A Framework for Studying EU Health Policy through a Political Determinants of Health Lens: The Case of the European Health Union

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Abstract

Context: The COVID-19 pandemic has highlighted how the European Union (EU) impacts national health systems and people's health. In November 2020, the European Commission launched the European Health Union (EHU) to better coordinate and maximise EU Member States' abilities to deal with cross-border health threats. This paper scrutinises the early institutionalisation of the EHU and its implications for EU health policy as a political determinant of health (PDoH).

Methods: The study explores how EU health policy may be appreciated from a PDoH perspective. It draws from EU documents and existing research to analyse the early-stage institutionalisation of the EHU. The study complements this policy output-focused perspective with an outcome-based exploratory assessment of EU health policy as a PDoH focusing on three examples: joint vaccine procurement, health investments under the Recovery and Resilience Facility and the development of a European Health Data Space.

Findings: The study shows that the policy change triggered by the EHU and the potential impact on citizens' health are not necessarily congruent: modest change can have a potentially strong impact on health outcomes and vice versa.

Conclusions: The study argues that the PDoH perspective provides a useful and complementary approach to policy output-based perspectives, allowing for a more comprehensive assessment of the EU's role in health.

Keywords European Union, European Health Union, COVID-19 Pandemic, Political Determinants of Health

In the context of the Coronavirus disease (COVID-19) pandemic, the European Commission launched the European Health Union (EHU) with the aim of building a mechanism that better coordinates and maximises European Union (EU) Member States' abilities to prepare for and respond to public health threats and emergencies. The Commission's EHU strategy has been widely considered a potential turning point for EU health policy, particularly against the

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backdrop of long-lasting fragmented EU competencies in health and a de-prioritisation of health policy at the EU level in past legislatures (e.g., Greer, de Ruijter, and Brooks 2021). However, a question remains about the EHU's potential for improving the health of individuals and communities across the EU. The EHU has so far mainly been discussed in terms of institutionalisation and policy change at the EU level (e.g., Greer, de Ruijter, and Brooks 2021; Brooks et al. 2023), which in turn implicitly includes assumptions about its effect on health outcomes in the Member States, albeit, without examining them more systematically.

Some scholars argue that "the Commission's EHU proposal was no 'big bang'"(Deruelle 2021) and that the EHU's "[legislative] steps are big in the field of health, but they also remain limited" as most of these measures promote "a much more vigorous use of existing policy tools rather than a novel form of integration" (Greer et al. 2022: 23; see also Brooks et al. 2023). Others point to the potential medium-term effect of the EHU as a new health governance strategy aiming for more "member state cooperation and expansion of the EU's role" (Kickbusch and de Ruijter 2021; see also Fraundorfer and Winn 2021).

This article focuses on the early institutionalisation process underpinning the EHU and examines it from a political determinants of health (PDoH) perspective. Although it has been defined in different ways, this approach emphasises the importance of considering the potential implications of political processes, structures, and policy outputs when addressing public health issues. The value of a PDoH perspective is that it provides a health outcome-oriented perspective on EU health policy. We argue that the PDoH perspective can be a useful tool to capture the relevance of the EHU and its policy outputs for health outcomes in Member States, as EU health research is commonly skewed towards the analysis and

evaluation of EU health integration, without thoroughly investigating how it ultimately affects the health of EU citizens to date.[1]

The contribution of this study is twofold: Firstly, it offers a conceptual framework to assess EU health policy focussing on its effects on policy outcomes. Secondly, it presents an in-depth analysis of the early institutionalisation of the EHU from a PDoH perspective. Using three concrete examples, including joint COVID-19 vaccine procurement, health investments under the Recovery and Resilience Facility (RRF) and the development of a European Health Data Space (EHDS), the complex relationship between changes in health policy at the European level and resulting implications for population health outcomes in the EU are thoroughly examined. In doing so, the article seeks to contribute towards building bridges between EU and public health research and their respective perspectives on the role of EU health policy for public health.

EU Health Policy from a PDoH Perspective

What Is Political about PDoH: Applying the Concept to EU Health Policy Research

The debate on PDoH has increasingly gained traction over the last decade in public health research.[2] It relates to the concept of addressing "the causes of the causes" (McKee 2017: 1) for health outcomes at the individual and societal levels and emphasises "that health issues need to be brought into the political arena to advance population health" (Mackenbach 2014: 1). The PDoH perspective thus corresponds to a (re)discovery of the 'political' in public

[1] One example is the research on Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The Directive has been discussed at length in the literature, sometimes critically as a gateway to the liberalisation of national health systems, sometimes more positively as strengthening the role of EU health actors. According to the Commission's evaluation of the Directive in 2022, "Patient mobility remains very low and its impact on national healthcare budgets marginal" (European Commission 2022c: 9).

[2] The fact that political conditions are central factors influencing public health has already been recognised and formulated earlier in public health research. One only has to think of Rudolf Virchow's famous statement "Medicine is a social science and politics is nothing else but medicine on a large scale". The PDoH perspective builds on these notions and reflects earlier research and debates (Mackenbach 2009).

health research, especially as PDoH are increasingly acknowledged as central drivers of the social determinants of health (SDoH), i.e., the influence of social-structural factors (e.g., income, status, education, ethnic group, age, and gender) on public and individual health (Dawes, Amador, and Dunlap 2022). This shift has prompted research on welfare state generosity, party politics, and democracy and their effect on public health and health inequalities (e.g., Barnish, Tørnes, and Nelson-Horne 2018). Many of these findings resonate well with established political science research.

Kickbusch (2015: 1) argues that "(...) looking at health through the lens of political determinants means analysing how different power constellations, institutions, processes, interests, and ideological positions affect health within different political systems and cultures and at different levels of governance". From this perspective, PDoH include all political factors that impact health as a political outcome (Dawes, Amador, and Dunlap 2022). Dawes, Amador, and Dunlap (2022) point to voting, governments, and policies as central political determinants, which public health researchers and practitioners should engage with. Others such as Mishori (2019: 2) conceptualise the PDoH further as "rules, laws, and regulations that affect our health care system and our population's health".

Starting from the classical distinction of the three dimensions of the "political" (i.e., policy, politics and polity), the policy dimension is central to an understanding of PDoH, as formulated in recent public health research, given that it *directly* affects the health and well-being of individuals, while political processes (politics dimension) and institutional structures (polity dimension) work more *indirectly* through shaping and influencing how and which policies are formulated (Muntaner et al. 2010; Mackenbach 2014).[3] For this reason, this

[3] For example, the design of out-of-pocket payment schemes (policy) directly impacts the use of health services across the entire spectrum of care (Rezayatmand, Pavlova, and Groot 2013). However, the party composition of coalition governments (politics) or the welfare regime type (polity) determines how likely it is for such policies to be promoted.

article conceptualises the *PDoH approach as policy outcome-oriented*, seeking to understand how EU laws and policies affect health outcomes.

In contrast, existing literature on EU health law and policy (e.g., Hervey, Young, and Bishop 2017) has predominantly focused on understanding the political processes of health policy integration and cooperation themselves, examining the EU's health powers (e.g., de Ruijter and Brooks 2022) that lead to specific EU health policy *outputs* (e.g., regulations, directives, programmes, etc.) or analysing how and to what extent EU health policies are implemented and influence Member States' health systems and policies. The relationship between the two research perspectives is complementary: to examine and evaluate the design and impact of EU health policies, an informed assessment of the political conditions, legal competences, and decision-making processes at the EU level is indispensable. Furthermore, insights from EU policy implementation research are vital as they highlight the practical challenges of policy implementation in Member States. Ultimately, the PDoH perspective goes one step further by not only asking "how EU policies are being put into practice" (Treib, Mastenbroek, and Versluis 2022: 464) but how these implemented policies affect public health.

EU Health Policy as a PDoH: Developing an Analytical Framework

Understanding EU health policy as a PDoH is about asking how EU health policies affect healthcare, public health, and ultimately, health outcomes and how effective they are in doing so (Brooks 2022). Ideally, this implies the existence of (observable) "causal effects of political decisions on the health of populations" (Mishori 2019: 2); however, public health experts and political scientists alike agree that such links are conceptually, methodologically, and empirically rather difficult to ascertain (e.g., Mackenbach 2014). In this section, we develop a framework to analyse EU health policy as a PDoH.

Building on the previous section, an assessment of the EU's role as a PDoH, in our understanding, has to start with illuminating the policy output dimension as the central locus of analysis. Policy objectives, governance mechanisms, and instruments of EU health policy – and their changes – become the first analytical step for assessing the mechanisms between policy output and the actual policy outcome (Rütten et al. 2003). Central to this study is a second analytical step that focuses on assessing the impact of EU policies on health policy outcomes concentrating on the systematic investigation of the policy intermediary mechanisms taking place between the various levels. Table 1 gives a stylised overview integrating these two dimensions into a framework to analyse different relationships and interconnections of EU (health) policy as a PDoH in the EU multi-level governance system.

The *first dimension* captures the *policy outputs* generated by the EU. Analysing the specificities and variance in European health policy output, which differ significantly from health policy at national level, is central to determine the EU's respective PDoH quality. It consists of three categories:

I. *Policy area.* The EU is a multi-level governance political system, in which health is primarily a Member State competence but is exercised through different policy avenues (Hervey and Vanhercke 2010). Greer and others differentiate between three faces or areas of EU health policy (Greer 2014; Greer et al. 2022; Brooks 2022): The **first face** has traditionally been the most direct and explicit impacting public health policy. It is legally anchored in Article 168 on the Treaty on the Functioning of the European Union (TFEU), which gives the EU some shared competences in public health, including the regulation of substances of human origin, however, largely limiting health policy and healthcare interventions to coordinative and complementary actions. The **second face** includes the EU's internal market and the EU's power to regulate, for example, pharmaceuticals or professional qualifications as a part of a market for services or goods, which is consequential for health and healthcare in Member States (Article 114 TFEU). The **third face** is rooted in the EU's

Economic and Monetary Union (EMU) governance framework (Article 121 and Article 126 TFEU): European surveillance of Member State economic and fiscal policies including coordination, monitoring, and recommendations on taxes, (health) spending and (healthcare) policies that affect the state's fiscal, economic, and social trajectory. The result is a set of various health-related EU competences across a range of areas, but also a persistent tendency for an asymmetrical integration in favour of market-related policies (Greer et al. 2022: 243).

II. *Health policy objectives*. European health policy has specific objectives in supporting Member States' health systems, which are defined in the treaties and the various EU health programmes (see for instance European Parliament and of Council of the EU 2021b). The WHO (2010) distinguishes between six building blocks for the strengthening of health systems: service delivery, health workforce, information, medical products, vaccines and technologies, financing, and governance/leadership. Greer et al. (2022: 4-5) indicate, that the three faces of EU health policies address these domains in different ways and to a different degree. Moreover, these domains have different functions which must be considered when assessing the PDoH quality of EU health actions: Leadership/governance and health information are cross-cutting components forming the basis for the other health system blocks, financing and the health workforce are key input components of health systems, while service delivery and medical products and technologies reflect the immediate outputs of the health system (WHO 2010).

III. *Policy instruments.* The policy dimension can be further characterised by the type of policy instrument wielded. Fahy, Mauer and Panteli (2021) differentiate between instruments such as legislation and policy statements, funding, information, and technical assistance as types of EU tools that can offer support to Member States. Furthermore, they highlight the important role of the EU health agencies (e.g., European Medicines Agency) in providing information and technical support to Member States. Building on this conceptualisation, the EU health policy toolbox can range from binding regulatory or legal

instruments (including EU regulations or directives) to softer policy instruments aimed at coordinating Member State activities. The latter includes the country-specific recommendations generated within the scope of the European Semester, but also non-binding instruments such as Commission Communications or Council Recommendations. In addition, policy can be exercised through financial instruments (EU funding mechanisms), as well as coordinative activities between different Member States (e.g., joint research projects and data collection mechanisms). Apart from treaty reforms, which can fundamentally change the general depth and scope of EU competence in health policy (Greer et al. 2022: 9 ff.), policy innovation usually takes place at and through the instrument level, for example through the formulation of new health policy strategies and objectives, the adoption of new institutions (e.g., agencies) or funding mechanisms through EU legal acts, or changes in the governance of coordinating health activities at EU level (e.g., European Semester).

The *second dimension* (*policy outcomes)* puts forward four analytical categories that assess the mechanism of how and to what extent EU health policy outputs can impact health outcomes, which can be broken down by i) type of effect (direct or indirect), ii) strength of effect (weak, medium, and strong), iii) scope (broad or limited) and iv) direction of effect (positive or negative outcomes on health and/or health systems).

I. *Type of effect*. Building on the recent work of Kunißen (2023: 80-84), we can conceptually distinguish between two general types of effects through which public policies, and thus EU policies, affect health outcomes:

- A direct effect where health policies directly impact the health of citizens (e.g., improving access to treatment or health insurance), and
- An indirect effect where (economic and social) policies influence social determinants of health (SDoH) (e.g., early childhood education and care) and moderate the effect SDoHs have on health outcomes (e.g., unemployment benefits reducing psychosocial stress). The effect of policies in other areas, such as environmental and climate policy,

on health (whether this is conscious or occurs as a byproduct of that policy) is also encapsulated in this category. For example, the regulation of vehicles can have positive impacts on air quality, affecting respiratory health.

II. *Strength of effect*. The strength of the effect refers to the intensity of the policy in terms of how it impacts national health policies and health outcomes. This relates to well-established research on EU policy change and implementation (e.g., Treib, Mastenborek, and Versluis 2022), where strength of effect tends to correlate with the political willingness and administrative capacity accompanying policy implementation processes (Falkner et al. 2005).

III. *Scope of effect*. The scope of effect refers to the extent or breadth of the impact of an EU health policy on a target group or context. This can vary as policies can be directed towards only one or a few Member States (e.g., country-specific recommendations on health in the European Semester) potentially impacting their populations or be tailored to impact only a small sub-group of a population.

IV. *Direction of effect*. The last category addresses the (potential) direction of the effect. Although this remains an empirical question, the literature generally tends to predict an overall positive effect of EU public health policy on Member State health policies and systems, while taking national variations among Member States into account. Conversely, market integration and the EU's economic governance are generally regarded as constraining or mixed factors with regards to promoting better health outcomes (McKee, Mossialos, and Belcher 1996; Hervey and Vanhercke 2010; Greer 2014).

[Table 1 about here]

Methods and Data

We assess the PDoH qualities of the EHU by applying the analytical framework and categories presented in Table 1.

Building on EU documents as the primary data source and on existing research, we first map the early-stage institutionalisation of the EHU as a new policy output following the first part of the framework. We complement this policy output-focused perspective with an outcome-based exploratory assessment by exemplarily mapping the pathways by which EU health policies potentially influence health outcomes following the second part of the framework. We use three examples, including the joint procurement of vaccines, the implementation of health-related reforms and investments through the RRF, and the creation of the EHDS, which are illustrative representations of the three layers depicted in Figure 1, to discuss the different dimensions of effect for each and provide a complementary perspective to bridge the analytical gap between the EHU as specific policy output of EU politics and its potential health effect on EU citizens.

By making use of this framework, we aim to, on the one hand, capture the institutionalisation of the EHU and characterise the policy innovations it has triggered at the EU level. On the other hand, this heuristic allows us to look at the role of EU health policies and EHU measures for health outcomes in the Member States. Using concrete case studies, we offer a description of what has happened as a result of EU policy interventions; where appropriate, we adopt a counterfactual perspective, and consider what has and may have happened in the absence of EU interventions. In many cases, information on the implementation of EHU policies and on the effects of the measures are primarily available from EU institutions. In the sense of a triangulation of results, we have tried to corroborate the findings through various sources and studies. This was not always possible and therefore highlights the need for further research.

The EHU as a Political Determinant of Health

The Early Institutionalisation of the EHU: A Perspective on Policy Outputs

In November 2020, the European Commission released a Communication on "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats" putting forward a series of policy proposals to help Europe out of the public health crisis fomented by COVID-19 (European Commission 2020a). At its core, Communication 2020/724 focused on strengthening the Union's preparedness and response (P&R) capacity to cross-border health threats. The document included three legislative proposals in line with current provisions of the Treaty of the functioning of the EU; the Treaty sets out the EU's actions to focus on "supporting, complementing or supplementing" the Member States' activities in Public Health (Article 6 TFEU) including "monitoring, early warning of and combating serious cross-border threats to health", amongst other activities (Article 168 TFEU). All three proposals crossed the stage of institutional approval and have been adopted as legislative acts.

The first proposal entailed upgrading Decision 1082/2013/EU on serious cross-border health threats to a Regulation with a broader set of responsibilities, including the EU-wide recognition of a Public Health emergency triggering supranational response mechanisms and the introduction of a standardised EU pandemic preparedness plan, enabling the EU to hold Member States accountable to updating their national plans and P&R capacities in regular intervals (European Parliament and of Council of the EU 2022c). The second and third proposals related to expanding the mandate of two EU agencies, the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), to bolster coordinated EU-level action and improve the management of cross-border health threats. Regulation (EU) 2022/123 expands the EMA's mandate in relation to monitoring and mitigatíng the risk of critical medicines and medical supplies, coordinating studies related to the safety and effectiveness of vaccines, coordinating assessments of clinical trials, and providing scientific advice on clinical trials (European Parliament and of Council of the EU

2022a). Regulation (EU) 2022/2370 expands the ECDC's mandate to support EU-level health coordination and management (European Parliament and of Council of the EU 2022b). This includes the areas of epidemiological surveillance, health risks preparedness and response, the provision of non-binding recommendations, and risk management as well as mobilising an EU Health Task Force for Member State assistance and building EU reference laboratories networks. To ensure better and equal access to medicines, protective masks and necessary equipment in the future, Communication 2020/724 also proposed to establish the Health Emergency Preparedness and Response Authority (HERA), tasked with monitoring cross-border health risks, developing and diversifying reliable supply chains, and ensuring adequate stockpiling in the event of a future emergency. In September 2021, HERA was established through a Commission Decision and is functioning as a Commission service (European Commission 2021b).

Overall, the proposals of Communication 2020/724 elicited an expansion of EU activities and responsibilities in public health through a delineated set of interventions. However, these primarily foresaw strengthening existing infrastructures and mechanisms with a focus on pandemic preparedness and response (e.g., see Greer et al. 2022: 20 ff.). Nevertheless, the EHU can be viewed as having unfolded with a broader conceptualisation over the past three years, encompassing several strands of action that are not or only just mentioned in the EHU communication published in late 2020. This includes the revision of the EU's general pharmaceutical legislation and the pooling of expertise to deliver coordinated scientific assessments of new health technologies as part of the 2021 Regulation on Health Technology Assessments (European Parliament and Council of the EU 2021c).

Another central element of the current Commission's health policy portfolio is represented by Europe's Beating Cancer Plan, which despite the subsidiary role of EU health policy, aims to deliver a set of tools to strengthen preventive and curative cancer care (European Commission 2021a). The portfolio further includes the proposals for an EHDS,

which in its current conception aims to enable health information to be exchanged and wielded across the EU to improve healthcare delivery and research (European Commission 2022b). For years, civil society and the public health community have called upon the Commission to review the 2010 Global Health policy statements. A new strategy document was launched in November 2022 with ambitious prospects anchored in three overarching priorities: i) to improve health and well-being across the life course, ii) to strengthen health systems and advance universal health coverage (UHC), and iii) to apply a One Health approach to prevent and combat health threats (European Commission 2022e). These objectives are to be delivered in concert with various EU policy strands and financial mechanisms.

As highlighted in the EHU communication, an early reaction to the pandemic at EU level was to dispense additional funding to support the emergency response through instruments like the Emergency Support Instrument. Coincidentally, the transition to a new 7-year Multiannual Financial Framework was underway when COVID-19 struck countries in the EU, which heavily influenced agenda setting towards investing in health systems by bolstering existing financial tools (e.g., EU4Health) and incorporating health objectives into new (albeit temporary) financial mechanisms such as the RRF (Fahy, Mauer, and Panteli 2021; Mauer et al. 2022). The Communication highlighted how Member States can access these funding instruments for a range of interventions, such as improving health system infrastructure (e.g., Cohesion Policy funds, RRF) or investing in cancer prevention (e.g., EU4Health, Horizon Europe), although common initiatives are only binding to a limited extent and enforceable with varying degrees of conditionality, e.g. monitoring and approving health investments and reforms in national Recovery and Resilience Plans (NRRPs), at the national level.

As captured in Figure 1, the outputs of the 2020 EHU Communication are nested within a broader set of EU initiatives that can be viewed as part of or contributing to the

(early) institutionalisation of an EHU more generally. Hence, we distinguish three layers of actions, with the innermost pertaining to the core policies of the EHU Communication, the intermediate level referring to actions within the current EU health portfolio and the outermost to broader actions with relevance for health. In line with the analytical scope of this article this outermost layer only features the RRF, although other policy and funding instruments can be considered relevant here.

[Figure 1 about here]

In line with the analytical framework (Table 1), the different colour framing of the initiatives indicates the essential character of the respective policy instruments wielded, including regulatory/legislative changes, new strategies, and policies to strengthen coordinated action between Member States and an expansion of funding and institutional capacity. Since these initiatives primarily envision strengthening existing infrastructures and mechanisms with a focus on pandemic preparedness and response at the EHU's core, most of them fall within the first face of EU health policy (e.g., Brooks et al. 2023). However, some initiatives also include new policy objectives, governance strategies and funding mechanisms, such as the RRF, which as an economic recovery instrument may be viewed as part of the third face of health policy, or the new Global Health Strategy, which brings together the work of different Commission Directorate Generals, including SANTE (health and food safety), INTPA (development cooperation and international partnerships) and TRADE (trade), and hence constitutes a fourth face of health policy, encompassing both market integration (second face) as well as other EU policy branches with potential (unintended) impacts on health in the EU.

Exploring the PDoH Qualities of the EHU: A Perspective on Policy Outcomes

Viewed through a PDoH lens, it is crucial to understand to what degree these EHU initiatives have a (quantifiable) impact on health systems and population health across EU countries.

This question extends to which health-related areas are impacted, whether the effect of EHU measures is direct or indirect and to what extent these policies trickle down to impact people's health outcomes across the EU (see Table 1). In this section, we apply the framework to the examples of joint vaccine procurement, the RRF and the EHDS to illustrate its conceptual merit.

Joint Vaccines Procurement during the COVID-19 Pandemic

Lacking coordination on vaccine procurement and distribution activities among Member States during the Swine flu pandemic of 2009 contributed to vaccine hoarding in some countries and lack of and inequitable access in others, marking an incisive moment that precipitated better and more collaborative action on vaccine procurement in view of the next health emergency in Europe. (cf. de Ruijter 2021) Article 5 of Decision 1082/2013/EU on serious cross-border threats to health included provisions for the joint procurement of medical countermeasures years before COVID-19 struck (European Parliament and of Council of the EU 2013). As of April 2020, the Joint Procurement Agreement (JPA), an instrument to coordinate the procurement of vaccines and medications in preparation for outbreaks of infectious diseases, had been signed by 37 countries, including all EU and EEA countries. Its provisions foresee that in order to be adequately prepared in the event of a serious cross-border threat to health, the institutions of the EU, together with countries that have joined the JPA, "may engage in a joint procurement procedure with a view to the advance purchase"[4] of vaccines, antivirals and medical countermeasures. This offers participating countries a complementary approach to national procurement processes. The overarching aims of this joint procurement mechanism were to secure 1) equitable access to relevant medical

[4] European Commission. "Joint Procurement of medical countermeasures". https://health.ec.europa.eu/other-pages/basic-page/joint-procurement-medical-countermeasures_en , p. 2 [30.11.2023].

countermeasures and 2) an improved security of supply, together with more balanced prices for the countries that are part of it (cf. McEvoy and Ferri 2020).

After the critical experiences at the beginning of the pandemic, the Commission and Member States were concerned that the possibility of Member States concluding their contracts individually with vaccine manufacturers would lead to competitive bidding (Greer et al. 2022: 106). As a result, the procurement procedure for vaccines was initially conducted in a centralised manner outside the existing JPA and covered by the Emergency Support Instrument (ESI) as part of the EU's vaccines strategy (European Commission 2020b). The Commission was authorised to conduct the joint purchasing of COVID-19 vaccines on behalf of the Member States via advance purchase agreements (APAs) with vaccine manufacturers. Through the EU vaccines strategy and the purchasing of COVID-19 vaccines for all EU Member States, the European Commission was able to accelerate the development, manufacturing, and deployment of vaccines against COVID-19 early in the pandemic and to secure vaccines for the EU's population (European Commission 2020b; Vogler et al. 2021; Della Corte 2023). By the end of 2021, it had signed €71 billion worth of contracts securing up to 4.6 billion doses (European Court of Auditors 2022).

While the joint purchasing of vaccines proved far from perfect and was not fully able to prevent rushed decision-making on procurement and distribution of vaccines across the EU, it can be considered one of the largest and most impactful joint public health actions in EU history (e.g., Kirkegaard 2021; Greer et al. 2022: 102-104; European Court of Auditors 2022). Nearly 750 million vaccine doses were delivered to Member States and almost 70 % of the EU's adult population were fully vaccinated by the end of 2021.[5][6] According to the European

[5] See Edouard Mathieu, Hannah Ritchie, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Joe Hasell, Bobbie Macdonald, Saloni Dattani, Diana Beltekian, Esteban Ortiz-Ospina and Max Roser. 2020. "Coronavirus Pandemic (COVID-19)". Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/coronavirus' [30.11.2023]

[6] European Centre for Disease Prevention and Control. 2023. „COVID-19 Vaccine Tracker". https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#summary-tab [30.11.2023]

Centre for Disease Prevention and Control (ECDC) and WHO/Europe, the COVID-19 vaccination programme saved the lives of almost 500 000 people across Europe, including some 236 000 in the EU, already shortly after its widespread roll-out, and over 1 million lives in Europe when considering the period between December 2020 and March 2023.[7]

A second key action based on the existing JPA followed in the later emergency response to COVID-19, when almost 3.5 million COVID-19 treatments were secured through the mechanism by November 2022 (European Commission 2022d). Via HERA, a key pillar of the EHU described earlier in the text, the Commission signed a joint procurement framework contract for the supply of Paxlovid, a SARS-CoV-2 protease inhibitor oral treatment for patients with COVID-19 at risk of developing severe disease, with Pfizer and for an initial period of 12 months. Thirteen EU and EEA Member States and EU candidate countries participated in the procurement and were able to purchase up to 3,427,517 five-day treatment courses of the orally administered drug. (ibid.)

Taking stock of the COVID-19 experience, Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (Council of the EU 2022) was proposed by the European Commission, advancing provisions for the procurement and purchase of such countermeasures and crisis-relevant raw materials under the EHU umbrella in emergency situations moving forward (cf. Vogler et al. 2021).

A caveat to be noted when considering the impact of joint procurement of (essential) medicines and vaccines, is that their acquisition alone is usually not enough to foster better

[7] Meslé Margaux MI, Brown Jeremy, Mook Piers, Hagan José, Pastore Roberta, Bundle Nick, Spiteri Gianfranco, Ravasi Giovanni, Nicolay Nathalie, Andrews Nick, Dykhanovska Tetiana, Mossong Joël, Sadkowska-Todys Małgorzata, Nikiforova Raina, Riccardo Flavia, Meijerink Hinta, Mazagatos Clara, Kyncl Jan, McMenamin Jim, Melillo Tanya, Kaoustou Stella, Lévy-Bruhl Daniel, Haarhuis Freek, Rich Rivka, Kall Meaghan, Nitzan Dorit, Smallwood Catherine, Pebody Richard G. Estimated number of deaths directly averted in people 60 years and older as a result of COVID-19 vaccination in the WHO European Region, December 2020 to November 2021. Euro Surveill. 2021;26(47):pii=2101021. https://doi.org/10.2807/1560-7917.ES.2021.26.47.2101021.

health care, leading to better health outcomes. In fact, the COVID-19 pandemic has highlighted the potential discrepancy between the procurement and the actual delivery of vaccines and medicines. When service delivery structures and rollout capacities for delivery are not in place, or if there is a demand issue, the effect and degree of these measures is mediated (Kirkegaard 2021).

Healthcare Reforms and Investments in the RRF

According to the EHU communication, the RRF represents "an unprecedented opportunity for [...] enhancing the preparedness and resilience of [their] national health systems and ensuring equal access to affordable and quality health care" (European Commission 2020a: 13). The RRF, 723.8 billion euros in grants and loans, is the centrepiece of NextGenerationEU (NGEU), aiming for a swift recovery from the economic, social and health consequences of the COVID-19 pandemic. Although the RRF is not focused on funding health policies (unlike the EU4Health programme), financial support to structural reforms and investments in health is given a prominent role. The RRF regulation explicitly features health resilience among its six policy pillars aiming, amongst other goals, to improve the "accessibility and capacity of health and care systems" (European Parliament and of Council of the EU 2021a: 19).

The RRF's governance builds on the European Semester procedure (Vanhercke and Verdun 2022) and Member States' submissions of tailored national recovery and resilience plans (NRRPs) subjected to approval by the Commission and the Council. The NRRPs include a package of reforms and investments to be financed by the RRF and implemented by 2026 based on the Country-Specific-Recommendations, policy recommendations made by the European Commission and endorsed by the Council after evaluation of the Member States' National Reform Programmes, for the years 2019 and 2020. The Commission monitors these plans via a detailed set of targets and milestones whereby their fulfilment and approval are the preconditions for the disbursement of funds.

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The RRF can be considered a PDoH through the financial support it offers for structural reforms and investments in national health systems. In total, more than EUR 43.0 billion (or 8.7% of total grants and loans under the RRF) are earmarked for health-related activities in the 27 national RRPs (European Commission 2023a: 58). The substantial effect on health outcomes varies due to the specific institutionalisation of the RRF:

- Firstly, no running health costs can be covered by the RRF. The focus of health related RRF investments is "mainly for capital investment (i.e., infrastructure) and not for current expenditures" (Corti and Vesan 2023: 518). Most funded structural reforms are aimed primary health care and better care provision. Next to infrastructure, health(care) digitalisation, investment in social services and healthcare workforce training are major reform and investment categories. Accordingly, the health-related common indicator 12 in the RRF scoreboard measures the annual capacity of new or upgraded health facilities supported by the RRF (18.65 million people/per year until the evaluation December 2022).[8]
- Secondly, the effect varies according to differences in resource allocation between Member States and the priorities formulated in the NRRPs. For example, funding for health reforms and investments in the initial NRRPs varied between 33.2 (Estonia) and 1.2 (Luxembourg) percent of allocated funding per Member State (European Commission 2021c: 4). Relatedly, Germany, for example, uses almost all investment for the digitalisation of healthcare, while Italy invests comprehensively in healthcare infrastructure and health service delivery. Funding is used for local health networks, telemedicine, homecare and the integration between health and social care.

[8] European Commission. 2023b. „Common indicator 12: Capacity of new or modernised health care facilities." Recovery and Resilience Scoreboard. https://ec.europa.eu/economy_finance/recovery-and-resilience-scoreboard/RRFCI12.html [30.11.2023]

First studies show that the RRF effectively supports Member States in implementing (health) reforms and pursuing investments which would not have been possible for these Member States without RRF grants (or loans), for instance, due to restrained financial capacities (Corti and Vesan 2023). However, due to the nature of the RRF and its focus on health system resilience, the impact on citizens' health is more indirect than in the case of joint vaccination procurement. In line with the EU's competences and mandate in the area of health, the RRF does not directly fund running costs of health service delivery, nor does it provide social measures for citizens to ensure equal access to affordable and quality health care.

Despite the focus on health infrastructure instead of financing running costs or health services, the reforms and investments are short to medium-term-orientated as new care infrastructure or skills improvement of the healthcare workforce are set to be implemented between 2022 and 2026. Moreover, the characteristics of the EU as a multi-level governance system put the reform and absorption capacity of Member State administration and healthcare systems in the spotlight. The Technical Support Instrument (TSI), an EU instrument that provides technical expertise to EU Member States, can support Member States with implementation but its use is demand-driven and requires Member States to apply for it through the European Commission (European Parliament and of Council of the EU 2021a).

Overall, the performance-based positive conditionality of the RRF, in which health is only one part of many policies, has strengthened the effect on national health systems and indirectly the health of EU citizens, especially in the Member States where health reforms and investments are prominently featured in the RRPs. Particularly for countries with limited financial capacity for capital investment, the RRF is an opportunity to substantially improve existing health infrastructure. Another important element of the RRF is the moderating effects on social and economic determinants of health (Brooks 2022), which funding from the NGEU

and the RRF has also enabled. A significant amount of RRF funds is being used to address broader social and welfare issues, including for example education and training and thus likely influences the social determinants of health. However, not only is this effect indirect, but it also varies considerably between Member States as some are not foreseeing to invest strongly in welfare aspects and thus in turn do not promote the improvement of social determinants.

The Road toward a European Health Data Space (EHDS)

The European Health Data Space's objective is twofold: to facilitate data use for health care delivery and allow patients better access to their personal health data (primary use), and to create a supportive data environment for research, innovation, and policy (secondary use). In May 2022, the Commission published a proposal for a Regulation setting out the regulatory, infrastructural, and legal conditions for its implementation (European Commission 2022b). Although the proposal has been welcomed by many representatives in the Public Health community, there has also been some reticence around issues such as data protection, cybersecurity, and the scope of secondary data use for research purposes (OJ C 486, 21.12.2022, 123–128). Although the EHDS is set to comply with EU data protection legislation, how the future data space will ensure the safe exchange of health data across borders while protecting personal health data from leaks and misuse remains a major concern for citizens and stakeholders alike. In addition, technical barriers including differing levels of digital infrastructure maturity across EU Member States and the current lack of interoperability across major data hubs and repositories, including health care facilities, may hamper the timely implementation of the data space.

Nevertheless, the EHDS harbours the potential for EU citizens to claim ownership of their personal data and to inform health care delivery, as patients gain the capacity to share health information with their health care providers (European Commission 2022a). This may

foster health literacy among EU citizens and may improve the quality of care received, informing clinical decisions and potentially reducing waste and inefficiencies in European health systems with a possibly direct and positive impact on the health of EU citizens. However, an effective implementation also requires adequate levels of access and digital literacy among the population and health workforce to avoid exacerbating existing inequalities. Targeted measures to ensure EHDS plans are accompanied by adequate digital capacity building need to be given serious consideration given the current divide in internet access and digital literacy across Europe, both within and across countries (e.g., van Kessel et al. 2021).

Over many years, the EU has invested in initiatives to establish sound framework conditions for the pooling and sharing of data across national borders at Union level. Notable examples include the Health programme-funded joint actions BRIDGE Health and InfAct, the eHealth Digital Service Infrastructure under the Connecting Europe Facility to allow for ePrescriptions and patient summaries to be exchanged across borders and, most recently, the Population Health Information Research Infrastructure (PHIRI) under Horizon Europe. Notably, in the area of rare diseases, the cross-border exchange of health information has been promoted under the European Reference Networks (ERNs) initiative. The 24 ERNs have established disease-specific platforms that allow healthcare providers across the EU, who are caring for patients with different types of rare conditions, to connect with each other and exchange clinical information. A web-based interface, the Clinical Patient Management System, enables virtual consultations among providers to discuss diagnostic and treatment information, as well as other forms of collaboration, including the development of guidelines and clinical decision support tools for conditions requiring highly specialised management.

A look at the literature offers an insight into some of the practical outputs these networks have produced since their inception, including the development of care pathways and various collaborations with patient groups (Talarico et al. 2020), although governance

issues and integration into national ecosystems are some of the challenges reported to date (Tumiene et al. 2021). Following a broader assessment of the Directive on patients' rights in cross-border health care (2011/24/EU), the Commission launched a targeted evaluation process of existing ERNs in December 2022 to assess whether the current set-up is delivering the expected outcomes, including in the clinical setting. Evidence from the first evaluation suggests the ERNs have been successful platforms for the management of rare conditions, with 1.7 million patients in treatment with ERN members, participation of ERN patients in 732 clinical trials and around 1500 hospital units offering care in the ERN network as members to date[9]; outcomes of the ongoing evaluation process will provide further insights into whether these existing cross-country data exchanges have been benefitting patients at large scale.

The practical implementation and potential impact of the EHDS is difficult to foresee at the time of writing this article, as the EHDS proposal is still under discussion. Nevertheless, building on the many existing EU initiatives and reflecting on the positive impacts of the ERNs, access to health data within the EHDS could potentially improve the clinical reality of many patients and providers across Europe, if existing hurdles and incompatibilities can be successfully overcome. Beyond the potentially direct impact on care, the pooling of large data cohorts could support and foster research and innovation in areas where data is currently difficult to come by like rare and low-prevalence diseases, and thereby, as argued by the Commission, contribute to the development of better treatment and management options for millions of patients (European Commission 2022a). Lastly, the EHDS may provide impetus for the advancement of national policies and support the digital transition across those Member States, who may still need to accelerate digitalisation processes at national level to meet the requirements for implementation of the new data space.

[9] Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare, https://health.ec.europa.eu/system/files/2022-05/crossborder_evaluation-dir201124eu_study_frep_en.pdf [30.11.2023]

Discussion

The early institutionalisation of the EHU is largely assessed in the literature as a process of evolutionary integration and policy change. New governance mechanisms have been added on top of existing structures, with the focus of the EHU resting on cross-border health threats and crisis preparedness. The EHU does not represent a paradigm shift in how the EU seeks to integrate health policy, according to the prevailing view among researchers (e.g., Greer et al. 2022: 23). This is not least because the primary competences in EU health policy have remained unchanged mainly focusing on the build-up of existing governance structures and policies (e.g., Brooks et al. 2023).

Our outcome-oriented perspective offers a nuanced assessment of the EHU as depicted in Table 2. The new instruments and legislation around the joint procurement of vaccines and medical countermeasures were prompted by the COVID-19 experience and, to some extent, built up on existing (albeit insufficient) policy mechanisms. Yet, the effect and scope of the EU vaccine strategy on people's health proved more direct and stronger in its immediacy than other policy processes under the EHU and recent EU health policy in general. The RRF as a significant policy innovation but a marginal element of the EHU, varies in terms of its effect: on the one hand, its focus is on capital investments, such as health system infrastructure, and thus more indirectly impacting patients; on the other, the resources that have been earmarked for health vary greatly between the Member States. Moreover, the RRF exerts an indirect effect through its influence on SDoH reforms and investments, which in turn can impact health outcomes in the medium- to long-term. One should also not forget that the RRF is a temporary instrument and funding may not be made available (at least to this extent) beyond the ongoing Multiannual Financial Framework (MFF). The launch of the EHDS has two potential effects: on the individual level, it may help to improve patient care, allowing patients to share their personal data with health care professionals and strengthen the quality and

efficiency of health services; on the societal and health system level, improved healthcare research and disease surveillance on the basis of large patient datasets might improve health outcomes on the medium- to long-term. However, especially the individual effects such as personalised care or improved patient engagement, are strongly linked to health literacy and as such mediated through SDoH, and in the case of patient safety or clinical decision-making, dependent on structural aspects of the healthcare system and the digital maturity of infrastructure across different Member States.

Overall, Table 2 highlights the EHU's – and the EU's – relevance as a PDoH for EU citizens. It also indicates that there is a significant degree of variation in the (expected) effect of EHU measures on health outcomes, which complements the assessments of the quality of policy formulation and change through the EHU at EU and Member State level. The analysis confirms our argument that the nature of EU health policy output, and in our case the EHU, should be complemented with an outcome-oriented perspective to fully grasp its relevance in the EU multi-level system.

[Table 2 about here]

Conclusion

This paper analysed the early institutionalisation of the EHU from a PDoH perspective. We argued that the PDoH perspective complements research on EU health integration and law by adopting a stronger outcome perspective and asking how European health policy affects the health of citizens in the EU.

Based on this definition, we have developed an analytical framework for the empirical analysis of European health policy as a PDoH. We used this exploratory framework to analyse the early-stage institutionalisation of the EHU and illustrate the merit of complementing this with a PDoH perspective. We found specific patterns and variations in the expected effect of EHU measures on health outcomes, which somewhat contrasts with the multiple assessments

of EU health policy research detecting rather similar qualities of policy change. We have examined these effects qualitatively using three illustrative examples as a first attempt to assess the (potential) effect of the EHU on people's health across the EU.

One of the main policy implications of this research, the framework helps make visible to policy makers and stakeholders the link between EU policy and health outcomes in Member States and starts to unpack the impact of the former on the latter. The framework also reveals areas where policy makers should dedicate resources to generate, collect, and/or make data available publicly that may help scholars map, study, and better understand the EU-Member State link.[10]

This is what future research engaging with the EU as a PDoH should focus on. The relationship between EU health policy outputs and health outcomes needs to be further conceptualised and monitored to be able to better explain when, how and why policy outputs do or do not lead to specific policy outcomes. This includes investigating and mapping the pathways by which the EHU and its policies influence Member States' health systems and health outcomes, including intentional and unintentional effects for public health over short-, mid-, and long-term. More empirical research and sophisticated research designs are needed to apply and refine the framework developed in this article for the analysis of policies such as the EHU, and to gain a more comprehensive picture of the EU's significance for health. This may include statistical analysis to quantify the degree of influence of policies and their direction when data allow for it. Also, complementing EU data with those from other, non-EU-sources will potentially add to the validity and robustness of the analysis.

Ultimately, our findings suggest that the degree of EU health policy integration, which remains limited at a time when the momentum for a stronger EHU institutionalisation may be waning, may not necessarily be reflective of the strength, direction, or effect of policies on

[10] We owe this argument to the reviewers for which we want to thank them.

population health and health outcomes. In the case of vaccine procurement, for instance, the impact has been quite substantial and direct. This highlights the added value of complementary outcome-guided perspectives in analysing EU health policies as PDoH. Our analysis also suggests that timing plays a key role in determining the scope and impact of policy outputs, an aspect which would also be of interest to explore in future research. Momentum for the budgetary commitments made to health in instruments like the EU4Health and the RRF appears to have been driven by the COVID-19 crisis, creating a political window of opportunity for the advancement of policies which perhaps would not have been or would not be possible again under different circumstances. Looking ahead, this raises important questions about how political attention and resources may shift in the upcoming political mandate and financial cycle with new pressing economic and geopolitical challenges.

■■■

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Table 1 Analytical Framework of EU Health Policy as a PDoH

Dimension	**Category**	**Attributes**	**Explanation**
1. Policy output	I. Policy area	First Face, Second Face, Third Face of EU Health Policy	First Face of health policy action under Article 168 TFEU; Second Face of health-related market integration (e.g., pharmaceuticals; health services); Third face of economic governance, health financing and spending (health CSRs in the European Semester) (see Greer 2014)
	II. Policy objective	Health system domains targeted by EU health policies	Service delivery, Health workforce, Information, Medical products, vaccines and technologies, Financing, Governance/Leadership (see WHO 2010; see also Greer et al. 2022)
	III. Policy instrument	Regulatory, Funding, Coordinative/ Supportive	Instruments: Regulatory (regulations, directives) and other legislative instruments; Financial support and funding (e.g., health or research programmes); Policy coordination via (hard) soft law (e.g., Country-Specific-Recommendations in the European Semester); Coordinative and benchmarking activities (e.g., best practice exchanges, cross-country research projects)

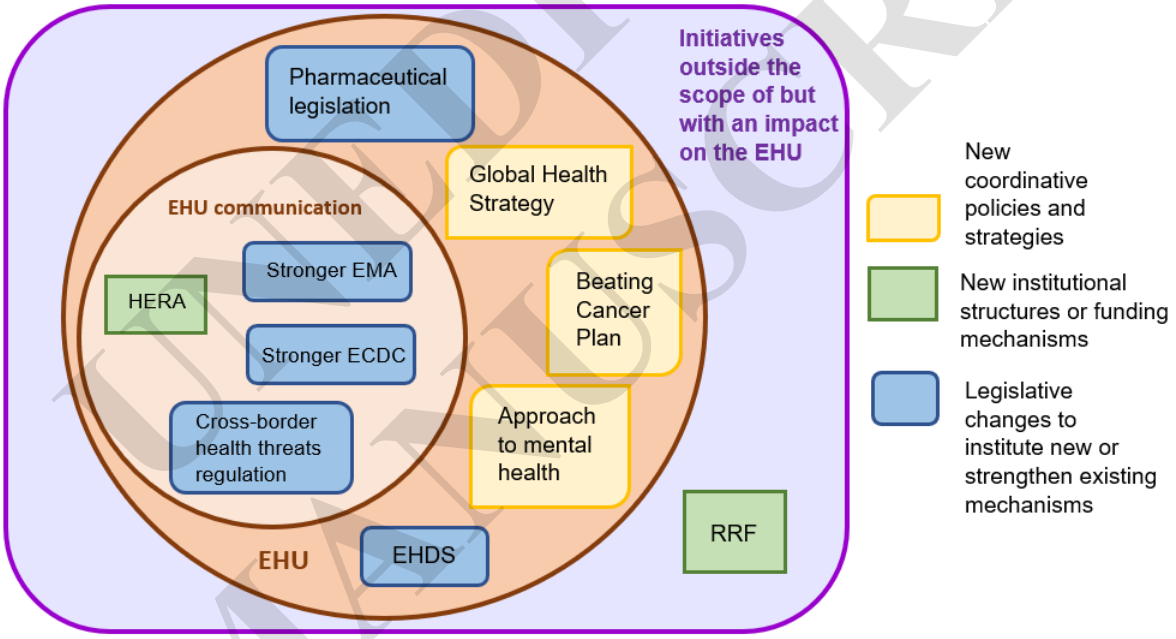
2. Policy outcome	I. PDoH Mechanism	Direct vs. indirect effect	Direct effect: EU health policy works via national health policies/systems as a PDoH on health outcomes Indirect effect: EU policies (e.g., economic, social) work via national (economic, social) policies as moderator on health outcomes through influencing SDoH or other health determinants (e.g., climate)
	II. Strength of effect	Strong effect, medium effect, low effect	Population health is strongly/weakly affected by EU policies and their implementation through Member States (e.g., implementation of directive)
	III. Scope of effect	Broad scope, limited scope	Broad scope refers to policies which have an impact on most or all Member States (e.g., legislation on tobacco, alcohol, or occupational health) vs. limited scope refers to policies which have an impact on few or single Member States (e.g., country-specific recommendations)
	IV. Direction of effect	Positive effect, negative effect on health	Positive effect (e.g., improving health infrastructure), negative effect (e.g., EU austerity policies lead to cuts in national health spending, resulting in reduced health services and potentially poorer health outcomes.)

Table 2 Mapping of the EHU as PDoH across the illustrative cases of joint vaccine procurement, RRF and EHDS.

Dimension	Category	Joint Vaccine Procurement	RRF	EHDS
1. Policy Output	I. Policy area	First Face	Third Face	First Face
	II. Policy objective (WHO building blocks)	Medical products, vaccines, and technologies	Service delivery (infrastructure), Health workforce, Financing	Service delivery, Information
	III. Policy instrument	Legislative expansion of actions and coordination	New governance and funding mechanisms	Legislative changes to institute new or strengthen existing mechanisms
2. Policy Outcome	I. PDoH Mechanism	Direct effect	Direct and (mostly) indirect effect (SDoH)	Direct and indirect effect (strengthening data availability for research)
	II. Strength of effect	Strong effect	Weak – Strong effect (depending on implementation within Member States)	Weak – Strong effect (depending on implementation within and across Member States)
	III. Scope of effect	Broad	Medium (varies between Member States based on the NRRPs)	Medium – Broad (potentially applies to all Member States and citizens)

	IV. Direction of effect	Positive (despite limitations regarding distribution and roll-out of vaccines)	Positive (NRRPs do focus on expansion of capacities and resources, not retrenchment)	Potentially positive (if data and infrastructure gaps can be overcome and if accompanied by policies to strengthen health literacy and digital inclusion. Risk of exclusion, concerns with data privacy and misuse of data)

Figure 1 Policy outputs nested within and contributing to the European Health Union.



Notes: ECDC: European Centre for Disease Prevention and Control; EHDS: European Health Data Space; EHU: European Health Union; EMA: European Medicines Agency; HERA: Health Emergency Response Authority; RRF: Recovery and Resilience Facility; Approach to mental health = Comprehensive approach to mental health.