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EU health policy in the aftermath of COVID-19: neofunctionalism and crisis-driven integration

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ABSTRACT

In March 2020, the COVID-19 pandemic shook the European Union (EU). The EU responded to the multifaceted challenge with an integrative leap forward. Member States substantially increased their investment in existing health policy tools such as civil protection and financing for health initiatives. There was innovation in EU law, where a process of redefining public health began, and in strategies for vaccines and pharmaceuticals, where the EU took on a direct and significant role in medicines procurement for the first time. We use the framework of neofunctionalism to analyse developments in health policy during the pandemic to further understand the dynamics of integration and, in particular, to understand why EU Member States opted for further integration in response to the pandemic. As neofunctionalism might predict, Member States solved problems born of integration with more integration: preserving the internal market, insuring against disasters, preventing border closures and enhancing EU power in vaccine development and procurement. Reflecting decades of entrepreneurs who had created various mechanisms, they primarily built on pre-existing, if often weak, structures and enhanced EU governance more than competencies.

KEYWORDS European integration; health policy; neofunctionalism; crisis; COVID-19

Introduction

For all the conversation about threats to European integration, or the European Union (EU) itself, decades of crisis have often led to greater integration. The financial crisis, Brexit, and COVID-19 were all seen as containing the seeds of European disintegration but instead left behind greater integration (Quaglia & Verdun, 2023).

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The initial weeks of the COVID-19 pandemic saw EU Member States abandon commitments to solidarity and ignore existing health policy coordination structures. Within months, though, the EU switched to a distinctly integrative response, particularly in the field of health. In a series of decisions and initiatives adopted since late spring 2020, the EU and its Member States have outlined their intention to increase health cooperation and build a 'European Health Union'. While media and political debate often focuses on putative existential threats to the EU, scholarly debate focuses on the conditions in which crises lead to greater integration, and the extent to which integrative decisions taken in one crisis shape the next. In other words, the debate is about questions which are best viewed as falling within the basic scholarly framework of neofunctionalism.

In this article, we ask whether – and which – neofunctionalist theories of integration explain the development of EU health policy since 2020. There has been a considerable program of theoretical elaboration of neofunctionalism in recent years, and we draw on it, in combination with case studies, to gauge the explanatory power of these concepts.

We use contemporary developments in EU health policy, particularly those that are taking shape under the heading of the European Health Union (EHU), to explore patterns of neofunctional integration following COVID-19. In-depth analysis of five new initiatives, announced by the European Commission between May and November 2020, examines the drivers and dynamics of cooperation in the field of health. Particular attention is paid to the role of crisis in prompting (dis)integration and how this fits with the dominant, neofunctional narrative of EU health policy development.

EU health policy integration prior to COVID-19

EU health policy, until recently, was a very marginal policy area. It is that marginality, in part, which makes it a useful case to examine the explanatory power that neofunctionalism has in explaining European integration. Unlike many other areas of domestic policy, such as labour law, environmental protection, or financial regulation, there is no established EU role for health policy. That makes health, like immigration, border, or defence policy, an opportunity to understand the drivers of integration. It is a case of integration rather than EU policymaking within a largely established system. Specifically, it is a case about integration in social policy, which has historically lagged and been shaped by market-making policies.

Most public health and health care policy in the European nation states is formed with little reference to the EU. European health law and policy has largely been shaped as a 'by-product' of other policies, such as trade, internal market regulation, and labour law ('social policy'), (Brooks & Guy, 2021; de Ruijter, 2019; Greer, 2006). Member States have shown a clear commitment

to subsidiarity and, over time, have displayed an intense reluctance to expand EU oversight of their policies. One notable example in this regard is the Commission's (ultimately unsuccessful) attempt to integrate health care into EU services policy, embodied in the 2004 proposal for a Services Directive ('Bolkestein Directive'). More generally, across Treaty revisions, Member States were serious enough about subsidiarity to not just write an elaborate and obviously constraining Treaty base for public health (Art. 168 TFEU) but also to include within it the equivalent of large 'no trespassing' signs:

The European Parliament and the Council (...) may also adopt incentive measures (...) designed to protect and improve human health (...) excluding any harmonisation of the laws and regulations of the Member States. (Art. 168 (5) TFEU)

Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. (Art. 168(7) TFEU)

As these two Treaty recitals indicate, health law and policy contain two broad areas of activity with quite different logics of spillover and integration: that of 'health care' and 'public health' (de Ruijter, 2019; Hervey, 2017). Health care is the sub-field of policy that addresses the 'organization and delivery of health services and medical care', meaning the panoply of medical professionals, health insurers, hospitals, and the taxes that pay for them, which dominate public discussions and electoral debates on health. Health care is a large and politically salient domestic policy area with intense interest group politics; to integrate health care directly would require addressing the enormous inequalities between Member States and is therefore unlikely (Greer et al., 2019).

The borders of public health, the second element of EU health law and policy, are famously hard to define because they could include almost any effort to address morbidity and mortality at the population level, but they clearly include communicable disease control and response to outbreaks (Greer & Jarman, 2021). By contrast to health care policy, the area of public health connected with communicable diseases and health emergencies is, in many ways, a textbook case of cross-border externalities. International cooperation in this area has been subject of some of the oldest global legal agreements, which can be traced back to the International Sanitary Conferences in 1851 (Liverani & Coker, 2012).

The implication of this split within the health field is that the study of EU health policy contains a range of cases to compare, from health care services (where the desire for a shared health policy is weak but EU policies impinge) to the complex politics of areas like non-communicable diseases (NCDs) or

occupational safety and health (where the functional value of cooperation is recognized but interest group politics are conflictual), to the comparatively clear public health case for coordination in communicable disease control. The simple fact that health care is largely redistributive within a closed public system while public health (and civil protection) is concerned with managing externalities, which can be cross border, would suggest a far slower, less certain, and more roundabout path to integration for the former.

In the sections which follow, we analyse the extent to which this presumption, and the broader neofunctional thesis, is playing out in post-COVID EU health law and policy. Our analytical framework is drawn from the dynamic, long-term neofunctional story of health policy sketched above but focuses on a static assessment of the outcomes of the COVID-19 crisis (Nicoli, 2020); we elaborate on this in the next section. We then describe the changes that have been made to EU health policy in response to the crisis focusing, in particular, on the package of legislative proposals that now comprise the EHU.

The EU COVID-19 response as a case study of neofunctional integration

Neofunctionalism has been used extensively in the discourse on European health policy to explain its existence in the absence of explicit Member State political will to integrate their health care markets or public health approaches (Greer & Kurzer, 2013; Steffen, 2005). For one example, mandatory testing for tuberculosis in meat and milk became an integrated matter in direct response to the need to prevent the spread of bovine tuberculosis through trade in unpasteurised products (Council Directive 64/432/EEC, 1964). At the same time, the history of the EU's role in health has been one of integration driven by crisis. The catechism starts in the 1980s with action against cancer, HIV and illegal drugs, moves through variant Creutzfeldt–Jakob (vCJD, 'mad cow') disease and H1N1 influenza A, leading to the 2020 decisions taken in response to the COVID-19 pandemic.

Classic neofunctionalism holds that dynamic, long-term integration occurs as the result of two core mechanisms: spillover and transfer of loyalty (Saurugger, 2014). Broadly speaking, spillover occurs when the original goal of a policy or decision cannot be reached without further action in another field. The neofunctional literature has subsequently elaborated various types and categories of spillover, including functional (where economic and market interdependence drives further integration), political (where state and non-state actors perceive positive benefits from and thus push for further integration) and cultivated (where integration is driven by supra-national institutions) spillover (Niemann, 2021). The second, less convincing, mechanism is transfer of loyalty. Neofunctionalism holds that political and

economic elites, in the first instance, and later the wider citizenry, will shift their attention to the supranational level. Early accounts focused on the shifting interests and expectations of elites but later anticipated a 'transfer of allegiance' by citizens as well (Haas, 1964). In contrast to its main rival theory, intergovernmentalism, neofunctional integration is driven by economic interest groups, transnational social movements and supranational governance institutions.

The neofunctional account of EU health policy development offers a compelling narrative. The origins of health policy are found in decisions to coordinate social security systems and occupational health and safety standards, taken as a result of pressures created by the free movement of workers. Later, new Treaty competences in the area of food and blood safety followed the outbreak of vCJD, itself the result of a weakly-regulated common European market for live animals. Similarly, a series of decisions by the Court of Justice of the EU prompted the long, complex, and ultimately integrative legislative process that created the framework for cross-border healthcare, against the original preferences of Member States. The EU health policy arena is now characterized by a well-networked collection of transnational NGOs and interest groups, three core agencies and a variety of issue-specific configurations in the European Parliament and Council of the EU, all of which maintain regular dialogue with the Directorate General for Health and Food Safety (DG SANTE; the creation of which, in the 1990s, was also a response to a multi-dimensional policy crisis). In sum, the neofunctional explanation of how integration will unfold in the long-term – how chains of decisions, spillover and integration are linked together – is well illustrated in the health policy case.

The early literature on neofunctionalism had little to say about crisis and its particular role in (or influence on) integration. However, the core assumptions of neofunctionalism – bounded rationality, uncertainty, unintended consequences – lend themselves to theorizing crisis (Niemann, 2021, p. 122). Bounded rationality and uncertainty, which are intensified during a period of crisis, are a cause of unintended consequences, which then create new pressures or crises further down the line. Most neofunctional accounts have understood these 'problems' to be endogenous, 'produced by the very functioning of the integration process' (Lefkofridi & Schmitter, 2015, p. 8). Despite this, neofunctionalism is commonly utilized to analyse crises that have a clear exogenous dimension; the euro crisis (Jones et al., 2016; Nicoli, 2020; Niemann & Ioannou, 2015), the refugee crisis (Genschel & Jachtenfuchs, 2018; Niemann & Speyer, 2018) and crises of instability in the EU neighbourhood (Bergmann & Müller, 2021) are all recent examples. We start from an assumption that whilst the initial catalyst of a crisis might be exogenous – the outbreak of a highly contagious disease in a country outside of the EU, for instance – the crisis that faces the EU is one of how

to respond within the confines of its internal structures. Crises test and threaten the leadership, institutions, and policy decisions of the EU, revealing weaknesses and shifting preferences toward increased or decreased cooperation. In this way, they are internalized and analysed in terms of integration pressures.

Some of the later neofunctional literature sought to describe the role of crisis more explicitly; we draw here on two works in particular. Schmitter's (1970) revised neofunctional framework, the first of these, conceptualizes the long term, dynamic integration process outlined above as a series of cycles (initiating, priming, transforming) and combines this with a model of short term, 'crisis-provoked decisional cycles' (p. 842). It foresees that, on aggregate, each cycle of crisis response will lead to a greater role and significance for regional-level institutions and policies (Schmitter, 2004). Any given crisis might induce different reactions, however, and the strategic options available to Member States when responding include spillover, spill-around, build-up, retrenchment, muddling-around, and spill-back (Schmitter, 1970, p. 846).

The result in a particular case is established by observing the extent of change in competence (whether the scope of supranational functions is increased or decreased) and governance (whether the adopted solutions are governed in a more intergovernmental or supranational manner). This is dependent upon a number of scope conditions. Nicoli (2020) identifies the degree of pre-existing integration, the autonomy of supranational actors, policy interdependence and the distribution of the costs of non-integration as shaping change in competence, and the nature of the policy (whether it has high or low political sensitivity), the degree of common identity within the polity, the existence of governance interdependencies (mismatches between national and supranational governance) as determining change in governance (pp. 903–904).

Drawing on these frameworks and scope conditions, we can identify some *hypotheses*. First, neofunctionalist theory of any kind would predict integration as a result of the pandemic. The COVID-19 pandemic presents a crisis that has all three of the characteristics that make failing forward – and thus further integration – more likely (Jones et al., 2021, p. 8), these being: encompassing, affecting all Member States; unfamiliar, thus generating uncertainty and pushing decision-makers beyond conventional ways of thinking and; existential, in that it is widely perceived to present a threat to the Union as a whole.

Second, the costs of failing to integrate and coordinate responses, as exemplified early in the crisis (see below), are likely to affect all countries roughly equally, another scope condition that favours integration. In terms of governance, disease is a field with clear interdependencies which should facilitate an integrative response. Third, combining the frameworks in

Schmitter (1970, p. 846) and Nicoli (2020, p. 902), we would expect to see one of three responses, which are all integrative: spillover (an increase in competence and supranational governance), spill-around (an increase in the scope of competence but based on an intergovernmental governance structure), or build up (an increase in supranational governance but confined to the existing scope of competences).

Since there was already some degree of integration in the area of health threats, and the Commission has some autonomy (underpinned by Treaty mandate) in the field of public health, we would anticipate that these competences would expand as response. Health is a field with a strong lock-in effect. This would predict build-up of existing agencies such as EMA and ECDC, combined with some spillover in areas such as EU financing where there is an existing EU role but few constraints on adding priorities, and spill-around in areas of coordination where there is little or no existing EU structures that can be repurposed and where states exercise authority that they would prefer not to transfer to EU structures.

Build-up is indeed what we found, though with some policies containing detailed areas of current or potential spillover. The competencies infrastructure of EU public health governance already existed. In 2020, the EU decided to give it far more authority and importance. There are two possible exceptions which could come to be seen as spillover. One is the revision of the Health Threats Decision. The governance of that area has been largely intergovernmental; it could become sharply more focused on EU institutions, and clarify its real competences. The other is the Commission's Health Emergency, Preparedness and Response Authority (HERA), which could expand EU competences over time.

EU policy responses in health after COVID-19

Early responses to the pandemic presented the potential for a sea change in the field of health, but it was not clear which way the tides would go. There was an initial, highly public, period of *saue qui peut* in which the EU was about as disintegrated as we have seen in years. Member States closed borders, introduced travel and export controls, seized shipments of equipment, issued contracts in highly unusual ways, failed to activate the EU civil protection mechanism that would share supplies, and generally, amidst the panic and fear of March and April 2020, showed little solidarity or even pragmatic recognition of their shared fate.

The spill-back was relatively limited, and quickly reversed, however. The European Commission was publicly clear that it would fight against infringements of the internal market and facilitated various schemes such as 'green lanes' to facilitate freight shipments, while tacitly approving a wide variety of state aids and competition law practices that governments adopted

(thereby living to fight another day in those areas). It even experimented with a redefinition of public health, the impact of which is yet to be seen. Traditionally, public health in EU law has meant largely what it means in the law of international trade: it is a basis for a Member State exception to a free trade provision (see Weatherill & Beaumont, 1999). In its reinterpretation, the Commission argued that public health should be understood at the EU level – inverting its meaning from that of grounds for a national level exemption to legal authority for coordinated action.

The Commission had the political warrant to do this because Member States were quickly learning just how interdependent their health systems and economies had become. Narrowly, for example, Italy was the key producer of a number of highly relevant medical products, so cutting off Italy was an obviously bad policy. More broadly, the first wave taught the same lesson as Brexit: European economies are very interdependent and interference with any part of a supply chain can have unpredictable and negative effects. The very short experiment in partial border closures was immediately economically harmful at a time when governments were frantically trying to avoid a broader economic crisis. The result was that the moment of spillback was almost over before it began. Member States soon made ostentatious offers of help to each other (e.g., treating each other's patients) and began talking about more integrative responses. Angela Merkel, at the time German Chancellor and chair of the German Presidency of the Council, stated that she would even consider a Treaty change to strengthen the EU's powers in health (Stone, 2020). Similar calls were echoed in the European Parliament. In the end, Treaty change was not pursued; instead, the European Commission, capitalising on the clear shift in national preferences *vis-à-vis* health integration, published a set of legislative proposals that together would establish a European Health Union (European Commission, 2020a). What exactly the EHU is or will be is still unclear but, via the broad set of integrative legal instruments published to date, it is set to establish a general expansion of the EU's role in the field of health, particularly in its emergency capacities.

The most important aspects of the EHU legislative package are the expansion of the powers and mandate of the European Medicines Agency (EMA) and the European Centre for Disease prevention and Control (ECDC); the revision and expansion of the existing communicable disease legislation (in the Health Threats Decision) and; the creation, via reform of an existing Commission unit, of the Health Emergency, Preparedness and Response Authority (HERA). Alongside these, a fifth decision increases the funding available for health and cross border threats, in support of the EHU. We cannot prioritize or rank their importance because they vary by the scale of change relative to the status quo on that particular area at the start of 2020, in the overall importance of that area, and in the uncertainty as to what exactly what will happen.

The European Centre for Disease prevention and Control (ECDC)

The ECDC was an established agency in 2022, and it gained powers (building) with some expansion into new areas of risk management (spillover). The proposal to extend the mandate of the ECDC (not yet adopted at the time of writing) assigns the Centre a number of new tasks, establishes resources to better fulfil its existing responsibilities, and links the Centre's work more closely with other parts of the health security framework (European Commission, 2020b). Under the new proposal, its capacity for risk assessment is strengthened – via an increased budget and national obligations to provide necessary data – and it takes on a new role in contributing to risk management (Pacces & Weimer, 2020). The latter, which institutionalizes activities undertaken during the pandemic response (Deruelle & Engeli, 2021), involves gathering scientific information on interventions (such as the provision of personal protective equipment (PPE), the restriction of large gatherings, etc.) and producing guidance on the best approach.

To assist in these tasks, a number of new or adapted bodies are created. The Early Warning and Response System for communicable diseases (which ECDC oversees) will be authorized to use digital platforms and artificial intelligence techniques, integrated in the new European Health Data Space, to support epidemiological surveillance. Two new networks will be put under the ECDC's management – one for reference laboratories to develop diagnostics and testing methods in the event of an outbreak, and one to coordinate national blood and transplant services, to facilitate testing of the donor population. The ECDC will also be responsible for creating an 'EU Health Task Force', a set of outbreak assistance teams that can be deployed to assist in the event of an emergency, both within the EU and in third countries.

A key role of the ECDC will be its involvement in national preparedness and response planning. In addition to contributing to the training of national professionals and the guidance of national planning activities, the Centre will have the authority, for the first time, to issue recommendations to Member States on the improvement of their prevention, preparedness and response programmes. These recommendations will be non-binding but they introduce an element of supranational steering which did not exist before. While the ECDC's cognitive integrative drive in the area of EU public health, through its information gathering and distribution role, has been underway for some time (Busuioc, 2013), this gives it more of a formal warrant to act and obliges it to rely less on persuasion.

Underpinning these extended tasks and responsibilities, the proposal ensures that the work of the ECDC is integrated more firmly into the wider health security framework. The new networks, as well as the national preparedness planning policy and the general expansion of health security activities to encompass a wider range of threats, are part of the revision of the Health

Threats Decision (European Commission, 2020c). The provision of the data and information that the ECDC needs to fulfil its functions – new and existing – is supported by changes under the Health Threats Decision that oblige Member States to communicate all relevant scientific and epidemiological information to the Centre (via the EWRS where a threat is detected) (European Commission, 2020a, Art 4.). By strengthening these synergies and expanding the scope of the ECDC's work to cover that included under the Health Threats Decision, the proposals expand both the operational powers and internal integration between administrative actors in the health security framework.

The European Medicines Agency (EMA)

The EMA, an established agency, saw a build-up of power, as its regulatory role was expanded and directed towards managing, for example, the availability of medicines. The regulation extending the mandate of the EMA, which has already been adopted, provides for a similar task expansion, building on the experience of the pandemic. However, it limits this expansion to emergency situations whilst drawing on existing structures in a way which might support spillover into other areas in future (European Commission, 2020d). Under the new Regulation, the EMA takes on a role in monitoring and mitigating shortages of medicinal products and medical devices. This is a new task which introduces an element of supranational coordination into a field not previously governed at EU level. It will create an Emergency Task Force (ETF) to provide advice on scientific questions related to the development of treatments/vaccines and on clinical trial protocols. Furthermore, the EMA will now provide the secretariat with expert panels on medical devices (established under the medical device regulation, discussed below). The purpose of this transfer of management is to support the EMA's monitoring of medical device shortages. On the medicinal products side, the Agency's work will be supported by a Medicine Shortages Steering Group (MSSG), that will establish lists of critical medicinal products for monitoring and provide recommendations on necessary action.

The system requires Member States to report to the Agency any shortages of medicinal products that are likely to lead to major event or a public health emergency. The competent national authority is to inform the Agency of the shortage and provide it with information from the marketing authorization holder. If the Agency considers that there is a major event because of the shortage it should inform the Commission and any other Member States, and may request the assistance of the MSSG. The Group should then evaluate the situation and provide advice to the Commission and the Member States on what action should be taken. If the MSSG anticipates shortages that could pose a threat, this can also trigger Agency procedures to, for instance, fast track medical countermeasures procedures.

Whilst these functions, or functions similar to them, have been performed by the EMA in different contexts for many years, the Regulation extends their application to emergency situations. To do this will establish links with the Health Threats Decision; the recognition of an emergency provided for in the Decision will trigger the provisions set out in the EMA Regulation (European Commission, 2020c; European Parliament & Council of the EU, 2013). It also makes links to the existing medicines regulations – for instance in sharing the findings of the ETF – and medical devices regulation (see below). By contrast to the ECDC proposal, the EMA regulation draws a clear and deliberate line which limits its newly assigned roles to emergency situations. As such, it presents elements of both spill-around and build-up, in that the scope of integration is discretely increased (to cover monitoring and mitigation of shortages) and new tasks are governed supranationally (by a strengthened agency) but the Regulation is careful to delimit the scenarios in which these new authorities can be exercised (stopping short of decisive spillover).

Interestingly, whilst government minimalism (Nicoli, 2020) seems to have tempered extension of the EMA's mandate in non-emergency situations, the Regulation has simultaneously facilitated a reform that was deemed politically infeasible during a previous, pre-COVID legislative debate. During the negotiation of the new medical device regulation in 2017, the possibility of a role for the EMA – to bring medical devices regulation in line with existing practice in the regulation of medicinal products – was rejected for political reasons relating to the EU's competitive position in the global marketplace (Jarman et al., 2021). Though confined to emergency scenarios, the new EMA Regulation establishes a stronger role for the Agency in this field, just as was proposed during the medical devices debate. As such, it creates a foundation for the potential spillover of these governance structures and the future integration of quality, safety and efficacy assessment across medicines and medical devices. The set-up of the MSSG and the new Agency role as a secretariat for the medical devices expert panels is a sensitive one, given that Member States might not have an interest in revealing exactly what their stockpiles of medicines and medical devices look like. The availability of medicines and medical counter measures falls, concerningly, in an area where the EU has no legal competence (access to medical care); although the role of the EMA here is to monitor, a space for potential spillover is created.

European Health Emergency preparedness and Response Authority (HERA)

HERA, while connected to major ambitions, is a building exercise so far. On 16 September 2021 the European Commission adopted a Decision establishing

the HERA. Since it is essentially a Commission Unit – replacing, or renaming the previous C3 Health Threats Unit in DG SANTE as its own DG – the establishment was fairly straightforward and implemented via a Commission Decision. The idea of HERA, as suggested in an earlier Communication in 2020, is to mirror the United States’ Biomedical Advanced Research and Development Agency (BARDA), in which the government and industry coordinate incentives and collaboration in biomedical research for medical countermeasures. Keen to replicate the BARDA model, the Commission set up a HERA ‘incubator’ in February 2021, dedicated specifically to research and development of COVID-related medicines (European Commission, 2021a). Since September 2021, the incubator has been integrated within the newly-established HERA.

The goal of HERA is to prevent, detect, and rapidly respond to health threats (natural, accidental or deliberate origin). It will have a budget of €6 billion over six years and will operate in two ‘modes’: the preparedness mode, which is its default status, and a crisis response mode, which is activated after the formal recognition of a health emergency in the Health Threats Decision (see below). Importantly, the HERA is complemented by a Council Regulation for ensuring the supply of medicinal countermeasures in case of a health emergency (European Commission, 2021a). This creates a Health Crisis Board which will oversee, among other things, the procurement of medicines in an emergency.

The HERA centralizes and coordinates the EU’s crisis and response mechanisms. As such, we can think of its creation as an example of ‘build-up’, in that Member States have conceded greater authority to the EU, but without creating a new mandate. The Health Crisis Board, by contrast, is a more intergovernmental instructure and thus more resemblant of spill-around. This is a very new type of institutional set up; the ‘board’ structure is usually seen in EU agencies, Member State involvement in Commission Services (of which the HERA is an example) is usually organized within the existing committee structures. The reasons for the HERA’s peculiar legal character are doubtlessly political, and likely based largely on the need to create and launch it as quickly as possible. Meanwhile, the strong role for national representatives in its governance mirror the minimalism seen in the EMA regulation, where the logic of greater integration is acknowledged by Member States remaining reluctant to cede additional powers.

The health threats decision

The revision of the Health Threats Decision is perhaps the most politically interesting of the EHU proposals. Introducing some ideas that were tabled and dismissed after the 2009 Swine Flu outbreak, it extends the EU’s role in

national policy, strengthens its role in the event of an emergency and lays the foundation for integration beyond the field of crisis response.

In the aftermath of the Swine Flu outbreak, the Commission proposed that the EU should have a greater role in guiding and supporting national preparedness and planning – ‘spillover’ – but was rebuffed. The result was an institutional architecture that emphasized intergovernmentalism – ‘spill-around’. The new revision revives this idea, giving the EU (and the ECDC) a role in advising, auditing, and monitoring national plans on emergency preparedness and response – in other words, another proposal for spillover. Furthermore, the proposal would give the Union the right to declare a public health emergency for the whole of the EU. Beyond the legal effect of enabling the fast-tracked approval of medicines and other countermeasures, this right has important political implications. As evidenced by the WHO’s execution of its similar instrument, the declaration of a health emergency is a delicate and weighty responsibility, often leading to politically-charged debates on the timeliness of the decision, and its impacts and effectiveness. Though an important role, it exposes the Commission to new realms of complexity and political sensitivity (Brooks & Geyer, 2020).

The Commission unit which the HERA subsumes was responsible for the coordination of the Health Security Committee (HSC), an ‘intergovernmental forum’ for information sharing and coordination, where decisions are based on consensus among Member States (Decision No 1082/2013/EU). It lives on, however, under the revised Health Threats Decision, and is moved to the centre of decision-making. This is a considerable step forward, given that the HSC was only formalized in the 2013 Health Threats Decision, following the Swine Flu outbreak. Within it, Member States are represented at a high ministerial level, under the auspices of the Commission. The HSC is a relatively odd figure in the EU’s institutional structure, given that it is not a committee in charge of controlling a delegated executive power, as is the role of most other committees. During negotiations on the revision of the Decision, which is still ongoing, the Council has questioned the relationship between its own health formation (the Employment, Social Policy, Health and Consumer Affairs Council) and the HSC, since both are comprised of senior health officials. The HSC has seen the growth of its institutional capacities and a proliferation of working groups and constellations.

If the revised Health Threats Decision is adopted as proposed, it will be spillover, institutionalizing a more intergovernmental process. Member States will clearly have identified advantages to endowing the EU with particular responsibilities, such as those to declare a public health emergency and to audit national preparedness plans. They will also have seen the value of sacrificing some degree of autonomy – over the negotiation of contracts for medical countermeasures, for instance – to the supranational level. Such decisions would all be strong examples of political spillover.

The EU4Health programme and the Union Civil Protection Mechanism

If budgets are one of the best statements of political priorities, then COVID-19 is a sign that the EU is taking health and civil protection much more seriously relative to 2019, or any previous year. Two existing spending programmes – one slated to be eliminated as of 2020, and one that was largely new as of 2020 – gained responsibilities as well as new resources in a case of spillover. Though adopted prior to its announcement, the new EU Health Programme and the revision of the Union Civil Protection Mechanism (UCPM) are designed to support the EHU, by increasing funding and resources for health security and health policy more widely. Together, they mark a significant step in EU health integration.

EU health policy has traditionally been rooted in its Health Programme, which was first established in 2003. It was due to lose its dedicated funding stream and instead be absorbed into a wider European Social Fund within the new EU budget for 2021. However, the pandemic highlighted both the necessity of coordinated action and the risks associated with inequalities between health systems. In May 2020, the Commission reversed its pre-COVID decision to disband the Health Programme and, when presenting its revised multi-annual financial framework for the 2021–2027 period, included within it a new programme, called EU4Health. Most significantly, EU4Health has a budget of €5.1 billion, more than 10 times as much as the previous programme. While much of EU4Health’s work will focus on crisis response and communicable diseases, the regulation stipulates that a minimum of 20 per cent of the funds must be reserved for health promotion and disease prevention activities (European Parliament & Council of the EU, 2021), and the work programme foresees action to strengthen health systems, improve access to healthcare and strengthen the data infrastructure to support better policy-making (European Commission, 2021b). As such, the EU4Health Programme may lay the foundation for a wider integration of health systems, as well as vaccine policy, health data reporting and surveillance and emergency preparedness planning.

Similar increased salience has seen the EU’s civil protection structures strengthened. The Treaty language on civil protection is restrictive, allowing EU authorities to support and complement Member States’ response to a crisis (Art. 196 TFEU) and to assist victims of disasters (Art 214 TFEU). During COVID-19, the flaws of a system which depends on the availability of nationally controlled resources in times when scarcity affects all Member States were revealed, and Member States moved to address the UCPM’s weaknesses. The stockpiling instrument – RescEU – was first expanded to include medical equipment and countermeasures, and later saw its budget grow from €766.5 million for the 2014–2020 period to €772.7 million for

2021 alone (Annex Decision 2021/522; European Commission, 2020e). Moreover, the role of the UCPM has increased considerably. Importantly, the medical supplies needed for RescEU are purchased centrally, giving the EU far greater control than it currently enjoys under the system of joint procurement in the Health Threats Decision.

The increased budgets seen in the EU4Health Programme and the UCPM illustrate the salience of health coordination and the recognition, on the part of Member States, that a greater degree of integration is in their interest. Whilst the spillover itself is political in nature, it creates the potential for cultivated integration, if the Commission and other actors can exploit their new resources to justify greater responsibility, and functional spillover, for instance in the disjuncture between the UCPM and Health threats Decision mechanisms for joint procurement.

Conclusion

The EU Member States, after a brief period of national egoism in the spring of 2020, opted for an integrated response to the pandemic. The spilling-back dynamics of March to May 2020 – border closures, limits on the export of key goods, and uncoordinated rulemaking on travel – generated ill will while interfering with important commerce and even the basic provision of health care (by disrupting key supply chains). The result was that national governments, perhaps surprisingly quickly, changed track and began to speak of much more ambitious EU policy, and even the possibility of Treaty changes. Pending something so dramatic as a Treaty negotiation, however, they proved that there was considerable scope for spillover within the range of existing policy tools. EU health *care* policy, which had been the subject of much indirect integration (via the application of internal market rules) and such Member State resistance to actual integration, remained relatively un-integrated.

What could go wrong? The new agendas, with the exception of the changes to the Health Threats Decision and to some extent the organization of HERA are, at the time of writing, entrenched for the short term. Spending items are incorporated into the EU's multi-year financial framework and changes to agency mandates in legislation. This means that immediate reversal of the changes is unlikely. What seems more of a risk is that one or more of the new initiatives fails to generate a supporting coalition that will maintain or expand their budgets and activities. Entrenching the changes of 2020–2022 and any further spillover likely depend on an informal coalition of member state governments, political parties, and interest groups. It is also possible that the EU's strategy of building in public health, with limited spillover, will turn out to look insufficient to respond to another crisis, which could once again lead to changes in its health policy trajectory.

The changes are concentrated in public health, not health care, and it is noticeable that the ones established to date create very little EU authority over member states. Except for the potential pressure that may come of EU monitoring and auditing of national preparedness and response capacities, information, money, and the recalibration of existing EU agency activities are the key tools, not obligations on member states. Furthermore, the changes are focused on public health. This particular logic might not be the best way to address COVID-19, prepare for future pandemics, or improve health in Europe, but the application of neofunctionalist logic shows how they would come about.

Finally, it is noticeable that while there were fairly small examples of spillover (e.g., in the broader goals of EU4Health relative to the Health Programme, or HERA), what we saw in most cases was building. That is partly because the Commission had already created something which could be viewed as an embryonic or prototypical version of the policy tool that was adopted. HERA's creators have the stated ambition of replicating the US BARDA, but they are building on a longstanding Commission Unit. EU4Health builds on the older Health Programmes. In other words, the Commission showed a level of institutional entrepreneurship, often years before the actual event, which contributed to the form if not the salience or adoption of the proposals.

The striking thing about most political systems in the first two years of COVID-19 was how little change the pandemic prompted (Greer et al., 2021). The EU stands out for the scale of the change in something as fundamental as its role, and for the consistently integrating direction it has taken. We have argued that the best explanation is neofunctionalist: the level of integration within the EU meant that Member State governments had no dis-integrating response available to them, and so invested heavily in EU public health. Recognized federations such as Brazil, Canada, the United States and India all showed the importance of a well-led federal government in a well-integrated economy, sometimes through the tragic results of a cautionary tale. The EU showed why governments in a well-integrated economy might want to rapidly constitute a supranational system capable of managing that integrated economy's public health.

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