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Sustainability and Resilience in the German Health System

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This report was produced on behalf of PHSSR as part of its pilot phase, in order to apply and test a framework for the analysis of health system sustainability and resilience. The positions and arguments presented herein are the authors' own, and do not represent the views of AstraZeneca, the World Economic Forum or the London School of Economics and Political Science.

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Executive Summary

This is the report of the German country team for the Partnership for Health System Sustainability and Resilience (PHSSR), an initiative by the London School of Economics (LSE), the World Economic Forum and AstraZeneca. The aim of the report was to identify key factors relating to the sustainability and resilience (during the COVID-19 pandemic) of the German health system along five domains: Governance, Financing, Workforce, Medicines & Technology and Service Delivery. This analysis was guided by a sustainability and resilience framework developed by the LSE. Table 1 gives an overview of key findings from the report. In addition to a rapid review of available literature, five interviews were conducted with four stakeholders in order to generate additional insights and feedback for the report. These interview partners were Prof. Christoph Straub of BARMER (a large German statutory insurance fund), Prof. Alexander Krämer of Bielefeld University, Dr. Georg Rüter of the Catholic Hospital Association of Ostwestfalen, and Dr. Martin Danner of the *BAG Selbsthilfe* (a patient advocacy group).

Table 1: Key Findings of the German PHSSR Report

Domain	Sustainability	Resilience
Governance	Key governance sustainability factors in Germany are the health system's corporatist self-administration structure and German federalism, in which the <i>Länder</i> are responsible for many health policy areas.	Germany's response to COVID-19 was mostly successful in the early stages of the pandemic in terms of governance resilience. However, local public health authorities, who play a key role in pandemic response, were understaffed and underfunded for decades.
Financing	Germany's statutory insurance financing mechanism is currently successful, but faces risks from demographic change, economic downturn, and rising costs from technological advances. Hospital investments by the <i>Länder</i> are currently insufficient.	The German health system is capable of accumulating reserves in both the national Health Fund and through individual insurance funds, the size of these reserves is heavily regulated.
Workforce	Germany has a large healthcare workforce, but workload is very high. Workforce sustainability is threatened by a future lack of general practitioners in rural areas and nurses in long-term care/nursing homes. There are significant legal hurdles to professional delegation and substitution; task-shifting from physicians to nurses is uncommon.	Although local public health authorities are understaffed, Germany was able to rapidly, but temporarily, expand its public health workforce during the COVID-19 pandemic.
Medicines & Technology	The German AMNOG process for the adoption of new medications is robust and offers rapid access to new drugs but lacks	Stockpiling provisions of German pandemic preparedness plans were not diligently followed, adversely impacting health system resilience. Germany did not

	<p>regular and systematic economic cost-benefit analyses.</p> <p>Germany remains an important location for pharmaceutical research and production, although its significance has been surpassed by other nations in recent decades.</p> <p>While Germany struggles to digitise its health system, there have been significant efforts in recent years to improve its overall digital infrastructure.</p>	<p>have a national reserve of medicines, medical technologies and consumables.</p> <p>Germany is relatively independent of non-European countries for pharmaceutical imports but significantly less independent for basic pharmaceutical production materials. Germany participates in the European Joint Procurement Agreement for medical countermeasures.</p>
<p>Service Delivery</p>	<p>Control and supervision of physicians and care providers in the German health system are predominantly finance-based, not quality-based.</p> <p>Patients covered by statutory insurance have free choice of provider, but some incentives exist to treat their general practitioner as a gatekeeper to specialist care.</p> <p>Cross-sectoral coordination of care and the promotion of new care models represent a problem area due to the strict separation of financing, provider remuneration, planning procedures and regulatory responsibility between care sectors.</p> <p>Chronic disease prevention efforts are an uncoordinated patchwork of preventive services provided by many organisations and institutions.</p>	<p>Germany's COVID-19 response efforts included the rapid expansion of hospital and ICU capacity. Reserve funds were used to finance hospital bed space and ICU capacities.</p> <p>Elective procedures were delayed due to COVID-19, although surprisingly effective cross-sectoral coordination allowed outpatient services to reduce the strain on inpatient care by handling many non-severe COVID-19 cases.</p>

Based on the findings of the report and the stakeholder interviews, several recommendations for increasing the sustainability and resilience of the German health system were formulated for each domain. Table 2 gives an overview of these recommendations, which include both concrete policy proposals and general calls for reform.

Table 2: Key Recommendations of the German PHSSR Report

Domain	Sustainability	Resilience
Governance	Recommendation 1A: Reform of planning processes, including the linkage of inpatient and outpatient planning	Recommendation 1B: Prioritising local public health authorities and strengthening the federal government's role in questions of pandemic response
Financing	Recommendation 2A: Moving from dual financing of hospital costs to a monistic financing system Recommendation 2B: Reforming the DRG system, moving from activity-based to flat-rate reimbursement for contingency costs	Recommendation 2C: More strongly incentivising the accumulation of sufficient financial reserves
Workforce	Recommendation 3A: Ensuring an adequate future level of nursing and care professionals across regions Recommendation 3B: Simplifying the employment of foreign nationals in the German healthcare system	Recommendation 3C: Increased protections for healthcare workers (adequate provision of PPE, safety education) Recommendation 3D: Strengthening of the public health workforce: increased hiring and training
Medicines & Technology	Recommendation 4A: Incorporating regular cost-benefit analyses into the AMNOG process Recommendation 4B: Addressing supply bottlenecks through expanded reporting, critical medication reserves and incentives for European pharmaceutical production	Recommendation 4C: Increasing stockpiling capacity through stockpiling requirements for pharmacies, physicians, and hospitals as well as public reserves. Recommendation 4D: European production of critical medications and relevant raw materials
Service Delivery	Recommendation 5A: Structural reforms of the hospital sector: decreased hospital capacity and more quality-oriented specialised treatment facilities Recommendation 5B: Establishing procedures for regional cross-sectoral care planning using fixed-capacity and activity-based criteria Recommendation 5C: Empowering relevant actors and institutions to use available quality data to monitor, control and enforce care quality	Recommendation 5D: Measures aiming for a reduction in non-emergency treatment during shocks while simultaneously guaranteeing the continued provision of sufficient levels of emergency care

1. Health System Governance

1.1 Governance Sustainability

German health governance is characterised by high government involvement and significantly influenced by German federalism. Governmental actors are supplemented by the health system's so-called "self-administration structure" (*gemeinsame Selbstverwaltung*): While governments create legal frameworks and regulations for the health system, significant governance roles are afforded to care and insurance providers, organised into associations and public law corporations (*Verbände*).

The German Federal Ministry of Health (BMG) sets major national health policy and controls subordinate upper-level agencies (Simon, 2013, p. 125), including the Robert-Koch-Institute (RKI), tasked with disease prevention and control, and the Federal Center for Health Education (*Bundeszentrale für gesundheitliche Aufklärung*, BZgA), responsible for public awareness and health education. The BMG is advised by an independent advisory council (*Sachverständigenrat zur Begutachtung der Entwicklungen im Gesundheitswesen*). State-level health and social ministries as well as subordinated state health agencies perform various duties, especially planning and distributing hospital capacity and capital investments (Simon, 2013, p. 127). However, these state investments remain insufficient (Busse, Blümel, & Spranger, 2017, p. 147) and state control of inpatient planning hinders cross-sectoral coordination, as outpatient planning is the responsibility of regional Associations of Statutory Health Insurance Physicians (*Kassenärztliche Vereinigungen*). State-level decision-makers also have their own legislative and regulatory powers in health issues (Land, 2018, p. 80). Although states may not enact policies contradicting federal health law, this regional independence creates further possibilities for planning incompatibility.

The self-administration structure has significant decision-making authority in Health Technology Assessment (HTA) and benefits definition. Chief among its actors is the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA). The G-BA consists of impartial voting members and voting representatives of the National Association of Statutory Health Insurance Funds (*Spitzenverband Bund der Krankenkassen*, GKV-SV), the National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung*, KBV), the National Association of Statutory Health Insurance Dentists (*Kassenzahnärztliche Bundesvereinigung*, KZBV), and the German Hospital Federation (*Deutsche Krankenhausgesellschaft*, DKG) (Simon, 2013, p. 129). Patient advocacy organisations are represented by non-voting members, although patient participation in health system governance has been on the rise since 2004.

The G-BA has independent legislative authority and can directly enact binding regulations. In particular, it is responsible for making coverage decisions for statutory insurance funds, regulating the conduction of HTAs and determining the benefits of proposed treatments to inform the price negotiations (Busse, Blümel, & Spranger, 2017, pp. 67-69). While private insurance providers must at least match statutory benefits, they may set their own, potentially more expansive, benefit schemes (although they do not conduct their own HTAs). This transfer of power to non-state entities operating independently from the BMG is a defining feature of the German health system's decentral governance and contributes to both the delinking of health system planning from the political cycle and increased public trust in health system decision-making. However, it may hinder the public's ability to hold decision-makers accountable. Although the self-administration structure's transparency has been criticised in the past, the G-BA makes its decisions in public hearings, which members of the public may attend (Simon, 2013, p. 130).

The German health system is governed by a unique structure of governmental and non-governmental decision-makers. This structure insulates health system planning from political considerations (to a degree) but may complicate accountability and chains of command. Independent expertise is valued by decision-makers and stakeholders are either directly engaged in policy formation or at least have the right to be heard.

1.2 Governance Resilience

Disease surveillance in Germany is governed by the *Infektionsschutzgesetz* (IfSG), which empowers the RKI to conduct epidemiological surveillance and early warning efforts. For instance, doctors and other care providers must report cases of COVID-19 to local public health authorities within 24 hours; cases are then reported to state health agencies and the RKI (RKI, 2020a, p. 31). However, this process is inconsistently applied and often suffers from outdated technology and reporting delays.

In 2005, the states and federal government published a comprehensive National Pandemic Plan (NPP). This plan was successfully implemented during the 2009 influenza pandemic, after which it was improved and updated with the involvement of experts and various stakeholders (RKI, 2020a, p. 6). At the onset of the COVID-19 pandemic, the NPP allowed for a rapid mobilisation of public health resources (Wieler, Rexroth, & Gottschalk, 2020). But despite this national plan, it is local public health authorities, of which there are around 400, who are responsible for public health measures such as testing and contact tracing. And although contact tracing began earlier than in other countries and early successes bought valuable time (Wieler, Rexroth, & Gottschalk, 2020), local public health authorities were insufficiently prepared for their responsibilities during a nationwide pandemic due to decades of inadequate funding (Arentz & Wild, 2020, pp. 21-22).

Public health coordination between governance levels has been moderately successful so far. While state policies have occasionally diverged, states and the federal government have also issued joint contact bans and other cooperative policies (Wieler, Rexroth, & Gottschalk, 2020). In January 2020, coordination provisions of a federal infectious disease regulation were activated, allowing for better information exchange between local, state and federal actors (RKI, 2020a, p. 23). Despite initial setbacks, cross-sectoral coordination has also been a success (Arentz & Wild, 2020, p. 21): outpatient services handled many non-severe COVID-19 cases, relieving the strain on inpatient services.

In their pandemic response efforts, German health officials at the state and federal level sought and valued scientific expertise and implemented public health measures based on expert input (Arnold, 2020, pp. 5-6). While there were some early policy failures, guidelines and regulations were regularly updated to reflect new knowledge and developments. In a joint effort between the RKI, BMG, and BZgA, these decisions have usually been communicated transparently to the German public, which has been broadly receptive to public health messaging (Arnold, 2020, pp. 2-3).

Finally, it should be considered how government attempts to strengthen resilience during a shock can harm long-term sustainability. For example, the inefficient distribution of ventilators to care providers by the government harms sustainability while not contributing significantly to resilience.

1.3 Governance Recommendations

Recommendation 1A: The German health system's sustainability could be improved through a reformed planning process. This would entail depoliticising hospital planning by limiting the role of state governments, as well as linking inpatient and outpatient planning efforts, thus reducing planning inefficiencies. Increasing the involvement of patients in policymaking relative to other stakeholders could also be considered.

Recommendation 1B: Governance sustainability and resilience could be improved through the long-term prioritisation of local public health authorities, whose important role in health system governance has not been reflected in the provision of necessary resources and funding. These local actors require a significant increase in funding, both during and prior to health system shocks. The flexibility of German federalism, with local actors adapting and implementing national public health policies to best suit their region, is only a strength if these local actors are equipped to fulfill their role.

Recommendation 1C: Federalism can also provide an obstacle to a coordinated national response to health system shocks. A possible improvement would be to strengthen the role of the federal government in questions of pandemic response.

2. Health System Financing

2.1 Financing Sustainability

Germany's health system is funded mainly by an assortment of insurance schemes, dominated by the statutory health insurance system, which provided 56.8% of total funding in 2018 (Destatis, 2020b). Additional funding is provided by private insurance and other insurance systems, such as statutory accident or care insurance. Private individuals, employers, and the state supply the remaining health system funds. Table 1 shows the share of private and public health funding as well as the share of out-of-pocket expenses. Statutory health insurance funding is collected, but not immediately spent by individual insurance providers. Rather, the collected income-based employer and employee contributions are pooled in a national Health Fund (*Gesundheitsfonds*) and supplemented by tax-funded federal payments. The Health Fund then distributes funding to the statutory insurance providers based on the morbidity of their covered population using a risk compensation schedule (*Risikostrukturausgleich, RSA*) (Busse, Blümel, & Spranger, 2017, pp. 120, 127). This occurs in the context of individuals having freedom to choose among statutory health insurance providers, and these providers not being allowed to turn down individuals based on their health profile (guaranteed issue).

Table 1: Funding indicators of financing sustainability, 2010-2019

Funding Indicator	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Share of public health funding	72.0	71.8	71.8	72.7	73.3	73.3	73.6	74.0	74.0	-
Share of private health funding	28.0	28.2	28.2	27.3	26.7	26.7	26.4	26.0	26.0	-
OOPS; share of CHE	14.0	14.0	14.1	13.3	12.9	13.0	12.9	12.7	-	-

Notes: Values in %. OOPS: out-of-pocket spending, CHE: current health expenditures. Public funding: tax funds and statutory insurance. Private funding: private insurance, private households and nonprofits, and employers. Hyphens indicate data not yet available.

Source: Destatis, WHO Global Health Expenditure Database

Spending projections for the statutory insurance system and the Health Fund are conducted by an estimation committee (*Schätzerkreis*), consisting of experts from both the Ministry of Health and the GKV-SV (BAS, 2016). This committee projects the number and income of those covered by statutory health insurance, the income of the national Health Fund and the expenses of statutory insurance providers for the period of one year. An overview of health spending as a share of GDP and by health system sector is given in Table 2.

Table 2: Spending indicators of financing sustainability, 2010-2019

Spending Indicator	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Health spending; share of GDP	11.4	11.0	11.1	11.2	11.2	11.4	11.5	11.6	11.7	-
Outpatient health spending	49.8	49.6	49.5	49.6	50.0	50.2	50.2	49.7	49.6	-
Inpatient health spending	36.9	37.3	37.4	37.4	37.4	37.1	36.9	36.8	36.5	-
Public health spending	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	-

Notes: Values in %. GDP: gross domestic product. Spending on public health is equated with spending on *Gesundheitsschutz*. Hyphens indicate data not yet available.

Source: Destatis

Statutory health insurance providers may not accumulate significant surpluses or deficits, as their financing structure is organised as a pay-as-you-go system, in which yearly expenditures should correspond exactly to allocated funds (apart from a small fluctuation reserve). They may, however, use small surpluses achieved through the efficient use of funding received from the Health Fund to accumulate small financial reserves or distribute them to their customers. Statutory insurance providers must compensate deficits by increasing the individual contributions customers pay. There is no provision for the bailout of financially struggling statutory insurance providers, but these struggles may be alleviated through (voluntary or mandatory) fusion with other statutory providers.

The situation differs for private insurance providers, who insure approximately 10% of the German population (PKV, 2020). These providers are permitted to accumulate significant funding reserves and do so in the form of so-called *Alterungsrückstellungen* (PKV, 2017). These reserves help private insurers account for demographic change and medical costs that rise with the age of the insured, although they can be used for other purposes as well.

With an individual mandate and guaranteed issue (Ridic, Gleason, & Ridic, 2012, p. 114), the German health system has achieved near-universal health insurance coverage: less than 1% of the population are not covered (Destatis, 2020a, p. 31). However, some groups are at higher risk of non-coverage. These include self-employed individuals and freelancers. While some unemployed individuals who were previously self-employed remain undercovered, the government pays the insurance costs of the vast majority of unemployed individuals (Simon, 2013, p. 184).

Provider payment mechanisms differ between care providers. Hospital costs are split by type of cost: investment costs are paid by state governments, while operating costs are covered by payments from statutory and private insurance providers and patients, with payment based on Diagnosis Related Groups (DRGs) and additional fees (*Zusatzentgelte*) for specialised services (Busse, Blümel, & Spranger, 2017, pp. 138, 145). There remains a significant need for hospital financing reform: hospital planning does not sufficiently meet the population's medical needs and investment payments are inadequate (Sachverständigenrat, 2018, p. 763). Outpatient providers who participate in the statutory health insurance system are paid on a fee-for-service basis (Ridic, Gleason, & Ridic, 2012, p. 114) through a two-step process in which state-level Associations of Statutory Health Insurance Physicians receive funds from statutory health insurance providers and divide these funds among physicians based on patient morbidity and services provided (Busse, Blümel, & Spranger, 2017, pp. 150-151). However, outpatient physicians are only paid up to defined maximum limits per average patient. These fee-for-service payments are complemented by lump-sum payments, especially for general practitioners.

In theory, the German health system has a progressive financing system with near-universal coverage, although there is a regressive contribution cap for high-income individuals and some population groups remain undercovered. However, its financing sustainability suffers with regard to hospital financing, where investment costs are insufficient and capacity planning is not efficient and does not reflect the medical needs of the population. Additionally, general spending projections are limited to one year. Germany also has an older population than many comparable countries; as the financing of the statutory health insurance system depends on the income of the covered population, the German health system's financing sustainability is threatened by demographic change in the country. Table 3 illustrates these demographic changes and threats to sustainable financing. Finally, the rapidly rising costs of medical innovation and modern treatment options pose an even more significant risk to the financing sustainability of German health insurance providers.

Table 3: Demographic and government debt indicators of financing sustainability, 2010-2019

Demographic/Debt Indicator	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Share of population over 65	20.6	20.7	20.8	20.9	21.0	21.1	21.2	21.4	21.5	21.8
Labor force participation rate	54.6	54.7	54.9	55.1	55.2	55.1	55.0	55.4	55.7	56.0
Government debt; share of GDP	82.3	79.7	81.1	78.7	75.6	72.3	69.3	65.1	61.8	59.6

Notes: Values in %. GDP: gross domestic product

Source: Destatis, Eurostat

2.2 Financing Resilience

German law requires funds to be held in reserve by both individual statutory insurance providers and the national Health Fund. The Health Fund must reserve a financial cushion no lower than 20% and no higher than 50% of its average monthly expenses (§ 271 II SGB V), while individual insurance providers must set a reserve amount no lower than 25% of their average monthly expenses (§ 261 SGB V). In recent years, small surpluses by statutory insurance providers have accumulated into significant financial cushions for individual insurance funds, jointly totaling 21 billion Euros in mid-2020 (BMG, 2020a). This is in addition to financial reserves in the national Health Fund, which totaled 10 billion Euros in January 2020. By comparison, in June 2020, private health insurance providers had accumulated over 270 billion Euros (PKV, 2020) of financial reserves (*Altersrückstellungen*).

These financial cushions enhance the financing resilience of the German health system, which was able to flexibly utilise Health Fund reserves for pandemic response and public health efforts. For example, in the first six months of 2020, over 7 billion Euros from the Health Fund reserve were spent on reimbursing hospitals for reserving beds, increasing intensive care capacities and other pandemic response measures (BMG, 2020a). Beyond these reserves, significant federal funding was made directly available to health insurance providers in order to pay for testing and financial relief for care providers. However, attempts by the federal government during the ongoing pandemic to force statutory insurance providers with significant reserves to surrender these reserves rather than providing additional government funding may be a disincentive for these providers to accumulate sufficient financial reserves in the future.

2.3 Financing Recommendations

Recommendation 2A: The current dual financing system has led to inadequate hospital investments. Moving toward a monistic financing system, in which both investment and operating costs are covered by statutory health insurance providers, may help alleviate these problems. Such a financing system could also decouple investment and planning decisions from political cycles (Sachverständigenrat, 2018, p. 238).

Recommendation 2B: Reforming the DRG system and moving from activity-based reimbursement toward flat-rate reimbursement for contingency costs may lead to better financial incentives for hospitals providing care and better reflect the care situation of individual hospitals (Sachverständigenrat, 2018, p. 764).

Recommendation 3C: While the statutory health insurance system is capable of acquiring financial cushions, the size of these reserves is heavily regulated. Financial reserves may not exceed limits set by federal legislation and recent legislative reforms have required statutory insurance providers to begin lowering their reserves through payments to and lower rates for their insured population (BMG, 2018). The German health system relies on income-based payments (which may suffer during a pandemic and corresponding economic downturn); accumulating sufficient financial reserves should be more strongly incentivised.

3. Workforce

3.1 Workforce Sustainability

Germany has a large healthcare workforce, contributing to the health systems workforce sustainability: In 2018, over 5.6 million people were employed in the German health system (Destatis, 2020c). The healthcare workforce has been expanding in recent years, growing by 18% between 2009 and 2018. With 4.3 physicians and 12.9 nursing professionals per 1,000 inhabitants in 2017 (OECD, 2019, pp. 173,179), Germany is considerably ahead of OECD averages (3.5 and 8.8, respectively). Table 4 shows the evolution of numbers of physicians and nursing professionals since 2008. While the size of the German healthcare workforce is considerable, this has not translated into lower caseloads. On the contrary, caseloads per fulltime equivalent for physicians and nursing professionals are significantly larger than in comparable EU countries (Arentz & Wild, 2020, p. 5). Additionally, due to a higher workload and the lower prestige of non-specialised medicine, Germany suffers from a lack of general practitioners in rural areas, while population centers are overserved (Klose & Rehbein, 2017). Due in part to this geographic mismatch and the shifting demographics of both physicians and providers, the country's substantial healthcare workforce may not correspond adequately to population medical needs in the coming years, threatening workforce sustainability.

Table 4: Profession size indicators of workforce sustainability, 2008-2017

Profession Size Indicators	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Physicians	3.6	3.7	3.8	3.8	3.9	4.0	4.1	4.1	4.1	4.2
Nurses and midwives	11.5	11.8	12.0	12.1	12.2	12.5	12.8	12.9	13.1	13.2

Notes: Values in amount per 1,000 population. Inclusion criteria may create differences between World Bank and OECD data on health workforce size.

Source: World Bank

Aligning the workforce with these needs is complicated by the distribution of financing, education and planning responsibility for healthcare workers among federal, state, and private actors (Busse, Blümel, & Spranger, 2017, pp. 177-179), reflecting the health system's decentralised governance structure. Federal standards govern many aspects of medical education and workforce planning, state governments are responsible for regulating and financing academic medical education, whereas continuing medical education and personnel development are within the purview of healthcare workers' professional associations. The state-level Associations of Statutory Health Insurance Physicians are also responsible for the planning and regional distribution of physicians (in cooperation with statutory insurance providers). This responsibility separation can complicate national long-term workforce planning, but allows such planning to better reflect regional needs, perhaps enhancing workforce sustainability (although specific planning regions could be better drawn to more effectively target actual regional needs). Additionally, the health system remains capable of workforce planning in response to system-wide pressures and risks: For example, federal legislation aiming to increase the number of general practitioners through education funding and pay raises was passed in 2015, while state governments have also increased their activity in this area.

Germany emphasises professional development for health workers. Structured (sub-)specialisation curricula are in place for physicians, who are required to complete a multi-year specialisation after their academic education. Additionally, all health workers involved in the outpatient treatment of patients covered by statutory health insurance must undergo continuous professional development through their professional associations (Busse, Blümel, & Spranger, 2017, pp. 182-184). Professional development will only increase in relevance in the upcoming years, as digitalisation and new technologies increase the need for new digital skills within the workforce.

Especially compared to similar European countries, the German health system is heavily reliant on physicians, who enjoy higher prestige than nursing professionals (EXPH, 2019, p. 54) and may therefore be reluctant to transfer care responsibilities to non-physicians, despite general approval for such transfers among the population (Jedro, et al., 2020, p. 589). Perhaps most importantly, there are significant legal hurdles to professional delegation and substitution in the German health system. These factors impede task-shifting and cross-profession cooperation: a 2019 report found no significant task-shifting in the German health system (EXPH, 2019, p. 18).

In recent years, job satisfaction for German healthcare workers has diverged significantly by profession; Table 5 gives an overview of several factors related to job satisfaction and working conditions. While physician job satisfaction rose by 14.4% from 1990 to 2012, job satisfaction among nursing professionals fell by 7.5% (Alameddine, Bauer, Richter, & Sousa-Poza, 2015, pp. 3-4), driven mainly by a decline among part-time nursing employees. Although there was no corresponding increase in turnover for nursing professionals in the same time period (Alameddine, Bauer, Richter, & Sousa-Poza, 2017, p. 4), insufficient salary increases (primarily in long-term care/nursing homes), high workloads, low status and other factors contribute to the possibility of a future nurse shortage (Alameddine, Bauer, Richter, & Sousa-Poza, 2015, pp. 6-7).

Table 5: Working condition indicators of workforce sustainability, 2017/2019

Working Condition Indicator	
Remuneration, general practitioner	4.4
Remuneration, salaried specialist physician	3.5
Remuneration, self-employed specialist physician	5.4
Remuneration, hospital nurse	1.1
Migratory inflow of physicians	3,800
Migratory outflow of physicians	- 1,898

Notes: Remunerations data from 2017, given as ratio to average wage. In-/Outflow data from 2019, given as absolute values.

Source: OECD, Bundesärztekammer

The sizeable German healthcare workforce and its continuous professional development are a sign of sustainability, although caseloads for healthcare professionals remain high compared to the European average due to high number of hospitals and increased demand owing to aging of the population. Meanwhile, a reliance on physicians and inability to transfer care responsibility to other health professionals adversely affect workforce sustainability. National long-term workforce planning efforts may be inhibited by Germany's complex distribution of planning and education responsibility. Finally, declining job satisfaction and employment conditions among nursing professionals present a long-term risk to workforce sustainability. However, public awareness of these risks is high and policymakers have begun to respond. For example, nursing work has been decoupled from DRGs and education fees for nursing trainees have been removed.

3.2 Workforce Resilience

Although significantly increasing the number or workload of healthcare professionals appears unfeasible due to the already large size and workload of Germany's health workforce, personnel capacities were successfully reallocated in response to COVID-19 by, for example, delaying elective procedures (Arentz & Wild, 2020, p. 21; Paffenholz, et al., 2020, p. 1592). Simultaneously, Germany was able to rapidly expand its public health workforce through support from several thousand soldiers dispatched by the German army (Schulz, 2020) and the hiring of short-term "containment scouts" (Wieler, Rexroth, & Gottschalk, 2020), both of which are assisting local public health authorities in contact tracing and other public health measures.

COVID-19 represents an ongoing threat to healthcare workers' emotional and physical health: by late October 2020, the RKI had reported over 18,700 infections among employees of hospitals, outpatient clinics and other medical facilities (RKI, 2020b, p. 5). Although safety procedures and guidelines for healthcare workers are in place, with many employers providing specific COVID-19 training, the workforce has suffered from a lack of personal protective equipment (PPE), especially in the outpatient sector and in the East German states (Paffenholz, et al., 2020, pp. 1592-1593). Training measures are not equally available: physicians and inpatient employees receive COVID-19 training significantly more often than nurses and outpatient employees, respectively.

3.3 Workforce Recommendations

Recommendation 3A: To increase the German health system's long-term workforce sustainability, additional measures should be implemented to ensure an adequate level of nursing and care professionals and sufficient cooperation between physicians and nurses, especially in light of demographic change. This requires a multi-pronged approach, including elevating the status of nursing and other non-physician healthcare professions, increasing their pay and benefits, and encouraging task-shifting between physicians and nursing professionals, especially concerning minor treatments and drug administration.

Recommendation 3B: Simplify the employment of foreign nationals in health jobs in Germany through the reduction of bureaucratic hurdles.

Recommendation 3C: Regarding resilience, protections for healthcare workers should be increased, especially through the adequate provision of personal protective equipment. Disparities in workplace safety between sectors and professions adversely affect workforce resilience: employees at outpatient facilities and nursing professionals should receive additional personal protective equipment and COVID-19 training.

Recommendation 3D: The public health workforce in Germany must be strengthened through the creation of more permanent positions within local public health authorities and through increased educational/vocational training for public health jobs.

4. Medicines and Technology

4.1 Medicines and Technology Sustainability

In the German health system, HTAs and other processes relating to the adoption of new medications, procedures and medical technologies differ between different settings and types of medical innovation. For new medications, this adoption process is governed primarily by the Pharmaceutical Market Reorganisation Act (*Arzneimittelmarktneuordnungsgesetz, AMNOG*) of 2010.

First, new medications must go through regulatory approval procedures. Although it is possible to request national approval through the Federal Institute for Medications and Medical Products (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*), most pharmaceutical companies submit innovative medications for EEA-wide approval with the European Medicines Agency (EMA). When regulatory approval has been gained for a new medication, the manufacturer may take it to market in Germany immediately at a freely chosen price. In this time period, statutory health insurance providers fully reimburse these new medications. This allows very rapid access to new treatments for German patients without access limitations based on economic decisions, increasing sustainability.

Within the first year after approval, an HTA process takes place in order to determine the relative effectiveness and appropriate pricing of the new medication. Based on materials submitted by the pharmaceutical companies, the Federal Joint Committee evaluates the benefit of the new medication in relation to appropriate

comparative therapies. If an additional benefit is found, the manufacturer and the GKV-SV negotiate a price based on the size of and scientific evidence for this additional benefit, as well as prices in other European countries and the annual therapy costs of the comparative therapy. If no additional benefit is found, the price is set at the level of the annual therapy costs of the comparative therapy. This price applies to the new medication beginning in the 13th month after approval. Should these negotiations fail, the price is decided on by an arbitration board, consisting of neutral members and representatives of both manufacturers and insurance providers. Should one of the negotiating parties reject the price set by the arbitration board, that party may request an economic cost-benefit evaluation of the new medication, which is conducted by the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG). However, these evaluations must be financed by the requesting party. Consequently, since the passage of AMNOG, no economic evaluations have been conducted through this process, creating space for the improvement of sustainability through the incorporation of regular, systematic economic evaluations into the HTA process.

The rapid adoption mechanisms for new medications indicate high sustainability and the overall approval and HTA process in the German health system is robust. For example, over 70 new cancer drugs were adopted between 2015 and 2019, according to data from the Federal Joint Committee. However, unless they are later proven to be unsafe, Germany has no provision for the de-adoption of low-value/obsolete medicines and technologies. Rather, safe medicines remain on the market even if better alternatives exist, potentially inhibiting sustainability but increasing competition and therapeutic choice for patients and physicians. However, the pricing procedure for unproven additional benefits ensures that these therapies do not lead to higher costs.

While new medications are adopted through this AMNOG process, new and innovative non-pharmaceutical treatments and operating procedures may be adopted by hospitals without an HTA process, potentially encouraging cost-effective innovation, as these new procedures are reimbursed according to existing DRGs. If the costs of new procedures exceed the DRG-based reimbursement, hospitals can apply for the creation of a new DRG through a process administered by an independent calculation institute (InEK). Meanwhile, new outpatient procedures must be approved by the Federal Joint Committee before adoption by outpatient healthcare providers.

Germany also remains an important location in terms of pharmaceutical research and development capabilities. While new global players in pharmaceutical research and production have begun to emerge among developing nations, Germany's domestic research capacity for drugs and medical technologies remains strong, with the German Association of Pharmaceutical Research Companies (*Verband der forschenden Pharma-Unternehmen*, vfa) representing 45 global leaders in medical innovation, including both well-established companies, such as Bayer, and comparatively new players, such as BioNTech. In fact, in November 2020, BioNTech and Pfizer announced a COVID-19 vaccine candidate with over 90% efficacy, highlighting the continued significance of Germany as a pharmaceutical research location (Pfizer & BioNTech, 2020). Nevertheless, Germany's significance as a pharmaceutical location has been surpassed by other countries in areas such as research or development (Bräuninger, Straubhaar, Fitzner, & Teichmann, 2008, p. 6). Beyond research and development, Germany remains a strong player in pharmaceutical production (vfa, 2020); German pharmaceutical companies have already begun selecting locations for COVID-19 vaccine production.

However, problems remain for the sustainability of Germany's medicines supply. In late November of 2020, BfArM reported 249 supply chain bottlenecks for various medications and dosages, ranging in type from common painkillers to more complex treatments and in length from short-term to multi-year bottlenecks (BfArM, 2020a). While these numbers must be seen in relation to the total number of medications on the German market, and while a large majority of unavailable medications can be replaced through other drugs or therapies (Korzilius, 2019), rising delivery bottlenecks for a wide range of medications represent a threat to the long-term sustainability of the German health system in the domain of medicines and technology.

4.2 Digital Health and Sustainability in Germany

Beyond pharmaceuticals and medications, Germany has recently introduced significant policy innovations designed to increase the adoption and accessibility of digital health services and innovative digital technologies. Three efforts are especially relevant to health system sustainability: attempts to increase usage of remote medicine (such as remote consultations), the improved adoption of digital health applications (*Digitale Gesundheitsanwendungen*, DiGAs), and the implementation of electronic patient records and prescriptions.

The 2015 Secure Digital Communication and Applications in Healthcare Act (*Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen*) provided for the inclusion of remote consultations conducted by physicians for patients with certain indications into the statutory insurance benefit scheme. This inclusion was realised in mid-2017. However, in the first 21 months after these provisions entered into force, the remote consultation option was chosen by a very small minority of patients (Gensorowsky, Surmann, Schmidt, & Greiner, *Nutzungsgrad und Nutzergruppen der Online-Videosprechstunde in der ambulanten ärztlichen Versorgung*, in press). But this may be changing; new research indicates that not only have a large number of patients made their first experiences with remote consultations during the COVID-19 pandemic (Gerlof, 2020), but also that many are willing to continue using them after the pandemic. In Germany, remote consultations appear to be here to stay.

Germany has also introduced regulations for the adoption of digital health applications, such as cell phone apps treating depression or anxiety. Since the entry into force of the Digital Care Act (*Digitale-Versorgung-Gesetz*, DVG) in late 2019, these DiGAs can be prescribed by physicians and are reimbursed by statutory health insurance providers. With lower evidentiary standards and a 3-month fast-track approval process, gaining approval for DiGAs (which are classified as low-risk) is less strictly regulated than approval for pharmaceuticals (BfArM, 2020b). This has been the subject of criticism, but also offers an opportunity for innovative and flexible responses to patient needs.

Finally, there have been significant efforts in recent years to improve the overall digital infrastructure of the German health system. While electronic patient records are currently in use only by individual insurance providers, this will change in 2021. Due to new legislation, all statutory insurance providers will offer electronic patient records (BMG, 2019a) and pharmacies, hospitals, and outpatient physicians will be required to connect to the new digital healthcare infrastructure (BMG, 2020b), with other care providers able to connect voluntarily. This represents a critical step toward a more digital and sustainable health system.

4.3 Medicines and Technology Resilience

German pandemic preparedness plans discuss the importance of emergency health supply stockpiles during a pandemic and recommend such stockpiles be created. However, the stockpiling provisions of these plans were not diligently followed prior to the onset of the COVID-19 pandemic, adversely impacting health system resilience. While pharmacies are required by law to keep small stockpiles, Germany did not have a national reserve of medicines, medical technologies and consumables as of 2019. This may have contributed to some of Germany's shortages of PPE, especially masks, during the first wave of the COVID-19 pandemic. While some medication shortages have been reported in recent months (Sonnenholzner, 2020), replacement therapies can be swapped for many of these medications.

In a positive sign for health system resilience, Germany is relatively independent of non-European countries for pharmaceutical imports, with a diversified procurement portfolio in addition to Germany's domestic manufacturing capabilities (Braml, Teti, & Aichele, 2020). However, this applies mainly to finished pharmaceutical products: Germany is significantly less independent when it comes to basic pharmaceutical production materials. In addition, Germany participates in the Joint Procurement Agreement for medical countermeasures (JPA). Approved by the European Commission in 2014, the JPA now includes all EU and EEA member states, the UK, Kosovo, and a number of EU membership candidates and potential candidates.

In response to the COVID-19 pandemic, the JPA enabled the signing of procurement frameworks and agreements for treatments and vaccines.

4.4 Medicines and Technology Recommendations

Recommendation 4A: Although Germany has a strong adoption process for new medications in the form of AMNOG, balancing rapid market access with later HTA procedures, the lack of regular and systematic economic cost-benefit evaluations denies decision-makers critical information and represents a threat to health system sustainability with regards to medicines and technology. Rather than giving negotiating parties the option to request a self-financed economic evaluation only after negotiation failures, adoption procedures should be reworked to include a systematic economic evaluation of new medications as a standard element of the process. Additionally, expanding cost-benefit evaluations to include medical infrastructure and other aspects of care provision could be considered.

Recommendation 4B: Supply bottlenecks in Germany could be addressed through a three-pronged set of measures. First, Germany's voluntary bottleneck reporting system could be expanded, with emerging medication bottlenecks being rapidly reported to the appropriate authorities. At the same time, manufacturers or wholesalers could be required to keep reserves of critical medications in order to avoid short-term bottlenecks. Finally, financial incentives (such as long-term purchase guarantees) should be put in place to keep pharmaceutical production in Europe, lessening dependence on other countries and global developments.

Recommendation 4C: In order to strengthen health system resilience with regards to medicines and technology, it is critical that Germany drastically increase its stockpiling capacity for essential medicines, devices, and consumables. However, there is disagreement over the optimal form for such stockpiles. While policymakers have suggested a central national stockpile under control of the federal government (afp/aerzteblatt.de, 2020), this may lead to inefficiency in distribution and waste. Instead, it may be more prudent to choose a combined approach, in which sufficiently strong stockpiling requirements for pharmacies, physicians, and hospitals are adopted and supplemented through state-level stockpiles and a federal reserve of high-priority medicines and consumables, stored at a number of decentralised locations (similarly to the US Strategic National Stockpile). Such an approach may strike the right balance between preparedness and flexibility, enhancing resilience.

Recommendation 4D: Finally, expanding European pharmaceutical production capacities may represent a partial alternative to stockpiling. These production capacities should focus on important medications that are no longer highly profitable for pharmaceutical companies to produce and should include not only the medications themselves, but also relevant raw materials. Such an expansion could take the multiple forms, such as expanded production subsidies or state-administered production facilities.

5. Service Delivery

5.1 Service Delivery Sustainability

Control and supervision of physicians and care providers in the German health system are predominantly finance-based, not quality-based. The majority of such controls focus on economic analyses of physicians' prescribing behavior, rather than on evaluations of the quality of care (Busse, Blümel, & Spranger, 2017, p. 220), although provisions exist for the inspection of individual physicians due to "other damages", such as the violation of medical regulations. There are no widespread financial incentives for individual physicians to provide higher-quality care, although private initiatives such as the Bertelsmann Foundation's *Weisse Liste* offer patients quality-focused assessments of potential care providers. However, the degree to which patients base care decision on third-party quality ratings is debated in the literature (Lako & Rosenau, 2009).

Although the German health system includes an agency dedicated to monitoring care quality in the form of the Institute for Quality Assurance and Transparency in Healthcare (*Institut für Qualitätssicherung und Transparenz im Gesundheitswesen*, IQTIG), the agency does not possess enforcement powers. IQTIG monitors the quality of care across the German health system, with a special focus on hospitals. Beyond IQTIG, local public health authorities play a role in supervising hygiene conditions for hospitals and other care providers in their jurisdictions, while the BZgA monitors the quality of disease prevention efforts (Busse, Blümel, & Spranger, 2017, pp. 186-189). Large data sets concerning healthcare quality are collected by these and other actors throughout the German health system but are not actively utilised for quality supervision and control.

Regarding service delivery efficiency, the average length of hospital stays in Germany has been slowly but steadily declining in recent years, falling from 9.7 days in 2000 to 8.1 days in 2008 and further to 7.3 days in 2018 (RKI; Destatis, 2020). For patients suffering from acute myocardial infarction, the average length of hospital stays has also decreased, but remained above the average of all patients. In particular, average length of stay for these patients fell from 10 days in 2000 to 9.0 days in 2008 and to 7.7 days in 2018. The German health system financially incentivises hospitals to reduce readmission rates: The treatment of patients returning to a hospital for the same condition within 30 days is reimbursed as part of the initial DRG – hospitals do not receive additional payment for the treatment of these patients.

Patients covered by statutory health insurance enjoy free choice of care provider in the German health system. In particular, patients are not required to see a primary physician before accessing specialist care. However, several measures are in place to incentivise patients treating their general practitioner as a de facto – if not de jure – gatekeeper to specialist care. For example, statutory insurance funds do not pay for direct access to some care providers, such as physical therapists or speech therapists, without a referral. Additionally, statutory insurance providers are required by law to offer their covered population a general practitioner-focused care model (*Hausarztzentrierte Versorgung*, HzV); insured individuals who choose to voluntarily participate in their insurance provider's HzV commit themselves to visiting their general practitioner and only accessing specialist care with a referral from this general practitioner (BMG, 2020c). In return, for example, shorter waiting times are possible in practice. Exceptions to these access limitations include emergency treatment, gynecological care, pediatricians, and ophthalmologists. Almost 6 million patients in Germany choose their insurance provider's HzV option (Deutscher Hausärzteverband, 2020), although regional differences exist in the adoption of HzV programmes, with the state of Baden-Württemberg emerging as a leader in general practitioner-focused care models (Universitätsklinikum Heidelberg; Goethe-Universität Frankfurt am Main, 2018).

Cross-sectoral coordination of care and the promotion of new care models represent a problem area in the German health system, threatening sustainability in the domain of service delivery. The main cause of problems in this area is the strict separation of care sectors in Germany (Sachverständigenrat, 2018, p. 764). Inpatient and outpatient care is subject to different financing and provider remuneration systems and different regulations by various governance actors, complicating integration efforts. In recent years, several efforts to overcome this separation and establish new cross-sectoral care programmes have met with limited success.

Established in 2012, the outpatient specialist medical care programme (*Ambulante Spezialfachärztliche Versorgung*, ASV) is a novel care concept for the diagnosis and treatment of rare or complex diseases. While ASV has the potential to increase substitution of inpatient by outpatient services, high participation requirements and bureaucratic hurdles have led to a dearth of significant results (Korzilius & Osterloh, 2017).

Administrative burdens and regulatory rigidity have also hindered the decades-long effort by German health decision-makers to promote integrated care contracts (*Integrierte Versorgung*). In integrated care models, statutory health insurance providers and care providers from different sectors sign contracts allowing for the provision of cross-sectoral care, such as outpatient care being provided by hospitals. Although changes in relevant legislation sparked an increased interest in integrated care contracts in the mid-2000s, progress in this area remains unsatisfactory (Sachverständigenrat, 2018, p. 764). Recent efforts to promote integrated

care include the expansion of the programme to new types of contractual partners and the establishment of the *Innovationsfonds*, which has funded research into new care models with 225 million Euros annually between 2016 and 2019 (BMG, 2019b) and 160 million Euros annually starting in 2020.

The coordination of complex care across professional groups (and, for some diseases, across sectors) is the goal of Germany's Disease Management Programmes (DMPs). These programmes aim at coordinated care provision to patients suffering from specific chronic diseases, such as diabetes, breast cancer, or chronic back pain based on contracts between statutory health insurance providers and regional Associations of Statutory Health Insurance Physicians. However, the effectiveness of DMPs remains limited by the small number of indications for which DMPs exist (Sachverständigenrat, 2018, p. 765).

While there exists a national prevention conference, which develops and maintains a national prevention strategy, chronic disease prevention efforts in Germany are characterised by a wide array of responsible governmental and non-governmental actors with overlapping areas of responsibility at the federal, state, and local level. This leads to an uncoordinated patchwork of preventive services provided by hundreds of organisations and institutions (RKI; Destatis, 2015, pp. 242-243), which adversely affects sustainability in disease prevention. Due to the large number of actors involved in preventive care, this report will briefly outline a selection of the most important institutions: local public health authorities, the RKI, statutory health insurance providers and the BZgA.

A central role in disease prevention is afforded to local public health authorities, which fulfill duties in disease monitoring, diagnosis, and reporting. These local public health authorities cooperate with the federal RKI, especially with regards to disease reporting efforts. Statutory health insurance providers have an important role in financing prevention efforts: Since 2000, preventive care measures included in statutory insurance benefit schemes have been successively expanded by both legislative action and benefit expansion by individual insurance providers. Finally, the BZgA is the key creator and disseminator of health education and public messaging in the German health system, with responsibilities including sexual education, family planning, addiction prevention and health education for children, youth and the elderly, as well as messaging campaigns regarding organ, tissue and blood donations.

5.2 Service Delivery Resilience

Service delivery resilience in the German health system was affected by many of the same factors affecting resilience in other domains. As described in the financing section of this report, Germany's COVID-19 response efforts included the rapid expansion of hospital and ICU capacity. A key policy instrument in this expansion was the use of reserve funds to finance hospital bed space and intensive care capacities (BMG, 2020a).

Elective procedures were delayed due to COVID-19, although surprisingly effective cross-sectoral coordination allowed outpatient services to reduce the strain on inpatient care by handling many non-severe COVID-19 cases (Arentz & Wild, 2020, p. 21). Analysis of claims data from Germany's first lockdown in March and April 2020 has shown a 39% reduction in hospital cases compared to 2019 (WIdO, 2020). Although these reductions were stronger among elective treatments (79% reduction in arthrosis-related hip replacement surgery), emergency treatments also saw a significant reduction (31%, 18% and 37% reduction in the treatment of heart attacks, strokes and transient ischemic attacks, respectively).

5.3 Service Delivery Recommendations

Recommendation 5A: In order to strengthen the sustainability of service delivery in the German health system, decision-makers should consider structural reforms of the German hospital sector. In particular, hospital planning should be quality-oriented, with specialised treatment facilities focused on the delivery of high-quality care in their field replacing the current system of overwhelmingly general-purpose hospitals. Establishing procedures for the regional planning of cross-sectoral care using both fixed-capacity and activity-based criteria,

as opposed to planning strictly segregated by sector, could also contribute to a more sustainable planning landscape.

Recommendation 5B: Furthermore, integrated care models should be expanded in order to promote cross-sectoral care, a critical aspect of service delivery sustainability. As a first step in this direction, the *Sachverständigenrat* recommends the “authorisation of pharmacists as equivalent contractors in the context of integrated care models” (*Sachverständigenrat*, 2018, p. 765). The *Innovationsfonds* plays an important role in researching and promoting new care models. For this reason, it is critical that funding for the programme is sustained at sufficient levels beyond the current 2020-2024 funding period.

Recommendation 5C: Throughout the German health system, relevant actors and institutions should be empowered to use available quality data to monitor and control quality of care. This would require granting the IQTIG or another agency at least some enforcement powers. This strengthening of quality control mechanisms would represent an increase in service delivery sustainability.

Recommendation 5D: With regards to service delivery resilience, health decision-makers must aim for a reduction in non-emergency treatment while simultaneously guaranteeing the continued provision of sufficient levels of emergency care. While financial incentives to hold hospital capacity in reserve are important policy tools for a resilient pandemic response, policymakers must ensure that these incentives do not lead hospitals to reduce their care capacity for purely financial reasons; public health must be the primary motivator. Public messaging campaigns are another important tool for informing patients of both the risks of elective, non-urgent treatment during a pandemic and the importance of not neglecting their emergency care needs.

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Annex I. Case Study – Digitalisation

Context and Case Study Goals

Digitalisation in health systems has become a major focus for policymakers, industry and researchers in recent years. Moreover, the cost-effective use of digital health services and digital health infrastructure is a key property of sustainable health systems. Two types of digitalisation in particular are highly relevant to health system sustainability and resilience. These are the digitalisation of health system processes, such as the use of electronic patient records systems, and the digitalisation of healthcare provision.

This case study examines how the digitalisation of processes and care provision can contribute to health system sustainability and resilience, using as examples the German health system's upcoming introduction of an electronic patient record (*Elektronische Patientenakte*, ePA) as well as its use of remote patient consultations as a form of digital care. This question cuts across the five domains of sustainability and resilience used in the PHSSR pilot phase. As this case study considers the use of digital technology in organising and providing healthcare, its largest implications are for the domains of medicines & technology as well as service delivery. Increased efficiency and other potential savings strongly impact the financing domain. However, the governance domain significantly influences whether and how digital health programmes are adopted and implemented. Finally, digital health initiatives also have an impact on the duties of the health workforce.

Case Analysis

While the German health system has shown its willingness and ability to embrace the benefits of digitalisation with regards to billing, past progress on digital information systems has been limited. In particular, implementation of an electronic insurance card stalled prior to its planned introduction in 2006, with many of the card's features remaining unusable more than a decade later. However, recent legislative action has mandated the introduction of the ePA by statutory insurance providers starting in 2021 (BMG, 2019a), which will allow primary and secondary care providers to access important health and treatment information. The implementation of the ePA was delayed by German governance priorities. In particular, strict German data protection regulations have proven to be a significant obstacle to programmes such as the ePA, with debates between federal officials and statutory insurance providers about the ePA's conformity with federal and European data protection law (DAZ.online, 2020). Use of the ePA will remain optional to patients, who must choose to opt in to the programme.

Beyond enhancing sustainability in the medicines & technology domain, the ePA may also contribute to increased service delivery sustainability in several ways. In particular, this information exchange could improve coordination between different sectors and providers and lead to quality improvements through a reduction of therapeutic errors, drug-drug interactions and superfluous treatment (Bertram, Püschner, Gonçalves, Binder, & Amelung, 2019, pp. 4-6). Improved access to patients' treatment information may also allow primary care providers to take a more active role in care management for patients with multiple providers. Streamlining patient access to their own medical data and strengthening information transparency may also improve treatment adherence and trust in their treatment specifically and the health system in general.

Recent years have also seen new efforts by German health decision-makers to further digital care provision. Remote consultations were added to Germany's statutory insurance benefit scheme in 2017, allowing physicians to remotely examine, diagnose and treat patients with a variety of indications. While new digital healthcare tools have the potential to increase health system sustainability across domains by improving access and timeliness of care and creating additional treatment flexibility for patients and providers, they also bring important benefits for service delivery resilience. Remote consultations do not require physical contact between patients and providers, allowing care providers to maintain healthcare services during a pandemic. In fact, utilisation of remote consultations, which were rarely chosen by patients before the onset of the COVID-

19 pandemic (Gensorowsky, Surmann, Schmidt, & Greiner, in press), has risen dramatically in 2020, with many patients willing to continue using remote consultations after the pandemic has ended (Gerlof, 2020).

Furthermore, digitalisation of health system processes and healthcare provision are expected to bring significant economic benefits. In particular, the transition to unified electronic health records – digitally accessible to providers – and the use of online interaction between patients and providers, such as remote consultations, patient monitoring and E-triage are estimated to deliver up to 6.4 billion and 8.9 billion Euro in savings for the German health system (McKinsey, 2018), respectively, with a corresponding effect on the system's financing sustainability.

Germany is falling behind the curve in digital health (Thiel, et al., 2018). In response, the country has recently implemented a number of new health system digitalisation initiatives. The success of these initiatives depends on a number of factors. With regard to electronic patient records, German health system decision-makers must carefully balance the importance of data protection with the utility of the newly introduced ePA. For example, the ePA has enormous potential to not only streamline patient care across the health system, but also provide medical researchers with an unprecedented data set. Beyond data protection concerns, the ePA's effect on health system sustainability and resilience will depend on its utilisation level: if an insufficient number of patients choose to opt in to the programme, its benefits will not be fully realised. With regard to remote consultation, the question of utilisation levels also looms large. While many patients indicate they are open to using remote consultations, it is unclear whether utilisation of this option will remain sufficiently high after the conclusion of the COVID-19 pandemic.

Key Findings, Recommendations and Limitations

If successful, the German health system's recent efforts to digitalise health system processes and care provision through the creation of an electronic patient records system and the use of remote consultations will bring significant benefits for health system sustainability and resilience. Their success will depend on their ongoing implementation.

In order for the ePA to achieve sufficient utilisation, use of the system should be organised on an opt-out, rather than an opt-in basis, with patients automatically enrolled by their insurance provider unless they explicitly object. Furthermore, the ePA should be implemented in such a way as to allow researchers access to de-identified medical data. Looking beyond electronic medical records, the German health system cannot rely on ongoing pandemic shocks to drive patient demand for digital care. After the COVID-19 pandemic, decision-makers should therefore implement measures to incentivise and simplify the continued use of remote consultations.

This case study is, by nature of its brevity, limited in scope. The German health system is complex, as are the ongoing efforts to increase its level of digitalisation. Many of the efforts discussed here are extremely recent or not yet fully implemented. The purpose of this case study was therefore to provide a brief overview of new health system digitalisation initiatives in Germany and their potential to affect sustainability and resilience across various domains; further research will be needed in order to judge the extent to which the ePA and remote consultations have fulfilled this potential.

Future research will also be required into the effect of digital health applications (*Digitale Gesundheitsanwendungen*, DiGAs), which were added to Germany's statutory insurance benefit scheme in 2019. For example, web-based apps to treat anxiety or depression can be prescribed to patients and are financed directly by the sickness funds. While lower regulatory restrictions for reimbursement of DiGAs than for other therapies (like drugs) have been criticized, DiGAs represent an innovative digital care model whose efficacy should be continually evaluated.

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Annex II. Case Study – Rural Healthcare

Context and Case Study Goals

Regional disparities in access to healthcare and the existence of underserved, often rural, regions represent a serious threat to health system sustainability and resilience, with patients in underserved regions often unable to access quality care in a timely fashion. For example, rural patients may be at increased risk of cardiovascular disease if they are afforded insufficient access to screenings and preventive care due to a lack of general practitioners or cardiologists in their area. Consequently, optimising the location of health services delivery can make an important contribution to sustainability and resilience. While Germany currently does not suffer from a lack of physicians or general practitioners, demographic changes in both population of physicians and the general population threaten to create new issues in the upcoming years.

The purpose of this case study is to evaluate recent efforts by the German health system to improve access to timely, high-quality medical care in rural areas. The evaluated efforts include legislative and regulatory changes to the needs planning process and to instruments designed to address the over- or underprovision of care. The focus will be placed on outpatient care, and on general practitioners in particular. Several domains of sustainability and resilience are relevant to this line of inquiry. Specifically, the German health system's complex governance structure impacts the needs planning process and the implementation of other instruments, while the geographic distribution of outpatient physicians directly impacts sustainability and resilience in the domains of workforce and service delivery.

Case Analysis

Increasing the availability of timely, high-quality medical care in rural areas is a complex undertaking. Interlocking trends have caused increased movement toward urban centres by both the general population and physicians in particular: As more young people move away from rural communities and into larger cities, these areas become increasingly less attractive, including for (young) physicians. At the same time, the population remaining in these communities is older and more morbid, increasing demand for medical care while supply diminishes. Addressing these complex issues calls for a multi-pronged approach. This case study will focus on three important elements of such a strategy. These are: a needs planning process for physicians which sufficiently reflects rural care needs, instruments to incentivise the movement of physicians into underserved areas as well as instruments designed to disincentivise the movement of physicians to overserved areas.

Effective needs planning represents a key component of strategies to provide better care to rural regions. Outpatient planning in the German health system is mainly the responsibility of the regional Associations of Statutory Health Insurance Physicians (*Kassenärztliche Vereinigungen, KV*). The process is regulated by the Federal Joint Committee's Needs Planning Directive (*Bedarfsplanungsrichtlinie*), which creates a nationwide framework for regional planning efforts. Since 2012, significant changes have been made to the needs planning process in Germany, with the potential to increase health system sustainability and resilience. Whereas in the 1990s, needs planning was a mechanism designed to keep the rising number of doctors under control (Sundmacher, et al., 2018, p. 199), it is now a mechanism designed to distribute physicians to where they are most needed. To this effect, a 2013 revision of the Needs Planning Directive created four care levels, each with separate planning regions. These planning regions increase in size and decrease in number as care becomes more specialised. For general practitioners, this reform represented a significant increase in the number of planning regions and a move to smaller geographical subdivisions, which "far better matches actual health care needs" (Sachverständigenrat, 2014, p. 99).

Overall, changes to the Needs Planning Directive since 2012 have significantly reformed the needs planning process in Germany, with uniform federal planning standards supplemented by mechanisms to strengthen regional flexibility, such as adjustments for regional morbidity or demographics (G-BA, 2017). These post-2012

reforms represent steps toward reducing regional inequality in access to healthcare, potentially increasing health system sustainability.

The needs planning process is supplemented by instruments designed to reduce the number of under- and overserved regions. For underserved regions, these include financial incentives (Sundmacher, et al., 2018, pp. 193-194) such as service guarantee fees or revenue guarantees. Additionally, hospitals in underserved regions can be empowered to take up outpatient care responsibilities on a case-by-case basis. Alternatively, statutory insurance providers and local governments can operate their own care facilities. Finally, a new structural fund (*Strukturfonds*), which is jointly financed by the regional Associations of Statutory Health Insurance Providers and Physicians, aims to provide financial support for the establishment of new physicians' practices in regions that are underserved or at risk of becoming so.

Beyond these efforts to motivate existing physicians to establish practices in underserved regions, new measures have been implemented to increase the number of medical students who will become general practitioners in these regions after their medical education is complete. One such measure is the *Landarztquote*, which would allow privileged access to medical education for students who agree to provide care in a rural area for a certain duration (Martini & Ziekow, 2015, p. 18). North Rhine-Westphalia became the first state to use a *Landarztquote* in 2019 (Ministerium für Arbeit, Gesundheit und Soziales des Landes Nordrhein-Westfalen, 2019), and several other German states have decided to implement or are considering implementing the programme. While there are legal and constitutional questions about the feasibility of such a scheme, a 2015 report commissioned by the Federal Ministry of Health found that it could be implemented in permissible ways (Martini & Ziekow, 2015, pp. 209-214). Furthermore, general medicine has become a stronger focus of both academic and practical components of medical education in Germany (BMBF, 2017), including expanded internships for medical students in rural general practitioners' practices. These educational reforms aim to contribute to the movement of new physicians to underserved rural areas.

However, a focus only on underserved regions is insufficient. In order to minimise regional disparities, providers must also be incentivised to leave or avoid moving to overserved regions. Several instruments are available to achieve this. In particular, the process of replacing retiring outpatient physicians has been reformed, with replacements limited to case-by-case exceptions in overserved regions (Busse, Blümel, & Spranger, 2017, pp. 249, 254). Additionally, financial incentives and regulatory instruments are available in order to close existing practices in overserved regions. In general, physicians may not settle in overserved regions without being granted case-by-case exemptions.

For a number of reasons, there has been little improvement in the number of general practitioner planning regions with inadequate provision levels since despite these reforms to the needs planning process and to instruments combatting under- and overprovision. First, the revised Needs Planning Directive did not have the anticipated effect of increasing the number of physician practices and accreditations nationwide. Instead, "the total number of practices decreased under the new Directive across all four care levels" (Sachverständigenrat, 2014, p. 100).

Furthermore, instruments to combat over- and underprovision have seen insufficient use. With regard to overserved regions, financial incentives for the voluntary relinquishment of practices proved mostly ineffective, while revised rules establishing that newly vacant practices in severely overserved regions shall be bought back by the responsible KV have rarely been used in practice. In underserved regions, financial incentives played "only a marginal role" (Sachverständigenrat, 2014, p. 104) as of 2014. At the same time, practices owned by regional associations or local governments remained rare. The insufficient use of these instruments was compounded by non-uniform definitions and determinations of which regions were at risk of becoming underserved.

However, a more fundamental deficit adversely affected needs planning in the German health system. In particular, the target values that form the basis of the Needs Planning Directive were not based on objective

analyses or estimations of medical need, but rather on historical data at certain dates (mostly from the 1990s), insufficiently adjusted to actual population morbidity (Sundmacher, et al., 2018, p. 138). This leads to a planning process that is not sufficiently aligned with actual population medical need.

Key Findings, Recommendations and Limitations

Major legislative and regulatory reforms as well as the introduction of new instruments to combat under- and overprovision of care since 2012 represent an important step toward health system sustainability and resilience in Germany by aiming to reduce regional disparities and ensure timely access to quality healthcare for the entire population. However, these reforms were limited in their overall effectiveness by the sparse use of available instruments and by fundamental flaws in the needs planning process, such as in the definition of target values.

In response, 2018 reports by the advisory council (*Sachverständigenrat*) and the Federal Joint Committee called for important reforms, including to the needs planning process. These recommendations (Sundmacher, et al., 2018, pp. 201-203; *Sachverständigenrat*, 2018, p. 99) include smaller, more homogenous planning regions and a national monitoring of instrument usage and effects. Perhaps more importantly, the reports call for a stronger focus on actual morbidity and a reform of the system of target values based on historical data. This is highly relevant to health system sustainability, as the current target values do not match true population need. The recommended shift to cross-sectoral planning would also represent an important step towards sustainability and resilience, especially in the governance domain. Finally, the recommended establishment of a prospective planning process, including medical education and anticipated physician retirements, would substantially improve the German needs planning process and allow the better integration of needs planning and other instruments focused on education.

In 2019, the Federal Joint Committee completed a revision of the Needs Planning Directive called for in the GKV-VSG. While much remains to be done (such as increased cross-sectoral planning), this revision implemented many of the above recommendations, changed the way target values are calculated, increased regional flexibility in needs planning and created new instruments to combat over- and underprovision of care. Further research will be necessary to evaluate the effect of both these reforms and other recently introduced instruments discussed in this case study.

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