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Why Did a Weaker Centre Deliver More Coordinated Vaccine Outcomes?

A Comparative Analysis of COVID-19 Vaccine Procurement and Rollout in the European Union and the United States

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Introduction

The COVID-19 pandemic represented an unprecedented global shock, simultaneously disrupting public health systems, economic structures, and political governance across the world.

Beyond its immediate epidemiological impact, the crisis exposed the institutional mechanisms through which political systems organize collective action under conditions of uncertainty, particularly in compound polities where authority is distributed across multiple levels of government.

In such contexts, crisis management depends not only on available resources or formal competences, but on the ways in which responsibilities are allocated and coordination is achieved among actors operating within the same governance framework.

Traditional theories of federalism have long associated stronger central authority with greater effectiveness in responding to systemic crises, emphasizing the advantages of centralized coordination, fiscal capacity, and policy coherence.

However, more recent contributions challenge this assumption by highlighting how institutional configurations shape strategic behavior.

The COVID-19 crisis offers a valuable empirical setting in which these dynamics can be observed.

As an exogenous and symmetric shock affecting different governance systems simultaneously, it brought to the surface structural features that are often less visible in routine policymaking, revealing how institutional arrangements translate into distinct patterns of interaction among political actors.

This thesis investigates the governance of the COVID-19 pandemic through a comparative analysis of the European Union and the United States, using vaccine procurement and rollout strategies as a critical empirical lens through which to assess coordination and crisis governance.

It starts from a central puzzle: why did the European Union, often described as an incomplete and institutionally weak polity, manage to deliver a relatively coordinated and cohesive response in vaccine strategy, while the United States, endowed with stronger federal powers and greater fiscal capacity, experienced higher levels of fragmentation and political conflict?

Addressing this question requires moving beyond conventional assumptions about institutional strength and effectiveness and instead examining how different governance architectures shape the behavior of political actors under conditions of crisis.

The analysis is grounded in the theoretical framework of fiscal federalism and, more specifically, in the reinterpretation of Hamilton’s Paradox, extended through the Alexander-Shaw argument.

From this perspective, political outcomes are shaped not solely by the formal allocation of competences, but by the incentive structures embedded within different systems of governance, which influence whether actors respond to crisis through competition or coordination.

This framework allows the thesis to explain how different configurations of central authority generate distinct patterns of intergovernmental behavior in times of crisis.

The pandemic thus serves as a critical test of these theoretical expectations.

The divergent trajectories of the European Union and the United States cannot be fully explained by differences in administrative capacity or resource endowment alone but reflect deeper structural dynamics related to the organization of authority and interdependence within each system.

Against this backdrop, the thesis adopts a comparative framework, based on a qualitative comparative case study approach. It analyzes institutional structures and policy responses through official documents, policy outputs, and secondary literature, linking institutional design to crisis outcomes, focusing on how different configurations of central authority and intergovernmental relations shape coordination, policy coherence, and political cohesion.

In doing so, the thesis contributes to the development of the Alexander-Shaw paradigm by demonstrating that the paradoxical relationship between central weakness and effective coordination extends beyond fiscal governance to the domain of pandemic crisis management, particularly in the area of vaccine procurement and rollout.

Through an in-depth analysis of vaccine procurement and rollout, the study shows that the European Union's relatively limited central authority, combined with high levels of interdependence among member states, generated incentives for collective action and contributed to a more unified response.

By contrast, the stronger and more politically contested federal center of the United States contributed to fragmented decision-making and uneven policy implementation.

This thesis is structured as follows.

Chapter One examines the institutional frameworks of the European Union and the United States, outlining their legal, political, and organizational features in order to highlight the key structural differences that shape their respective approaches to crisis governance.

Chapter Two provides the empirical and contextual background, analyzing the nature, diffusion, and global impact of the COVID-19 pandemic.

Chapter Three presents the core comparative analysis of vaccine procurement and rollout strategies in the European Union and the United States, showing how their institutional configurations influenced coordination, policy implementation, and overall outcomes.

The conclusion then draws together the findings, reflecting on their theoretical implications for the Alexander-Shaw paradigm and discussing their broader relevance for understanding how different governance systems respond to complex transnational crises.

1. EU and US Institutional Framework

A comparative analysis of EU and US vaccine strategies requires first situating both actors within their respective institutional architectures, as this focus will allow to understand the countermeasures implemented, why EU and US behaved in the way they did and the unprecedented outcome of Covid-19, with the vaccine strategy mirroring the paradox that emerged during the pandemic.

These two actors differ significantly, from a political and legal perspective, which inevitably shape both their economic and healthcare systems. The United States of America is a Federal Constitutional Republic with a presidential system, where power is divided between the Central Government and the 50 Constituent States (GlobalEDGE, 2025), while the European Union cannot be considered as a federal state, or even a state. It is a political entity created through treaties ratified by the sovereign European States. It is a blend of the supranational and intergovernmental system (Simms, 2017).

Moreover, the analysis of the institutional frameworks of the European Union and the United States is crucial to understand the paradox on which this thesis is grounded: the disease constituted a stress-test for the EU and US, resulting in the former being able to coordinate member states' vaccine procurement and rollout and promote political cohesion, while the latter discovered its fragility, turning into a chaotic system, unable to enforce a fractured policy, marred by fractious state-federal relations, unable to overcome partisan polarization to face together the disease, resulting in enhancing the divisions and uneven public uptake (Rossen et al., 2022).

This empirical paradox reflects dynamics that were theoretically anticipated by Hamilton's Paradox, which captures a core intertemporal dilemma of fiscal federalism whereby the credibility of central government intervention shapes national behavior in crisis conditions.

Indeed, when the federal center is fiscally strong and politically capable of ex post intervention, national governments anticipate rescue and therefore face softened budget constraints, which incentivize strategic overspending, rent-seeking, and intensified horizontal rivalry for central transfers (Rodden, 2005).

Conversely, when the center lacks either fiscal capacity or political authority to provide credible bailouts, national governments internalize the full costs of fiscal distress, leading to harder budget constraints, greater fiscal adjustment, and, in crisis contexts, enhanced coordination and cooperation among sub-units as they seek collective solutions in the absence of a central backstop.

Thus, counterintuitively, central weakness may promote discipline and cooperative behavior, while central strength can exacerbate moral hazard and intergovernmental conflict, because the structure

and perceived credibility of central authority shape collective behavior under conditions of uncertainty (Rodden, 2005).

Additionally, the paradox challenged traditional federalist theories, which stated that federalism is a system especially resilient in times of crises (Elazar, 1976), while the European Union was considered an incomplete system.

The pre-pandemic federalist theories were strengthened also by the Global Health Security Index, which in 2019 declared the US as the best prepared country to face a pandemic, thanks to its huge resources and abilities (Global Health Security Index, 2021).

Nonetheless, the expectations built on traditional assumptions were completely overturned by the disease, because the COVID-19 crisis revealed the structural dynamics predicted by the Hamiltonian credibility dilemma, as it highlighted both the weaknesses of a strong-centered federation and the surprising resilience of EU (Alexander-Shaw, Ganderson and Schelke, 2023), showing that central governments faced persistent credibility problems in committing to subnational support, an issue that fostered competition rather than cooperation in decentralized systems (Rodden, 2006).

The COVID-19 pandemic provides an empirical setting in which these theoretical dynamics extend beyond fiscal stabilization to the broader domain of crisis governance, demonstrating that a relatively weak fiscal center such as the EU can, under specific institutional incentives, elicit cooperative behavior from member states and effectively manage a collective descent into crisis, advancing a broader institutional insight: systems characterized by structurally weak central authority may, under crisis conditions, generate stronger cooperative incentives than formally stronger federations (Alexander-Shaw, Ganderson and Schelke, 2023).

This was evident in the creation of the NextGenerationEU recovery instrument, which can be depicted as a Hamiltonian moment of collective debt and fiscal solidarity (Woźniakowski, 2023).

By contrast, the U.S. federal system, despite its stronger formal fiscal powers, experienced institutional and political obstacles that complicated a unified national response, illustrating the paradoxical effects of different fiscal federalism architectures on pandemic crisis management (López-Santana and Rocco, 2021).

These insights are particularly relevant in examining the COVID-19 vaccine procurement and rollout, where the EU's centralized approach contrasted sharply with the U.S.'s decentralized federal system.

Against this theoretical and empirical backdrop, the analysis turns to the institutional frameworks of the European Union and the United States, as these emerged as key factors in shaping Covid-19 outcomes.

European Union Institutional Framework

The European Union is a political entity created and grounded in treaties ratified by the sovereign European States. These are primarily the Treaty on European Union, signed in 1992 in Maastricht (European Parliament, 1992), complemented by the Treaty on Functioning of the European Union, signed in Lisbon in 2009 (European Commission, 2020), which clearly defined the field of competences of the European Institutions and their limits, establishing that some of the decision-making powers of the member states are delegated to the Central Institutions (Eurostat, n.d.). It is a blend between the supranational and intergovernmental system (Simms, 2017).

This means that EU countries have delegated certain powers and responsibilities to the EU institutions (EU Commission, EU Parliament, EU Council, Council of the European Union, European Central Bank, among others) even though this pooling of powers remained subjected to member states 'consensus, which constitutes a significant limitation, as the states preserve control over Treaty changes and the possibility to withdraw from the EU, as happened in 2020 with the United Kingdom.

The EU represents an unprecedented experiment in balancing national and collective interests (Council on Foreign Relations, 2023).

To exercise the competences conferred by the Treaties, the European Union relies on a complex institutional framework designed to balance supranational decision-making with the interests of the member states. The EU institutional system is composed of several key bodies, each with distinct roles and responsibilities in the legislative, executive, and judicial processes. Together, these institutions ensure the formulation, implementation, and enforcement of EU policies, while respecting the principle of conferral, according to which the Union may act only within the limits of the competences granted by the Treaties. Their interaction reflects a system of shared governance, in which authority is distributed among EU institutions and national governments rather than centralized in a single body.

Digging deep into the institutional system, currently there are 7 European institutions, 9 EU bodies, and over 30 decentralized agencies (European Union, 2026).

However, not all these entities played a significant role in facing Covid-19 crisis or had to deal with vaccine procurement and rollout. The authorities that influenced the outcome were the EU Commission, the EU Parliament, the EU Council, the Council of the European Union, the EU Central Bank (ECB), the European Centre for Disease Prevention and Control (ECDC), and the European Medicines Agency (EMA).

It is imperative to dissect the mandates, competences, and functions of each of these institutions within the EU institutional framework, to understand their effective role in times of crises.

The EU Institutional Framework: The European Parliament

The European Parliament is structured as a multilevel and internally differentiated institution, developed to merge political representation, legislative efficiency, and oversight capacity. It is the principal representative institution of the European Union, exercising legislative, budgetary, and supervisory duties.

This institution is composed of the Members of the European Parliament (MEPs), who are directly elected in their own member states. MEPs currently are 720; they aren't organized in national delegations, but in transnational groups reflecting their political ideologies, mirroring Parliament's supranational nature (Hix and Høyland, 2011).

The EU Parliament organized its work around permanent committees, each one specialized in a well-defined policy area.

The MEPs elect a President, entitled to represent the Parliament externally and guarantee the regular conduct of parliamentary work, assisted by a Bureau which covers financial and administrative aspects. This system allows the institution to play a key role in drafting reports, propose amendments, and scrutinize the European Commission, constituting the core engines of the legislative activity (Corbett, Jacobs and Neville, 2016).

Thanks to this structure, the Parliament derives its legitimacy straight from the universal suffrage, as MEPs are directly elected by citizens. Overall, the Parliament's internal organization reflects an institutional design aimed at balancing democratic representation with functional specialization within the EU's complex governance system.

Moreover, the EU Parliament plays a key role in the European legislative system, as it participates as a co-legislator in the ordinary legislative procedure, alongside the Council of the European Union.

Together, these two institutions examine, amend, and adopt legislative proposals drafted and submitted by the European Commission, as established by Article 289 and Article 294 TFEU (European Union, 2012).

Indeed, Parliament has the power to propose amendments at multiple stages of the legal procedure, approve or reject legislation. This institution is also involved in special legislative procedures, covering a consultative role (European Union, 2012).

These legislative powers have transformed the Parliament from a marginal consultative body into a central actor in EU law-making, enhancing democratic legitimacy while embedding legislative authority within a system of interinstitutional balance (Hix and Høyland, 2011; Craig and de Búrca, 2021).

Other than their legislative competences, the EU Parliament and the Council exercises budgetary authority, examining, eventually amending, approving or rejecting the draft of the annual EU budget proposal submitted by the EU Commission, with the Parliament entitled of doing the same also over non-compulsory expenditures (Craig and de Búrca, 2021).

Moreover, the Union lacked a general capacity to borrow on capital markets for macroeconomic stabilization purposes: borrowing was legally limited to specific back-to-back lending instruments, such as balance-of-payments assistance or financial support mechanisms, rather than discretionary fiscal expansion (European Union, 2016; De Grauwe, 2012). Expenditure was organized under the Multiannual Financial Framework (MFF), approved by the Parliament, the Council and the EU Council, having as a purpose to fix spending ceilings for seven-year periods and constrain rapid fiscal reallocation (European Council, 2013).

Beyond budget adoption, the Parliament exercises ex post financial oversight through the discharge procedure, by which it evaluates the Commission's implementation of the budget based on reports from the European Court of Auditors and may approve, postpone, or refuse discharge (European Union, 2012).

Additionally, the Parliament controls the activities of the Commission, carrying out this duty through hearings, parliamentary questions, and committee work, having the possibility of endorsing the nomination of the Commission and eventually obliging its resignation by means of a censure.

The EU Institutional Framework: The Council of the European Union

Moving on, the Council of the European Union is organized as a multi-layered intergovernmental body, conceived to merge national executives into European processes, and carries out legislative, budgetary, policy-coordination, and external action roles through negotiation and enforcement of EU laws, but also by reaching international agreement and organizing national policies (European Union, n.d.; Simoncini, 2025).

This institution entrenches the intergovernmental dimension of decision-making within the EU's architecture, as it is formed by the government ministers from each member state.

The presidency of the Council is organized in a rotating system, under which each member state presides over Council meetings for a six-month period, except for the assembly involving foreign affairs, as these are chaired by the High Representative for Foreign Affairs and Security Policy (European Union, n.d.).

At the political level, the Council meets in various configurations depending on the policy area under discussion, bringing together the relevant national ministers from each member state. This system allows the ministers with relevant portfolios to participate directly in policy formulation and decision-making (European Union, n.d.; van den Brink, 2023).

Decision-making within the Council is governed by a mix of qualified majority voting, unanimity, and simple majority rules, depending on the legal basis and policy area, which balances collective action with protection of sensitive national interests (European Union, n.d.).

The Council operates in the limits imposed by the Treaties, which established its field of competence as a mix of exclusive and shared jurisdictions.

The Council is also responsible for adopting measures in areas where member states have granted exclusive power to the Union, reinforcing the supranational elements of the EU system (Craig and de Búrca, 2021)

In these areas, the Council acts as a co-legislator with the European Parliament by sharing competences in domains such as the internal market, customs unions, environment, consumer protection, energy, transport, economic, social, and territorial cohesion (European Union, 2008). In these domains, both the Council and Parliament must approve legislative acts drafted by the Commission, ensuring a balance of power between national governments and the Union's representative body (Fabbrini F., 2015).

The Council also retains coordination responsibilities in policy areas such as economic governance and employment (European Union, 2008), which complement the Commission's work and ensure that EU decisions reflect the interests of member states. However, it is in these shared policy areas that intergovernmental elements still play a strong role, as the Council is the main decision-making body in the areas of foreign policy and security policy (European Union, 1997), where decisions often require unanimity among member states, reinforcing national sovereignty (Scharpf, 2021).

As it is designed, the preparatory and technical work of the Council is executed by the Committee of Permanente Representatives (COREPER), formed by member states ambassadors to the EU and their

deputies, entitled to play a coordinating and agenda-setting role, fulfilled by filtering, negotiating, and preparing materials before ministerial assemblies (Corbett, Jacobs and Neville, 2016).

Furthermore, behind COREPER there is a broad system of qualified working parties and committees, composed of national officials and experts who carry out policy negotiations and draft compromise texts.

The EU Institutional Framework: The European Council

Digging inside the European institutional framework, the European Council covers a peculiar position, as it is formed by the head of state or government of the member states and the President and it is responsible for defining the overall political direction and priorities of the Union, without any legislative function.

Other than head of states or government, even the President of the EU Commission and the High Representative for Foreign Affairs and Security Policy are part of this institution, while the President of the Council is elected every two and a half years, being responsible for representing the Union during foreign affairs meetings (European Union, 2012).

The role covered by the EU Council changed significantly following the enforcement of the Treaty of Lisbon, as it evolved from being a merely informal summit into a formal EU institution, responsible for setting strategic agendas and resolving complex or sensitive issues through its leadership during difficult periods, without engaging directly in the EU law making (European Union, 2012).

While the European Council does not legislate, its decisions often influence the direction of legislative and policy outcomes by providing mandates for action to the European Commission and Council of the European Union, contributing to shaping EU policy development (Dawson, 2024).

Moreover, the EU Council conditioned the European attitude to external relations, trade agreements, and diplomatic actions, particularly in sensitive areas like sanctions and defense policy.

The EU Institutional Framework: The European Medicines Agency

Among the institutions that covered an important role during the Covid-19 crisis, there is the European Medicines Agency (EMA). It is a decentralized agency of the European Union responsible for the scientific evaluation, supervision, and safety monitoring of medicines across the EU.

The EMA administers the centralized marketing authorization procedure, thanks to the legal framework enshrined by Regulation (EC) No 726/2004, enabling specific categories of medicinal products, particularly innovative and biotechnology-based medicines, to obtain a single authorization valid in all member states (European Union, 2004; European Medicines Agency, n.d.)

This agency is structured around scientific committees, notably the Committee for Medicinal Products for Human Use (CHMP), which conduct independent assessments of the quality, safety, and efficacy of medicines and issue scientific opinions that are subsequently formalized by the European Commission into legally binding authorizations applicable throughout the Union (European Medicines Agency, n.d.). Beyond authorization, the Agency coordinates pharmacovigilance activities at the EU level, ensuring continuous monitoring of medicines placed on the market and facilitating cooperation among national regulatory authorities through a networked system of shared administration (European Medicines Agency, n.d.).

The European Medicines Agency (EMA) is a paradigmatic example of EU regulatory governance, because it embodies the Union's distinctive model of network-based administration (Vos, 1999)

Rather than operating as a fully centralized federal regulator, the EMA functions through a system in which supranational scientific coordination is combined with the active participation of national competent authorities. Its scientific committees, including the Committee for Medicinal Products for Human Use (CHMP), are composed of experts nominated by member states, while the Agency provides the procedural framework, methodological standards and coordination necessary to ensure consistent evaluation across the Union. In this sense, regulatory authority is neither exclusively supranational nor purely national but embedded in a multi-level structure characteristic of EU governance (Vos, 1999).

This institutional configuration promotes harmonization within the internal market by ensuring that medicines authorized through the centralized procedure are subject to uniform scientific standards valid across all member states, thereby reducing regulatory fragmentation and supporting the free movement of pharmaceutical products (Permanand, 2006). At the same time, the continued involvement of national authorities in scientific assessment and pharmacovigilance preserves domestic administrative expertise and reinforces institutional legitimacy, limiting concerns over excessive centralization (Krapohl, 2008). The EMA thus exemplifies the EU's regulatory state logic, in which integration is achieved through coordinated expertise and shared administrative responsibility rather than hierarchical federal control (Vos, 1999; Krapohl, 2008).

The EU Institutional Framework: The European Centre for Disease Prevention and Control

Like EMA, even European Centre for Disease Prevention and Control (ECDC) is a decentralized EU agency, created by Regulation (EC) No 851/2004, to provide specialized scientific expertise at the Union level (European Union, 2004).

The ECDC supports the prevention and control of communicable diseases through epidemiological surveillance, risk assessment, and technical guidance to member states and EU institutions (European Union, 2004).

Resembling EMA's structure, even ECDC is based on scientific authority, technocratic independence, and network coordination, rather than direct political control (Busuioc, Groenleer and Trondal, 2012). However, while the former agency exercises quasi-regulatory powers in the centralized authorization of medicinal products, the latter operates primarily through information-sharing, coordination, and non-binding recommendations, as public health remains largely a national competence, as established by Article 168 TFEU (Greer and Löblová, 2017).

ECDC is an agency designed to complement the more formal regulatory authority of the EMA, as it was conceived as an information sharing and coordination center (Mounier-Jack and Coker, 2006).

The EU Institutional Framework: The European Commission

Moving on, the European Commission is composed of the College of Commissioners, a team of 27, each one from a different member state. Among these members, there are the President of the Commission, 5 Executive Vice-Presidents, a High Representative for Foreign Affairs and Security Policy/Vice President and 20 Commissioners (European Commission, n.d.).

The College is structured into a system of Directorates-General (DGs) and Services, each responsible for well-defined policy areas, such as competition, trade, environment, or health. This apparatus is designed to function like ministries in a national government: DGs should draft policy proposals, carry out impact evaluations, and manage legislative dossiers, assisted by service departments and executive agencies (European Commission, n.d.).

A key role in fostering internal coordination is played by the Secretariat-General, having as a main role the assistance of President and the College by guaranteeing collegiality, consistency, and efficiency of action, coordinating policy planning and cross-cutting work across DGs in line with strategic priorities (European Commission, n.d.).

The Commission architecture also includes specialized service departments, like the Legal Service, designed to deliver independent legal assistance and represent the institution in judicial proceedings, participating in the rule of law and the right interpretation of EU law (European Commission, n.d.).

Assisting the DGs there are also internal services dedicated to internal audit, translation, human resources, and logistic support to guarantee administrative and operational persistence of Commission's work (European Commission, n.d.).

All these organs allow the Commission to submit coherent policy proposals, enforce decisions successfully, and coordinate the EU's administrative capacity.

The Commissioners collectively exercise political leadership, define strategic priorities and enforce binding decisions on Commission acts, pursuing the general interest of the Union and being independent from their country of origin, embodying the supranational character of the Commission.

This organ is the primary executive institution of the European Union, conferred with legislative initiative, executive authority, and supervisory competence within the European institutional structure.

Article 17 of the Treaty of the European Union (TEU) and other provisions of the Treaty on the Functioning of the European Union (TFEU) legally enabled the Commission to propose new laws in areas of competence of the Union, i.e. customs unions, competition rules for the internal market, monetary policy for the euro-area states, common commercial policy and conservation of marine biological resources., which are areas of exclusive EU competence.

Indeed, the EU competences are divided into exclusive EU competences, shared competences between EU Institutions and member states, and supporting/coordinating competences, in which the EU could only assist the state's actions. Fields outside this system are exclusively of Members States' competences.

Beyond areas of exclusive competence, the EU Commission practices its legislative initiative mainly within fields of shared competence and supporting, coordinating, or complementary competence, as defined by the Treaties. In areas of shared competence, such as the internal market, environment, transport, energy, and consumer protection, the Commission is entitled to propose binding legislative acts, although member states retain the ability to legislate until the Union has exercised its competence (European Union, 2012).

By contrast, in areas of supporting or coordinating competence, including public health, education, culture, and civil protection, the Commission's role is limited to proposing measures that support or coordinate national action, as it is expressly prohibited from initiating legislation that would harmonize member states' laws (European Union, 2012).

In addition to this, the Commission could manage and implement EU policies, allocate EU annual budget and funding programs, and it should oversee the right application of the EU laws in the member states, guaranteeing compliance with the Treaties (European Union, 2008).

Concerning its budgetary proposals, it must be said that the European Union budget is very small, around 1% of EU Gross National Income, primarily financed through national contributions and traditional own resources (European Commission, 2020; Heinemann, 2017), and the Union had no independent capacity to tax or borrow for economic stabilization against economic downturns (Eichengreen, 2024). This means that each member state decides independently how to invest its national budget, relying only on its own finances to stimulate the economy.

While dealing with these aspects, the EU Commission plays also a central role in ensuring fiscal coordination within the European Union (EU) through its oversight and enforcement of the Stability and Growth Pact (SGP).

The SGP sets fiscal rules for member states, aiming to maintain economic stability by limiting budget deficits to 3% of GDP and public debt to 60% of GDP. In the aftermath of the sovereign debt crisis, this supervisory framework was further reinforced through the adoption of the Treaty on Stability, Coordination and Governance (TSCG), commonly known as the Fiscal Compact (European Union, 2014).

Although concluded as an intergovernmental agreement outside the EU Treaties, the TSCG strengthened the monitoring responsibilities of the European Commission by entrusting it with assessing whether member states had properly incorporated the balanced budget rule into their domestic legal systems and by reinforcing its role within fiscal surveillance procedures. In cases of non-compliance, the Commission may initiate proceedings before the Court of Justice of the European Union (European Commission, 2017).

These reinforced fiscal constraints are embedded within the broader framework of the European Semester, the annual cycle of economic and budgetary coordination through which the European Commission exercises its surveillance and agenda-setting function (Verdun and Zeitlin, 2018).

The Semester provides an annual cycle through which the European Commission sets strategic priorities in the Annual Sustainable Growth Strategy, conducts in-depth country analyses, and drafts Country-Specific Recommendations that are subsequently adopted by the Council of the European Union. This process has strengthened the Commission’s agenda-setting and monitoring authority, as it centralizes surveillance functions and enhances its informational and technical leverage over member states’ economic policies, while still operating within a framework that combines hard law mechanisms with soft coordination and peer review (Bauer and Becker, 2014; Dawson, 2018; Zeitlin and Vanhercke, 2018).

In this context, the Commission ensures that national economic policies align with EU goals of sustainable growth and fiscal discipline (European Commission, 2021).

Additionally, the Commission plays a key role in providing flexibility in fiscal rules when necessary, allowing for temporary deviations to accommodate member states' economic needs, particularly in times of financial stress or to facilitate structural reforms. This flexibility is balanced with the need for long-term fiscal sustainability, as the Commission helps to coordinate economic strategies across the EU to foster economic resilience and convergence (Beetsma et al., 2018).

Being the only institution with legislative initiative, the Commission drafts and submits legislative proposals to the EU Parliament and the Council of the European Union, defining the European agenda (European Commission, n.d.).

The EU Institutional Framework: The Institutional Balance

Because in the EU sovereignty is shared and delegated, rather than monolithic, making the European authorities not absolute, but limited to well-defined fields, the Parliament and the Council are entitled to scrutiny Commission decisions, enforcing budgetary control, with external audit delivered by the European Court of Auditors as a result of an institutional balance, aiming at fostering financial accountability and transparency (Craig and de Búrca, 2021; European Union, n.d.).

This system guarantees that the EU institutions do not exceed their field of competence, enshrined in the Treaties, and that they do not encroach on other institutions' jurisdictions. As it was designed, institutional balance requires that each subject act in accordance with the powers conferred on it by the EU law, entitling the Court of Justice of the European Union (CJEU) to uphold and oversee the respect of this principle, safeguarding the principle of conferral and institutional balance (European Union, n.d.; Simoncini, 2025; van den Brink, 2023).

This interinstitutional approach places the European Commission as the sole initiator of legislation but constrains it by requiring that binding laws only enter into force with the joint approval of the European Parliament and the Council of the European Union under the ordinary legislative procedure; such mechanisms distribute legislative authority and act as mutual checks on unilateral action (European Union, n.d.; Simoncini, 2025).

These constraints reflect the principle of conferral and illustrate how the Commission's agenda-setting power is structurally conditioned by the scope and nature of EU competences, balancing supranational initiative with the preservation of national regulatory autonomy (Craig and de Búrca, 2021).

Furthermore, the European Parliament exercise perpetual oversight over the Commission's acts, ranging from approval of the Commission's appointment, investigation through parliamentary questions and hearings, to the capacity of enforcing motion of censure against Commission acts (Craig and de Búrca, 2021; European Union, n.d.).

The interinstitutional balance is a fundamental concept that allows us to understand both the legal distribution of competences and the political dynamics around which the EU institutions are constrained (Craig and de Búrca, 2021; van den Brink, 2023).

This system is not designed to be a strict separation of powers in the constitutional interpretation, but rather to exercise authority via a shared and negotiated institutional role.

By doing so, the Union combines supranational initiative, mainly through the Commission's agenda and executive role, with intergovernmental control exerted by member states via their representatives sitting in the Council and in the EU Council, mirroring EU's hybrid constitutional structure and guaranteeing that political choice remains entrenched in national interest, rather than becoming autonomously centralized (Fabbrini F., 2015; van den Brink, 2023).

Additionally, even where the Commission is entrusted with delegated or implementing powers, these competences remain tightly circumscribed by institutional control mechanisms that reflect the EU's distinctive approach to executive authority. From a theoretical perspective, delegation to the Commission does not imply a transfer of autonomous decision-making power, but rather a form of conditional delegation embedded within a principal–agent relationship, in which the European Parliament and the Council retain the capacity to revoke delegated powers, object to delegated acts, and supervise implementation through ex ante and ex post controls.

As emphasized in the literature on EU governance, such arrangements are designed to mitigate risks of agency drift and to preserve intergovernmental influence over supranational administration, ensuring that executive discretion remains politically accountable and legally constrained. In this sense, EU executive authority is best understood not as an independent locus of power, but as structurally embedded within a dense system of interinstitutional constraint that reflects the Union's hybrid constitutional order and member states' persistent concern with maintaining control over delegated competences (Fabbrini F., 2015; Scharpf, 2021).

Moreover, the Covid-19 crisis highlighted long-standing frictions between supranational institutions and member states sovereignty in crucial fields like public health (Scharpf, 2021). These frictions represent the practical manifestation of the paradox on which is grounded this thesis, because,

notwithstanding these tensions, European Union was able to deliver an effective countermeasure to Covid-19 crisis, as predicted by Hamilton's Paradox (Rodden, 2005).

Indeed, as it will better explained in the following chapter, even though the EU Commission stepped up and played a leading role in vaccination strategy, this role was politically enabled rather than autonomously exerted, because member states collectively decided to give up part of their sovereignty to enforce the Commission to act on their behalf through decisions taken within the Council and the European Council (Della Corte, 2022).

The EU Institutional Framework: The Eurosystem and the Single Market

The dynamics of delegated authority and shared sovereignty are not confined to the legislative and executive spheres but extend deeply into the monetary domain through the institutional design of the Economic and Monetary Union (EMU).

At the heart of EMU lies the Eurosystem, the institutional arrangement entrusted with the exclusive competence for conducting monetary policy in the euro area under the Treaties.

This institutional framework is composed of European Central Bank (ECB) and all the national central banks whose member states decided to adopt the euro as a single currency, composing the so-called Eurozone.

The Eurosystem is responsible for drafting and enforcing the Single Monetary Policy for the Eurozone, replacing national monetary policy by implementing a common supranational regime.

The Single Monetary Policy is a system created to define centrally monetary conditions for countries who adopted euro. This strategy is grounded in Articles 127 and 282 TFUE, looking to keep prices stable.

In practical terms, the Single Monetary Policy involves setting key interest rates, conducting open market operations, managing liquidity in the banking system, and steering inflation expectations across the euro area rather than at the national level (Issing et al., 2001).

Within this framework, the ECB exercises decision-making authority, setting as a goal maintaining price stability, which in practical terms means looking to keep inflation rates below or close to 2% over the medium term, a mandate designed to anchor inflation expectations and support sustainable economic activity (European Central Bank, n.d.).

The ECB is one of the key European institutions, as it is responsible for the Eurozone monetary policy, and it is structured around three decision-making bodies: the Governing Council, composed of the six members of the Executive Board and the governors of the national central banks of euro-area

member states. It is the supreme decision-making body, which establishes monetary policy, interest rates and strategic orientation (European Central Bank, n.d.).

Another entity of the ECB is the Executive Board, formed by the President, Vice-President and four other members appointed for non-renewable eight-year terms, being responsible for implementing monetary policy and managing the ECB's day-to-day operations (European Central Bank, n.d.).

Finally, there is the General Council, which includes the President and Vice-President of the ECB together with the governors of all EU national central banks, even those outside the euro area. This council implements mainly advisory and coordinated functions, mirroring the EU's differentiated monetary integration (European Central Bank, n.d.).

In addressing EU monetary policy and keeping inflation rate stable, national central banks are entitled to carry out the operational tasks necessary to execute these policies, as they conduct open market operations and manage liquidity provision (European Union, 2016; de Haan and Eijffinger, 2016).

Beyond monetary policies, the ECB is responsible also for supervising significant banks under the Single Supervisory Mechanism (SSM), established to enhance the stability of the banking sector and ensure consistent supervisory practices across the euro area (European Central Bank, n.d.).

ECB's independence is enshrined in the EU legal order to protect it from political interference. However, it remains accountable to the European Parliament and other EU institutions through regular reporting and hearings, balancing autonomy with democratic oversight (de Haan and Eijffinger, 2016).

Shifting the focus, the European Union is fundamentally structured around the Single Market, which constitutes the cornerstone of European economic integration.

This system is defined as an area without internal frontiers in which the free movement of goods, services, capital, and persons is ensured (European Union, 2016).

The legal framework on which it is grounded is Article 114 TFEU, which provides the Union with the competence to adopt harmonization measures aimed at improving the establishment and functioning of the internal market (European Union, 2008).

The four freedoms at the core of the Single Market have been progressively shaped and enforced through the jurisprudence of the CJEU, which has emphasized their direct effect and supremacy within the EU legal order (Craig and de Búrca, 2021).

The integrity of the system is further safeguarded by supranational enforcement mechanisms, particularly the European Commission's role as guardian of the Treaties and the Union's robust competition and state aid regime under Articles 101 and 109 TFEU, designed to prevent distortions arising from anti-competitive practices or selective national interventions (European Union, 2008; Monti, 2010).

Within this broader framework, the establishment of Economic and Monetary Union and the creation of the ECB complement market integration by eliminating exchange-rate volatility and reducing transaction costs among euro-area member states, thereby deepening economic integration while maintaining the broader regulatory architecture that applies to the entire Union (De Grauwe, 2012; Baldwin and Wyplosz, 2022).

The EU Institutional Framework: The Crisis Management before Covid-19

Before the outbreak of the COVID-19 pandemic, the EU's experience with the global financial and euro-area crises had given rise to a distinct model of crisis governance operating alongside the ordinary Treaty framework. It is this pre-pandemic configuration, shaped by emergency instruments, intergovernmental innovation, and constrained fiscal integration, that constitutes the point of departure for assessing how later crises transformed both the Union's institutional trajectory and prevailing assumptions about its structural limits, in light of Hamilton's paradox and its contemporary elaboration by Alexander-Shaw (Alexander-Shaw, Ganderson and Schelke, 2023; Rodden, 2005).

To understand the nature of this pre-pandemic configuration, it is necessary to examine how crisis governance operated in practice prior to 2020: the EU evolved through a pattern of incremental institutional adaptation in response to successive shocks, most notably the global financial crisis, the euro-area sovereign debt crisis, and the migration crisis.

The EU model was defined as one of emergency governance or a kind of new intergovernmentalism, in which member states retained ultimate political authority while EU institutions facilitated coordination and technical implementation (Bickerton, Hodson and Puetter, 2015; Fabbrini S., 2016).

The concept of emergency governance captures the emergence of decision-making practices during the euro-area crisis that relied on exceptional instruments, executive dominance, and accelerated procedures operating alongside, and sometimes stretching, the ordinary Treaty framework (White, 2015; Dawson and de Witte, 2013). Rather than consolidating supranational authority, crisis responses were constructed through intergovernmental agreements outside or alongside the EU Treaties, thereby preserving national control over core redistributive and budgetary functions (Fabbrini S., 2016).

The establishment of the European Stability Mechanism (ESM), a permanent intergovernmental financial assistance mechanism designed to provide conditional support to euro area member states facing severe financing difficulties (European Stability Mechanism, n.d.), and the Treaty on Stability, Coordination and Governance exemplified this approach: both instruments were negotiated as intergovernmental treaties among member states, limiting the autonomous fiscal authority of supranational institutions while reinforcing conditionality and national responsibility (Aerts and Bizarro, 2020; Pennesi, 2018; Kusak et al., 2013).

This configuration produced an intergovernmental union in which crisis governance strengthened executive coordination among national governments without transforming the EU into a fiscal federation (Fabbrini S., 2016; Di Dario, 2017).

Moreover, the legal architecture of the euro-area response reflected deliberate political choices, preserving the primacy of national fiscal sovereignty, even as supranational institutions such as the European Commission and the European Central Bank gained enhanced monitoring roles (Dawson and de Witte, 2013). The Commission's authority expanded primarily in the domain of surveillance, through the establishment of the European Semester, but not in autonomous fiscal capacity (Fabbrini S., 2016).

Indeed, the post crisis trajectory is depicted as failing forward, because incomplete institutional reforms addressed immediate market pressures without resolving the structural asymmetry between monetary integration and fiscal fragmentation (Jones, Kelemen and Meunier, 2016).

The absence of a centralized fiscal stabilization function meant that redistribution remained politically contested and nationally mediated, reinforcing what many scholars identify as the EU's hybrid nature: a highly integrated regulatory state with limited central fiscal sovereignty (Majone, 2014).

Thus, pre-pandemic crisis management was a system in which integration deepened without a corresponding transfer of sovereign authority to supranational actors. In this model, the European Council and the Council of the EU became central arenas for strategic crisis decision-making, while the European Commission and other supranational bodies functioned as coordinators, agenda-setters, and implementers rather than autonomous political executives (Bickerton, Hodson and Puetter, 2015).

Additionally, deliberative intergovernmentalism replaced traditional Community-method supranationalism in key policy domains, reinforcing consensus-based executive coordination among national leaders.

Even where supranational actors such as the EU Commission or the European Central Bank played prominent roles, their authority operated within carefully circumscribed mandates, often subject to intense intergovernmental negotiation and judicial scrutiny.

More specifically, the ECB effectively assumed emergency stabilization functions through its lender-of-last-resort commitment and unconventional instruments, which reshaped the practical boundaries of monetary authority and raised acute questions of democratic control (van 't Klooster, 2018).

At the same time, crisis action was juridically stabilized and delimited through a dense layer of judicial review and constitutional contestation: the CJEU's endorsement of the ESM architecture and on the ECB's crisis measures have been widely read as pivotal in legitimating exceptional tools while tying them to conditionality and Treaty-compatible rationales (Borger, 2013; Tridimas, 2016).

This broader governance pattern also extended beyond the euro area: scholarship on the 2015–2016 migration crisis shows that, despite Commission entrepreneurship, outcomes were largely shaped by member-state bargaining, differentiated compliance, and weak solidarity, revealing similar constraints on supranational authority in a distributive, sovereignty-sensitive policy field (Niemann and Zaun, 2018; Trauner, 2016).

Consequently, pre-COVID EU crisis governance did not entail the creation of a centralized emergency authority comparable to that found in federal systems. Instead, it relied on negotiated delegation, temporary instruments, and legally bound supranational action, preserving the primacy of member states in politically sensitive domains such as fiscal stabilization and public health. This configuration generated crisis management architecture that was capable of collective coordination but structurally constrained in its capacity for hierarchical enforcement or autonomous fiscal intervention.

Taken together, this pre-pandemic crisis architecture suggested limited capacity for centralized emergency action in highly distributive policy domains. The EU remained characterized by monetary integration without full fiscal union, executive intergovernmental dominance, and constrained supranational authority, a configuration widely described as structurally incomplete and prone to failing forward (Jones, Kelemen and Meunier, 2016; Scharpf, 2021).

In such a system, where redistributive decisions remained politically sensitive and nationally mediated, collective responses to asymmetric shocks were expected to be slow, fragmented, and contested (Rodden, 2005; Fabbrini S., 2016). From this perspective, the Union appeared institutionally ill-equipped to manage a time-sensitive, redistributive public health emergency

requiring centralized procurement, fiscal risk-sharing, and rapid implementation, thereby reinforcing pre-pandemic expectations of structural constraint rather than federal-style crisis capacity.

United States of America Institutional Framework

The United States of America is a Federal Constitutional Republic with a presidential system, where power is divided between the Central Government and the 50 Constituent States (GlobalEDGE, 2025).

This system is grounded on a single, codified text: the Constitution, developed in 1787 (U.S. National Archives and Records Administration, n.d.).

This charter was conceived as the most important document, operating as the supreme and binding source of political authority. Through its articles, it creates the institutions and defines the limits of the federal government's authority and powers, while leaving all the others to the single States jurisdiction (National Constitution Center, n.d.; Lawson et al., 2025).

As a consequence of this framework, the central government could exercise only the powers established by the Constitution, though all the other non-mentioned domains remain of competences of the States, establishing constant dynamic of shared competences, at both national and states level.

Unlike systems based primarily on parliamentary sovereignty or uncodified conventions, the U.S. constitutional order is textually entrenched and hierarchically superior to ordinary legislation, functioning as the supreme source of political authority. Indeed, Article VI of the US Constitution introduces the Supremacy Clause, which establishes that this document, and laws and treaties made pursuant to it, are the Supreme Law of the Land, prevailing over conflicting state law and binding state judges accordingly (Library of Congress, n.d.)

This creates a vertically integrated legal hierarchy in which all public authority must be traceable to constitutional authorization.

However, the relevance of the Constitution does not lie exclusively in its hierarchical superiority, but in the institutional structure it establishes (Young, 2005). Beyond its function as the supreme legal authority, the Constitution operates as an organizational blueprint that distributes public power both horizontally and vertically, fragmenting competences across multiple bodies and levels of government. Through the principles of separation of powers and federalism, it designs a system in which institutions are interdependent, mutually limiting, and structurally constrained (Kong, 2025).

The functioning of the American political order, therefore, depends less on constitutional supremacy in the abstract and more on the interaction among the institutions it creates (Lhotta, 2023; Young, 2005)

Understanding the U.S. system requires examining how authority is distributed and how these institutions interact within that structure.

The US Institutional Framework: The Vertical Division of Powers

In this context, the core of US institutional architecture is federalism, the Constitution's vertical division of powers between national government and states.

In this system, sovereignty is split between the national government, equipped with enumerated powers, and the states, which retain broad residual authority. More specifically, the former can legislate only within the competences specifically granted by the US Constitution in Article I Section 8, such as taxing and spending for the general welfare, regulating commerce between states, coning money, declaring war, and raising armed forces and those powers implied through the Necessary and Proper Clause (Van Alstyne, 1987).

Powers beyond this list generally cannot be exercised by the national legislature unless they are fairly implied from these express grants, reflecting the design on which US is grounded: a system with a national government of limited and delegated authority rather than one of general jurisdiction (Library of Congress, n.d.).

Moreover, the enumeration of congressional powers is intended to function as a substantive constraint, reinforcing the idea that federal authority must be grounded in a textual grant rather than presumed sovereignty (Van Alstyne, 1987). Indeed, scholars conceptualize federalism as a constitutional principle embedded in the architecture of limited national competences and state sovereignty, emphasizing that enumeration is central to preserving the vertical balance of power (Young, 2007).

The Tenth Amendment affirms that powers not delegated to the United States nor prohibited to the states are reserved to the states or the people, thereby establishing the doctrine of residual authority (Cornell Law School Legal Information Institute, n.d.).

Furthermore, the decision to create a system with the absence of a defined list of state powers was intentional, reflecting the understanding that states retained broad, general police powers over internal governance (Natelson, 2003). Indeed, constitutional silences regarding state authority operate as structural reservations of power, reinforcing the asymmetry between limited federal competences and plenary state authority (Claus, 2018).

Following this path, federal action must be justified under one of the Constitution's enumerated grants, most prominently the commerce clause or the spending power, while regulatory authority

over public health, safety, and welfare remains presumptively with the states unless preempted by valid federal law (Killion, 2021; Adkins, 2023).

Practically, the Constitution established a system where federal authorities can act strongly through commerce power and spending power. About the former, Article 1 Section 8 of the Constitution establishes that Congress may regulate interstate commerce and tax and spend for the general welfare, equipping the federal government with substantial reach within a system of divided sovereignty (National Constitution Center, n.d.). Additionally, the Supreme Court sentenced that the commercial clause allows regulation not only of the channels and instrumentalities of interstate commerce but also of intrastate activities that substantially affect interstate markets, as was framed by the Court in two different judgments: Wickard vs Filburn and Gonzales vs Raich (Barnett, 2001; Cushman, 1998).

Complementing this regulatory authority, Congress's spending clause power allows it to allocate federal funds to states and attach conditions designed to advance national objectives, a practice considered both as a cooperative or coercive federalism, depending on design and fiscal leverage, being on the verge of unconstitutionality (Bagenstos, 2008; Mettler, 2002)

In combination, commerce power enables direct regulation of nationally integrated markets, while the spending power allows indirect steering of state policy through fiscal incentives—providing the institutional basis for strong federal influence even where implementation authority remains decentralized.

While the Tenth Amendment entrenches residual authority, the Supremacy Clause is essential, guaranteeing that federal law prevails in conflicts between federal and state rules (Library of Congress, n.d.).

The US Institutional Framework: The Horizontal Division of Power

Another fundamental part of the US institutional framework, which complemented the vertical division of sovereignty and is crucial in understanding the US authority's redistribution and allocation of sovereignty, is the horizontal division of power. The U.S. constitutional order fragments authority horizontally within the federal government itself through the doctrine of separation of powers.

This constitutional design established that the U.S. powers are separated between three co-equal branches of the federal government: The President, being the leader of the executive and administrative powers, The Congress, composed by the House of Representatives and the Senate, which all together constituted the legislative power and are entitled to enforce the federal laws, and

the U.S. Supreme Court, which interprets Constitution and laws, and it is the highest representative organism of the judiciary power. US sovereignty, as established in the Constitution, is shared and integrated, preventing concentration of power and forcing governance through institutional rivalry, bargaining, and oversight rather than hierarchical command.

The US Institutional Framework: The Horizontal Division of Power – The President

Digging deep into the three branches system, the President is enforced with the executive power and charged with ensuring that the laws are rightfully executed, establishing the office as the constitutional head of the executive branch and the primary agent of national administration. This kind of formulation has served as constitutional foundation for both administrative control and claims of inherent executive authority.

Moreover, presidential authority is not limited to textual clauses but also derives from structural presumption and longstanding practice, especially in foreign affairs and emergency governance (Library of Congress, n.d.).

In institutional terms, the President of the United States holds a multi-faceted role that spans several core functions within the governmental system: as the chief executive, the President is responsible for enforcing and administering federal laws, overseeing the vast administrative state, and managing federal agencies and departments (Library of Congress, n.d.).

As the chief administrator, the President directs the execution of policies, often through executive orders and signing statements, which allow unilateral action within the bounds of existing statutory frameworks (Moe and Howell, 1999). These powers are not merely formal; they are deeply embedded in the constitutional structure, which grants the President considerable authority to shape administrative outcomes.

The President also serves as chief diplomat, responsible for shaping U.S. foreign policy, negotiating treaties, and managing international relations. The constitutional power to negotiate treaties, subject to Senate ratification, and the power to appoint ambassadors reflect the President's central role in global diplomacy. In this capacity, Presidents often use executive agreements, which are informal accords that do not require Senate approval, to bypass the constraints of formal treaty-making, thereby asserting significant unilateral foreign policy influence (Klein, 2014).

In addition to these executive and diplomatic roles, the President assumes a critical role in the legislative process. While the President does not legislate directly, the executive has powerful tools for influencing legislation. The veto power is one of the most significant tools available to the

President, allowing the executive to reject bills passed by Congress, thereby forcing legislative revisions (Edwards, 2003).

In addition, the President's agenda-setting power is a key aspect of their legislative role. By proposing budgets, outlining policy priorities in annual addresses like the State of the Union, and using public speeches and media, the President can shape national priorities and influence the legislative agenda (Cameron, 2000).

Furthermore, appointment and removal powers provide the President with significant influence over the judiciary and executive bureaucracy, as the President appoints federal judges, including Supreme Court justices, and heads of key agencies. The President's ability to remove appointed officials from office also allows for direct control over the administration's direction, especially when there is a shift in presidential priorities (Moe & Howell, 1999).

Finally, the President's role as a crisis manager is often highlighted in times of national emergency. Through emergency declarations and the invocation of statutory powers such as the National Emergencies Act and the Stafford Act, the President can exercise a range of powers without the immediate consent of Congress, reflecting a unique aspect of presidential authority that is designed to address urgent issues like natural disasters, national security threats, or economic crises (Corwin, 1957; Riegelhaupt, 2021; Katz, Attal-Juncqua and Fischer, 2017). These tools are rooted in legal delegations that allow the President to take decisive action in moments of national need, often bypassing traditional checks from Congress.

Having outlined the scope and institutional constraints of presidential authority, it is essential to examine the method of presidential selection, as the electoral process itself shapes the political legitimacy and strategic position of the executive within the constitutional system.

The President is elected through the Electoral College system, a procedure instituted by Article 2 of the US Constitution (U.S. National Archives and Records Administration, n.d.), which established that citizens vote in a general election held every four years, but technically they are voting for a slate of electors pledged to a presidential candidate. Each state is allocated a number of electors equal to its total representation in Congress, House members plus two Senators, and most states use a winner-take-all system. A candidate must receive an absolute majority of the 538 electoral votes, meaning that preferences should be at least 270, to win the presidency. If no candidate achieves a majority, the election is decided by the House of Representatives, with each state delegation casting one vote (Dietz and Lin, 2024; Erikson, Sigman and Yao, 2020).

However, Presidential authority is heavily conditioned by the partisan configuration of Congress and the broader institutional environment in which interbranch bargaining occurs. Indeed, ideological distance between Democrats and Republicans has increased legislative gridlock, weakened cross-party coalition-building, and reduced the likelihood of durable statutory compromise (Binder, 1999; McCarthy, Poole and Rosenthal, 2006).

In a highly polarized Congress, presidents face greater obstacles in advancing their legislative agendas, securing appropriations, because parties become more internally cohesive and externally polarized, the overlap in policy preferences necessary for bipartisan compromise diminishes, making statutory agreement more difficult and less durable (Cameron, 2000). Moreover, presidents rarely move members of Congress through persuasion alone; instead, their legislative effectiveness is largely a function of existing partisan alignments and institutional opportunities (Edwards, 2003).

Consequently, when legislative bargaining becomes prohibitively costly, executives may shift toward unilateral instruments, such as executive orders, regulatory action, or emergency powers (Howell, 2003).

Having said that, it can be understood why presidential power should be considered relational and context-dependent: it expands or contracts not solely because of constitutional text, but because polarization reshapes bargaining space, institutional incentives, and the feasibility of interbranch cooperation within the separation-of-powers system.

Polarization thus reshapes the strategic context of presidential action, altering not only policy outputs but also the balance between interbranch negotiation and unilateral initiative (McCarthy, Poole and Rosenthal, 2006).

This polarization will affect even US covid-19 countermeasures, especially concerning vaccine procurement and rollout, as will be explained in the following chapters.

The US Institutional Framework: The Horizontal Division of Power – The Congress

Having already examined the presidency, it is now essential to turn to Congress to more fully understand how the United States' horizontally divided system of powers operates in practice.

Article I of the U.S. Constitution vests legislative authority in a bicameral Congress, formed by the House of Representatives and the Senate, embedding a dual principle of representation that combines population-based representation with state equality (Library of Congress, n.d.).

The House is designed to be the more electorally responsive chamber: its seats are apportioned among the states by population using decennial census data, and the total number of House seats is fixed at 435 by statute.

Its representatives are elected every two years, typically from single-member districts (U.S. Census Bureau, n.d.).

The Senate, by contrast, embodies equal state representation: each state elects two senators to six-year, staggered terms, organized into classes so that roughly one-third of seats are elected every two years. This system meant to produce continuity and a different electoral time horizon from the House (U.S. Senate, n.d.; U.S. Census Bureau, n.d.).

Beyond this bicameral design, Congress operates through a complex internal organization that structures how legislative authority is exercised in practice. Much of the substantive work of policymaking and oversight is conducted within standing committees and subcommittees, which possess jurisdiction over specific policy domains and serve as gatekeepers for hearings, amendments, and bill advancement (Cameron, 2000; McCubbins and Schwartz, 1984).

Party leadership further conditions legislative outcomes by controlling floor procedures, agenda scheduling, and member coordination—particularly in the House, where centralized majority control heightens agenda power relative to individual members (Cox and McCubbins, 2020).

Bicameralism adds an additional institutional layer, as differences between House and Senate bills are reconciled through conference committees or informal negotiations, reinforcing inter-chamber negotiation as a structural feature of lawmaking (Koger, 2017).

Beyond its composition, Congress performs a constitutionally grounded and institutionally elaborated set of functions that position it at the core of national policymaking within the horizontal separation of powers.

It has the authority to legislate, tax and spend, regulate interstate and foreign commerce, declare war, and enact all laws necessary and proper for executing its enumerated powers, thereby providing both substantive competences and broad implied authority.

Central among these functions is the power of the purse, which gives Congress decisive control over federal appropriations and, consequently, over administrative capacity and policy implementation.

Rooted in Article I, Section 9 of the United States Constitution, which provides that “No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law”, this authority

ensures that executive action is financially contingent upon legislative authorization (Madison, 1788; Ferguson, 1961).

In institutional terms, appropriations legislation not only allocates resources but also structures administrative behavior by specifying funding levels, imposing conditions, setting reporting requirements, and sometimes restricting the use of funds for particular purposes (U.S. Government Accountability Office, 2016; Chemerinsky, 2019).

Congress uses budgetary instruments both prospectively and retrospectively to shape and discipline bureaucratic discretion. Prospectively, legislators embed detailed instructions in authorization and appropriations statutes that define program objectives, eligibility criteria, spending ceilings, timelines, and procedural obligations, thereby narrowing the range of permissible administrative interpretation before implementation begins (McCubbins, Noll and Weingast, 1987; Ferejohn and Shipan, 1989).

Through mechanisms such as earmarks, line-item allocations, riders, and conditions on the use of funds, Congress can structure agency priorities and signal policy preferences without rewriting underlying substantive law (Wildavsky, 1984).

Moreover, scholars demonstrate that Congress strategically calibrates the precision of statutory language depending on political uncertainty and preference divergence, using specificity to reduce agency drift when interbranch trust is low (Huber and Shipan, 2002).

Retrospectively, Congress employs the budget cycle as a monitoring and corrective device. Through hearings, reporting requirements, Government Accountability Office reviews, and the threat of funding reductions, delays, or rescissions, legislators can respond to perceived administrative overreach or underperformance.

Oversight often operates through a kind of fire alarm mechanism, in which external actors trigger congressional scrutiny that may then translate into fiscal consequences. Appropriations renewals thus function not merely as technical funding exercises but as recurring opportunities to reassess agency behavior and recalibrate discretion.

In this sense, budgetary politics constitutes a dynamic system of control: administrative authority is never fully settled but remains contingent upon continued legislative tolerance and financial support, reinforcing Congress's central role in structuring the practical boundaries of executive action within the separation-of-powers framework (McCubbins and Schwartz, 1984; Epstein and O'Halloran, 1994).

The US Institutional Framework: The Horizontal Division of Power - The Supreme Court

Having examined Congress's role within the horizontally structured constitutional order, the analysis now turns to the judiciary as the third branch in this allocation of authority.

Under Article III of the United States Constitution, the judicial power of the United States is vested in a supreme Court, whose institutional role has evolved into that of the final arbiter of constitutional meaning and the central guardian of the separation of powers (Library of Congress, n.d.).

Although the Constitution does not explicitly mention judicial review, the authority of the Supreme Court of the United States to invalidate federal and state laws was firmly established in Marbury v. Madison, embedding the Court within the architecture of horizontal and vertical power control (Monaghan, 1987; Whittington, 2007).

Structurally, the Supreme Court of the United States sits at the apex of the federal judiciary established under Article III of the United States Constitution. The Constitution creates the Court but leaves its size and internal organization to Congress.

By statute, the Court has consisted of nine justices, i.e. one Chief Justice and eight Associate Justices. The Chief Justice presides over oral arguments and conferences, assigns majority opinions when in the majority, and performs additional constitutional functions such as presiding over presidential impeachment trials in the Senate, while Associate Justices participate equally in deliberation and decision-making (Library of Congress, n.d.).

Jurisdictionally, the Court exercises primarily appellate jurisdiction, reviewing decisions from lower federal courts and state supreme courts on federal questions, while possessing limited original jurisdiction in cases involving states and certain diplomatic officials.

Through the discretionary writ of certiorari, the Court selects a small fraction of petitions for review each term, allowing it to shape its docket and focus on cases of broad constitutional or national importance (Baum, 2019).

Through the doctrine of *stare decisis*, its prior decisions function as binding precedent, structuring future adjudication and reinforcing the stability and coherence of constitutional law over time (Lee, 1999).

This combination of life tenure, collegial decision-making, discretionary agenda control, and constitutionally grounded jurisdiction defines the institutional structure within which the Court performs its constitutional functions.

Moreover, judicial review positions the Court as both a legal and political institution: it resolves disputes over federal–state competences, adjudicates separation of powers conflicts between Congress and the President, and enforces constitutional rights, thereby shaping the boundaries of governmental authority (Whittington, 2005; Friedman, 2009).

The Court's authority rests not on enforcement power but on institutional legitimacy and compliance by the elected branches, making its influence contingent yet durable within the broader constitutional order (Gibson, Caldeira and Baird, 1998).

The US Institutional Framework: Check and Balance System

Because the horizontal division of power is based on three equal branches, the separation of competence is based on a check and balance system, which allows to prevent the concentration of power in any single branch of government by requiring interbranch oversight, mutual control, and institutional cooperation, thereby safeguarding constitutional limits and promoting accountability within the separation-of-powers framework (Neustadt, 1960; Przygoda, 2018).

This dispersion of authority forces presidents and legislators to bargain and build coalitions across branches, constraining unilateral action and enhancing institutional responsiveness to competing interests (Neustadt, 1960; Przygoda, 2018).

Considering so, Presidential authority in the US system is structurally balanced through a combination of interbranch checks, statutory design, and political competition. While the President possesses unilateral tools, their use is conditioned by legislative configuration and can be curtailed through statutory override, appropriations control, or judicial invalidation (More and Howell, 1999).

Among these mechanisms, judicial review constitutes the principal legal avenue through which such invalidation occurs. Through this function, the judiciary provides a distinct legal check on presidential power by reviewing the validity of executive action under constitutional and statutory constraints. Courts can enjoin or invalidate presidential directives—directly or through review of executive-branch implementation—when they exceed delegated authority or conflict with separation-of-powers requirements, thereby converting constitutional limits into enforceable constraints on unilateral executive action (Johnson, 2015; Manheim and Watts, 2019).

Beyond the power to invalidate executive action, the judiciary also constrains presidential authority by delineating the scope of executive privilege and presidential immunity. Although courts have recognized executive privilege as grounded in the constitutional separation of powers, they have rejected its absolute character, subjecting claims of confidentiality to judicial balancing when

weighed against competing constitutional interests such as the administration of justice (Rozell, 1994; Fisher, 2004).

In this way, the judiciary prevents the executive from unilaterally shielding information from legal scrutiny, reinforcing the principle that presidential power remains accountable to law. Similarly, judicial doctrine defines the contours of presidential immunity, distinguishing between official acts, for which it is granted substantial protection, and unofficial conduct, for which the President may be subject to civil litigation (Pfiffner, 1999; Shane, 1989).

By constructing and policing these doctrinal boundaries, courts ensure that claims of privilege or immunity do not elevate the President above constitutional and legal constraints, thereby embedding executive authority within a framework of adjudicative oversight.

Another key check on presidential power comes from Congress, which structures and limit executive discretion through detailed statutory frameworks, oversight mechanisms, and administrative procedures, controlling fiscal appropriations, an essential tool for curbing presidential initiatives (Cameron, 2000). The executive's ability to impact policy is heavily influenced by legislative preferences, as Congress can override presidential vetoes, block appointments, and control funding (Cameron, 2000).

Indeed, the Congress has the power to allocate or withhold funding for presidential initiatives, thus controlling the implementation of many executive actions. By conditioning funding or attaching stipulations to appropriations bills, Congress can force the executive to adhere to its policy preferences or avoid certain policies (Howell, 2003)

Beyond funding, Congress exerts oversight through investigative hearings and the authorization of executive actions. Congressional committees can subpoena documents, request testimony from executive officials, and hold hearings to scrutinize the actions of the President and executive agencies. This is part of Congress's check and balance function, which ensures that executive actions align with legislative intent and statutory mandates (Moe and Howell, 1999).

Also, as mentioned above, Congress has the authority to override presidential vetoes with a two-thirds majority in both chambers, providing a direct counterbalance when the President acts in opposition to congressional preferences (Moe and Howell, 1999). This power ensures that even if a president issues a veto, it is not an impenetrable barrier to legislative will, thereby preventing unilateral executive decisions from overriding the public's legislative preferences (Strauss, 1984).

Furthermore, the Senate's confirmation role in approving presidential appointments to key positions, such as cabinet secretaries and federal judges, allows Congress to shape the executive branch's priorities by approving or rejecting the President's nominees (Strauss, 1984).

In addition to these institutional and policy-based constraints, Congress retains the ultimate constitutional check of impeachment. Under Article I of the Constitution, the House of Representatives holds the power to impeach the President for Treason, Bribery, or other high Crimes and Misdemeanors, while the Senate possesses the authority to try impeachments and remove the President by a two-thirds majority (U.S. Senate, n.d.; Columbus State Community College Library, n.d.).

Although rarely used, this mechanism operates as a formal accountability safeguard, deterring serious abuses of executive power and reinforcing the principle that presidential authority remains subject to constitutional limits.

In combination, these powers enable Congress to maintain significant oversight and limit the scope of presidential authority, ensuring that the executive branch remains responsive to the legislative branches will.

Moreover, while Congress is a central constraint on presidential action, US architecture also equips the executive and judiciary with countervailing tools that discipline legislative power and prevent durable congressional dominance. Two checks are especially important: the presidential veto (and its anticipatory effects on bargaining) and judicial review of statutes.

The President's veto is not merely a last-ditch rejection device; it is a structural gate on lawmaking that raises the coalition threshold for major policy change and thereby protects the status quo unless Congress can assemble sufficiently broad agreement. Thanks to the presence of this tool, outcomes are shaped across multiple stages—agenda selection, threat issuance, and override calculations—such that the veto power systematically conditions legislative behavior even when not formally exercised (Rohde and Simon, 1985). In this sense, the veto functions as an ex-ante constraint: anticipating a likely veto, congressional majorities often modify bills, build larger coalitions, or avoid proposals that cannot survive executive opposition (Rohde and Simon, 1985).

The veto thus operates as a formal negative power: Congress cannot enact legislation over presidential opposition without assembling an extraordinary coalition. In this way, legislative authority is conditioned on executive assent or super majoritarian persistence.

Moreover, Congress is further constrained by the judiciary through the doctrine of judicial review. Thanks to this tool, federal courts may invalidate statutes that exceed Congress's enumerated powers or violate constitutional protections.

This mechanism ensures that congressional authority remains subordinate to constitutional limits. Courts routinely assess whether legislation conforms to structural principles such as federalism, separation of powers, and individual rights. When statutes are found unconstitutional, they are rendered unenforceable, thereby directly nullifying legislative action (Dorf and Adler, 2003; Marbury v. Madison, 1803).

In practice, the checking function operates not only through invalidation but also through interpretation: courts can narrow statutes, enforce procedural constraints, and mediate disputes that arise when Congress attempts to control executive implementation or insulate legislative goals from executive or constitutional limits.

Judicial review thus constitutes a vertical constitutional check within the horizontal separation of powers framework: Congress legislates, but the judiciary determines constitutional validity.

Moving on, a complete checks-and-balances account must also explain how courts are institutionally constrained by elected branches and by structural features of the constitutional system.

Indeed, Judicial personnel are selected through a shared interbranch mechanism: the President nominates federal judges, and the Senate provides advice and consent (DeConcini, 1992). This arrangement prevents the judiciary from self-perpetuation and ensures that judicial composition reflects political accountability through elected institutions.

The appointments process operates as an ongoing structural check, as each vacancy allows the elected branches to influence the ideological and interpretive direction of the courts (Joondeph, 2006).

While federal judges enjoy life tenure and salary protection under Article III of the Constitution, they may be removed through impeachment by the House of Representatives and conviction by a two-third vote in the Senate. Although rarely invoked, this mechanism provides a constitutional safeguard against judicial misconduct or abuse of office (Johnson, 2015; Strauss, 1984).

The availability of impeachment reinforces that life tenure does not equate to absolute independence; judicial authority remains contingent upon adherence to constitutional standards of conduct.

Additionally, Article III grants Congress authority to ordinate and establish the inferior federal courts and to regulate the appellate jurisdiction of the Supreme Court. Through this power, Congress

determines the number of lower federal courts, the size of the Supreme Court and the scope of federal jurisdiction.

This structural authority enables Congress to shape the institutional framework within which the judiciary operates. While such powers are constrained by constitutional limits, they represent a significant formal check on judicial reach.

Taken together, these mechanisms demonstrate that the U.S. checks-and-balances system is reciprocal rather than hierarchical. Congress is checked by the presidential veto and judicial review; the judiciary is checked by appointments, impeachment, and congressional control over court structure and jurisdiction. Each branch possesses constitutionally defined tools that prevent institutional consolidation and ensure that governmental authority remains divided, interdependent, and limited.

The US Institutional Framework: The Federal Reserve Bank

The Federal Reserve System (the Fed) is the central bank of the United States, created by the Congress in 1913 to promote monetary and financial stability and to serve the public interest.

Structurally, the Fed contains three core components: the Board of Governors, the Federal Reserve Banks, and the Federal Open Market Committee (FOMC). The Board of Governors is a seven-member federal agency in Washington, D.C., whose members are appointed by the President and confirmed by the Senate to long, staggered terms to insulate policy from short-term political pressures (Federal Reserve System, 2021).

The twelve regional Reserve Banks operate across distinct districts and execute many of the Fed's operational functions while bringing regional economic perspectives to policy deliberations (Federal Reserve System, 2021).

The FOMC, composed of the Board and selected regional bank presidents, is the system's monetary policy-making body, setting targets for interest rates and guiding open market operations (Federal Reserve System, 2021).

Its role encompasses conducting national monetary policy, regulating and supervising financial institutions, maintaining payment and settlement systems, and providing financial services to depository institutions and the federal government (Federal Reserve System, 2021).

These functions are typically grouped into four core pillars of modern central banking: first, in conducting monetary policy, the Federal Reserve pursues its dual mandate of price stability and maximum employment primarily through open market operations, interest on reserves, and forward

guidance, using its control over short-term interest rates to influence inflation expectations and aggregate demand (Clarida, Galí and Gertler, 1999; Bernanke and Mishkin, 1997).

Second, as a regulator and supervisor, the Fed oversees bank holding companies and state-chartered member banks, contributing to macroprudential stability by mitigating systemic risk and monitoring interconnected financial institutions (Goodhart, 2011; Tarullo, 2014).

Third, its responsibility for payment and settlement systems, i.e. operating infrastructures such as Fedwire and clearing services, positions it at the core of financial market functioning, reducing transaction costs and counterparty risk while safeguarding liquidity in times of stress (Kahn and Roberds, 2009).

Fourth, as fiscal agent and provider of liquidity to depository institutions, the Fed acts as lender of last resort, supplying emergency credit under Section 13(3) of the Federal Reserve Act to prevent contagion and stabilize markets, a role extensively analyzed in both historical and contemporary scholarship on central banking (Gorton and Metrick, 2013).

Moreover, the Fed's governance blends public accountability and operational independence, as Congress defines its statutory objectives, including the dual mandate of price stability and maximum employment, while delegating to the central bank discretion over the instruments used to achieve them.

According to several scholars, higher degrees of central bank independence can be associated with lower and more stable inflation without long-run costs in output (Alesina & Summers, 1993). In the U.S. case, independence is operational rather than goal-based: Congress establishes the mandate and retains oversight through reporting requirements and confirmation of Board members, but the Federal Reserve exercises autonomy in setting interest rates, conducting open market operations, and deploying its balance sheet (Bernanke, 2010; Binder & Spindel, 2017).

At the same time, the Fed's accountability is institutionalized through semiannual testimony before Congress, publication of minutes and economic projections, and external auditing, embedding transparency mechanisms within a framework designed to balance democratic control with technocratic policy execution.

The US Institutional Framework: The Crisis Management before Covid-19

Before the outbreak of the COVID-19 pandemic, the United States' experience with major emergencies, including the September 11 attacks, Hurricane Katrina, the Great Recession, and the

2009 H1N1 influenza outbreak, had consolidated a distinct model of crisis governance embedded within, yet partially exceptional to, the ordinary constitutional framework.

This pre-pandemic configuration reflected dual institutional logic: on the one hand, crisis response could be rapidly federalized through executive activation of delegated statutory authorities (rather than through ad hoc constitutional transformation), and on the other hand, implementation authority remained structurally dispersed across states and localities (de Biase and Dougherty, 2021; Kettl, 2020).

In practice, presidents could "switch on" federal coordination and resources by invoking a series of emergency pathways, most prominently a Stafford Act declaration, which usually is operationalized through FEMA), a National Emergencies Act declaration, or a public health emergency determination by HHS, each of which expands federal convening capacity, funding streams, and regulatory flexibility while remaining grounded in congressional delegation (Katz, Attal-Juncqua and Fischer, 2017).

More specifically, the Stafford Act framework enables the President, upon a governor's request, to declare a major disaster or emergency, thereby unlocking federal disaster relief funds, authorizing direct federal assistance, coordinating interagency logistics, and reimbursing state and local governments for response expenditures. Crucially, this pathway does not displace state authority; rather, it overlays federal fiscal and logistical capacity onto state-led operations, reflecting a cooperative federal structure (Katz, Attal-Juncqua and Fischer, 2017; Waugh and Tierney, 2007).

By contrast, the National Emergencies Act functions as a meta-framework: it does not itself create substantive powers but activates authorities embedded in other statutory provisions once the President formally declares a national emergency. As scholars of presidential emergency powers note, this mechanism has historically enabled executives to reallocate funds, regulate economic transactions, or adjust administrative requirements without returning to Congress for immediate legislative revision (Fisher, 2013; Moe and Howell, 2020).

The public health emergency determination under the Public Health Service Act, meanwhile, empowers the Secretary of HHS to waive certain regulatory constraints, facilitate emergency use authorizations for medical countermeasures, and access the Public Health Emergency Fund, while coordinating national surveillance and guidance through agencies such as the Centers for Disease Control and Prevention (Kershner and Sunshine, 2017; Michaud et al., 2025).

Together, these overlapping statutory pathways form a layered activation structure: rather than creating a single centralized emergency constitution, U.S. law provides modular triggers that expand executive discretion within legislatively defined boundaries.

Moreover, prior to the COVID-19 pandemic, the United States' crisis management architecture rested on a combination of centralized fiscal authority, unified regulatory competence, and executive mobilization tools embedded within a federal constitutional order.

At the core of this structure there was the federal government's consolidated taxing and borrowing power, which enabled macroeconomic stabilization and large-scale deficit spending without requiring intergovernmental negotiation among constituent units (Georgiou, 2023).

These tools were entrenched in the American fiscal federalism, which is characterized by strong subnational autonomy coexisting with a central government capable of redistributive intervention and countercyclical stabilization. This fiscal capacity had been demonstrated during the Great Recession, when Congress authorized extensive financial support and stimulus measures that were implemented through executive agencies (Tooze, 2018).

Moreover, the executive branch retained access to industrial policy instruments such as the Defense Production Act of 1950, permitting the prioritization of contracts and expansion of manufacturing capacity in situations deemed vital to national defense or emergency preparedness (Moe and Howell, 2020).

At the same time, implementation authority in public health remained largely decentralized, reflecting the enduring logic of cooperative federalism in which federal actors steer subnational governments through conditional funding, administrative guidance, and coordination rather than direct command (Kincaid, 1990; Béland et al., 2021).

This configuration combined centralized fiscal and regulatory capacity with dispersed operational authority, producing a crisis management framework that was legally robust, administratively layered, and capable of rapid federal activation while preserving formal adherence to constitutional separation of powers and federalism , but also risks coordination gaps, uneven capacity across states, and legal uncertainty during rapidly evolving crises (Katz, Attal-Juncqua and Fischer, 2017).

At the same time, the multiplicity of declarations can produce institutional complexity, fragmented accountability, and strategic layering of authorities, reinforcing the hybrid character of pre-pandemic U.S. crisis governance, simultaneously centralized in activation yet decentralized in implementation (Katz, Attal-Juncqua and Fischer, 2017).

Taken together, this pre-pandemic configuration depicted the United States as a mature fiscal federation endowed with centralized borrowing power, and statutory industrial mobilization authority, which are institutional attributes commonly associated with high-capacity crisis governance.

Yet, the COVID-19 pandemic would reveal that formal federal capacity does not automatically translate into coherent crisis management outcomes, thereby providing a critical test of whether pre-existing structural advantages were sufficient to generate coordinated action in a highly decentralized federal system confronted with a nation nationwide public health emergency.

2. COVID-19: Disease, Diffusion, and Impact

COVID-19 as a Global Pandemic

COVID-19 is an infectious disease caused by the severe acute respiratory syndrome SARS-CoV-2 (World Health Organization, 2025), which provoked an unprecedented global health crisis from its spread in late 2019 until its official end, declared in 2023. The virus is characterized by high human-to-human transmissibility, including pre-symptomatic and asymptomatic transmission, which contributed to its rapid global spread (He et al., 2020).

COVID-19 as a Global Pandemic: The International Health Regulations

In fighting the virus, states implemented International Health Regulations, a legally binding framework for states parties to prevent, prepare for, protect against, and respond to the international spread of disease, while avoiding unnecessary interference with international traffic and trade (World Health Organization, 2005).

IHR established a step-by-step process to monitor and eventually respond to the diffusion of potential threats to human health. IHR's Annex 2 introduced a technical, rule-based approach to help determine whether an event occurring within its territory should or not be reported to WHO and how to behave towards the disease.

Delving deep into Annex 2 decision instrument, it established that there are some diseases which should be reported immediately to WHO, as they are always unusual and serious, and these viruses are Smallpox, Poliomyelitis, SARS and Human influenza. If the event does not comprehend those viruses, the state should evaluate the situation through four criteria: if the public health impact is serious, if the event is unusual or unexpected, if there is a serious possibility of international spread and if the virus could force states to adopt travel or trade restrictions.

After having evaluated the situation, if the analysis of the ongoing event is positive to two of the four questions, the state should notify WHO within 24 hours of that evaluation through National IHR Focal Point, as established by Article 6 of the International Health Regulation (World Health Organization, 2025). This provision established also that the state that assessed the threat should keep on furnishing information to WHO over case definitions, lab results, number of cases and eventually deaths, and the measures implemented.

Once the WHO Director-General receives the information, he should determine, in accordance with the state party, whether the documented event represents or not a Public Health Emergency of

International Concern (PHEIC), as established by Article 12 of the IHR (World Health Organization, 2025).

Following this acknowledgment, the Director-General should implement Article 48 and Article 49 of IHR, creating an Emergency Committee, composed of experts from the IHR Expert Roster, with the aim of getting advice over the possible PHEIC declaration.

Finally, once Emergency Committee provides its opinion, Director-General takes its final decision considering all the information received, and if he declares the event as a PHEIC, he should also determine if the event is a pandemic emergency (World Health Organization, 2025).

COVID-19 as a Global Pandemic: Early Diffusion

Focusing on the spread of COVID-19, the first case was registered in December 2019 and was reported by the Wuhan Municipal Commission as a cluster of cases of pneumonia of unknown origin in Wuhan, China. Within short time the situation quickly escalated, the virus spread rapidly across countries and on 13 January 2020 it was reported the first case in Thailand, meaning that the virus was no longer geographically contained, raising international concern.

After several reports of human-to-human transmissions, as the virus met Annex 2 requirements, the WHO Director General convened an Emergency Committee under the International Health Regulations (IHR, 2005) on 22 January 2020, to assess whether the virus constituted a Public Health Emergency of International Concern (PHEIC) (World Health Organization, 2025).

However, due to the impossibility of the independent members to reach consensus based solely on the evidence provided, because of the absence of clear information about virus' transmissibility and impact, they planned to meet again ten days later.

As the situation quickly escalated, the Emergency Committee was reconvened eight days later, on 30 January 2020, and this time the members unanimously reached the consensus and advised the Director General that SARS-CoV-2 outbreak constituted a Public Health Emergency of International Concern (PHEIC). Following this statement, the Director General declared a PHEIC, being only the 6th time since IHR was approved that this declaration was made. At that time, the recorded cases of COVID-19 outside China were less than 100, and deaths caused by the disease were zero (World Health Organization, 2020).

Following such declaration, in just a few days WHO, to help states facing the virus, especially the ones with the weakest health system, released the international community's Strategic Preparedness and Response Plan.

The goal was to prepare for and respond to COVID-19, looking to stop further transmission of the virus, and at the same time reduce the effect that it had on economic, health systems and communities (World Health Organization, 2020).

By the time the SPRP was published, there were 11.953 confirmed cases around the world, 11.821 of whom were in China, and the other 132 spread across 23 countries. There were also 259 confirmed deaths caused by the virus (World Health Organization, 2020).

The SPRP established a set of strategic objectives, grounded in WHO's early risk evaluation of the disease. Starting from an initial judgment of states risks and vulnerabilities, the document settled down six strategic objectives: stop, or at least limit, human-to-human transmission, act promptly to identify and isolate cases, comprehend and curtail animal-to-human transmission, fulfil knowledge gaps concerning severity, spread, treatments and other aspects of the virus, provide an effective and clear communication and counter misinformation, minimize social and economic breakdown (World Health Organization, 2020).

Moreover, specific attention was given to risk communication and on countering the spread of misinformation. The document stressed out the importance of operational measures such as surveillance, laboratory diagnostics, infection prevention and control in healthcare settings, fast reaction team, health screening and safe management of suspected cases at airports, ports, and border crossings, prioritizing countries based on risk and vulnerability mapping derived from IHR core capacity levels and likelihood of case importation (World Health Organization, 2020).

To properly implement these strategic priorities, the World Health Organization, in close cooperation with national authorities, UN Agencies, technical partners like the Global Outbreak Alert and Response Network (GOARN), research institutes, non-governmental organizations (NGOs) and Private Sector Partners, conceived the response around three pillars: Rapid International Coordination and Operational Support, Scaling Up Country Readiness and Response and Accelerating Research and Innovation.

Progresses were checked through a set of indicators tied to IHR obligations and core abilities: the ratio of states reporting their first verified case to WHO within 24 hours, the percentage of laboratory results available within 72 hours for the first alleged cases, enforcement of national public health emergency coordination systems or operations centers, preparedness and operational readiness indices based on the IHR State Parties Self-Assessment Annual Reporting (SPAR) tool; the percentage of alerts, suspected or confirmed cases detected at points of entry; the percentage of countries that have established referral systems for patient care; the proportion of healthcare facilities

with triage capacity and with isolation capacity; and the percentage of countries that have contextualized risk communication and community engagement strategies (World Health Organization, 2020).

Moreover, in order to be able to implement all these countermeasures, the experts estimated a three-month fund requirement for USD $675,680,427 million, divided mainly in three sections: $30,577,500 million for Coordination & Support, $640,361,927 million for Country Preparedness & Response and $4,741,00 million for Research & Innovation (World Health Organization, 2020); however, these forecasts extremely underestimated the scale and impact of the virus.

After the release of the Strategic Preparedness and Response Plan, on 11-12 February WHO convened a Research and Innovation Forum with more than 400 experts from around the world, to assess the current level of knowledge about the new COVID-19 disease, identify gaps and work together to accelerate and prioritize the research needed to help stop this outbreak and prepare for any future outbreaks (World Health Organization, 2020).

Furthermore, by early February there were 28.276 confirmed cases worldwide, with the virus identified in more than 25 countries, resulting as the cause of 565 deaths (Wu, Chen et Chan, 2020).

COVID-19 as a Global Pandemic: Early Diffusion - The WHO-China Joint Mission

As the outbreak intensified in early 2020, 25 experts from around the world and the WHO visited Wuhan, Guangdong, Sichuan and Beijing, as part of the WHO-China Joint Mission from 16 to 24 February. Their goal was to assess the epidemiological characteristics of SARS-CoV-2 and evaluate China's response strategy. By the conclusion of the mission, confirmed cases in China were around 75,465, while the number of reported deaths was 2.858 (World Health Organization, 2020).

The scientific expedition succeeded in reaching several important breakthroughs, such as that the virus was very similar (96%) to a bat SARS-like virus (BatCov RaTG13), they even discovered the way in which virus was transmitted: droplets and close contact, meaning that it was easier to contract the virus in communities, household and clusters. These were very important findings, laying the ground for possible countermeasures against the disease.

However, beyond epidemiological insights, the report drew international attention to China's governance approach, which was a three-stage system.

During the initial response, which lasted until 20 January 2020, authorities focused on surveillance, investigation, containment of a virus that was still considered a localized outbreak, they conducted epidemiological investigations, the viral genome was sequenced and shared internationally, and

COVID-19 was formally classified as a Class B infectious disease, triggering a stronger legal response framework (World Health Organization, 2020).

As transmission accelerated, Chinese Government implemented the response and switched to Stage Two, which introduced stringent containment measures, most notably the lockdown of Wuhan as a cordon sanitaire. Mobility was suspended, schools and workplaces were closed, temporary hospitals were constructed, and grid-based neighborhood management systems were implemented to monitor movement, isolate cases, and coordinate essential supplies (Liu et al., 2021; Shangguan and Wang, 2022).

Nevertheless, Stage Two failed to slow the spread of the virus and reduce the intensity of the pandemic, lasting only from 20 January to 7 February, because the situation rapidly escalated, and it required stricter and drastic measures.

From 8 February, China's Government entered Stage Three, developed to control clusters and start designing reopening society and economy. Rather than relying solely on blanket lockdowns, authorities introduced a geographically differentiated risk-classification system. Provinces and municipalities were categorized according to epidemiological indicators, including recent case counts and transmission intensity, and were assigned tailored restrictions ranging from strict lockdown to gradual reopening (He F. et al., 2021; He Y. et al., 2021).

This risk-tiered approach allowed differentiated reopening while maintaining centralized coordination. Low-risk areas resumed production with monitoring; medium-risk regions applied targeted controls; high-risk areas remained under strict restrictions.

The risk-based differentiated strategy was conceived to enable provinces and municipalities to adjust their policies according to standardized classification criteria, established by Chinese Central Government, specifically by the Joint Prevention and Control Mechanism of the State Council, the authority entitled to oversee China's epidemic response (World Health Organization, 2020).

By doing so, local authorities could implement restrictive measures only on their own territory, tailored to their specific epidemiological situation, being able to fight the disease but at the same time avoiding territories with low infection rates from being affected by unnecessary strict restrictions, enabling economies to restart without suffering side effects from measures that were not proportionate to their level of infection (He Y. et al., 2021).

Moreover, Zhejiang Province's Five-Color Epidemic Chart, depicted in Figure 1, operationalized this logic at the local level, combining epidemiological data, mobility patterns, and digital health codes to calibrate interventions in real time (He F. et al., 2021).

The significance of this system lay less in its specific color scheme than in its governing rationale: restrictions were layered, rule-based, and explicitly linked to measurable epidemiological thresholds. The approach attempted to reconcile public health control with economic continuity, allowing subnational authorities to apply proportionate measures within a nationally coordinated framework (He F. et al., 2021).

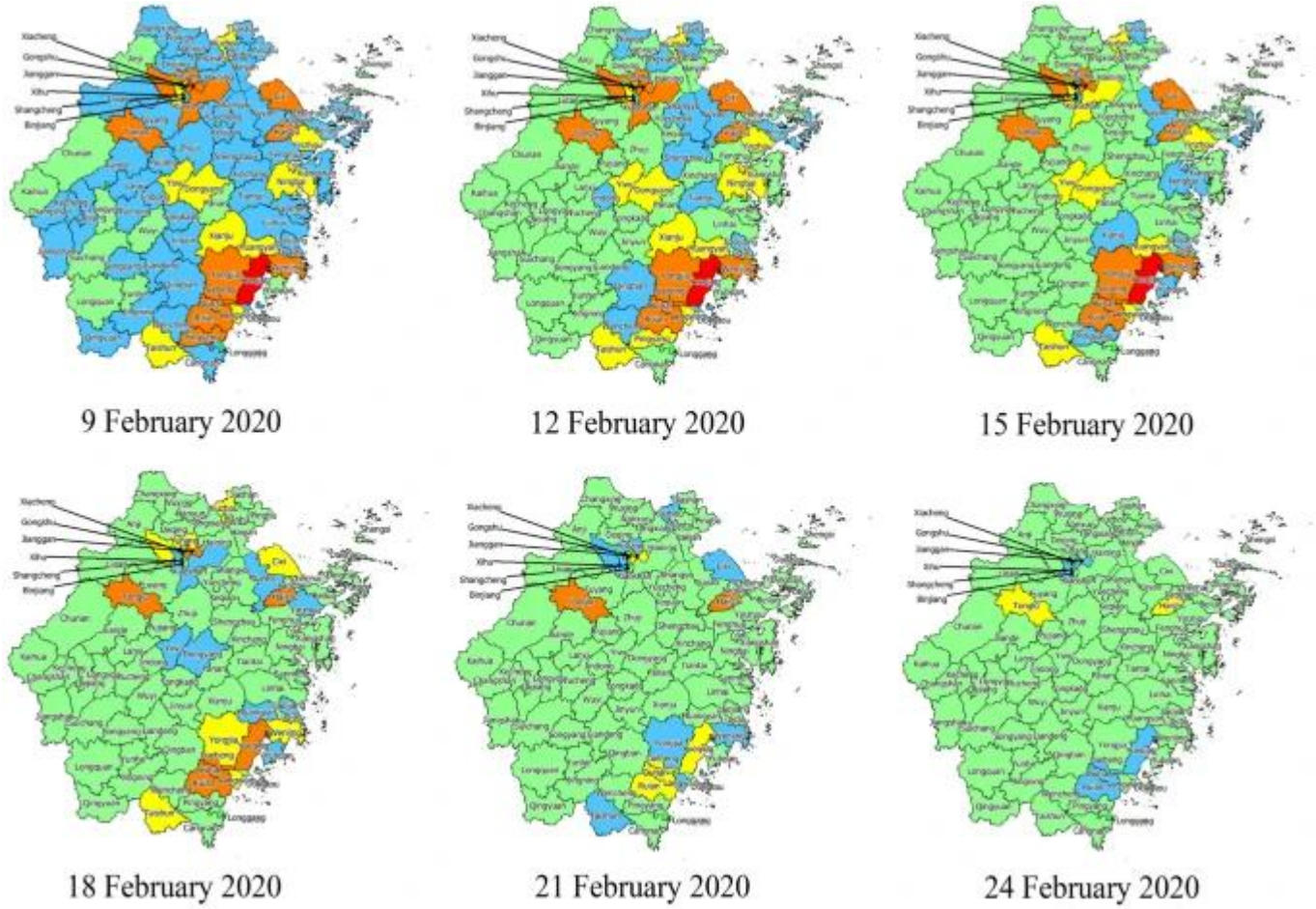

Figure 1: Five-colour epidemic charts of county-level epidemic risk in Zhejiang province from 9 to 24 February 2020. Source: He F. et al., 2021

This system allowed flexibility, transparency, and effective communication with the citizens over the evolution of the disease, improving public trust and productive collaboration (He F. et al., 2021).

By highlighting all the benefits that this method brought in fighting the disease, the WHO-China Joint Mission Report. significantly contributed to shape the countermeasures adopted by other countries. In addition to this, thanks to scientific publications, research articles, international news outlets and think tank who frequently dissect China's epidemic response system, and due to international

policymakers' constant studies of China's nuanced approach, the world discovered the peculiar strategy implemented in the Zhejiang Province.

Even though states did not explicitly replicate the Five-Colour Epidemic Chart set up in China; after getting in touch with that system, they quickly understood its importance and its benefits in fighting a disease never experienced before.

Thanks to this system, local administrations could implement economic reopening in areas where the disease was less harsh, significantly reducing the potential impact of COVID-19 and putting in place targeted lockdown and other restrictive measures, without affecting areas where the scientific evidence showed less contagious (Yang & Yu, 2023).

COVID-19 as a Global Pandemic: The Global Health Crisis

Following the WHO-China Joint Mission, because the virus kept spreading around the world, on 11 March 2020 the World Health Organization, concerned about the severity of the disease, officially declared COVID-19 a pandemic, publicly recognizing the global scale of the virus (World Health Organization, 2020).

In the period precedent to this statement, since its early diffusion in December 2019, the epidemiological situation seriously worsened outside China. This statement was crucial, because it marked the transition from a regional health crisis to a systemic global shock affecting health systems, economies, and governance structures simultaneously.

Indeed, by mid-February WHO registered contagion in at least 24 countries, such as France, Germany, Japan, and Singapore (World Health Organization, 2020).

COVID-19 as a Global Pandemic: The Global Health Crisis – Community Transmission Chain

Community transmission chains emerged early because infections were not detected quickly enough to interrupt onward spread.

In the first weeks of the outbreak, surveillance systems faced a structural delay between infection, symptom onset, care-seeking, testing, and confirmation, so by the time the first cases were recognized in a given locality, multiple generations of transmission could already have occurred.

This delay was amplified by substantial under-ascertainment: a large share of infections was never documented, because symptoms were mild, atypical, or absent; because testing capacity and case definitions were initially restrictive; and because clinical recognition was still evolving (Li et al., 2020).

Modeling work that integrates epidemiological and mobility data suggests that, prior to major control measures, undocumented infections accounted for the majority of total infections and were a major driver of spread, effectively hiding transmission while still sustaining it in the community (Nishiura et al., 2020).

Once established, transmission expanded through local contact and mobility networks, such as households, workplaces, health-care settings, and community mixing, where short-range movement and inter-city connectivity created repeated opportunities for seeding and re-seeding of outbreaks.

Analyses linking case growth to mobility patterns show that population movement strongly shaped the geographic dispersion of early transmission, and that, even after the initial epicenter was identified, local chains of transmission were already forming outside Wuhan, consistent with network-driven diffusion rather than isolated introductions (Kraemer et al., 2020).

Internationally, the earliest spread beyond China was propelled by exportations, particularly from Hubei while outbound movement was still substantial. These findings were supported by the Global Epidemic and Mobility Model (GLEAM) framework, through which scholars estimated that the Wuhan travel quarantine and early international travel restrictions had their clearest impact at the international scale, reducing case importations abroad by nearly 80% until mid-February (Chinazzi et al., 2020).

Crucially, modeling analyses indicate that the measurable reduction in international case importations became evident only after a substantial number of infections had already been introduced into multiple countries.

In other words, by the time travel restrictions significantly curtailed cross-border mobility, SARS-CoV-2 had already been exported abroad through earlier waves of passenger traffic, allowing transmission chains to take root in several settings. As a result, although travel bans reduced the volume of incoming infected travelers, their implementation occurred too late to prevent the initial establishment of sustained community transmission in many affected regions, thereby limiting their effectiveness as a standalone containment strategy (Chinazzi et al., 2020).

Additionally, enforcing quarantine as a countermeasure delayed pandemic expansion in China by just 3 to 5 days, because major Chinese and international cities were already infected before the enforcement of the restrictions (Chinazzi et al., 2020).

These investigations were implemented when the community transmission chain was already established in Europe and in other regions, being among the reasons that led WHO to declare COVID-19 a pandemic (Ferguson et al., 2020).

However, later phylogenetic studies discovered that the virus was already silently diffused in EU communities, overturning the idea that COVID-19 was driven by foreign imported cases, as it was the result of a prolonged local spread (du Plessis et al., 2021).

These findings found further confirmations in early transmission dynamics, as these highlighted the incredible pace of transmission that the virus sustained once it got in touch with new populations (McBride, 2020).

COVID-19 as a Global Pandemic: The Global Health Crisis – Early Countermeasures

To properly address the pandemic, putting as a priority stopping the contagion, countries were forced to adopt radical countermeasures.

Indeed, the initial phase of the pandemic in early 2020 represented one of the most extensive and rapid global policy responses in recent history, driven by the urgent need to both protect public health and mitigate economic harm.

In the absence of vaccines or effective treatments during the early phase of the COVID-19 pandemic, governments worldwide implemented a suite of non-pharmaceutical interventions (NPIs), ranging from national lockdowns, stay-at-home orders, closure of schools and non-essential workplaces, to restrictions on public gatherings, looking to reduce viral transmission and relieve escalating pressure on health systems.

By the end of April 2020, almost half of humanity (i.e. over 3,9 billion people) was constrained by lockdown or stay-at-home policies implemented by local government to fight the disease, forcing social distancing.

Moreover, these countermeasures were implemented globally, meaning that international borders were closed, travel and public gatherings halted, and schools remained closed for several months, affecting education and child development (World Health Organization, 2023)

The policy choices enforced were grounded in established epidemic control theory and reinforced by early empirical insights from the WHO China Joint Mission, which concluded that rapid, large-scale containment measures in Wuhan and other provinces were temporally associated with a downturn in reported cases, reduced mobility, and a slowing of epidemic growth (World Health Organization, 2020).

The Mission's findings underscored that, in the absence of biomedical countermeasures, layered NPIs could interrupt transmission and flatten epidemic curves, providing critical time for health-system adaptation (OECD, 2020; World Health Organization, 2020).

More broadly, beyond their immediate role in suppressing transmission and protecting health-system capacity, NPIs were also intended to slow epidemic growth and "buy time" for the development, testing, and large-scale deployment of effective vaccines, considered essential for achieving a durable resolution of the pandemic (Gozzi, Bajardi and Perra, 2021).

Reflecting this evidence-informed guidance, governments rarely copied China wholesale. Instead, they translated the underlying principle, layered restrictions calibrated to perceived risk, into their own institutional settings (Delussu, Tizzoni and Gauvin, 2022).

As the pandemic evolved, many states adopted tiered or color-coded regimes (in which restrictions tightened or loosened across territories) that echoed China's staged, risk-differentiated approach, even though the administrative machinery and political justifications differed (Abdel-Motaal and Chun, 2025).

Taken together, the WHO–China Joint Mission did not merely report a public-health episode; it helped stabilize expectations about what serious early pandemic governance looked like. It reinforced a governing rationale that layered NPIs could buy time, which was used to expand beds and staffing, reorganize care pathways, establish testing and tracing capacity, and design economic compensation, while also giving political leaders a framework for justifying extraordinary limits on mobility as a temporary, rule-based response to systemic risk.

Moreover, the speed and stringency with which governments implemented NPIs influenced both health and economic outcomes during early 2020. Faster adoption of containment measures was correlated with lower peaks in mortality and reduced burden on health services, whereas delayed responses generally led to higher case counts and greater subsequent strain on public health resources (Siedschlag and Yan, 2020).

In this way, flattening the curve became simultaneously a health objective and a political-economic strategy: managing a shock by slowing its immediate peak impact to protect core institutions and sustain governability under conditions of scarcity and uncertainty (Demirgüç-Kunt, Lokshin and Torre, 2021).

However, while NPIs helped reduce transmission and avert health system collapse, they also triggered significant economic contraction and social disruption, underscoring the difficult choices policymakers faced at the time (Nguyen, Minh Ngo and Dinh Nguyen, 2024).

COVID-19 as a Global Pandemic: The Economic Downturns

The same instruments that rapidly reduced face-to-face contact (stay-at-home orders, workplace closures, limits on gatherings and travel) also froze large parts of the service economy, disrupted production networks, and compressed household incomes in ways that were immediate, unevenly distributed, and politically contentious.

As well depicted in Figure 2, at the macro level, official assessments converged on the view that 2020 constituted a historically sharp synchronized downturn: global GDP contracted by roughly 3.3–3.5% due to overlapping supply disruptions, demand retrenchment, and exceptional uncertainty (Gagnon, Kamin and Kearns, 2023).

At the same time, the contraction transmitted across borders through trade and value chains: the WTO reports that the volume of world merchandise trade fell by 5.3% in 2020, while trade in commercial services contracted far more steeply, with travel and transport being the most affected, mirroring how mobility restrictions and risk avoidance struck directly at globalized service flows

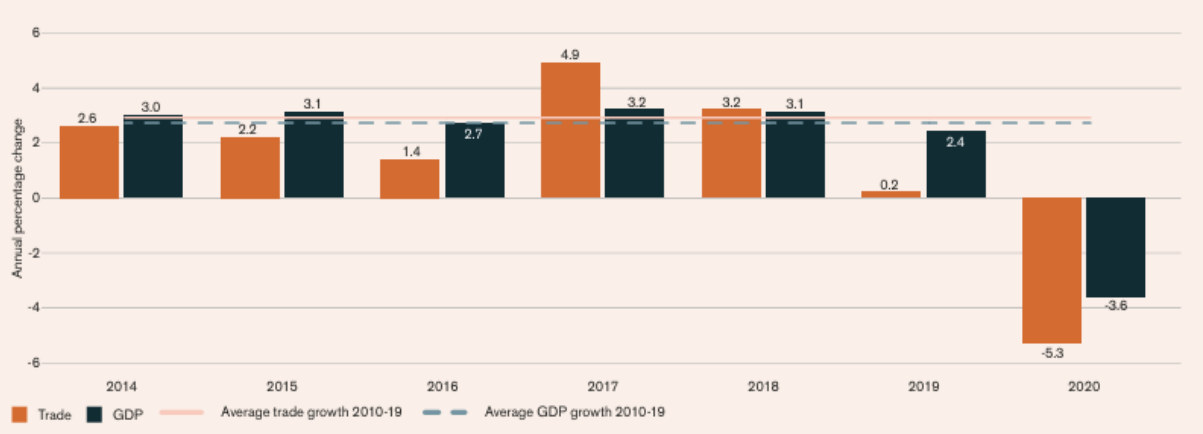

Figure 2: World merchandise trade volume and real GDP growth, from 2014 to 2020. Source: World Trade Organization, 2021

The labor-market consequences, central in political-economy framing, were equally stark. International Labour Organization assessments estimate that 8.8% of global working hours were lost in 2020 compared to late-2019, a shock with especially severe implications for workers in customer-facing sectors and for those without the protections of stable contracts or the option to work remotely (International Labour Organization, 2021).

At the same time, the global unemployment rate increased markedly in 2020. According to estimates, the world unemployment rate rose from about 5.4 % in 2019 to around 6.6 % in 2020, reflecting the severe disruption of labour markets worldwide as economies contracted and firms scaled back operations (Dahiam Saif Ghaleb, 2024).

These data reflected how lockdowns and social distancing measures curtail economic activity, and in many countries labour-force participation declined as workers withdrew from active job search amid continuing uncertainty.

Beyond the collapse in output and trade, the 2020 downturn was characterized by a sharp contraction in cross-border investment and by historically large, though highly uneven, fiscal interventions.

Global Foreign Direct Investments (FDI) fell to roughly $1 trillion in 2020 (about one-third below pre-pandemic levels), reflecting the abrupt interruption of international production and heightened uncertainty that delayed or cancelled greenfield and infrastructure projects (Koçak and Barış-Tüzemen, 2022; Hayakawa, Hoon Lee and Young Park, 2022).

At the same time, governments deployed historically large fiscal packages, but with major cross-country dispersion: advanced economies mobilized much larger budgetary support and guarantees than emerging markets, highlighting how “policy space” conditioned crisis management and reinforced asymmetric recoveries (Alberola et al., 2021).

These asymmetries were mirrored in broader macro-financial legacies, as public borrowing surged and debt ratios reached record highs (approaching around 100% of GDP at the global level), underscoring how stabilization was effectively reached through expanded state balance sheets (Kose, Ohnsorge and Sugawara, 2021).

COVID-19 as a Global Pandemic: The end of the Public Health Emergency of International Concern

By the time the WHO declared the end of COVID-19 as a Public Health Emergency of International Concern on 5 May 2023, the pandemic had undergone multiple epidemiological phases, forcing countries to shape their countermeasures as a reaction to the different variants in which COVID-19 turned during the pandemic.

In December 2020, thanks to the unprecedented effort put in place worldwide, the first COVID-19 vaccines were approved, marking an important shift in fighting the disease. As the vaccination campaign started, in 2021 approximately 5 billion people received at least one vaccine dose (Cheng

et al., 2023), boosting population immunity, leading to the downfall of death rates and of the hardest symptoms of the virus.

However, the virus changed, and several variants emerged, renewing waves of infection and fear. Among these, the most remarkable were the Alpha variant (B.1.1.7) the Delta (B.1.617.2) and Omicron (B.1.1.529) which put under more stress the health systems and the vaccines effects, due to their easier transmissibility and mortality.

Indeed, even as vaccines proved to be effective also against these variants, COVID-19 deaths continued to increase, surpassing the 5 million in early 2022 (Reuters, 2022).

While the virus evolved, national countermeasures implemented changed significantly, thanks to the scientific insights gained by WHO and scientists worldwide, as they dissected the virus and increased their knowledge.

Indeed, the proliferation of Omicron highlighted how even the stringent countermeasures enforced by national authorities had limits: in fact, even though the NPIs measures were re-imposed in January 2022, the variant spread across all communities.

However, thanks also to the diffusion of vaccines, several countries changed their approach towards the emergency, lifting or relaxing the restrictions and starting threating COVID-19 as an endemic threat, bringing back a kind-of normality in late 2022.

At the time that the global disease was considered under control, over 760 million confirmed cases of COVID-19 worldwide had been reported, with more than 6,9 million deaths (World Health Organization, 2025), even though some researchers sustain that the true death toll is even higher.

The broader trajectory of COVID-19 invites a closer examination of how institutional architecture and fiscal capacity conditioned crisis management, beginning with the European Union and then the United States, where different degrees of centralization, coordination, and political integration shaped not only immediate containment strategies but also the effectiveness of subsequent recovery and vaccination policies, reflecting Alexander Shaw’s work and Hamilton paradox in crisis management.

The European Union and COVID-19

Against this global backdrop of epidemiological shock and economic disruption, the European Union constitutes a particularly instructive case for examining how crisis management unfolded within a highly integrated yet nationally grounded system.

As a polity characterized by deep economic integration but limited central authority in core sovereign domains, the EU embodies the structural tension at the heart of Hamilton's paradox and Alexander Shaw's theory of crisis governance. The pandemic therefore offers the opportunity to assess how such a system, neither a fully federal state nor a loose intergovernmental arrangement, operates under conditions of systemic stress.

To understand how the crisis unfolded within the Union, it is first necessary to outline the configuration of its healthcare system, beginning at the central level.

The European Union and COVID-19 – The Healthcare System

The European Union does not operate as a single, unified EU healthcare system in the way that individual countries run national health services. Instead, health systems in the EU are organized, financed, and delivered primarily by each member state.

Indeed, the European Union's role in health policy is primarily supportive, coordinative, and complementary rather than directive because the foundational treaties explicitly allocate primary responsibility for health systems to the member states (Seitz, 2023; European Commission, n.d.).

Article 168 TFEU states that, while the Union may act to protect and improve human health, EU action shall respect the responsibilities of the member states for the definition of their health policy and for the organization and delivery of health services and medical care, and may only support, coordinate or supplement national policies in those fields rather than replace them (European Union, 2008).

This reflects the broader constitutional principle of conferral, whereby the EU can act only within competences voluntarily granted by member states in the treaties, leaving non-conferred competences, like the organization and financing of healthcare, firmly in national hands (Seitz, 2023).

Moreover, EU involvement is one of coordination and complementation, whereby the Union can facilitate cooperation, set cross-border standards (such as patient mobility rights), and address transnational health challenges, but does not establish a unified health system or harmonize national health provision.

Instead, EU health policy operates within a multi-level governance framework, recognizing substantial institutional and policy autonomy for member states while seeking to align efforts on shared objectives such as disease prevention, cross-border health threats, and patient rights (Greer, 2017).

In practice, the European Union's health landscape encompasses a diversity of national health-system models, reflecting different historical, institutional, and political choices about how healthcare should be financed and delivered rather than a single EU-wide scheme.

Traditionally, member states health systems are identified between two central archetypes: tax-funded "Beveridge" models and social insurance "Bismarck" models (Gaeta et al., 2017).

The Beveridge model, historically associated with the United Kingdom and later adopted in varying forms by other countries with national health systems, like Spain, Sweden, Denmark, Portugal, and Italy, is a publicly funded and largely publicly administered approach to healthcare (Gaeta et al., 2017)

It is financed primarily through general taxation, meaning that healthcare spending is drawn from the same pool of public revenues that fund other government services such as education, infrastructure, and defense. In this system, the government typically either owns healthcare facilities outright or acts as the principal payer, directly employing healthcare professionals or tightly regulating private providers.

Care under the Beveridge model is generally provided free at the point of use, so patients do not face direct charges for most medical services when they receive treatment. Instead, the financial risk is shared collectively across the population through taxes. The model is grounded in the principle that healthcare is a social right rather than a market commodity, emphasizing universal access, equity, and solidarity (World Economic Forum, 2020; Kutzin, 2009).

A prominent example is the National Health Service (NHS) in the United Kingdom, established in 1948, which was designed to ensure that medical care would be available to all residents based on need rather than ability to pay. While the model often achieves broad coverage and strong cost control through centralized budgeting, it can also face challenges such as waiting times, resource constraints, and political pressures over funding levels.

In contrast, the Bismarck model is structured around compulsory social health insurance, financed primarily through payroll-based contributions shared between employers and employees rather than general taxation. First introduced under Chancellor Otto von Bismarck in late 19th-century Germany,

the model was designed to provide workers with protection against illness while maintaining social stability and economic productivity (Busse et al., 2017; Gaeta et al.,2017).

At the core of the system are non-profit sickness funds (Krankenkassen), which collect mandatory contributions and pool financial risk across members. Although these funds operate independently, they are tightly regulated by the state to ensure standardized benefits, financial transparency, and equitable access.

Contributions are typically income-related rather than risk-based, meaning individuals pay according to their earnings, not their health status—reinforcing principles of solidarity and cross-subsidization between healthy and sick, young and old, and high and low-income groups (Busse et al., 2017; Saltman et al.,2004).

Healthcare services under the Bismarck model are delivered through a mixed system of public and private providers. Hospitals may be publicly owned, private non-profit, or private for-profit, while physicians often work in private practice but are reimbursed through negotiated fee schedules agreed upon by insurers and provider associations.

Unlike systems fully funded by general taxation, the Bismarck model preserves a pluralistic organizational structure while maintaining universal or near-universal coverage through mandatory participation (Busse et al., 2017; Saltman et al.,2004).

Countries such as Germany, France, Belgium, Austria, Czech Republic, Slovakia, Slovenia and Netherlands operate systems derived from the Bismarck tradition, though each has adapted the framework to its own political and social context. While this model often achieves strong patient choice and relatively short waiting times, it can involve complex administrative coordination and higher overall expenditures compared to more centralized, tax-funded systems.

Both these ideal types, however, are analytical constructs: in reality, few countries adhere strictly to a pure model. Most EU member states exhibit hybrid characteristics, integrating elements of both models, together with mixed financing arrangements that combine taxation, social insurance contributions, and sometimes supplementary private insurance or out-of-pocket payments.

This hybridization reflects pragmatic policy responses to fiscal pressures, demographic ageing, and evolving expectations about quality and choice, and means that institutional frameworks and benefit entitlements vary considerably within these broad categories (Jakubowski and Busse,1998).

Despite this structural diversity, broad normative commitments are shared across EU health systems.

Almost all member states pursue universal or near-universal coverage, solidarity-based risk-pooling, so that the healthy subsidize the sick and the wealthy subsidize the less well-off, and statutory guarantees of access to a basic package of healthcare services.

These shared goals of access, equity, and financial protection shape health policy across Europe, even as countries differ in how entitlements are defined, the degree and forms of cost-sharing they employ, such as co-payments, how providers are paid (i.e. global budgets, capitation, or fee-for-service), and the governance structures that regulate performance (Gaeta et al., 2017; Jakubowski and Busse, 1998).

Taken together, this constitutional allocation of competences and the coexistence of heterogeneous financing and delivery models produce a structurally fragmented health governance landscape at the European level.

Indeed, EU health policy is characterized less by centralized authority than by regulatory integration without system integration, meaning that while certain market-correcting or coordination mechanisms exist, the Union lacks direct operational control over healthcare financing, service delivery, or emergency response infrastructure (Greer, 2017).

There is no EU health ministry, no standing fiscal capacity dedicated to healthcare expenditure, and no treaty-based competence to harmonize national health systems. Instead, twenty-seven ministries of health retain primary authority over procurement decisions, reimbursement rules, public health administration, and crisis logistics.

This dispersion of fiscal, administrative, and regulatory authority would ordinarily be expected to complicate rapid, unified action in the face of a transnational health emergency.

In this sense, the EU entered the COVID-19 crisis not as a centralized health actor comparable to a federal state, but as a legally constrained and institutionally decentralized polity whose capacity for collective action in healthcare depended fundamentally on voluntary coordination among sovereign governments.

Considering so, the emergence of a centralized vaccine procurement strategy during the pandemic represents a significant and analytically unexpected departure from the Union's established mode of health governance.

The European Union and COVID-19 – The Crisis

The outbreak of COVID-19 reached Europe within a broader institutional context characterized by the European Union's dual governance structure. As discussed in the previous chapter, the EU

operates through a system in which supranational institutions coexist with strong national authority, particularly in policy domains where competence remains primarily with the member states.

Healthcare represents one of the clearest examples of this institutional duality: while the Union may support coordination and cooperation, responsibility for the organization, financing, and delivery of healthcare services lie predominantly with national governments.

This institutional configuration significantly shaped the conditions under which the pandemic unfolded across the continent.

During the first months of 2020, several member states experienced rapid increases in infections and mortality, placing extraordinary pressure on healthcare infrastructures and exposing structural vulnerabilities in areas such as medical supply chains, crisis preparedness, and cross-border coordination.

The scale and simultaneity of the shock generated significant health and socio-economic damage across the Union, while also highlighting the limitations of purely national responses within a highly interconnected European space.

Understanding how the pandemic initially unfolded across Europe, and the extent of the disruption it produced, is therefore essential for analysing the pressures that emerged for greater coordination at the European level. These developments would ultimately create the political and institutional conditions under which more centralized responses, such as joint vaccine procurement, could emerge, illustrating dynamics consistent with the Hamilton Paradox.

These dynamics became visible as the virus spread rapidly across multiple member states, exposing the limits of nationally fragmented responses.

Indeed, the pandemic unfolded across Europe with remarkable speed during the early months of 2020, transforming a public-health threat into a systemic crisis affecting both health systems and the broader European economy.

The first wave of SARS-CoV-2 infections in Europe emerged in late February 2020, when sustained community transmission was first identified in northern Italy and rapidly expanded across several European countries, producing sharp increases in both confirmed cases and mortality within a few weeks (Cereda et al., 2020).

By 27 April 2020, Europe had recorded approximately 1.36 million confirmed cases and more than 124,500 deaths, representing the largest concentration of infections worldwide at that time (Cereda et al., 2020).

During March and April 2020, the exponential growth in contagion led to severe pressure on healthcare systems, particularly in countries such as Italy and Spain, which became the early epicenter of the pandemic in Europe, as the excess mortality reached 54.3% in Spain and 49.6% in Italy in March 2020, illustrating the extraordinary pressure placed on national health systems during the initial outbreak (Eurostat, 2024).

Hospitals faced shortages of intensive care capacity, medical personnel, and critical supplies, revealing the limited preparedness of national health systems for a shock of this magnitude. In this context, reducing hospitalizations and preventing severe cases rapidly became a central priority for policymakers, increasing the strategic importance of vaccine development and large-scale immunization campaigns as the most sustainable exit strategy from the crisis (Supady et al., 2021).

Mortality surveillance systems confirmed the magnitude of the crisis: pooled data from the European Mortality Monitoring network estimated over 159,000 excess deaths between week 10 and week 20 of 2020, the period corresponding to the peak of the first wave (EuroMOMO, 2020).

These data illustrate how rapidly the epidemic escalated during the spring of 2020, transforming an initially localized outbreak into a continent-wide public health emergency characterized by a sudden surge in infections, hospitalizations, and deaths.

Furthermore, comparative analyses of mortality patterns indicate that Europe experienced over 800,000 excess deaths during 2020–2021, corresponding to roughly an 11% increase in mortality compared with expected levels, with nearly 88% of excess deaths occurring among individuals aged 65 and over (Rossen et al., 2022).

These data capture indirect effects related to healthcare disruptions, delayed diagnoses, and broader social and economic consequences of the pandemic (Rossen et al., 2022).

In parallel, the health crisis was accompanied by a profound economic shock as governments implemented lockdowns, mobility restrictions, and large-scale containment measures aimed at slowing viral transmission (Dreger, 2022), as will be explained in the following section.

These interventions, although essential from a public health perspective, led to an abrupt contraction in economic activity across Europe. The temporary closure of non-essential businesses, restrictions on travel and social interaction, and disruptions to global supply chains significantly reduced production, consumption, and investment.

As a result, the European economy experienced one of its deepest downturns in the post-war period. Indeed, as depicted in Figure 3, the EU's GDP contracted by approximately 5,6%, according to the

World Bank, reflecting the widespread suspension of economic activity during the strict containment phases of the pandemic.

Figure 3: European Union GDP from 2000 to 2021. Sources: World Bank Group, 2026.

Labour markets across the European Union were also severely disrupted by the COVID-19 pandemic.

The introduction of lockdowns and restrictions on economic activities led to a sharp decline in labour demand, resulting in widespread temporary layoffs, reduced working hours, and job losses (Fana, Torrejón Pérez and Fernández-Macías, 2020).

However, the employment impact of the crisis was highly uneven across sectors, reflecting the degree to which activities relied on physical proximity and face-to-face interaction. Sectors such as tourism, hospitality, retail, arts and entertainment, and passenger transport were disproportionately affected because social distancing measures and mobility restrictions significantly limited their operations (Fana, Torrejón Pérez and Fernández-Macías, 2020).

Indeed, during the first phase of the pandemic many non-essential service activities were temporarily closed by government confinement decrees, which generated substantial employment losses and labour market instability across EU countries.

The scale of the economic disruption was reflected not only in employment indicators but also in industrial activity. By April 2020, European industrial production levels were 27% lower than in the same period of the previous year, a decline that exceeded the contraction experienced during the 2008–2009 global financial crisis (CECE, 2020).

This disruption is reflected in the evolution of labour market indicators during the pandemic. As illustrated in Figure 4, employment (yellow bars) experienced a sharp contraction in 2020 while the unemployment rate (blue line) increased after several years of decline, highlighting the abrupt impact of the pandemic on European labour markets.

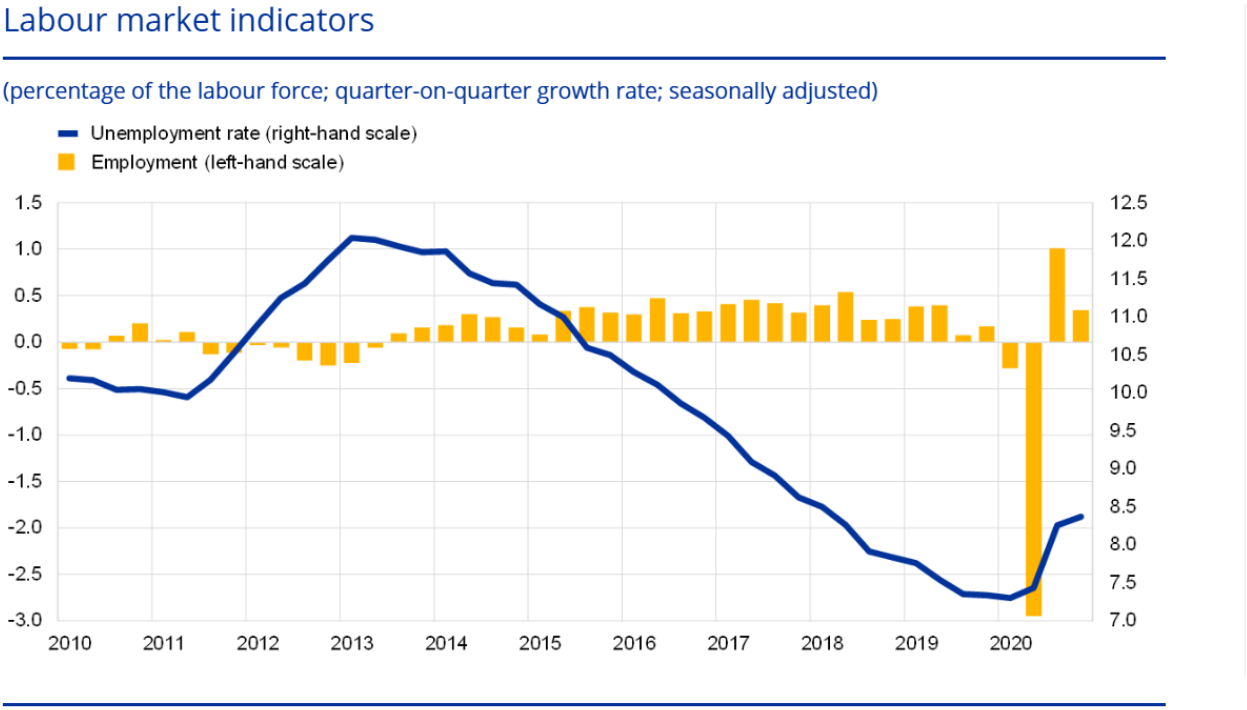

Figure 4: Labour market indicators in the European Union from 2010 to 2020. The blue line represents the unemployment rate, while the yellow bars show the quarter-on-quarter growth in employment. Sources: European Central Bank, 2021.

More broadly, however, the pandemic highlighted structural vulnerabilities in service-based economies: industries dependent on human mobility and direct social interaction experienced far larger declines in activity than sectors where telework or digitalization could partially substitute for physical presence.

Therefore, the labour market consequences of the crisis were concentrated among workers in customer-facing occupations, many of whom experienced income losses, temporary furloughs, or transitions into unemployment during the early stages of the pandemic (Fana, Torrejón Pérez and Fernández-Macías, 2020).

Empirical analyses confirm that the severity of the economic shock was closely linked to the intensity and duration of containment measures implemented by governments, which simultaneously suppressed demand and disrupted supply (Deb et al., 2021).

NPIs interventions were essential to limit viral transmission, yet they also generated significant economic disruptions by simultaneously suppressing demand and constraining supply.

On the demand side, restrictions on mobility and uncertainty about the evolution of the pandemic led households to reduce consumption, particularly for services requiring physical presence such as travel, hospitality, and entertainment. On the supply side, the temporary closure of businesses, disruptions to global value chains, and workplace safety constraints limited production capacity across many sectors (Deb et al., 2021).

Additionally, regions and countries implementing stricter or longer-lasting containment policies tended to experience larger short-term declines in economic activity and employment, reflecting the direct impact of these measures on both consumption and production dynamics (Fana, Torrejón Pérez and Fernández-Macías, 2020; Chetty et al., 2020).

These findings highlight the dual nature of containment policies: while crucial for public health, they also played a central role in shaping the depth and distribution of the economic downturn during the pandemic.

Building on these observations, academic studies increasingly characterize the pandemic as a simultaneous health and economic crisis, in which containment policies and behavioral responses contributed to significant contractions in GDP across European economies. The combination of rising mortality rates, the intense pressure placed on national healthcare systems, and the sharp economic downturn produced an unprecedented multidimensional crisis within the European Union (Morgenstern et al., 2023).

In a highly integrated political and economic area, such developments quickly revealed the limitations of purely national responses, which constituted the first countermeasures adopted during the initial phase of the crisis, and intensified the need for coordinated action at the European level, reinforcing Alexander-Shaw's theory.

The European Union and COVID-19 – Early National Countermeasures

When COVID-19 began spreading rapidly in Europe in early 2020, the Union did not possess the instruments typically associated with a centralized health authority. Crisis preparedness, hospital capacity, procurement of medical equipment, and the implementation of public health measures were

largely managed by national administrations, reflecting the constitutional allocation of competences embedded in the EU treaties.

From a theoretical perspective, this institutional configuration would normally be expected to produce fragmented responses to a transnational health emergency.

Yet Alexander Shaw's theory of the Hamilton Paradox suggests that severe crises may generate political pressures that challenge these institutional constraints. In moments of systemic stress, collective-action problems can become sufficiently acute so that governments find incentives to pursue deeper cooperation or institutional innovation at higher levels of governance, even in policy areas traditionally dominated by national authority (Alexander-Shaw, Ganderson and Schelke, 2023; Rodden, 2006).

The development of the COVID-19 crisis in Europe therefore provides a particularly relevant empirical setting in which to observe these dynamics.

In the very early phase of the COVID-19 outbreak in Europe, which lasted from January to March 2020, the first countermeasures were implemented primarily at the national level, reflecting the EU's limited competences in public health and the absence of an immediate supranational crisis framework.

Governments such as Italy, France, and Germany rapidly introduced non-pharmaceutical interventions, including quarantine zones, restrictions on mass gatherings, school closures, mobility limitations, and the reintroduction of internal border controls within the Schengen area, effectively suspending free movement across large parts of the Union, alongside efforts to expand testing capacity, epidemiological surveillance, and emergency public-health coordination mechanisms. (Gandy et al., 2020).

Italy's lockdown of municipalities in Lombardy and Veneto in February 2020 represented one of the first large-scale containment efforts in Europe and soon influenced similar measures across other member states (Adobati, Comi and Ghisalberti, 2021).

However, these early national responses were often fragmented and poorly coordinated across the European Union.

Indeed, member states adopted unilateral containment measures, relying on domestically designed emergency measures, including border closures, export restrictions on medical equipment, and divergent public-health regulations, that frequently disrupted the functioning of the single market and cross-border supply chains, as these measures were adopted rapidly and often without prior coordination among governments (Carreno et al., 2020; Freudlsperger et al., 2024).

For instance, several governments temporarily restricted the export of personal protective equipment and other medical goods, generating tensions among member states and raising concerns about the erosion of internal market principles during the early months of the crisis.

The timing, intensity, and design of these measures varied significantly across member states, reflecting differences in epidemiological conditions, institutional capacities, and domestic political considerations.

Such fragmentation exposed the structural difficulties of managing a transboundary health emergency within a political system where competences are divided across levels of governance (Anderson et al., 2020). While coordination mechanisms existed within the EU's health security framework, they were initially insufficient to ensure rapid collective action in the face of escalating epidemiological uncertainty.

As a result, early crisis management was characterized by nationally driven policy experimentation and uneven responses across member states, illustrating the limits of purely domestic approaches to crises that unfold within highly integrated political and economic spaces (Boin, Ekengren and Rhinard, 2020). In this sense, the early phase of the pandemic highlighted the tension between national sovereignty in health policy and the transnational nature of pandemic threats.

Parallelly, the pandemic quickly revealed the extent of interdependence among European economies and societies. Disruptions to mobility, production networks, and logistics in one member state rapidly reverberated across the Union's integrated economic space, amplifying the economic consequences of containment policies and demonstrating how unilateral measures could generate cross-border spillovers (Anderson et al., 2020). Supply chain disruptions, shortages of medical equipment, and the breakdown of cross-border mobility illustrated the systemic vulnerabilities created by deep economic integration without equally integrated crisis-management capacities (Moosavi, Fathollhai-Fard and Dulebenets, 2022).

Within the framework proposed by Alexander Shaw, such dynamics can be understood as a typical early stage of crisis governance in complex political systems with a relatively weak central authority, in which actors initially produce decentralized responses through established institutional routines and nationally bound capacities before gradually recognizing the need for more coordinated solutions (Alexander-Shaw, Ganderson and Schelke, 2023; Rodden, 2006).

As the consequences of fragmented responses became increasingly visible, the pandemic began to function as a catalyst for collective problem recognition, creating political pressure for greater coordination and joint action at the European level.

The early reliance on national measures therefore did not simply reflect institutional constraints; it also constituted a critical phase in the evolution of the crisis, through which the limitations of fragmented governance became evident and opened the political space for the subsequent development of more coordinated European responses (Alexander-Shaw, Ganderson and Schelke, 2023).

The European Union and COVID-19 – EU Countermeasures

Building on the recognition of these limitations, EU institutions gradually assumed a more active role in managing the crisis and mitigating its broader economic and social consequences.

This shift was made possible by a combination of existing treaty competences, pre-existing legal instruments for cross-border health threats, and the Commission's coordinating authority within the internal market framework.

Although public health remains primarily a national competence, EU law provides mechanisms allowing the Union, particularly the EU Commission, to support, coordinate, and supplement member state action in situations with significant cross-border implications.

Under Article 168 TFEU, the European Union holds only a supporting competence in public health, meaning that responsibility for the organization and delivery of health services remains primarily with the member states. The provision allows the Union to support, coordinate, or supplement national policies, while explicitly prohibiting harmonization of national health systems.

Nevertheless, the treaty also authorizes the adoption of incentive measures, coordination mechanisms, and health protection actions across all EU policies, creating a legal basis for EU-level involvement during cross-border health threats (Greer et al., 2020; de Ruijter, 2019)

Alongside this health-specific provision, the Commission was able to rely on broader market-regulation powers, particularly Article 114 TFEU, which enables the adoption of measures necessary for the establishment and functioning of the internal market.

Because the pandemic generated significant disruptions to cross-border trade, supply chains, and the free movement of goods and people, these internal market competences provided an important legal pathway for EU intervention (Tuominen, Salminen and Halonen, 2022).

Moreover, although formally designed to approximate national laws affecting the internal market, the Commission has historically used Article 114 as a regulatory gateway to address policy problems that simultaneously affect market integration and public health, allowing supranational institutions to act even in areas where formal competences remain limited (McHale and Hervey, 2015; de Ruijter, 2019).

In this sense, internal market law has frequently served as the legal vehicle through which the EU addresses transnational health risks embedded in cross-border economic activity (Greer et al., 2022).

The COVID-19 crisis provided a particularly clear illustration of this dynamic. In the early months of the pandemic, the national measures enforced threatened the integrity of the single market. The Commission therefore framed many of its early interventions in terms of preventing market fragmentation and safeguarding the free movement of essential goods, rather than directly regulating public health responses (Froman and Mossialos, 2021).

Through communications, guidelines, and implementing measures, it sought to coordinate national actions and ensure the continued circulation of medical supplies, pharmaceuticals, and critical workers across the Union.

Additionally, EU-level measures concerning the temporary export authorization scheme for personal protective equipment, and later the creation of the EU Digital COVID Certificate (a proof that a person has been vaccinated against COVID-19, received a negative test result, or recovered from the virus, enabling safe and free movement within the European Union), were justified in part by the need to avoid divergent national rules that could undermine free movement within the Union (Greer et al., 2022). In these cases, the internal market competence enabled supranational coordination precisely because the public health emergency had immediate implications for cross-border mobility and economic integration.

Consequently, the pandemic created both political and institutional conditions for an expanded interpretation of the Commission's coordinating role. In response to member states' unilateral measures, the Commission increasingly framed its interventions as necessary to safeguard the integrity of the single market while supporting public-health protection, thereby stretching the practical scope of its coordinating mandate within existing treaty limits (Greer et al., 2020).

Within this framework, one of the central tools enabling this coordination was the Joint Procurement Agreement (JPA) for medical countermeasures, originally established in 2014 following the EU Decision on serious cross-border threats to health, i.e. Decision 1082/2013 (European Parliament and Council, 2013).

The JPA allows participating member states to jointly purchase vaccines, therapeutics, or protective equipment through a centralized tendering process organized by the Commission. By pooling demand and negotiating collectively with suppliers, the mechanism was designed to strengthen bargaining power, ensure equitable access among participating states, and reduce competition between national governments during emergencies.

The Commission activated and expanded this mechanism, organizing coordinated procurement procedures for items such as personal protective equipment, ventilators, testing kits, and eventually vaccines through advance purchase agreements.

EU institutions also strengthened operational and logistical capacities in the health sector through mechanisms such as the rescEU strategic reserve, which was expanded during the pandemic to include stockpiles of medical equipment including ventilators, protective gear, and laboratory supplies.

Managed through the EU Civil Protection Mechanism, rescEU enabled the Commission to coordinate the distribution of critical resources to member states facing acute shortages, thereby supplementing national preparedness capacities (Greer et al., 2022).

In addition, the Commission supported enhanced epidemiological coordination through agencies such as the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), both of which played key roles in monitoring the spread of the virus, issuing risk assessments, and accelerating regulatory procedures for vaccines and treatments. In particular, the EMA implemented rolling review procedures to speed up the scientific evaluation of COVID-19 vaccines while maintaining EU regulatory standards for safety and efficacy (Greer et al., 2021).

Beyond procurement coordination and the safeguarding of the internal market, EU central institutions also introduced additional financial, logistical, and institutional instruments aimed at strengthening collective crisis management and supporting member states' health systems and economies.

One of the most significant initiatives was the creation of Next Generation EU (NGEU) and its central component, the Recovery and Resilience Facility (RRF), adopted in 2020 as an extraordinary financial instrument to support economic recovery following the pandemic (Fabbrini F., 2022).

Unlike traditional EU budgetary tools, NGEU was financed through large-scale common borrowing by the European Commission on financial markets, marking an unprecedented step in EU fiscal integration (de la Porte and Jensen, 2021).

Its adoption was made possible by the exceptional economic shock generated by the COVID-19 pandemic and by political learning from previous crises, which convinced member states that a coordinated fiscal response was necessary to avoid economic divergence and instability within the Eurozone (Fabbrini F., 2022).

Indeed, the pandemic created a critical juncture that facilitated agreement on a common recovery instrument, as governments feared that asymmetric economic impacts could threaten the integrity of

the single market and monetary union. Moreover, the experience of the eurozone crisis and its unresolved economic imbalances encouraged policymakers to adopt a more solidaristic and preventive approach, using common borrowing and redistribution to stabilize the EU economy and reduce political fragmentation across member states (de la Porte and Jensen, 2021; Fabbrini F., 2022).

Through the RRF, member states gained access to grants and loans conditional on the submission of national recovery plans aligned with EU policy priorities, i.e. green transition, digital transformation, smart, sustainable and inclusive growth, social and territorial cohesion, health and economic resilience and policies for the next generation.

This mechanism represented a major innovation in EU economic governance, as it combined fiscal solidarity with policy coordination and strengthened the Commission's role in overseeing national reform agendas (de la Porte and Jensen, 2021; Fabbrini F., 2022).

In parallel, other financial instruments were mobilized to address the immediate socio-economic consequences of the crisis. These included the Support to Mitigate Unemployment Risks in an Emergency (SURE) program, which provided loans to member states to finance short-time work schemes and employment protection measures, as well as credit lines made available through the European Stability Mechanism (ESM) and lending programs by the European Investment Bank to support businesses and public investment (Fernandez, 2021).

Adopted in April 2020, the SURE instrument allowed the European Commission to borrow on capital markets and provide up to €100 billion in loans to member states to support national short-time work schemes and similar measures designed to preserve employment during the pandemic (European Commission, 2020).

This tool represented an important innovation in EU social and economic policy, as it introduced a form of temporary European solidarity in labor market stabilization by pooling financial resources to support national welfare instruments. Additionally, by enabling governments to subsidize reduced working hours rather than resorting to layoffs, the instrument helped cushion the immediate employment effects of lockdown measures and economic disruption (Ladi and Trarouhas, 2020).

Alongside SURE, the Eurogroup agreed on additional financial safety nets designed to provide liquidity and fiscal support to member states and businesses. One element was the creation of a pandemic crisis support credit line within the European Stability Mechanism, which offered precautionary financial assistance to euro area countries to cover health-related expenditures linked to the COVID-19 crisis (European Stability Mechanism, 2020).

Although the instrument was only lightly used, it represented a rapid adaptation of the ESM's existing toolkit to the specific circumstances of the pandemic.

At the same time, the European Investment Bank (EIB) launched a large guarantee fund to mobilize financing for small and medium-sized enterprises, which were particularly vulnerable to the economic shock caused by lockdowns and supply chain disruptions (de la Porte and Jensen, 2021).

The combination of SURE, ESM credit lines, and EIB lending programs formed a coordinated financial safety net designed to protect employment, maintain access to credit, stabilize the European economy and prevent asymmetric shocks during the acute phase of the crisis (Fabbrini F., 2022).

Taken together, these financial, logistical, and regulatory initiatives significantly expanded the scope of EU-level crisis governance. While the treaties continued to limit the Union's direct authority over national health systems, EU institutions leveraged existing financial instruments, civil protection mechanisms, and regulatory agencies to complement national responses and enhance collective resilience.

The pandemic thus accelerated the development of a more integrated framework for European crisis management, demonstrating how the EU can deploy a combination of economic, regulatory, and coordination tools to address transnational emergencies even within the constraints of limited formal competences in public health (Greer et al., 2022; Fabbrini F., 2022).

Moreover, according to Alexander-Shaw, this process reflects the logic of Hamilton's paradox: the very weakness of the center can become a catalyst for its strengthening when crises reveal that decentralized responses are insufficient to manage collective risks. As governments and policy actors increasingly recognized the economic and public-health costs of fragmented crisis management, the Commission was able to mobilize existing legal instruments, particularly those related to the internal market, regulatory coordination, and crisis management, to promote joint responses and reduce policy divergence across member states. Consequently, the pandemic did not expand the EU's treaty-based authority in public health but reconfigured the political and institutional context in which existing competences were exercised, enabling supranational institutions to assume a more prominent coordinating role in managing the collective dimensions of the crisis (Alexander-Shaw, Ganderson & Schelkle, 2023; Boin, Ekengren and Rhinard, 2020).

The United States of America and COVID-19

Following the examination of the European Union, the United States offers a contrasting institutional setting through which to analyze crisis governance during the COVID-19 pandemic.

As a consolidated federal state endowed with significant national fiscal and administrative capacity, the United States differs markedly from the European Union's partially integrated supranational system, where central authority remains constrained by member state sovereignty. Yet the American system is also characterized by constitutionally entrenched state authority in key domains of public health, creating a complex balance between federal leadership and decentralized implementation.

In line with Alexander Shaw's framework, this institutional configuration suggests a dynamic distinct from that observed in the European Union: whereas systems with limited central authority may experience pressures toward greater coordination and integration during crises, mature federal systems tend to exhibit significant policy variation and intergovernmental contestation even as the central government mobilizes resources.

The pandemic therefore provides a valuable case for assessing how a federal polity with strong national capacity but decentralized public health authority responds to systemic stress. To understand how the crisis unfolded in the United States, it is first necessary to outline the institutional organization of its healthcare and public health system, beginning with the role of federal authorities and their relationship with state-level governance.

The United States of America and COVID-19 – The Healthcare System

The healthcare system of the United States is characterized as a mixed, multi-payer system in which both public and private actors finance and deliver health services.

Unlike many other high-income countries that have adopted universal health coverage systems guaranteeing access to health services for all residents, the United States relies on a fragmented and pluralistic insurance model.

In this system, coverage is obtained through a combination of private and public sources rather than through a single national health program. The majority of non-elderly Americans receive coverage through private health insurance, most commonly employer-sponsored plans, which historically developed as a consequence of wage controls during World War II and were later reinforced by favorable tax policies that encourage employers to offer health benefits as part of compensation packages (Blumenthal, Collins and Fowler, 2020).

In practice, employer-sponsored insurance (ESI) operates through group health plans arranged by employers with private insurance companies to provide coverage to employees and, frequently, their dependents (Claxton, Rae and Winger, 2025).

Employers typically select one or more insurance plans offered by private insurers and negotiate the terms of coverage, including provider networks, covered services, and cost-sharing structures. Employees may then choose among the available options during an annual enrollment period and usually contribute to the cost of premiums through payroll deductions, while employers cover a substantial share of the total premium cost (Buchmueller and Monheit, 2008).

Within this framework, most employer-sponsored plans involve a cost-sharing arrangement between employers and employees.

Employers generally pay the majority of the insurance premium, while employees contribute the remaining portion and are also responsible for additional out-of-pocket payments such as deductibles, copayments, and coinsurance when accessing medical services.

Employer-sponsored insurance also functions as a key intermediary between individuals and the private insurance market. Rather than purchasing coverage independently, employees obtain insurance through their workplace, where the employer administers enrollment, premium payments, and plan selection (Buchmueller and Monheit, 2008).

Although ESI remains the dominant form of coverage for working-age Americans, its structure means that access to health insurance is closely tied to labor market participation. Workers in stable, full-time employment are significantly more likely to receive employer-sponsored benefits, whereas individuals in part-time, temporary, or low-wage jobs often lack access to such coverage and must rely on individual insurance markets or public programs when eligible (Claxton, Rae and Winger, 2025).

Alongside private insurance, several government programs provide coverage to specific population groups.

The federal Medicare program primarily serves adults aged 65 and older as well as certain younger individuals with long-term disabilities or end-stage renal disease. Medicaid, jointly funded by federal and state governments, provides coverage to low-income individuals and families, although eligibility criteria and benefits vary across states. In addition, the Children's Health Insurance Program (CHIP) extends coverage to children in families whose incomes are too high to qualify for Medicaid but insufficient to afford private insurance (Tikkanen and Abrams, 2020).

Together, Medicare, Medicaid, and CHIP form the backbone of the U.S. public insurance system, covering tens of millions of Americans.

Despite this mix of public and private programs, significant gaps in coverage have historically persisted.

Prior to the implementation of the Affordable Care Act (ACA) in 2010, a substantial proportion of the population remained uninsured due to factors such as income thresholds, employment instability, and the high cost of private insurance (Kominski, Nonzee and Sorensen, 2017). The ACA introduced reforms aimed at expanding insurance coverage, strengthening consumer protections in insurance markets, providing subsidies for lower-income households purchasing private coverage, and encouraging new payment and delivery models designed to improve quality and efficiency of care (Obama, 2016).

However, because participation in Medicaid expansion varies by state and private insurance continues to play a dominant role, the United States remains the only high-income country without a universal health coverage system, resulting in ongoing disparities in access, affordability, and health outcomes (Schneider et al., 2021).

Governance of the U.S. healthcare system is also characterized by a significant division of authority between federal and state governments, reflecting the broader federal structure of the American political system.

Within this framework, responsibilities for financing, regulating, and administering health services are distributed across multiple levels of government, creating a system in which national policy goals are often implemented through state-level institutions and regulatory mechanisms. This federalist structure has historically shaped the development of health policy in the United States, producing a system that combines national programs with substantial regional variation in implementation and oversight (Huberfeld, 2018; Sparer, 2019).

The federal government plays a central role in financing healthcare and establishing overarching policy frameworks. Major public insurance programs, including Medicare, are administered at the federal level and financed largely through federal revenues.

The federal government also establishes nationwide regulatory standards through major legislation, most notably the Affordable Care Act (ACA).

Federal agencies such as the Centers for Medicare and Medicaid Services (CMS) also play a critical role in defining reimbursement policies, quality reporting requirements, and demonstration programs that influence healthcare delivery across the country (Abrams et al., 2015).

At the same time, state governments retain substantial authority over the administration and regulation of health services within their jurisdictions.

One of the most important examples of this shared responsibility is Medicaid: while the federal government establishes broad eligibility guidelines and provides significant funding, states administer their own Medicaid programs and retain discretion over important aspects such as eligibility thresholds, covered services, and payment rates for providers (Rosenbaum, 2011).

As a result, Medicaid policies and coverage levels vary significantly across states, particularly following the ACA's Medicaid expansion provision, which the Supreme Court made optional for states in 2012 (Rosenbaum, 2011).

States also play a primary role in regulating private health insurance markets and healthcare providers. State insurance departments oversee insurance licensing, market conduct, and compliance with consumer protection regulations, while professional licensing boards regulate physicians, nurses, and other healthcare professionals (Oberlander, 2016).

In addition, states exercise regulatory authority over healthcare facilities through mechanisms such as hospital licensing and, in some cases, certificate-of-need programs that control the expansion of healthcare infrastructure (Field, 2007).

These regulatory responsibilities contribute to significant variation in insurance market rules, provider supply, and healthcare infrastructure across states.

Public health governance further illustrates the decentralized nature of the U.S. system. State and local governments bear primary responsibility for public health activities, including disease surveillance, vaccination programs, environmental health regulation, and emergency preparedness. Local public health departments often serve as the frontline institutions responsible for implementing health protection measures and responding to public health crises, while federal agencies such as the Centers for Disease Control and Prevention (CDC) provide guidance, funding, and technical support. This multilayered governance structure can promote policy experimentation and local adaptation, but it may also lead to inconsistencies in public health capacity and response across jurisdictions (Turnock, 2016).

Consequently, the decentralized governance structure of the U.S. healthcare system produces considerable variation across states in eligibility criteria for public programs, insurance regulation, provider payment policies, and public health infrastructure. While this arrangement allows states to tailor policies to local conditions and political preferences, it can also contribute to geographic disparities in access to healthcare services, insurance coverage, and population health outcomes.

These differences reflect the broader dynamics of American federalism, in which national policy frameworks coexist with substantial state-level autonomy in health system governance (Oberlander, 2016).

In addition to its complex insurance arrangements and governance system, the organization of healthcare delivery in the United States is characterized by a largely decentralized network of providers operating primarily in the private sector (Cutler and Morton, 2013; Enthoven, 2009).

Unlike many health systems in which the state plays a central role in both financing and delivering healthcare services, the U.S. system separates these functions across a diverse array of public and private actors. Hospitals, physician practices, and outpatient facilities may operate as nonprofit, for-profit, or public institutions, while physicians may work independently, within group practices, or as employees of hospital systems and integrated delivery networks.

This pluralistic structure reflects the historical development of the U.S. healthcare sector, in which medical professionals and private organizations retained substantial autonomy over clinical practice and institutional governance (Cutler and Morton, 2013; Enthoven, 2009).

Although the pluralistic provider landscape allows for significant innovation, specialization, and technological advancement, it also contributes to fragmentation in care delivery. Patients frequently receive services from multiple unconnected providers, and information sharing across institutions can be limited despite the growing adoption of electronic health records.

This fragmentation can create inefficiencies, duplication of services, and gaps in continuity of care, particularly for patients with complex or chronic conditions who require coordinated management across multiple settings. As a result, improving care coordination and integration has become a central focus of recent health policy initiatives aimed at enhancing the efficiency and quality of the U.S. healthcare system (Tikkanen and Abrams, 2020).

Another defining characteristic of the U.S. healthcare system is its exceptionally high level of expenditure compared with other high-income countries.

The United States consistently spends a substantially larger share of its GDP on healthcare while not achieving uniformly superior population health outcomes.

This high spending is driven primarily by higher prices for medical services, pharmaceuticals, and administrative processes rather than greater utilization of care alone. The presence of multiple insurers, complex billing procedures, and extensive administrative requirements contributes significantly to overall system costs. As a result, healthcare affordability remains a persistent challenge for many households, particularly those facing high deductibles and other out-of-pocket expenses within private insurance plans (Papanicolas, Woskie and Jha, 2018; Tikkanen and Abrams, 2020).

In this context, the United States entered the COVID-19 pandemic with a highly fragmented health system characterized by decentralized governance, strong reliance on private actors, and significant variation across states in both insurance coverage and public health capacity.

Examining the early federal response to the crisis through the lens of Alexander Shaw's theoretical framework therefore provides an opportunity to assess how institutional fragmentation and existing governance structures shaped the trajectory of national crisis management.

The United States of America and COVID-19 – The Crisis

The outbreak of COVID-19 in the United States unfolded within the institutional and structural context of the American healthcare and economic system.

As previously discussed, the United States relies on a highly complex healthcare structure characterized by fragmented insurance coverage, a strong role for private actors, and substantial variation in access to medical services across socio-economic groups and geographic regions. When the SARS-CoV-2 virus began spreading across the country in early 2020, this institutional configuration formed the backdrop against which the health emergency and its broader societal consequences developed.

From a theoretical perspective, crises of this scale can generate pressures that challenge existing institutional arrangements. The Alexander–Shaw paradox suggests that severe systemic shocks may expose structural weaknesses within existing governance systems and generate political pressures for institutional adaptation. In the case of highly centralized federations, crises of this magnitude may also reveal tensions between federal authority and decentralized policy implementation ((Alexander-Shaw, Ganderson and Schelke, 2023).

The initial spread of COVID-19 across the United States followed a trajectory broadly comparable to that observed in Europe during the early months of 2020.

Sustained community transmission became evident in March 2020, and infections increased rapidly during the spring, marking the beginning of the first major epidemic wave in the United States (Schuchat, 2020).

As transmission accelerated, healthcare systems in several metropolitan areas, particularly in the Northeast, experienced severe strain. Hospitals in cities such as New York, Boston, and Detroit reported rapid increases in COVID-19 admissions, with intensive care units approaching or exceeding capacity and shortages of critical resources such as ventilators and personal protective equipment (Sandhu et al., 2022).

Indeed, by mid-April 2020 New York had already recorded 6,839 COVID-19 deaths, highlighting the surge of cases (Scafetta, 2020).

The concentration of cases in densely populated urban centers amplified pressures on hospital infrastructure during the early phase of the pandemic, illustrating how local health systems could become overwhelmed when confronted with rapid surges in severe respiratory illness.

Similar patterns of hospital strain had already been observed in parts of Europe earlier in 2020, underscoring the comparable epidemiological dynamics of the first pandemic wave across industrialized countries.

Mortality rates increased sharply during this period as well.

Using data from the U.S. National Center for Health Statistics, scholars estimated 87,001 excess deaths between 1 March and 25 April 2020, representing approximately 17 % more deaths than expected based on historical trends; only 65 % of these excess deaths were officially attributed to COVID-19, indicating that a substantial share may have resulted from indirect consequences of the pandemic, including disruptions to healthcare access and delayed treatment for other conditions (Woolf et al., 2020).

As the pandemic continued into the summer of 2020, the cumulative mortality burden increased further. Updated analyses estimated 225,530 excess deaths between March and July 2020, corresponding to an overall 20 % increase in all-cause mortality compared with expected levels, with approximately two-thirds of these excess deaths directly attributed to COVID-19 (Woolf et al., 2020).

The cumulative health impact of the pandemic became even more evident when examining mortality trends over the following two years. By the end of 2021, the United States had recorded more than

700.000 deaths attributed to COVID-19, while broader analyses of excess mortality revealed that the pandemic produced one of the largest mortality shocks experienced in the country in recent decades (Kandula et al., 2024).

These developments contributed to a marked decline in national life expectancy, which fell by nearly two years in 2020 alone—one of the most significant annual reductions observed in the post-war period (Woolf, Masters and Aron, 2021).

Moreover, infection rates, hospitalization risks, and mortality were disproportionately concentrated among socio-economically disadvantaged populations and racial and ethnic minority groups, reflecting structural inequalities in employment conditions, housing density, and access to healthcare (Tai et al., 2021). In this sense, the pandemic not only generated a major public-health emergency but also amplified pre-existing disparities embedded within American society.

In parallel with these epidemiological developments, the pandemic generated a severe economic shock across the United States. As infections spread rapidly during the spring of 2020, economic activity contracted sharply, producing one of the most abrupt downturns in modern American economic history.

Real-time economic indicators show that consumer spending, business revenues, and employment levels declined dramatically during the early months of the pandemic as households and firms reacted to the health emergency and the uncertainty surrounding its evolution (Chetty et al., 2020).

Indeed, consumer spending fell by approximately 31 % between January and mid-April 2020, with the decline concentrated in sectors requiring face-to-face interaction such as restaurants, hotels, and entertainment services. The resulting collapse in demand led to a 61 % decline in revenues among small businesses in high-income urban areas during the same period, contributing to widespread layoffs among low-wage workers (Chetty et al., 2020).

These microeconomic disruptions were rapidly reflected in macroeconomic indicators. U.S. real GDP fell by $1.61 trillion between the first and second quarters of 2020, corresponding to a 29.9 % annualized contraction, as shown in Figure 5, corresponding to the largest quarterly decline recorded since the beginning of modern national accounts statistics (Chetty et al., 2020).

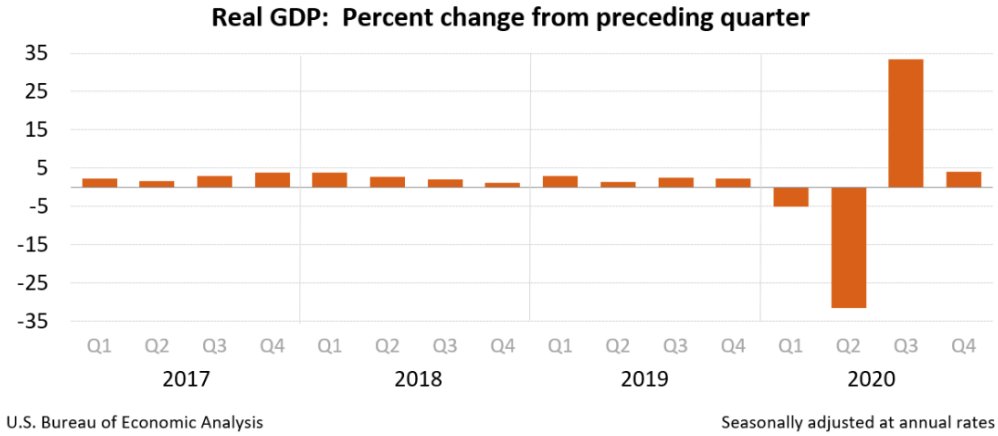

Figure 5: US Real GDP Percent change compared to the preceding quarter, with the sharpest decline in the second quarter of 2020. Sources: Bureau of Economic Analysis, 2021.

Consumer spending alone accounted for roughly $1.20 trillion of this decline, highlighting the central role of reduced household consumption in driving the recession (Chetty et al., 2020).

The labor market experienced an equally dramatic shock. The unemployment rate increased from 3.5 % in February 2020 to 14.7 % in April 2020, reflecting the loss of more than 20 million jobs in a single month, with the largest employment losses occurring in service sectors dependent on in-person interactions such as leisure, hospitality, and retail (U.S. Bureau of Labor Statistics, 2020)

In parallel, international trade flows contracted drastically: U.S. exports of goods and services fell by 15.9% to $2.1 trillion, while imports declined 9.5% to $2.8 trillion in 2020, representing the largest contraction since 2009 and widening the U.S. trade deficit by 18.2% to $681.7 billion, as highlighted by Figure 6 (Yildirim and Saccomanno, 2021).

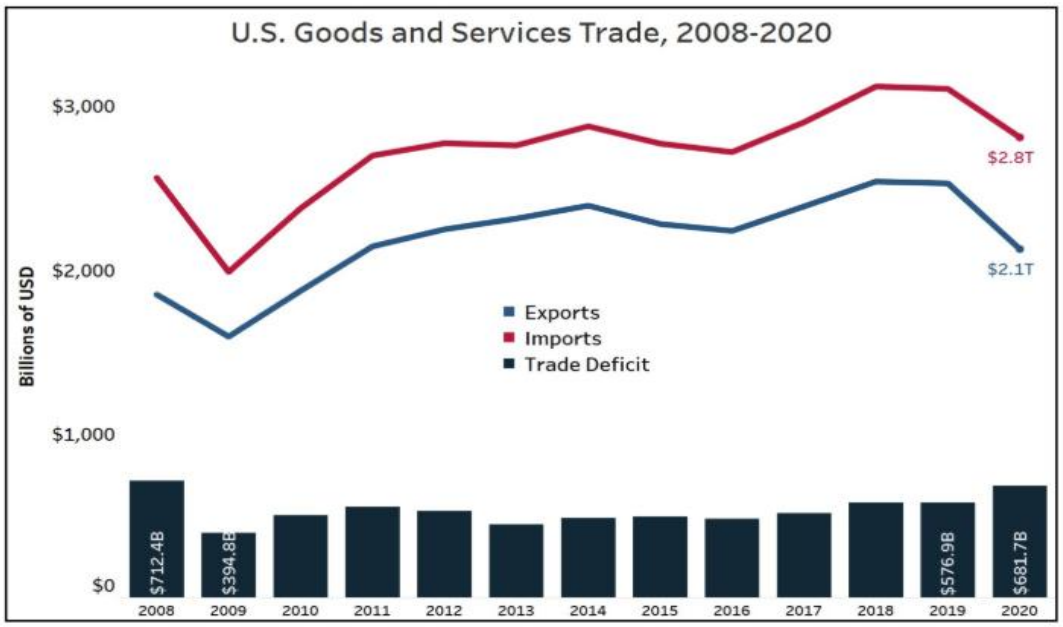

Figure 6: Level of US Exports, Imports and Trade Deficit from 2008 to 2020. Sources: Yildirim and Saccomanno, 2021

The economic contraction was highly uneven across sectors. Activities dependent on physical proximity, including hospitality, travel, and entertainment, experienced the largest declines in output and employment, while sectors compatible with remote work were comparatively less affected (Chetty et al., 2020; Coibion, Gorodnichenk and Weber, 2020).

Taken together, these developments illustrate the scale and simultaneity of the shock generated by COVID-19 in the United States. The rapid escalation of infections and mortality during the spring of 2020 placed extraordinary pressure on healthcare infrastructures, while the parallel contraction in economic activity produced severe labor-market disruptions and income losses.

The pandemic therefore constituted a multidimensional crisis affecting both the health system and the broader socio-economic structure of the United States, creating the conditions under which significant political and institutional pressures could subsequently emerge.

The United States of America and COVID-19 – The Countermeasures

From a theoretical perspective, the institutional configuration of the United States would traditionally be expected to enable the federal government to play a decisive coordinating and fiscal role during a nationwide emergency.

However, the corollary to Hamilton's Paradox developed by Alexander Shaw suggests that crises of this magnitude may instead expose the tensions inherent in strong-centered federation.

When the center possesses substantial fiscal and policy capacity, systemic shocks can create incentives for subnational governments to shift political and fiscal burdens upward, potentially intensifying intergovernmental and partisan conflict rather than producing straightforward coordination.

Such dynamics were visible throughout the COVID-19 crisis in the United States and became particularly salient during the vaccination campaign, when reliance on federal resources coexisted with significant political and intergovernmental tensions (Alexander-Shaw, Ganderson and Schelkle, 2023; Rodden, 2006).

The U.S. response in the healthcare domain was an embodiment of Shaw's paradox.

While the federal government provided guidance during the COVID-19 pandemic primarily through agencies such as the Centers for Disease Control and Prevention (CDC), the response was characterized by a lack of centralized coordination, leading to significant variation in how policies and resources were implemented across states and localities (DeSalvo et al., 2021).

This decentralization reflects the U.S.'s federalist structure, where authority over public health emergencies is shared among federal, state, and local governments, rather than being centralized in a single national public health authority (Berquist, Otten, and Sarich, 2020).

As a result, while the CDC offered guidance on disease mitigation, the federal government did not directly coordinate the procurement or distribution of critical supplies such as medical equipment and PPE. States and local health departments were left to secure and allocate resources independently, with wealthier states generally better equipped to manage shortages, while poorer or rural states faced greater challenges (Kettl, 2020; DeSalvo et al., 2021).

Mid-crisis shifts in how states could access the Strategic National Stockpile (SNS) further complicated the situation, leaving local governments uncertain about federal support.

Originally designed as a centralized buffer for large-scale emergencies, the SNS was inadequately prepared for a pandemic of such magnitude. Early in the crisis, the federal government allowed states to manage their own procurement efforts, while maintaining that federal support would be available if necessary. However, this policy was inconsistent, as federal agencies like FEMA often delayed or limited the distribution of resources, leading to confusion about the role of the federal government (Murray, 2020; Cuffari, 2023; Frontz, 2023).

The Trump administration's encouragement of states to seek resources in the open market, combined with unclear guidance on accessing the SNS, created a situation where states competed for supplies

rather than receiving coordinated federal assistance, aligning with Alexander-Shaw's framework (GAO, 2020).

This uncertainty, coupled with the urgency of the pandemic, forced local governments to scramble for alternative suppliers, which was particularly challenging for under-resourced areas that lacked the infrastructure to make large-scale purchases (Bartley et al., 2020).

Further complicating the situation was the involvement of the private sector, which played a central role in resource procurement and distribution. Early in the pandemic, the federal government relied heavily on private companies to supply PPE, ventilators, and vaccines. However, this reliance on market-driven solutions resulted in inflated prices, supply chain bottlenecks, and challenges in ensuring equitable access to resources (GAO, 2020).

Companies, driven by profit motives, often prioritized high-paying customers, which meant that vulnerable populations or under-resourced states faced delays or insufficient supplies. Additionally, the lack of centralized procurement through federal channels created a competitive market for resources, leading to inefficiencies and resource hoarding, further exasperating inequities (Moosavi, Fathollhai-Fard and Dulebenets, 2022).

These fluctuations in policy and the inability of local governments to depend on federal support compounded existing inequities in public health preparedness. Wealthier regions, with more resources, were better equipped to negotiate the procurement process, while poorer areas were left vulnerable, unable to secure the necessary resources for an adequate response (Mheidly et al., 2022).

These compounded challenges were a direct result of the lack of a cohesive, federal strategy to manage the crisis, which left local and state entities struggling to fill the gap.

For instance, states like California and New York, with higher levels of healthcare infrastructure and financial resources, were able to rapidly scale up testing and secure medical supplies. In contrast, other states faced significant challenges due to a lack of sufficient resources and were slower to respond (Andraska et al., 2021).

Moreover, the disease magnified systemic health equity disparities that have long plagued the U.S. healthcare system.

Socioeconomic status, race, and geographic location were significant determinants of how well individuals and communities could respond to the pandemic, with marginalized groups, particularly Black, Latino, and Native American populations, facing higher rates of infection and mortality (Mackey et al., 2020).

Indeed, these communities were overrepresented in essential jobs that could not be performed remotely, increasing their exposure to the virus. Additionally, lower socioeconomic status often correlates with overcrowded living conditions, making social distancing difficult and facilitating virus transmission (Mackey et al., 2020).

Racial minorities in urban centers and rural areas often faced additional barriers, such as limited access to healthcare infrastructure, lack of insurance, limited access to quality care and mistrust of the healthcare system, both of which hindered effective pandemic management (Williams and Cooper, 2020).

Moreover, the patchwork nature of state-level responses, without a unified federal strategy, led to delays and shortages in securing PPE and medical supplies. This uneven distribution resulted in healthcare workers in some states facing severe shortages of PPE, while others had access to an abundance of these supplies.

The fragmented approach to pandemic management hindered the effective mobilization of resources and led to confusion about the proper channels for securing vital medical equipment.

The reliance on local response meant that certain states were able to implement stringent lockdowns and social distancing protocols early in the pandemic, others, often in regions with weaker healthcare or less alignment with federal mandates, faced political and logistical barriers.

For example, states with conservative political leadership, such as Florida and Texas, were slower to adopt lockdown measures and faced resistance to mask mandates, which further compounded the lack of centralized coordination (Andraska et al., 2021).

The delayed federal response to COVID-19 also significantly impacted the effectiveness of the U.S. pandemic management.

This postponement was partly due to a lack of preparedness within the federal government, but also due to conflicting political priorities that hindered timely action.

These discrepancies in responses not only created challenges in containing the virus but also contributed to disparities in health outcomes, as more populous and resource-rich states were often more successful in mitigating the spread.

Additionally, public trust in health institutions played a pivotal role in the U.S. pandemic response. Communities with higher levels of trust in government and public health institutions were more likely to comply with public health measures such as mask mandates, lockdowns, and vaccination campaigns (Geisterfer-Black et al., 2022).

However, political polarization and misinformation significantly undermined public trust in health authorities like the CDC and the WHO.

States with conservative leadership, such as Florida and Texas, were particularly resistant to federal guidelines on social distancing and mask-wearing, reflecting a broader partisan divide that influenced pandemic management (Andraska et al., 2021).

This erosion of trust not only led to lower compliance rates with public health directives but also hindered efforts to achieve herd immunity through vaccination. The politicization of health recommendations and the spread of misinformation about COVID-19 vaccines were major barriers to achieving a unified national response.

In response to the sharp economic downturn induced by the COVID-19 pandemic, the U.S. Congress enacted several major relief packages, most prominently the Coronavirus Aid, Relief, and Economic Security (CARES) Act in March 2020.

This $2.2 trillion package aimed to stabilize household incomes, sustain consumer spending, and support firms facing dramatic revenue losses (Sahm, 2021).

Key elements included Economic Impact Payments, i.e. stimulus checks, enhanced unemployment benefits, including the $600 weekly Federal Pandemic Unemployment Compensation bonus, and the Paycheck Protection Program (PPP) designed to subsidize payrolls for small businesses.

Stimulus payments reached an estimated 160 million individuals and were associated with measurable increases in short-term consumer spending, particularly early in the pandemic (Chetty et al., 2020).

Economic modeling suggests that these measures meaningfully mitigated aggregate welfare losses; one structural analysis estimates that CARES Act provisions reduced economic welfare losses by around 20% relative to a no-relief counterfactual, redistributing benefits toward lower-income households that faced the greatest exposure to earnings shocks (Kaplan, Moll and Violante, 2020).

In addition to the CARES Act, the U.S. Congress enacted a sequence of major relief laws throughout 2020–2021 to address both the public health emergency and the severe economic downturn caused by the COVID-19 pandemic.

The earliest response was the Coronavirus Preparedness and Response Supplemental Appropriations Act (March 2020), which provided $8.3 billion emergency funding to federal agencies for vaccine and therapeutic development, testing infrastructure, and other public-health capabilities early in the outbreak (Dowling et al., 2020).

Shortly thereafter, the Families First Coronavirus Response Act, by allocating $192 billion, expanded paid sick and family leave, funded free COVID-19 testing, and increased nutrition assistance and Medicaid funding to support vulnerable households affected by the crisis (Moss et al., 2020).

Following CARES Act, in April 2020 the Paycheck Protection Program and Health Care Enhancement Act augmented with $484 billion funding for the PPP and added resources for hospitals and diagnostic testing (Painter et al., 2020).

As the pandemic persisted, the Consolidated Appropriations Act, approved in December 2020, combined roughly $900 billion in supplemental COVID-19 relief with annual appropriations, extending and expanding many CARES Act programs such as direct payments, enhanced unemployment insurance, and SNAP benefits, while also providing additional support for businesses and public health infrastructure.

Finally, the American Rescue Plan Act, enforced in 2021, represented another large fiscal intervention, as it allocated $1.9 trillion, that built on earlier measures with further direct stimulus payments, extended unemployment support, enhanced child and earned income tax credits, substantial fiscal relief for state and local governments, and dedicated funding for vaccine distribution and safe school reopening efforts (Armstrong et al., 2021).

However, although the federal government authorized broad relief, actual delivery of benefits often fell to state agencies, revealing significant challenges within the decentralized U.S. federal system.

While the federal government allocated substantial funding and issued broad directives, the responsibility for translating these policies into actionable relief largely rested with state and local governments, which varied widely in their administrative capacity, political context, and fiscal resources.

Indeed, decentralization, while offering flexibility, also exacerbates disparities in policy implementation.

State governments possess varying levels of institutional capacity to absorb and distribute federal funds, and differences in political leadership further influenced the timeliness and effectiveness of relief measures, with some states leveraging stronger administrative apparatuses and prior public health investments and others constrained by limited fiscal resources, fragmented systems, or partisan polarization that affected responsiveness and coordination (de Biase and Dougherty, 2021).

For instance, partisan sorting, where states with different political affiliations implement federal policies in divergent ways, has been shown to significantly impact the efficiency of economic measures, even under uniform federal mandates (Birkland et al., 2021).

Moreover, states' fiscal capacities and administrative infrastructures were critical in determining the reach and effectiveness of relief efforts, particularly in the areas of economic assistance and public health response (OECD, 2021).

In this highly decentralized system, the differential state capacities in policy execution ultimately resulted in uneven economic outcomes, reinforcing the notion that federalism's structural features, such as state autonomy and local decision-making, can both enable tailored responses and foster significant disparities in program effectiveness (Alexander-Shaw, Ganderson and Schelkle, 2023).

These dynamics, rooted in federal tensions, partisan conflict, and the fragmented nature of state-level responses, set the stage for the challenges the US faced in its vaccine procurement and rollout. Understanding these early failures in coordination is essential to understand the complexities of the vaccine distribution process, which will be explored in the following chapter

3. Vaccine Procurement and Rollout

Vaccine development was a cornerstone of the strategies adopted by the EU and the US to combat the COVID-19 pandemic.

Unlike other public health measures that primarily focused on limiting the immediate spread of the virus and alleviating short-term impacts, vaccines represented a more enduring solution. They were instrumental not only in reducing transmission but also in preventing severe disease and death, thereby making a substantial contribution to pandemic control (Machado et al., 2022).

The long-term benefits of vaccination stemmed from their ability to prime the immune system, providing protection against the virus and significantly reducing the risk of contracting the disease, and lowering the likelihood of severe illness in case of infection (Tortorice, Rappuoli, and Bloom, 2024).

Vaccines thus played a pivotal role in enabling the gradual reopening of societies and economies, which was essential for the restoration of normalcy. The global investment in vaccine research and development was enormous, with spending reaching approximately $9.2 billion for research alone (Tortorice, Rappuoli, and Bloom, 2024), while the total global expenditure, including vaccination campaigns, reached $246.2 billion at the end of 2023 (Chen et al., 2025).

Despite these shared global objectives, the approaches to vaccine procurement and rollout diverged notably between the EU and the USA, influenced by their respective healthcare systems and pandemic management strategies.

These differences shaped not only the speed and efficiency of vaccine distribution but also the broader public health outcomes.

In this context, the European Union's approach to vaccine procurement and rollout can be understood as further reinforcing the Alexander-Shaw paradox. Shaw's theory posits that decentralized systems, often perceived as inefficient, can still yield superior outcomes when collaboration and coordination mechanisms are effectively utilized. The EU's strategy, characterized by its collaborative framework and collective decision-making, exemplifies this paradox by achieving more favorable results despite its decentralized structure.

In contrast, the United States faced significant challenges stemming from its fragmented healthcare system and political communication issues, which hindered consistent vaccine distribution and delayed coordinated action.

This chapter aims to critically analyze and compare the EU and US strategies, demonstrating how the EU's approach not only aligns with but strengthens the Shaw paradox, offering valuable insights into the effectiveness of collective action in crisis management.

EU Vaccine Procurement and Rollout Strategy

The European Union's approach to vaccine procurement and rollout, while often seen as a product of its decentralized structure, exemplifies the potential for collective action and coordination to overcome challenges and achieve superior outcomes, strengthening the Alexander-Shaw paradox.

In the early stages of the COVID-19 pandemic, the European Union's response was constrained by its limited competences in public health.

According to Article 168 TFEU, health policy remains a largely national competence, with the EU's role restricted to supporting and complementing national efforts, primarily through coordination and providing assistance where necessary (Treaty on the Functioning of the European Union, 2008).

As a result, the EU did not initially step in as the main actor in vaccine procurement, leaving these responsibilities to member states.

This legal framework led to a fragmented response, as national governments took the lead in managing their own public health strategies, with the EU's involvement remaining secondary in the early phase of the crisis.

EU Vaccine Procurement and Rollout Strategy – Early Member States Procurement

In the early stages of the COVID-19 vaccine procurement, European Union (EU) member states initially took an uncoordinated approach to securing vaccine supplies.

Larger, wealthier countries with greater political influence, such as Germany and France, were able to secure early agreements with vaccine producers.

These states leveraged their strong negotiating capacities and pre-existing relationships with pharmaceutical companies to strike bilateral deals, allowing them to secure significant vaccine doses for their populations. In contrast, poorer EU member states, particularly those with fewer resources or weaker diplomatic leverage, struggled to negotiate similar agreements (De Maio, 2021).

The disparity in bargaining power led to a situation where wealthier countries had a head start in the vaccine race, while poorer states were left with limited access to supplies (De Maio, 2021).

However, as the pandemic intensified, it became clear that this fragmented approach was proving ineffective in ensuring equitable access to vaccines for all EU member states.

The uncoordinated scramble for vaccine doses led to a competitive race among nations, with wealthier states securing early agreements with pharmaceutical companies and leaving poorer states at a distinct

disadvantage. This competition, where larger nations gained priority access to vaccines at the expense of smaller ones, undermined the EU's foundational principle of solidarity (Della Corte, 2023).

As a result, the lack of a coordinated procurement strategy exacerbated divisions within the Union, with some member states unable to secure sufficient supplies due to their weaker negotiating positions, thus delaying the broader EU effort to secure vaccines (De Maio, 2021).

This lack of coordination and internal competition, which intensified as the pandemic worsened, threatened to fracture the EU's unity and delayed the overall vaccination effort across the continent (European Court of Auditors, 2022).

The real turning point came when EU member states realized that their fragmented approach was counterproductive. As the pandemic progressed, it became increasingly evident that COVID-19 was not just a national problem, but a European one. The virus did not recognize borders, and the failure to achieve widespread vaccination in all member states would impede the continent's ability to control the disease (PubAffairs Bruxelles, 2021).

This realization led to a shift in mindset, with EU leaders recognizing that a coordinated, unified response was necessary.

In response, several powerful member states, including France, Germany, Italy, and the Netherlands, formed the Inclusive Vaccine Alliance in April-May 2020 (Van Bael and Bellis, 2020).

This alliance aimed to pool resources and negotiated jointly with vaccine producers to ensure fair and equitable access to vaccines for all EU countries (European Court of Auditors, 2022).

However, the formation of the Inclusive Vaccine Alliance raised serious concerns among other EU member states. Smaller and poorer countries feared that the early deals brokered by the alliance, particularly with companies like AstraZeneca, would exclude them from access to vaccines or leave them with insufficient supplies (Della Corte, 2023; Castiello, 2024).

This created a sense of division within the EU, as some member states worried that the union would fragment into multiple tiers of vaccine access, with a few nations benefitting from preferential treatment at the expense of others (De Maio, 2021).

This fear of unequal access to vaccines undermined the EU's goal of solidarity, and tensions within the Union increased as the situation became more urgent.

In response to these concerns, the EU Commission intervened to transform the Vaccine Alliance into a broader EU framework.

As the urgency of securing vaccines for all member states became more apparent, the EU began to play a leading role in negotiating bulk contracts with pharmaceutical companies, aiming to ensure equitable access across the Union and restore its core principles of solidarity and collective action.

EU Vaccine Procurement and Rollout Strategy – EU Procurement Strategy

On 12 June 2020, the EU Council agreed on the necessity for joint action to foster the development and deployment of COVID-19 vaccines.

This strategy focused not only on ensuring rapid, sufficient, and equitable supplies for EU member states but also on enhancing collaborative frameworks among the states (European Court of Auditors, 2022).

A significant component of this strategy was the promotion of a shared vaccine portfolio, funded by European instruments. This approach marked a pivotal shift from traditional intergovernmentalism, where decisions were made through national governments, to a more coordinated European strategy, underlining the collective approach to healthcare in the face of the pandemic (Arroyo et al., 2024).

This shift, however, also highlighted the absence of a central authority with the ability to enforce healthcare-related decisions across the EU.

As the need for central coordination became increasingly apparent, member states formally entrusted the EU Commission to act on their behalf in matters of vaccine procurement, signaling a significant move toward greater EU-wide cooperation (European Commission, 2020).

Moreover, the crisis served as a catalyst for deeper European integration, as the member states recognized that their individual efforts were insufficient to meet the scale of the challenges posed by the pandemic.

This collective decision signaled a broader acknowledgment of the need for supranational governance in addressing a global health crisis.

This joint program highlighted also how, even though the Commission took the lead and was able to furnish political leadership, it was more efficient when able to count on member states' support, evidencing that the duality of the European system is far from over, with supranational initiatives needing being backed up by member states, showing a prominent role of the intergovernmentalism.

By authorizing the Commission to handle vaccine procurement and distribution, the member states acknowledged that only through unity and a coordinated response they could effectively navigate the

crisis and secure the necessary vaccines for their populations (Ladi and Wolff, 2025; Arroyo et al., 2024).

This decision underscored the growing role of the EU in healthcare policy, demonstrating that the pandemic's scale and scope necessitated a level of integration that transcended national borders.

This decision also directly reinforced the broader insight of the Alexander-Shaw paradox, which suggests that systems characterized by weaker central authority, such as the European Union, can, under certain institutional conditions, generate stronger cooperative incentives (Alexander-Shaw, Ganderson and Schelke, 2023).

The paradox, initially formulated to elucidate the dynamics of fiscal and political coordination within federations, finds broader relevance in the context of the EU's pandemic response.

It underscores a general principle: supranational systems, such as the EU, which operate with relatively decentralized control, can foster substantial cooperation among member states in times of crisis. (Alexander-Shaw, Ganderson and Schelke, 2023; Boin and Rhinard, 2023).

Despite the potential for national fragmentation, the European Commission's central role in coordinating vaccine procurement and distribution strengthened and embodied the Alexander-Shaw paradox.

The Commission’s authority and the collective commitment of EU member states fostered cooperation rather than exacerbating divisions, highlighting the critical role that supranational institutions can play in managing global crises, even when their central authority is weaker than that of a typical federal system (Arroyo et al., 2024).

Rather than competing for vaccine supplies or pursuing fragmented, national responses, the EU’s centralized strategy promoted political cohesion and solidarity, reinforcing the collective interests of the Union (Alexander-Shaw, Ganderson and Schelke, 2023; Ladi and Wolff, 2025).

In line with this, on June 17, 2020, the European Commission presented the EU Vaccines Strategy, marking a key milestone in the common procurement process for COVID-19 vaccines (European Court of Auditors, 2022).

This initiative was launched based on the belief that pooling resources, sharing risks, and combining efforts would yield better results.

Consequently, the EU engaged in negotiations as a single entity, with the European Commission at the helm and supported by an executive board composed of member state representatives.

This joint effort showcased that while the Commission took the lead in managing vaccine procurement, the initiative's success depended heavily on the backing of member states, highlighting the ongoing importance of intergovernmental cooperation within the EU framework (Della Corte, 2023).

Moreover, this measure demonstrated that the duality of the European system is far from over, with supranational initiatives needing backing from member states, thus emphasizing the continued prominence of intergovernmentalism (Martinsen and Goetz, 2022).

Despite this, the Commission's leadership marked a significant shift toward a more coordinated European approach, countering the early trend of national responses, often referred to as *"coronationalism"* (Deters and Zardo, 2022).

To define and regulate EU joint procurement, the European Union triggered its financial and legal measures.

EU Vaccine Procurement and Rollout Strategy – EU Procurement Strategy – The Legal Framework

The legal foundation that enabled the European Commission to take a leading role in the procurement of COVID-19 vaccines and coordinate the EU's pandemic response was rooted in several key provisions within the TFEU and related legal instruments.

While the EU's health policy traditionally was restricted as largely supportive rather than regulatory, as outlined in Article 168 of the TFEU, the emergence of a global health crisis necessitated the invocation of emergency legal frameworks that granted the Commission expanded powers.

These frameworks not only empowered the EU to take swift action but also provided the legal authority for joint procurement and cross-border coordination, ensuring that member states could respond collectively to the pandemic's challenges.

The key legal mechanism that enabled the European Commission to lead vaccine procurement and coordinate the EU's response to the pandemic was Article 122 TFEU.

Specifically, Article 122 was designed to address severe emergencies, granting the EU Council, upon a proposal by the Commission, the authority to adopt emergency measures in situations of exceptional disruption, such as supply shortages (European Union, 2008).

Article 122(1) empowered the Council to take action in economic emergencies, while Article 122(2) provided financial assistance to member states affected by natural disasters or extraordinary events (European Union, 2008).

By invoking this legal framework, the Commission was able to negotiate vaccine contracts on behalf of member states, ensuring a coordinated and unified procurement effort (European Court of Auditors, 2022; Deters and Zardo, 2022).

Guaranteeing the Commission this capacity was a strategic move: by pooling the negotiating authority of all 27 member states, the EU leveraged collective demand to avoid fragmentation and prevent a competitive 'vaccine scramble' among states, which characterized early pandemic responses elsewhere (McEvoy and Ferri, 2020).

Joint negotiation on behalf of all member states meant that smaller or less wealthy countries were not disadvantaged in securing supply, something that individual national bargains risked due to asymmetric bargaining power and limited market reach (European Court of Auditors, 2022).

This aggregation of demand helped the EU secure larger contracts and diversify suppliers more effectively than if member states had acted alone, ensuring broader access to vaccines without early supply restrictions tied to the economic size or purchasing capacity of single countries (Castiello, 2024; McEvoy and Ferri, 2020).

In addition to these provisions, several pre-existing legal frameworks facilitated the EU's swift response.

Notably, Decision 1082/2013 on Serious Cross-Border Threats to Health provided essential tools for crisis management, including a surveillance system for infectious diseases and the Early Warning and Response System (EWRS), which facilitated rapid exchange of disease-related information (European Parliament and Council, 2013).

Article 5(1)(d) and Article 11 of the decision were particularly instrumental in enabling the EU to negotiate joint vaccine procurement through the establishment of the Joint Procurement Agreement (European Parliament and Council, 2013).

The establishment of a joint vaccine procurement framework was made possible through the Advance Purchase Agreement (APA), which granted the European Commission the authority to negotiate contracts with pharmaceutical companies specializing in vaccine production.

The APA allowed the Commission to negotiate contracts with pharmaceutical companies, securing a set number of vaccine doses at a fixed price, contingent on successful approval, and regulatory certification (Boulet et al., 2021).

The APA was a critical tool in securing access to vaccines at a time when supply chains were under intense pressure and the need for coordinated action was paramount (European Court of Auditors, 2022).

A key element of the APA was the Commission's commitment to funding clinical trials and vaccine production upfront. By providing financial support for research and manufacturing, the EU mitigated some of the financial risks borne by pharmaceutical companies, enabling them to scale up production before knowing the full outcome of clinical trials (Florio et al., 2023).

This risk-sharing model was designed to incentivize pharmaceutical companies to expedite vaccine development and manufacturing, even in the absence of guarantees that the vaccines would be successful (European Court of Auditors, 2022).

Early investments in production capacity not only ensured that once vaccines were approved, they would be available in large quantities but also helped to stabilize the pharmaceutical industry during a time of extraordinary uncertainty. This strategic financial commitment underscored the EU's proactive approach to securing vaccines while distributing the financial risks across public and private sectors.

Moreover, Decision 1313/2013 enhanced the EU's capacity for emergency procurement, logistics coordination, and stockpiling of critical supplies, all of which were crucial in responding to the public health crisis (European Parliament and Council, 2013).

The decision established the RescEU program, which allowed for the creation of reserves of medical supplies and equipment, and provided the legal foundation for coordinated emergency responses across member states.

Additional legal frameworks further supported the EU's ability to manage the pandemic: Article 196 TFEU and Article 214 TFEU facilitated the creation of the EU Civil Protection Mechanism (UCPM), which enabled the Union to assist member states and manage coordinated mutual support through the RescEU program (European Union, 2008).

This legal framework also enabled the establishment of an emergency logistical network, ensuring that stockpiles could be rapidly mobilized and distributed to areas in greatest need, further strengthening the Union's ability to react swiftly to evolving public health threats.

In addition to the role covered by the EU Commission, European agencies such as the European Medicines Agency (EMA) and the European Center for Disease Prevention and Control (ECDC) intensified their efforts and played a pivotal role in coordinating the strategy.

A key innovation introduced by the EMA was the rolling review procedure, which became central to the scientific evaluation of potential vaccines. Unlike traditional regulatory procedures, which typically required a complete dossier before evaluation, the rolling review allowed the EMA to assess vaccine data as it became available (Marinus et al., 2022).

This not only accelerated the evaluation process but also significantly shortened the typical vaccine development timeline, reducing it from the usual 10 to 15 years to less than 24 months (Marinus et al., 2022).

As data were constantly reviewed, the EMA could make timely decisions, allowing vaccine candidates to progress to approval much more quickly than under standard procedures (European Court of Auditors, 2022).

This innovative approach, however, was part of a broader regulatory framework aimed at ensuring the highest possible safety standards. While many other countries, such as the United States and the United Kingdom, opted for emergency-use authorizations to expedite vaccine approval, the European Commission and EMA enforced a more stringent Conditional Market Authorization process (Ghadanian and Schafheutle, 2023).

This procedure meant that vaccines had to be approved under full EU pharmaceutical law, subjecting them to rigorous safety and efficacy standards. While this made the approval process somewhat slower compared to the faster-track emergency procedures adopted by other countries, it had the advantage of maintaining higher safety standards and holding vaccine producers legally accountable for their products (Deutsch, 2020).

As a result, pharmaceutical companies could not shift responsibility for adverse effects to European institutions, thereby bolstering public trust in the vaccines and the regulatory process.

Furthermore, in October 2020, the EU Commission, in collaboration with the ECDC, issued comprehensive guidance to assist member states in the development of national vaccination plans.

These guidelines were designed to address critical logistical challenges, including vaccine distribution chains, storage requirements, and the identification of priority groups for vaccination (Arroyo et al., 2024).

The priority groups included high-risk populations, such as the elderly and healthcare workers, who were considered the most vulnerable to severe outcomes from COVID-19 (European Commission, 2020). The aim of these guidelines was to ensure that member states were well-prepared to launch fast and efficient vaccination campaigns as soon as doses became available.

In parallel to this, the ECDC played a pivotal role in facilitating the exchange of technical information between the immunization experts of member states.

This collaborative effort allowed for a constant flow of updates on vaccine development and enabled the sharing of best practices across the EU.

By actively monitoring vaccine development and progress, the ECDC ensured that each member state's vaccination strategy was based on the latest scientific evidence and was aligned with overall EU objectives (European Centre for Disease Prevention and Control, 2023).

While each member state ultimately had the autonomy to determine which population categories to prioritize within their national vaccination plans, the ECDC's guidance and recommendations were highly influential.

Member states widely adopted the suggested prioritization, leading to a largely consistent approach across the EU. This collaborative effort ensured that vaccination campaigns were not only timely but also equitable, with vulnerable populations receiving vaccines first (Forman and Mossialos, 2021).

By the end of 2020, the European Union had successfully established a coordinated procurement and regulatory framework for vaccine distribution.

Finally, on 21 December of the same year, the EMA issued a favorable opinion on the first COVID-19 vaccine, the BioNTech/Pfizer mRNA vaccine, and the European Commission simultaneously granted market authorization (Deutsch, 2020).

The Commission handled supply and financial aspects, ensuring that sufficient doses were procured and distributed across the member states, while the European Medicines Agency (EMA) ensured that the vaccines met the EU's rigorous safety and efficacy standards (European Court of Auditors, 2022).

The ECDC, in turn, worked closely with the Commission to help implement the guidelines and monitor the vaccination rollout, fostering alignment among member states.

This well-orchestrated collaboration between EU institutions, alongside close communication with member states, enabled the EU to roll out one of the most ambitious vaccination campaigns in history.

EU Vaccine Procurement and Rollout Strategy – EU Procurement Strategy – Economic Framework

The EU Commission's vaccine strategy represented a distinct form of public-private risk-sharing that combined political leverage with targeted financial instruments to accelerate vaccine development and secure supply.

Central to this approach were APAs backed by down-payments from the Emergency Support Instrument (ESI), whereby the EU provided upfront funding to vaccine producers in return for future delivery commitments (Della Corte, 2023).

This funding amounted to a total of €2.7 billion, and was primarily allocated towards investments in manufacturing capacity, aimed at scaling up vaccine production and addressing supply chain bottlenecks (Kelly, 2020; European Commission, 2023).

This mechanism, acting as a financial tool for crisis management, allowed the Commission to reduce the financial uncertainty borne by industry, effectively sharing scientific and economic risk with private partners (Kirkegaard, 2021).

Beyond the APA and ESI, the EU vaccine strategy was supported by a broader financial architecture combining multiple EU funding instruments with member state purchase commitments.

These complementary financial mechanisms contributed to different stages of vaccine development, production, and deployment.

Early-stage research and clinical development were supported through the EU's Horizon 2020 research program, which mobilized approximately €1 billion for COVID-19-related research projects, including vaccine technologies and clinical trials (Mugabushaka, 2021).

These funds primarily financed collaborative research consortia and biotechnology firms developing vaccine candidates and supporting clinical testing infrastructure.

Parallel to this research funding, the European Investment Bank (EIB) provided targeted financing to biotechnology companies to accelerate vaccine development and scale up manufacturing capacity (Mazzucato and Li, 2020).

For example, BioNTech received a €100 million EIB loan supported by the InnovFin Infectious Diseases Finance Facility under Horizon 2020 guarantees, aimed at financing clinical trials and expanding production infrastructure for the BNT162 vaccine program (Mazzucato and Li, 2020).

Although these loans represented only a fraction of the broader EIB pandemic response package, amounting to up to €5 billion for healthcare and life-science projects, they illustrate the role of development finance in supporting industrial capacity and innovation within the European vaccine sector (Fahy, Mauer and Panteli, 2021)

While EU-level funding mechanisms primarily addressed early innovation risks and production capacity constraints, the largest share of procurement expenditure was ultimately borne by the member states themselves.

By November 2021, the EU Commission had signed approximately €71 billion worth of COVID-19 vaccine contracts, which far exceeded the funding available from the ESI. As a result, EU member states also contributed to the purchase, benefiting from collective negotiated low prices and risk-sharing agreements that spread the financial burden across all countries involved (Kleine et al., 2024).

This collective model, often described in public health economics as a form of pool purchasing, enabled the member states to secure favorable pricing and terms by leveraging the EU's collective bargaining power (Parmaksiz et al., 2022).

Furthermore, the costs were partly offset by the use of national health budgets, a mechanism commonly used in centralized procurement systems to mitigate individual country expenditure (Parmaksiz et al., 2022).

From an industrial perspective, this system was equally beneficial for the pharmaceutical companies involved in vaccine production. By offering guaranteed demand through advance agreements and financial support, the EU's risk-sharing strategy created a stable environment for producers.

These financial guarantees, alongside funding to establish or expand manufacturing lines, incentivized pharmaceutical companies to scale production capacity quickly, as observed in similar public-private partnerships during health crises (Qi, 2025).

This financial security helped alleviate concerns about the financial viability of vaccine production, encouraging companies to invest in the necessary infrastructure without the risk of unsold stock.

The success of the joint vaccine procurement initiative was also heavily influenced by the European Union's vast bargaining power.

Indeed, by pooling demand for over 450 million citizens, the EU effectively transformed fragmented national markets into a single large buyer, strengthening its negotiating position vis-à-vis pharmaceutical companies operating in a highly concentrated global vaccine market (Bongardt and Torres, 2021; Arroyo et al., 2024).

Pharmaceutical companies were incentivized to enter into agreements with the EU, as it guaranteed substantial sales volumes across multiple member states (Deters and Zardo, 2022).

In economic terms, this form of joint procurement increased the Union's monopsony-like purchasing power, enabling the European Commission to negotiate more favorable contractual conditions and prices than individual member states could have achieved independently (Vogler et al., 2021).

The centralization of negotiations also prevented competition between member states for scarce supplies, a dynamic that could have driven prices upward and exacerbated inequalities in vaccine access across Europe, as occurred at the beginning of the disease (Kleine et al., 2024).

Moreover, by aggregating demand through APAs, the Commission was able to leverage the scale of the European Single Market to secure large production commitments from manufacturers, thereby improving supply predictability and reducing transaction costs associated with multiple bilateral negotiations (McEvoy and Ferri, 2020).

In addition to the economic leverage, the political backing from EU member states strengthened the Commission's negotiating position.

The member states' commitment to a collective procurement strategy ensured the successful implementation of the APA, as they agreed to the distribution of the vaccine doses in line with the EU's priorities, guaranteeing that no member state would have been left behind, struggling to gain vaccines (Vogler et al., 2021).

This collective political support helped streamline the procurement process and ensured that vaccine acquisition and distribution decisions were made in the best interest of all EU countries, particularly those that were most vulnerable (European Parliament, 2021).

By comparing vaccine procurement prices across jurisdictions, the effectiveness of the European Commission's negotiation strategy becomes evident.

For instance, AstraZeneca supplied doses to the European Union at approximately $3.50 per dose, whereas the United States paid around $4.00, meaning the EU secured the vaccine at 14.3% lower cost. An even larger difference can be observed in the Pfizer/BioNTech contract, where the EU paid $14.76 per dose compared to $19.50 in the United States, representing a price reduction of about 32.1% (Ang, 2021).

Figure 7 highlights the Commission's ability to leverage centralized procurement and collective bargaining power to obtain more favorable prices for member states (Ang, 2021).

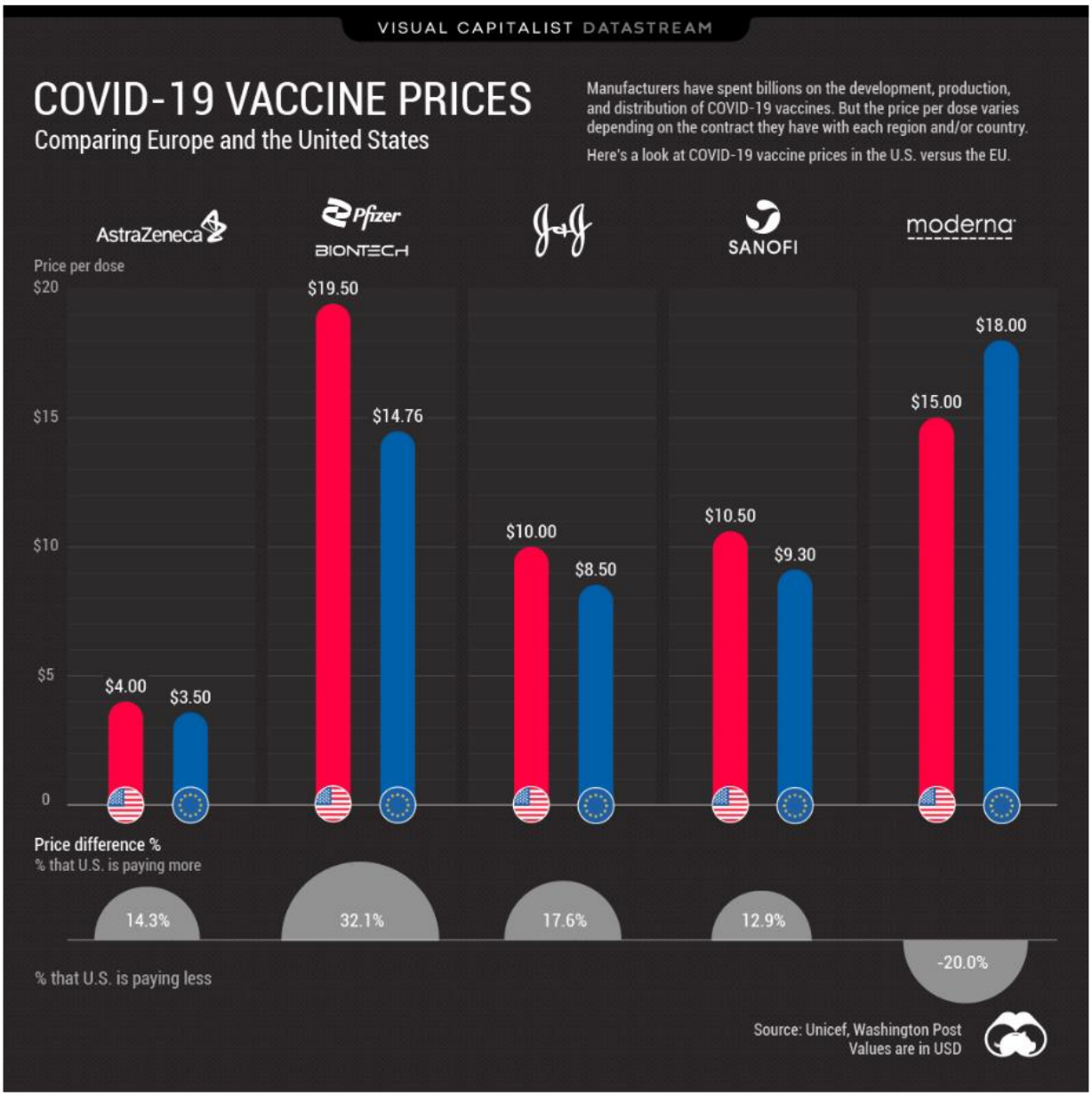

Figure 7: Comparison between vaccine prices of European Union and United States of America. Sources: Ang, 2021.

Moreover, by combining financial support, risk-sharing mechanisms, and the enormous bargaining power derived from the European Single Market, the EU was able to secure access to vaccines, negotiate favorable terms, and ensure that vaccines were distributed equitably across all member states.

The APA model established through the EU's coordinated procurement strategy has since been recognized as one of the most effective tools for managing global health emergencies, providing a blueprint for future collaborative efforts in vaccine procurement and distribution.

EU Vaccine Procurement and Rollout Strategy – EU Procurement Strategy – Strengths and Weaknesses

The EU's joint procurement of COVID-19 vaccines represents a unique case of crisis-driven supranational coordination in health policy, illustrating both the integrative potential and the institutional constraints of the European Union's governance framework.

In this respect, the vaccine initiative also provides empirical support for the Alexander-Shaw paradox, showcasing that the EU system, characterized by relatively weak central authority can nonetheless generate strong incentives for cooperation among their constituent units (Alexander-Shaw, Ganderson and Schelke, 2023).

While the EU's collective procurement strategy enhanced solidarity among member states and strengthened the Union's bargaining power in negotiations with pharmaceutical companies, the approach also exposed structural limitations related to complex decision-making procedures, regulatory caution, and the need to reconcile supranational coordination with national competences.

On the one hand, the centralized procurement mechanism helped mitigate the asymmetries that would likely have emerged if member states had competed individually for vaccine supplies.

By pooling demand across the entire Union, the European Commission was able to negotiate lower prices, secure a diversified vaccine portfolio, and guarantee proportional distribution of doses among member states regardless of their economic or political leverage (Vogler et al., 2021; McEvoy and Ferri, 2020).

Importantly, all member states participated in the joint procurement scheme and received access to vaccines according to a population-based allocation key, ensuring that no country was left to negotiate alone in a highly competitive global market (Arroyo et al., 2024).

This collective arrangement reduced the risk that smaller or less affluent states would be marginalized in the global vaccine race and reinforced the principle of solidarity embedded in EU integration (Deters and Zardo, 2022).

By aggregating demand for over 450 million citizens, the EU effectively acted as a single purchaser, transforming fragmented national markets into a unified negotiating bloc and preventing a fragmented dynamic of internal vaccine nationalism (Vogler et al., 2021).

Beyond economic leverage and equitable access, the EU strategy also placed a strong emphasis on safeguarding population health and maintaining public trust in vaccination (Greer et al., 2020).

Rather than relying on emergency-use authorizations, as adopted in some other jurisdictions, the European Union opted to approve COVID-19 vaccines through the Conditional Marketing Authorization (CMA) procedure under EU pharmaceutical law.

This regulatory pathway required more comprehensive data on safety, quality, and efficacy before authorization, while still allowing accelerated assessment through mechanisms such as rolling reviews conducted by the EMA (Greer et al., 2020; Arroyo et al., 2024).

Although this approach slightly lengthened the initial approval timeline, it ensured that vaccines remained subject to the full legal framework governing pharmaceutical products in the EU, including continued monitoring obligations and manufacturer liability (Ghadanian and Schafheutle, 2023).

This regulatory choice reflected a deliberate prioritization of public health protection over speed alone, aiming to preserve high safety standards and maintain public confidence in vaccination campaigns (Forman and Mossialos, 2021).

Indeed, in contexts where vaccine hesitancy represented a potential barrier to uptake, the emphasis on rigorous scientific evaluation and regulatory transparency helped strengthen trust in the safety and legitimacy of the vaccines approved for the European population (Greer et al., 2022).

Moreover, the initiative strengthened political cohesion and institutional cooperation within the Union, demonstrating how supranational coordination can emerge even in policy areas where the EU traditionally has limited competences (Boin and Rhinard, 2023; Ladi and Wolff, 2025).

In this sense, the procurement strategy represented not only a public health instrument but also a significant example of crisis-induced integration, reinforcing the role of the Commission as a coordinator of collective action while ensuring that all member states remained integrated within a shared framework of vaccine access, safety regulation, and public health protection.

At the same time, the strategy revealed several institutional and operational weaknesses.

The EU's governance structure required extensive consultation with member states and coordination across multiple institutions, which slowed negotiations and limited the Commission's capacity to act as swiftly as more centralized political systems (Deters and Zardo, 2022).

In addition, the enforcement of the CMA significantly slowed initial vaccine authorization compared with countries such as the United States and the United Kingdom (Forman and Mossialos, 2022).

For example, the Pfizer-BioNTech vaccine received its CMA from the European Medicines Agency on 21 December 2020, more than three weeks after the United Kingdom had granted emergency authorization and begun administering the vaccine to its population (Deutsch, 2020).

The slower pace of approval generated frustration and skepticism across several member states, particularly as other countries were already vaccinating their populations (Deters and Zardo, 2022).

Although the EU's vaccination campaign ultimately achieved widespread coverage, the early delay highlighted the tension between regulatory rigor and the urgency of emergency response, raising broader questions about the balance between speed and safety in pandemic governance.

Another structural limitation concerned the financial architecture of the procurement system. Although the European Commission coordinated negotiations and provided limited upfront funding through the Emergency Support Instrument, the majority of vaccine purchase costs were ultimately borne by the member states themselves.

This arrangement reflected the EU's limited fiscal capacity and the fact that health policy and healthcare financing remain primarily national competences, highlighting the continued reliance of supranational initiatives on national resources within the EU's multi-level governance framework (Kleine et al., 2024; Parmaksiz et al., 2022).

Taken together, these dynamics illustrate a central trade-off inherent in the EU's multi-level governance system: the collective procurement model successfully ensured equitable access and preserved solidarity among member states, but the same institutional features that facilitated cooperation, i.e. shared decision-making, legal safeguards, and regulatory rigor, also constrained the speed and flexibility of the initial response.

In this sense, the EU vaccine strategy simultaneously confirms the integrative potential highlighted by the Alexander-Shaw paradox while also revealing the practical limits of supranational crisis management within a system where authority remains partially decentralized.

EU Vaccine Procurement and Rollout Strategy – Vaccine Development

Although the EU played a significant role in coordinating vaccine procurement and distribution, much of the early technological development of the most widely used COVID-19 vaccines occurred outside the EU or through transatlantic collaborations.

The first vaccines authorized in Europe included the mRNA vaccines developed by Pfizer-BioNTech and Moderna and the viral-vector vaccines developed by Oxford-AstraZeneca and Johnson & Johnson (Bellino, 2021).

The Pfizer-BioNTech vaccine combined German biotechnology research with US pharmaceutical manufacturing and financing, while Moderna's vaccine was primarily developed in the United States using mRNA technology platforms (Thorn et al., 2022).

By contrast, the Oxford-AstraZeneca vaccine originated from research at the University of Oxford, with the underlying ChAdOx technology largely funded by public and charitable sources (estimated at 97–99% of identifiable funding) before being commercialized in partnership with AstraZeneca, a British Swedish multinational pharmaceutical company headquartered in Cambridge, UK. (Cross et al., 2022).

The geographical distribution of COVID-19 vaccine innovation, largely concentrated in the United States and, to a lesser extent, the United Kingdom and Germany, had several implications for the European Union's vaccine approval, procurement, and rollout.

While important scientific contributions originated in Europe, a substantial share of early-stage financing, large-scale clinical trials, and manufacturing capacity was concentrated in the United States (Daems and Maes, 2022; Ruiz et al., 2024).

Programs like Operation Warp Speed, which will be better addressed later, provided extensive public funding and advanced market guarantees to US-based developers, enabling rapid scaling of production before regulatory approval.

The limited concentration of vaccine development within EU territory had important implications for the Union's vaccination campaign and policy response.

On the one hand, reliance on vaccines developed partly or primarily outside the EU constrained the bloc's ability to secure immediate priority access to early production (Gleißner et al., 2021; Arroyo et al., 2024).

Countries that had heavily financed domestic vaccine development, such as the United States and the United Kingdom, were able to combine research funding with advance purchase commitments and early manufacturing scale-up, which translated into faster initial vaccination campaigns (Abbas and Babar, 2021).

By contrast, the EU's approach relied largely on negotiating supply contracts with pharmaceutical companies once vaccine candidates had reached advanced stages of development (Arroyo et al., 2024).

This dependence on external production sites and global supply chains contributed to early supply shortages and delays in the first months of the EU rollout, particularly when manufacturing bottlenecks and export restrictions emerged in early 2021 (European Court of Auditors, 2022).

At the same time, the international character of vaccine development also generated certain advantages for the EU. Transatlantic research collaborations, such as the partnership between BioNTech and Pfizer, allowed European scientific innovation to be combined with large-scale industrial production and financing capacities located outside the Union (Thorn et al., 2022).

Moreover, while the relative absence of fully EU-based vaccine development may have slowed the initial pace of vaccine access, the EU's institutional framework ultimately allowed the bloc to secure a diversified vaccine portfolio and achieve high vaccination coverage across member states.

More broadly, the experience exposed structural vulnerabilities in Europe's biomedical innovation and manufacturing ecosystem. The reliance on external financing, development pipelines, and production capacity prompted renewed debates on "strategic autonomy" in health and pharmaceutical policy within the EU.

Subsequent initiatives, such as the strengthening of European vaccine manufacturing networks and the establishment of the Health Emergency Preparedness and Response Authority (HERA), reflect attempts to address these dependencies and enhance the EU's capacity to respond more autonomously to future health emergencies (Forman and Mossialos, 2021; Greer et al., 2022).

EU Vaccine Procurement and Rollout Strategy – EU Rollout Strategy

Member states enacted their vaccination campaigns under coordination from the European Commission, which organized a common start to the rollout on 27 December 2020, symbolically designated "EU Vaccination Day."

In line with the Commission's commitment that no member state would be left without access to vaccines, the jointly procured doses were distributed simultaneously across the Union, ensuring that all countries could begin immunization at roughly the same time (Deutsch, 2020).

This coordinated launch also had a strong political and symbolic dimension. By administering the first vaccinations on the same day, or immediately thereafter, most member states sought to convey the image of a cohesive European Union acting collectively in response to the pandemic (Kerr, 2020).

The synchronized rollout emphasized solidarity and the benefits of centralized procurement and regulatory cooperation, highlighting how joint negotiation with pharmaceutical companies and

centralized authorization through the EMA enabled a unified response to a shared public health crisis (Arroyo et al., 2024).

In this way, the first vaccination campaigns were presented not only as a public health intervention but also as an early tangible outcome of unprecedented EU-level coordination in health policy.

EU Vaccine Procurement and Rollout Strategy – EU Rollout Strategy – Role of the Central Institutions

As it was designed, the rollout phase was coordinated by the Commission and member states, which collaborated over attribution and distribution, delivering vaccines pro-rata by population, as was established by agreements enforced in 2020 (Deters, 2024).

Moreover, while allocation followed this strategy, member states retained some flexibility to exchange or postpone portions of their allocated doses through coordinated mechanisms, allowing governments to adjust procurement volumes to national vaccination strategies and storage capacities (Deters and Zardo, 2022).

Within this framework, the Commission was responsible for ensuring that the allocation rules defined in the APAs were implemented consistently across the Union.

This included coordinating delivery schedules with pharmaceutical companies, notifying member states of expected shipments, and facilitating adjustments when production delays or supply constraints emerged (European Court of Auditors, 2022).

In doing so, the Commission acted as a central hub connecting manufacturers, EU regulatory bodies, and national health authorities, thereby mitigating coordination failures that could have arisen from fragmented bilateral negotiations (Deters and Zardo, 2022).

At the same time, member states retained primary responsibility for organizing and implementing vaccination campaigns at the domestic level, including the establishment of prioritization groups, the management of national distribution networks, and the administration of doses to their populations (Wouters et al., 2021).

This division of responsibilities reflected the broader institutional structure of EU health policy, where the Union provides coordination and strategic oversight while operational implementation remains largely national (Greer et al., 2022).

Consequently, the rollout phase relied on a form of multilevel governance in which the Commission ensured coherence in supply and allocation across the EU, while member states translated these

centrally coordinated deliveries into vaccination strategies adapted to their healthcare systems and epidemiological contexts.

In this context, the Commission also assumed an important brokerage function between vaccine manufacturers and national authorities, intervening when operational challenges arose regarding delivery timetables, contractual obligations, or regulatory clarifications (Della Corte, 2023).

By centralizing these interactions, the Commission helped streamline communication and reduce transaction costs for member states, which otherwise would have had to negotiate individually with suppliers during a period of severe global supply shortages (Vogler et al., 2021).

Additionally, in order to safeguard the timely delivery of vaccines to member states during a period of severe global supply constraints, the European Commission introduced an export authorization mechanism in late January 2021 (Petti, 2022).

The system required that any COVID-19 vaccine shipment produced within the European Union and destined for export be authorized by the member state where the vaccines were manufactured, while the Commission was notified in order to maintain EU-wide oversight of export flows (Petti, 2022; European Commission, 2023).

The measure responded to broader concerns that doses produced within the Union could be redirected toward higher-paying international markets before contractual obligations to EU member states were fulfilled.

Although sometimes portrayed as an export restriction, the mechanism functioned primarily as a monitoring and leverage instrument rather than a strict ban. Empirical data show that more than 95 percent of export requests were approved, with over 150 million doses exported from the EU to numerous countries during the first half of 2021 (De Maio, 2021).

The mechanism therefore had mainly preventive and signaling effects: by increasing transparency over export flows and demonstrating the Union’s willingness to enforce contractual commitments, it encouraged manufacturers to prioritize deliveries to EU member states.

Once supply pressures eased, the Commission phased out the authorization requirement and replaced it in early 2022 with a lighter monitoring system that tracked vaccine exports without requiring prior approval (European Commission, 2023).

Alongside the Commission’s operational role, EU agencies contributed to the monitoring and governance of the rollout.

The EMA played a central role by monitoring vaccine safety through EU pharmacovigilance systems and issuing scientific assessments regarding booster doses, age eligibility, and potential adverse events, thereby supporting member states in adapting their vaccination strategies (Greer et al., 2022)

The ECDC implemented a comprehensive surveillance and reporting system to track vaccine distribution and uptake across EU/EEA countries, publishing regular data on doses delivered and administered through the European Surveillance System (TESSy) (European Centre for Disease Prevention and Control, 2021).

This monitoring infrastructure increased transparency and facilitated policy coordination by enabling comparisons of national vaccination progress.

Furthermore, expert advisory structures such as National Immunization Technical Advisory Groups (NITAGs) supported evidence-based policymaking by pooling epidemiological evidence and national experiences (European Centre for Disease Prevention and Control, 2021).

Moreover, coordination between national authorities was further facilitated through the EU Health Security Committee, which served as a forum for member states and the Commission to exchange information on vaccination strategies, address supply challenges, and align public health responses during the rollout (Deruelle, 2022).

Beyond operational monitoring, transparency also became a key political dimension of the EU vaccination strategy.

Significant pressure from the European Parliament, the European Ombudsman, civil society actors, and segments of the European public pushed the European Commission to increase openness regarding vaccine procurement agreements.

Early criticism focused on the limited disclosure surrounding the Advance Purchase Agreements (APAs) negotiated with pharmaceutical companies, particularly concerning liability clauses, delivery schedules, and pricing conditions.

In response, starting in early 2021 the Commission began publishing redacted versions of several APAs, including contracts concluded with CureVac, AstraZeneca, Sanofi-GSK, Pfizer/BioNTech, Moderna, and Johnson & Johnson (General Court of the European Union, 2024).

Although commercially sensitive elements were partially obscured, the release of these documents represented an unprecedented step toward transparency in EU pharmaceutical procurement and rollout.

This initiative served both to respond to institutional oversight and to reinforce public trust by demonstrating that the Commission had negotiated contracts under reasonable conditions and within a collective European framework (Greer et al., 2022; Deters and Zardo, 2023).

Alongside these disclosures, the Commission also strengthened its public communication strategy by regularly publishing updates on vaccine deliveries, production forecasts, and distribution progress across member states.

These measures reflected a broader institutional learning process within EU crisis governance, in which transparency and proactive communication were increasingly deployed as tools to enhance accountability and maintain political legitimacy during the vaccination rollout.

Through these collaborative expert networks, member states were able to rapidly update prioritization strategies and vaccination guidelines as new scientific evidence emerged, contributing to a more adaptive and coordinated European vaccination campaign (Deters, 2023).

Together, these mechanisms illustrate how EU institutions supported the rollout primarily through coordination, mediation, and oversight functions rather than through direct implementation of vaccination campaigns.

EU Vaccine Procurement and Rollout Strategy – EU Rollout Strategy - Early Issues, Public Trust and Vaccine Hesitancy

Despite the coordinated start of the vaccination campaign, the early rollout phase exposed several operational challenges across member states.

In many countries, the administrative and logistical structures required to sustain a rapid mass vaccination campaign were not fully prepared, contributing to a slower-than-expected pace of immunization during the first months of 2021, particularly among priority groups such as healthcare workers and elderly populations (Forman and Mossialos, 2021).

While the EU had centralized vaccine procurement, the organization and implementation of vaccination campaigns remained a national competence, meaning that differences in healthcare infrastructure, distribution capacity, and administrative procedures significantly influenced national rollout performance.

In practice, the EU institutions coordinated the acquisition and allocation of doses, but each government was responsible for translating these deliveries into operational vaccination campaigns, including the establishment of vaccination sites, appointment systems, prioritization schemes, and the mobilization of healthcare personnel (Wouters et al., 2021).

This institutional arrangement reflects the broader structure of EU health governance, in which public health remains primarily a national responsibility while the Union plays a supporting and coordinating role (Greer et al., 2022).

Consequently, member states entered the vaccination phase with markedly different administrative capacities and health-system structures, which contributed to uneven early rollout outcomes across the Union.

Over time, however, these differences gradually narrowed as governments adapted their strategies, expanded vaccination infrastructure, and simplified distribution procedures. Several countries increased the number of vaccination centers, involved pharmacies and general practitioners in vaccine administration, and introduced more flexible prioritization mechanisms to accelerate uptake (Deters and Zardo, 2022).

To mitigate these disparities, EU institutions, primarily the EMA, the ECDC and the Commission, introduced several coordination mechanisms aimed at strengthening national implementation, as already explained in the precedent paragraph.

Moreover, this process of policy learning and institutional adaptation allowed member states to progressively overcome initial bottlenecks and scale up vaccination capacity during the first half of 2021, contributing to a more rapid increase in vaccination coverage across the EU despite the early difficulties (Greer et al., 2022).

In addition to logistical preparedness challenges, the early phase of the vaccination campaign was also affected by rigid prioritization frameworks that initially limited the flexibility of national vaccination programs.

Many member states adopted strict priority rules aimed at ensuring that vulnerable groups, particularly healthcare workers, elderly populations, and residents of long-term care facilities, received vaccines first (Arroyo et al., 2024).

While these guidelines reflected sound public health principles, their early implementation sometimes created operational inefficiencies.

In several cases, unused doses remained temporarily in storage because national systems lacked mechanisms to quickly reallocate appointments or transfer vaccines to lower-priority groups when scheduled recipients were unavailable.

As a result, the initial pace of vaccine administration across the European Union was slower than expected. By March 2021, approximately 10 percent of the EU population had received a first vaccine

dose, while vaccination campaigns progressed significantly faster in countries such as the United Kingdom and the United States, where first-dose coverage exceeded 30 percent (De Maio, 2021; Greer et al., 2022).

This discrepancy reflected a combination of factors, including the operational challenges described above and differences in procurement strategies.

Unlike the United Kingdom and the United States, which pursued more aggressive early procurement policies and invested heavily in securing rapid delivery, EU negotiations initially placed greater emphasis on price control, liability conditions, and collective risk-sharing among member states (Reinl, Katsanidou and Potzschke, 2023).

This approach partly reflected the novelty of the Commission's role in negotiating pharmaceutical contracts on behalf of all member states, an unprecedented responsibility for EU institutions (Wouters et al., 2021).

More broadly, this strategy reflected a deliberate policy trade-off between ensuring equitable access to vaccines among member states and maximizing the speed of procurement and delivery, prioritizing solidarity and collective bargaining over rapid bilateral agreements

The slow pace of vaccination in the first months of 2021 was further exacerbated by significant supply disruptions affecting some of the vaccines procured through the EU strategy.

In January 2021, AstraZeneca informed the European Commission that it would deliver substantially fewer doses than initially scheduled for the first quarter of the year, citing production problems at manufacturing facilities in Belgium.

The announcement implied a reduction of roughly 60 percent compared with the quantities originally anticipated, forcing several member states to adjust their vaccination plans and delay parts of their immunization campaigns (European Court of Auditors, 2022; Greer et al., 2022).

The situation soon escalated into a contractual dispute between the Commission and the company. While EU authorities argued that AstraZeneca should mobilize all production sites listed in the contract, including facilities located in the United Kingdom, to fulfill its delivery commitments, the company maintained that the agreement was based on a best reasonable efforts clause rather than a strict delivery obligation (Wouters et al., 2021).

Beyond the immediate supply shortfall, the controversy exposed the vulnerability of the EU vaccination strategy to global production bottlenecks and raised political concerns regarding the prioritization of vaccine deliveries to European populations.

In response, and in order to reinforce oversight over vaccine supply chains, the European Commission introduced the export authorization mechanism in late January 2021 requiring that COVID-19 vaccines produced within the EU and destined for export receive prior authorization from national authorities and notification to the Commission (European Commission, 2023).

By increasing transparency over vaccine flows and demonstrating the Union's willingness to defend its contractual rights during a period of scarcity, the measure strengthened the Commission's negotiating position with manufacturers while also reassuring member states and European citizens that EU institutions were actively safeguarding the availability of doses within the Union.

In this sense, the mechanism contributed not only to stabilizing supply management but also to reinforcing institutional credibility and public confidence in the collective vaccination strategy during one of its most politically sensitive phases (Greer et al., 2022).

Transparency measures adopted by EU institutions, including the publication of vaccine procurement contracts and regular communication on vaccine deliveries and safety monitoring, were also intended to strengthen public confidence in the vaccination campaign and demonstrate the accountability of European decision-making processes (Greer et al., 2022).

Despite these efforts to reinforce institutional credibility and stabilize vaccine supply, the success of the vaccination campaign also depended on the ability of governments and EU institutions to maintain public confidence in the vaccines themselves.

During the early stages of the rollout, vaccine hesitancy emerged as a significant challenge across several member states, influenced by widespread media attention to potential side effects, evolving scientific guidance, and uncertainty surrounding newly developed vaccines.

Public confidence was particularly affected in March 2021, when several European countries temporarily suspended the use of the AstraZeneca vaccine following reports of rare thrombotic events (Mahase, 2021).

Although the EMA later confirmed that the benefits of vaccination clearly outweighed the risks, the precautionary suspensions generated confusion among the public and temporarily slowed vaccination campaigns in several countries (Mahase, 2021).

More broadly, the vaccination effort became intertwined with a complex information environment characterized by misinformation and geopolitical narratives.

Disinformation campaigns circulating online, including efforts to promote alternative vaccines such as Russia's Sputnik V while casting doubt on Western vaccines, contributed to undermining public confidence in some contexts (Petrova-Geretto, Vodenitcharova and Petrova, 2024).

EU institutions sought to counter these narratives through strategic communication initiatives and monitoring activities coordinated by the European External Action Service, which identified and exposed foreign disinformation targeting European vaccination efforts (EEAS, 2020; Greer et al., 2022).

The EMA also played an important role in maintaining public confidence by continuously monitoring vaccine safety through EU pharmacovigilance systems and publicly communicating scientific assessments of potential side effects, including the investigation of rare thrombotic events associated with the AstraZeneca vaccine.

Nevertheless, levels of vaccine acceptance varied considerably across the Union. While countries such as Malta and Denmark rapidly achieved high vaccination coverage, others, including Bulgaria and Romania, faced persistent hesitancy linked to lower levels of trust in public institutions and healthcare systems

To address these challenges, EU institutions implemented a coordinated communication strategy aimed at strengthening vaccine confidence across member states.

The EU Commission and the ECDC developed communication toolkits, information campaigns, and guidance for national authorities in order to provide clear and consistent messaging on vaccine safety, regulatory procedures, and the benefits of vaccination.

Through these initiatives, EU institutions sought to complement supply coordination with communication strategies designed to strengthen public trust and sustain the momentum of the vaccination campaign, reinforcing citizens' trust in the vaccination process (Petrova-Geretto, Vodenitcharova and Petrova, 2024).

As a result, maintaining public confidence in vaccines became a central component of the EU vaccination strategy, since the effectiveness of joint procurement and distribution ultimately depended on citizens' willingness to accept vaccination.

EU Vaccine Procurement and Rollout Strategy – EU Rollout Strategy – Strengths and Weaknesses

The rollout phase of the EU vaccine strategy displayed several important strengths, particularly in terms of coordination and solidarity.

Through centralized procurement and pro-rata distribution of doses, the EU Commission ensured that all member states could begin vaccination campaigns at roughly the same time, symbolically reinforced by the common start on “EU Vaccination Day.”

The Commission also performed an important brokerage function between vaccine manufacturers and national authorities, mediating contractual disputes, coordinating delivery schedules, and centralizing interactions with pharmaceutical companies.

This coordinated strategy helped prevent intra-EU competition for scarce vaccines, significantly reduced transaction costs, and avoided the fragmentation of purchasing strategies that could have disadvantaged smaller or less economically powerful member states.

By negotiating collectively with pharmaceutical companies, the EU also strengthened its bargaining power and ensured more equitable access to vaccines across the Union (Arroyo et al., 2024).

In response to early supply uncertainties, the Commission also introduced an export authorization mechanism to monitor vaccine shipments produced within the EU and ensure that contractual obligations toward member states were respected.

Although most export requests were approved, the mechanism increased transparency over vaccine flows and strengthened the Union’s negotiating leverage with pharmaceutical manufacturers

In operational terms, EU institutions played a crucial coordination role throughout the rollout. The Commission managed delivery schedules and contractual implementation with manufacturers, while the EMA ensured continuous pharmacovigilance and provided scientific guidance on vaccine safety and usage.

At the same time, the ECDC monitored vaccination progress across member states through centralized data systems, allowing governments to compare performance, identify bottlenecks, and adapt their strategies.

Together, these mechanisms increased transparency and facilitated policy learning across national administrations.

Beyond logistical coordination, EU institutions also played an important role in shaping the communication environment surrounding the vaccination campaign.

The rollout occurred in a context characterized by significant public uncertainty, vaccine hesitancy, and the spread of misinformation through both domestic political debates and transnational disinformation campaigns.

In response, the Commission, together with the EMA, the ECDC, and national authorities, sought to broadcast a coherent and science-based message regarding vaccine safety, regulatory procedures, and the benefits of immunization. Regular public communication on vaccine approvals, safety monitoring, and delivery forecasts was designed to reinforce the credibility of the EU regulatory framework and maintain public trust in vaccination.

Parallel initiatives also aimed to counter misinformation circulating online, including narratives questioning vaccine safety or promoting geopolitical alternatives, through coordinated factchecking, strategic communication, and monitoring activities conducted in cooperation with the European External Action Service and national governments.

By promoting consistent messaging and transparency, EU institutions attempted to mitigate public mistrust and support the acceptance of vaccines across diverse national contexts.

Another important strength of the EU rollout strategy was the credibility and robustness of the Union's regulatory framework, which played a crucial role in legitimizing the vaccination campaign.

The centralized evaluation process conducted by the EMA ensured that COVID-19 vaccines authorized within the EU underwent a rigorous scientific assessment based on common safety, quality, and efficacy standards.

Through the use of accelerated procedures such as rolling reviews, the EMA was able to evaluate emerging clinical data in real time while maintaining the integrity of the regulatory process.

Although this approach initially resulted in slightly slower authorizations compared with countries such as the United Kingdom or the United States, it contributed to strengthening the perceived reliability and transparency of vaccine approval within the Union.

Continuous pharmacovigilance monitoring further reinforced this credibility by allowing EU authorities to rapidly assess and communicate potential side effects, such as the rare thrombotic events associated with some vaccines.

In this sense, the EU regulatory system not only ensured the safety of vaccines distributed across member states but also supported the broader legitimacy of the vaccination campaign, demonstrating the capacity of EU institutions to combine scientific rigor with coordinated crisis management.

EU institutions also provided practical support to member states during the implementation of vaccination campaigns.

Through expert networks, surveillance systems, and coordination platforms such as the Health Security Committee, national authorities were able to exchange information on vaccination strategies, adapt prioritization frameworks, and address operational challenges as they emerged.

This facilitated policy learning and helped governments gradually scale up vaccination capacity despite initial logistical difficulties.

These measures also reflected a broader process of institutional learning within EU crisis governance, in which transparency, coordinated communication, and centralized monitoring mechanisms were progressively strengthened to maintain political legitimacy during the vaccination campaign.

At the same time, the rollout revealed several weaknesses, most of which were concentrated in the initial months of the vaccination campaign in early 2021.

Because the operational implementation of vaccination campaigns remained largely a national competence, differences in healthcare infrastructure, administrative capacity, and logistical preparedness produced uneven early rollout performance across member states.

Several countries initially struggled to establish large-scale vaccination infrastructures, appointment systems, and distribution networks capable of administering doses rapidly, particularly among priority groups such as healthcare workers and elderly populations.

These structural differences reflected the broader multilevel governance arrangement of EU health policy, where the Union provides coordination and strategic oversight while national authorities retain responsibility for implementation (Greer et al., 2022).

Consequently, the early months of the rollout were characterized by considerable variation in vaccination speed across the Union.

Supply-side challenges further exacerbated these early difficulties. The most significant disruption occurred in January 2021 with the AstraZeneca delivery shortfalls.

This reduction, estimated at roughly 60 percent of the planned deliveries, forced several member states to revise vaccination schedules and temporarily slowed immunization campaigns.

The dispute that followed between the European Commission and the company highlighted the vulnerability of the EU strategy to global production bottlenecks and contractual ambiguities, particularly regarding “best reasonable efforts” clauses governing delivery obligations.

More broadly, the EU vaccination campaign initially progressed more slowly than those of the United Kingdom and the United States, which had secured larger early supplies through more aggressive advance purchasing and had approved vaccines earlier through national regulatory procedures.

Operational factors also contributed to the slower pace observed during the first phase of the rollout.

Many member states adopted strict prioritization frameworks designed to ensure that vulnerable populations were vaccinated first. While these policies were epidemiologically justified, their early implementation sometimes generated inefficiencies.

In some cases, vaccination systems lacked sufficient flexibility to reallocate unused doses quickly when priority recipients were unavailable, leading to temporary delays in administration.

Over time, governments adapted these strategies by expanding vaccination sites, involving pharmacies and general practitioners, and simplifying appointment systems, which significantly accelerated vaccination rates during the spring and summer of 2021.

Finally, the early phase of the campaign was accompanied by communication and trust-related challenges.

Public debate surrounding vaccine safety, particularly after several European countries temporarily suspended the use of the AstraZeneca vaccine in March 2021 due to reports of rare thrombotic events, generated confusion and briefly slowed vaccination uptake in some contexts.

In addition, early criticism regarding the limited transparency of vaccine procurement contracts and the redaction of certain contractual clauses raised concerns among policymakers and segments of the public.

Although EU institutions later responded by publishing redacted versions of several Advance Purchase Agreements and strengthening communication on vaccine safety and deliveries, these issues initially affected public confidence in the vaccination campaign.

Overall, however, many of these weaknesses proved transitional, as member states progressively expanded vaccination capacity, supply stabilized, and coordination mechanisms improved during the subsequent phases of the rollout.

More broadly, the rollout phase also illustrates the dynamics described in the Alexander–Shaw paradox.

In the context of the COVID-19 pandemic, although health policy remained largely a national competence, governments collectively delegated significant coordinating functions to EU

institutions, including vaccine procurement, allocation mechanisms, regulatory evaluation, and strategic communication.

Rather than replacing national authority, this process temporarily strengthened the role of the EU as a coordinating and mediating center, demonstrating how crises can generate incremental expansions of supranational capacity even within a system formally characterized by limited central competences.

EU Vaccine Procurement and Rollout Strategy – Evidence

By the end of the COVID-19 pandemic emergency phase, the European Union's centralized vaccine procurement and rollout produced mixed but generally positive results.

The EU's Vaccines Strategy, launched in June 2020, used joint advance purchase agreements negotiated by the European Commission to secure a diversified portfolio of up to 4.6 billion vaccine doses worth about €71 billion for member states, aiming to guarantee equitable access and avoid competition between national governments (European Court of Auditors, 2022; Arroyo et al., 2024).

By the end of the COVID-19 pandemic emergency phase, vaccination coverage in the European Union had reached high levels. According to official datasets compiled from national health authorities, around 74–75 % of the total EU population had completed a full primary COVID-19 vaccination series by 2023, following the large-scale rollout coordinated through the EU's joint procurement strategy (Trading Economics, 2023; Mathieu et al., 2024).

In cumulative terms, EU member states administered over 940 million vaccine doses by October 2023, reflecting both primary vaccinations and booster campaigns implemented throughout 2021–2023 (Mathieu et al., 2024).

These high levels of vaccine uptake translated into substantial public-health benefits, particularly in terms of mortality reduction and protection of vulnerable populations.

Peer-reviewed modelling studies estimate that COVID-19 vaccination prevented a large number of deaths across Europe: approximately 1.56 million deaths were averted in the European Region between December 2020 and March 2023, corresponding to a 59 % reduction in expected COVID-19 mortality, with around 96 % of the lives saved occurring among individuals aged 60 years and older (Meslé et al., 2024).

These findings highlight the crucial role of vaccination and booster campaigns in protecting high-risk groups and mitigating the most severe outcomes of the pandemic.

Beyond direct mortality reduction, the EU's centralized procurement mechanism contributed to ensuring relatively equitable vaccine access among member states, stabilizing supply during a period of global scarcity, and reducing the risk of intra-EU competition for limited vaccine doses, thereby strengthening the Union's collective capacity to respond to cross-border health emergencies (Arroyo et al., 2024).

US Vaccine Procurement and Rollout Strategy

As the COVID-19 pandemic rapidly escalated in 2020, the United States, alongside the European Union, quickly recognized the profound threat posed by the virus.

From the outset the US acknowledged that vaccines would be the primary tool to combat the disease, control the pandemic and transitioning from emergency containment measures to a sustainable resolution.

The US response to vaccine development and distribution, however, was shaped by its unique political, social, and governance structures. The speed at which vaccines were developed and distributed in the US was unparalleled, driven by a combination of federal investment, public-private partnerships, and substantial involvement of private-sector pharmaceutical companies.

Operation Warp Speed (OWS), launched in May 2020, was the flagship initiative designed to expedite vaccine development and manufacturing, and it played a critical role in the rapid deployment of vaccines by providing financial support and facilitating regulatory approvals (Slaoui and Hepburn, 2020).

However, the US vaccine strategy extended beyond Operation Warp Speed. It involved substantial federal funding and coordination through Operation Warp Speed and additional initiatives, such as the American Rescue Plan, to support vaccine procurement and distribution.

While Operation Warp Speed focused on vaccine development and manufacturing, the broader distribution relied on federal guidance, with state and local governments managing the rollout, often with support from private-sector partnerships like pharmacies.

Yet, despite the remarkable speed in vaccine development, the US vaccine strategy faced significant challenges in its implementation.

The decentralized nature of the US federal system meant that states had significant autonomy in distributing vaccines, leading to uneven outcomes across the country.

The political landscape further complicated this effort. Vaccine hesitancy and resistance to public health measures, often influenced by political ideology, were particularly pronounced in certain states, further hindering equitable access (Birkland et al., 2021).

These complexities can be understood through the framework of the Alexander-Shaw Paradox, which highlights the tension between centralized and decentralized political systems in managing large-scale crises, particularly COVID-19 pandemic.

While the US system enabled swift innovation and the rapid development of vaccines, its decentralized political structure created significant challenges in ensuring a unified and equitable rollout.

The same federalist system that allowed for innovation and private-sector involvement also facilitated disparities in vaccine distribution, as the ideological divides between federal and state authorities, fueled by political polarization, shaped the response (Kerr, Panagopoilos and van der Linden, 2021).

The paradox underscores how governance structures that facilitate rapid responses can also hinder effective coordination, leading to fragmented outcomes (Alexander-Shaw, Ganderson and Schelke, 2023).

Thus, the US vaccine strategy offers a concrete example of the Alexander-Shaw Paradox. While the US demonstrated remarkable capacity for rapid vaccine development, the decentralization of the distribution process and the ideological polarization between federal and state authorities resulted in an uneven and fragmented rollout.

This paradox highlights the enduring complexities of US governance, where innovation and speed can be offset by the challenges of achieving national unity and equitable implementation, especially during a deeply polarized crisis.

To better understand the complexities of the US vaccine strategy, it is essential to examine the role of Operation Warp Speed, the pivotal initiative that accelerated vaccine development and manufacturing, and how its objectives and execution contributed to both the successes and challenges of the broader vaccine rollout.

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed

As the COVID-19 pandemic escalated, US leaders sought an expedited solution to the health crisis, culminating in the announcement of Operation Warp Speed (OWS) in May 2020 (Centers for Disease Control and Prevention, 2020).

Designed as a public-private partnership, OWS aimed to fast-track vaccine development and manufacturing, with leadership provided by the Department of Health and Human Services (HHS) and the Department of Defense (DOD) (Siddalingaiah, 2021).

The ambitious goal was to significantly compress the vaccine research and development timeline, which would normally span several years, to just a few months, aiming to secure vaccines for the US population by January 2021 (U.S. Department of Health and Human Services, 2020).

In order to reach this goal, OWS was explicitly designed to reduce both the scientific and market risks associated with relying exclusively on public investments for vaccine development.

Historically, vaccine development can take several years, with substantial financial risk for private companies.

In contrast, OWS sought to mitigate these risks by creating a diverse portfolio of vaccine candidates, drawing from multiple technological platforms, such as mRNA, viral vectors, and protein subunits (Howard and Wright, 2021).

This diversified approach was intended to maximize the chances of success, ensuring that even if some candidates failed in clinical trials, others might succeed, thus securing a reliable vaccine supply for the US population.

By July 2020, the US government had already signed multi-million-dollar agreements with several pharmaceutical companies, including Pfizer/BioNTech, Moderna, Johnson & Johnson (Janssen), AstraZeneca/Oxford, Novavax, and Sanofi/GSK (Siddalingaiah, 2021).

These agreements combined direct investments in research and development, grants for scaling manufacturing, and advance purchase commitments for millions of doses, even before any vaccine candidate had completed clinical trials (Siddalingaiah, 2021; Bok et al., 2021).

To support the rapid development and distribution of these vaccines, OWS implemented a strategy designed to accelerate the development timeline while maintaining strict safety standards (Bok et al., 2021).

One the key innovations of this approach was its emphasis on conducting multiple vaccine development steps in parallel rather than sequentially (Lopez, 2020).

Traditionally, vaccine development follows a stepwise progression, with each phase, preclinical, clinical trials (Phases 1, 2, and 3), and manufacturing, completed before moving to the next. However,

OWS redefined this process by overlapping clinical trial phases with the scaling of manufacturing (Bok et al., 2021).

This allowed vaccine manufacturers to begin large-scale production of vaccine doses while clinical trials were still in progress, ensuring that millions of doses would be ready for distribution as soon as the vaccine received approval from the U.S. Food and Drug Administration (FDA).

This parallel approach effectively reduced the timeline from years to mere months without compromising the safety or regulatory scrutiny of the development process (Howard and Wright, 2021).

Operation Warp Speed also invested heavily in expanding domestic manufacturing infrastructure and securing critical supply chains, funding large-scale production facilities and supporting "at-risk" manufacturing during clinical trials so that vaccine doses could be produced in advance of regulatory approval, ensuring immediate availability once authorization was granted (Winch et al., 2021).

This strategy was an extraordinary response to the urgency of the pandemic, enabling the United States to be among the first nations to secure a ready supply of vaccines upon approval.

Moreover, to further accelerate vaccine development, the FDA promulgated clear guidelines concerning COVID-19 vaccine approval, including the use of Emergency Use Authorizations (EUAs) established under Section 564 of the Federal Food, Drug, and Cosmetic Act.

The EUA mechanism, which was pivotal in expediting the approval of COVID-19 vaccines, allowed manufacturers to apply for approval based on interim Phase 3 trial results, rather than waiting for full licensure, which would typically require long-term follow-up data (Koritala et al., 2021).

To receive an EUA, vaccines only needed to demonstrate a minimum efficacy of 50% in preventing symptomatic COVID-19 infection and provide two months of valid data showing sustained effectiveness and safety (Howard and Wright, 2021).

This approach drastically shortened the approval timeline, allowing vaccines to be distributed far more quickly than traditional vaccine approval processes would allow.

Nevertheless, while the compressed timeline allowed for expedited approval, regulators and manufacturers alike were clear that safety standards would not be sacrificed. The rigorous nature of Phase 3 trials remained intact, with each vaccine undergoing testing with tens of thousands of participants (Mena Lora et al., 2022).

Despite the accelerated pace, these trials were critical in ensuring that the vaccines were both safe and effective before mass distribution.

Additionally, the Government Accountability Office (GAO) found that while manufacturers adapted the traditional vaccine development pathway, they did not circumvent key stages in the regulatory process (U.S. Government Accountability Office, 2021).

Instead, they conducted trials and scaled manufacturing concurrently, ensuring that the safety and immunogenicity of the vaccines were rigorously tested through the usual clinical trial phases.

The enormous financial resources allocated by the federal government played a crucial role in enabling manufacturers to conduct these large-scale trials in parallel with manufacturing efforts, minimizing the typical delays associated with securing funding and producing sufficient trial materials (Siddalingaiah, 2021).

Indeed, for US negotiators, the price of the vaccine was not the primary concern; instead, the focus was on speed and quantity.

The US paid significantly higher prices per dose compared to other countries, which underscored the government's prioritization of rapid vaccine access over cost containment (Kerr, Panagopoulos, and van der Linden, 2021).

This willingness to pay a premium reflected the broader economic and political strategy: the US needed to ensure that vaccines would be developed and distributed as quickly as possible to control the pandemic, particularly in the context of a looming presidential election.

In fact, a successful and rapid vaccination campaign would not only save lives but also facilitate a quick economic reopening, which was critical to President Trump's re-election prospects.

By the summer of 2020, as the election approached, an effective response to the pandemic, symbolized by a successful vaccine rollout, became a key tool in bolstering political support and strengthening the administration's standing with voters (Kerr, Panagopoulos, and van der Linden, 2021).

Moreover, the US government offered manufacturers substantial legal protection. Through the Public Readiness and Emergency Preparedness Act (PREP), vaccine producers were granted immunity from liability for any injuries potentially caused by the vaccines, a critical measure intended to shield companies from the typical risks associated with fast-tracked medical products (Siddalingaiah, 2021).

This decision was based on the widespread belief among US authorities that by removing legal risks and maximizing the financial incentives for pharmaceutical companies, they would be more motivated to accelerate the vaccine development process (Nagar, Cacodcar and Kesselheim, 2025).

By assuming both the financial and legal risks that are typically borne by private firms, OWS aimed to unlock the full innovative potential of the US pharmaceutical sector, ensuring a rapid response to the pandemic.

This strategy of public-private collaboration and the use of market incentives reflect a longstanding American tendency to rely on the private sector to address public crises, demonstrating the value placed on innovation, speed, and market-driven solutions in US governance (Kerr, Panagopoulos, and van der Linden, 2021).

The rapid progress achieved under Operation Warp Speed was therefore not only the result of scientific and regulatory acceleration, but also of an economic framework specifically designed to mobilize large-scale funding, reduce investment risks, and stimulate rapid vaccine production.

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Economic Framework

Operation Warp Speed rested on an explicitly risk-socializing economic framework: instead of waiting for proof of efficacy and then financing procurement, the US government used a portfolio model that combined push funding for R&D and at-risk manufacturing with pull incentives through advance purchase commitments, while HHS and DOD used flexible contracting tools, including other transaction authority, to move money quickly and let firms scale production before trial readouts were complete (Bonnifield, 2022; O'Leary et al., 2023).

To shift uncertainty away from private firms and onto the federal balance sheet, extraordinary resources were mobilized through an economic framework for OWS.

Congress first created the fiscal base through the CARES Act, which provided $27.015 billion to the Public Health and Social Services Emergency Fund (PHSSEF) for COVID-19 prevention, preparedness, and response, including vaccine and countermeasure development and procurement (Holt, 2020).

Within that broader envelope, HHS stated that Congress had directed almost $10 billion specifically to OWS-related activities, including more than $6.5 billion for BARDA countermeasure development and $3 billion for NIH research, each addressing different stages of the biomedical innovation pipeline (U.S. Department of Health and Human Services, 2020; Noreika and Burrows, 2020).

In the context of COVID-19, the funding channelled through the Biomedical Advanced Research and Development Authority (BARDA) was the key financial and contractual interface between the state and industry: as HHS's medical-countermeasure authority, it used its pre-existing preparedness mandate and contracting infrastructure to fund the late-stage clinical development, at-risk manufacturing, technology transfer, and large-scale production capacity, often through public-private partnerships with pharmaceutical firms (U.S. Department of War, 2020).

In parallel, resources allocated to the National Institutes of Health (NIH) supported earlier-stage scientific research and clinical infrastructure, including basic and translational research on SARS-CoV-2 biology, immunology, and vaccine platform technologies, as well as the coordination of large clinical trial networks such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

This included funding to retrofit or expand manufacturing facilities, procure raw materials, and produce millions of doses before regulatory approval, thereby allowing vaccine candidates to move rapidly from clinical trials to large-scale supply (Collins and Stoffels, 2020).

Together, these complementary funding streams illustrate the broader economic architecture of Operation Warp Speed, in which federal investment covered multiple stages of the innovation chain, from basic biomedical research to industrial-scale production, in order to compress development timelines and reduce the financial risk faced by private vaccine developers, enabling parallel progress across research, clinical testing, manufacturing scale-up, and procurement.

OWS therefore did not follow the conventional sequential model in which governments wait for successful efficacy results before financing procurement; instead, it adopted a portfolio approach across multiple vaccine platforms and financed overlapping stages of clinical development, plant retrofitting, manufacturing scale-up, and pre-purchase commitments.

This strategy was a form of emergency industrial policy based on schedule compression, portfolio diversification, and public assumption of downstream production risk (Slaoui and Hepburn, 2020).

Official GAO oversight confirms the scale of this intervention: by mid-November 2020, contract awards for six OWS vaccine candidates included at least $10 billion in obligated funding and a total potential value of at least $18 billion, with substantial use of other transaction authority and other flexible contracting tools to accelerate execution (U.S. Government Accountability Office, 2020).

By October 31, 2020, HHS had already obligated about $13.3 billion for vaccines, as highlighted by Figure 8, and $2.8 billion for therapeutics from COVID-19 emergency appropriations (Howard and Wright, 2021).

Company	Type	Contract Value	Specifications	Doses per Person	Current Phase (Preliminary Effectiveness – U.S. Strain)[a]	Storage
Pfizer/BioNTech	mRNA[b]	$5.97B	300 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna	mRNA	$4.94B $954M	300 million doses Development	2	Phase III (94.5%) EUA Issued	Cold storage (6 mos, -20° C) Refrigerator (30 days, -2° to -8° C)
AstraZeneca/ Oxford Univ.	Viral Vector[c]	$1.2B	300 million doses	2	Phase II/III (70%)	Refrigerator (-2° to -8° C)
Johnson & Johnson (Janssen Pharmaceuticals)	Viral Vector	$1B $456M	100 million doses Development	1	Phase III (72%) EUA Issued	Refrigerator (3 mos, -2° to -8° C)
Novavax	Protein[d]	$1.6B	100 million doses	2	Phase III (95.6%)	Refrigerator (-2° to -8° C)
Sanofi/GSK	Protein	$2.04B $30.8M	100 million doses Development	2	Phase I/II	Refrigerator (-2° to -8° C)
Merck/IAVI[e]	Viral Vector	$38M	Development[f]	1	DISCONTINUED	N/A

Figure 8: Vaccine candidates supported by BARDA and other US agencies, establishing contract value, number of doses and required number of doses per person, as of March 2021: Siddalingaiah, 2021.

Economically, this meant that OWS functioned as a public risk-pooling mechanism: the federal government absorbed much of the technological, regulatory, and manufacturing risk in order to buy speed, making early large-scale production rational for firms even before trial readouts were complete (Castillo et al., 2021).

OWS approach reflected a strategic shift that combined public sector investment with private sector innovation, leveraging market incentives to achieve public health objectives.

Moreover, the strategy enforced meant that the US government was effectively placing large public financial bets on multiple private-sector vaccine developers despite the inherent uncertainty of biomedical innovation, since none of the firms involved could guarantee that their vaccine candidates would ultimately prove safe and effective (Van Norman, 2020).

Taxpayer resources were committed to vaccine candidates that could have ultimately failed during clinical testing, but policymakers judged that the expected social benefits of rapid vaccine availability far outweighed the financial risk of unsuccessful candidates, given the severe health and economic damage caused by the COVID-19 pandemic (Slaoui and Hepburn, 2020).

The government's assumption of financial risk was crucial in accelerating vaccine development, as it provided pharmaceutical companies with the capital necessary to scale production without the usual financial burden of uncertain outcomes (Kerr, Panagopoulos, and van der Linden, 2021).

The use of public-private partnerships (PPPs) and market-based incentives in OWS reflects a deeply entrenched tendency in US governance to rely on the private sector as a primary driver of innovation, especially in times of crisis.

Historically, the US has frequently turned to market-driven solutions to solve complex public challenges, such as in the areas of technology, defense, and health (Qi, 2025).

The strategic partnership between the federal government and pharmaceutical companies in OWS is a direct continuation of this model, wherein the government provides initial funding, legal protections, and large-scale purchase guarantees, while the private sector delivers innovation and efficient production at scale.

This synergy is designed to combine the strengths of both sectors, with the private industry contributing expertise in research and development, while the government supports these efforts through funding and risk mitigation (Kerr, Panagopoulos, and van der Linden, 2021).

Additionally, the US Department of Health and Human Services, on September 23, 2020, made a public statement announcing that, with assistance from CDC, it would support state and local jurisdictions in vaccine preparedness by allocating $200 million in federal funds.

These resources were distributed through cooperative agreements administered by the CDC to help public health authorities strengthen the operational infrastructure required for mass vaccination, including planning for vaccine distribution, improving data and immunization information systems, training healthcare personnel, expanding cold-chain storage capacity, and preparing local vaccination sites.

The funding was designed to ensure that state, territorial, and large metropolitan health departments could rapidly deploy vaccination campaigns once vaccines received regulatory authorization, thereby aligning logistical preparedness with the accelerated timelines created by OWS.

In economic terms, this allocation illustrates that the OWS framework extended beyond financing vaccine research and procurement to also include public investment in delivery infrastructure, recognizing that the success of rapid vaccine development depended equally on the capacity of the public health system to distribute doses efficiently at scale.

Moreover, this public-private model was not only about maximizing speed but also ensuring that market incentives aligned with national priorities.

By offering lucrative contracts, guaranteed purchases, and legal protections, the US government effectively incentivized pharmaceutical companies to prioritize vaccine development over other projects, fostering intense competition among firms to deliver the first safe and effective vaccine (Bonnifield, 2022).

This strategy capitalized on the competitive drive of the private sector, accelerating innovation through the same mechanisms that drive efficiency and technological advancement in non-pandemic times.

In this way, OWS exemplified the US commitment to leveraging its market-driven economy to address urgent public health needs, reflecting the broader tendency in US governance to favor efficiency, innovation, and speed, particularly in emergency situations.

This market-driven approach, however, was not without its critics.

Indeed, such a reliance on private firms for public health solutions raises concerns about equity and accountability. The involvement of private sector entities with a profit motive, especially when they are provided with significant government subsidies, could potentially lead to prioritization of profit over broader public health needs (Qi, 2025).

Additionally, critics point out that the reliance on private companies in addressing a public health crisis may result in disparities in access, as private firms may be incentivized to focus on lucrative markets rather than equitable distribution.

This economic architecture was operationalized through a network of federal institutions, whose distinct mandates and capacities shaped the design, financing, and implementation of the US vaccine development and procurement strategy.

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Role of the Institutions

Operation Warp Speed was conceived as a public–private partnership jointly coordinated by the Department of Health and Human Services (HHS) and the Department of Defense (DoD) (Siddalingaiah, 2021).

Within the operational structure of OWS, overall strategic coordination was led by a dedicated leadership team headed by Moncef Slaoui, appointed as Chief Scientific Advisor, and General Gustave F. Perna of the U.S. Army, who served as Chief Operating Officer.

This leadership model combined scientific expertise with military operational management, allowing the program to integrate vaccine selection, research funding, manufacturing expansion, and distribution planning across federal agencies and private-sector partners (Slaoui and Hepburn, 2020).

Within this framework, US federal institutions played complementary and highly specialized roles in accelerating the development and authorization of COVID-19 vaccines. The HHS acted as the central coordinating authority, mobilizing several subordinate agencies that together covered the full pipeline of vaccine innovation, from basic research to regulatory approval and public-health implementation (U.S. Government Accountability Office, 2021).

In particular, the National Institutes of Health (NIH) contributed to the scientific and clinical research components of Operation Warp Speed by supporting fundamental studies on SARS-CoV-2 and collaborating with private manufacturers on vaccine design and early-phase clinical trials.

Through initiatives such as the ACTIV partnership, NIH scientists worked directly with pharmaceutical companies to standardize protocols, accelerate clinical testing, and generate robust data on vaccine safety and immunogenicity (Corey, 2025).

Another central actor was the Biomedical Advanced Research and Development Authority (BARDA), an HHS agency responsible for supporting the advanced development and procurement of medical countermeasures against emerging health threats.

Under Operation Warp Speed, BARDA served as the primary federal interface with the pharmaceutical industry, allocating billions of dollars in funding to vaccine developers and supporting late-stage clinical trials and manufacturing scale-up.

By financing multiple vaccine platforms simultaneously and enabling production capacity before efficacy results were finalized, BARDA helped reduce the time normally required to translate laboratory discoveries into large-scale vaccine supply (Slaoui and Hepburn, 2020).

Moreover, The Food and Drug Administration (FDA) played a crucial regulatory role, ensuring that the accelerated development process maintained established safety and efficacy standards.

The agency oversaw clinical trial protocols, monitored data from phase I–III trials, and ultimately evaluated vaccine candidates for Emergency Use Authorization (U.S. Food and Drug Administration, n.d.; Slaoui and Hepburn, 2020).

While Operation Warp Speed encouraged parallelization of development, manufacturing, and testing, FDA review procedures remained essential for verifying that vaccines met regulatory thresholds for safety, quality, and effectiveness before being distributed to the public (Krause and Gruber, 2020).

Additionally, the Centers for Disease Control and Prevention (CDC) contributed the public-health and epidemiological expertise necessary for the implementation phase of the vaccination campaign.

The agency developed national vaccination guidelines, coordinated surveillance systems to monitor vaccine safety and effectiveness, and worked with state and local health authorities to plan distribution strategies and prioritize population groups for early immunization (e.g., healthcare workers and vulnerable populations).

Through these activities, the CDC ensured that vaccines developed under Operation Warp Speed could be effectively integrated into the broader US public-health response to the pandemic (U.S. Center for Disease Prevention and Control, 2020).

Meanwhile, the DoD played a central operational role within Operation Warp Speed by providing logistical coordination, supply-chain management, and large-scale distribution capabilities that supported the rapid manufacturing and deployment of COVID-19 vaccines (Winch et al., 2021).

Drawing on its expertise in complex global logistics and emergency operations, the DoD worked alongside the HHS to manage the operational planning of the program, particularly through the leadership of military personnel responsible for coordinating production timelines, distribution networks, and procurement processes (Van Norman, 2020).

Moreover, the involvement of the military enabled the integration of advanced planning tools, contracting mechanisms, and real-time logistics monitoring systems typically used in large-scale defense operations, which were adapted to track vaccine doses, raw materials, and manufacturing capacity across multiple pharmaceutical partners (Slaoui and Hepburn, 2020).

A key component of the DoD's contribution involved coordinating the industrial supply chain required for vaccine manufacturing, including the procurement of specialized materials such as lipid nanoparticles, vials, syringes, and cold-chain equipment (Bok et al., 2021).

To manage these activities, the Dod established the Joint Acquisition Task Force (JATF), which applied defense procurement frameworks to secure critical manufacturing inputs and coordinate industrial contracts with pharmaceutical companies and suppliers (Bok et al., 2021).

Created in March 2020 within the Office of the Under Secretary of Defense for Acquisition and Sustainment, the JATF served as the single-entry point to the DoD acquisition enterprise for interagency pandemic response efforts, enabling civilian agencies such as the HHS and the Federal Emergency Management Agency (FEMA) to access the Department's contracting expertise and procurement authorities (Office of the Under Secretary of Defense, 2020).

In practice, the JATF coordinated the rapid awarding of contracts, the mobilization of the defense industrial base, and the application of mechanisms such as the Defense Production Act and rapid contracting authorities, which allowed the federal government to accelerate the expansion of domestic manufacturing capacity for essential medical and vaccine-related supplies.

By applying defense logistics frameworks and working with private manufacturers, the department helped identify supply bottlenecks and expand production capacity before vaccine candidates had completed clinical trials, a strategy that significantly reduced the time needed to scale manufacturing once vaccines were authorized (Kim, Marks and Clemens, 2021).

Furthermore, the DoD supported the creation of centralized distribution plans that relied on existing military logistics infrastructure and partnerships with commercial distributors to ensure that vaccine doses could be transported quickly to states and healthcare providers nationwide.

In addition to supply-chain coordination, the DoD contributed to strategic distribution planning and data integration, collaborating with federal agencies and private logistics firms to design a nationwide allocation system capable of delivering vaccines under strict cold-storage requirements (Van Norman, 2020).

This included coordinating with transportation providers and deploying digital tracking systems that allowed federal authorities to monitor shipments and inventory in real time, thereby ensuring rapid delivery while maintaining quality and security standards.

In addition to the agencies directly involved in biomedical research and public-health implementation, OWS relied on additional institutional actors responsible for financial governance, strategic coordination, and industrial procurement.

The US Department of the Treasury contributed to the financial architecture of the program by facilitating the allocation and oversight of the large federal resources mobilized through emergency legislation such as the CARES Act and subsequent pandemic relief packages.

These funds supported advance purchase agreements, manufacturing scale-up, and risk-sharing arrangements with pharmaceutical companies, enabling the federal government to finance multiple vaccine candidates simultaneously and absorb part of the financial risk associated with accelerated development (Lalani et al., 2023).

Through this coordinated institutional architecture, Operation Warp Speed integrated scientific research, industrial production, and military logistics, creating an unprecedented federal framework

aimed at delivering hundreds of millions of vaccine doses to the US population in record time (Slaoui and Hepburn, 2020).

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Strengths and Weaknesses of the Procurement Strategy

A balanced assessment of the Operation Warp Speed (OWS) procurement phase highlights both significant strengths and notable weaknesses.

One of the central strengths of OWS' procurement model was its ability to mobilize financial resources and institutional coordination in order to dramatically accelerate vaccine development and production.

The US government adopted a strategy of large-scale public investment combined with advance purchase commitments and "at-risk" manufacturing, effectively transferring a significant portion of the technological and financial uncertainty associated with vaccine development from private firms to the public sector.

By assuming these risks, the federal government enabled pharmaceutical companies to scale manufacturing capacity and proceed with expensive late-stage clinical trials simultaneously rather than sequentially, thereby compressing development timelines that normally span several years into less than twelve months.

This approach addressed a well-known market failure in vaccine innovation: because vaccines historically offer lower and more uncertain returns than other pharmaceutical products, private firms often underinvest in their development without substantial public incentives.

Through substantial grants, manufacturing subsidies, and guaranteed procurement contracts, OWS created a policy environment in which firms could pursue rapid development without bearing the full financial consequences of potential failure, making large-scale investment rational even before efficacy results were available (Lalani et al., 2023; Florio et al., 2023).

A further strength of the procurement strategy was its portfolio-based investment model, which diversified risk across multiple vaccine technologies and developers.

Instead of concentrating resources on a single candidate, the US government simultaneously funded several vaccine platforms, including mRNA, viral vector, and protein-subunit technologies, thereby increasing the probability that at least one candidate would succeed.

This selectionist or portfolio strategy allowed policymakers to hedge against the high failure rates typical of biomedical innovation while maintaining competitive pressure among firms to deliver effective vaccines quickly.

Indeed, this diversified investment strategy was a key factor in enabling vaccines to be developed, tested, and made available within roughly eight months, a timeframe unprecedented in modern vaccine development (Winch et al., 2021).

The procurement phase also demonstrated an exceptional capacity for industrial mobilization and supply-chain expansion, which was essential to translating scientific breakthroughs into immediate large-scale vaccine availability.

OWS invested billions of dollars not only in research and clinical trials but also in expanding manufacturing infrastructure, securing raw materials, and preparing distribution logistics before regulatory approval.

This forward-financing of production capacity ensured that millions of vaccine doses could be manufactured while clinical trials were still ongoing, eliminating the delays that would normally occur between regulatory authorization and mass production.

By allocating substantial public resources, estimated at nearly $10 billion in early funding alone, the United States was able to rapidly build a domestic vaccine manufacturing base capable of supplying large quantities of doses immediately after authorization, a critical factor in the early vaccination rollout (Daems and Maes, 2022).

Finally, the strength of the OWS procurement framework lay in its institutional coordination across multiple federal agencies and the private sector, which allowed scientific research, industrial production, and logistical planning to proceed in parallel.

Through collaboration among the Department of Health and Human Services, BARDA, the Department of Defense, and regulatory agencies such as the FDA, the program integrated funding, clinical trials, manufacturing scale-up, and distribution planning into a single coordinated effort.

This cross-institutional structure enabled rapid decision-making, streamlined contracting, and efficient allocation of resources, thereby transforming what would normally be a fragmented biomedical innovation process into a highly centralized emergency program capable of delivering vaccines at unprecedented speed.

These achievements were made possible not only by large-scale financial commitments but also by the institutional architecture of the US biomedical innovation system. Pre-existing agencies such as

the NIH and BARDA provided established mechanisms for funding research and partnering with pharmaceutical firms, while flexible procurement authorities and emergency contracting tools allowed federal agencies to rapidly negotiate large advance purchase agreements and support at-risk manufacturing.

At the same time, the integration of civilian health institutions with the logistical capabilities of the DoD enabled the coordination of research, industrial production, and supply-chain management within a single operational framework.

Together, these institutional capacities allowed the United States to implement an unprecedented procurement strategy capable of delivering vaccines at record speed.

However, the procurement strategy also had important limitations.

Indeed, although OWS transferred a large share of the scientific and financial risks of vaccine development from private companies to the public sector, it did not consistently impose strong public-interest conditions in return.

While the US government invested heavily in the development, manufacturing, and purchase of mRNA COVID-19 vaccines, significantly reducing the financial uncertainty faced by pharmaceutical companies, much of this public funding was not accompanied by strict requirements related to affordability, equitable distribution, or global access.

As a result, pharmaceutical firms largely retained control over intellectual property, pricing, and commercialization decisions. In practice, this meant that while the government absorbed much of the development risk, private companies maintained substantial influence over how the vaccines were priced, licensed, and distributed (Lalani et al., 2023).

A second weakness concerned accountability and transparency in procurement itself. Peer-reviewed commentary has criticized the secrecy surrounding vaccine costs and purchasing arrangements, arguing that governments became partners in secrecy by tolerating limited disclosure of manufacturing costs and heavily redacted advance purchase agreements.

This is especially significant because vaccine R&D and manufacturing had already been underwritten by taxpayers on an unprecedented scale.

Indeed, the absence of transparent cost data made it difficult to verify whether prices reflected genuine production costs or monopoly rents, while Morten similarly characterizes the NIH–Moderna case as an instance of private capture of value created by the public (Light and Lexchin, 2021).

The legal architecture of OWS also generated concerns about imbalanced risk allocation. Liability protections granted under the PREP Act were designed to encourage rapid development and large-scale production of vaccines and other medical countermeasures during a public health emergency.

By granting manufacturers, distributors, and program planners' broad immunity from civil liability, the policy aimed to reduce the legal risks that might otherwise discourage firms from participating in accelerated vaccine development during the pandemic.

From a policy perspective, such protections were considered a necessary mechanism to mobilize the pharmaceutical industry quickly in the face of a global health crisis.

However, legal scholars have argued that the compensation mechanisms available to individuals harmed by such countermeasures were significantly weaker than those available under the traditional National Vaccine Injury Compensation Program (VICP), which normally governs routine vaccines in the United States.

Instead of the VICP, individuals alleging injuries from COVID-19 vaccines authorized under emergency provisions were directed to seek redress through the Countermeasures Injury Compensation Program (CICP), an administrative program established under the PREP Act (Zhao et al., 2022).

Unlike the VICP, which allows petitioners to participate in hearings before special masters, provides broader eligibility for compensation, and offers legal representation and appellate review, the CICP operates through a far more restrictive administrative process.

Claims are evaluated internally by the Health Resources and Services Administration (HRSA), petitioners have limited opportunities to present evidence or participate directly in proceedings, and decisions are not subject to the same forms of judicial review that characterize the VICP system (Zhao et al., 2022).

From a governance perspective, this institutional design contributed to the perception that OWS disproportionately shielded pharmaceutical manufacturers from legal exposure while providing comparatively limited protections for individuals potentially harmed by vaccines.

While the removal of liability risks undoubtedly facilitated rapid private-sector participation and accelerated vaccine production, the imbalance between strong industry protections and relatively weak compensation mechanisms raised broader questions about fairness, accountability, and public trust.

In emergency procurement contexts such as OWS, critics argue that effective governance requires not only incentives for rapid innovation but also robust mechanisms for transparency, oversight, and compensation in order to maintain public legitimacy and confidence in vaccination programs (Whelan, 2022; Zhao et al., 2022).

Moreover, from a broader political-economy perspective, OWS exposed the limits of relying on profit-oriented firms to deliver public goods under emergency conditions.

The system worked exceptionally well at accelerating innovation, but profit-driven biomedical models can diverge from public-health needs when access, affordability, and technology sharing are not built into contracts from the start.

The result is a procurement strategy that succeeded at speed, but was weaker on distributive justice, and transparency (Heled, Rutschman and Vertinsky, 2020).

Another limitation of the US procurement strategy was the way in which the political context surrounding OWS contributed to the later politicization of vaccination in the United States.

Although the most visible partisan polarization emerged during the vaccine rollout phase in 2021, several scholars argue that the foundations for this polarization were partly shaped during the procurement and development stage in 2020 (Bolsen and Palm, 2021; Schneider et al., 2021).

Because OWS was launched and publicly promoted by the Trump administration in the midst of the 2020 presidential election campaign, the accelerated vaccine development timeline quickly became embedded in partisan political narratives.

Public debate increasingly focused on whether political pressure might influence regulatory decision-making, particularly regarding the possibility of authorizing a vaccine before the election (Bolsen and Palm, 2021).

These concerns prompted senior officials at the FDA to publicly defend the independence of the regulatory process and emphasize that scientific standards would not be compromised (Krause and Gruber, 2020).

At the same time, research on pandemic communication in the US shows that political elites and media coverage frequently framed COVID-19 responses, including vaccine development efforts, through partisan lenses, contributing to growing ideological divisions in public trust toward federal health institutions (Gollust, Nagler, and Fowler, 2020).

Empirical studies further demonstrate that public confidence in COVID-19 vaccines became highly responsive to partisan cues from political leaders, suggesting that the politicization of vaccine development during the procurement stage shaped how different political groups later perceived vaccine safety and legitimacy (Kerr, Panagopoulos, and van der Linden, 2021).

Similarly, political science research has found that trust in government pandemic responses and willingness to accept vaccination increasingly aligned with partisan identity in the United States during 2020 and 2021 (Grossman et al., 2020).

True to be said, although OWS succeeded in accelerating vaccine procurement and development, its close association with electoral politics and partisan messaging represented a governance weakness: by linking a highly technical biomedical procurement program to an already polarized political environment, it contributed to the conditions that later undermined public trust and intensified partisan divisions during the vaccine rollout phase.

In this sense, the political tensions surrounding Operation Warp Speed already reflected the dynamics described by Alexander-Shaw, whereby the strong institutional capacity of the US federal centre generates incentives for vertical partisan competition between states and the national government; the early politicization of vaccine procurement thus foreshadowed the intense state–centre and inter-party polarization that would later characterize the US vaccine rollout (Alexander-Shaw, Ganderson and Schelke, 2023).

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Vaccine Development

In the US, COVID-19 vaccine development was strongly supported by the country's highly concentrated biotechnology and pharmaceutical ecosystem, which hosts a large share of the world's leading vaccine developers and advanced biomedical research institutions.

Two of the first vaccines authorized were the mRNA vaccines developed by Moderna and by Pfizer in partnership with BioNTech. The Moderna mRNA-1273 vaccine was developed in close collaboration with the NIH, particularly the Vaccine Research Center, building on decades of publicly funded research into mRNA platforms and coronavirus spike-protein stabilization (Lalani et al., 2023).

Similarly, the Pfizer-BioNTech vaccine combined BioNTech's mRNA technology with Pfizer's clinical development capabilities and extensive US-based manufacturing and regulatory infrastructure (Thorn et al., 2022).

More broadly, the United States hosts a large proportion of global vaccine manufacturers and biopharmaceutical firms, alongside leading research universities and federal biomedical agencies,

creating a dense innovation ecosystem that facilitated rapid vaccine design, testing, and industrial scale-up during the pandemic (Okuyama, 2024).

This concentration of biotechnology companies, venture capital investment, and advanced biomanufacturing capacity positioned the US as a central hub of COVID-19 vaccine innovation and development, generating important advantages during the development phase.

Having production facilities located domestically allowed developers to rapidly translate laboratory research into industrial-scale manufacturing, facilitating close coordination between research teams, clinical trial organizers, and production sites (Slaoui and Hepburn, 2020).

Furthermore, this proximity significantly accelerates technology transfer, process optimization, and regulatory oversight during vaccine development (O'Callaghan, Blatz and Offit, 2020).

Moreover, analyses of the global vaccine innovation landscape highlight that countries hosting strong domestic pharmaceutical manufacturing sectors were better positioned to mobilize production capacity and rapidly convert scientific breakthroughs into deployable vaccines during the pandemic (Lalani et al., 2023; Okuyama, 2024).

In addition to these structural advantages, large-scale public funding during the pandemic further accelerated vaccine research and industrial scale-up.

Through substantial federal investments, estimated at around $18 billion to support vaccine development and early manufacturing through Operation Warp Speed, and over $30 billion in broader public spending related to vaccine development, procurement, and scale-up, the US government financed multiple vaccine candidates simultaneously and supported clinical trials, manufacturing infrastructure, and technology development, thereby reducing the financial risks faced by pharmaceutical companies and biotechnology firms (Kim, 2021; Lalani et al., 2023).

Together, the combination of long-standing public investment in biomedical research, a highly developed biotechnology sector, and extensive domestic manufacturing capacity allowed the United States to move from viral genome sequencing to authorized vaccines in less than a year, an unprecedented timeline in modern vaccine development (Lalani et al., 2023).

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Vaccine Rollout

At the outset of the vaccination campaign phase, the United States faced the challenge of translating the remarkable success of vaccine development and procurement into an effective nationwide distribution system.

While the federal government, primarily through Operation Warp Speed, had rapidly secured and financed hundreds of millions of vaccine doses, the transition from procurement to public administration revealed the structural characteristics of the US health governance framework.

The federal government retained ownership of vaccine supplies and coordinated their allocation to states and territories, providing doses free of charge after having financed their development and purchase.

However, the operational responsibility for the final stages of distribution and administration was largely delegated to state and local authorities, which were expected to collaborate with hospitals, pharmacies, community health centers, and other private healthcare providers (Duggar et al., 2024).

This arrangement produced a hybrid public–private distribution model, reflecting long-standing patterns in the US healthcare system (Amara et al., 2021).

As a consequence, the United States did not implement a single centralized vaccination program; rather, it developed a decentralized system of state-led vaccination campaigns operating under federal coordination. Each state designed its own prioritization schedules, appointment systems, and distribution logistics, within a broad framework established by federal health authorities (Jain, Schwarz and Lorgelly, 2021; Duggar et al., 2024).

This structure was partly the result of deliberate policy design and partly a consequence of the US federal system, in which states retain primary jurisdiction over public health.

Even in the context of a nationwide emergency, the federal government's role was therefore largely limited to coordination, funding, and guidance rather than direct management of vaccination programs (Iacocca et al., 2025).

Recognizing these institutional constraints, the HHS and the CDC emphasized early in the pandemic that a successful vaccination effort would depend on close collaboration across federal, state, local, tribal, and territorial governments, as well as public and private healthcare institutions (HHS, 2020).

Indeed, in preparation for vaccine deployment, the CDC issued interim planning guidance on August 4, 2020, providing state and local health departments with planning assumptions and operational steps necessary to develop jurisdiction-specific COVID-19 vaccination strategies (Michaud and Kates, 2020).

Later that month, on August 27, 2020, the CDC urged US governors to ensure that vaccination sites and distribution infrastructures would be fully operational by November 1, 2020, underscoring the

urgency of building nationwide logistical capacity ahead of vaccine authorization (Hughes et al., 2021).

Building upon these early preparatory measures, federal health authorities continued to refine the operational framework for vaccine distribution in the months preceding vaccine authorization.

On September 16, 2020, the CDC released the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, a detailed guidance document designed to support the organization of vaccination campaigns at the state, territorial, tribal, and local levels (Centers for Disease Control and Prevention, 2020).

The playbook outlined logistical and administrative requirements, including cold-chain management, prioritization strategies, data reporting systems, and coordination mechanisms among federal and subnational actors, and required all jurisdictions to develop and submit comprehensive vaccination plans by October 16, 2020, with the aim of facilitating coordination across the decentralized public health system (Kim, Marks and Clemens, 2021).

Shortly afterwards, on September 23, 2020, the HHS announced that, in collaboration with the CDC, it would allocate $200 million in federal funding to assist state and local jurisdictions in strengthening their preparedness for vaccine deployment, supporting activities such as infrastructure development, workforce training, and operational planning for distribution (CDC, 2020; Hughes et al., 2021).

Furthermore, the longstanding underfunding of the US public health system became particularly evident during the COVID-19 pandemic, as limited institutional capacity and constrained resources significantly complicated efforts to contain the disease and organize large-scale vaccination campaigns (Michaud and Kates, 2020).

Public health authorities had long been aware of these structural weaknesses and warned that, without a substantial increase in federal funding, many states would struggle to effectively implement vaccination programs.

Nevertheless, the allocation of federal resources specifically dedicated to vaccine deployment was initially delayed, as Congress proved reluctant to approve additional funding for implementation.

Only in late December 2020 was a relief bill enacted that allocated nearly $8 billion to support state vaccination efforts, by which point the first vaccine doses had already begun to be administered across the country. This delay created additional operational pressures for state and local authorities, many of which faced significant difficulties in organizing the large-scale rollout and managing the distribution and administration of vaccine doses (Rattner and Pramuk, 2021).

Alongside these planning efforts, federal authorities also designed the logistical architecture responsible for transporting vaccines from manufacturers to vaccination sites.

The federal vaccine distribution architecture was designed to combine centralized logistical coordination with decentralized implementation, bringing together federal agencies, private industry, and state-level public health systems. In this framework, the DoD worked alongside the CDC and private-sector partners to establish a centralized distribution network capable of rapidly delivering vaccines across the country (Duggar et al., 2024).

The distribution pathway was structured so that vaccine doses moved from manufacturers to national distributors and subsequently to state-designated vaccination sites.

For most vaccines, distribution was managed through McKesson Corporation, which acted as the primary national distributor under federal contracts, whereas Pfizer opted to manage its own shipping and distribution logistics directly from its manufacturing facilities (Goralnick, Kaufmann and Gawande, 2021).

From these distribution hubs, doses were delivered to points of dispensing and vaccination centers established and administered by individual states, reflecting the decentralized organization of the US public health system (Duggar et al., 2024).

Given the unprecedented scale and urgency of the vaccination effort, the federal government mobilized significant logistical resources, including substantial support from the military.

The DoD contributed through a dedicated logistics coordination hub and the deployment of specialized technological tools, most notably the Tiberius platform, a data management system designed to track vaccine supply, support allocation decisions, and optimize the distribution process across jurisdictions (Goralnick, Kaufmann and Gawande, 2021; Lalani et al., 2023).

These measures were central to the logistical framework developed under OWS.

Overall, the federally coordinated supply chain proved largely effective in transporting vaccines from manufacturers to vaccination sites nationwide.

In particular, it succeeded in maintaining the stringent cold-chain requirements necessary for mRNA vaccines, such as those developed by Pfizer and Moderna, which required ultra-low-temperature storage and specialized handling.

Despite these efforts to create a coherent national framework, a significant limitation remained: the federal guidelines were non-binding, reflecting the constitutional allocation of primary public health authority to the states (Maani and Galea, 2020).

Consequently, each state ultimately implemented its own vaccination strategy, adapting federal recommendations to local administrative capacities and political priorities.

This arrangement produced substantial variation in eligibility criteria, prioritization schemes, and distribution logistics across jurisdictions, effectively generating a patchwork of vaccination systems rather than a single unified national rollout (Jain, Schwarz and Lorgelly, 2021).

In the initial phase of vaccine distribution, most states broadly followed CDC recommendations by prioritizing healthcare workers and residents of long-term care facilities (Dooling et al., 2020).

However, as vaccine supply increased in early 2021, significant divergences began to emerge. Some states chose to prioritize older adults, particularly individuals aged 65 and above, as occurred in Florida, while others expanded eligibility first to essential workers and critical infrastructure personnel before lowering age thresholds (Peek, Persad and Emanuel, 2021).

The timing of eligibility expansion also differed substantially across jurisdictions. Although federal authorities repeatedly called for a rapid transition toward universal adult eligibility, nationwide eligibility was only reached on April 19, 2021, when all states had opened vaccination access to adults (Schmidt et al., 2021).

While this milestone had been anticipated since the early planning stages of Operation Warp Speed, its realization ultimately occurred through state-level decisions rather than through a single federally mandated rollout, further highlighting the decentralized character of the US vaccination campaign.

Despite the effectiveness of the federal distribution infrastructure, major challenges emerged during the final stage of vaccine delivery and the coordination mechanisms established for national distribution.

Additionally, the principal challenges emerged during the last mile phase of the vaccination campaign.

Tasks such as scheduling appointments, organizing vaccination clinics, communicating eligibility criteria, and ensuring equitable access fell primarily under the authority of state and local health departments.

Because these entities differed significantly in administrative capacity, technological infrastructure, and public health resources, the final stages of vaccine administration exhibited considerable variability across jurisdictions, highlighting the structural inequalities and coordination challenges inherent in the decentralized US public health system (Hughes et al., 2021).

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Vaccine Rollout - Last Mile Distribution Issues, Inequalities and Partisan Polarization

Beginning in December 2020, the first phase of the COVID-19 vaccine rollout in the United States lasted until approximately February 2021 and was characterized by a combination of rapid mobilization and significant operational improvisation.

On the one hand, the early rollout produced notable achievements.

Within one month of administering the first dose, more than 10 million individuals had received at least one vaccination, a milestone largely enabled by the federal government's expedited procurement and distribution efforts through OWS, as well as the strong initial uptake among healthcare workers and other priority groups (Lopez, 2021).

On the other hand, the early stage of the campaign was marked by a substantial imbalance between supply and demand.

Limited vaccine availability and the absence of streamlined appointment systems generated widespread frustration among the public, as many individuals encountered significant barriers when attempting to secure vaccination appointments (Goralnick, Kaufmann and Gawande, 2021).

These challenges were closely linked to the institutional structure of the US' public health system.

The federal government adopted a strategy that prioritized vaccine development, procurement, and allocation to states, while leaving most operational aspects of last-mile distribution to state and local authorities (Winch et al., 2021).

As a result, states were required to independently design and implement their own distribution infrastructures, including eligibility verification procedures, appointment scheduling platforms, and communication strategies (Sun et al., 2021).

While decentralization assigned operational responsibilities for vaccine distribution to state and local authorities, effective implementation still required strong coordination between levels of government. In practice, however, the early stages of the vaccination campaign unfolded in a highly contentious political environment that complicated intergovernmental collaboration (Greer et al., 2020).

The rollout occurred in the aftermath of the 2020 presidential election and during the transition between administrations, a period characterized by intense partisan polarization and institutional uncertainty. These political dynamics added an additional layer of complexity to an already challenging logistical operation.

The Trump administration frequently emphasized the success of Operation Warp Speed in accelerating the development and procurement of COVID-19 vaccines, portraying the initiative as a major scientific and technological achievement.

Indeed, the program significantly reduced the time required to develop and produce effective vaccines by combining federal funding, regulatory flexibility, and public–private partnerships (Goralnick, Kaufmann and Gawande, 2021).

Nevertheless, the federal government faced substantial criticism for its limited preparation for the distribution phase of the vaccination campaign.

While OWS successfully fostered vaccine development, it was argued that less attention was devoted to designing a coherent national strategy for the operational phases of vaccine delivery, particularly regarding coordination with state and local authorities responsible for last-mile distribution (Winch et al., 2021).

These shortcomings became evident in late 2020, when public health departments and hospital systems across the country reported significant uncertainty regarding the upcoming vaccination campaign.

Many state and local officials indicated that they lacked crucial information necessary to organize mass vaccination programs, including clear estimates of the number of doses they would receive and the expected timing of shipments (U.S. Government Accountability Office, 2021).

Without reliable forecasts of vaccine allocations, local authorities struggled to plan staffing levels, schedule vaccination appointments, and organize distribution sites.

In large-scale immunization campaigns, advance logistical planning is essential to ensure efficient vaccine delivery, and the absence of timely communication from federal authorities therefore created significant operational challenges (Tewarson, Greene and Fraser, 2021).

As a result of these coordination problems, providers often scheduled vaccination appointments based on expected deliveries that ultimately failed to materialize, forcing them to cancel previously scheduled appointments and reschedule large numbers of patients (Royal, 2021). Such disruptions

slowed the pace of vaccination and contributed to frustration among both healthcare providers and the public.

The lack of clear communication also generated a cycle of mutual accusations between federal and state authorities. Federal officials frequently criticized state governments for administering vaccines too slowly or for failing to use available doses efficiently.

Conversely, many state officials argued that delays and logistical difficulties were largely the result of insufficient federal guidance, inconsistent information regarding vaccine shipments, and delays in the distribution of federal funding needed to support vaccination infrastructure (Goldberg, Layne and Caspani, 2021).

This exchange of blame reflected deeper structural tensions within the US federal system, where public health responsibilities are divided among multiple levels of government, mirroring Alexander-Shaw paradigm (Alexander-Shaw, Ganderson and Schelke, 2023).

Subsequent oversight reports confirmed that these governance challenges played a significant role in shaping the early rollout.

Investigations conducted by federal oversight bodies highlighted several operational difficulties affecting the initial vaccination campaign, including weaknesses in strategic planning, limited federal guidance for state authorities, and inadequate communication regarding vaccine allocation and delivery schedules (U.S. Government Accountability Office, 2021; U.S. House Committee on Oversight and Reform, 2021).

From a broader perspective, these challenges illustrate how political dynamics and intergovernmental coordination problems can significantly influence the implementation of large-scale public health interventions.

Beyond intergovernmental coordination challenges, the US vaccination campaign was also shaped by high levels of partisan polarization, which further complicated cooperation between federal and state authorities and influenced the implementation of public health measures.

Indeed, as the pandemic intensified, the United States increasingly exhibited divergent policy approaches to vaccination that were closely aligned with partisan political orientations.

COVID-19 crisis in the US was not only a public health emergency but also a highly politicized event, in which policy preferences, risk perceptions, and levels of trust in federal authorities became strongly associated with partisan identity (Rocco, Béland and Waddan, 2020).

This polarization translated into two distinct governance approaches: one favoring stronger federal coordination and intervention, and another emphasizing state autonomy and resistance to perceived federal overreach.

Following his inauguration in January 2021, President Joe Biden sought to reassert federal leadership in the vaccination campaign by expanding national coordination and logistical support.

The administration implemented a series of measures, among which there were the establishment of large-scale federal mass vaccination sites, the mobilization of the Federal Emergency Management Agency (FEMA) and National Guard personnel, and the expansion of the Federal Retail Pharmacy Program, which distributed vaccines directly to pharmacy chains to complement state-level allocations.

These initiatives contributed to a rapid increase in vaccination capacity, with daily administration rates reaching approximately 2.5 million doses by March 2021 (De Maio, 2021).

From a public administration perspective, these measures reflected a shift toward greater federal involvement in last-mile distribution, aiming to overcome coordination failures observed during the initial rollout phase.

However, the expansion of federal involvement in vaccine distribution and public health policy was met with resistance from several Republican-led states. Some governors opposed the establishment of federally operated vaccination sites or declined certain forms of federal logistical support, arguing that such interventions were unnecessary or infringed upon state authority (Tewarson, Greene and Fraser, 2021).

For instance, Florida Governor Ron DeSantis publicly rejected the need for FEMA-operated vaccination sites, contending that the primary issue was not distribution capacity but rather the availability of vaccine doses (Royal, 2021).

More broadly, resistance extended to federal efforts to introduce vaccine mandates for specific categories of workers, which were framed by opponents as excessive federal intrusion into state governance and individual liberties (Tewarson, Greene and Fraser, 2021).

Political polarization shaped not only policy preferences but also interpretations of the appropriate balance between federal authority and state autonomy.

Republican-led states generally adopted a governance approach that prioritized decentralization and individual freedom, often resisting federal mandates and, in some cases, prohibiting measures such as vaccine passports or employer-based vaccination requirements.

In contrast, Democratic-led states were more likely to support assertive public health interventions and to collaborate with federal authorities, framing vaccination as a collective responsibility and a necessary condition for reopening economic and social activities (Kettl et al., 2020)

Importantly, this polarization did not imply a complete partisan divide in support for vaccination itself, early in the rollout, both political parties broadly endorsed vaccine development and uptake.

However, significant differences emerged in policy implementation, public communication, and willingness to adopt restrictive measures aimed at increasing vaccination rates.

As a result, the vaccination campaign became embedded within broader partisan conflicts, contributing to variation in policy responses across states and complicating efforts to achieve a coordinated national strategy (Kerr, Panagopoulos, and van der Linden, 2021).

Moreover, partisan polarization not only shaped political discourse but also had direct implications for policy implementation, contributing to fragmented public health responses and uneven coordination across states (Kettl et al., 2020; Greer et al., 2020).

The combination of decentralized responsibilities, limited federal coordination, and uncertain vaccine supply had important consequences for the practical organization of vaccination campaigns. In particular, state and local authorities were required to rapidly develop mechanisms to allocate appointments and manage public demand for vaccination.

To manage appointment allocation, many states introduced digital booking systems and telephone hotlines through which individuals could schedule vaccination slots.

However, these systems frequently proved inadequate to handle the unprecedented surge in demand. Online platforms often crashed due to heavy traffic, were complex, fragmented, and difficult to navigate, particularly for older adults who were among the primary priority groups for vaccination, while telephone hotlines were overwhelmed, leading to waiting times that sometimes lasted several hours (Ankenbauer and Lu, 2025).

Limited digital literacy, lack of reliable internet access, and the need to constantly monitor appointment availability placed many seniors at a disadvantage compared to younger or more technologically proficient individuals (AWS, 2021).

Consequently, individuals resorted to alternative strategies to access vaccines, such as repeatedly refreshing websites, traveling long distances to vaccination sites with available appointments, or waiting overnight outside vaccination centers.

The fragmentation of the appointment and distribution systems further exacerbated these difficulties. In the absence of a unified national platform, not only did each state develop its own booking system, but in many cases counties, hospital networks, pharmacies, and other providers implemented separate scheduling infrastructures.

This multiplicity of systems created substantial informational barriers for the public and contributed to confusion about eligibility criteria, vaccine availability, and appointment procedures (Zhang et al., 2022).

In Florida, for example, the initial vaccination strategy for older adults relied on a first-come, first-served system at vaccination sites.

Although intended to ensure rapid distribution of available doses, this approach quickly generated significant logistical problems. Long queues formed at vaccination centers, with some individuals waiting for hours or even overnight in order to secure a dose (Peek, Persad and Emanuel, 2021).

In several instances, these crowds led to public disorder and concerns about safety and fairness, ultimately prompting authorities to abandon the model and transition toward appointment-based scheduling systems designed to better regulate demand and reduce congestion at vaccination sites (Zhang et al., 2022).

Such fragmentation significantly complicated last-mile distribution by undermining coordination and transparency across jurisdictions.

Federal leadership explicitly acknowledged this decentralized model. For instance, then-Secretary of Health and Human Services Alex Azar stated that OWS primarily focused on accelerating vaccine development and ensuring procurement, while the practical modalities of distribution were left largely to state governments (Sun et al., 2021).

From a last-mile distribution perspective, the early phase of the US vaccination campaign thus illustrates the tensions inherent in decentralized governance structures.

While federal investment successfully accelerated vaccine production and initial distribution, the lack of a coordinated national strategy for appointment management, communication, and local delivery created bottlenecks that complicated access for many individuals and amplified geographic inequalities in vaccine uptake.

Beyond scheduling systems, the mechanisms used for allocating vaccine doses across states also became a source of debate and policy adjustment during the early rollout.

Initially, federal authorities distributed vaccine supplies primarily on a per-capita basis, allocating doses proportionally according to state population size (Hyder et al., 2021).

While this approach provided a simple and administratively efficient formula, it quickly attracted criticism from several state governments.

In particular, states with relatively older populations argued that population-based allocation failed to adequately account for differences in demographic risk profiles, especially given that older adults faced significantly higher risks of severe illness and mortality from COVID-19 (Hyder et al., 2021).

According to these critics, the per-capita method did not sufficiently reflect the public health objective of prioritizing populations most vulnerable to the disease.

Instead of formally redesigning the allocation formula, federal authorities gradually adopted more informal adjustments to the distribution process.

When certain states demonstrated slower initial uptake or were unable to utilize their allocated doses quickly, some of those vaccines were redirected to other states that had demonstrated greater capacity to administer them.

Importantly, these reallocations generally occurred only with the consent of the state originally assigned the doses, thereby preserving the formal allocation framework while introducing a degree of operational flexibility (U.S: Government Accountability Office, 2021).

Although this practice helped mitigate potential wastage and improved short-term efficiency, it also highlighted the reactive nature of early distribution governance and the absence of a fully articulated national strategy for managing last-mile vaccine delivery.

While these logistical and governance challenges affected the overall efficiency of vaccine distribution, they also had important consequences for equity in vaccine access across different social groups.

Indeed, empirical analyses indicate that vaccine uptake initially favored wealthier and predominantly white populations, while Black, Latino, and lower-income communities experienced comparatively lower access to vaccination opportunities (Zilinsky and Theocharis, 2025).

These disparities reflected structural inequalities embedded within both the health system and the logistical organization of the vaccination campaign.

A central factor contributing to these disparities was the design of appointment and access systems. Indeed, while these systems were administratively convenient and capable of allocating appointments

rapidly, they tended to privilege individuals with reliable internet access, higher levels of digital literacy, flexible work schedules, and greater mobility.

Conversely, individuals belonging to lower socioeconomic groups often faced substantial barriers in navigating complex online booking systems, monitoring appointment availability, or traveling to vaccination sites.

As a result, groups already experiencing socioeconomic disadvantage were less able to compete effectively for limited vaccination slots during the initial stages of the rollout (Schmidt et al., 2021).

Geographic and infrastructural factors further amplified these inequities. Early vaccine distribution relied extensively on hospitals, large health systems, and retail pharmacy chains as primary vaccination providers.

However, these facilities are unevenly distributed across the United States, and many low-income or historically marginalized neighborhoods have comparatively limited access to such healthcare infrastructure.

Consequently, residents of disadvantaged areas frequently faced longer travel distances or fewer available appointment slots, further constraining their ability to receive vaccinations during the early rollout (Hughes et al., 2021).

Local and federal authorities began to address these disparities once the unequal distribution patterns became more visible.

In response, public health agencies expanded outreach efforts by directing vaccine supplies toward community health centers and deploying mobile vaccination clinics in underserved neighborhoods.

These initiatives aimed to reduce geographic barriers and reach populations that were less likely to access traditional healthcare facilities.

A more systematic strategy emerged in March 2021 under the administration of President Joe Biden, which prioritized vaccine distribution to underserved communities through Federally Qualified Health Centers and mobile vaccination units (Steinzor, 2025). These measures sought to incorporate equity considerations more explicitly into the operational design of the vaccination campaign.

At the same time, the decentralized structure of the US public health system allowed individual states and local authorities to adopt tailored strategies to mitigate disparities.

Some jurisdictions established large vaccination sites in underserved neighborhoods, while others collaborated with community organizations, religious institutions, and local advocacy groups to promote vaccination and facilitate appointment access.

Partnerships with trusted community actors proved particularly important in reaching populations historically marginalized within the healthcare system.

Over time, these combined efforts contributed to a gradual reduction in racial disparities in vaccination rates.

Nevertheless, the improvements emerged only after the early rollout had already produced significant inequalities in access.

Structural features of the US healthcare system help explain these patterns. The American health system is largely market-driven and characterized by a relatively weak social safety net compared to many other high-income countries.

As a result, vulnerable communities often face longstanding barriers to accessing healthcare services. In addition, the fragmentation of healthcare providers makes it more difficult to identify and reach individuals who are not regularly connected to mainstream medical services, including uninsured populations.

While the previous sections have highlighted how institutional fragmentation and political polarization shaped the organization and equity of vaccine distribution, these dynamics also had important consequences for public attitudes toward vaccination and ultimately for vaccine uptake.

Although the Biden administration successfully expanded vaccine supply and distribution capacity, by mid-2021 the United States struggled to sustain uniformly high vaccination coverage across all states, with substantial variation emerging along political and geographic lines.

A significant portion of the population either refused or delayed vaccination, limiting the overall effectiveness of the campaign.

As a consequence of the partisan polarization, partisan identity became a strong predictor of individuals' willingness to receive a COVID-19 vaccine, reflecting the broader politicization of the pandemic.

Political elites and media ecosystems played a key role in shaping public perceptions. Republican leaders and conservative media outlets were more likely to express skepticism toward certain public

health measures, including vaccine mandates, often framing them as infringements on individual liberty.

Social media platforms amplified these dynamics by facilitating the rapid spread of misinformation and conspiracy theories, including unfounded claims about vaccine safety and side effects. Such narratives found fertile ground among populations characterized by low institutional trust, contributing to the diffusion of vaccine skepticism (Steinzor, 2025).

These narratives contributed to reinforcing hesitancy among segments of the population already distrustful of government intervention.

More broadly, COVID-19 countermeasures became deeply embedded within ongoing political conflicts in the United States. Since the early stages of the pandemic, several conservative political figures had downplayed the severity of the virus or criticized mitigation policies promoted by federal authorities.

This politicization extended into the vaccination phase, where skepticism toward vaccines persisted among some groups despite their development having been initiated under the Trump administration.

The association of the rollout phase with the Biden administration further reinforced partisan interpretations of vaccination policies.

Overall, the early US vaccine rollout highlights how institutional fragmentation and political polarization jointly shaped last-mile distribution, producing not only logistical inefficiencies and social inequalities, but also influencing public trust and ultimately limiting vaccine uptake.

US Vaccine Procurement and Rollout Strategy – Operation Warp Speed – Vaccine Rollout – Strengths and Weaknesses

The US vaccine rollout under Operation Warp Speed (OWS) displayed a combination of significant structural strengths and notable governance weaknesses.

A principal strength of the rollout was the effectiveness of the federally coordinated distribution infrastructure, which, through collaboration between public agencies and private logistics partner, enabled rapid nationwide delivery of vaccines and reliable maintenance of complex cold-chain requirements, supporting high early administration rates.

This strength was rooted in the ability to scale pre-existing immunization distribution systems, such as those developed under routine programs and prior pandemic planning, into an unprecedented national operation capable of delivering nearly one billion doses to over 100,000 provider sites across all US jurisdictions (Duggar et al., 2024).

The integration of centralized coordination with established distribution contractors and extensive provider networks (including pharmacies and healthcare facilities) ensured broad geographic reach and rapid throughput, while leveraging private-sector expertise in transportation and logistics enhanced efficiency and flexibility.

Critically, the system demonstrated a high degree of logistical sophistication by successfully handling vaccines requiring frozen and ultra-cold storage, conditions widely recognized in the literature as among the most challenging aspects of vaccine distribution, where even minor temperature deviations can compromise efficacy.

The US rollout's capacity to maintain cold-chain integrity at scale therefore reflects a significant operational achievement, indicating not only robust infrastructure but also effective coordination mechanisms and real-time distribution management.

Collectively, these features enabled a rapid acceleration of vaccine administration in the early phase of the campaign, highlighting how centralized logistical design combined with public–private collaboration can enhance the speed and reliability of large-scale immunization efforts.

Additionally, the rollout benefited from strong logistical and operational support from federal agencies, including the deployment of FEMA, the National Guard, and federal personnel to support vaccination sites. This surge capacity helped stabilize and accelerate last-mile delivery, particularly after the initial rollout phase, contributing to a sharp increase in daily vaccination rates in early 2021 (De Maio, 2021).

Moreover, over time, the rollout demonstrated adaptive capacity in addressing equity gaps, with targeted strategies such as reallocating doses, expanding distribution to community health centers, and deploying mobile vaccination units in underserved areas.

Although these measures were implemented after initial disparities emerged, the literature highlights them as evidence of institutional learning and policy adjustment within the rollout phase (Schmidt et al., 2021).

However, the implementation of vaccination at the population level revealed substantial weaknesses.

A central weakness of the US vaccine rollout was that federal coordination stopped short of creating a uniform implementation model, leaving states to translate broad CDC recommendations into their own eligibility rules, sequencing decisions, booking systems, and site networks.

This produced substantial divergence between federal guidance and state practice, particularly in the ranking of priority groups, which reduced national consistency and made access dependent on place of residence rather than on a common public-health logic (Jain, Schwarz and Lorgelly, 2021).

Additionally, there were wide jurisdictional variations in whether and how states incorporated equity into allocation plans, reinforcing the characterization of the rollout as a fragmented patchwork rather than a coherent national campaign (Schmidt et al., 2021)

This institutional fragmentation also weakened operational preparedness in the crucial last-mile phase.

Indeed, many states had to build delivery systems while simultaneously confronting inadequate infrastructure, staffing constraints, and insufficient early resources, which made it difficult to translate vaccine availability into smooth administration (Tewarson, Greene and Fraser, 2021).

In practice, decentralization meant that hospitals, counties, pharmacies, and state health departments often relied on overlapping or disconnected systems for appointments and communication, increasing administrative burdens and public confusion.

More broadly, federalism amplified these coordination problems because divided authority required strong intergovernmental leadership and information-sharing, yet the US response was marked by uneven national direction and significant cross-state divergence.

A further weakness was that the rollout's heavy reliance on digital access and existing healthcare infrastructure reproduced social inequalities.

These technology-dependent registration systems disadvantaged groups with less internet access, lower digital literacy, and fewer resources to navigate complicated booking processes, affecting especially counties with higher Black populations, in rural areas, and in harder-hit communities which were less likely to serve as vaccination sites, indicating that lower uptake was partly a problem of access rather than simply hesitancy.

Finally, political polarization compounded these administrative weaknesses by undermining trust, policy coherence, and the willingness of actors across levels of government to converge on a common strategy.

The pandemic responses in the US became strongly polarized, with major partisan differences in risk perception and protective behavior. Moreover, politicization directly contributed to vaccine resistance.

In a rollout system already dependent on voluntary coordination across federal, state, and local institutions, this partisan environment made it harder to sustain a unified public-health message and encouraged divergent state approaches to implementation.

From a broader theoretical perspective, these dynamics can be interpreted through the lens of the Alexander-Shaw paradox, according to which strong federal centers may generate competitive, zero-sum political dynamics rather than cooperative problem-solving.

In the US vaccine case, the combination of substantial federal capacity and entrenched partisan competition reduced incentives for intergovernmental collaboration, contributing to conflictual state–federal relations and fragmented policy implementation (Alexander-Shaw, Ganderson and Schelke, 2023).

Overall, the literature suggests that while the logistical backbone of the rollout was robust, the interaction between decentralization, uneven state capacity, and politicized federalism limited coordination, efficiency, and equity in vaccine administration.

US Vaccine Procurement and Rollout Strategy – Evidence

By the end of the COVID-19 public health emergency phase, the United States' vaccine procurement and rollout strategy, anchored in Operation Warp Speed, yielded rapid early vaccine availability and substantial public-health benefits, though with more pronounced inequities compared to the European Union.

hrough large-scale federal investments and advance purchase agreements with multiple manufacturers, the US secured hundreds of millions of doses before regulatory approval, enabling vaccination to begin as early as December 2020 (Slaoui and Hepburn, 2020; Bok et al., 2021).

By mid-2023, approximately 69–70% of the total US population had completed a primary vaccination series, with higher coverage among older age groups but lower uptake in certain regions and socio-demographic groups (Mathieu et al., 2024; CDC, 2023).

In cumulative terms, over 670 million vaccine doses had been administered in the United States by 2023, including extensive booster campaigns targeting waning immunity and emerging variants (Mathieu et al., 2024).

Peer-reviewed modelling studies indicate that vaccination had a major impact on reducing mortality and severe disease. Estimates suggest that COVID-19 vaccines prevented between 2.2 and 3.2 million deaths in the United States between December 2020 and November 2022, corresponding to a reduction of more than 50% in expected mortality during that period (Meslé et al., 2024).

The majority of averted deaths occurred among older adults, reflecting prioritization strategies in the initial rollout phases. Vaccination also substantially reduced hospitalizations and alleviated pressure on healthcare systems, particularly during successive waves driven by the Delta and Omicron variants (Tenforde et al., 2021).

However, unlike the EU's centralized distribution model, the US relied on a federally coordinated but state-administered rollout, which contributed to significant geographic and socio-economic disparities in vaccine access and uptake.

Despite these challenges, the US strategy demonstrated the effectiveness of early large-scale investment in vaccine development and procurement, enabling rapid deployment and generating considerable reductions in mortality and severe outcomes, while highlighting the importance of addressing structural inequalities in public health delivery systems.

EU vs US Vaccine Strategies - Explaining the EU's More Remarkable Outcome

The COVID-19 pandemic constituted an unprecedented global crisis that simultaneously strained public health systems, disrupted economic activity, and tested the resilience of political institutions worldwide.

In the absence of effective treatments during the early phases of the outbreak, governments relied heavily on non-pharmaceutical interventions to contain transmission and "buy time" for the development of vaccines, which ultimately emerged as the cornerstone of a durable exit strategy from the pandemic.

Once available, vaccines not only reduced severe illness and mortality but also enabled the gradual reopening of societies and economies, making their procurement and rollout a central dimension of crisis governance.

Despite facing the same epidemiological threat and pursuing similar objectives, the European Union and the United States adopted markedly different approaches to vaccine procurement and rollout. These divergences were deeply rooted in their respective institutional architectures.

The US, as a federal state endowed with strong central fiscal and administrative capacities, might have been expected to deliver a more coherent and effective response.

By contrast, the EU, characterized by limited competences in public health and a fragmented system of shared sovereignty, appeared institutionally ill-equipped to coordinate a unified vaccination strategy.

Conventional theories of federalism would therefore predict superior performance by the US and coordination failures within the EU (Elazar, 1976).

However, the empirical outcomes of the pandemic challenge these expectations.

Rather than facilitating coordination, the strong federal center in the US became a focal point of partisan conflict and intergovernmental tension, contributing to a fragmented and politically contested vaccine rollout.

Conversely, the EU, despite its structural limitations, succeeded in developing a joint procurement strategy, coordinating distribution across member states, and preserving political cohesion within the Union.

This counterintuitive outcome reflects a broader theoretical insight captured by the Alexander-Shaw paradox: systems with weaker central authority can, under crisis conditions, generate stronger incentives for cooperation, as constituent units recognize the absence of a reliable central backstop and are therefore compelled to act collectively (Alexander-Shaw, Ganderson and Schelke, 2023).

It is within this theoretical and empirical framework that the comparison of EU and US vaccine strategies becomes particularly revealing.

The EU's approach, based on joint procurement, risk-sharing mechanisms, and coordinated allocation, was not without shortcomings, especially in its initial phases.

Yet precisely because it was achieved under conditions of limited central authority, legal constraints, and the constant risk of fragmentation, its outcome can be considered more remarkable.

The EU did not simply deliver vaccines; it transformed an initially fragmented and competitive landscape into a coordinated system that ensured equitable access across member states and reinforced political solidarity.

In contrast, the US, despite possessing greater resources and institutional capacity, struggled to translate these advantages into a unified and depoliticized vaccination strategy.

The following sections builds on the preceding analysis by directly comparing EU and US vaccine procurement and rollout outcomes in light of their institutional constraints.

They highlight how the EU's coordinated strategy, despite structural limitations, represents a more notable achievement, while the US case shows that greater central capacity did not ensure cohesion.

Together, these findings reinforce the Alexander-Shaw paradox, illustrating that the EU's performance is more remarkable when assessed relative to its institutional context.

EU vs US Vaccine Strategies – Procurement

The procurement strategies adopted by the European Union and the United States during the COVID-19 pandemic reflected their distinct institutional structures and produced markedly different dynamics in terms of coordination, bargaining, and political cohesion.

In the US, vaccine procurement was driven by a centralized, state-led approach under Operation Warp Speed, which mobilized substantial federal funding to accelerate vaccine development, secure early production capacity, and guarantee large advance purchases from pharmaceutical companies.

This strategy enabled rapid access to vaccines and prioritized speed and domestic supply, but it also operated within a highly politicized federal environment, where coordination between federal and state authorities was often fragmented and shaped by partisan conflict.

By contrast, the EU initially experienced a fragmented phase in which member states pursued bilateral agreements, exposing inequalities in bargaining power and raising concerns over unequal access.

However, this dynamic was quickly reversed through the creation of a joint procurement framework, under which member states collectively mandated the European Commission to negotiate Advance Purchase Agreements on their behalf.

This shift transformed the EU into a single, large buyer, allowing it to pool demand, share financial risks, and secure more favorable prices while ensuring proportional distribution across all member states.

Although this approach was slower in its initial stages and constrained by legal and institutional limitations, it ultimately prevented intra-European competition and reinforced solidarity, ensuring that smaller and less wealthy countries were not excluded from access to vaccines.

When assessed comparatively, the EU's procurement strategy stands out not for its speed alone, but for its capacity to transform institutional weakness into coordinated collective action, thereby exemplifying the Alexander-Shaw paradox.

A system characterized by limited central authority and high interdependence was nevertheless able to generate a unified and equitable procurement framework, revealing how structural constraints can generate incentives for cooperation rather than fragmentation.

In contrast, the United States, despite its superior fiscal capacity and centralized instruments, most notably in accelerating vaccine development and securing early supply, being among the first to authorize and deploy vaccines, illustrates the limits of central strength in the absence of cohesive political alignment and inconsistent public communication, which contributed to the spread of vaccine skepticism and uneven public uptake.

The federal government's prominent role became embedded in partisan contestation, undermining the credibility and consistency of public communication and contributing to the diffusion of vaccine skepticism.

From a theoretical perspective, this divergence reflects the broader Hamiltonian credibility dilemma: where central authority is strong and expected to act decisively, subnational actors and political

opponents have greater incentives to contest, shift responsibility, or politicize policy outcomes (Rodden, 2005).

By contrast, the European Union, despite a slower start, placed greater emphasis on regulatory rigor, collective risk-sharing, and coherent communication through centralized agencies, prioritizing public trust and safety over speed alone.

Additionally, the relative weakness of the center increased the perceived costs of non-cooperation, encouraging member states to internalize collective risks and support a common framework.

This approach, grounded in stricter approval procedures and coordinated messaging, helped sustain confidence in vaccines and reinforced the legitimacy of the overall strategy.

As a result, the EU's procurement policy can be understood not only as a mechanism for securing doses, but as a broader exercise in polity maintenance, where the preservation of trust, solidarity, and institutional credibility became integral to the effectiveness of the vaccination campaign itself.

EU vs US Strategies – Rollout

The rollout phase of COVID-19 vaccination further accentuated the structural differences between the EU and the US, revealing how institutional design shaped not only the speed but also the coherence and equity of distribution.

In the US, the federal government retained significant control over vaccine supply, procurement contracts, and distribution logistics, yet the implementation of vaccination campaigns was largely delegated to individual states, resulting in substantial variation in eligibility criteria, prioritization, and administrative efficiency.

This decentralization interacted deeply with the country's polarized political environment, transforming what could have been a technocratic public health operation into a contested political issue.

Partisan polarization shaped both elite decision-making and mass behavior: Republican- and Democratic-led states often adopted diverging strategies in prioritization, mandates, and outreach, reflecting broader ideological cleavages over the role of government, individual liberty, and public health authority.

At the same time, inconsistent and sometimes conflicting communication from federal and state authorities, particularly during the transition between administrations, contributed to public confusion and eroded trust in the vaccination campaign.

Vaccines themselves became politicized symbols, with uptake rates increasingly correlating with partisan affiliation, media consumption, and trust in government institutions.

This dynamic was further exacerbated by the spread of misinformation and the absence of a unified national messaging strategy, which hindered efforts to achieve widespread vaccine acceptance.

As a result, the rollout was not only administratively uneven but also socially fragmented, with significant disparities in access, distribution efficiency, and vaccination rates across states and demographic groups.

In this context, the US' strong central capacity did not translate into cohesive implementation; instead, it became embedded within a polarized federal system that amplified divergence rather than coordination, ultimately undermining the effectiveness and uniformity of the national vaccination effort.

By contrast, the EU adopted a hybrid model in which vaccines were centrally procured and allocated according to a population-based key, while member states retained responsibility for national rollout strategies.

Although this approach initially led to slower deployment, partly due to supply constraints and stricter regulatory procedures, it ultimately ensured a high degree of coordination and convergence across countries.

Common guidelines issued by EU institutions, particularly regarding priority groups, alongside continuous information-sharing among national authorities, contributed to a relatively uniform vaccination framework, limiting disparities between member states.

Beyond these operational features, the EU rollout was reinforced by a broader effort to maintain transparency and public trust.

The EU Commission and relevant agencies regularly communicated procurement decisions, regulatory evaluations, and delivery schedules, while the European Medicines Agency's more stringent authorization process, combined with tools such as rolling reviews, helped frame vaccination as a scientifically grounded and accountable process.

This emphasis on transparency, even when exposing delays or contractual disputes, played a key role in sustaining public confidence across diverse national contexts.

At the same time, the principle of solidarity remained central: the population-based allocation mechanism ensured that all member states, regardless of size or economic capacity, received

proportional access to vaccines, preventing the emergence of internal vaccine nationalism and reducing inequalities that had characterized the initial procurement phase.

Importantly, the EU system also demonstrated a capacity for institutional learning and correction.

Early shortcomings, such as delays in deliveries and contractual tensions with pharmaceutical companies, did not lead to fragmentation, but instead triggered adjustments in procurement strategy, increased production support, and more assertive coordination by the Commission.

This ability to recalibrate while preserving collective commitment highlights a key strength of the EU model: rather than collapsing under pressure, the system adapted through iterative coordination between supranational institutions and member states.

In this sense, the rollout phase not only consolidated the gains achieved during procurement but also illustrated how a structurally decentralized system could generate cohesion, resilience, and policy correction in the face of crisis, whereas the US case shows that stronger federal capacity does not automatically translate into cohesion when political polarization and institutional incentives undermine collective action.

EU vs US Vaccine Strategies – Evaluating Outcomes

Overall, both the European Union and the United States ultimately achieved substantial results in their vaccination campaigns, reaching high levels of immunization and significantly reducing COVID-19-related mortality and severe illness. In this sense, both systems proved capable of delivering effective biomedical outcomes and contributing to the broader containment of the pandemic.

However, when these results are assessed in light of their respective institutional conditions, a crucial distinction emerges.

The United States achieved its outcomes within a system endowed with strong central authority, extensive fiscal capacity, and advanced biomedical infrastructure, advantages that, in principle, should have facilitated a more coherent and unified response.

Yet, these structural strengths were partly offset by political polarization, fragmented intergovernmental relations, and inconsistent communication, which introduced inefficiencies and disparities in both procurement and rollout.

By contrast, the European Union reached comparable outcomes despite operating within a far more constrained institutional framework, characterized by limited competences in public health, complex decision-making procedures, and an inherent risk of fragmentation among member states.

Precisely because of these constraints, the EU's ability to transform initial disunity into a coordinated procurement system, ensure equitable distribution, sustain public trust, and preserve political cohesion renders its performance particularly noteworthy.

In line with the Alexander-Shaw paradox, the EU case demonstrates that weaker central authority, rather than constituting a liability, can generate stronger incentives for cooperation and collective problem-solving.

Therefore, while both actors succeeded in epidemiological terms, the EU's results can be considered more remarkable, as they reflect not only effective crisis management but also the capacity of a structurally decentralized system to produce unity, resilience, and solidarity under conditions that would have been expected to lead to fragmentation.

4. Conclusion

This thesis set out to investigate a central paradox of the COVID-19 pandemic: why did the European Union, often portrayed as an incomplete and institutionally weak polity, manage to coordinate an effective vaccine strategy, while the United States, equipped with stronger federal capacities, experienced fragmentation and less coherent outcomes?

At first glance, this empirical reality appears to contradict the core expectations of traditional federalist theory, which associates stronger centralization with greater efficiency and crisis-management capacity.

However, by grounding the analysis in the theoretical framework of Hamilton's Paradox and its extension through the Alexander-Shaw argument, this research has demonstrated that such expectations overlook a crucial dimension of institutional design: the incentive structures that shape the behavior of constituent units under conditions of uncertainty.

In this perspective, institutional strength is not merely a function of formal powers, but of the credibility of central intervention and the strategic calculations it induces among subnational actors.

More specifically, the findings of this thesis show that a strong federal center, such as that of the United States, can unintentionally foster intergovernmental competition, political polarization, and coordination failures, because the presence of a powerful yet politically contested center generates uncertainty over leadership, responsibility, and policy direction.

In this context, federal authority became a site of partisan conflict rather than a stabilizing coordinating force, prompting states to adopt divergent strategies shaped by political alignment, electoral incentives, and inconsistent federal guidance.

Conversely, a system like the European Union, characterized by limited central authority, constrained fiscal capacity, and a high degree of interdependence among sovereign member states, generates stronger incentives for cooperation.

Precisely because the EU lacks the capacity to impose unilateral solutions or provide automatic intervention, member states are compelled to internalize the full costs of failure and to actively support collective mechanisms.

This dynamic fosters coordination, as governments recognize that only through joint action can they effectively manage a crisis that transcends national borders.

Therefore, the core argument advanced in this research is that the divergent outcomes observed in the EU and the US vaccine strategies are not paradoxical anomalies or contingent deviations from theoretical expectations, but rather the logical and predictable consequence of distinct institutional incentive structures embedded within their respective systems of governance.

In this sense, the findings not only support but also extend the Alexander-Shaw paradigm by demonstrating its applicability to the domain of public health crisis governance.

What initially appears as a contradiction, namely, a weaker polity outperforming a stronger one, can instead be understood as the empirical manifestation of how different configurations of authority, responsibility, and interdependence shape political behavior under crisis conditions.

At the same time, it is essential to stress that both systems ultimately achieved a fundamental and highly significant objective: they were able to rapidly scale up vaccination campaigns and substantially reduce mortality and severe health outcomes.

Despite their differences in coordination, timing, and internal cohesion, both the European Union and the United States succeeded in deploying vaccines at an unprecedented speed, contributing decisively to limiting the human cost of the pandemic and enabling the gradual reopening of their societies and economies.

However, the EU's outcome is particularly remarkable given its limited competences in health policy and its initially fragmented response.

The divergence between the two cases, therefore, does not lie in success versus failure, but rather in the degree of coordination, equity, and political cohesion through which these outcomes were achieved.

In this sense, the COVID-19 pandemic did not merely function as a stress test of administrative or logistical capacity; rather, it acted as a critical revealing moment, bringing to the surface the underlying dynamics that ordinarily remain less visible in routine policymaking.

The crisis amplified structural features of both systems, exposing how governance architectures translate into distinct patterns of interaction between central and subnational actors.

In the United States, the federal center became entangled in partisan competition and coordination was undermined by conflicting signals and decentralized implementation.

In the European Union, by contrast, the relative weakness of the central level, combined with high interdependence and the absence of automatic hierarchical control, generated incentives for member

states to converge, cooperate, and ultimately engage in forms of polity maintenance by empowering supranational mechanisms in order to avoid mutually detrimental outcomes.

This outcome was not immediate but emerged through a process of initial fragmentation followed by progressive centralization, as member states recognized the inefficiencies and risks of uncoordinated action.

This shift was operationalized through concrete instruments such as joint procurement, Advance Purchase Agreements, and centralized regulatory coordination by EU agencies.

Ultimately, the comparative evidence of the COVID-19 vaccination campaigns shows that, while both the European Union and the United States were able to reduce mortality and scale up immunization, the EU's more coordinated approach highlights how institutional structures that foster cooperation can translate into more cohesive and equitable crisis responses.

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