field of medical countermeasures and coherent coordinated detached testing around the MS (European Commission, 2021 b). HERA is furthermore going to work with a strengthened capacity in terms of cross-border communication in public health policy (European Commission, 2021 b).

Unlike the ECDC, HERA will work more towards foresight concerning potential threats in the EU and orient on the response mechanism (European Commission 2021 d). Furthermore, HERA will work in close collaboration with the pharmaceutical industry and EMA and elaborate on the stockpiling and other medical measures such as vaccines (European Commission, 2020; European Commission 2021 d).

The presentation of HERA concludes the background section, and in the next chapter, the literature review will be shown in order to get an overview of the previous research within this field, the gap in the literature, and the relevance of the puzzle of this thesis.

3 Literature review

The literature review will provide a section regarding the strong autonomy the Member States have concerning health policy and the limitations the EU was standing for in terms of measurements and capacity, from a scholarly perspective. This is important for the general understanding of the crisis preparedness in the EU and the legal regulations affecting public health.

The literature review also presents the previous studies and research that have been made by scholars and public health officials regarding crisis preparedness and cross-border threats such as infectious diseases. International organizations and researchers have repeatedly presented how the coordination and preparedness have been inadequate and could be improved to better tackle future threats such as infectious diseases, pandemics, and epidemics. The previous research in this field is of importance to be able to grasp the foundation behind the structure of the crisis preparedness mechanisms before the creation of HERA, in order to answer the question regarding the timing of its formation. The literature is also highlighting the gap in the literature regarding the creation of HERA and why this is a topic of importance that needs to be investigated further. In addition, it presents the challenges by the current crisis preparedness system that the EU was facing. These paragraphs are of importance in the understanding of the struggles and shortcomings that appeared in public health. This will be elaborated further in the analytical part in order to answer the research question.

3.1.1 European Public Health and autonomy of the Member States

European public health is mentioned reputedly throughout the text and this concept will now be explained further and more in-depth. European public health is an umbrella term for a range of actions the EU is working on to improve public health – hence the health measures that are not carried out by the Member States themselves (European Parliament, 2021). The EU is working to prevent the Member States from pandemics and to be better prepared for such a disaster (ibid). This is of specific importance for this paper since the goal is to investigate and answer why the HERA and hence the crisis preparedness and coordination were not existing before the COVID-19 pandemic outbreak. The analytical part of the thesis will describe this section further and investigate the crisis preparedness before and after the COVID-19 outbreak.

To grasp the public health policy and the crisis preparedness of the European Union further, Article 168 of the Treaty of the Functioning of the European Union will be explained. This will be followed by a presentation on the autonomy of the member states regarding the public health policy and strengthening the understanding of why the EU has had limited capacity to tackle the COVID-19 pandemic.

Article 168 of the Treaty of the Functioning of the European Union (TFEU) is covering public health (TFEU, article 168). The first paragraph is stating how “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities” (TFEU, Article 168(1)). Scholars are arguing how the article has given the main responsibilities regarding health policy for the national member states and their regulations (Greer et al, 2014; Guy, 2020; Durelle and Engeli 2021).

The authors of the reports express how the Member States have had strong autonomy concerning health policy (Greer et al, 2014). It has been a policy area considered to belong to the Member States authorities as far as possible without the EU intervening gratuitously (ibid, p 20). Furthermore, the scholars are also presenting the fact that there are only a few joint competencies in the TFEU, in terms of public health policy (ibid).

They are also demonstrating how the EU just has the capacity to accommodate and encourage the Member States and their decisions (ibid). The strong autonomy of the Member States regarding health policy could affect the crisis preparedness of the European Union, and hence be an important tool in the understanding of HERA and why it was not founded before 2021. The advice from public health officials in WHO and ECDC will now be presented, to understand what challenges the EU has been standing in front of.

3.1.2 Advice and pressure from WHO and ECDC

“Today, in an interconnected world, bacteria and viruses travel almost as fast as e-mail and financial flows. Globalization has connected Bujumbura to Bombay and Bangkok to Boston. There are no health sanctuaries. No impregnable walls exist between a world that is healthy, well-fed, and well-off and another that is sick, malnourished, and impoverished. Globalization has shrunk distances, broken down old barriers, and linked people. Problems halfway around the world become everyone's problem” (Gro Harlem Brundtland, 2003, p 417).

The quote is taken from Gro Harlem Brundtland as she reacted to the SARS outbreak in 2003 and wrote an article about the difficulties and challenges the world was facing in terms of infectious diseases (Gro Harlem Brundtland, 2003). At the time she worked as the general director of WHO (United Nations Foundation), and the SARS shed new light on globalization and its effects and how infectious diseases could spread across the world with rapid speed. In her article, she urges

the world to take action by elaborate surveillance and extending the system of response regarding infectious diseases (Gro Harlem Brundtland, 2003, p 422). Harlem Brundtland also stressed the importance of the nations around the world to not only extend and collect data on the national surveillance but also be able to report this and interconnect the information in an international setting. Lastly, the author called on the world to take this outbreak seriously and to extend the capacity of resources, assets, collaborations, and preparation (Gro Harlem Brundtland, 2003, pp 422-423). She argued for how the next infectious diseases outbreak could be even deadlier and worse than the previous one and the world needs to be prepared to tackle it before it hits (ibid).

The next shocking and feared outbreak occurred in 2009, the H1N1pdm09 virus, also referred to as the H1N1 influenza pandemic (CDC).

The WHO conducted a report regarding the threat assessment after the pandemic was over, they showed how the nations to a global extent were still not equipped and prepared for a pandemic (WHO, Pandemic Influenza Risk Management, 2013, p 3). They further elaborated on how the nations worldwide needed to develop their own pandemic preparedness plans, including practices, and surveillance and appoint experts (WHO, Pandemic Influenza Risk Management, 2013, pp 26-27). WHO also advised the member states to develop cross-border pandemic preparedness by developing cooperation with bordering nations (ibid). This could be preceded by contributing with data and carrying out practices together (ibid). This advice was addressed to the WHO member countries and hence the EU member states (WHO).

Another public health authority that is working in close collaboration with the WHO and WHO/Europe is the ECDC. In 2017, the ECDC published the report “Guide to revision of national pandemic influenza preparedness plans” (ECDC, 2017). The report provided advice regarding cross-border pandemic preparedness. They suggested an international approach where the member states in the EU shared the data and preparedness plans with each other and had open communication in order for the EU to respond to pandemic threats as a union (ibid). In order to do so, they furthermore prompted common practices and strategies in case of an outbreak of infectious disease that requires cooperation (ibid). The ECDC, therefore, argued for the importance of having a coordinated coherent way of sharing information, tips, and useful information between the Member States for the best possible preparedness (ibid).

To sum it up, this subsection shows how the WHO and ECDC on several occasions urged the Member States to develop their crisis preparedness capacities with national pandemic plans and better communication and coordination between the Member States and the institutions. They argued that if these advices could be followed, the EU would have a stronger and more coherent crisis preparedness in case of infectious disease outbreaks. The next section is showing how similar advice was also given by scholars.

3.1.3 Information from scholars

Droogers et al are in their article from 2019 presenting how the Member States and their pandemic plans tended to lack any form of communication plan in case of an infectious disease outbreak (Droogers et al, 2019, p 588). The authors also stressed the discrepancy of the pandemic plans around the Member States and how their dissimilarities could be an obstacle in terms of general coordination between each other (ibid).

Brattberg and Rhinard (2011) addressed the problem of underdeveloped and inadequate preparedness plans and how the EU had urged the MS to develop them more extensively. In addition, the authors also stated how the Member States slowly handed out power to the EU institutions as they realized the positive effects of doing so in order to tackle a cross-border health threat (Brattberg and Rhinard, 2011, p 14). They are also demonstrating how the Member States at the same time had difficulties giving up their autonomy and allowing the EU to take legal decisions in pandemic control (ibid). The Member States found it difficult to agree on how to implement collaboration and what power the Court and Commission shall be given (ibid).

Holmberg and Lundgren are in their article from 2016 revising the national pandemic plans of a few selected Member States after the H1N1 pandemic in 2009 and the new Health Threat Decision in 2013. In their study, they are presenting how the different MS are all focused on different components and factors regarding the pandemic planning (Holmberg and Lundgren, 2016). They are arguing how this could have negative consequences and effects in a future pandemic, and that they are lacking important cohesion (ibid)

In conclusion, scholars have been urging for a coordinated cohesion between the Member States in terms of their crisis preparedness planning regarding infectious diseases throughout the years. Even though reforms have been made between the different studies, the scholars still advise a stronger cohesion, coordination, and communication, in order to be prepared for a pandemic outbreak. The advice from scholars and the previously mentioned recommendations from ECDC and WHO is highlighting the relevance of this thesis and its puzzle. The advice has been clear, explicit, and numerous, but besides this, the reforms have not been enough, which is a puzzle worth investigating.

The following subsection is further going to present the gap in the literature and the inspiration for this thesis as well as the challenges that the EU has been standing in front of during the corona pandemic.

3.1.4 The gap in the literature and the inspiration for the thesis

The inspiration for this thesis is partly based on the paper by Durelle and Engeli from 2021. Their study investigates how the ECDC has changed throughout the years and what impact the COVID-19 pandemic has had on the organization and its extended mandate, from a HI perspective. The timeline of the paper provides important events for the ECDC and its powers as well as general institutional changes in the public health policy (Durelle and Engeli, 2021). When the paper was written, the HERA was not yet created, and could hence not be discussed. Since it is an organization of high importance covering the preparedness and coordination of the EU, this thesis contributes to the extended discussion regarding the creation and questions why it was not already existing before the COVID-19 pandemic outbreak, considering the pressure from international organizations and scholars. The paper by Durelle and Engeli highlighted a sample of the challenges and obstacles the EU has been facing as the pandemic outbreak was appearing, and those will be presented in the section below.

3.1.5 Challenges in the crisis preparedness

The study by Brooks and Geyer argued how the recent pandemic revealed in what way these authorities and their capability were unsatisfactory and did not work out as planned (Brooks and Geyer 2020, p 1058). The authors are stressing how this could be explained through several factors. One of the factors highlighted was the limited and restricted maintenance from the MS to actually account for their crisis preparedness and response plans from their own governments. Another problem that the authors addressed covered how the meetings by the HSC were structured. According to them the HSC coordination was deficient, there was a slow response when the pandemic hit, and the meetings were not attended by every Member State (Brooks and Geyer 2020, p 1059). Another issue was based on the problem that ECDC did not get the data from the Member States that they were supposed to be supplied with (ibid).

The CPM is as already mentioned working to prevent disasters and crises by pooling and gathering resources from the member states to support and help each other in crises. The authors are illustrating that when the COVID-19 pandemic outbreak hit Europe, the response and solidarity of helping each other was low as the Member States prioritized themselves and their own crisis preparedness (Brooks and Geyer 2020, pp 58-60). Italy requested support but did not get much response for this reason (ibid).

This is demonstrating the challenges the EU has been tackling in terms of crisis preparedness and the capacity to respond to infectious diseases and disasters.

To sum up the literature review, this section has been providing a section including the autonomy of the Member States in the policy of public health, which is a section of importance to be able to understand the foundation of the crisis preparedness mechanism and their somewhat limited capacities, which is useful in the aim of

answering the research question. The paragraphs of advice from WHO and ECDC and scholars help grasp the previous research within this field and what advice has been given to the institutions and the Member States previously, in order to understand the puzzle and importance of this thesis. Lastly, the section covered the gap in the literature and inspiration for this thesis as well as the challenges the EU has been struggling with regarding crisis preparedness in public health after the COVID-19 outbreak. The latter is of importance to further grasp the shortcomings of the agencies, organizations, and institutions to understand why the institutional change was possible in order to find the mechanisms and answer the research question.

4 Theoretical framework

The disposition of the theoretical part will start with a brief description of the theory of historical institutionalism (HI), its connection to European integration, and a section about why history matters. This will be followed by the concepts of critical junctures, near-misses, and path dependence. Thereafter the paper will explain the concepts of positive feedback and exogenous shocks which are two perceptions of high importance in this approach and relevant concepts for this thesis. Lastly, a hypothesis is being presented connected to the theory and previous research.

4.1 Historical institutionalism

For groups competing for the same resources, historical institutionalism explains the group behavior through politics (Hall and Taylor, 1996). Hall and Taylor explain this as ways in which institutional structures in a political organization are benefiting certain interests and discharging other ones (Hall and Taylor, 1996, p 937). The theory is further focusing on the outcome of an institution and its construction (Steinmo, 2008).

An institution can be explained as “formal or informal procedures, routines, norms and conventions embedded in the organizational structure of the polity or political economy” (Hall, Taylor, 1996, p 938). Steinmo explains institutions as rules, either formal or informal (Steinmo, 2008).

To be able to adjust an institution, there must be a willingness and capacity from actors with influence to replace the institutions with new thoughts (Steinmo, 2008, p 170). An institutional change, therefore, requires an actor to first address the problem, and then find a solution that would lead to a better outcome. This also requires change by actors who provide power, in order to change the status quo (Steinmo, 2008). In the case of this thesis, HI will be used to understand the institutional change in the European Union within the public health policy and crisis preparedness. The theory can be a useful tool in terms of explaining the rather slow development of crisis preparedness in public health policy and the creation of the HERA after the COVID-19 outbreak.

The theory of HI demonstrates how history matters and the author Sven Steinmo shows this by demonstrating three important reasons why history shall not be neglected. His first argument for why history matters are that different political

proceedings occur in a historical setting which is of high importance for the decisions (Steinmo, 2008, p 127). An example of this, Gershenkron demonstrates how the timing of an event is of high relevance regarding the outcome (Gershenkron, 1962). The author uses industrialization as an example. Most recent nations to go through industrialization will learn the lessons from the first ones experiencing it and will therefore avoid mistakes they would otherwise have faced (ibid).

Steinmos second reason is based on lessons learned in the past. Political decisions need to be adapted to the situation and setting, which is based on experience from the past. The third and last reason history matters are based on how the past changes the prospects of future actions (Steinmo, 2008, p 128). The standpoint that history matters will be of relevance for my thesis in order to explain the public health policy and its institutional change and how the history is of importance for future decision making.

4.1.1 Historical institutionalism and European integration within the public health policy of the EU

Historical institutionalism has been used as a method within European integration in order to describe political and institutional changes, especially in the long term (Christiansen and Verdun, 2020). This approach has also been used in the study of comparative politics in the context of European integration as well as in the settings of the European institutions, the enlargement, and crises, to mention some the areas (Christiansen and Verdun, 2020).

Historical institutionalism is relevant for the thesis since I am investigating the crisis preparedness of the EU's public health policy, and this theory is applicable and suitable for crisis preparation in order to understand the institutional change, which is the aim of this thesis. I will also use comparative studies and process tracing to investigate the public health policy during a rather long time period from 2003 to 2021, which makes the theory appealing for this thesis.

Public health has not always been a natural policy in European integration. This does mainly depend on the high autonomy provided to the member states within this policy. The path did however change to some degree when the European Court of Justice took decisions that had high importance for future decision making, which is shown in the article by Greer (2008).

The path dependency was changed as the court decided upon two cases called Kohll and Decker in 1998. Both cases had to do with the mobility of patients, as they requested money from an insurance company in Luxembourg where they lived. They had gotten treatment in another EU country and wanted economic compensation, and it got denied. This led to a suing order from the private persons. The outcome of the suing order was that "The Court ruled in both cases that the

Luxembourg insurance funds' denials were unjustified discrimination on the basis of the member state of the provider" (Greer, 2008, p 222).

Another resolution of high importance was how the Court decided upon this judgment as belonging to the internal market and hence article 49, and not social security (ibid). According to the author, the decisions made by ECJ could be seen as a change in the path dependency since health policy was now considered a policy regarding the internal market (Greer, 2008).

This example is of importance since these happenings can help to explain the development of the health policy in the European Integration. Without these decisions taken by the ECJ, one might argue that the health policy would be considered to be a national domestic concern, under the category of social security. This example could also be seen through the theory of HI. The theory shows how difficult it is to change a decision, what happens at an early stage is of high importance for future decision making (Pierson, 2004).

Public Health Policy as a part of European integration is described as "chaordic" by the authors Lamping and Steffen (2009). By using this word, they refer to the fact that public health policy and its Europeanization could be seen as both chaotic and filled with order at the same time (Lamping and Steffen, 2009, p 1361). The paper aims to answer the question regarding how European integration affects public health policy (ibid). Their result shows how the influence of the EU has a great impact on the Member States, even though their formal and legal rights are rather low since the Member States have quite high autonomy in the policy of health (Lamping and Steffen, 2009, pp 1374-1375). The authors show how Member States have a high willingness of extending the mandate and increasing the influence of the EU in crisis situations and critical junctures (Lamping and Steffen, 2009, pp 1363-1364). As an example of this, the Commission established guidance in connection to the outbreak of SARS, and AIDS as well as the bioterrorism and its threats in 2003 (ibid).

This example illustrates how the EU could have a rather high influence on the Member States within public health even though their legal influence is limited. The Member States are willing to give up parts of their autonomy in times of crises and critical junctures. Next up, I will explain the concepts of path dependence, critical juncture and near-misses as well as exogenous shocks, which are concepts of high importance in this thesis.

4.1.2 Path dependence

This section will explain path dependence followed by critical junctures and near-misses which are concepts of high relevance in HI and for my case and thesis.

A particularly important concept within the study of historical institutionalism is path dependence. With roots in the field of economics, the concepts aim to explain how institutions remain, even though the initial efficiency of the institution may no longer be present (Fioretos et al 2016, p 9). To turn around a path can hence be a complicated and difficult process within institutions.

Pierson defines path dependence as "what happened at an earlier point in time will affect the possible outcomes of a sequence of events occurring at a later point in time" (Pierson, 2000, p 252). He is furthermore describing the concept as history matters, which is a broader definition (ibid). Pierson is stressing the importance of noticing the path in order to understand a certain social variable and its impact (Pierson, 2000, p 252).

The theory of historical institutionalism combined with path dependence gives the opportunity to analyze historical causality (Cappocia, 2016, p 2). Furthermore, this model supported the theory of how decisions in the past will have powerful and long-standing consequences for different institutions (ibid). There are two different perspectives in terms of path dependence: positive feedback by Pierson and historical contingency by Mahoney (Pierson 2004, Mahoney 2000). This thesis will use the positive feedback approach which will be explained in the next paragraph.

4.1.3 Positive feedback

Institutions, organizations, and strategies tend to follow a pattern of positive feedback. The concept demonstrates how different actors within institutions tend to not let go of current institutions, since that would be a higher cost than sticking with the old one. This leads to the effect of locks-in when change is highly difficult and complicated (Pierson 2004; Polack 2018).

When positive feedbacks occur, this will also be reflected in the politics through viscous processes (Polack, 2018). This will be visible when politicians or actors are hanging on to current institutions or political landscape, unwilling to change them in a broad manner (Polack, 2018, p 4). An example of a positive feedback situation is the layout of the keyboard called QWERTY, which David is portraying in his article from 1985. The scholar is showing how the layout of the keyboard originates from the 19th when errors easily occurred, in which this composition was the best one to avoid them (David, 1985). Nowadays, technology is developed and there are other ways of arranging the keyboard, that would potentially be more efficient (ibid). The institution is however locked-in and the incentive for changes is low, and we are therefore still using the combination of QWERTY on modern keyboards.

In connection with positive feedback, the concept of lock-ins is likely to occur, which means that no institutional change will appear even though there might be political changes (Polack, 2018, p 4). Pierson is in this sense stressing the

importance of timing and sequence: what happens in an early stage can affect institutions for a long period.

Another example of this that relates to public health policy is demonstrated in the article by Saxonberg, Sirovata, and Janouřkova in 2013. Their article aims to describe how some policy areas could keep their path dependence whilst other policy areas could change their institutions after the fall of the communistic regime in the Czech Republic.

They are doing so by investigating several policies in the Czech Republic such as family policy, health care, and labor market policy which all went through an exogenous shock followed by a critical juncture or near-miss. Exogenous shocks are a powerful event and could change the institutions (Gerschewski, 2021, p 223) which will be further described later on in the next section of the thesis. A critical juncture can be explained as a timeframe when the possibility of change is increasing and is closely linked to exogenous shocks (Collier and Collier, 1991). Near miss is a situation where there could have been room for change, but instead, it went back to the status quo (ibid). This concept will be explained more in the next section. The exogenous shock led to institutional change in some the cases such as in labor policy. The authors explain this through the fact that the labor policy which actually managed to change its institutions had a weak legacy from the previous government. This led to an ability to easily adapt to change and try something new because there was no path dependence in that policy area (Saxonberg et al, 2013).

Public Health on the other hand did not change its legacy due to a strong path dependency on the previous government. There was a high degree of satisfaction regarding childcare as well as health care, and there was no willingness to change these institutions. This meant that even though there might have been exogenous shocks and critical junctures or near-misses regarding the health policy, the path dependence made any change hard regarding health policy, in comparison to labor policy which had the opposite outcome (Saxonberg et al, 2013).

The health policy in the Czech Republic is just one example of how path dependence can create lock-in which makes institutional change rather difficult. The example could help the understanding of the European public health policy and the lack of institutional changes in situations where there have been several exogenous shocks and critical junctures or near-misses, but without any institutional change, due to the strength of the path dependence. Another concept that is associated with path dependence is critical junctures and near-misses, which will be explained in the next section, as well as exogenous shocks. Finally, the interconnection between these concepts will be stated before the hypothesis is presented.

4.1.4 Critical junctures and near-misses

The concept of critical junctures is a category of historical institutionalism and is frequently used in terms of comparative historical analysis (Cappocia, 2016, p 1). Furthermore, it is used to examine institutional change from a historical perspective in contexts such as organizations and authorities (ibid). The concept has been described as a timeframe of importance that will appear in different ways depending on the setting such as nation or similar, and which will have an impact on the outcome and affect it dissimilar (Collier and Collier, 1991, p 29).

The perception originates from Lipset and Rokkan who demonstrated how the European party diversity in the 1960s as a result of resolutions and enlargements which occurred during so-called crucial junctures (Lipset and Rokkan, 1967). In terms of studying institutional change, the concept of critical junctures has had a central role since the scholars Collier and Collier did a study about labor incorporation which showed how politicians' choice between party-led or state-led labor incorporation had an impact on the result of the regime and hence the institution (Collier and Collier, 1991).

A more in-depth description of the concept can be found by Cappocia (2016, p 1) who explains it as follows: "Critical junctures are defined as "relatively short periods during which there is a substantially heightened probability that agents' choices will affect the outcome of interest" (ibid). Short periods can be explained as time frames when critical junctures are shorter as the following path dependence and its passage of time (ibid, p 4).

Another relevant concept for the thesis that needs to be addressed within the critical juncture approach is the near misses. Cappocia and Kelemen are demonstrating that a critical juncture does not necessarily lead to institutional change, which seems to be a common belief and a misconception (Cappocia and Kelemen, 2007). Instead, they are showing how a critical juncture can lead to the status quo and go back to the original state of the institution before the critical juncture appeared. This is called a near-miss (Cappocia and Kelemen, 2007, p 352).

Critical junctures and near-misses are of relevance for this thesis because they can help to explain what time frames have been of importance for institutional change and hence the pandemic crisis preparedness. The approach can also help to understand the near misses where no institutional change appeared even though the change was expected to happen.

4.1.5 Exogenous shock

The author Gerschewski is describing an exogenous shock as a very powerful happening or event which has the capacity to change the institutional direction and

setting. He is demonstrating how exogenous shocks can affect the institutional outcome (Gerschewski, 2021, p 223). As an example of this, he is presenting how the “1982 debt crisis bankrupted developmental states and forced economic adjustment” (ibid). Other examples of exogenous shocks include the terror of 9/11 and the COVID-19 pandemic (Soluk et al, 2021, pp 365-366). In this case, the COVID-19 pandemic could be seen as an exogenous shock that would have the capacity to change the institutions in the health policy, which this concept is important for the thesis.

4.1.6 Interconnection between exogenous shocks, critical juncture and path dependence

In this section, the interconnection between the concepts of the thesis will be explained.

Exogenous shocks and critical juncture correlate with each other which is being demonstrated by the authors Collier and Collier (1991). They are using a model to describe the framework of critical juncture and how it interconnects with the other concepts. It starts with the so-called antecedent condition which is also referred to as a baseline (ibid, p 30). The authors are describing this as “a baseline against which the critical juncture and the legacy are assessed” (Collier and Collier, 1991, p 30). Furthermore, this works as the conditions in a certain area such as politics or economy, before the crisis or shock is hitting. This is followed by the exogenous shock which will potentially lead to a critical juncture.

As to connect this model to my case with the public health of the EU, the antecedent condition could be seen as the public health. The cleavage or exogenous shock could be explained through the different infectious diseases, epidemics and pandemics. They have triggered the critical juncture or near misses, depending on the situation. One could argue that the COVID-19 pandemic and SARS could be seen as a critical juncture, whilst previous infectious diseases such as H1N1 or Ebola could be seen as near misses. This is based on the fact that SARS led to the creation of the ECDC and COVID-19 led to reforms such as the creation of HERA and the extended mandates of EMA and ECDC.

Path dependence is connected to the concepts since the timing of an event will affect the outcome - history matters. The path dependence will hence have an important effect on the exogenous shock and critical juncture or near miss. If a certain policy or institution is following a path dependence, it will be difficult to change this pattern even though there might be powerful exogenous shocks, due to high costs of change when a path is locked in.

The next paragraph will state the hypothesis of the thesis based on the theoretical framework and the background and previous research.

4.1.7 Hypothesis

The public health policy within the EU follows historical institutionalism, and the different pandemics, epidemics, and infectious diseases could act as exogenous shocks. Following the theory, one could assume that the previous pandemics were not powerful enough to act as exogenous shocks and critical juncture able to change the path dependence, but rather as near misses. That could explain the lack of institutional change in times when infectious diseases were more than active and causing a big threat to the EU. Based on the HI theory and previous research, the hypothesis will be the following:

H1: The previous infectious diseases were not powerful enough exogenous shocks to change the path dependence and hence the institutions and pandemic preparedness within the European Union.

H2: The strength of the COVID-19 pandemic worked as a strong exogenous shock able to break path dependence and generate institutional change and the creation of HERA.

5 Methodology

This section presents the methodology of this thesis. A comparative case study will be combined with process tracing. These compatible methods will be explained and elaborated further in the text as well as the operationalization of concepts. This will be followed by the operationalization of the potential causal mechanism and its hypothesis and the case selection and material. The last section includes a reflection on the limitations of both the theory and the methodology.

5.1 Comparative Case Study and the Case selection

Case studies are applicable when investigating a case during a longer timeframe and gaining in-depth knowledge about this specific topic. It usually includes a certain policy, program, environment, or something of similar character (Knight, 2001, p 7040). By using more than one case, the scholar gets the opportunity to generalize, in order to find out whether there is any causality between the chosen factors (ibid).

The design of the study is usually formed in a way in which the researcher tests a theory by doing a hypothesis (Knight, 2001, p 7040). The scholar is hence using the different cases to be able to test the hypothesis (ibid). In order to collect data about the cases, the study usually contains quantitative and qualitative information (Goodrick, 2014, p 1). These criteria are well suited for this thesis since it is investigating two different cases during a longer time frame from 2003 to 2021, which will test a hypothesis. The method will be used together with process tracing, in order to find the eventual causal mechanisms behind the creation of HERA. It is however difficult to find causality and a term that one shall be careful of using (ibid). Bearing that in mind, the thesis will still aim at investigating if there are paths that could be considered closeness to causality. My case is following the approach called the method of difference. In this approach, the variables are the same, with different independent variables and a different dependent variable (Bleijenbergh, 2010). This method is useful for the thesis since the variables are similar, with a different dependent variable (x), which in this case is an exogenous shock. The dependent variable (y) is also dissimilar in the two cases. On these grounds, this is a useful method for the thesis.

Case 1 2003-2019	Case 2 2019-2021
WHO, ECDC and scholars demonstrating the threat of infectious diseases	WHO, ECDC and scholars demonstrating the threat of infectious diseases
Strong autonomy amongst the Member States within the health policy	Strong autonomy amongst the Member States within the health policy
Low budget within the public health policy	Low budget within the public health policy
Not x – relatively weak exogenous shock	X – strong exogenous shock
Not y (No institutional change) no HERA	Y (institutional change) HERA

Figure 1

Figure 1 shows the variables that this thesis is using. The independent variable is the x in figure 1 and is based on the exogenous shock with its different scope. I want to investigate whether the exogenous shock affects the dependent variable – y, which is institutional change, and hence HERA or not. The exogenous shock is selected as an independent variable since it is present in the pandemics and epidemics the thesis aims to study. The exogenous shock is affecting the critical juncture or near miss and has an important impact on the path dependence.

HERA is the dependent variable. In this case, institutional change more concretely signifies if the HERA was present or not, which was not the circumstance in case 1 but case 2. The dependent variable is crucial for the possibility of finding causality between the strength of the exogenous shock and the institutional change, which is needed to answer the research question regarding why HERA was not already existing before the COVID-19 pandemic outbreak. The dependent and independent variables will be explained more in-depth under the section operationalization, as well as the other variables.

The timeframe of 2003-2019 on case 1 is selected because the outbreak of SARS spread across the world around 2003, which led to the creation of ECDC two years

later. In 2019, the outbreak of the COVID-19 pandemic started. In between those years, the world and EU were hit by several cases of infectious diseases, pandemics, and epidemics. As for the timeframe and available material of this thesis, the first case will be based on SARS, H1N1, and Ebola – as exogenous shocks. The dependent variable is the lack of HERA.

The COVID-19 pandemic outbreak spread in a rapid manner around 2019. In 2021, the creation of HERA was a fact. These happenings explain the timeframe of the second case. The COVID-19 pandemic is hence working as the exogenous shock (independent variable), and HERA is working as a dependent variable.

5.2 Process tracing

The comparative case study will be combined with the method of process tracing. Process tracing could be described as a method used in order to locate causal mechanisms. This is being conducted by consuming a comprehensive and specified investigation based on a within-case study (Beach and Pedersen, 2019, p 1). The procedure is carried out with the purpose of examining causal mechanisms to clarify how it functions more concretely in an authentic example in form of a case (ibid). The authors Bennett and Checkel are furthermore describing process tracing as an investigation when the “intermediate steps in a process make inferences about hypotheses on how that process took place and whether and how it generated the outcome of interest” (Bennett and Checkel, 2014, p 6). The important factor in process tracing is not to find the outcome of a case, but rather to find the in-between processes leading to the outcome (Beach and Pedersen; Bennett and Checkel). Bennett and Checkel are further presenting how this method is being used by finding the “intervening causal process, the causal chain and causal mechanism between an independent variable and the outcome of the dependent variable” (Bennett and Checkel, 2014, p 6).

In the case of this thesis, process tracing could be applied in the search for causal mechanisms and the in-between factors leading to the creation of HERA, to be able to answer the research question regarding why it was not created before the COVID-19 pandemic. In order to be able to generalize the causal processes outside this specific case and rather investigate what this thesis is a case of, one needs to combine process tracing together with a comparative case study (Beach 2017, p 14). On that ground, this thesis will use both comparative case studies as well as process tracing.

There are several ways of using process tracing: theory-testing, theory-building, and explaining-outcome (Beach, 2017). This thesis will be using theory-testing

process tracing (Beach, 2017, pp 17-19). Theory-testing is used when the scholar aims to investigate the causal mechanism of a case after a hypothesis has been made. The author first needs to address the X and Y variables, followed by a hypothesis about the causal mechanism that are connecting those two variables together. Such a creation could be as follows: Cause → Mechanism → Outcome (Beach, 2017, p 17). The hypothesized mechanisms could be based on several factors, and the author would need to gather information and evidence that strengthens the hypothesis before testing it in the empirical part (ibid, pp 17-19). The causal mechanism requires an operationalization of the theory to follow the assumed outcome.

The method of process tracing is suitable for this thesis since the aim is to investigate the potential causal mechanism between the independent and dependent variables, in order to answer the research question. With a theory-testing approach, the thesis would try to answer the puzzle of the mechanisms by using the theory of historical institutionalism and exogenous shocks, and path dependence. More concretely, this would mean that for my case, the X and Y factors would be exogenous shocks (X) and HERA (Y), and the causal mechanisms would be critical juncture or near miss and path dependence or no path dependence. That would follow the model: Exogenous shock → Near miss or critical juncture → path dependence or no path dependence → HERA or no HERA.

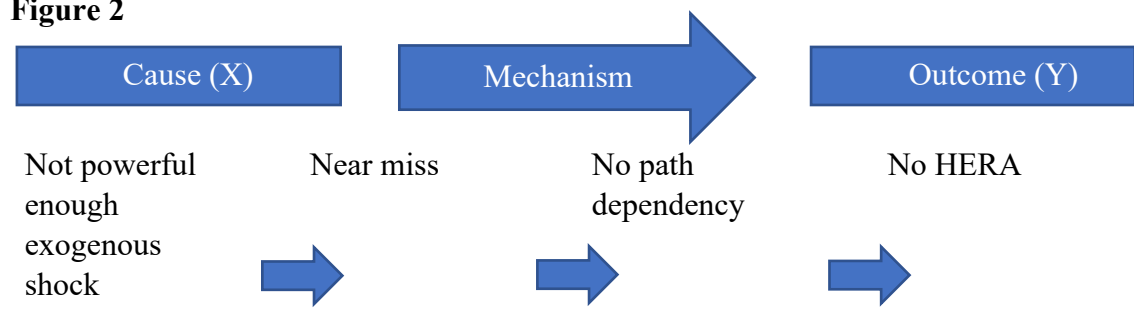
H1: The previous infectious diseases were not powerful enough exogenous shocks to change the path dependence and hence the institutions and pandemic preparedness within the European Union

H2: The strength of the COVID-19 pandemic worked as a strong exogenous shock able to break path dependence and generate institutional change and the creation of HERA

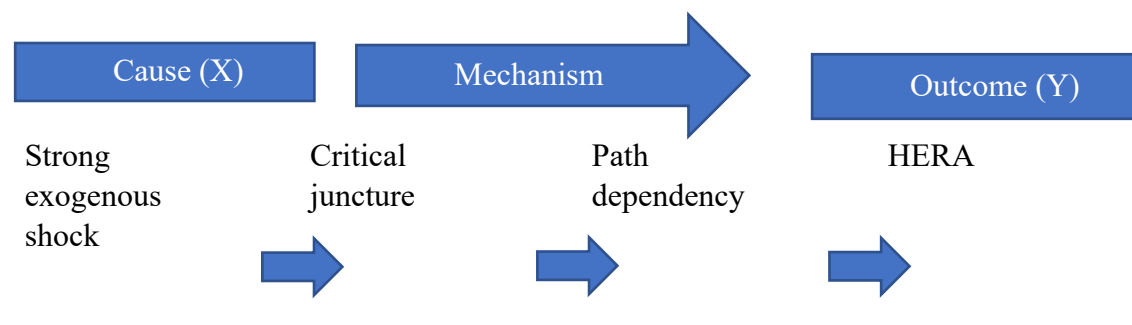
The operationalization on the causal mechanism and the theocratization would hence be:

H1:

Figure 2



H2:
Figure 3



Sources: my own formation built on Beach (2017, pp 6, 17-19)

5.3 Interconnection between the case study and process tracing

Before moving on to the sections on operationalization and limitations, a few points need to be taken into consideration when it comes to the two cases chosen in this thesis. Even though the thesis is using two separate cases, it is relevant to illustrate how the cases are not necessary “unique cases”, but rather interconnected to each other. The different pandemics, epidemics, and infectious diseases before the COVID-19 pandemic all generated change in different manners. The ECDC was created shortly after the SARS outbreak and the Health Threat Decision was implemented a few years after the H1N1 pandemic. It could hence be argued that it is easier to establish HERA later on, as the previously mentioned institutions have already been founded and implemented, which is paving the way for HERA and the further development of crisis preparedness coordination and cohesion within the public health policy. It could furthermore be argued that the creation of HERA is not only an outcome of the strength of the exogenous shocks but also a result of the previous institutions, which is important to keep in mind. The decision of combining a case study and process tracing is furthermore carefully selected in order to take this into consideration.

The reason for choosing the research question and investigating the puzzle regarding why HERA was not invented earlier is still of high relevance since it illustrates the crisis preparedness and coordination in the EU, after several outbreaks of infectious diseases. These outbreaks furthermore generated advice from scholars – to strengthen the coordination, cohesion, and communication between the Member States and EU institutions in case of a new pandemic or epidemic, and to have a stronger preparedness. Even though these events did lead to reforms, these reforms mainly focused on surveillance, assessment, and data

collection, and did not so much focus on previously mentioned factors such as cohesion between the MS and EU's institutions. It is therefore of importance to highlight the importance of those previously mentioned factors and investigate why HERA was created first after the COVID-19 pandemic outbreak.

5.4 Operationalization

In this section, the dependent and independent variables will be explained and elaborated on, as well as other relevant concepts used in the thesis. The operationalization is of importance because the concepts need to be explained concretely. Without any concrete explanation, the concept could be misinterpreted since it can be abstract (Martinez, 2017). The operationalization is necessary for the reader to fully understand the terms and the setting and hence follow the study and examine an eventual hypothesis (ibid). The dependent variable will be explained, followed by the independent as well as the variables and other relevant concepts.

The dependent variable is HERA, which in this thesis is the operationalization of coordination since HERA is working with preparedness and response. HERA is hence an example of how the EU manages to operate coordination in the public health policy. HERA is also indicating institutional change since it shows how reform has been made and changed the path dependency. When using HERA, the thesis is furthermore expressing both institutional change from a HI perspective and measuring the way in which the EU manages to coordinate crisis preparedness.

The independent variable is exogenous shocks. Exogenous shocks can be described as mentioned in the theoretical framework as “a very powerful happening or event which has the capacity to change the institutional direction and setting” (Gerschewski, 2021, p 223). In the case of this thesis, such a powerful event is a crisis or disaster. Even more specific, such a crisis or disaster includes infectious disease, pandemic, epidemic, or similar happening which has the potential to change the path dependency and hence the institutions. Exogenous shocks can have different strengths and scope and vary in severity and this thesis both mentions strong exogenous shocks and weak exogenous shocks. In this case, a strong one has the capacity to change the path dependency and institutions. An example could be the SARS outbreak in 2003 which led to the creation of ECDC shortly after. A weak exogenous shock is by contrast a shock that led to a near miss instead of a critical juncture and did not lead to any path dependence or institutional change. Such an example could include the Ebola outbreak in western Africa, which did not lead to extended institutional changes to a high degree or extent.

The other variables of the thesis are first the strong autonomy amongst member states in terms of public health policy. The second variable is the pressure from international organizations such as ECDC, WHO, and scholars regarding the threat of infectious diseases and the importance of developing the crisis preparedness

mechanisms in the cross-border EU member states. The last variable is the rather low budget within the public health policy. Regarding the last variable, it is important to mention how the new Multinational Financial Framework (MFF) was implemented in 2021. It had a higher budget for the pandemic preparedness after the COVID-19 pandemic outbreak regarding the NextGenerationEU which is a crisis package adding 750 billion euros for the recovery (Council of the European Union; European Commission). The NextGenerationEU aims to help the EU after the COVID-19 pandemic and to focus on an EU which is digital and green (ibid). This crisis package is the most comprehensive one so far (ibid) and is not to be compared with anything else. The higher budget could have an effect on the crisis preparedness since it made it possible to carry out measures that would otherwise have been difficult to conduct. To make sure that the new MFF budget does not affect the outcome, the “low budget within the public health policy” refers to the one before 2021.

The variables are used to take the measurement of the outcome an independent variable can have on the dependent variable (Webb, 2017). To do so, it is importance to control the variables to assure neutrality and to avoid the result being affected by other factors (ibid). The previously mentioned variables for this thesis are therefore used to avoid a result that depends on other factors such as the MFF budget, the autonomy of the member states, or the pressure from public health officials.

5.5 Material

In this thesis, the primary sources have been a selection of documents from the European Commission, ECDC, and WHO. From the EC I have primarily been using documents as decisions or proposals such as the document on the Health Threat Decision of 2013 and the Decisions behind this document. The documents have also been based on decisions for the creation of HERA and proposals. Besides this, I have used sources from the EC AND EU for information regarding the institutions and agencies. Another main primary source for the thesis has been the ECDC. The agency has conducted several valuable reports and publications regarding the exogenous shocks I have investigated. Their documents have consisted of lessons learned from SARS and H1N1 and the measures being made by the EU as a response. They have also provided documents regarding the crisis preparedness in the EU concerning public health. The ECDC has also provided sources with information and facts concerning infectious diseases.

The third primary source used has been the WHO. Their documents, reports, and assessments have helped understand the scope and response to the exogenous shocks in the EU and what advice the WHO has been given to the EU. Just like the previously mentioned organizations, the WHO has been useful regarding facts

about infectious diseases. In addition, I also used articles from the CDC which is the American counterpart to the ECDC.

The secondary sources consisted of scientific articles and literature regarding public health. The articles were found through the university page of Lund University and its search monitor called “lub search”. Through this function, I was also finding the relevant literature I needed. For the analysis, the documents and reports have been selected from the relevant years for the thesis, hence from 2003-to 2019 and 2019-to 2021.

The reliability of the sources is high. This is based on the fact that the documents and reports are written by public health officials from ECDC, WHO, and EC. These organizations could be considered reliable since they are official institutions. The scientific articles are created by scholars in the area of public health and are being uploaded to the university database. Some of the scientific articles are being found through the documents by ECDC, WHO, and EC, which is strengthening their relevance and reliability.

5.6 Limitations

There is a difference of opinion amongst scholars regarding HI and what approach that is most useful to explain institutional change (Farell, 2018). Besides the approach covering path dependence, which is the one used in this thesis, there is another one called incremental change which includes “layering, conversion, drift, and revision” (ibid, p 34). The various perspectives perceive an institutional change in different ways: the path dependence approach believes in rapid changes caused by exogenous shocks often during critical junctures, and the incremental approach rather believes in successive changes (Farell, 2018). The limitation of path dependence theory is the fact that there is a disagreement regarding which approach to be used to explain the institutional change, which I think is important to acknowledge. The choice of using the path dependence approach was however carefully considered as it has the tools of explaining exogenous shocks such as infectious diseases, pandemics, and epidemics which are included in my cases. On that grounds, the theory was the most likely one to be able to explain the reason behind the creation of HERA and why it was not already there before the COVID-19 pandemic outbreak.

Another limitation of the thesis was the uneven amount of available material to analyze in terms of the exogenous shocks and hence the independent variable. Case 1 had three different exogenous shocks to investigate: SARS, H1N1 and Ebola. As the literature for H1N1 was comprehensive and generous with a large range of useful material, this was not quite the case for the material of Ebola. The material selected for SARS was approximately smaller than the one for H1N1 but more extensive than the available documents regarding the Ebola virus. For case 2, there

was a decent amount of material available considering the fact that the case only covered the years 2019-2021.

Analysis

The analytical part aims to answer the puzzle regarding why HERA did not exist before the COVID-19 pandemic outbreak. HERA was first created after the COVID-19 pandemic outbreak. This has attracted attention and pressure from international health organizations such as WHO and ECDC as well as scholars. They have exposed the threats that the EU could be facing in case of a pandemic and what measures the EU needs to develop in terms of having a stronger crisis preparedness.

The analysis begins with the first case which covers the years from 2003-to 2019. This will be followed by the second case in 2019-to 2021. As mentioned in the chapter covering the material, this case study will be combined and analyzed from a process tracing perspective.

5.7 Case 1 Pre COVID-19 outbreak (2003-2019)

This section focuses on case 1 with the purpose of answering the first hypothesis: *H1: The previous infectious diseases were not powerful enough exogenous shocks to change the path dependence and hence the institutions and pandemic preparedness within the European Union.*

This will be preceded by a process tracing approach by an in-depth investigation of the scope of the exogenous shocks such as previous pandemics, epidemics, and infectious diseases. This thesis is focusing on SARS, H1N1, and Ebola, because of the strengths and scope of the diseases. The response from the EU together with their coordination will be analyzed, as well as the final outcome of the previously mentioned exogenous shocks, and whether the path dependence and hence the institutions were changed by them and how. The scope of the exogenous shocks will now be presented, together with the following critical juncture or near miss and final outcome.

5.7.1 Scope of the exogenous shocks, critical junctures or near misses, path dependence and outcome

To understand why an organization such as HERA was not created before the COVID-19 pandemic, the scope of the previous infectious diseases needs to be addressed to understand the strength of the exogenous shocks and what consequences they had for the health institutions and if they were able to develop institutional change and how. Given the limited time scope of this thesis, the exogenous shocks analyzed will be SARS, H1N1, and Ebola. In any case, it is important to bear in mind that this is a sample of infectious diseases that have existed during the last two decades. They are chosen because they are repeatedly mentioned in various reports, documents, and scientific articles and could hence be considered of high importance in describing and summarizing the EU's emergency preparedness in public health.

SARS

The scope of the exogenous shock

As the epidemic emerged in 2003 in Asia and spread across the world (CDC, 2017) this was shaking the world with fear and opened up the discussion and debate on pandemic preparedness. This event affected the EU and its crisis preparedness in terms of infectious diseases and pandemics. In a report from the Commission in 2003, they stated how the EU and its health policy mechanism were underdeveloped and the preparedness and assets needed to be strengthened, in case of any new infectious disease outbreaks (European Commission, 2003, p 5). The EC stressed how they could manage to handle the SARS outbreak since it was a relatively small outbreak that did not affect as many people in terms of contaminated persons (European Commission, 2003, p 14). If the outbreak would have been more extensive and contained a larger number of cases, the EU would have been ill-equipped (ibid, pp 14-15). Furthermore, the Commission strongly recommended the EU to develop their crisis preparedness in case of a larger outbreak of any infectious disease (ibid). They recommended measures such as cross-border plans in terms of infectious diseases as well as strengthened capacities for hospitals (ibid). The outbreak eventually led to the creation of the ECDC in 2005 as a respond (ECDC, 2015). The organization works with surveillance and data collection in the EU and has no legal right of decision making in the EU and is instead providing recommendations for member states.

In conclusion, it is difficult to measure the strength of the exogenous shock in terms of the outbreak of SARS since it at the one hand led to the creation of the ECDC and therefore to some extent had an impact on the institutional change. On the other hand, the creation of ECDC was something that had been discussed before the outbreak of the SARS and was already discussed as the threat of bioterrorism accord (Greer et al, 2020, p 58), which could have strengthened the argument of creating

the ECDC. There are therefore more nuances involved in the creation of ECDC, even if the SARS outbreak is considered one of the main arguments. One could hence argue for the exogenous shock as strong, and it led to a critical juncture since the ECDC was created shortly after. The exogenous shock was however not strong enough for creating anything similar to HERA and it did not have the capacity to change the path dependence, which will be further elaborated on in the section below.

SARS and path dependence

Considering the fact that ECDC was created after the SARS outbreak, this would indicate that the scope of the exogenous shock was rather big since it had the capacity to lead to the creation of ECDC and create critical juncture. It is however of importance to once again mention how this exogenous shock was not big enough to change the path dependence in regard to creating any organ similar to HERA and cover crisis preparedness and “prevent, detect and respond to health emergencies” (State of the Union, 2021). Even though the ECDC was created, the role given to the organization and the mandate did not allow it to coordinate and prevent in a cross-border manner the way HERA did. Instead, the ECDC focused on data sharing across the member states and surveillance. It is therefore complex to measure the outbreak as either weak or strong. Therefore, one could consider the outbreak as strong since it led to some sort of institutional change in terms of the creation of ECDC, and hence generated critical juncture. Since it was not strong enough for creating anything similar to HERA, it could thus be considered as an exogenous shock that was not strong enough to affect the path dependence. At this point, the crisis preparedness plans were still something kept to the national authorities of the member states and not something handled by the EU. The path dependence was hence not changed, in that manner.

H1N1

The scope of the exogenous shock

2009 was overshadowed by another infectious disease outbreak – the A H1N1 or (H1N1pdm09 virus), also called the swine flu (de Ruijter, 2019; CDC 2019). In the beginning of June that year, WHO acknowledged the outbreak as a pandemic and addressed it as the uppermost level of danger (de Ruijter, 2019, p 122). The fear of the pandemic and its scope and potential damages was hence high public health officials around the world and actors in public health in the EU as well (de Ruijter, 2019). The pandemic had a composition of genes that was unknown for researchers and it tended to affect young adults to a higher extent than elderly, who probably had resistance from any other similar virus from back in time (CDC, 2019). With those happenings being demonstrated, one could argue for the H1N1 being a strong exogenous shock since it was a pandemic, it had the highest rate of security danger, young people were affected hard and the virus was not similar to anything known. According to the theory of HI, exogenous shocks have the capacity to lead to critical junctures which are time periods when the probability of change could be possible

and affect the path dependence and hence the institutions. The H1N1 could thus in theory have the capacity to change the path dependence within the public health policy. The outcome of the exogenous shocks will be presented in the next subsection.

Response from the EU, near miss, and lack of path dependence

There was a large apparatus of actors involved in the actions to be taken and the decisions to be made after the pandemic broke out, in the EU. These actors involved both formal and informal institutions. The formal institutions included the ECDC and EMA (de Ruijter, 2019, p 123). The recommendations from WHO International Health Regulations (IHR) also needed to be taken seriously in the decision-making process (de Ruijter, 2019). Informal institutions instead consisted of the so-called Friends of the presidency, and HSC (ibid). Friends of the presidency was a group composed by the presidency at the time – Sweden and was coping with international issues that a pandemic could lead to (de Ruijter, 2019, p 129). Such topics could be the sector of transport and cooperation (ibid). HSC could be considered an informal institution concerning the lack of legislative mandate (de Ruijter, 2019, p 127). Friends of the presidency were created as an answer to the time-consuming institutionalization of HSC (de Ruijter, 2019, p 136). This is however indicating that the number of actors involved and their different responsibilities and legal powers – both formal and informal once made the coordination somewhat difficult to manage.

Besides the different actors involved and their capacity to coordinate the response, the Member States also faced difficulties concerning the lack of cross-border coordination which led to a lack of cohesion and consistency, which will be presented below (ECDC, 2017).

In 2017 the ECDC wrote a technical report in cooperation with WHO/Europe. They revised the Member States pandemic plans and stated the lessons learned from the swine flu outbreak (ECDC, 2017). The report identified many measures that needed to be improved to strengthen the EU's crisis preparedness in case of a new pandemic influenza outbreak. The national preparedness plans had flaws as they lacked subnational plans in the several Member States, which led to a long and protracted response (ECDC, 2017, p 4). Since the authorities of the member states are the ones that hold the responsibility for the preparedness plans, they are not necessarily coherent. This was the case as the H1N1 appeared, and the lack of cohesion and coordination made the approaches from the member states different (ECDC, 2017, p 16). To be able to improve the cross-border coordination, communication, and data sharing in order to improve the cohesion and consistency, the decision No 1082/2013/EU was created in 2013 (ibid). This shows how the EU faced several difficulties during the H1N1 pandemic in terms of coherent crisis preparedness plans and cross-border coordination.

Even though the pandemic could be considered as a rather strong exogenous shock in terms of scope and strength, it could be argued that it led to a so-called near miss, where the path did not change to any broad extent. It led to the creation of the previously mentioned decision No 1082/2013/EU. Even though the decision strengthened factors such as data sharing, surveillance, early warning, assessments, response coordination, and medical countermeasures, it did not consist of any organ capable of gathering crisis preparedness, coordination, cooperation, and response measures together, such as HERA. Although the decision could be considered an institutional change to some extent, it was not the sort of institutional change that would be needed for coordinating the member states in the public health in terms of pandemic preparedness. The member states would still have a rather strong autonomy, even though there had been several flaws and difficulties during the H1N1 pandemic, and the path dependence was hence not changed. The next subsection is presenting the Ebola, its exogenous shock, and the response from the EU.

EBOLA

Scope of the exogenous shock

Ebola virus disease (EVD) was first discovered in the mid-70s in South Sudan and the Democratic Republic of the Congo (WHO, 2021). Throughout the years, there have been a few cases in Africa, and in 2014-2016 the infectious disease spread in western Africa and caused an epidemic (ibid). Guinea, Liberia, and Sierra Leone were mostly affected by the disease (ibid). Approximately more than 28 000 people got infected by the disease in these three countries (CDC, 2019). EVD also spread through countries such as Senegal, Mali, and Nigeria (ibid). Besides western Africa, Ebola did reach the European Union, and one case each was found in the United Kingdom, Spain, and Italy (ibid).

From a European perspective, the scope of the shock was not severe, since Europe only detected a few cases in total. From a global perspective, the epidemic could be considered a big shock considering the number infected and the rapid spread, and considering the fact that it is a highly contagious disease.

Response from the EU and lack of path dependence

The risk assessments predicted a low risk spreading of the disease in Europe (Timen et al, 2015, p 187). There are however divided opinions regarding the response from the EU concerning EVD and how the virus outbreak was handled. The criticism is based on how flights from western Africa to Europe got canceled and how health care workers coming back from those areas were isolated and/or prohibited from going back to work (Timen et al, 2015, p 187). These measurements were not based on scientific grounds (Timen et al, 2015). The media shared fear and rumors that went against the science based on scholars and public

health officials (ibid). One institutional change was the appointing of an Ebola coordinator (Watson, 2014). The EU also prepared measures to take care of health personnel that returned from western Africa and invested money in research on infectious diseases (ibid). The exogenous shock did not generate any path dependence in the field of public health policy, as small measurements in the EU were implemented in connection to the Ebola outbreak. The changes did not affect the coordination, cohesion, or communication in terms of public health policy in the EU.

The outbreak of Ebola is highlighting how scholars and public health have been neglected in certain situations in favor of the media and common beliefs, in this case. This does not necessarily explain why HERA was not created, but it demonstrates how public health officials are on some occasions being ignored, and how member states might instead implement their own decision, sometimes without scientific evidence.

The analysis of case 1 is demonstrating how the exogenous shocks of H1N1 and SARS had an effect on the public health institutions, and the shocks led to both the creation of ECDC and the cross-border health threat decision in 2013. The shocks were however not of enough strength to change the crisis preparedness coordination between the Member States and the institutions, as the ECDC is working with data gathering and surveillance, and the cross-border decision with the capacity to provide early warning and assessments to mention some measures. None of the exogenous shocks led to the creation of any authority such as HERA with the capacity to provide pandemic crisis preparedness and coordination and cohesion between the MS and the EU's institutions. The exogenous shock from the Ebola virus was not strong enough to change the path dependence even though minor measures were implied.

5.8 Case 2 Post COVID-19 outbreak (2019-2022)

This section aims to answer the second hypothesis of the thesis: *H2: The strength of the COVID-19 pandemic worked as a strong exogenous shock and was able to break path dependence and generate institutional change and the creation of HERA.* In order to do so, documents from the EU and ECDC will be analyzed to further understand the events leading to the creation of HERA. The scope of the exogenous shock will be revised together with the consequences of the shock leading to the creation of HERA, in order to understand the mechanisms behind the organization.

5.8.1 Scope of the exogenous shocks, critical junctures or near misses, path dependence, and final outcome

Scope of the exogenous shock

The last exogenous shock that is going to be analyzed is the coronavirus pandemic that broke out in 2019. Considering the fact that as this thesis is being written, there have been 519 729 804 reported cases of people that got infected by the disease (WHO). This furthermore generated at least 6 268 281 deaths, around the world (ibid). For the European region, the cases are currently 218 493 419 (ibid). Besides the concrete number of reported cases, the virus also affected the world as many countries went into lockdown. The lockdown and isolation affected people around the world differently. As some countries went into total lockdown and isolation, the opportunity to work and get an income and meet their friends and family was taken away from them. The EC stressed how this pandemic could be considered the “most acute global economic challenge in modern history” (European Commission, 2021 c, p 1). The health care system was affected strongly throughout the planet, and the infectious disease was creating suffering worldwide. An exogenous shock has as previously mentioned the capacity to change the institutions. On that grounds, the COVID-19 pandemic could be considered a strong exogenous shock, with the capacity to change the current institutions.

The EU has faced criticism for not acting fast enough with measurements against the COVID-19 pandemic outbreak (European Parliament, 2021 b). They also got criticized for the incoherency of the pandemic plans in the Member States and how they lacked coordination (ibid). In general, the pandemic plans were also considered to be underdeveloped (ibid). From a legal perspective, the EU did not have much power to intervene, as the Member States have a high degree of autonomy in terms of health policy (ibid). The previously mentioned decision from 2013 – the Health Threat decision within cross-border threat provided the EU with a role of support, surveillance, organization, and assessments of risks (European Court of Auditors, 2021). These proceedings were conducted through authorities such as HSC and ECDC (ibid). Even though the EU had these institutions working with crisis preparedness within health threats, the pandemic highlighted the flaws and shortcomings in the current system regarding health preparedness and coordination (European Parliament, 2021 b). The EC stressed that the pandemic did “exposed the need to strengthen the EU’s crisis preparedness and management of cross-border health threats” (European Parliament, 2021 b, p 2). The lack of a coordinated system regarding planning and preparedness for pandemics in and in-between member states was hence a major struggle the EU was standing in front of as the pandemic outbreak was appearing (European Commission, 2021 c).

Critical juncture and path dependence

The Member States were willing to give up some of their autonomy in favor of decision making at the EU level to handle the crisis (European Commission, 2021 c, p 4) in combination with the proposals set up by the EU as a response to the pandemic outbreaks such as the European Health Union and creation of HERA. Based on those grounds, one could argue for the outbreak to be classed as a critical juncture, since it was a timeframe with a “heightened probability that agents’ choices will affect the outcome of interest” (Cappocia 2016, p 1). In this case, the agents were the EU institutions and the Member States, and the probability of these agents affecting the outcome got increased. This is based on the previously mentioned documents showing how the EU was facing severe cross-border threats and at the same time lacked coordination, cohesion, and communication between each other and the institutions, which changed their common attitude regarding how strong autonomy the Member States should have within public health. They were suddenly willing to offer more legal power to the EU to solve the crisis, which is implying it to be a critical juncture (European Commission, 2021 c, p 4).

Shortly after the pandemic outbreak, the EC put forward the proposal regarding the European Health Union covering the extended mandate for the ECDC and reinforced the role of EMA, and HERA (European Commission 2020 b; European Commission 2020 c, European Commission 2021 d). The proposal of HERA was decided upon and implemented two years later (European Commission 2021 e). The outcome of the crisis has thus been extended institutions working with public health crisis preparedness. The institutions are working with the previously mentioned factors of development such as coordination, cohesion, and communication, to mention some of them. This could hence be considered as an event changing the path dependence, as the Member States decided to delegate some of their power within the public health, in favor of the institutions and the EU, to be able to develop the coordination, cohesion, and communication in pandemic crisis preparedness.

To conclude case 2 of the analysis, the COVID-19 pandemic has highlighted how inadequate the national plans of the Member States have been and how poorly coordinated they have been. During the recent pandemic, the exogenous shock was of a larger scope and more extensive than the previously mentioned ones such as SARS and H1N1, which generated a critical juncture and led to institutional change.

5.8.2 Discussion

The thesis aimed to answer the puzzle concerning why HERA was not created before the COVID-19 pandemic outbreak. The findings show how fundamentally important it has been for the Member States to maintain their sovereignty and

autonomy over public health. The vision of making its own decisions as closely as possible to the citizens and deciding upon their own domestic health has permeated decisions and the founding of new institutions over the last two decades.

The SARS outbreak and its relatively strong exogenous shock had the capacity to generate institutional change, as the agency ECDC was created only two years later. The mandate and legal power of the ECDC were however restricted to data collection, surveillance, and guidance. Together with HSC and WHO, the Member States were supposed to cooperate and implement national pandemic preparedness plans and provide the ECDC with data, a system that in the end had flaws and needed to be developed. At this time, the exogenous shock was strong, but still not of that scope to be able to change the Member States attitude concerning a more coherent and coordinated way of planning for a future pandemic or infectious disease outbreak.

The H1N1 pandemic was the next infectious disease outbreak to challenge the current pandemic crisis preparedness across the Member States. This pandemic once again demonstrated how under-equipped the Member States were, and how they lacked coordination, cohesion, and communication. The exogenous shock was of the strength to affect the institutions and create the Health Threat Decision in 2013. The exogenous shock was however not strong enough to affect the path dependence and change the attitude concerning health policy and their strong autonomy, even in terms of cross-border threats. Health was still considered to be a concern of the Member States and their own domestic authorities. The Health Threat Decision did manage to improve the measurements regarding cross-border threats such as data sharing, early warning and response, and preparedness planning in the Member States. The coordination, cohesion, and communication in terms of an outbreak of an infectious disease was however still a comprehensive problem between the Member States and the EU, even after the H1N1 pandemic and the Health Threat Decision. This would be shown as the COVID-19 pandemic outbreak occurred. The H1N1 pandemic did however not manage to change the path dependence in that manner; the coordination was still insufficient, and the Member States prioritized their sovereignty in the health policy, regardless of the advice from WHO and ECDC.

The outbreak of Ebola in western Africa and the few imported cases to Europe were handled with a few reforms. An Ebola coordinator was appointed and measurements to take care of health care staff from the infected areas back to the EU were implemented. The exogenous shock of the outbreak could hence be considered as weak since it did not lead to a critical juncture or a path dependence.

The COVID-19 pandemic was a severe exogenous shock. Once again, the challenges and flaws of the crisis preparedness system in the EU in terms of infectious diseases were clear. As the different Member States all implied different strategies around Europe in terms of vaccines, distance and isolation to mention a

few factors, the dissatisfaction was spreading. The lack of cohesion between the Member States was hence a problem.

Some Member States got affected worse than others, such as Italy at the beginning of the outbreak. It was difficult to provide aid as the Member States tended to prioritize their own nations. The COVID-19 pandemic was challenging the core values concerning sovereignty in public health, solidarity, cohesion, and coordination. The strength of the exogenous shock had the capacity to change the path dependence on public health. This led to the creation of HERA and extended the mandate for the ECDC and EMA. The Member States were willing to change the institutions and hand out some of their power in order to create a crisis preparedness system that would be coherent and coordinated, which was not the case during the previous exogenous shocks.

Although the covid-19 pandemic was something new of its kind in terms of scope and consequences, this thesis nevertheless shows the challenges and difficulties that existed in the EU before the outbreak. The research question of the thesis was the following: *Why did HERA not exist before the COVID-19 pandemic outbreak?* This could hence be answered as a combination of factors. The Member States wanted to maintain their autonomy in terms of public health, and it was, therefore, difficult to break the path dependence and enforce institutional change. The several actors involved in public health also made the process slow. The previous exogenous shocks such as the SARS, H1N1, and Ebola were not strong enough to be able to change the path dependence and create any institution similar to HERA.

6 Conclusion

The thesis aimed to answer the research question regarding why HERA was not created before the COVID-19 pandemic outbreak. Furthermore, it intended to find the mechanisms behind the creation of HERA, and investigate how and why the EU and its public health policy had an uncoordinated and incoherent crisis preparedness and planning among the Member States and institutions. To be able to answer the research question, a background section of previous EU institutions and agencies concerning crisis preparedness and planning in the public health policy was conducted, together with a literature review based on previous research on the topic. This section was demonstrating how public health officials and scholars had been giving advice regarding the uncoordinated, incoherent, and limited communication between the Member States regarding crisis planning and preparation. These advices were given by several scholars and organizations such as ECDC and WHO throughout the last two decades but without any major improvements. This was followed by the theoretical framework of historical institutionalism and exogenous shocks and path dependence. The framework was suitable for understanding institutional changes and how exogenous shocks such as infectious diseases, pandemics, and epidemics could generate a change in the path dependence and hence change the institutions. Based on the background section, previous research, and theoretical framework, two hypotheses were created: *H1: The previous infectious diseases were not powerful enough exogenous shocks to change the path dependence and hence the institutions and pandemic preparedness within the European Union.*

H2: The strength of the COVID-19 pandemic worked as a strong exogenous shock able to break path dependence and generate institutional change and the creation of HERA.

After the section of the hypotheses, the methodological chapter was presented. The methodology was conducted through a combined method of a case study and process tracing, in order to answer the research question and find the mechanisms behind the creation of HERA and why it was not present before the COVID-19 pandemic outbreak. The case study was based on two cases: case 1 from 2003 to 2019 and case 2 from 2019-to 2021. 2003 was chosen since that was the year of the outbreak of SARS until 2019, which was the year of the outbreak of the COVID-19 pandemic. The second case went from 2019 until 2021 based on the fact that HERA was created in 2021. Lastly, the analysis and discussion were presented.

The analysis showed how the path dependence in public health policy was strong and difficult to break. The Member States wanted to maintain a high level of autonomy and sovereignty regarding public health and decide as much as possible

within their own governments. The exogenous shocks of SARS and H1N1 both led to some forms of institutional change in the EU such as the creation of the ECDC in 2005 and the Health Threat Decision in 2013. The pandemic of Ebola did not have any major impacts on the EU institutions, besides appointing an Ebola coordinator, to mention some of the measurements.

The exogenous shocks were however not powerful enough to change the path dependence and make the Member States hand out some of the autonomy to the EU and its institutions, to strengthen the cohesion, coordination, and communication between the MS. The COVID-19 pandemic was however of such strength and scope to be able to generate change in the path dependence, and for the MS to suddenly give up some of their otherwise strong autonomy regarding the public health policy. The analysis is furthermore illustrating how difficult it has been to change the path dependence on public health policy in the EU and hence generate institutional change, such as HERA. This could help try to answer why HERA was not created earlier.

To sum up the main findings and results of the thesis, the aim was to answer the research question: *Why did HERA not exist before the COVID-19 pandemic outbreak?* This puzzle has been answered through a combination of case study and process tracing with support of the theoretical framework and path dependence and exogenous shocks. The analysis of the paper shows that path dependence in public health policy could be considered strong and difficult to break. Even though epidemics and pandemics of high scope and strength have been present during the last two decades such as SARS and H1N1, the MS have still preferred to decide upon their national level in public health policy. The Member States were hence not willing to give up their autonomy easily after the previous exogenous shocks, even though reforms and changes were made. It took a strong exogenous shock as the COVID-19 pandemic to change this path and make the Member States give up parts of their sovereignty in public health.

For future research, the attitude amongst the Member States concerning their autonomy and sovereignty within public health policy could be elaborated on and examined further. As the COVID-19 pandemic outbreak crossed Europe, the EU and ECDC got criticized shortly thereafter for their slow response and for not taking sufficient measures. The ECDC did however not have the legal mandate to conduct more measurements besides the surveillance and data collection, to mention a few factors. How much power, mandate, and capacity shall the EU's institutions be able to have, when it comes to public health policy? Is this a policy that should mainly be based on the MS preferences or is it more important to focus on having a coherent and coordinated EU, and restrict more of the sovereignty from the Member States? It is therefore a puzzle to further develop and survey their attitudes amongst the Member States to better understand how the public health policy can be more coherent and coordinated, and still consider the MS preferences.

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