



THE DEVELOPMENT OF EU HEALTH POLICY AND THE COVID-19 PANDEMIC: TRENDS AND IMPLICATIONS

Journal:	<i>Journal of European Integration</i>
Manuscript ID	Draft
Manuscript Type:	Special Issue Article
Keywords:	EU health policy, Complexity, Policy agenda, COVID-19

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Manuscripts

Article 3-**8150 (including title page 215) words****THE DEVELOPMENT OF EU HEALTH POLICY AND THE COVID-19 PANDEMIC:
TRENDS AND IMPLICATIONS****Dr Eleanor Brooks**

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EU health policy is a policy forged in crisis. Whilst maintaining the strict limitations on the EU's role that are described in the treaties, scandals and scares have historically been followed by incremental but integrative policy change. Given this trend, should we be expecting a radical expansion of EU health policy in the aftermath of Covid-19? And, if so, what parameters and characteristics might this new agenda have? As we enter the period in which the EU will try to elaborate its new health policy, this paper uses a Complexity perspective to assess how the emerging agenda compares to existing and historical EU action on health, the kind of decision-making that we are likely to see in the different areas of action, and the limitations of EU health policy development as it pushes into more political and complex areas of policy.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge collaborative work on the EU's Covid-19 response, undertaken with Scott L. Greer (Michigan) and Anniëk de Ruijter (Amsterdam), which underpins parts of section one. Any errors remain with the authors.

INTRODUCTION

The ability of the European Union (EU) to respond exhaustively and effectively at the outset of the Covid-19 pandemic was curtailed by the health competences assigned to it in the Union's founding treaties. The EU's role in health is narrow, limited over the years by national governments keen to retain control of their health policies and systems. The current treaties permit the EU to harmonise national laws in a small set of specific areas, such as organs and substances of human origin, pharmaceuticals and medical devices. In all other areas of health, including crisis response, pharmaceutical procurement and infectious disease management, the EU's role is limited to supporting national policies and encouraging coordination. Consequently, its initial health policy response was constrained. The EU did not have the necessary stockpiles to respond to requests for personal protective equipment (PPE) and other critical resources, and was not able to stop the wave of export bans adopted by national governments seeking to retain what supplies they had. Whilst frustrating, this response reflected the design and intention of member states (Brooks, de Ruijter and Greer 2020a).

More so than other policy areas, the progress of EU public health policy can be measured in terms of crisis and response (Greer, de Ruijter and Brooks 2020). For instance, the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003 promoted the creation of the European Centre for Disease Prevention and Control (ECDC), and poor coordination during the swine flu epidemic in 2009 resulted in the creation of a mechanism for joint procurement of vaccines. These and other examples illustrate a pattern in which crisis has commonly preceded incremental but important steps in the development and integration of EU health policy. Hence, given the scale of the Covid-19 pandemic, one would expect to see substantial changes in the EU health agenda. But, is this happening?

To address this question, this article explores post-Covid-19 EU health policy, looking not only at change in policy content, but also at how this new content is likely to shape decision-making dynamics by bringing new, increasingly complex and politically contentious issues onto the EU's agenda. The first part presents the EU's response to Covid-19. It describes the extent and limitations of the EU's role and reviews the changes that have since been proposed, sketching the likely scope and content of the post-Covid health agenda.

In the second part, the article adopts a Complexity perspective and utilises one of the key tools for applying this in a policy setting – the Complexity Diagram. This allows us to visualise the core, decision-making characteristics of EU health policy, illustrating its varying complexity. Drawing on previous work in this field, we plot the EU health agenda onto the Diagram at four points in time, charting its development in 2000, 2010, at the start of 2020 and, finally, in the post-Covid period (the latter drawing on the work presented in section one). In mapping change over time, we assess the potential impact of Covid-19 upon what was, as we will show, a relatively stable trend.

A final section reflects upon the potential trajectory of the EU's post-Covid health agenda and the resulting shifts in decision-making. The article concludes that Covid-19 has amplified the drift of EU health policy into more complex terrain, and that whilst this trend might be seen

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3 as a positive indication of maturity and success within the policy area, it is not without its
4 challenges.
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6 **THE EU'S HEALTH POLICY RESPONSE TO COVID-19**

7 **From national to collective action**

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10 When Covid-19 hit, the EU had two main governance frameworks through which it could
11 organise its immediate response to the public health crisis. The first was the health security
12 framework set up by the 2013 Decision on Serious Cross Border Threats to Health (herein the
13 Health Threats Decision), which establishes a set of structures for emergency planning,
14 preparedness and response. The second was the Civil Protection Mechanism (CPM), which
15 facilitates cooperation between member states in the event of a disaster. Both performed as
16 intended and expected in the first phase of the crisis but, reflecting the EU's limited health-
17 related powers, their capacity and reach was inevitably insufficient.
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22 The Health Threats Decision (European Parliament and Council 2013) was adopted in the
23 aftermath of the Swine Flu outbreak. It defines the role of member states and various EU-level
24 institutions¹ in (a) emergency planning and preparedness, (b) ongoing surveillance and data
25 collection, and (c) crisis response and coordination. Member states are to report on their
26 emergency planning and preparedness situation every three years, so that the Commission
27 can facilitate discussion of these provisions within the Health Security Committee (HSC, see
28 below). Data collection and surveillance is managed by the ECDC, which operates a network
29 of epidemiological information, communicated to it regularly by national authorities. In the
30 event of a crisis or the emergence of a new threat, an alert is raised via the Early Warning and
31 Response System (EWRS), triggering risk assessment from the ECDC and the start of
32 coordination of national responses via the HSC. The HSC – a committee of high-level national
33 representatives, assisted by the Commission and experts from relevant agencies – serves as
34 the venue in which national governments either consult on proposed measures to combat
35 serious threats to health in their territories or, where action had to be taken urgently, inform
36 their counterparts of such measures already adopted (de Ruijter 2019). Where the situation
37 overwhelms the capacity of a given member state, Article 11(4) of the Decision instructs
38 national governments to activate the CPM.
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45 Whilst the HSC eventually became a valuable hub, coordination meetings were infrequent
46 and poorly attended in the initial weeks of the crisis and many member states had not reported
47 on their preparedness and response plans as required (Beaussier and Cabane 2020: 5). The
48 consequent lack of information about national capacities limited the relevance of ECDC
49 guidance and exacerbated weaknesses in the surveillance system. The ECDC relies on data
50 being transferred from national authorities, which commonly lack the infrastructure to collect
51 and/or the will to communicate this, and is itself under-resourced and lacking in power to
52 enforce national reporting (Greer 2012). Though a long-acknowledged problem, the
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59 ¹ For the Commission, action is generally led by the relevant units within the Health and Food Safety
60 Directorate, DG Santé.

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3 limitations faced by the ECDC, and consequently to its capacity to support member states,
4 have been highlighted by the pandemic.
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7 The Health Threats Decision also establishes a Joint Procurement Agreement (JPA) for the
8 collective purchase of 'medical countermeasures' (medicines, personal protective equipment
9 (PPE), laboratory supplies etc.). The EU's role here is limited – the Commission manages the
10 call for goods but no EU funds are used; national governments express interest and, once the
11 contract is finalised, may then purchase under its terms (McEvoy and Ferri 2020). During the
12 pandemic, six procurement competitions have been launched, seeking to secure PPE,
13 ventilators, testing kits, and intensive care medicines. Exploratory talks have been concluded
14 on all six competitions and three contracts issued to date, though the JPA proved too slow and
15 intergovernmental to be much use during the initial, emergency period (de Ruijter et al. 2020:
16 18; see also van Schaik et al., this issue).
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21 The EU's second crisis-response governance framework, the CPM, is essentially a
22 matchmaking system. Member states report to the EU a list of their available strategic
23 resources (fire-fighting equipment, expert rescue teams, evacuation transport) which could be
24 deployed in the event of an emergency. In 2019, the CPM was 'upgraded' with the addition
25 of RescEU, a common stockpile of transport, medical equipment and field hospitals². In a
26 crisis, a member state can make a request and activate the CPM, at which point the relevant
27 resources are identified and their deployment from the member state which hosts them to the
28 state which needs them is coordinated. Whilst this system successfully provided resources for
29 forest fires in Sweden in 2018, for example, it is not designed to respond to a situation in which
30 all member states require the same resources at the same time. As Covid-19 unfolded, national
31 governments were either already facing the pandemic or fearful that it would soon breach
32 their borders, and responded by seeking to keep strategic resources at home – a reaction
33 exemplified by the silence which met Italy's request for supplies of PPE in February (Greer,
34 de Ruijter and Brooks 2020).
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41 The initial response afforded by existing EU governance frameworks was thus limited and
42 widely criticised (Paces and Weimar 2020; Renda and Castro 2020). Italy's CPM experience
43 transpired to be indicative of a wider, if temporary, abandonment of member states'
44 commitment to solidarity. Through March and April, national governments adopted border
45 closures and bans on the export of crucial supplies, obstructing freedom of movement and
46 exhibiting behaviour indicative of European disintegration (Dimitrakopoulos and Lalis 2020).
47 Remarkably, however, as the pandemic entered 'phase 2', the EU began to play a more active
48 role and value of collective action seemed to become apparent to national leaders (Alemanno
49 2020). Travel and export bans were lifted, collective procurements were organised and a
50 common 'exit strategy' was agreed (European Commission 2020d). The HSC became a stable
51 venue for coordination of national actions and governments began to work together, perhaps
52 now seeing the need for a(nother) EU 'rescue of the nation state' (Brooks, de Ruijter and Greer
53 2020a). As in previous episodes, the crisis has exposed weakness and highlighted the added
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59 ² A further amendment, made in April 2020, created the first RescEU stockpile of equipment relevant
60 specifically to public health crises, including ventilators, PPE and basic medicines.

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3 value of collective response. The question now is whether and how this will be
4 institutionalised in an expansion of the EU's health policy.
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6 **The post-Covid EU health agenda: incremental but integrative**

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8 The full extent of any change to the EU's health policy powers and agenda is still to be
9 determined but, from adopted initiatives and ongoing debates, the potential parameters of
10 this change can already be identified.
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13 Early calls for treaty revision, to increase the EU's formal health powers, were quickly rejected
14 as both infeasible and unnecessary. Consensus among academic lawyers is that, though
15 patchy, the EU's legal basis for health already permits considerable action *where this is*
16 *supported by political will* (Guy 2020; Hervey and de Ruijter 2020; Pernhagen et al. 2020), and
17 that the same lack of will that constrains ongoing activity is likely to obstruct formal treaty
18 change (Clemens and Brand 2020). As if to illustrate this point and demonstrate the potential
19 of the existing competence, the Commission has either adopted or announced the upcoming
20 publication of a range of initiatives.
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24 At the centre of these is the EU4Health Programme, announced in May and currently awaiting
25 adoption by the legislature (European Commission 2020a). EU4Health saw renewed ambition
26 from the Commission, reversing pre-existing plans that would have seen health absorbed into
27 the much broader European Social Fund Plus and earmarked just €413 million in the new
28 multi-annual financial framework. The stand-alone EU4Health Programme is likely to see a
29 budget of €1.7 billion, an unprecedented sum for health policy³ and lists the objectives of
30 increasing preparedness for cross-border health threats, strengthening health systems, and
31 making medicines and medical devices available and affordable. Though similar to previous
32 programmes and yet to be elaborated into tangible actions, EU4Health's objectives are based
33 on broad recognition of 'a general need for...structural transformation...and systemic reforms
34 of health systems across the Union' (European Commission 2020a: para 15). If stretched to
35 their fullest, these provisions would underpin a significant expansion in the EU's health
36 activity, into politically sensitive and substantively complex areas.
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42 Supporting and elaborating on specific aspects of the EU4Health programme, several other
43 initiatives are in the pipeline. A communication on short-term health preparedness, published
44 in July, extends the role of the ECDC to production of guidelines on issues pertaining not only
45 to risk assessment but also risk management (interoperability of contact tracing apps,
46 management of potential 'super-spreading events', and optimisation of hospital space). Under
47 the EU Vaccine Strategy, adopted in June, the EU's executive will sign Advance Purchase
48 Agreements (APAs) with pharmaceutical companies, on behalf of member states, and then
49 coordinate the supply and distribution of any eventual vaccine (European Commission
50 2020c). This is a significant change, since the JPA provides for collective purchase but does not
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57 ³ The €9.4 billion health budget originally proposed by the Commission was cut by the European
58 Council in July to €1.7 billion. The EU legislature reached provisional agreement on the new budget
59 on 10 November 2020, but this is still to be formally adopted by the European Council and European
60 Parliament.

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3 give the Commission a role in distribution. Looking to the longer-term challenges facing
4 vaccine development, a Pharmaceutical Strategy is due to be published by the end of 2020. It will
5 be aimed at addressing access to medicines, pharmaceutical supply chains and innovation in
6 the sector (European Commission 2020b).
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9 In sum, and reflecting wider dynamics of EU integration, the crisis has unfolded (to date) with
10 an initial period of intergovernmental and nationalistic responses, then muddling through
11 towards an eventual adoption of integrative and collective, if patchwork, solutions. In other
12 words, it displays all the dynamics of 'failing forward' (Greer, de Ruijter and Brooks 2020;
13 Jones, Kelemen and Meunier 2015). But, at this stage in its development, and given the
14 increasing sensitivity and uncertainty of the issues that the EU finds itself moving into, what
15 kind of decision-making is likely to characterise this new agenda? We utilise the lens offered
16 by Complexity approaches to assess the changing dynamics of EU health policy.
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20 21 **DEVELOPMENT AND DYNAMICS OF EU HEALTH POLICY: A COMPLEXITY** 22 **PERSPECTIVE** 23

24 Complexity, a general term covering a wide range of complex, adaptive, emergent systems
25 and phenomena, originates in the natural sciences (Coveney and Highfield 1995). Though no
26 one Complexity theory exists, Complexity approaches have in common the examination of
27 whole systems, rather than their individual components and, as such, challenge traditional,
28 linear, reductionist approaches to scientific inquiry (Byrne 2005; Geyer and Rihani 2010;
29 Richardson and Cilliers 2001). From the 1990s, Complexity spread across the social and policy
30 sciences (Byrne and Callaghan 2013; Castellani and Hafferty 2010; Geyer and Cairney 2015),
31 and has gained particular traction in health and health policy (Alexander 2010; Greenhalgh
32 and Papoutsis 2018; Sturmburg and Martin 2013).
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36 In European integration, Complexity acts as a bridge between the more positivist and
37 reflectivist theoretical perspectives (Geyer 2003; Geyer and Rihani 2010; Lehmann 2018).
38 Complexity recognises the importance of orderly structures and institutions and the ability to
39 make positivist claims about them. Nevertheless, it also recognises the inherent
40 unpredictability and uncertainty in all complex systems and the incredible diversity and
41 variety of human interpretations of those systems – hence the importance of reflexivity.
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45 Applied to policy and governance, Complexity is a rejection of the traditional modernist
46 world view of order, causality, reductionism, predictability and determinism that marks the
47 foundation of the more extreme versions of New Public Management (NPM) and Evidence-
48 Based Policy Making (EBPM). Complexity overlaps with the pragmatist policy tradition
49 (Ansell and Geyer 2017; Sanderson 2009) and reminds us that policy-makers operate in a
50 continually shifting environment and, whilst some norms and institutions are relatively
51 stable, others are in almost constant flux. Policy-makers must accept uncertainty and change
52 as features of complex systems and realise that policy making is often as much art as it is
53 science. The real skill is recognising what decision-making strategies and methods are
54 appropriate to radically different contexts and situations.
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59 **The Complexity Diagram** 60

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Within the broad field of Complexity and policy there are a wide range of concepts and tools. Here we apply just one, the Complexity Diagram. The Complexity Diagram is a simple and effective tool for thinking about any policy area from a Complexity perspective.⁴

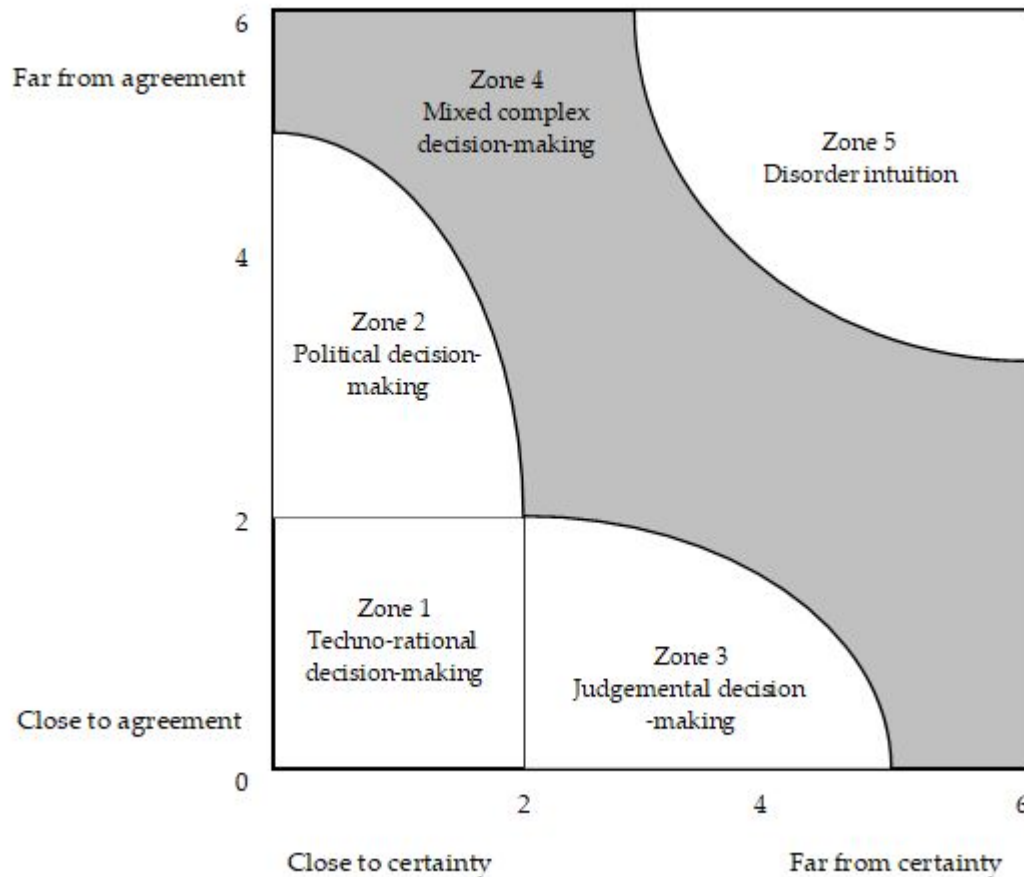


Figure 1: The Complexity Diagram

As shown in Figure 1, the Complexity Diagram combines two axes based on the degree of certainty and of agreement for a particular policy area. High levels of certainty indicate that the issue is well known and easily understood, while low levels of certainty imply that it is unknown/unknowable and that there are great differences in opinion over the issue, even among experts. Meanwhile, high levels of agreement denote substantial public agreement over the nature of, and solution to the issue, while low levels of certainty imply substantial public debate and disagreement. These two axes create five main zones of decision-making:

⁴ The Complexity Diagram – also called a Stacey Diagram/Matrix – was developed by Ralph Stacey in the early 1990s (Stacey 1993). Stacey later distanced himself from it over concerns that it was too limiting; see R. Stacey, D. Griffin and P. Shaw (2002) *Complexity and Management: Fad or Radical Challenge to Systems Thinking?* London: Routledge. However, the diagram remains popular in a number of Complexity-related academic areas.

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- 3 • Zone 1 (techno-rational): *high certainty-high agreement*. In this zone, the issue is well
- 4 understood, and the response agreed between the majority of key stakeholders. Data
- 5 on the issue is clear, abundant and easily accessible. Repetitive techno-rational
- 6 decision-making based on evidence-based actions and audit and targeting strategies
- 7 works well here.
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- 11 • Zone 2 (political): *high certainty-low agreement*. In this zone, data is clear and abundant
- 12 and experts understand the problem. However, the stakeholders disagree over how to
- 13 respond to it. In this case, more evidence is of little use and political bargaining and
- 14 consensus building become key decision-making tactics.
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- 17 • Zone 3 (judgemental): *low certainty-high agreement*. Here the main stakeholders agree
- 18 about the nature of the issue, but there is no simple answer or policy response to it.
- 19 Multiple strategies are possible and experts disagree over them. Judgemental and
- 20 discretionary decision-making becomes increasingly important.
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- 23 • Zone 4 (mixed complex): *mixed certainty-mixed agreement*. This is the most common
- 24 zone of policy- and decision-making. Data may be uncertain and contested. It is an
- 25 area in which stakeholders and experts disagree, to varying levels, over the nature of,
- 26 and responses to the issue. This requires a flexible response that blends political
- 27 decision-making with evidence-based processes and discretionary decision-making.
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- 30 • Zone 5 (disorderly): *low certainty-low agreement*. This is the most difficult area where
- 31 everyone disagrees and no one has a clear answer. Evidence is poor, limited and
- 32 continually shifting. The issue is highly emotive and politicised. Here, incremental
- 33 steps are important, and intuitive responses may be just as important as evidence-led
- 34 thinking.⁵
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Utilising the Complexity Diagram to map the development of EU health policy

41 What can the Complexity Diagram tell us about EU health policy and the new health agenda
 42 that is being forged in the aftermath of the Covid-19 crisis? Our goal is to map how the nature
 43 of decision-making in EU health policy – the extent to which it is techno-rational, political,
 44 judgemental, complex or disorderly – has changed over time, and might shift again under the
 45 new health agenda. We first identify four aspects which constitute the EU health policy
 46 agenda at any given time:

- 47 A. The treaty base upon which health action is taken
- 48 B. Secondary EU law (regulations, directives and decisions adopted via the EU's
- 49 legislative processes) that affect health
- 50 C. Soft law and policy initiatives (non-legislative action) relating to health, and
- 51 D. Institutional structures relating to health.
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⁵ This discussion of the Complexity Diagram is based on Webb and Geyer (2020).

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3 Under the relevant aspects, we compiled a list of key treaty articles, legislative proposals,
4 policy initiatives and institutions, ordered chronologically. The list is based upon a review of
5 major academic works on the development of EU health policy (cf Greer et al. 2014; 2019;
6 Hervey et al., 2017; Mossialos et al., 2010; Steffen, 2005), a search of the European Parliament's
7 Legislative Observatory for files coded *Health legislation and policy* (undertaken August 2020),
8 a review of the EU Health Programmes from 2003 (when the first was launched) to present,
9 as well as information drawn from the policy documents analysed above. The purpose was
10 not to be exhaustive but rather to identify the key topics, issues and arguments which have
11 occupied the EU's health agenda over the years, acknowledging that there will have been
12 many, less visible (and often less contested) activities happening on the side-lines.
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17 We then independently 'scored' the listed treaty bases, secondary law, policy initiatives and
18 institutional developments, according to the degree of certainty and agreement that
19 characterises the issue or topic that they relate to. We use a scale of 0 to 6, where 0 indicates
20 complete certainty and agreement, and 6 indicates complete uncertainty and disagreement.
21 For example, the 1992 European Drug Prevention Week initiative was scored by both authors
22 as 2,1, representing a certainty score of 2 and an agreement score of 1. This reflects the
23 considerable understanding among experts of which policy interventions might work best,
24 and the widely agreed nature of the problem of drug addiction. A round of pilot scoring,
25 based on a small sample, was reviewed for consistency of approach and final scores were
26 averaged between the two authors.
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31 Finally, we selected four time periods from which to draw a 'snapshot' of the EU's health
32 agenda, to facilitate mapping of change over time. We thus split the list into the health agenda
33 as it stood in 2000, in 2010, at the start of 2020, and as it is likely to appear in the latter part of
34 2020 and beyond (the 'post-Covid' health agenda). For each time period, we took an average
35 score for each aspect – for treaty base, secondary law, policy initiatives and institution-
36 building – to give four scores for each snapshot. These are explained and plotted on to the
37 Complexity Diagram below.
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41 *Limitations*

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43 There are obvious limitations to this approach and analysis. Though experts in the field, we
44 have a range of personal biases that will affect our scoring of the 'certainty' and 'agreement'
45 of particular aspects. Moreover, the definitions of 'certainty' and 'agreement' are not
46 significantly precise to enable highly accurate scoring; we chose a scoring range of 0 to 6 so as
47 to balance precision and detail. Similarly, we are not comparing precisely similar policies or
48 political and technical issues surrounding the policies. However, we are confident that the
49 existing strategy creates some interesting insights and provides a valuable starting point
50 which we and others can build upon in further work.
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55 **EU health policy: 2000, 2010, 2020 and Covid**

56 EU health policy in 2000: Cooperation on key, common challenges

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58 Table 1 presents an overview of the key features of the EU health agenda in 2000, as well as
59 the average score for each aspect, used to plot its position on the diagram in Figure 2.
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Table 1: Four key aspects of EU health policy in 2000 (with combined scores for certainty, agreement)

A. Treaty base (1.0, 1.5)
Article 100A of the SEA
Articles 3(o) and 129 of the Maastricht Treaty
Article 152 of the Amsterdam Treaty
B. Key secondary law (1.5, 2.5)
Directives on tobacco labelling, advertising, tar yield and tax
Directives on medical devices (including <i>in vitro</i> and active implantable)
Directive on Direct-to-consumer-advertising of prescription drugs
C. Key soft law and policy initiatives (2.0, 1.3)
Action plans (e.g. 'Europe Against Cancer', Europe Against AIDS')
European Drug Prevention Week
EU Public Health Action Plan
D. Building blocks of the institutional structure (1.8, 1.5)
Founding of early health-related NGOs
DG Health and Consumers (now DG SANTE)
European Monitoring Centre Drugs & Drug Addiction, European Medicines Agency

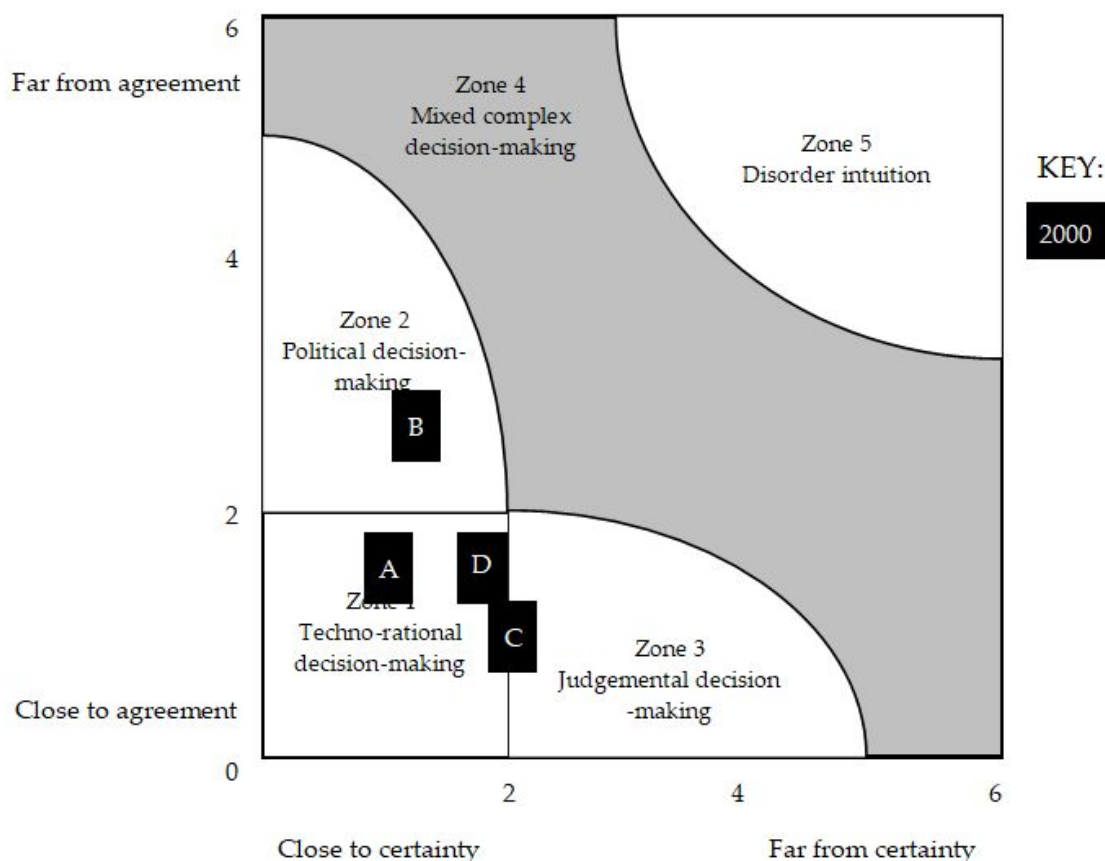


Figure 2: The main zones of EU health policy in 2000

Explanation for scoring/positioning

It was not until the late 1980s and early 1990s that health gained a treaty base, and Aspect A (Treaty base, score 1.0, 1.5) falls in Zone 1 (techno-rational) because the resulting texts

carefully constrained the EU's role, limiting it to areas where cooperation was logically necessary (such as cross-border crises) and keeping it out of the more political and divisive issues that characteristic national health policy. Moreover, these developments were driven by functional spill-over from the internal market via the SEA, response to crises (the strengthening of the health mandate in the Amsterdam Treaty, for instance, is understood as a response to the BSE outbreak), and legal interventions by the Courts (Brooks 2012; Greer 2006). These drivers make use of bureaucratised and formalised structures.

Aspect B (legislation, score 1.5, 2.5) falls into Zone 2 (political). Public health legislation was limited primarily to pharmaceuticals and medical devices; uncontroversial, technical regulations which were linked to key markets. Explicitly market-led legislation – such as that on tobacco and direct-to-consumer-advertising of prescription drugs (DTCA-PD) – saw greater politicisation but still replicated the core positions of member states. In the case of tobacco, EU policy also reflected a growing recognition of the fundamental threat to health of tobacco usage, as well as the growing wave of local, national and international regulation at the time.

Soft law and policy initiatives (Aspect C, score 2.0, 1.3) in this period built on existing informal activities, gathering them within the first framework for EU action on health in 1994. Importantly, these centred on technical, research-related activities, such as cancer, HIV/AIDS and drug addiction, as well as more general health promotion, education and data collection issues. The solutions to these issues were not always clear but they networked clinical and professional actors who were largely agreed on the nature of the issues at stake, placing it on the boundary of Zone 3 (judgemental). The creation of a nascent network on health-related interest groups and a dedicated DG Health and Consumers was representative of the slowly growing need for both technical and political input into the increasingly complex issues being addressed in EU health policy, but also firm agreement about the need for institutional structures to support coordination (Aspect D, score 1.8, 1.5).

EU health policy in 2010: Regulating health and the market

Table 2 presents an overview of the key features of the EU health agenda in 2010, as well as the average score for each aspect, used to plot its position on the diagram in Figure 3.

Table 2: Four key aspects of EU health policy in 2010 (with combined scores for certainty, agreement)

A. Treaty base (1.0, 1.5)
Nice Treaty and draft constitutional treaty – no change
B. Key secondary law (1.7, 2.1)
Pharmaceutical legislation (orphan drugs, medicinal products, clinical trials etc.)
Directives on tobacco products, tax and sponsorship
General Food Law and nutrition and health claims regulation
Directives on blood, tissues and organs
Services Directive, Working Time Directive
C. Key soft law and policy initiatives (2.3, 1.7)
Health Programme I and II, plus FP7 funding
Council recommendations on cancer screening and patient safety
Council conclusions on common values & principles of EU health systems

Commission initiatives on drugs, smoking cessation etc.
D. Building blocks of the institutional structure (1.4, 1.9)
EU Health Forum, EU Platform diet, physical activity & health, EU Alcohol and Health Forum HSC
European Food Safety Authority, ECDC

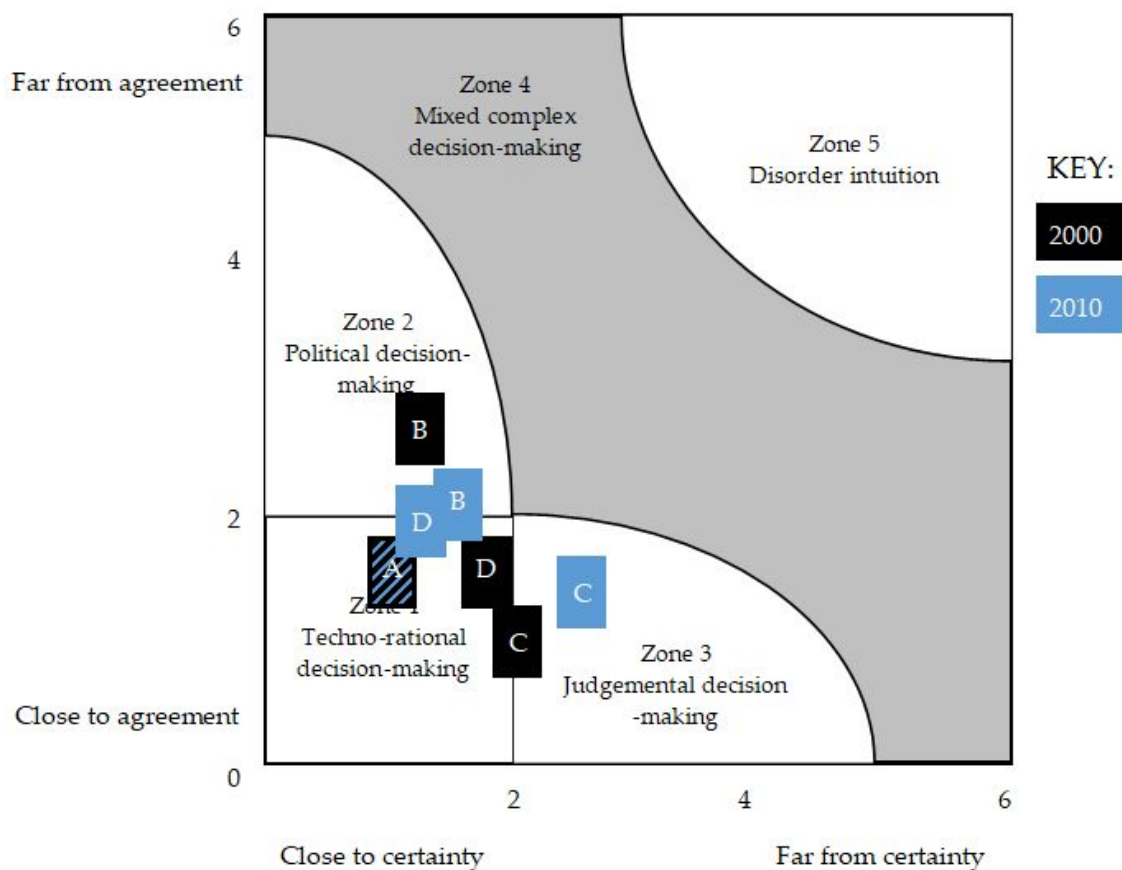


Figure 3: The main zones of EU health policy in 2010

Explanation for scoring/positioning

Little substantive treaty change occurred between 2000 and 2010, hence Aspect A (Treaty base, score 1.0, 1.5) was unchanged, but legislative activity increased considerably on the back of the strengthened mandate provided by the 1997 Amsterdam Treaty. This underpinned a steady stream of public health regulation, supported by the establishment of the EFSA and the ECDC in 2002 and 2005 respectively. The comparatively less political, more certain public health legislation counter-balanced fierce debate in other areas, placing Aspect B (legislation, score 1.7, 2.1) on the edge of Zone 2 (political). For instance, on the market side, health actors became skilled in utilising non-health treaty bases to pursue health objectives (examples include the regulation of tobacco advertising and food labelling). They were also preoccupied with the increasingly apparent threat posed by the application of internal market law to the health sector. A series of Court judgements, dating from the 1990s but reaching a high-water

mark in the mid-2000s, had raised fears that the EU's rigorous and liberalising regime of competition and state aid law might be systematically applied to health (Nickless 2002: 78).

Alongside the hive of legislative activity, the EU's softer public health policy (Aspect C, score 2.3, 1.7) was also growing in recognition and scope. The first EU Health Programme was adopted for the 2003 to 2008 period, and replaced by another for 2008 to 2013. The placement in Zone 3 (judgemental) reflects the expansion of the health agenda into less tractable issues (health inequalities, health promotion), where multiple solutions exist, particularly given the variety of member state health systems. This activity was complemented by the founding of European level bodies, such as the EU Health Forum and the HSC, the latter introducing an element of intergovernmental steering. This moved Aspect D (institutional structure, score 1.4, 1.9) a little further up the political axis, as the need for delegation, external input and member state control continued to grow.

EU health policy at the start of 2020: political oversight of health systems and fiscal sustainability

Table 3 presents an overview of the key features of the EU health agenda in 2020, as well as the average score for each aspect, used to plot its position on the diagram in Figure 4.

Table 3: Four key aspects of EU health policy at the start of 2020 (with combined scores for certainty, agreement)

A. Treaty base (1.7, 2.2)
Article 168 of the Lisbon Treaty, Charter of Fundamental Rights, Fiscal governance framework
B. Key secondary law (1.9, 2.4)
Tobacco products directive
Pharmaceutical legislation adopted (falsified medicines, clinical trials, medical devices) and withdrawn/pending (information to patients, health technology assessment)
Directive on Patients' rights in cross-border healthcare
Decision on Serious cross border threats to health
Regulation on Food information to consumers
C. Key soft law and policy initiatives (2.8, 2.4)
Health Programme III
Commissions initiatives on smoking cessation, digital care, cancer etc.
Action plans / joint actions eHealth, health workforce, health technology assessment, European Reference Networks, anti-microbial resistance etc.
Council Conclusions modern, responsive & sustainable systems
Commission staff working document on investing in health, Joint Assessment Framework for health, Communication on effective, accessible & resilient health systems
D. Building blocks of the institutional structure (3.0, 2.3)
Expert panel effective ways investing in health
Steering group promotion, prevention & NCDs

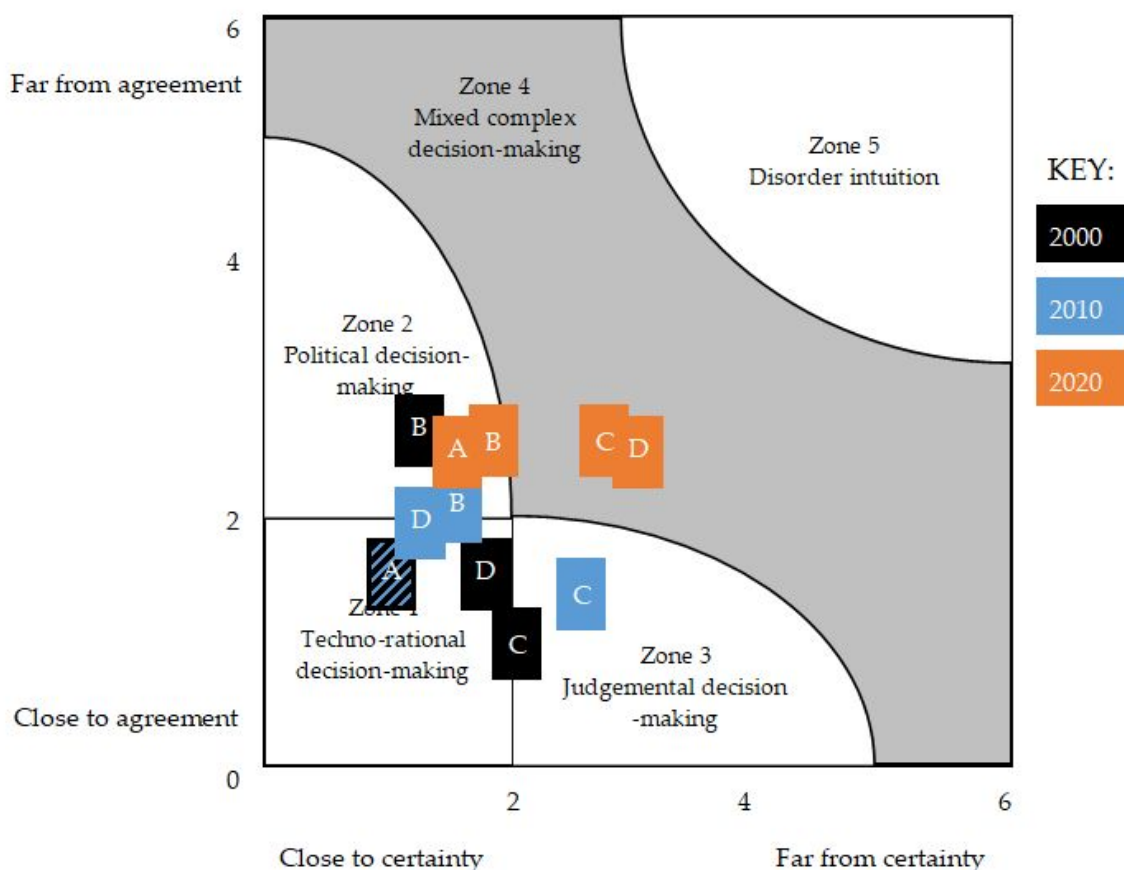


Figure 4: The main zones of EU health policy in 2020

Explanation for scoring/positioning

As the Lisbon Treaty came into force in 2009 the only major change to the health provisions – and thus the only shift in Aspect A (Treaty base) in Figure 2 – was in Article 168 TFEU. Like previous iterations, it is not a *health* article, but rather a *public health* article, reflecting member states' concern that the EU focus its attention on population-level measures and be excluded from involvement in health services (Greer et al. 2014: 20). Nevertheless, it expanded and consolidated the EU health mandate (Hervey and McHale 2015), pushing Aspect A (Treaty base, score 1.7, 2.2) into Zone 2 (political).

Aspect B (legislation, score 1.9, 2.4) moves further into Zone 2 (political) as some politically difficult legislative files progress. The Directive on Patients' Rights and the Tobacco Products Directive ended fraught and longstanding battles. Meanwhile, functional pressures continue to require legislation on medical devices and clinical trials, and shared risks from H1N1 influenza prompted new legislation in the area of health threats. Under the Juncker Presidency, there was considerably less legislative activity (Brooks and Bürgin 2020); the only new initiative – on health technology assessment – remains stuck in the Council at the time of writing, indicative of the politicised nature of health regulation in this period.

Aspect C (soft law and policy, score 2.8, 2.4) shifted squarely into Zone 4 (mixed complex). This reflects both a decline in the traditional areas of public health policy and an increase in the focus on health systems. Meanwhile, reflecting the relevance of the economic governance framework for health during this period, both the Council and the Commission produced a series of politically contentious soft law tools on the topic of health system sustainability and performance, and policy initiatives pivoted to address issues tied to the prevailing jobs and growth agenda of the Commission Presidency (eHealth/digital health, health technology assessment etc.). Aspect D (institutional structure, score 3.0, 2.3) moved into Zone 4 (mixed complex) as bodies are created to tackle some of the more difficult, and politically sensitive, aspects of public health and health systems policy.

EU health policy in the post-Covid era: political navigation of uncertain issues?

Table 4 presents an overview of the key features of the EU health agenda as it is likely to be characterised in the post-Covid period, as well as the average score for each aspect, used to plot its position on the diagram in Figure 5.

Table 4: Health Policy in the post-Covid period (with combined scores for certainty, agreement)

A. Treaty base (1.7, 2.2)
No change to Article 168 TFEU
B. Key secondary law (1.7, 1.0)
Emergency legislation on entry into force of medical device regulation, clinical trials with GMOs for Covid-19, use of EU Structural Funds for public health emergencies etc.
C. Key soft law and policy initiatives (3.3, 3.0)
Short term agenda on testing, contact tracing & public surveillance, supply of PPE, medicines and devices (Vaccines Strategy and Pharmaceutical Strategy, RescEU, etc.), non-pharmaceutical measures, support to vulnerable groups, mitigating seasonal influenza. Broader agenda on health systems strengthening, health inequalities and disease prevention.
D. Building blocks of the institutional structure (2.5, 2.5)
Strengthened roles for ECDC, HSC and Commission

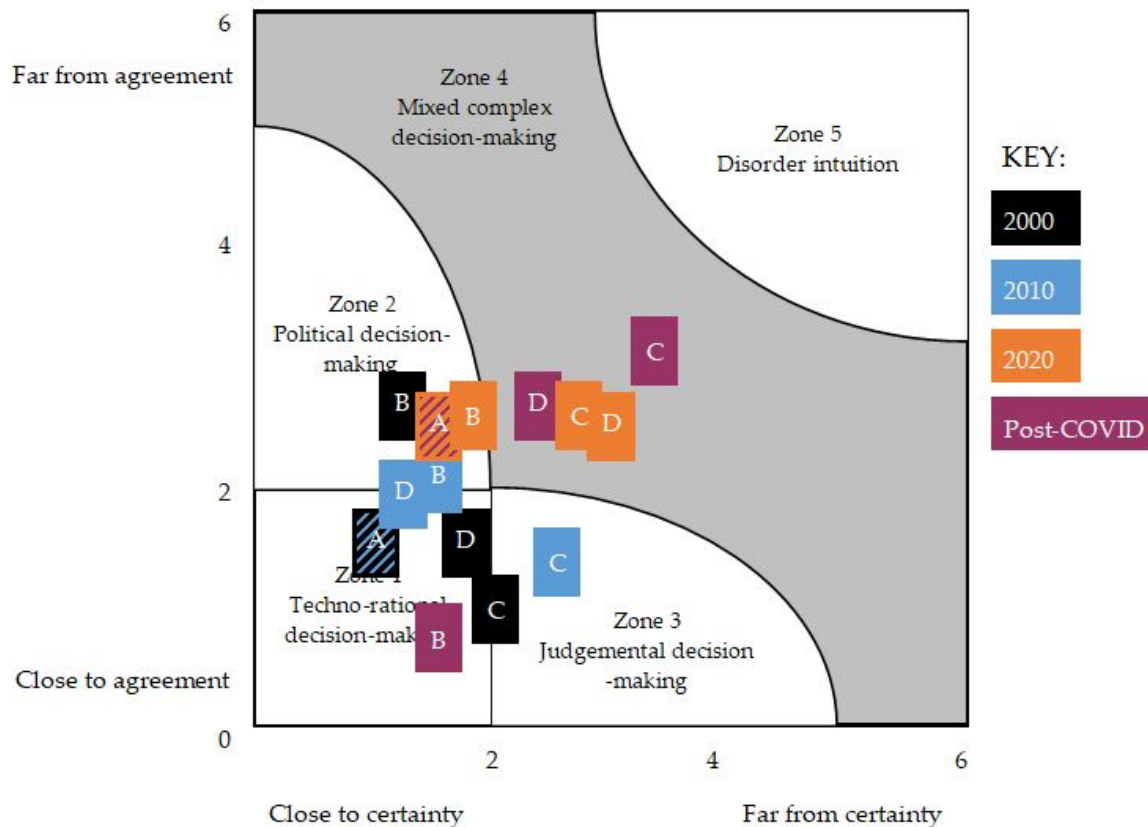


Figure 5: The main zones of health policy likely to be seen in the post-Covid period

Explanation for scoring/positioning

As of August 2020, treaty change has not been forthcoming and Article 168 TFEU looks set to remain without amendment. Similarly, though the documentation to date describes some role expansion for the ECDC, HSC and Commission, it is not yet clear whether this will represent a marked change. As such, Aspect A (Treaty base, score 1.7, 2.2) and Aspect D (institutional structure, score 2.5, 2.5) remain roughly where they were. Some benign secondary law (Aspect B, score 1.7, 1.0) was rapidly adopted in the early weeks and months of the crisis – delaying the implementation date of the new medical device regulations, for instance – but it is not clear which, if any, of the other priorities will require legislation. This is the aspect most subject to change as the agenda develops but, for now, it rests in Zone 1 (techno-rational).

The majority of action, both underway and planned, falls under soft law and policy initiatives (Aspect C, score 3.3, 3.0). Here, EU action on health is set to venture into greater uncertainty and disagreement. Support for testing, contact tracing and public surveillance will fall primarily to the ECDC but the HSC, an intergovernmental body, looks set to play a greater role. Mechanisms for public procurement and stockpiling might be simple enough to design, but issues of allocation and distribution have long hampered attempts to take collective action. The Pharmaceutical Strategy will seek to address issues around the production and supply chains of key medicines, but this public good will confront large and politically powerful industries. Evidence on the effectiveness of non-pharmaceutical interventions, another area

where the ECDC, Joint Research Centre and Commission will seek to offer guidance, is still emerging. The broader EU agenda, to support the strengthening of health systems and the wider promotion of health, contains some of the least certain – largely because of the vagueness of the objectives – proposals of all. Many of these have been on the EU's health agenda for decades and would be sensitive, politicised issues if tangible measures were adopted, but the complexity of the problems involved has traditionally seen them addressed via small, soft instruments.

From 2000 to the post-Covid period: the shift to complex decision-making

Finally, collating the scores across all four aspects for each time period, we can trace the broad movement of the EU health policy agenda (Figure 6). The average scores are as follows:

2000 (1.6, 2.0)	2010 (1.8, 1.9)
2020 (2.4, 2.4)	Post-Covid (2.8, 2.5)

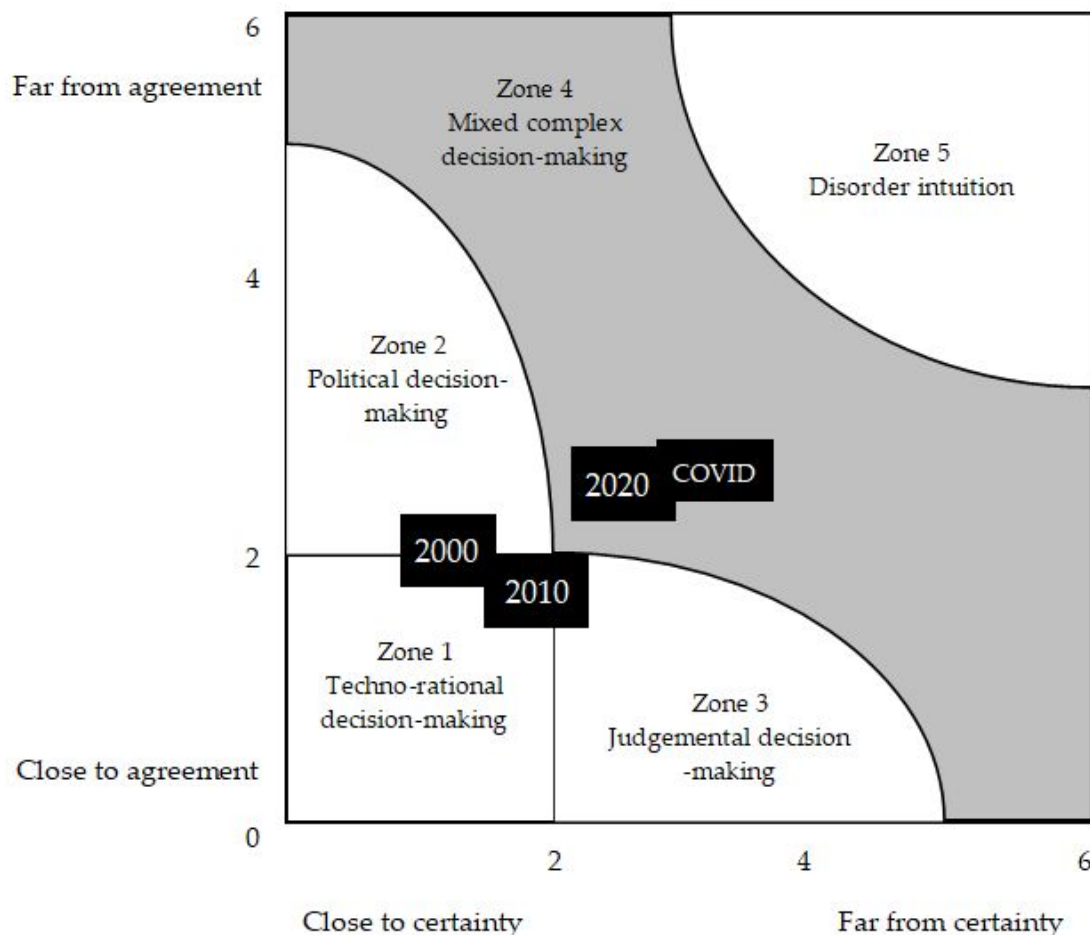


Figure 6: The main zones of health policy decision-making from 2000 to the post-Covid period

Fundamentally, Figure 6 shows us that the impact of Covid-19 upon the EU's health policy agenda is likely to be an outward shift, deeper into the zone of mixed, complex decision-making. This trend had already started by 2020, as both the tractability and consensus of EU

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3 health policy had begun to decline and all four aspects of the agenda had moved into the
4 political range (i.e. above a score of 2). In the post-Covid period, much looks set to stay the
5 same, in that the legal base will likely be unchanged and the EU will continue to legislate in
6 the techno-rational areas where it can support development of a vaccine and maintenance of
7 supplies to health systems. However, the certainty around its softer interventions – where it
8 will seek to support the fight against Covid-19 and recovery in its aftermath – has declined
9 considerably.

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13 This outwards shift might be interpreted as a sign of policy maturity. The EU's health policy
14 was never solely technocratic but it has steadily gained in value, salience and influence such
15 that it is now engaged in tackling the 'wicked problems' facing its members' health systems
16 and in pushing for common approaches and European norms where they have not previously
17 existed. By this interpretation, member state resistance is not a bad thing. Constant balancing
18 between the constituent parts of a system is a sign of a healthy, adaptive and evolving complex
19 system. Hence, the EU will need to continually show why and how it is helping to create better
20 outcomes and its 'added value' as a health actor, in order to remain trusted and to maintain
21 support for its newly-gained roles. Despite being seen as a weakness by some, from a
22 Complexity perspective, this continual balancing and justification process may be one of the
23 strongest attributes of EU policy making.

24 25 26 27 28 29 **CONCLUSION**

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31 Our aim in this article was to go beyond a review of the new elements of EU health policy and
32 visualise its development over time. We recognise the limits of this endeavour. The scoring
33 and positioning of agendas involves judgement calls, which means that there is room for
34 strengthening of the analysis. We offer our findings as a starting point, hopeful of
35 engagement, debate and further development of the project.

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38 Notwithstanding their limitations, the findings present interesting patterns and a clear
39 movement from the simpler zones, where EU health policy began, to the more complex and
40 contested zones. Since we conducted our main analysis, the Commission has announced that,
41 in November 2020, it will publish a package of measures that will form the 'building blocks
42 for a European Health Union' and strengthen the EU's health security framework (European
43 Commission 2020e). This will include extensions to the mandates of the ECDC and the
44 European Medicines Agency (EMA), and the creation of a new agency, based on the US
45 Biomedical Advanced Research and Development Authority (BARDA), as well as a new legal
46 framework for cross-border health threats. Furthermore, the Council of the EU has expressed
47 its commitment to taking 'a coordinating, proactive and leading role' in the strengthening of
48 global health security and the World Health Organization (WHO) (Council of the EU 2020).
49 Thus, it seems likely that the Commission will seek to repeat its 'traditional' reaction to public
50 health crises: creating and strengthening technocratic agencies, and carefully laying the
51 groundwork for potential expansion of its areas of activity, whilst avoiding formal treaty
52 change. Member states, meanwhile, may yet dampen some of this ambition, potentially
53 identifying the WHO as an alternative, and less 'supranational', venue within which to
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3 respond to the weaknesses highlighted by Covid-19. Change will be incremental, integrative
4 and carefully circumscribed by national governments and financial constraints.
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7 Where EU health policy expands – vaccines and other medicines, preparedness and
8 emergency planning, and health systems strengthening, for example – considerable
9 challenges lie ahead. Whilst, as noted above, such expansion is a sign of a policy area reaching
10 maturity, these issue areas are increasingly contested and politically sensitive. Success thus
11 requires new decision-making skills, greater responsibility and more political subtlety. A
12 strengthened and centralised mechanism for procurement of vaccines and other medical
13 countermeasures, to take just one example, will engage the EU in sensitive debates about
14 equitable distribution, technical assessments of clinical added value, negotiation of potential
15 contracts, and all while balancing the legitimate demands of national governments, the
16 pharmaceutical industry and patients/citizens. As such, and whilst the changes afoot mark a
17 major development for EU health policy, in many ways, the difficult part is only just
18 beginning. Maintaining support for the expansion of EU health policy while it moves into
19 much more contested and complex political terrain, in the midst of recovery from a global
20 pandemic, is the challenge now facing the EU's health actors. How they, the member states
21 and European society respond will be central to the where a post-Covid EU health policy goes
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For Peer Review Only

Article 3-

8616-8279 (abstract 140) words

THE DEVELOPMENT OF EU HEALTH POLICY AND THE COVID-19 PANDEMIC: TRENDS AND IMPLICATIONS

ABSTRACT

EU health policy is a policy forged in crisis. Whilst maintaining the strict limitations on the EU's role that are described in the treaties, scandals and scares have historically been followed by incremental but integrative policy change. Incremental change has historically followed scandals and scares, whilst maintaining the strict limitations on the EU's role, as described in the treaties. COVID-19 is a different kind of crisis, however. Rather than affecting a particular good (as with blood for transfusion or beef) or limited pool of member states (as with SARS or Swine Flu), it that affects almost every policy area all and is linked to public health infrastructure and health systems, as well as the internal market. Given this trend past developments in EU health policy, should we be expecting a radical expansion of EU health in this policy area in the aftermath of Covid-19? And, if so, what parameters and characteristics might this new agenda have? This opens a window of opportunity for change. As we enter the period in which the EU will try to elaborate its new health policy, this paper uses a Complexity ~~policy~~ perspective to assess how the emerging agenda compares to existing and historical EU action on health, the kind of decision-making that we are likely to see in the different areas of action, and the limitations of EU health policy development and s it pushes into more political and complex areas of policy. development and the implications for European integration.

INTRODUCTION

The ability of the European Union (EU) to respond exhaustively and effectively at the outset of the Covid-19 pandemic was curtailed by the health competences assigned to it in the Union's founding treaties. The EU's role in health competences are is narrow, curtailed/limited over the years by national governments keen to retain control of their health policies and systems. The current treaties permit the EU to harmonise national laws in a small set of specific areas, such as , namely organs and substances of human origin, blood and blood derivatives, pharmaceuticals, and measures in the veterinary and phytosanitary fields/medical devices. In all other areas of health, including crisis response, pharmaceutical procurement and infectious disease management, the EU's role is limited to supporting national policies, facilitating common approaches and encouraging coordination. Consequently, its initial health policy response was constrained. The EU did not have the necessary stockpiles to respond to requests for personal protective equipment (PPE) and other critical resources, and was not able to stop the wave of export bans adopted by national governments seeking to

retain what supplies they had. Whilst ~~if frustrating, the EU's health policy~~ this response to COVID-19 reflected the design and intention of member states (Brooks, de Ruijter and Greer 2020a).

~~COVID-19 has politicised the European Union's (EU) role in health to a degree far beyond previous crises. Initially, the increased attention was far from positive. The EU did not have the necessary stockpiles to respond to requests for personal protective equipment (PPE) and other critical resources, was slow to initiate joint procurement processes to acquire them, and was not able to stop the wave of export bans adopted by national governments seeking to retain what supplies they had. Whilst some expressed disappointment, this performance was to be expected. The EU's health competences are narrow, curtailed over the years by national governments keen to retain control of their health policies and systems. The current treaties permit the EU to harmonise national laws in a small set of specific areas, namely organs and substances of human origin, blood and blood derivatives, pharmaceuticals, and measures in the veterinary and phytosanitary fields. In all other areas of health, including crisis response, pharmaceutical procurement and infectious disease management, the EU's role is limited to supporting national policies, facilitating common approaches and encouraging coordination. If frustrating, the EU's health policy response to COVID-19 reflected the design and intention of member states (Brooks, de Ruijter and Greer 2020a).~~

~~The weaknesses of this model were laid bare became plainly apparent in the period immediately following the COVID-19 outbreak and, following criticism of the EU's response, there were soon calls for change. Whilst the extent of reforms and revised agendas is still being decided, there is considerable precedent for change in the aftermath of crisis. More so than other policy areas, the progress of EU public health policy can be measured in terms of crisis and response (Greer, de Ruijter and Brooks 2020). For instance, the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003 promoted the creation of the European Centre for Disease Prevention and Control (ECDC), and poor coordination during the swine flu epidemic in 2009 resulted in the creation of a mechanism for joint procurement of vaccines. These and other examples illustrate a pattern in which scandal, scare and emergency crisis has commonly been followed not only by harmonised product regulation but also by institution-building. Whilst mostly incremental, crisis has generally preceded incremental but important steps in the development and integration of EU health policy. Hence, given the scale of the Covid-19 pandemic, one would expect to see substantial changes and development in the EU health policy The question raised, in the summer autumn of 2020, is whether similar steps will be taken in response to COVID-19. Assuming some change, what impact this will have upon the EU's health policy agenda and parameters of, and to what extent will it mark a departure from existing decisionthe policy area making dynamics? But, is this at happening?~~

To explore address this question, ~~t~~ This article explores the EU's post-COVID-Covid-19 EU health policy agenda, looking not only at change in policy content, but also at how this new content is likely to shape decision-making dynamics by bringing new, increasingly complex and politically contentious issues onto the EU's agenda. The first part presents the EU's response to COVID-Covid-19. It identifies the relevant health policy tools that were available, describes how they were utilised in the extent and limitations of the EU's initial crisis

~~responserole-period~~, and reviews the changes that have ~~ince~~ been proposed ~~as this period has passed~~, sketching the likely scope and content of the post-Covid~~OVID~~ health agenda. ~~It draws on research conducted between March and August 2020, as part of ongoing projects tracing the EU's response to CovidOVID-19 from a health policy perspective. Its empirical basis is a review of key policy documents, press releases, public statements and media reporting, as well as previous work in the field of EU health policy, used to describe the EU's health competence at the start of the crisis, the interventions that this enabled, and subsequent proposals for change.~~

In the second part, the article adopts a Complexity perspective and utilises one of the key tools for applying this in a policy setting – the Complexity Diagram. ~~This allows us to visualise the core, decision-making characteristics of EU health policy, illustrating its varying complexity.~~ Drawing on previous work in this field, we plot the EU health agenda onto the Diagram at four points in time, charting its development in 2000, 2010, at the start of 2020 and, finally, ~~aspects of~~ the post-Covid~~OVID~~ period (the latter drawing on the work presented in section ~~onetwo~~). ~~This allows us to~~In mapping change over time, we assess the potential impact of Covid~~OVID~~-19 upon what was, as we will show, a relatively stable trend.

A final section reflects upon the potential trajectory of the EU's post-COVID-Covid health agenda and the resulting shifts in decision-making. The article concludes that ~~whilst CovidOVID-19 has amplified the drift of EU health policy into more complex terrain, and that whilst this trend might be seen as a positive indication of maturity and success within the policy area, it is not without its challenges. Moreover, despite the all-encompassing and intense nature of the pandemic, and the clear expansion of EU health policy activities, there have been relatively limited policy developments – due to the structural limitations of EU health policy and the challenges of developing European level policies in these much more complex and politically contentious areas.~~

THE EU'S HEALTH POLICY RESPONSE TO COVID-19

From national to collective action

~~When Covid-19 hit, the EU had two main governance frameworks through which it could organise its immediate response to the public health crisis. The first was the health security framework set up by the 2013 Decision on Serious Cross Border Threats to Health (herein the Health Threats Decision), which establishes a set of structures for emergency planning, preparedness and response. The second was the Civil Protection Mechanism (CPM), which facilitates cooperation between member states in the event of a disaster. Both performed as intended and expected in the first phase of the crisis but, reflecting the EU's limited health-related powers, their capacity and reach was inevitably insufficient.~~

~~The Health Threats Decision (European Parliament and Council 2013) was adopted in the aftermath of the Swine Flu outbreak. It defines the role of member states and various EU-~~

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4 level institutions¹ in (a) emergency planning and preparedness, (b) ongoing surveillance and
5 data collection, and (c) crisis response and coordination. Member states are to report on their
6 emergency planning and preparedness situation every three years, so that the Commission
7 can facilitate discussion of these provisions within the Health Security Committee (HSC, see
8 below). Data collection and surveillance is managed by the ECDC, which operates a network
9 of epidemiological information, communicated to it regularly by national authorities. In the
10 event of a crisis or the emergence of a new threat, an alert is raised via the Early Warning
11 and Response System (EWRS), triggering risk assessment from the ECDC and the start of
12 coordination of national responses via the HSC. The HSC – a committee of high-level
13 national representatives, assisted by the Commission and experts from relevant agencies –
14 serves as the venue in which national governments either consult on proposed measures to
15 combat serious threats to health in their territories or, where action had to be taken urgently,
16 inform their counterparts of such measures already adopted (de Ruijter 2019). Where the
17 situation overwhelms the capacity of a given member state, Article 11(4) of the Decision
18 instructs national governments to activate the CPM.

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24 Whilst the HSC eventually became a valuable hub, coordination meetings were infrequent
25 and poorly attended in the initial weeks of the crisis and many member states had not
26 reported on their preparedness and response plans as required (Beaussier and Cabane 2020:
27 5). The consequent lack of information about national capacities limited the relevance of
28 ECDC guidance and exacerbated weaknesses in the surveillance system. The ECDC relies on
29 data being transferred from national authorities, which commonly lack the infrastructure to
30 collect and/or the will to communicate this, and is itself under-resourced and lacking in
31 power to enforce national reporting (Greer 2012). Though a long-acknowledged problem,
32 the limitations faced by the ECDC, and consequently to its capacity to support member
33 states, have been highlighted by the pandemic.

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38 The Health Threats Decision also establishes a Joint Procurement Agreement (JPA) for the
39 collective purchase of ‘medical countermeasures’ (medicines, personal protective equipment
40 (PPE), laboratory supplies etc.). The EU’s role here is limited – the Commission manages the
41 call for goods but no EU funds are used; national governments express interest and, once the
42 contract is finalised, may then purchase under its terms (McEvoy and Ferri 2020). During the
43 pandemic, six procurement competitions have been launched, seeking to secure PPE,
44 ventilators, testing kits, and intensive care medicines. Exploratory talks have been
45 concluded on all six competitions and three contracts issued to date, though the JPA proved
46 too slow and intergovernmental to be much use during the initial, emergency period (de
47 Ruijter et al. 2020: 18; see also van Schaik et al., this issue).

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52 The EU’s second crisis-response governance framework, the CPM, is essentially a
53 matchmaking system. Member states report to the EU a list of their available strategic
54 resources (fire-fighting equipment, expert rescue teams, evacuation transport) which could
55 be deployed in the event of an emergency. In 2019, the CPM was ‘upgraded’ with the
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59 ¹ For the Commission, action is generally led by the relevant units within the Health and Food Safety
60 Directorate, DG Santé.

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3 addition of RescEU, a common stockpile of transport, medical equipment and field
4 hospitals². In a crisis, a member state can make a request and activate the CPM, at which
5 point the relevant resources are identified and their deployment from the member state
6 which hosts them to the state which needs them is coordinated. Whilst this system
7 successfully provided resources for forest fires in Sweden in 2018, for example, it is not
8 designed to respond to a situation in which all member states require the same resources at
9 the same time. As Covid-19 unfolded, national governments were either already facing the
10 pandemic or fearful that it would soon breach their borders, and responded by seeking to
11 keep strategic resources at home – a reaction exemplified by the silence which met Italy’s
12 request for supplies of PPE in February (Greer, de Ruijter and Brooks 2020).

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17 The initial response afforded by existing EU governance frameworks was thus limited and
18 widely criticised (Pacces and Weimar 2020; Renda and Castro 2020). Italy’s CPM experience
19 transpired to be indicative of a wider, if temporary, abandonment of member states’
20 commitment to solidarity. Through March and April, national governments adopted border
21 closures and bans on the export of crucial supplies, obstructing freedom of movement and
22 exhibiting behaviour indicative of European disintegration (Dimitrakopoulos and Lalis
23 2020). Remarkably, however, as the pandemic entered ‘phase 2’, the EU began to play a
24 more active role and value of collective action seemed to become apparent to national
25 leaders (Alemanno 2020). Travel and export bans were lifted, collective procurements were
26 organised and a common ‘exit strategy’ was agreed (European Commission 2020d). The
27 HSC became a stable venue for coordination of national actions and governments began to
28 work together, perhaps now seeing the need for a(nother) EU ‘rescue of the nation state’
29 (Brooks, de Ruijter and Greer 2020a). As in previous episodes, the crisis has exposed
30 weakness and highlighted the added value of collective response. The question now is
31 whether and how this will be institutionalised in an expansion of the EU’s health policy.

32 **The post-Covid EU health agenda: incremental but integrative**

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37 The full extent of any change to the EU’s health policy powers and agenda is still to be
38 determined but, from adopted initiatives and ongoing debates, the potential parameters of
39 this change can already be identified.

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44 Early calls for treaty revision, to increase the EU’s formal health powers, were quickly
45 rejected as both infeasible and unnecessary. Consensus among academic lawyers is that,
46 though patchy, the EU’s legal basis for health already permits considerable action *where this*
47 *is supported by political will* (Guy 2020; Hervey and de Ruijter 2020; Pernhagen et al. 2020),
48 and that the same lack of will that constrains ongoing activity is likely to obstruct formal
49 treaty change (Clemens and Brand 2020). As if to illustrate this point and demonstrate the
50 potential of the existing competence, the Commission has either adopted or announced the
51 upcoming publication of a range of initiatives.

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59 ² A further amendment, made in April 2020, created the first RescEU stockpile of equipment relevant
60 specifically to public health crises, including ventilators, PPE and basic medicines.

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3 At the centre of these is the EU4Health Programme, announced in May and currently
4 awaiting adoption by the legislature (European Commission 2020a). EU4Health saw
5 renewed ambition from the Commission, reversing pre-existing plans that would have seen
6 health absorbed into the much broader European Social Fund Plus and earmarked just €413
7 million in the new multi-annual financial framework. The stand-alone EU4Health
8 Programme is likely to see a budget of €1.7 billion, an unprecedented sum for health policy³
9 and lists the objectives of increasing preparedness for cross-border health threats,
10 strengthening health systems, and making medicines and medical devices available and
11 affordable. Though similar to previous programmes and yet to be elaborated into tangible
12 actions, EU4Health's objectives are based on broad recognition of 'a general need
13 for...structural transformation...and systemic reforms of health systems across the Union'
14 (European Commission 2020a: para 15). If stretched to their fullest, these provisions would
15 underpin a significant expansion in the EU's health activity, into politically sensitive and
16 substantively complex areas.

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19 Supporting and elaborating on specific aspects of the EU4Health programme, several other
20 initiatives are in the pipeline. A communication on short-term health preparedness,
21 published in July, extends the role of the ECDC to production of guidelines on issues
22 pertaining not only to risk assessment but also risk management (interoperability of contact
23 tracing apps, management of potential 'super-spreading events', and optimisation of
24 hospital space). Under the EU Vaccine Strategy, adopted in June, the EU's executive will
25 sign Advance Purchase Agreements (APAs) with pharmaceutical companies, on behalf of
26 member states, and then coordinate the supply and distribution of any eventual vaccine
27 (European Commission 2020c). This is a significant change, since the JPA provides for
28 collective purchase but does not give the Commission a role in distribution. Looking to the
29 longer-term challenges facing vaccine development, a Pharmaceutical Strategy is due to
30 published by the end of 2020. It will be aimed at addressing access to medicines,
31 pharmaceutical supply chains and innovation in the sector (European Commission 2020b).

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34 In sum, and reflecting wider dynamics of EU integration, the crisis has unfolded (to date)
35 with an initial period of intergovernmental and nationalistic responses, then muddling
36 through towards an eventual adoption of integrative and collective, if patchwork, solutions.
37 In other words, it displays all the dynamics of 'failing forward' (Greer, de Ruijter and Brooks
38 2020; Jones, Kelemen and Meunier 2015). But, at this stage in its development, and given the
39 increasing sensitivity and uncertainty of the issues that the EU finds itself moving into, what
40 kind of decision-making is likely to characterise this new agenda? We utilise the lens offered
41 by Complexity approaches to assess the changing dynamics of EU health policy.

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³ The €9.4 billion health budget originally proposed by the Commission was cut by the European Council in July
59 to €1.7 billion. The EU legislature reached provisional agreement on the new budget on 10 November 2020,
60 but this is still to be formally adopted by the European Council and European Parliament.

The short term, emergency response: limited by design

When COVID-19 hit, the EU had two main institutions through which it could organise its immediate response to the public health crisis. The first was the Civil Protection Mechanism (CPM), which facilitates cooperation between member states in the event of a disaster. The second was the ECDC, the EU's agency in charge of defending against infectious diseases. Both performed as intended in the opening weeks and months of the crisis but, reflecting the close delimitation of EU powers embodied in the treaties, their capacity and reach was insufficient.

The CPM is essentially a matchmaking system. Member states report to the EU a list of their available strategic resources (fire fighting equipment, expert rescue teams, evacuation transport) which could be deployed in the event of an emergency. The EU certifies and registers the relevant resources, and coordinates various training and simulation activities. In 2019, the CPM was 'upgraded' with the addition of RescEU, a common stockpile of aeroplanes, helicopters, medical equipment and field hospitals⁴. Should a disaster occur, a member state can make a request and activate the CPM, at which point the relevant resources are identified and their deployment from the member state which hosts them to the state which needs them is coordinated. Whilst this system successfully provided resources for forest fires in Sweden in 2018, for example, it is not designed to respond to a situation in which all member states require the same resources at the same time. As COVID-19 unfolded, national governments were either already facing the pandemic or fearful that it would soon breach their borders (Greer, de Ruijter and Brooks 2020) and re. As applications of public goods theory have shown was predictable, member states responded by seeking to keep strategic resources at home (Rhinard, Hollis and Boin 2012).

By contrast to the CPM, the ECDC had a 'good' crisis. Though a small agency — around 300 staff coordinating a network of experts based in member states — it has a well established system of surveillance and monitoring, as well as some public communication strategies. As the crisis developed, it gathered and communicated data, issued expert guidelines and maintained a central hub of information. Its contributions were inevitably filtered through national bodies, but nonetheless underpinned the detailed guidance issued by governments. As intended, it performed the role of 'risk assessor', channelling information and guidance to national authorities and to the Health Security Committee (HSC), the actors responsible for 'risk management'. The HSC was created as an informal, intergovernmental body in the aftermath of the anthrax and 9/11 attacks in the United States but was formalised in the 2013 Decision on Serious Cross Border Threats to Health (European Parliament and Council of the EU 2013). It is comprised of senior member state officials with the mandate to agree coordinated action, and supported by both the ECDC and the European Medicines Agency (EMA) (de Ruijter 2019). As the crisis developed, and once member states had realised the necessity of collective action and moved beyond their initial, nationalisticegotistical responses, the HSC provided a solid platform for coordination.

⁴A further amendment, made in April 2020, created the first RescEU stockpile of equipment relevant specifically to public health crises, including ventilators, PPE and basic medicines.

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Outside of the CPM and the ECDC, an additional, intergovernmental response mechanism was also activated, albeit after some delay. The Joint Procurement Agreement (JPA) was established in response to the uncoordinated experience of vaccine procurement during the swine flu and H1N1 influenza outbreaks. It sets out a process for the collective purchase of 'medical countermeasures' needed to combat a cross-border health threat. Though there have been four calls for supplies since the pandemic started, the JPA proved too slow and intergovernmental to be much use during the initial, emergency period (de Ruijter et al. 2020: 18; see also van Schaik et al., this issue).

This well institutionalised but minimal health emergency response system, like EU health policy as a whole, reflects the EU's basic structure as a regulatory state and member states' desire to limit the EU's influence over national health policy (Brooks, de Ruijter and Greer 2020a). The EU is, at root, an economic union and its institutions have considerable powers to regulate and maintain the single market. By contrast, they have a very limited mandate to directly target health. The member states have assigned the EU powers in some very specific areas of public health but tightly constrained its mandate beyond these areas. Consequently, the EU's greatest influence on health is often achieved via non-health policies. The regulation of tobacco advertising, of health professional qualifications and of cross-border access to care, not to mention its role in encouraging (and sometimes mandating) health system reforms via its fiscal governance framework, have a significant impact upon health and, despite the intentions of the member states, constitute powerful health policy tools. But they are rooted in internal market and monetary union legal frameworks; they do not target health explicitly. As such, EU health policy is characterised and shaped by a paradox – the EU's influence over health has expanded far further than member states intended and would prefer, but this expansion/encroachment has been based largely upon non-health competences and thus often affects health as a secondary consideration.

The EU's early response to COVID-19 made clear the drawbacks of this model, and the unprecedented scale of the disaster opened a much larger window of opportunity than previous crises. SARS, Ebola, H1N1, Bovine Spongiform Encephalopathy (BSE), HIV/AIDS and the myriad other health crises that the EU has faced in the past were generally confined to a few member states, if materialising in a significant way at all, and were relatively short-lived. COVID-19 has affected every member state and already wreaked havoc on the EU and global economies. In short, the salience of health policy in general, and the role of transnational health cooperation in particular, was as high in spring 2020 as it had ever been. Hence, given the continuing pandemic in late 2020, is now the time to move beyond the existing, limited model of EU health policy, to give the EU a greater role in explicitly and directly seeking to protect and improve health?

A window of opportunity...missed?

Initial signs looked promising. At the end of May, the European Commission presented a proposal for a revised and slightly increased EU budget – known as the multi-annual financial framework (MFF) – as well as a dedicated pandemic recovery package, titled Next Generation EU (NGEU). Together, these were worth €1.8 trillion. The special European Council

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3 summit at which they were agreed was the second longest summit in the EU's history, and
4 the result was an historic deal. For the first time, the EU will look to raise funds on the financial
5 markets, on behalf of its member states, to cover the €750 billion NGEU package. Moreover,
6 it will disburse €312.5 billion of this directly to the member states worst hit by the crisis as
7 grants, constituting the first transfers of this kind in the Union's history (see Wolff and Ladi,
8 this issue). The Commission's ambition was equally reflected in the health aspects of the
9 proposal. Reversing the pre-existing plans for EU health policy post 2020, which would have
10 seen health absorbed into the much broader European Social Fund Plus and earmarked just
11 €413 million, the Commission announced a new, standalone Health Programme—EU4Health
12—with a budget of €9.4 billion (European Commission 2020a). €7.7 billion of this was to come
13 from the NGEU package and the other €1.7 billion was built into the MFF.

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15 In short, at the end of May 2020, the Commission had seen the window of opportunity open
16 and was lining up to take a considerable jump through it. In many ways, it was successful.
17 The deal struck on NGEU constitutes a significant first step towards fiscal union and, though
18 the Council diluted, altered and cut several aspects of the Commission's original proposal, re-
19 balancing control of the funds in favour of member states, it would be inaccurate to
20 characterise the deal as anything less than a significant intensification of European integration.
21 A plot twist awaited the EU4Health Programme, however. Late in the Council negotiations, a
22 compromise text emerged in which the pandemic-related 'top-up' funding for EU4Health—
23 €7.7 billion under NGEU—was removed. Immediately the proposed budget for health fell
24 from €9.4 billion to €1.7 billion.

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26 Health was not the only casualty of the negotiations, as the so-called 'frugal states' pushed to
27 reduce the portion of the funds being centrally assigned in favour of transfers directly to
28 member states. The European Parliament was quick to make known its displeasure at the
29 Council's amendments and to remind the other EU institutions of its right to veto the MFF if
30 it is not satisfactory (European Parliament 2020). Negotiations were opened in late July and
31 are likely to continue for three or four months. In the meantime, the Commission has begun
32 to elaborate on its plans under the EU4Health Programme, and to mark out its new health
33 agenda.

34 35 36 37 38 39 40 41 42 43 44 **The post-COVID EU health agenda**

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46 Though the budget has yet to be finalised and plans are still under development, the handful
47 of policy announcements that have been made over the course of summer 2020 provide an
48 initial picture of the EU's future health agenda. Firstly, the EU4Health Programme states the
49 objectives of increasing preparedness for cross-border health threats, strengthening health
50 systems, and making health technologies (medicines and medical devices) available and
51 affordable (European Commission 2020a). It clearly responds to the need for improvements
52 in crisis preparedness and response but also capitalises on the salience of health more broadly,
53 by including long-standing EU health objectives, such as action to fight cancer, health
54 inequalities, antimicrobial resistance and access to care. Shortly after the EU4Health
55 Programme proposal was published, the Commission announced a European Vaccines
56 Strategy, to complement its planned Pharmaceutical Strategy. The latter will address longer-
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3 term issues, such as access to medicines, pharmaceutical supply chains and innovation in the
4 sector, and is due for publication at the end of 2020 (European Commission 2020b). The former
5 focuses on a vaccine for COVID-19 and proposes a centralised procurement mechanism which
6 addresses weaknesses in the JPA (European Commission 2020c). Most recently, Finally, in a
7 communication issued on 15 July 2020, the Commission outlines its short term health
8 preparedness plans, designed to mitigate the impact of further COVID-19 outbreaks and
9 prepare for strain upon European health systems as they enter the seasonal flu period.

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11 From these documents, an enhanced EU health agenda can be identified. If approved, it will
12 see the ECDC take a greater role in information collection and dissemination, as well as the
13 production of technical, scientific and best practice guidelines on issues pertaining not only to
14 risk assessment (via the COVID-19 data sharing platform, for example) but also risk
15 management (interoperability of contact tracing apps, management of mass gatherings and
16 other potential 'super-spreading events', and optimisation of hospital space). In some crucial
17 areas, the Commission's role will be considerably enhanced. Under the Vaccine Strategy, for
18 instance, the EU's executive will sign Advance Purchase Agreements (APAs) with
19 pharmaceutical companies, on behalf of member states, and then coordinate the supply and
20 distribution of any eventual vaccine. This is a significant change, since the JPA provides for
21 collective purchase but does not give the Commission a role in distribution. Similarly, new
22 stockpiles of medical equipment and critical supplies will be procured, managed and
23 distributed centrally for the first time. In other areas, the EU will take a traditional,
24 coordinating role, facilitating exchanges with member states on preparedness planning, the
25 use of non-pharmaceutical measures (such as local lockdowns), management of internal and
26 external borders during outbreaks, and bottlenecks in national procurement. In addition, and
27 some contrast, to these specific actions and roles, the EU4Health Programme is based on broad
28 recognition of 'a general need for...structural transformation of and systemic reforms of
29 health systems across the Union' (European Commission 2020a: para 15). Though less tangibly
30 elaborated in the documentation to date, the agenda being presented makes space for an EU
31 role in health systems strengthening, reducing health inequalities and fighting non-
32 communicable diseases. If fully utilised, this would mark a significant expansion of the EU's
33 health mandate.

34 35 36 37 38 39 40 41 42 43 44 45 46 47 **DEVELOPMENT AND DYNAMICS OF EU HEALTH POLICY: A COMPLEXITY** 48 **PERSPECTIVE**

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50 In the second part of the article we look at the current state of play in EU health policy from a
51 Complexity perspective, and using the Complexity Diagram in particular, in order to reveal
52 some of the underlying dynamics of its development and some of the challenges that it will
53 face as it moves into more contested and 'complex' fields of European health policy-making.
54 Complexity, a general term covering a wide range of complex, adaptive, emergent systems
55 and phenomena, originates in the natural sciences (Coveney and Highfield 1995). Though no
56 one Complexity theory exists, Complexity approaches have in common the examination of
57 whole systems, rather than their individual components and, as such, challenge traditional,
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4 linear, reductionist approaches to scientific inquiry (Byrne 2005; Geyer and Rihani 2010;
5 Richardson and Cilliers 2001).

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7 Complexity, a general term covering a wide range of complex, adaptive, emergent systems
8 and phenomena, has been extensively deployed in the natural sciences since the 1970s
9 (Coveney and Highfield 1995). From the 1990s, Complexity it also spread across the social and
10 policy sciences (Byrne, Byrne and Callaghan 2013; Castellani and Hafferty 2010; Geyer and
11 Cairney 2015), and has gained particular traction in health and health policy (Alexander 2010;
12 Greenhalgh and Papoutsis 2018; Holt 2004; Kernick 2004 ; Plsek and Greenhalgh 2001;
13 Sturmburg and Martin 2013). into a wide range of policy areas, and has been deployed by a
14 number of governments and international organisations⁵. There is no one theory of
15 Complexity; it is best thought of as a field, or approach (Byrne 2005; Moran 2007; Richardson
16 and Cilliers 2001). A Complexity perspective argues that, at the meta-theoretical level,
17 physical and social reality is composed of a wide range of continually interacting, orderly,
18 complex and disorderly phenomena. One can focus on different aspects (orderly, complex or
19 disorderly), but that does not mean that the others do not exist (Geyer and Rihani 2010).

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25 In European integration, Complexity acts as a bridge between the more positivist and
26 reflectivist theoretical perspectives (Geyer 2003; Geyer and Rihani 2010; Lehmann 2018).
27 Complexity recognises the importance of orderly structures and institutions and the ability to
28 make positivist claims about them. Nevertheless, it also recognises the inherent
29 unpredictability and uncertainty in all complex systems and the incredible diversity and
30 variety of human interpretations of those systems – hence the importance of reflexivity. With
31 its methodological openness, Complexity is similar to broader interpretations of
32 Constructivism. However, its foundation in and engagement with the natural sciences
33 provides it with an additional range of tools.

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37 Applied to a policy and governance setting, Complexity is a rejection of the traditional
38 modernist world view of order, causality, reductionism, predictability and determinism that
39 marks the foundation of the more extreme versions of New Public Management (NPM) and
40 Evidence-Based Policy Making (EBPM). Complexity overlaps with the pragmatist policy
41 tradition (Ansell and Geyer 2017, Sanderson 2009) and It reminds us that policy-makers
42 operate in a continually shifting environment and, whilst some norms and institutions are
43 relatively stable, others are in almost constant flux. As such, the imposition of centrally-
44 managed hierarchies, where compliance with rules is measured against targets and
45 performance indicators, is unlikely to result in policy success. Policy-makers must accept
46 uncertainty and change as features of complex systems and realise that policy making is often
47 as much art as it is science. The real skill is recognising what decision-making strategies and
48 methods are appropriate to radically different contexts and situations.
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57 ⁵ See Australian Public Service Commission, *Tackling Wicked Problems: a public policy perspective* (Canberra:
58 Australian Public Service Commission, 2007); Department for Education, *The Munro Review of Child*
59 *Protection: Final Report, A Child-Centred System Report Cm 8062* (2011); OECD Global Science Forum,
60 *Application of Complexity Science for Public Policy: New tools for finding unanticipated consequences and*
unrealized opportunities (OECD, September 2009).

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~~Complexity has made significant inroads into all areas of policy making, and health and health policy thinking in particular. Major Complexity inspired work covers general health, health policy, organisation and management of health, health and medicine, and clinical applications (Alexander 2010; Cooper and Geyer 2007; Greenhalgh and Papoutsi 2018; Holt 2004; Kernick 2004; Plsek and Greenhalgh 2001; Sturmburg and Martin 2013). In many ways, a Complexity perspective is a natural companion to human health and health policy since they are both fundamentally interdisciplinary, involving interacting physical, biological and social systems in a constantly emerging process.~~

The Complexity Diagram

Within the broad field of Complexity and policy there are a wide range of concepts and tools. Here we apply just one, the Complexity Diagram. The Complexity Diagram is a simple and effective tool for thinking about any policy area from a Complexity perspective.⁶

⁶ The Complexity Diagram – also called a Stacey Diagram/Matrix – was developed by Ralph Stacey in the early 1990s (Stacey 1993). ~~However, he~~ Stacey later distanced himself from it over concerns that it was too limiting ~~in reflecting the fully reflective nature of management processes~~; see R. Stacey, D. Griffin and P. Shaw (2002) *Complexity and Management: Fad or Radical Challenge to Systems Thinking?* London: Routledge. However, the diagram remains popular in a number of Complexity-related academic areas.

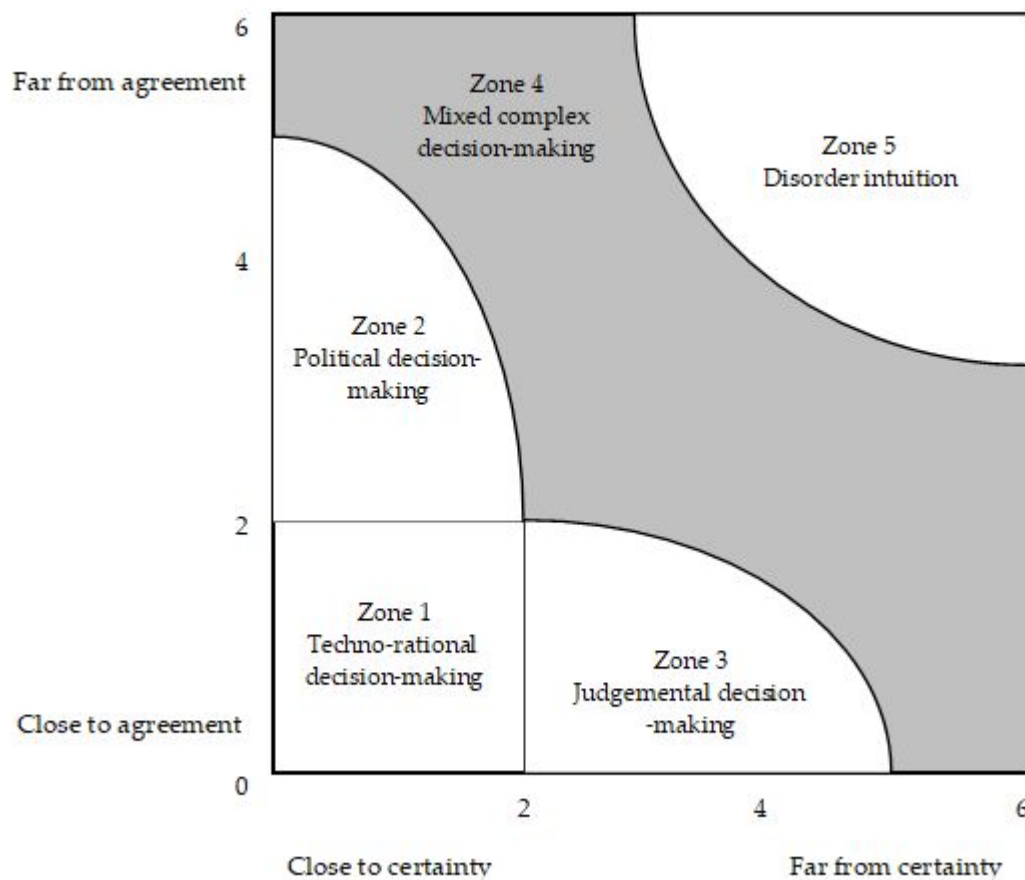


Figure 1: The Complexity Diagram

As shown in Figure 1, the Complexity Diagram combines two axes based on the degree of certainty and ~~the degree~~ of agreement for a particular policy area. High levels of certainty indicate that the issue is well known and easily understood, while low levels of certainty imply that it is unknown/unknowable and that there are great differences in opinion over the issue, even among experts. Meanwhile, high levels of agreement denote substantial public agreement over the nature of, and solution to the issue, while low levels of agreement imply substantial public debate and disagreement. These two axes create five main zones of decision-making:

- Zone 1 (techno-rational): *high certainty-high agreement*. In this zone, the issue is well understood, and the ~~policy~~ response agreed between the majority of key stakeholders. Data on the issue is clear, abundant and easily accessible. Repetitive techno-rational decision-making based on evidence-based actions and audit and targeting strategies works well here. ~~Bureaucratised and formalised responses and structures are optimised in this zone (e.g. NPM).~~
- Zone 2 (political): *high certainty-low agreement*. In this zone, ~~there data~~ is clear and abundant ~~data~~ and ~~the experts/actors~~ understand the problem. However, the

stakeholders disagree over how to respond to it. In this case, more evidence is of little use and political bargaining and consensus building become key decision-making tactics.

- Zone 3 (judgemental): *low certainty-high agreement*. ~~In this area, all of~~ Here, the main ~~actors-stakeholders~~ agree about the nature of the issue, but there is no simple answer or policy response to ~~the problem~~ it. ~~Available data may be partial, incomplete, or contradictory. Even experts do not know how to properly respond to it and/or there is significant debate over the best response. Here, m~~ Multiple strategies are possible and ~~experts disagree over them. Judgemental and may be required and~~ discretionary decision-making becomes increasingly important. ~~If the problem is intractable, more data may only reaffirm uncertainty.~~
- Zone 4 (mixed complex): *mixed certainty-mixed agreement*. This is the most common zone of policy- and decision-making. Data may be uncertain and contested. It is an area in which stakeholders and experts disagree, to varying levels, over the nature of, and responses to the issue. This requires a flexible response that blends political decision-making with evidence-based processes and discretionary decision-making.
- Zone 5 (disorderly): *low certainty-low agreement*. This is the most difficult area where everyone disagrees and no one has a clear answer. Evidence is ~~very poor, or~~ limited and ~~may be~~ continually shifting. ~~Moreover,~~ the issue ~~may be~~ highly emotive and politicised ~~effectively nullifying evidence-based strategies~~. Here, incremental steps are important, and intuitive responses may be just as important as evidence-led thinking.⁷

Utilising the Complexity Diagram to map the development of EU health policy

What can the Complexity Diagram tell us about EU health policy and the new health agenda that is being forged in the aftermath of the ~~COVID~~Covid-19 crisis? Our goal ~~here~~ is to map how the nature of decision-making in EU health policy – the extent to which it is technological, political, judgemental, complex or disorderly – has changed over time, and might shift again under the new health agenda. We first identify four aspects which constitute the EU health policy agenda at any given time:

- A. The treaty base upon which health action is taken
- B. Secondary EU law (regulations, directives and decisions adopted via the EU's legislative processes) that affect health
- C. Soft law and policy initiatives (non-legislative action) relating to health, and
- D. Institutional structures relating to health.

Under the relevant aspects, we compiled a list of key treaty articles, legislative proposals, policy initiatives and institutions, ordered chronologically. The list is based upon a review of major academic works on the development of EU health policy (cf Greer et al. 2014; 2019; Hervey et al., 2017; ~~McKee and Mossialos, 2002; McKee et al. 2002;~~ Mossialos et al., 2010;

⁷ This discussion of the Complexity diagram is based on Webb and Geyer 2020.

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3 Steffen, 2005), a search of the European Parliament's Legislative Observatory for files coded
4 *Health legislation and policy* (undertaken 8–August 2020), a review of the EU Health
5 Programmes from 2003 (when the first was launched) to present, as well as information drawn
6 from the policy documents analysed above, ~~including the EU4Health Programme and the~~
7 ~~Communication on short-term EU health preparedness~~. The purpose was not to be exhaustive
8 but rather to identify the key topics, issues and arguments which have occupied the EU's
9 health agenda over the years, acknowledging that there will have been many, less visible (and
10 often less contested) activities happening on the side-lines.
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14 We then independently 'scored' the listed treaty bases, secondary law, policy initiatives and
15 institutional developments, according to the degree of certainty and agreement that
16 characterises the issue or topic that they relate to. We use a scale of 0 to 6, where 0 indicates
17 complete certainty and agreement, and 6 indicates complete uncertainty and disagreement.
18 For example, the 1992 European Drug Prevention Week initiative was scored by both authors
19 as 2,1, representing a certainty score of 2 and an agreement score of 1. This reflects the
20 considerable understanding among experts of which policy interventions might work best,
21 and the widely agreed nature of the problem of drug addiction. A round of pilot scoring,
22 based on a small sample, was reviewed for consistency of approach and final scores were
23 averaged between the two authors.
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29 Finally, we selected four time periods from which to draw a 'snapshot' of the EU's health
30 agenda, to facilitate mapping of change over time. We thus split the list into the health agenda
31 as it stood in 2000, in 2010, at the start of 2020, and as it is likely to appear in the latter part of
32 2020 and beyond (the 'post-CovidCOVID' health agenda). For each time period, we took an
33 average score for each aspect – for treaty base, secondary law, policy initiatives and
34 institution-building – to give four scores for each snapshot. These are explained and plotted
35 on to the Complexity Diagram below.
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39 *Limitations*

40 There are obvious limitations to this approach and analysis: ~~personal, definitional,~~
41 ~~comparative and evidential~~. Though experts in the field, we have a range of personal biases
42 that will affect our scoring of the 'certainty' and 'agreement' of particular aspects. Moreover,
43 the definitions of 'certainty' and 'agreement' are not significantly precise to enable highly
44 accurate scoring; we chose a scoring range of 0 to 6 so as to balance precision and detail.
45 Similarly, we are not comparing precisely similar policies or political and technical issues
46 surrounding the policies. ~~We also focus only on the EU's 'internal' health agenda, excluding~~
47 ~~any 'external', global health agenda (for an overview of this, see van Schaik et al., this issue).~~
48 ~~Finally, given time constraints, we draw on a limited set of evidence beyond our knowledge~~
49 ~~of the policy areas to inform our positioning. Clearly, much could be done to improve and~~
50 ~~develop this research, such as increasing the number of experts scoring the policy areas (to~~
51 ~~improve confidence in the scoring outcomes) and expanding the range of comparable~~
52 ~~evidence for each policy area~~. However, we are confident that the existing strategy creates
53 some interesting insights and provides a valuable starting point which we and others can
54 build upon in further work.
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EU health policy: 2000, 2010, 2020 and ~~COVID~~Covid

EU health policy in 2000: Cooperation on key, common challenges

Table 1 presents an overview of the key features of the EU health agenda in 2000, as well as the average score for each aspect, used to plot its position on the Diagram in Figure 2.

Table 1: Four key aspects of EU health policy in 2000 (with combined scores for certainty, agreement)

A. Treaty base (1.0, 1.5)
Article 100A of the SEA
Articles 3(o) and 129 of the Maastricht Treaty
Article 152 of the Amsterdam Treaty
B. Key secondary law (1.5, 2.5)
Directives on tobacco labelling, advertising, tar yield and tax
Directives on medical devices (including <i>in vitro</i> and active implantable)
Directive on Direct-to-consumer-advertising of prescription drugs
C. Key soft law and policy initiatives (2.0, 1.3)
Action plans (e.g. 'Europe Against Cancer', Europe Against AIDS')
European Drug Prevention Week
EU Public Health Action Plan
D. Building blocks of the institutional structure (1.8, 1.5)
Founding of early health-related NGOs
DG Health and Consumers (now DG SANTE)
European Monitoring Centre Drugs & Drug Addiction, European Medicines Agency

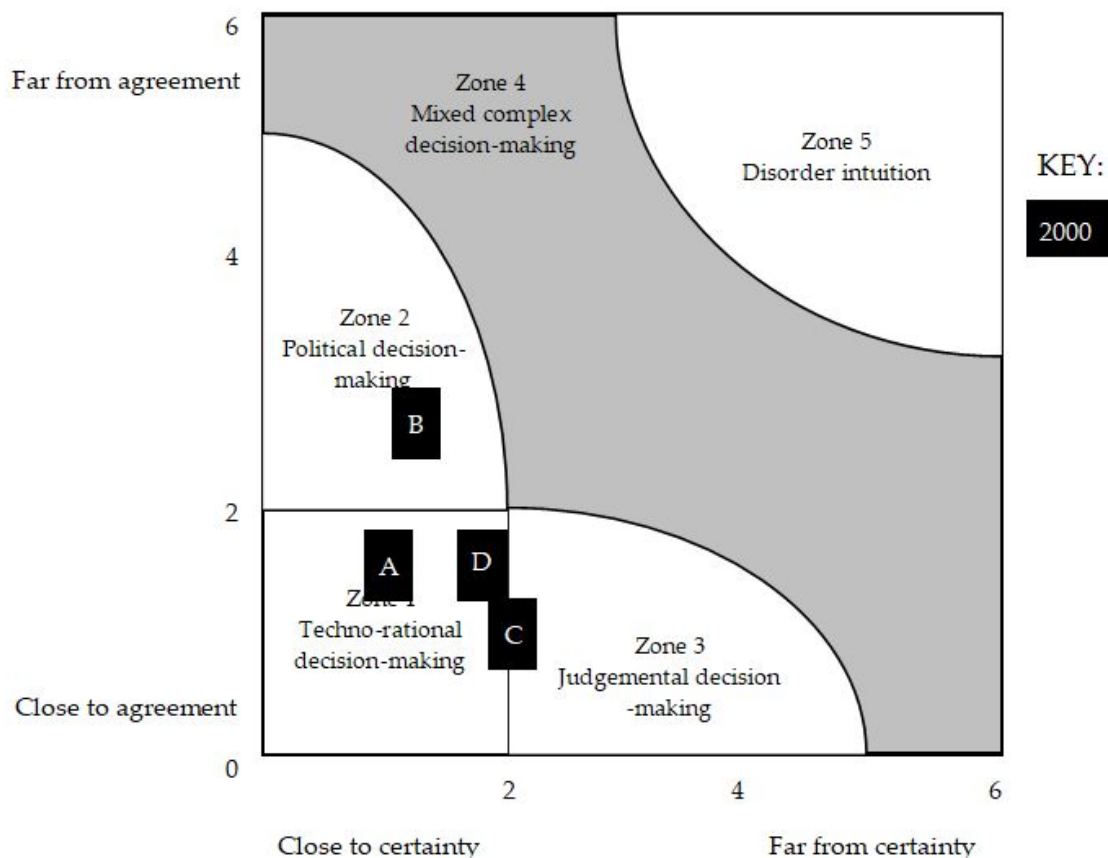


Figure 2: The main zones of EU health policy in 2000

Explanation for scoring/positioning

It was not until the late 1980s and early 1990s that health gained a treaty base, and Aspect A (Treaty base, score 1.0, 1.5) falls in Zone 1 (techno-rational) because the resulting texts carefully constrained the EU's role, limiting it to areas where cooperation was logically necessary (such as cross-border crises) and keeping it out of the more political and divisive issues that characteristic national health policy. Moreover, these developments were driven by functional spill-over from the internal market via the SEA, response to crises (the strengthening of the health mandate in the Amsterdam Treaty, for instance, is understood as a response to the BSE outbreak), and legal interventions by the Courts (Brooks 2012; Greer 2006; [Hervey 2002](#)). These drivers make use of bureaucratized and formalised structures.

Aspect B (legislation, score 1.5, 2.5) falls into Zone 2 (political). Public health legislation was limited primarily to pharmaceuticals and medical devices; uncontroversial, technical regulations which ~~also fed in~~ ~~were linked~~ to key markets. Explicitly market-led legislation – such as that on tobacco and direct-to-consumer-advertising of prescription drugs (DTCA-PD) – saw greater politicisation but still replicated the core positions of member states. In the case of tobacco, EU policy also reflected a growing recognition of the fundamental threat to health of tobacco usage, as well as the growing wave of local, national and international regulation at the time.

Soft law and policy initiatives (Aspect C, score 2.0, 1.3) in this period built on existing informal activities, gathering them within the first framework for EU action on health in 1994. Importantly, these centred on technical, research-related activities, such as cancer, HIV/AIDS and drug addiction, as well as more general health promotion, education and data collection issues. The solutions to these issues were not always clear but they networked clinical and professional actors who were largely agreed on the nature of the issues at stake, placing it on the boundary of Zone 3 (judgemental). The creation of a nascent network on health-related interest groups and a dedicated DG Health and Consumers was representative of the slowly growing need for both technical and political input into the increasingly complex issues being addressed in EU health policy, but also firm agreement about the need for institutional structures to support coordination (Aspect D, score 1.8, 1.5).

EU health policy in 2010: Regulating health and the market

Table 2 presents an overview of the key features of the EU health agenda in 2010, as well as the average score for each aspect, used to plot its position on the Diagram in Figure 3.

Table 2: Four key aspects of EU health policy in 2010 (with combined scores for certainty, agreement)

A. Treaty base (1.0, 1.5)
Nice Treaty and draft constitutional treaty – no change
B. Key secondary law (1.7, 2.1)
Pharmaceutical legislation (orphan drugs, medicinal products, clinical trials etc.)
Directives on tobacco products, tax and sponsorship
General Food Law and nutrition and health claims regulation
Directives on blood, tissues and organs
Services Directive, Working Time Directive
C. Key soft law and policy initiatives (2.3, 1.7)
Health Programme I and II, plus FP7 funding
Council recommendations on cancer screening and patient safety
Council conclusions on common values & principles of EU health systems
Commission initiatives on drugs, smoking cessation etc.
D. Building blocks of the institutional structure (1.4, 1.9)
EU Health Forum, EU Platform diet, physical activity & health, EU Alcohol and Health Forum
Health Security Committee
European Food Safety Authority, European Centre for Disease Prevention and Control

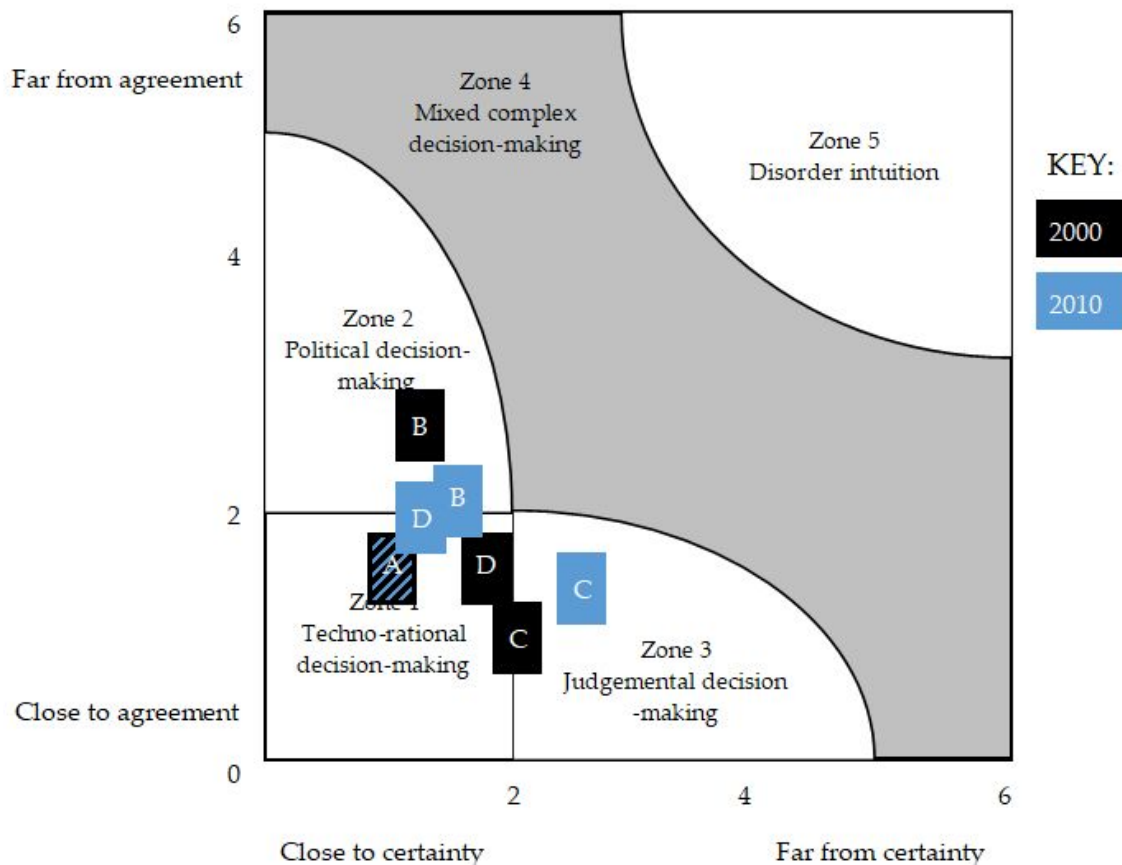


Figure 3: The main zones of EU health policy in 2010

Explanation for scoring/positioning

Little substantive treaty change occurred between 2000 and 2010, hence Aspect A (Treaty base, score 1.0, 1.5) was unchanged, but legislative activity increased considerably on the back of the strengthened mandate provided by the 1997 Amsterdam Treaty. This underpinned a steady stream of public health regulation, supported by the establishment of the EFSA and the ECDC in 2002 and 2005 respectively. The comparatively less political, more certain public health legislation counter-balanced fierce debate in other areas, placing Aspect B (legislation, score 1.7, 2.1) on the edge of Zone 2 (political). For instance, on the market side, health actors became skilled in utilising non-health treaty bases to pursue health objectives (examples include the regulation of tobacco advertising and food labelling). They were also preoccupied with the increasingly apparent threat posed by the application of internal market law to the health sector. A series of Court judgements, dating from the 1990s but reaching a high-water mark in the mid-2000s, had raised fears that the EU's rigorous and liberalising regime of competition and state aid law might be systematically applied to health (Nickless 2002: 78); ~~these manifested in intense battles over the inclusion of health in the Working Time Directive and the Services Directive, for instance.~~

Alongside the hive of legislative activity, the EU's softer public health policy (Aspect C, score 2.3, 1.7) was also growing in recognition and scope. The first EU Health Programme was

adopted for the 2003 to 2008 period, and replaced by another for 2008 to 2013. The placement in Zone 3 (judgemental) reflects the expansion of the health agenda into less tractable issues (health inequalities, health promotion), where multiple solutions exist, particularly given the variety of member state health systems and causality is uncertain, and the beginning of discussions on health systems, a closely guarded area of national competence. This activity was complemented by the founding of European level bodies, such as the EU Health Forum and the Health Security Committee HSC, the latter introducing an element of intergovernmental steering. This moved Aspect D (institutional structure, score 1.4, 1.9) a little further up the political axis, as the need for delegation, external input and member state control continued to grow.

EU health policy at the start of 2020: political oversight of health systems and fiscal sustainability

Table 3 presents an overview of the key features of the EU health agenda in 2020, as well as the average score for each aspect, used to plot its position on the Diagram in Figure 4.

Table 3: Four key aspects of EU health policy at the start of 2020 (with combined scores for certainty, agreement)

A. Treaty base (1.7, 2.2)
Article 168 of the Lisbon Treaty, Charter of Fundamental Rights, Fiscal governance framework
B. Key secondary law (1.9, 2.4)
Tobacco products directive
Pharmaceutical legislation adopted (falsified medicines, clinical trials, medical devices) and withdrawn/pending (information to patients, health technology assessment)
Directive on Patients' rights in cross-border healthcare
Decision on Serious cross border threats to health
Regulation on Food information to consumers
C. Key soft law and policy initiatives (2.8, 2.4)
Health Programme III
Commissions initiatives on smoking cessation, digital care, cancer etc.
Action plans / joint actions eHealth, health workforce, health technology assessment, European Reference Networks, anti-microbial resistance etc.
Council Conclusions modern, responsive & sustainable systems
Commission staff working document on investing in health, Joint Assessment Framework for health, Communication on effective, accessible & resilient health systems
D. Building blocks of the institutional structure (3.0, 2.3)
Expert panel effective ways investing in health
Steering group promotion, prevention & NCDs

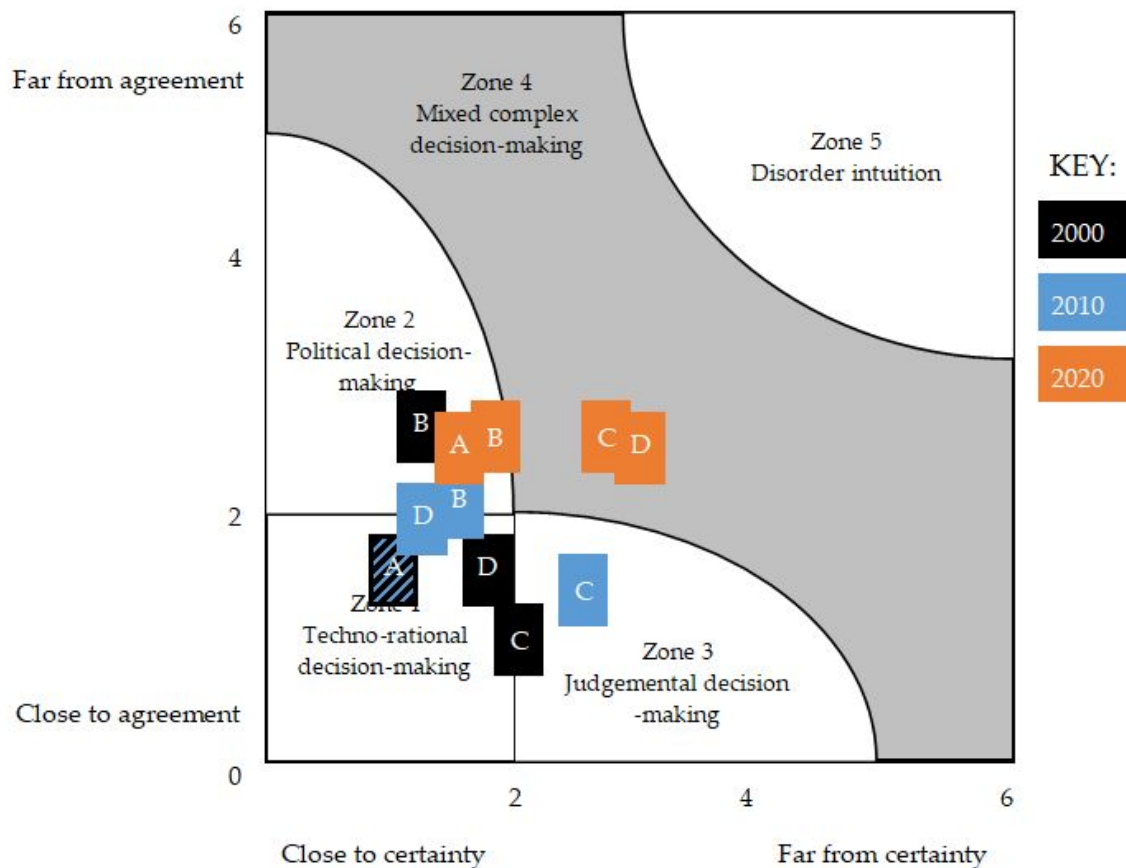


Figure 4: The main zones of EU health policy in 2020

Explanation for scoring/positioning

The end of 2009 sees the entry into force of the Lisbon Treaty and came into force in 2009 the only major change to the health provisions – and thus the only shift in Aspect A (Treaty base) in Figure 2 – in Article 168 TFEU. Like previous iterations, it is not a *health* article, but rather a *public health* article, reflecting member states' concern that the EU focus its attention on population-level measures and be excluded from involvement in health services (Greer et al. 2014: 20). Nevertheless, it expanded and consolidated the EU health mandate (Hervey and McHale 2015), pushing Aspect A (Treaty base, score 1.7, 2.2) into Zone 2 (political).

Aspect B (legislation, score 1.9, 2.4) moves further into Zone 2 (political) as some politically difficult legislative files progress. The Directive on Patients' Rights and the Tobacco Products Directive bring ended fraught and longstanding battles to an end. Meanwhile, functional pressures continue to require legislation on medical devices and clinical trials, and shared risks from H1N1 influenza prompted, in this case, prompt new legislation in the area of health threats. Under the Juncker Presidency, there was considerably less legislative activity (Brooks and Bürgin 2020); the only new initiative – on health technology assessment – remains stuck in the Council at the time of writing, indicative of the politicised nature of health regulation in this period.

Aspect C (soft law and policy, score 2.8, 2.4) shifted squarely into Zone 4 (mixed complex). This reflects both a decline in the traditional areas of public health policy and an increase in the focus on health systems. Meanwhile, reflecting the relevance of the economic governance framework for health during this period, both the Council and the Commission produced a series of politically contentious soft law tools on the topic of health system sustainability and performance, and policy initiatives pivoted to address issues tied to the prevailing jobs and growth agenda of the Commission Presidency (eHealth/digital health, health technology assessment etc.). ~~These areas of greater political disagreement, not least because they were not intended, by the drafters of the treaties, as areas in which the EU should have influence.~~ Aspect D (institutional structure, score 3.0, 2.3) moved into Zone 4 (mixed complex) as bodies are created to tackle some of the more difficult, and politically sensitive, aspects of public health and health systems policy.

EU health policy in the post-Covid~~COVID~~ era: political navigation of uncertain issues?

Table 4 presents an overview of the key features of the EU health agenda as it is likely to be characterised in the post-Covid~~COVID~~ period, as well as the average score for each aspect, used to plot its position on the Diagram in Figure 5.

Table 4: Health Policy in the post-Covid~~COVID~~ period (with combined scores for certainty, agreement)

A. Treaty base (1.7, 2.2)
No change to Article 168 TFEU
B. Key secondary law (1.7, 1.0)
Emergency legislation on entry into force of medical device regulation, clinical trials with GMOs for Covid COVID -19, use of EU Structural Funds for public health emergencies etc.
C. Key soft law and policy initiatives (3.3, 3.0)
Short term agenda on testing, contact tracing & public surveillance (greater ECDC and HSC role), supply of PPE, medicines and devices (Vaccines Strategy and Pharmaceutical Strategy, RescEU, etc.), healthcare surge capacity, non-pharmaceutical measures, support to vulnerable groups, mitigating seasonal influenza.
Broader agenda on health systems strengthening, health inequalities and disease prevention.
D. Building blocks of the institutional structure (2.5, 2.5)
Strengthened roles for ECDC, HSC and Commission

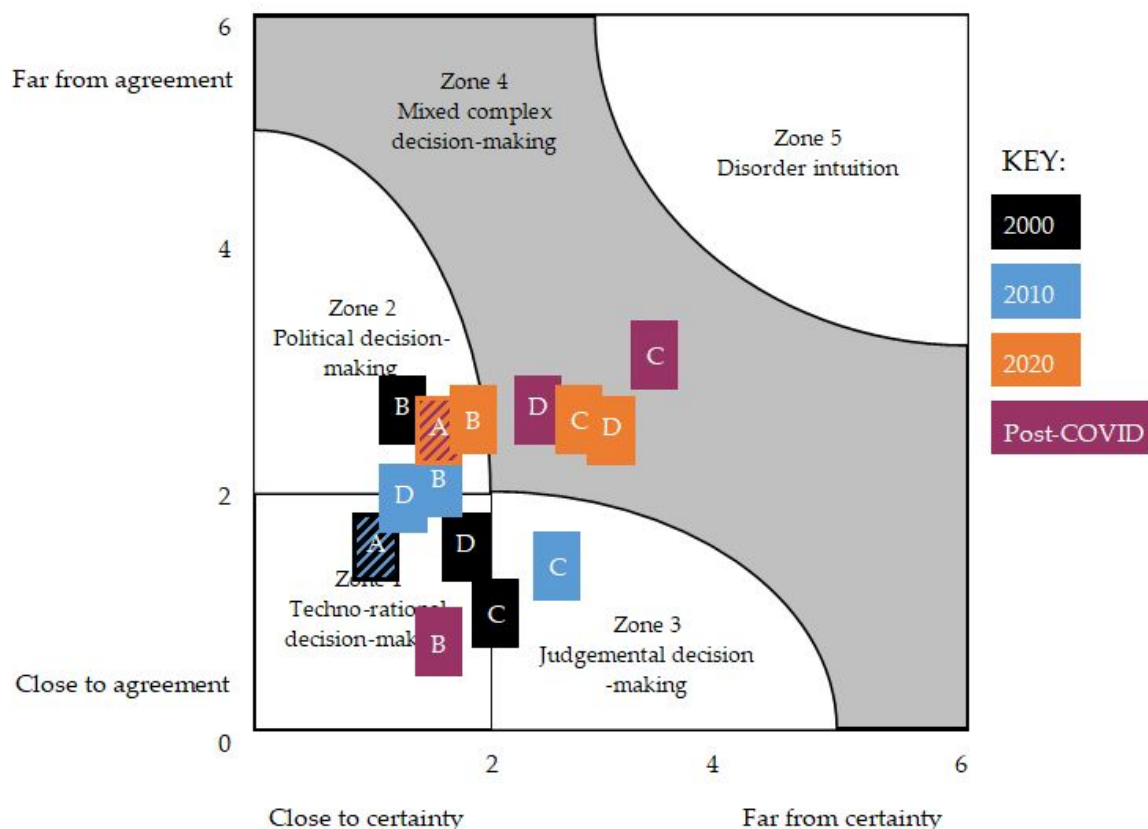


Figure 5: The main zones of health policy likely to be seen in the post-Covid period

Explanation for scoring/positioning

As of August 2020, treaty change has not been forthcoming and Article 168 TFEU looks set to remain without amendment. Similarly, though the documentation to date describes some role expansion for the ECDC, HSC and Commission, ~~this does not~~ is not yet clear whether this will represent a marked change. As such, Aspect A (Treaty base, score 1.7, 2.2) and Aspect D (institutional structure, score 2.5, 2.5) remain roughly where they were. Some benign secondary law (Aspect B, score 1.7, 1.0) was rapidly adopted in the early weeks and months of the crisis – delaying the implementation date of the new medical device regulations, for instance – but it is not clear which, if any, of the other priorities will require legislation. This is the aspect most subject to change as the agenda develops but, for now, it rests in Zone 1 (techno-rational).

The majority of action, both underway and planned, falls under soft law and policy initiatives (Aspect C, score 3.3, 3.0). Here, EU action on health is set to venture into greater uncertainty and disagreement. Support for testing, contact tracing and public surveillance will fall primarily to the ECDC but the HSC, an intergovernmental body, looks set to play a greater role. Mechanisms for public procurement and stockpiling might be simple enough to design, but issues of allocation and distribution have long hampered attempts to take collective action. The Pharmaceutical Strategy will seek to address issues around the production and supply chains of key medicines, ~~looking at how best to ensure secure supply chains and incentivise~~

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3 ~~the production of pharmaceuticals within the EU, issues with no clear solution and where~~
4 ~~this public good will confront large and politically~~ powerful industries ~~are core stakeholders.~~
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6 Evidence on the effectiveness of non-pharmaceutical interventions, another area where the
7 ECDC, Joint Research Centre and Commission will seek to offer guidance, is still emerging.
8 ~~Efforts to coordinate national border closures and other restrictions failed in the initial weeks~~
9 ~~of the COVID-19 crisis and rest largely on the goodwill of governments. Finally~~ ~~†~~
10 ~~The broader~~
11 ~~EU agenda, in which the EU will seek~~ to support the strengthening of health systems,
12 ~~vulnerable groups, the reduction of health inequalities~~ and ~~the~~ wider promotion of health,
13 contains some of the least certain – largely because of the vagueness of the objectives – ~~agenda~~
14 ~~proposals~~ ~~oints~~ of all. Many of these have been on the EU's health agenda for decades and
15 would be sensitive, politicised issues if tangible measures were adopted, but the complexity
16 of the problems involved has traditionally seen them addressed via small, soft instruments.
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20 From 2000 to the post-CovidCOVID period: the shift to complex decision-making
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22 Finally, collating the scores across all four aspects for each time period, we can trace the broad
23 movement of the EU health policy agenda (Figure 6). The average scores are as follows:
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25	2000 (1.6, 2.0)	2010 (1.8, 1.9)
26	2020 (2.4, 2.4)	Post-CovidCOVID (2.8, 2.5)

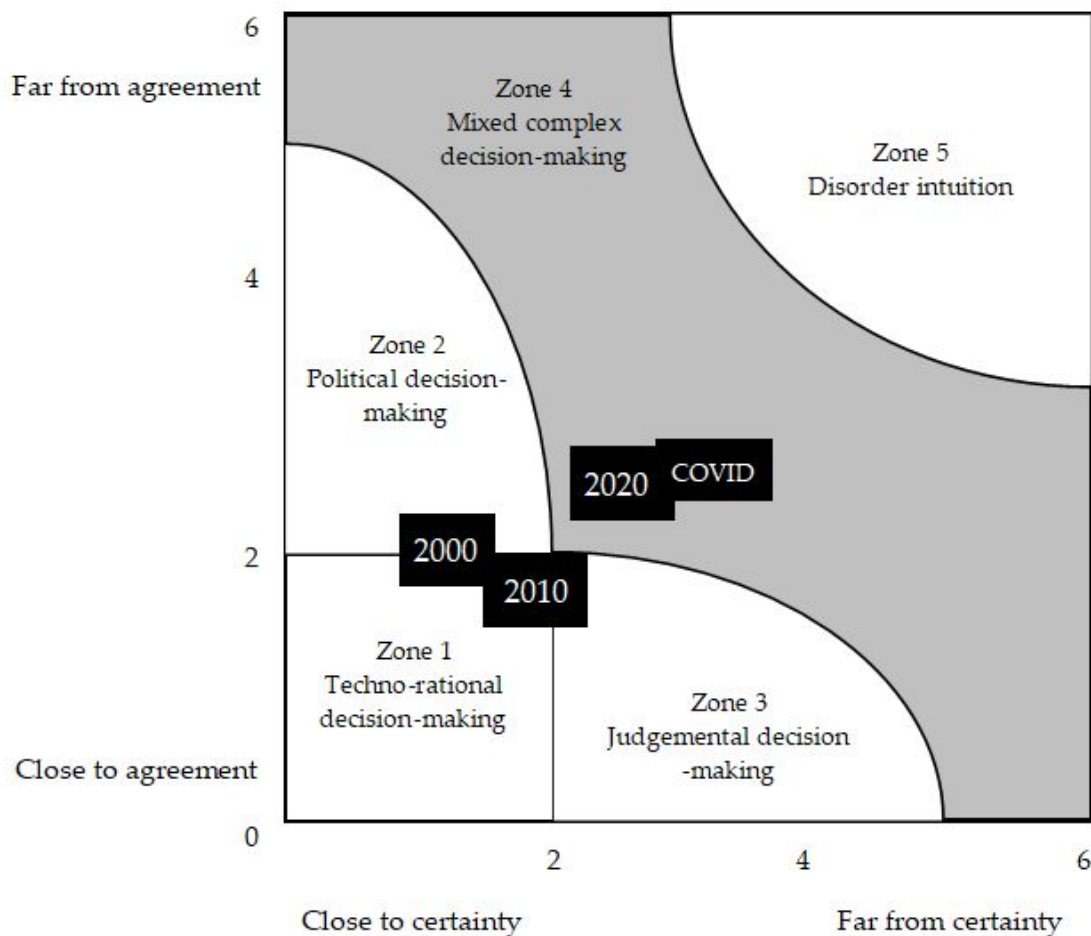


Figure 6: The main zones of health policy decision-making from 2000 to the post-Covid period

Fundamentally, Figure 6 shows us that the impact of Covid-19 upon the EU's health policy agenda is likely to be an outward shift, deeper into the zone of mixed, complex decision-making. This trend had already started by 2020, as both the tractability and consensus of EU health policy had begun to decline and all four aspects of the agenda had moved into the political range (i.e. above a score of 2). In the post-Covid period, much looks set to stay the same, in that the legal base will likely be unchanged and the EU will continue to legislate in the techno-rational areas where it can support development of a vaccine and maintenance of supplies to health systems. However, the certainty around its softer interventions – where it will seek to support the fight against Covid-19 and recovery in its aftermath – has declined considerably.

This outwards shift might be interpreted as a sign of policy maturity. The EU's health policy was never solely technocratic but it has steadily gained in value, salience and influence such that it is now engaged in tackling the 'wicked problems' facing its members' health systems and in pushing for common approaches and European norms where they have not previously existed. By this interpretation, member state resistance is not a bad thing. Constant balancing between the constituent parts of a system is a sign of a healthy, adaptive and evolving complex system. Hence, the EU will need to continually show why and how it is helping to create better

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3 outcomes and its 'added value' as a health actor, in order to remain trusted and to maintain
4 support for its newly-gained roles. Despite being seen as a weakness by some, from a
5 Complexity perspective, this continual balancing and justification process may be one of the
6 strongest attributes of EU policy making.
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10 11 CONCLUSION

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13 Our aim in this article was to go beyond a review of the new elements of EU health policy and
14 ~~to~~ visualise its development over time. We recognise the limits of this endeavour. ~~Others will~~
15 ~~almost certainly disagree with our scoring and positioning of the agendas, and~~ The scoring
16 and positioning of agendas involves judgement calls, which means that there is ~~clear~~ room for
17 strengthening of the analysis ~~by increasing both the detail considered and the involvement of~~
18 ~~other experts, practitioners and health actors in the data generation.~~ We offer our findings as
19 a starting point, hopeful of engagement, debate and further development of the project.
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23 Notwithstanding their limitations, the findings present interesting patterns and a clear
24 movement from the simpler zones, where EU health policy ~~rested in its earlier existence~~ began,
25 to the more complex and contested zones. Since we conducted our main analysis, the
26 Commission has announced that, in November 2020, it will publish a package of measures
27 that will form the 'building blocks for a European Health Union' and strengthen the EU's
28 health security framework (European Commission 2020e). This will include extensions to the
29 mandates of the ECDC and the European Medicines Agency (EMA) and the creation of a new
30 agency, based on the US Biomedical Advanced Research and Development Authority
31 (BARDA), as well as a new legal framework for cross-border health threats. Furthermore, the
32 Council of the EU has expressed its commitment to taking 'a coordinating, proactive and
33 leading role' in the strengthening of global health security and the World Health Organization
34 (WHO) (Council of the EU 2020). Thus, it seems likely that the European Commission will
35 seek to repeat its 'traditional' reaction to public health crises: creating and strengthening
36 technocratic agencies, and carefully laying the groundwork for potential expansion of its areas
37 of activity, whilst avoiding formal treaty change. Member states, meanwhile, may yet dampen
38 some of this ambition, potentially identifying the WHO as an alternative, and less
39 'supranational', venue within which to respond to the weaknesses highlighted by Covid-19.
40 Change will be incremental, integrative and carefully circumscribed by national governments
41 and financial constraints.
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49 Where EU health policy expands – vaccines and other medicines, preparedness and
50 emergency planning, and health systems strengthening, for example – As such, considerable
51 challenges lie ahead. Whilst, as noted above, ~~this such expansion~~ is a sign of a policy area
52 reaching maturity, ~~these issue areas are increasingly contested and politically sensitive.~~
53 Success ~~success in more contested and political policy zones~~ thus requires new decision-
54 making ~~skills, and both~~ greater responsibility and more political skill/subtlety. A strengthened
55 and centralised mechanism for procurement of vaccines and other medical countermeasures,
56 to take just one example, will engage the EU in sensitive debates about equitable distribution,
57 technical assessments of clinical added value, negotiation of potential contracts, and all while
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3 balancing the legitimate demands of national governments, the pharmaceutical industry and
4 patients/citizens. Evidence-based thinking and judgement-orientated processes, such as
5 academic debates and forums, may not work here; the recent experience of the UK during
6 Brexit, which saw the then Justice Secretary, Michael Gove, declare that Britain has ‘had
7 enough of experts’, offers a reminder of the potential for political backlash (Mance 2016).
8 Moreover, the trend revealed by the findings is that EU health policy is still developing and
9 that recent developments, amplified by the COVID-19 pandemic, demonstrate that EU health
10 policy is now becoming a more fully developed policy area, and one that is having a major
11 impact on European health policy and outcomes. ThisAs such, and whilst the changes afoot
12 mark-is a major development for EU health policy, but not an end point. In many ways, the
13 difficult part is only just beginning. ; m
14 Maintaining support for the expansion of EU health
15 policy while it moves into much more contested and complex political terrain, in the midst of
16 recovery from a global pandemic, is the challenge now facing the EU’s health actors. How
17 they, the member states and European society respond will be central to the where a post-
18 CovidCOVID EU health policy goes from here.
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For Peer Review Only

Response to referees – manuscript GEUI-2020-0174

Dear Professor Juncos,

Many thanks for your consideration of our article – *The development of EU health policy and the Covid-19 pandemic: Trends and implications* – submitted as part of the upcoming special issue on the coronavirus pandemic. The referee comments that we received were somewhat contradictory; the first raises several concerns, whereas the second concludes that ‘in terms of substance this article is fine as is – just needs to be shortened’. However, we found most of referee 1’s comments to be fair and constructive and, as such, have engaged in a full revision of the paper, using these comments as a starting point.

The referees offered a helpful combination of specific suggestions and broader reflections on the paper’s approach. On the latter, we agree with referee 1 that our explanation of what the Complexity perspective could add to the analysis of this case study needed strengthening, and that the coherence of the first and second parts of the paper could be improved. We also thank the referee for highlighting the difficulties with the core narrative of the paper, which focused on the *window of opportunity*. Re-reading our work, we can see this was a ‘hang over’ from the political context which existed when we started writing – to a great or lesser degree, most of the questions raised by the window of opportunity framing have since been answered and, through the various iterations of the paper, it was confusing our argument. As such, we have focused our revision of the paper on these points, elaborating our justification for using a Complexity approach, and re-structuring the narrative so that it no longer focuses on the potential window of opportunity, but rather on the concrete changes afoot.

Both referees also pointed to weaknesses in the conclusions of the paper, and their relationship to the earlier analysis. In light of our main revisions, we have rewritten the conclusion to offer a more direct consideration of the paper’s findings. The additional space needed to accommodate these changes (and to reduce the already lengthy word count) has been provided by condensing and re-writing the empirical section of the paper, to focus more narrowly on the proposed policy change. A more detailed account of how this has been done, and how the more specific comments have been addressed, can be found in the table overleaf.

Thank you again for the opportunity to resubmit, and to the referees for their helpful comments. We believe that this new version has been substantially improved as a result and hope that it will meet the approval of the editors and referees of the Journal of European Integration.

11 November 2020

Table of referee comments and author response

NB comments which feed into one another have been grouped together and thus don't always reflect the order in which they were presented in the original referee report. All page references are to the track-changed version of the text.

Referee 1 comments	Author response
<p>The paper needs to be more coherent, with stronger justification for the use of the Complexity perspective and its relevance to COVID-19. On the latter, suggest in particular that the relevance of Complexity's challenge to EBPM and NPM thinking is clarified.</p>	<p>We agree with and appreciate this point. We have focused our revision on ensuring that the relevance of a Complexity approach is more clearly stated (see, in particular, changes on page 10-11) and that the framework that Complexity offers is utilised throughout the paper (see additions to introduction, highlighting the focus on the complex nature of decision-making (page 2-3), and amendments throughout the empirical section, highlighting the varying complexity of particular policy issues and decision-making processes (page 5-6)). The way in which Complexity challenges EBPM and NPM models is clarified on page 11.</p>
<p>The conclusion flows from the second part but does not return to the first part of the paper, further reducing coherence.</p>	<p>Both referees rightly highlighted the conclusion as a particular area of weakness. This section has been completely rewritten (page 26).</p>
<p>On the empirical material in the first half of the paper, there is a need for updating. The referee also suggests that some of this section is 'speculation', perhaps referring to the assumption that the policy change documented is a response to COVID-19.</p>	<p>There was, of course, always a risk of rapid dating of material in the paper and, as the referee notes, much of the policy change documented was (and continues to be) in motion. The empirical sections have been updated as far as possible, noting that both the budget and the new Health Programme have yet to be formally adopted (pages 3-6).</p> <p>On the assumptions underlying the paper – referee 1 is right to note that we assume the changes documented to be a response to COVID-19. The preambles and statements which accompany the health policy initiatives that we review/include in the empirical section all make reference to COVID-19; indeed the EU4Health Programme marks a reversal of fortunes for health, which was due to be subsumed into other frameworks. We have sought to clarify and reiterate this point in the text (page 5). We have also clarified that, whilst we draw our analysis of what changes are likely to be seen over the coming months from the documentation, we cannot be certain which of the proposals will eventually be adopted or in what precise form.</p>
<p>The role of DG SANCO (in addition to the CPM and the ECDC) is not discussed in the paper (page 21)</p>	<p>We have reframed the account of the two governance frameworks which facilitate the EU's role in crisis response, which has altered the context in which this comment is made, but nonetheless added a footnote to clarify the role of DG Santé (page 4).</p>

1 2 3 4 5 6 7 8 9 10	The paper claims that the ECDC had a 'good crisis' but referee 1 disagrees with this assessment, stating that ECDC's reports were generic and did not play a role in decision-making at the national level (page 22)	Again, this point has been subsumed as part of the revisions but we have reiterated our assertion that these institutions performed as well as could be expected, within the parameters of their mandates and resources, and the dominant role of national governments in health policy and crisis response (pages 1; 4).
11 12 13	The HSC is mentioned but its relationship to the other institutions not elaborated.	This is a helpful point – the HSC's basis in the Health Threats Decision is now elaborated (page 4).
14 15 16 17 18 19 20 21	There is a contradiction between the claim that a window of opportunity was missed, and that we are seeing significant steps forward in integration (page 23)	This is an important point and speaks to the broader argument that the paper makes, which we have reviewed in light of the comments made. As noted in the cover letter above, we have completely overhauled the 'window of opportunity' narrative, and appreciate the referee's careful explanation of where the weaknesses in this lay.
22 23 24 25 26 27 28 29 30	The future role of the ECDC needs to be clarified (page 24)	The referee suggests that the paper implies a role for the ECDC in managing mass gatherings. We have reviewed the language, however, and it states that the ECDC will have a role in <i>producing guidance</i> on the management of such events, not in managing them directly. As such, we have not made an alteration here, but defer to the editors and can amend if they feel that our phrasing is unclear (page 6).
31	Referee 2 comments	Author response
32 33 34 35 36 37 38	The conclusions are a bit vague – suggest to highlight the conditions under which we might expect transfer of (what part of) health policy to the EU level, drawing on analysis. Be more explicit about findings of the paper.	Both referees rightly highlighted the conclusion as a particular area of weakness. This section has been completely rewritten (page 26).
39 40 41 42 43 44 45 46 47 48 49 50 51 52	Consider re-phrasing the caveat in the conclusion to something more neutral (specific suggestion made in review).	We thank the referee for the suggested text here and have borrowed some of this, whilst significantly paring back the caveat, as suggested.
53 54 55 56 57 58 59 60	Paper is too long – suggest some graphs to online appendix & check of graph word-count.	We note the word count and did ask the Journal editors for guidance here when we originally submitted (perhaps our original cover letter was mislaid somewhere in the process). Our strong preference is to keep the tables and graphs within the text if possible, since they don't simply support the analysis, they are the focus of its discussion. We have reduced the word count by ~400 words to this end but defer to the editors judgement on the necessity of an online appendix.
	References not in JEI house style.	Our understanding from the website is that JEI now accepts format-free submission. We are, of course, happy to adapt the references to house style post-acceptance, as per the instructions for authors.