



Implementing Electronic Health Records in Germany: Lessons (Yet to Be) Learned

POLICY PAPER

TUGCE SCHMITT 

 ubiquity press

ABSTRACT

Introduction: Ensuring access to the right information at the right time can improve the safety, effectiveness and efficiency of care. A systematic and detailed collection of patient records, commonly known as electronic health records (EHRs), forms the core of the information system architecture in integrated health systems.

Description: Since January 2021, seventeen years after the German legislation to implement EHRs (*elektronische Patientenakte*; ePA) came into force, the sickness funds in Germany have been offering their enrollees a downloadable application with which patients can access their personal EHRs through an electronic device. Looking at the ePA adoption process, it is now safe to argue that the deployment has been anything but successful. After two years of the launch, the number of ePA users amounts to not even 1% of the insured population in Germany, failing to move the needle on integrated care and health data integration. Based on a public policy theory, this article analyses the factors that are influencing the ePA implementation and secondary use of ePA data.

Discussion: As the German experience shows, the feasibility of digital health projects depends on several contextual factors: countries with a high degree of self-governance and federal structures have to manage complex coordination processes that often slow down or otherwise impede digitalisation processes. In addition, cultural peculiarities such as concerns about data protection and security can be a hindering factor for digitalisation. Whereas the new German government and European initiatives such as the European Health Data Space (EHDS) create an advantageous situation for the ePA implementation and secondary use of health data, the structural and cultural issues in Germany should be acknowledged and tackled.

Conclusion: Concerning the structural factors, a further reorganisation of the board of *gematik*, the key organisation of digital health solutions in Germany, should be considered. Cultural factors in Germany affect especially the secondary use of data; organising information campaigns, investing in (digital) health literacy of the population and designing a user-friendly ePA application are central in this context.

CORRESPONDING AUTHOR:

Tugce Schmitt

Hertie School, Berlin, Germany;
Department of International
Health, Care and Public Health
Research Institute – CAPHRI,
Faculty of Health, Medicine
and Life Sciences, Maastricht
University, Maastricht, The
Netherlands

t.schmitt@
maastrichtuniversity.nl

KEYWORDS:

electronic health records;
innovation uptake; health data
governance; integrated care;
data integration; national
health system; Germany

SCHLÜSSELWÖRTER:

Elektronische Patientenakte;
Akzeptanz von
Innovationen; Verwaltung
von Gesundheitsdaten;
Integrierte Versorgung;
Datenintegration; Nationales
Gesundheitssystem;
Deutschland

TO CITE THIS ARTICLE:

Schmitt T. Implementing
Electronic Health Records in
Germany: Lessons (Yet to Be)
Learned. *International Journal
of Integrated Care*, 2023;
23(1): 13, 1–13. DOI: [https://
doi.org/10.5334/ijic.6578](https://doi.org/10.5334/ijic.6578)

ZUSAMMENFASSUNG

Einleitung: Der Zugang zu den richtigen Informationen zur richtigen Zeit kann die Sicherheit, Wirksamkeit und Effizienz der Gesundheitsversorgung verbessern. Eine systematische und detaillierte Sammlung von Patientenakten, bekannt als *Electronic Health Records* (EHRs), bildet den Kern der Informationssystemarchitektur in integrierten Gesundheitssystemen.

Beschreibung: Seit Januar 2021, siebzehn Jahre nach Inkrafttreten der deutschen Gesetzgebung zur Einführung der elektronischen Patientenakte (ePA), bieten die Krankenkassen eine zum Download verfügbare Anwendung an, mit der Patienten über ein elektronisches Gerät auf ihre persönliche elektronische Patientenakte zugreifen können; bisher jedoch mit wenig Erfolg. Zwei Jahre nach der Inbetriebnahme beläuft sich die Zahl der ePA-Nutzer auf weniger als 1 % der gesetzlich versicherten Bevölkerung in Deutschland; es ist also nicht gelungen, die integrierte Versorgung und Datenintegration voranzutreiben. Basierend auf einer politikwissenschaftlichen Theorie, werden in dieser Studie Faktoren analysiert, welche die ePA-Einführung und die sekundäre Nutzung von ePA-Daten beeinflussen.

Diskussion: Wie die Erfahrungen mit der ePA in Deutschland zeigen, hängt die Umsetzbarkeit digitaler Gesundheitsprojekte von einer Vielzahl von kontextuellen Faktoren ab: Länder mit einem hohen Maß an Selbstverwaltung und föderalen Strukturen müssen komplexe Koordinationsprozesse bewältigen, die den Digitalisierungsprozess oft verlangsamen oder anderweitig behindern. Darüber hinaus können kulturelle Eigenheiten wie Datenschutz- und Sicherheitsbedenken die Digitalisierung behindern. Obwohl die neue Bundesregierung und europäische Initiativen, wie der Europäische Gesundheitsdatenraum (*European Health Data Space*; EHDS), die ePA-Implementierung und die Sekundärnutzung von Gesundheitsdaten begünstigen, sollten strukturelle und kulturelle Probleme in Deutschland berücksichtigt und angegangen werden.

Schlussfolgerung: Im Hinblick auf die strukturellen Faktoren sollte eine weitere Umstrukturierung der *gematik*, des wichtigsten Entscheidungsorgans für digitale Gesundheitslösungen in Deutschland, in Betracht gezogen werden. Kulturelle Faktoren in Deutschland beeinflussen vor allem die Sekundärnutzung von Daten; in diesem Zusammenhang sind das Organisieren von Informationskampagnen, die Förderung der (digitalen) Gesundheitskompetenz der Bevölkerung und die Gestaltung einer nutzerfreundlichen ePA-Anwendung von zentraler Bedeutung.

INTRODUCTION

INTEGRATED CARE, INTEGRATED DATA

Health data integration is an essential part of almost any integrated care project today, as it has become the cornerstone of virtually every comprehensive attempt to establish an integrated health system [1]. Aiming at improving the quality and safety of health services, integrated care can be best described as an approach to overcome healthcare fragmentations [2]. In this line of thought, the systems that enable a continuum of care should include data structures that can link patients' health information over time [3]. Interlinking the relevant parts of patient data and supporting the continuity of medical information through shared records enable delivering the right treatment at the right time [4]. The accumulation of information across time, location

and sectors creates an uninterrupted patient journey, contributing to a more integrated health system and saving costs at a similar or better quality of care [3, 5].

Indeed, ensuring access to the right information at the right time improves the safety, effectiveness and efficiency of care [6]. In highly fragmented health systems, information transfer between in-patient and out-patient care sectors is vulnerable to leaks and failures at their interfaces; a vulnerability that can be overcome by integrating and securing the flow of health data [7]. By connecting relevant data across sectors, not only clinical services but also public health measures can be optimised. Using the available, yet administratively isolated or dispersed sets of data in a meaningful way can provide relevant insights for more effective treatment programmes and prevention measures at the population level, e.g. when monitoring disease outbreaks. For this

reason, increasingly more health systems are taking advantage of the benefits of digitalisation and integrate data linkage into their public health surveillance activities [8].

A systematic and detailed collection of patient records, commonly known as electronic health records (EHRs), forms the core of the information system architecture in integrated health systems [9]. An EHR is a digital, longitudinal patient record that is available to healthcare professionals across a range of settings [10]. By enabling the flow of information between healthcare professionals, EHRs help improve the coordination of care, avoid complications and unnecessary hospitalisations, and increase cost-effectiveness [11], alongside contributing to guiding the clinical decisions of healthcare providers regarding diagnosis, management and treatment [12]. With the help of EHRs, patients' up-to-date medication history and past interventions can be made available to healthcare professionals, enabling them to be informed about the prescriptions issued by their colleagues and recognise preventable adverse interactions and mortality risks [13, 14].

According to the World Health Organization (WHO), EHRs play a vital role in supporting the diagnosis and treatment of patients through the provision of rapid, comprehensive and timely clinical information at the point of care [15]. Indeed, using EHRs is deemed even a prerequisite for high-quality care, as it is impractical and unrealistic to expect that patients can be the primary source of their complete and accurate health history for each new provider at each new point of contact [3]. This is even more so for emergency patients, elderly with specific diseases such as dementia, and those with complex care needs. Multi-morbid patients are typically treated by different medical specialists in varying healthcare facilities, and it is particularly for this reason essential to apply an integrated approach to treat them successfully [16]. EHRs support healthcare professionals in providing the right treatment at the right time by capturing patients' health history and information about past interventions, enabling a better coordination between specialised medical professions [3, 14]. With the availability of data on patient history across sectors, the quantity of medical interventions decreases whereas their quality should increase [17].

Apart from enabling better coordinated health service provision, EHRs are a valuable source of data that can improve the quality of health services and public health interventions [18]. Indeed, from a societal perspective a greater long-term benefit of EHRs is the information they can provide for population health research, and for planning, executing and evaluating policy interventions (secondary use or re-use of health data) [4]. Through increased data quality (higher accuracy, completeness, consistency, uniqueness, timeliness and reliability) and improved access to relevant information, EHR systems

can contribute to better health services and policies. Combined with other datasets, aggregated clinical data from EHRs can build the basis for evidence-informed health policies that benefit the society as a whole [19]; understanding the determinants of ill-health, planning of health workforce and efficiently monitoring of disease outbreaks, to name but a few examples. In this way, robust Health Information Systems (HIS) can be established at the national level for the benefit of (healthy) citizens and patients [20]. With the help of HIS, decision-makers can monitor, evaluate and improve health system performance, and make timely, evidence-informed decisions [21].

CONTEXTUAL FACTORS AFFECTING THE USE AND RE-USE OF HEALTH DATA IN GERMANY

When it comes to the integration of health services, Germany ranks at the bottom in international comparisons [22]. This is mainly because the sectors concerned with providing health services in Germany are financed, organised and governed in isolated administrative silos, providing minimal incentives for vertical integration, i.e. better coordination between primary and secondary care levels [23, 24, 25]. This fragmented and uncoordinated health service provision leads to inefficiencies, diminished quality of care and high rates of patient admission [25]. In accordance with the disconnected health services working in silos, also health data are scattered across different administrative levels in Germany, exacerbating the pitfalls of its fragmented system [23]. Isolated datasets make a realistic assessment of the health system performance difficult and create a vicious cycle by hampering any improvement or optimisation of the health system and limiting the potential effectiveness of efforts to move towards integrated care [3, 26].

Against the background discussed above, Germany could have (and considering the drawbacks of its highly fragmented health system, should have) started working towards integrated, person-centred and preventive care with the help of EHRs. Yet for more than a decade, the implementation of a cross-sectoral, nationwide EHR system has been stagnating within this fragmented field. Offering a scheme for (health) policy analysis, Leichter [27] orders the factors influencing public policies into four different areas in his work that has been seminal in the health policy literature [28]: i) *situational* factors refer to impermanent events such as political reform or change of the government; ii) *environmental* factors are those that exist outside the boundaries of a political system such as international agreements, obligations and pressures; iii) *structural* factors, in contrast, are concerned with the unchanging elements of the society and polity such as political structure that covers e.g. form of government, and the number, strength and legitimacy of interest groups; and lastly iv) *cultural* factors encompass, among others, national heritage and traditional social values.

As will be discussed below in detail, whereas the situational and environmental factors have pushed the agenda forward for integrated care and health data integration over the past few years (national health policies and international commitments such as European Health Data Space; EHDS), structural and cultural factors in Germany build obstacles in the primary and secondary use of ePA data.

To start with, one of the major structural issues impeding the successful implementation of ePA has been the role of the Federal Ministry of Health (MoH) during this process. Traditionally, the financing of Statutory Health Insurance (SHI) in Germany is decoupled from the federal budget, and government control measures in the health system are only indirectly possible [29]. Although recent developments have redrawn the political boundaries between the government and self-governance with increasing state intervention (especially since the early 2000s the regulatory interventions from MoH have considerably increased), the role of the federal government in health policies is mainly concerned with providing framework conditions and laws [30]. Most notably, while decisions on in-patient and out-patient care are taken at the federal level, the government itself is by law not involved in these negotiations [23]. The right to make decisions about medical care and the regulation of essential performance parameters on quality and efficiency lies with the actors of self-governing bodies of the SHI system; namely the sickness funds and representative organisations of healthcare providers at the Federal Joint Committee, in which power is concentrated. Similarly, the initial governance structure of *gematik*, the operating company for telematics infrastructure for the German health system, had been composed of the self-governing bodies of healthcare providers and sickness funds with equal ownership and voting rights at the time of its foundation in 2005 until its reorganisation in 2019. The principle of self-governance, combined with the federal government's (limited) competency in the field of healthcare provision and the lack of an overarching framework to force the commercial healthcare industry to deliver the necessary telematics infrastructure resulted in a delayed ePA roll-out that could take place no earlier than 2021 [13].

Especially the self-governance of healthcare providers played a great role in this delay and represented their interests at the federal level by resisting progress in the EHRs project [31], blocking its implementation [32] and stating that they otherwise would refuse to provide health services [33]. The main reason for these actions can be sought in theories on coalitions and interest representation. Drawing on the findings of Alford from 1975 on ideological and interest group barriers to reform in healthcare politics, Döhler [29] argues that one of the interest coalition structures in healthcare is formed

around market-shaped health policymaking; however, here 'the market' does not indicate the involvement of private industry but rather the lack of government involvement. This situation leaves the stage wide open for monopolists of the medical profession who aim to preserve their autonomy and fill the political vacuum, creating a challenging situation for other actors such as the public health administration, academia or health insurers. While these stakeholders may not necessarily oppose 'the market' dominated by the professional monopolists, they might endanger the autonomy of the medical profession that desires sovereignty and greater control over the healthcare sector. Hence, health policy decisions in Germany are mainly determined by the conflict between those two groups (monopolists of the medical profession vs. others), which results in blocking reform and maintaining the privileged *status quo*. Similarly, the stagnation of ePA roll-out was the reflection of a severe deadlock, as the main stakeholders of the self-governance model (medical associations and sickness funds) failed to reach an agreement at *gematik* for almost 15 years.

INTRODUCING EHRs IN GERMANY

As long as the self-administrative bodies had the institutional resources to block change, the ePA project stalled. Eventually, the Federal Audit Office published in 2019 a detailed inspection report on *gematik*, disclosing inefficiencies in its functioning since 2005 and calling for a top-down decision-making process within the organisation, to be managed by MoH [34]. Following this decision, *gematik* was authorised to make resolutions with a simple majority, and MoH obtained the controlling ownership of *gematik* with 51% voting rights in the board structure in the same year, allowing it to take decisions against self-governing bodies whose voting power shrank to 49% altogether. Although this power shift from self-governance to state administration was very controversial at the time, the then Health Minister, Jens Spahn, who also established a digitalisation department within the ministry, defended this step by stating that the *gematik*'s initial decision-making structure had been the main reason for digital health projects not moving forward for more than a decade [35]. In the second half of 2020, during Germany's Presidency of the Council of the European Union (EU), Spahn put also the EHDS high on the agenda to facilitate the use and re-use of health data not only within the country but also across the EU [36]. Arguably, this timely political move created a supportive environmental factor that offered a counterbalance to the existing structural factors in Germany (dominance of self-governing bodies in the field of integrated care and data sharing) affecting the implementation of ePA.

With MoH in the driver's seat of *gematik*, 17 years after the legislation to implement EHRs came into force (SHI Modernisation Act, 2004), sickness funds could finally in January 2021 start offering their enrollees a downloadable application with which patients can access their personal EHRs through an electronic device, obliging all the sickness funds to issue an ePA to their enrollees upon their request [37]. After successful registration through sickness funds, patients gained the chance to manage their ePA by downloading a mobile application on their personal devices via ePA-App that mirrors the EHRs of individuals, with each sickness fund offering its own ePA-App [38, 39]. By providing patients with the opportunity to share their medical data (e.g. diagnoses, performed therapy measures and treatment reports, medication plans) with their physicians, hospitals and pharmacies, ePA has had a great potential to build the backbone of a person-centred health system in Germany [40]. The use of ePA has been made voluntary for SHI-enrollees with an opt-in method [41].

However, looking at the first two years of the ePA adoption process, it is now safe to argue that the deployment has been anything but successful. Notably, implementing a cross-sectoral, longitudinal and nationwide EHR system can indeed overcome the drawbacks of Germany's highly fragmented healthcare sector. Done well, this long-awaited innovation can be the key instrument to shift the focus from curing illnesses to providing patient-centred care and prevention. Yet, making an innovation available to the public is not equal to its implementation in practice, as it has been once again proven in the case of ePA. As of January 2023, after two years of the launch, the number of ePA users amounts to little more than 594,000 [42], i.e. not even 1% of the SHI-insured persons in Germany, failing to move the needle on integrated care and health data integration. Apart from being a consequence of an opt-in consent policy, this low coverage can be explained by a poor deployment strategy.

In ePA, access to patients' data by healthcare providers is currently restricted and time-limited by default; only patients themselves can choose which health professionals should have access to their ePA and for how long. Patients have, moreover, full control over their own data; they decide which medical data should be stored or deleted [18]. However, in the launch year of ePA patients could share their data with healthcare professionals either completely or not at all, following an all-or-nothing approach. Hence, once the patient authorised a healthcare provider to access their ePA, the provider could gain a complete overview of the patient's medical data, however confidential, sensitive or irrelevant those might be to the actual treatment. Potentially, this lack of granular control had a negative influence on patients' willingness to share their data with healthcare providers [43], or even to apply for ePA. Bringing granularity to

ePA so that the medical information could be shared selectively with health professionals was made possible only in 2022, thus addressing one of the main critique points of the Federal Commissioner for Data Protection on ePA [40].

Another major technical issue was concerned with the interoperability of ePA data; lacking international standards in ePA specification caused short-sightedness that should have been avoided for better scalability and exchange of medical data, not only within but also beyond the country's borders [44]. Interoperability, which is the ability to exchange and make use of information, constitutes the backbone of cross-border digital public services across Europe [45]. To achieve an integrated health information system at the EU level, a collaborative action from member states towards harmonising their legal, organisational, semantic and technical interoperability is necessary [46]. Advancements in information and communications technology are an essential component to reach this aim, as technology provides compatible digital solutions that can eventually serve as the platforms to save and share necessary data [3]. However, it is now known that the main drivers to build an EU-wide health information system are concerned with less tangible aspects. A comprehensive assessment of member states' rules on health data in the light of the EU General Data Protection Regulation (GDPR) has unveiled that diverse organisational and legal obstacles specific to national circumstances are much harder to overcome than those related to technical and semantic barriers [47].

Indeed, research shows that EHR projects focus too heavily on technology, although factors such as acceptance, change management and roll-out strategy are at least as important for their implementation [48]. In addition to technical issues, other drawbacks relating to the application process pointed towards room for improvement in the launch of ePA. Having followed an opt-in approach, the implementation required action on the part of SHI-enrollees to confer their consent. Hence, sickness funds were allowed to enable patients' access to ePA only at their request. An additional hurdle that made the uptake of ePA even more difficult was the rather problematic application process. Instead of having been offered incentives to use ePA and benefiting from a low-threshold application process, motivated enrollees could obtain ePA only after several cumbersome security-related validation steps [18], and some sickness funds even required patients to visit their local offices in person to process their application [49]. Given the lockdowns and social distancing measures during the Covid-19 pandemic, such approaches were not particularly helpful in efforts to increase the number of SHI-enrollees to apply for ePA. Physicians, on the other hand, defended that it should not be the responsibility of healthcare staff to inform their patients about the use of EHRs.

Lastly, no public information campaign has been launched to raise awareness about ePA. The information service of the sickness funds has varied in depth and breadth, and online resources about the use of ePA have been scattered among a range of federal-level institutions. For instance, a service portal of MoH, *gesund.bund.de*, aims to provide reliable and comprehensible health-related knowledge, serving to promote citizens' health literacy and self-determination. To this end, *gesund.bund.de* publishes information on health topics, disease patterns and treatment options based on selected scientific and evidence-based sources, covering also digital health topics such as ePA [50]. While informing the public on the use of ePA is a laudable step, information on the website is far from sufficient to raise awareness about the use of ePA and increase buy-in from the public. A second institution, *gematik*, publishes also up-to-date information on ePA and organises webinars on this topic [51]. Although their services address both patients and providers, the focus of the site's activities lies rather in updating healthcare providers on ePA-related developments. Another institution, Independent Patient Counselling Service (*Unabhängige Patientenberatung Deutschland*; UPD), informs patients about ePA and answers questions via a help desk. However, arguably, a website and remote assistance fall short in motivating a large number of people to apply for ePA in the first place [52].

One of the best practices that could have been applied in this context is the information campaigns to mitigate the effects of Covid-19 in Germany. The federal government made substantial efforts in many languages to raise awareness about the Corona-Warn-App, a mobile application based on open source and a decentralised approach to help users determine whether they had any contact with an infected person [53]. A webpage of MoH serves as a one-stop shop for all sources of knowledge on this topic [54]. Although the ePA roll-out may not have the same level of public concern as tackling a once-in-a-century pandemic, the activities conducted for the latter could have served as a blueprint for the former. Ideally, one single institution should have taken on the responsibility of generating awareness about the benefits of ePA among the public. Information campaigns could have been organised, for instance through the Federal Centre for Health Education (*Bundeszentrale für gesundheitliche Aufklärung*; BZgA), and tailored to specific population groups whose expectations may vary by socio-demographic characteristics [55].

LESSONS (YET TO BE) LEARNED

IMPLEMENTATION OF EHRs

With the new coalition government in Germany since December 2021, the uptake of ePA may gather pace. As

stated under the heading 'Digitalisation in healthcare' of the coalition agreement, the governing parties seek to accelerate implementation with a GDPR-compliant opt-out approach [56]. The experiences of neighbouring countries suggest that the opt-out model is a more straightforward way to tackle problems resulting from the systemic fragmentation of the German health system [57]. For instance, in France, only 20% of the population was linked to an EHR even 13 years after its introduction, which is the reason why France too decided to adopt an opt-out model from 2022 onwards [58]. A different example of an EHR introduction experience can be drawn from Austria; a country that adopted an opt-out policy from the outset. Today, in contrast to the French 97% of Austrians use EHRs, which include information about discharge letters, laboratory results, out-patient medications, e-prescriptions and medication allergies [18]. Indeed, given that a considerable number of countries in Europe have a higher level of digitalisation and data integration in their health systems than Germany [59], it might be helpful to focus on the 'software' (governance, stakeholder interests) instead of 'hardware' (financial affordability, technological advancement) components when discussing the adoption of ePA. In this context, the Austrian case is worth exploring, not only because of its preferred implementation approach (opt-out) but also because of its cultural and structural similarity to Germany.

In the beginning, similar to France and Germany, the idea of using EHRs led to some anxiety among Austrian physicians relating to the additional workload and cost burden [60], besides increased transparency, cost pressure and reduced confidentiality of patient data [31]. Criticism was raised especially by the Austrian Medical Chamber and data protection advocates [61]. In their comprehensive study comparing EHR deployment in Austria and Germany, Bogumil-Uçan and Klenk [61] offer two explanations for why those voices could not gain the upper hand in policy discussions. The first reason is the dominance of the Austrian hospital sector in a more integrated governance structure. Unlike Germany, healthcare provision in Austria is strongly focused on hospital care, making the conflict about fragmented vs. integrated care less pronounced. Through ambulatory pre- and post-hospital treatments in out-patient clinics, the in-patient and out-patient care sectors are better integrated in Austria than in Germany. Moreover, since many salaried physicians in Austrian hospitals also work as specialists in out-patient care, it is assumed that they were even in favour of the implementation of EHRs as a result of their experiences with digital health applications in hospitals. The authors' second reason is that due to the pre-eminence of state actors in the hospital sector, the dominance of the in-patient sector in healthcare provision and the greater organisational integration of sickness funds, the main players in the Austrian

health systems are the federal government, regional governments and the Social Insurance Association. They thus have a structural advantage over healthcare providers in influencing policy decisions, including the adoption of EHRs. Unlike in Germany, where the self-governing bodies of healthcare providers had veto power in *gematik* to stall the roll-out of ePA, healthcare providers in Austria were not even included in the decisions of ELGA Limited Liability Company, owned by the ‘main players’, all of them being in favour of a comprehensive, nationwide EHR system from the outset.

Although suggesting the same ‘main player’ structure for taking decisions on ePA would be overly ambitious, Germany could bring more stakeholders to *gematik* and tilt the balance of power in favour of the end users of ePA. For instance, the plans of the Coalition about accelerating the decisions of the self-governing bodies and strengthening patient representation with a reform of the Federal Joint Committee (stated under the heading ‘Patients’ rights’ in the coalition agreement) are praiseworthy and in line with international recommendations for designing policies to deliver people-centred health [62]. Yet, patient participation should be expanded to other relevant key organisations beyond the Federal Joint Committee, such as *gematik*, i.e. the new digital health agency. Patients, and in general insured persons, are ultimately the end users of crucial health innovations in the SHI system, including EHRs. It is important that patients, especially those that are multi-morbid and chronically ill, should be able to work with such technologies. Therefore, patient representation should be an inherent component in the overall strategy for digitalisation in healthcare. Indeed, giving decision-making power to patients and citizens can be an even more effective approach in digital health projects than a top-down governance intervention from MoH to self-governing bodies [63].

SECONDARY USE OF EHR DATA

Thus far in Germany, only billing data from sickness funds have been used for health services research, available only with a considerable time delay and financial resources [59, 64]. Starting from 2023, it will be possible for patients to make their ePA data available to an authorised data custodian, subject to their informed consent. Patients will be able to choose the scope of their ePA data to be shared with the authorised centre and have the option to limit the data to certain categories, datasets and specific areas of scientific research; these data are then to be pseudonymised and encrypted by the centre [65]. The research data centre of the Federal Institute for Drugs and Medical Devices (*Forschungsdatenzentrum Gesundheit, Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM*) will serve as a research hub for ePA data for which patients in Germany grant access [47].

The national data-sharing policy to this end requires confirmation by insured persons to enable the use of their ePA data for research purposes (opt-in). Currently, claims data are being transferred automatically to the BfArM, and based on these data, the use of synthetic data (i.e. data artificially created through different algorithms that can mirror the statistical properties of the original data) is being tested to determine the optimal care through Artificial Intelligence (AI) solutions [66]. With an opt-in approach, the ePA data volume will be too low to create synthetic data and develop AI-supported solutions. Although good coverage across the entire population is essential in population health research to ensure that findings from the collected data are accurate, unbiased and representative, with an opt-in model, only the most engaged people who actively take steps to participate will be included in the data pool, restricting the chances of developing effective strategies for health at the population level [67].

Hence, considering the magnitude of data to be pooled and analysed, the opt-in requirement for the secondary use of health data will highly likely have a negative impact on the size and representativeness of the ePA data. A fictional example of this drawback is the following: in the case that 90% of the SHI-insured people in Germany choose to keep their ePA (opt-out) and 10% of those give consent for the re-use of their data for population health research (opt-in), the ePA data available for research will comprise only 9% of the SHI-insured population. Thus, the data collected may not represent the whole population accurately, making it challenging to develop evidence-based health policies at scale and draw lessons for improved clinical and prevention services. Similarly, although the right to delete ePA data may appear at a first glance to contribute to patient empowerment, it is not a good long-term strategy given the potential loss of valuable data that could be used in their clinical treatments or population health research. An integrated, person-centred and preventive health system should give equal importance to individual privacy and public health. Hence, a better approach to re-using ePA data could be to adopt an opt-out policy where patients can share their (pseudonymised) data for research unless they object, in line with the GDPR. Based on Art. 9(2) GDPR, EHR data in member states can even be collected for research purposes without any consent requirement and objection right as a standard policy when certain requirements are met [18].

However, an automated data transfer for the secondary use of ePA data might be politically difficult to introduce in Germany, a country where data security concerns are significant [68]. Indeed, the recommendations of the upper house (*Bundesrat*) to the Federal Government concerning Germany’s positioning on EHDS from September 2022, which included disapproval of some

parts of the secondary use of health data in EHDS, indicate a rather cautious approach to data transfer [69]. In Germany, national data protection regulations are highly developed, hindering cross-sectoral data exchange and integrated care. For instance, there is no unique personal identification number that could allow cross-sectoral linkages in the German social security system, and a linkage between different datasets that contain personal information is only permitted with the prior consent of the person concerned [18]. Part of the reason lies in the culture and motives that are rooted in history. Data collection on and surveillance of citizens during the Nazi era and later the Soviet era left the country with deep scepticism of any action that seeks to gather personal data [70]. In the aftermath, the governmental system was rebuilt to ensure that numerous people and institutions have access to a wide variety of information, but no single actor to all information about one person [71]. Understandably, most Germans today show conservative and protectionist behaviour when it comes to automatic data collection or transfer.

On the other hand, developing health policies without taking advantage of the insights that ePA data might offer will highly likely exacerbate the fragmentation issue that Germany is facing. Working through the variety and complexity of social, environmental and individual factors that can shed light on the causes of diseases might require too much time on the part of patients, especially if they belong to older age groups, are multi-morbid and have lower levels of (digital) health literacy. In an opt-in policy for the re-use of ePA data, patients should actively seek information, first, to decide whether to give consent to share their data and, second, to choose which datasets could eventually serve the purpose. An opt-out approach with necessary information provided to patients would simplify this process and ensure a nearly population-level data collection, respecting at the same time informational self-determination of citizens, which is a constitutional fundamental right in Germany [12]. This step would be especially crucial if the interlinkages and causal connections for preventive measures could be identified not with human intellect but with AI through large amounts of information.

Still, in the case that the current opt-in policy for the secondary use of ePA data remains unchanged, it should be accompanied by several measures to increase the number of people sharing their data. Culturally embedded concerns regarding data privacy are understandable and might be difficult to overcome in Germany due to damaging experiences in its history. To convince the public of the benefits of sharing ePA data, massive educational and information campaigns will be necessary. In this context, the role of the mainstream media should not be underestimated. At best, journalists become partners in informing the public regarding the benefits (and risks) of the secondary use of health data. At

worst, they take the advantage of the public's underlying fears about data privacy in order to attract viewers or readers. Bold political moves that could challenge the entrenched national reflex to protect data might risk disapproval from the mass media that has the power to amplify anxiety, as was the case in France during the EHR deployment process [72]. Under these circumstances, the strategic organisation of federal-level information campaigns will be crucial, not despite but because of the risk of being perceived as negligent regarding citizens' data privacy concerns.

For the secondary use of health data, if organising educational and information campaigns is one side of the coin, ensuring a high level of information literacy and trust of citizens on health matters is the other. Information literacy can be described as individuals' ability to find, retrieve, analyse and use relevant information. Health literacy, as a specific field of information literacy, focuses on health sciences and health communication. It implies the achievement of a certain level of knowledge, personal skills and confidence to take action to improve personal and public health [73]. According to the statistics of a comprehensive country comparison report from Europe, only 28% of the population in Germany has sufficient or excellent health literacy; the lowest among the 17 European countries that participated in the comparative study and 27 percentage points below average [74]. Germany has been investing in improving the health literacy of the population through *Nationaler Aktionsplan Gesundheitskompetenz*, a project funded by the Robert Bosch Foundation.

At the intersection of information literacy, digital literacy and health literacy, a new term has been coined in the past years: digital health literacy. At a minimum, digital health literacy skills require individuals' basic reading and writing proficiencies, working knowledge of using computers, and an understanding of how, why and when online health information is created, shared and received [75]. In line with the increasing trend toward the availability and use of digital health solutions across Europe, such as EHRs, there is a growing demand to improve the digital health literacy of populations [74]. The study mentioned above [74] also examined the digital health literacy levels of selected European countries. It conceptualises digital health literacy as the ability to search for, access, understand, appraise, validate and apply online health information and the ability to formulate and express questions, opinions, thoughts, or feelings when using digital devices. Similar to the health literacy outcomes, the digital health literacy level in Germany has been found to be the lowest among the 17 countries studied; 58% of the population in Germany report difficulties in digital health literacy, 20 percentage points below average [74].

Digital health literacy has a great impact on another essential element for the use of digital health services:

trust. Research shows that digital health literacy is positively associated with greater perceived trust in health information from online health communication channels and information sources [76]. Indeed, (digital) health literacy is fundamental to developing societal trust in digital health services and data-driven healthcare [77]. In light of cultural differences between Germany and other European countries in terms of citizens' trust in data sharing, scholars from Germany identify promoting digital health literacy as the key enabling policy action for integrating digital components into the German health system [78]. Within the concept of EHRs, a patient is an active partner who should access, add and manage health-related data, resulting in increased quality of care as well as the patient's compliance [31]; hence, ensuring digital health literacy sets the foundation for patients' participation, empowerment and self-determination in the German ePA [78].

Lastly, evidence also shows that in Germany a simple and safe interface design can be even more important for increasing usage of ePA than knowledge about their actual benefit or added value, which highlights the necessity to focus on the user-friendliness aspect of ePA data sharing options [78]. Due to a number of reasons such as i) the low level of information among the population regarding EHRs; ii) the culturally rooted concerns about health data security; and iii) a general disinterest in new and unfamiliar technologies, having a user-friendly ePA will be central for patients to manage their data [79]. For this reason, sharing and managing ePA data should be as simple as possible for the end users. Patients should be given the opportunity to simulate cases for managing their ePA data and become familiar with the available dataset options in online platforms through non-binding consultations. This aspect is especially crucial if they must opt in for the secondary use of their health data.

CONCLUSION

As becomes clear from the German experience, while the very nature of digital health projects foregrounds the technology for data processing and communication, the implementation of EHRs at scale requires a multitude of preconditions that go beyond storing and sharing information. Digital technologies can only provide the necessary tools and cannot on their own transform health sectors [6]; it is for this reason that the holistic plans of the new coalition government for digital innovations and infrastructure (not only introducing an opt-out policy for ePA but also providing a nationwide fibre-to-the-home coverage, ensuring digital civil rights, launching data custodians, creating a digital society and establishing a Federal Agency for Digital Communication, as stated in the coalition agreement [56]) will be central to the implementation of ePA and the secondary use of ePA data.

Country context should be taken into consideration in large-scale EHRs projects, especially if they aim to combine available health data currently located in different administrative silos. As ePA has shown, the feasibility of digital health projects depends on several contextual factors: countries with a high degree of self-governance and federal structures have to manage complex coordination processes that often slow down or otherwise impede digitalisation processes. In addition, cultural peculiarities such as concerns about data protection and security can be a hindering factor for digitalisation. This study discussed some of the main reasons behind the low uptake of ePA in Germany after two years of deployment and made recommendations for the future. It showed that whereas the new German government and European initiatives such as the EHDS create advantageous situational and environmental factors, the structural and cultural issues in the context of EHRs should be acknowledged and tackled; the former especially for the use of ePA data in clinical settings and the latter for their secondary use in research and health policies.

POLICY RECOMMENDATIONS

- Factors such as acceptance, change management and roll-out strategy are at least as important as technology in the deployment of EHRs and later for the re-use of EHR data; decision-makers should consider the contextual factors that may hinder the implementation process.
- As has been the case for the roll-out of ePA, state interventions might be necessary in large-scale digital health projects in Germany, challenging the existing power structures to the disadvantage of regulatory institutions in self-governance.
- A further reorganisation of the board of *gematik* (by giving voice to the actual end users of ePA) should be considered to overcome major structural impediments to the ePA implementation.
- Instead of the planned opt-in strategy for the secondary use of ePA data, an opt-out approach with necessary information provided to patients would ensure a high level of data collection, respecting at the same time their informational self-determination.
- Cultural factors in Germany affect especially the secondary use of data; organising information campaigns, investing in (digital) health literacy of the population and designing a user-friendly ePA are central in this context.

ACKNOWLEDGEMENTS

This study was funded by the Robert Bosch Foundation. The Foundation had no role in the study design, execution, analysis, and writing of the paper. I would

like to thank Prof. Dr. Kai Wegrich from the Hertie School who has been a source of inspiration and support. I also wish to thank the two reviewers for their valuable and constructive comments.

REVIEWERS

Volker Amelung, Medizinische Hochschule Hannover, Germany.

Vanja Pajić, University of Zagreb, Croatia.

COMPETING INTERESTS

The author has no competing interests to declare.

AUTHOR INFORMATION

Tugce Schmitt is an affiliated researcher at the Hertie School, where she worked as a Research Associate for the project *Neustart*, funded by the Robert Bosch Foundation. Previously, she had been a policy officer in one of the public law corporate bodies of the Federal Joint Committee (*Gemeinsamer Bundesausschuss*), contributing to federal-level directives on quality assurance of health services in Germany. The European projects that she has worked on in the past nine years are concerned with the patients' rights in cross-border healthcare (Directive 2011/24/EU), the Digital Single Market and the Europe's Beating Cancer Plan.

AUTHOR AFFILIATIONS

Tugce Schmitt  orcid.org/0000-0001-6893-6428
Hertie School, Berlin, DE; Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, NL

REFERENCES

- Leventer-Roberts M, Balicer R.** Data Integration in Health Care. In: Amelung V, Stein V, Goodwin N, Balicer R, Nolte E, Suter E (eds.), *Handbook Integrated Care*. Cham, Switzerland: Springer International Publishing. 2017; 121–9. DOI: https://doi.org/10.1007/978-3-319-56103-5_8
- Goodwin N.** Understanding Integrated Care. *Int J Integr Care*. 2016 Oct 28; 16(4): 6. DOI: <https://doi.org/10.5334/ijic.2530>
- Reynolds HW, Sutherland EG.** A systematic approach to the planning, implementation, monitoring, and evaluation of integrated health services. *BMC Health Serv Res*. 2013 May 6; 13(1): 168. DOI: <https://doi.org/10.1186/1472-6963-13-168>
- WHO.** Global strategy on digital health 2020–2025 [Internet]. Available from: <https://www.who.int/docs/default-source/documents/g54dhd2a9f352b0445bafbc79ca799dce4d.pdf>. Accessed January 2023.
- Milstein R, Blankart CR.** Special Care in Germany – Country Background Note: Germany [Internet]. Available from: <https://www.oecd.org/els/health-systems/Better-Ways-to-Pay-for-Health-Care-Background-Note-Germany.pdf>. Accessed January 2023.
- OECD.** Empowering the health workforce – Strategies to make the most of the digital revolution [Internet]. Available from: <https://www.oecd.org/health/health-systems/Empowering-Health-Workforce-Digital-Revolution.pdf>. Accessed January 2023.
- Coleman EA, Berenson RA.** Lost in Transition: Challenges and Opportunities for Improving the Quality of Transitional Care. *Ann Intern Med*. 2004 Oct 5; 141(7): 533–6. DOI: <https://doi.org/10.7326/0003-4819-141-7-200410050-00009>
- Haneef R, Delnord M, Vernay M, Bauchet E, Gaidelyte R, Van Oyen H, et al.** Innovative use of data sources: a cross-sectional study of data linkage and artificial intelligence practices across European countries. *Arch Public Health*. 2020 Jun 10; 78(1): 55. DOI: <https://doi.org/10.1186/s13690-020-00436-9>
- Protti D.** Integrated Care Needs Integrated Information Management and Technology. *Healthc Q*. 2009 Oct 16; 13(sp): 24–9. DOI: <https://doi.org/10.12927/hcq.2009.21093>
- Takian A, Petrakaki D, Cornford T, Sheikh A, Barber N.** Building a house on shifting sand: methodological considerations when evaluating the implementation and adoption of national electronic health record systems. *BMC Health Serv Res*. 2012 Apr 30; 12(1): 105. DOI: <https://doi.org/10.1186/1472-6963-12-105>
- Burnel P.** The introduction of electronic medical records in France: More progress during the second attempt. *Health Policy*. 2018 Sep 1; 122(9): 937–40. DOI: <https://doi.org/10.1016/j.healthpol.2018.07.022>
- Gand K, Richter P, Esswein W.** Towards Lifetime Electronic Health Record Implementation. *Stud Health Technol Inform*. 2015; 212: 225–32. DOI: <https://doi.org/10.3233/978-1-61499-524-1-225>
- Bertelsmann Foundation.** #SmartHealthSystems [Internet]. Available from: https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Gesamtstudie_dt.pdf. Accessed January 2023.
- Lang A.** Government capacities and stakeholders: what facilitates ehealth legislation? *Glob Health*. 2014 Jan 13; 10(1): 4. DOI: <https://doi.org/10.1186/1744-8603-10-4>
- WHO Europe.** From innovation to implementation: eHealth in the WHO European Region [Internet].

- Available from: https://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf. Accessed January 2023.
16. **Brandner A, Schreiwies B, Aguduri LS, Kunz A, Pensold P, Stein KE**, et al. The Patient Portal of the Personal Cross- Enterprise Electronic Health Record (PEHR) in the Rhine-Neckar-Region. *Stud Health Technol Inform*. 2016; 228: 157–61. DOI: <https://doi.org/10.3233/978-1-61499-678-1-157>
 17. **Baudendistel I, Winkler EC, Kamradt M, Brophy S, Längst G, Eckrich F**, et al. Cross-sectoral cancer care: views from patients and health care professionals regarding a personal electronic health record. *Eur J Cancer Care*. 2017; 26(2): e12429. DOI: <https://doi.org/10.1111/ecc.12429>
 18. **SVR Gesundheit**. Gutachten 2021 [Internet]. Available from: https://www.svr-gesundheit.de/fileadmin/Gutachten/Gutachten_2021/SVR_Gutachten_2021.pdf. Accessed January 2023.
 19. **Menachemi N, Collum TH**. Benefits and drawbacks of electronic health record systems. *Risk Manag Healthc Policy*. 2011 May 11; 4: 47–55. DOI: <https://doi.org/10.2147/RMHP.S12985>
 20. **Nøhr C, Parv L, Kink P, Cummings E, Almond H, Nørgaard JR**, et al. Nationwide citizen access to their health data: analysing and comparing experiences in Denmark, Estonia and Australia. *BMC Health Serv Res*. 2017 Aug 7; 17(1): 534. DOI: <https://doi.org/10.1186/s12913-017-2482-y>
 21. **Saigí-Rubió F, Pereyra-Rodríguez JJ, Torrent-Sellens J, Eguia H, Azzopardi-Muscat N, Novillo-Ortiz D**. Routine Health Information Systems in the European Context: A Systematic Review of Systematic Reviews. *Int J Environ Res Public Health*. 2021 Apr 27; 18(9): 4622. DOI: <https://doi.org/10.3390/ijerph18094622>
 22. **Toth F**. Integration vs separation in the provision of health care: 24 OECD countries compared. *Health Econ Policy Law*. 2020 Apr; 15(2): 160–72. DOI: <https://doi.org/10.1017/S1744133118000476>
 23. **Busse R, Blümel M, Knieps F, Bärnighausen T**. Statutory health insurance in Germany: a health system shaped by 135 years of solidarity, self-governance, and competition. *The Lancet*. 2017 Aug; 390(10097): 882–97. DOI: [https://doi.org/10.1016/S0140-6736\(17\)31280-1](https://doi.org/10.1016/S0140-6736(17)31280-1)
 24. **WHO Europe**. Ambulatory care sensitive conditions in Germany [Internet]. Available from: https://www.euro.who.int/__data/assets/pdf_file/0004/295573/ASCS-Germany-2015-rev1.pdf. Accessed January 2023.
 25. **OECD/European Observatory on Health Systems and Policies**. Germany: Country Health Profile 2019 [Internet]. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/germany-country-health-profile-2019_36e21650-en. Accessed January 2023.
 26. **Blümel M, Spranger A, Achstetter K, Maresso A, Busse R**. Germany: Health System Review 2020 [Internet]. Available from: <https://apps.who.int/iris/bitstream/handle/10665/341674/HIT-22-6-2020-eng.pdf>. Accessed January 2023.
 27. **Leichter HM**. A Comparative Approach to Policy Analysis: Health Care Policy in Four Nations. Cambridge: Cambridge University Press. 1979.
 28. **Walt G**. Health Policy: An Introduction to Process and Power (7th ed). Johannesburg: Witwatersrand University Press. 2004.
 29. **Döhler M**. Gesundheitspolitik nach der ‘Wende’: Policy-Netzwerke und ordnungspolitischer Strategiewechsel in Grossbritannien, den USA und der Bundesrepublik Deutschland. Berlin: Ed. Sigma. 1990.
 30. **Altenstetter C**. Insights From Health Care in Germany. *Am J Public Health*. 2003 Jan; 93(1): 38–44. DOI: <https://doi.org/10.2105/ajph.93.1.38>
 31. **Hoerbst A, Kohl CD, Knap P, Ammenwerth E**. Attitudes and behaviors related to the introduction of electronic health records among Austrian and German citizens. *Int J Med Inf*. 2010 Feb 1; 79(2): 81–9. DOI: <https://doi.org/10.1016/j.ijmedinf.2009.11.002>
 32. **Ärzteblatt**. Telemedizin und Telematikinfrastruktur: Auf der Zuschauertribüne [Internet]. Available from: <https://www.aerzteblatt.de/archiv/75260/Telemedizin-und-Telematikinfrastruktur-Auf-der-Zuschauertribue>. Accessed January 2023.
 33. **Lang A, Mertes A**. Die Einführung der elektronischen Gesundheitskarte in Deutschland: Der Einfluss von Interessenpositionen und Sektorzugehörigkeit auf die Entstehung des Implementationsnetzwerks. *Gesundheitswesen*. 2011 Jan; 73(01): e12–20. DOI: <https://doi.org/10.1055/s-0029-1246177>
 34. **Bundesrechnungshof**. Bericht an den Haushaltsausschuss des Deutschen Bundestages nach § 88 Abs. 2 BHO über die Einführung der elektronischen Gesundheitskarte und der Telematikinfrastruktur [Internet]. Available from: https://www.bundesrechnungshof.de/SharedDocs/Downloads/DE/Berichte/2019/elektronische-gesundheitskarte-volltext.pdf?__blob=publicationFile&v=1. Accessed January 2023.
 35. **Handelsblatt**. Interview Gesundheitsminister: “Manchen Ärzten ist die Digitalisierung einfach zu anstrengend” – Jens Spahn zieht Bilanz [Internet]. Available from: <https://www.handelsblatt.com/politik/deutschland/interview-gesundheitsminister-manchen-aerzten-ist-die-digitalisierung-einfach-zu-anstrengend-jens-spahn-zieht-bilanz/27752202.html>. Accessed January 2023.
 36. **Bundesgesundheitsministerium**. Germany’s Presidency of the Council of the European Union [Internet]. Available from: <https://www.bundesgesundheitsministerium.de/en/eu2020/en/german-eu-presidency.html>. Accessed January 2023.
 37. **Bundesamt für Justiz**. § 342 SGB 5 – Einzelnorm [Internet]. Available from: https://www.gesetze-im-internet.de/sgb_5/__342.html. Accessed January 2023.
 38. **gematik**. ePA-App [Internet]. Available from: <https://www.gematik.de/anwendungen/e-patientenakte/epa-app/>. Accessed January 2023.
 39. **Grote-Westrick M**. New German digital project paves the way for online access to personal

- electronic health records [Internet]. Available from: <https://blogs.bmj.com/bmj/2021/02/18/new-german-digital-project-paves-the-way-for-online-access-to-personal-electronic-health-records/>. Accessed January 2023.
40. **Datenschutz.** Elektronische Patientenakte (ePA) [Internet]. Available from: <https://www.datenschutz.org/elektronische-patientenakte/>. Accessed January 2023.
 41. **Bundesamt für Justiz.** § 341 SGB 5 – Einzelnorm [Internet]. Available from: https://www.gesetze-im-internet.de/sgb_5/_341.html. Accessed January 2023.
 42. **gematik.** TI-Dashboard [Internet]. Available from: <https://www.gematik.de/telematikinfrastruktur/ti-dashboard>. Accessed January 2023.
 43. **Henkenjohann R.** Role of Individual Motivations and Privacy Concerns in the Adoption of German Electronic Patient Record Apps—A Mixed-Methods Study. *Int J Environ Res Public Health*. 2021 Jan; 18(18): 9553. DOI: <https://doi.org/10.3390/ijerph18189553>
 44. **IHE.** Öffentliche Stellungnahme – Sicherstellen der Interoperabilität im eigentlichen Sinn: IHE Deutschland e.V. bemängelt proprietäre Verwendung internationaler Standards in aktueller ePA-Spezifikation [Internet]. Available from: <https://www.ihe-d.de/wp-content/uploads/2019/03/IHE-D-0%cc%88ffentliche-Stellungnahme-zur-IHE-Nutzung-in-den-Gematik-Spezifikationen-07-03-2019.pdf>. Accessed January 2023.
 45. **European Commission.** The New European Interoperability Framework [Internet]. Available from: https://ec.europa.eu/isa2/eif_en. Accessed January 2023.
 46. **TEHDAS Consortium Partners.** Recommendations to enhance interoperability within HealthData@EU [Internet]. Available from: <https://tehdas.eu/app/uploads/2022/12/tehdas-recommendations-to-enhance-interoperability-within-healthdata-at-eu.pdf>. Accessed January 2023.
 47. **Hansen J, Wilson P, Verhoeven E, Kroneman M, Verheij R, van Veen EB.** Assessment of the EU Member States' rules on health data in the light of GDPR [Internet]. Available from: <https://www.nivel.nl/sites/default/files/bestanden/1003988.pdf>. Accessed January 2023.
 48. **Deutsch E, Duftschmid G, Dorda W.** Critical areas of national electronic health record programs—Is our focus correct? *Int J Med Inf*. 2010 Mar 1; 79(3): 211–22. DOI: <https://doi.org/10.1016/j.ijmedinf.2009.12.002>
 49. **Weigand M.** 5 Punkte-Plan für eine erfolgreiche ePA [Internet]. Available from: <https://background.tagesspiegel.de/gesundheit/5-punkte-plan-fuer-eine-erfolgreiche-epa>. Accessed January 2023.
 50. **Bundesgesundheitsministerium.** Elektronische Patientenakte [Internet]. Available from: <https://www.bundesgesundheitsministerium.de/elektronische-patientenakte.html>. Accessed January 2023.
 51. **gematik.** E-Patientenakte [Internet]. Available from: <https://www.gematik.de/anwendungen/e-patientenakte>. Accessed January 2023.
 52. **UPD.** Elektronische Patientenakte (ePA)/Fragen und Antworten [Internet]. Available from: [patientenberatung.de/de/informationen/digitalisierung/fragen-und-antworten-elektronische-patientenakte-ePA](https://www.patientenberatung.de/de/informationen/digitalisierung/fragen-und-antworten-elektronische-patientenakte-ePA). Accessed January 2023.
 53. **Bundesregierung.** Corona-Warn-App [Internet]. Available from: <https://www.bundesregierung.de/breg-de/themen/corona-warn-app/corona-warn-app-englisch>. Accessed January 2023.
 54. **Bundesgesundheitsministerium.** Informationen zum Coronavirus [Internet]. Available from: <https://www.bundesgesundheitsministerium.de/coronavirus.html>. Accessed January 2023.
 55. **Riordan F, Papoutsi C, Reed JE, Marston C, Bell D, Majeed A.** Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK. *Int J Med Inf*. 2015 Apr 1; 84(4): 237–47. DOI: <https://doi.org/10.1016/j.ijmedinf.2015.01.008>
 56. **SPD, Bündnis90/Die Grünen, FDP.** Mehr Fortschritt wagen – Bündnis für Freiheit, Gerechtigkeit und Nachhaltigkeit. Koalitionsvertrag 2021 – 2025 zwischen der Sozialdemokratischen Partei Deutschlands (SPD), BÜNDNIS 90 / DIE GRÜNEN und den Freien Demokraten (FDP). 2021 [Internet]. Available from: <https://www.bundesregierung.de/resource/blob/974430/1990812/04221173eef9a6720059cc353d759a2b/2021-12-10-koav2021-data.pdf>. Accessed January 2023.
 57. **Aerzteblatt.** Elektronische Patientenakten: Deutsches Modell folgt vergleichsweise strengen Datenschutzrichtlinien [Internet]. Available from: <https://www.aerzteblatt.de/nachrichten/127819/Elektronische-Patientenakten-Deutsches-Modell-folgt-vergleichsweise-strengen-Datenschutzrichtlinien>. Accessed January 2023.
 58. **Observer Gesundheit.** Gute Behandlung mit schlechten Daten? [Internet]. Available from: <https://observer-gesundheit.de/gute-behandlung-mit-schlechten-daten/>. Accessed January 2023.
 59. **OECD.** Survey results: National health data infrastructure and governance [Internet]. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/survey-results-national-health-data-infrastructure-and-governance_55d24b5d-en. Accessed January 2023.
 60. **Hackl W, Hoerbst A, Ammenwerth E.** The Electronic Health Record in Austria: Physicians' Acceptance Is Influenced by Negative Emotions. *Stud Health Technol Inform*. 2009; 150: 140–4. DOI: <https://doi.org/10.3233/978-1-60750-044-5-140>
 61. **Bogumil-Uçan S, Klenk T.** Varieties of health care digitalization: Comparing advocacy coalitions in Austria and Germany. *Rev Policy Res*. 2021; 38(4): 478–503. DOI: <https://doi.org/10.1111/ropr.12435>
 62. **OECD.** Health for the People, by the People: Building People-centred Health Systems [Internet]. Available from: https://read.oecd-ilibrary.org/social-issues-migration-health/health-for-the-people-by-the-people_c259e79a-en. Accessed January 2023.
 63. **Caumanns J.** Zur Diskussion: Stand der Digitalisierung im deutschen Gesundheitswesen. *Z Für Evidenz Fortbild Qual*

- Im Gesundheitswesen*. 2019 Jun 1; 143: 22–9. DOI: <https://doi.org/10.1016/j.zefq.2019.04.002>
64. **EFI**. Gutachten zu Forschung, Innovation und Technologischer Leistungsfähigkeit Deutschlands 2022 [Internet]. Available from: https://www.e-fi.de/fileadmin/Assets/Gutachten/2022/EFI_Gutachten_2022.pdf. Accessed January 2023.
65. **Bundesamt für Justiz**. § 363 SGB 5 – Einzelnorm [Internet]. Available from: https://www.gesetze-im-internet.de/sgb_5/_363.html. Accessed January 2023.
66. **BfArM**. Forschung meets Datenschutz: Mit Künstlicher Intelligenz synthetische Gesundheitsdaten analysieren [Internet]. Available from: https://www.bfarm.de/DE/Aktuelles/Blog/_docs/2022-03-10-forschungsdatenzentrum.html. Accessed January 2023.
67. **Wellcome Trust**. Why an opt-out rather than an opt-in or consent? | Understanding patient data [Internet]. Available from: <http://understandingpatientdata.org.uk/news/why-an-opt-out>. Accessed January 2023.
68. **Schmitt T, Haarmann A, Shaikh M**. Strengthening health system governance in Germany: looking back, planning ahead. *Health Econ Policy Law*. 2023; 18: 14–31. DOI: <https://doi.org/10.1017/S1744133122000123>
69. **Bundesrat**. Vorschlag für eine Verordnung des Europäischen Parlaments und des Rates über den europäischen Raum für Gesundheitsdaten COM(2022) 197 final; Ratsdok. 8751/22 [Internet]. Available from: <https://www.bundesrat.de/SharedDocs/drucksachen/2022/0201-0300/256-1-22.pdf>. Accessed January 2023.
70. **Arora K**. Privacy and data protection in India and Germany: A comparative analysis [Internet]. Available from: <https://bibliothek.wzb.eu/pdf/2020/iii20-501.pdf>. Accessed January 2023.
71. **Kolain M, Molavi R**. Zukunft Gesundheitsdaten – Wegweiser zu einer forschungskompatiblen elektronischen Patientenakte [Internet]. Available from: https://www.bundesdruckerei-gmbh.de/files/dokumente/pdf/studie_zukunft-gesundheitsdaten.pdf. Accessed January 2023.
72. **Séroussi B, Bouaud J**. Adoption of a Nationwide Shared Medical Record in France: Lessons Learnt after 5 Years of Deployment. *AMIA Annu Symp Proc*. 2017 Feb 10; 2016: 1100–9.
73. **WHO**. Improving health literacy [Internet]. Available from: <https://www.who.int/activities/improving-health-literacy>. Accessed January 2023.
74. **The HLS19 Consortium of the WHO Action Network M-POHL**. International Report on the Methodology, Results, and Recommendations of the European Health Literacy Population Survey 2019–2021 (HLS19) of M-POHL [Internet]. Available from: <https://m-pohl.net/Results>. Accessed January 2023.
75. **Harris K, Jacobs G, Reeder J**. Health Systems and Adult Basic Education: A Critical Partnership in Supporting Digital Health Literacy. *HLRP Health Lit Res Pract*. 2019 Oct 3; 3(3 sp): 33–6. DOI: <https://doi.org/10.3928/24748307-20190325-02>
76. **Paige SR, Krieger JL, Stellefson ML**. The Influence of eHealth Literacy on Perceived Trust in Online Health Communication Channels and Sources. *J Health Commun*. 2017 Jan; 22(1): 53–65. DOI: <https://doi.org/10.1080/10810730.2016.1250846>
77. **ECHAlliance iHD**. Calls to Action on Health Data Ecosystems – Recommendations from multi-stakeholder roundtables [Internet]. Available from: <https://www.i-hd.eu/wp-content/uploads/2021/03/Calls-to-Action-on-Health-Data-Ecosystems-2021-DHE-IHD-.pdf>. Accessed January 2023.
78. **Samerski S, Müller H**. Digitale Gesundheitskompetenz in Deutschland – gefordert, aber nicht gefördert? Ergebnisse der empirischen Studie TK-DiSK. *Z Für Evidenz Fortbild Qual Im Gesundheitswesen*. 2019 Aug; 144–145: 42–51. DOI: <https://doi.org/10.1016/j.zefq.2019.05.006>
79. **Fischer P**. Eine empirische Untersuchung zur Akzeptanz der elektronischen Patientenakte in Deutschland [Internet]. Available from: <https://www.bifg.de/media/dl/Gesundheitswesen%20aktuell/2019/GWA2019-Kapitel%20Fischer.pdf>. Accessed January 2023.

TO CITE THIS ARTICLE:

Schmitt T. Implementing Electronic Health Records in Germany: Lessons (Yet to Be) Learned. *International Journal of Integrated Care*, 2023; 23(1): 13, 1–13. DOI: <https://doi.org/10.5334/ijic.6578>

Submitted: 28 March 2022 **Accepted:** 20 February 2023 **Published:** 10 March 2023

COPYRIGHT:

© 2023 The Author(s). This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International License (CC-BY 4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. See <http://creativecommons.org/licenses/by/4.0/>.

International Journal of Integrated Care is a peer-reviewed open access journal published by Ubiquity Press.