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How to Make Outpatient Healthcare Data in Germany Available for Research in the Dynamic Course of Digital Transformation

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Abstract. Introduction There is increasing interest on re-use of outpatient healthcare data for research, as most medical diagnosis and treatment is provided in the ambulatory sector. One of the early projects to bring primary data from German ambulatory care into clinical research technically, organizationally and in compliance with legal demands has been the RADAR project, that is based on a broad consent and has used the then available practice information system's interfaces to extract and transfer data to a research repository. In course of the digital transformation of the German healthcare system, former standards are abandoned and new interoperability standards, interfaces and regulations on secondary use of patient data are defined, however with slow adoption by Health-IT systems. Therefore, it is of importance for all initiatives that aim at using ambulatory healthcare data for research, how to access this data in an efficient and effective way. **Methods** Currently defined healthcare standards are compared regarding coverage of data relevant for research as defined by the RADAR project. We compare four architectural options to access ambulatory health data through different components of healthcare and health research data infrastructures along the technical, organizational and regulatory conditions, the timetable of dissemination and the researcher's perspective. **Results** A high-level comparison showed a high degree of semantic overlap in the information models used. Electronic patient records and practice information systems are alternative data sources for ambulatory health data - but differ strongly in data richness and accessibility. **Conclusion** Considering the compared dimensions of architectural routes to access health data for secondary research use we conclude that data extraction from practice information systems is currently the most promising way due to data availability on a mid-term perspective. Integration of routine data into the national research data infrastructures might be enforced by convergence of to date different information models.

Keywords. electronic health records, digital transformation, secondary use, routine data, data access, outpatient care, health services research, Germany

1. Introduction

The digitalization of the healthcare system in Germany and the structures needed for a modern healthcare system and data-driven medicine are continuously being created, with

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the primary objective of creating benefits for various stakeholders and to efficiently improve patient care [1]. There is a broad understanding, that availability of health data from routine care for secondary use is crucial for gaining new insights into clinical epidemiological research questions, for health services research and data-driven innovations [2]. Central components of a connected and digital healthcare system are information models which categorize and define entities as a basis for information exchange between actors and data integration from different sources.

In Germany there is a strong separation between inpatient and outpatient care, including reimbursement schemes, governance, stakeholders including their representative bodies, and different information models – partly reflecting the different data to be exchanged, partly reflecting different stakeholders responsible for the development of the standards. Large infrastructures for secondary use have been carried out in Germany within the Medical Informatics Initiative (MII) [3]: in all University Medical Centers, Medical Data Integration Centers (DICs) have been established. The DICs are responsible to extract data from primary hospital information systems into a common format, the MII Core Data Set (MII CDS), and organize the processes to make them available for research. The legal basis in terms of data protection is a broad consent signed by the patient [4].

On the other hand, the National Association of Statutory Health Insurance Physicians (KBV) has developed the KBV base profiles for exchange of data in outpatient care. Within the German Social Code Book V (SGB V) the research compatible German ePA has been defined that utilizes Medical Information Objects (MIOs) [5] based on the KBV base profiles. The ePA is patient-managed but provided by the respective health insurance company. It is intended to provide insured persons with their personal health data, e.g. findings, diagnoses, performed and planned therapies or treatment reports. The development of the ePA is planned iteratively, at first implementing basic document storage and at later stages enabling the exchange of MIOs as structured standardized data sets. The current expansion level 2.5 enables the deposit of MIOs, but practical use and dissemination of structured resources are limited due to MIO development status as well as availability of provider implementations. An overview of prospective ePA applications [6] available for end users can be found at the National Association of Statutory Health Insurance Funds. Within the ePA context § 363 of the SGB V defines the possibility to re-use data from a citizen's ePA for research by two regulatory routes (per § 363) examined in this paper. As the ePA is currently part of the German Telematics Infrastructure (TI), access and entry for certain user groups is implemented via suitable ID cards for health professionals ("Heilberufeausweis", short "eHBA") or the citizen identified via "eGK"-ID card. Therefore, currently research data may only be available through organizations that are part of the TI.

While the ePA is patient-managed, practice information systems are managed by general practitioners. To allow moving the whole clinical content stored in a practice management system to another one the archive and change interface for practice management systems (AWS) [7] profiles were developed based on the KBV base profiles. In terms of purpose, the AWS is the replacement of the Treatment Data Transfer interface BDT, which has allowed for archiving and moving clinical routine data in practice information systems in Germany since many years. With the definition of the AWS and the announced due date of June 2021 for implementation in the practice information systems, development of BDT was terminated in 2019. However, to date only few systems provide the AWS, therefore BDT is still the most available interface in Germany's practices.

Neither BDT nor AWS have been envisioned to be employed for research purposes, but provide – in contrast to most hospital information systems that are employed within the MII, at least a commonly defined and with regards to BDT a widely implemented interface. This is the reason why the BDT has been employed by the RADAR project, to extract healthcare data for a research network of General Practitioners. In RADAR, 40 variables from BDT data sets have been identified by domain experts as of scientific interest [8]. These variables have been categorized into eleven semantic groups which will be used for comparison in this paper: diagnoses, medication, laboratory results, findings, therapies, other procedures, time and date data, patient's general and permanent data, practice characteristics, cost unit and billing, including a relevance rating (classified as high, medium, low) in relation to health research [9].

With the dynamic digital transformation of the German health system with increasing momentum by European Health Data Space [10], the question arises, how health data in outpatient healthcare can be best made available for research with regards to current and future technical, organizational and regulatory requirements and options. Specifically, in regards of practical considerations: (How) can research data from practice management systems (PMS) be derived for secondary research in the future when xDT has been replaced and ePA is widely used. Which interfaces are used and where are semantic overlaps?

2. Methods

To identify possible way and challenges in the transition from the research infrastructure described above to the emerging digital health infrastructure, we compare the currently specified infrastructures including the information models in both the ambulatory healthcare sector and the MII as Germany's largest research infrastructure for clinical data re-use.

2.1. Information Models

For a first high-level comparison we have considered all data items within the aforementioned 11 semantic groups, regardless their rating. In the context of these semantic groups, we updated the semantic mapping to the current version of MII-CDS (version 1 [11]), that has been extended by several modules since the time of writing of [9]. We further extended the mapping by the standards developed in the context of outpatient care, the KBV base profiles (version 1.4[2]) and the KBV profiles of the AWS (version 1[3]). All profiles are investigated as defined as HL7 Fast Healthcare Interoperability Resource (FHIR) profiles found in the Simplifier. A FHIR Profile was considered to map to a semantic group, if there was a semantic overlap.

2.2. Data access routes

In analogy to the data flow from the primary hospital information systems to the data integration centers within the MII architecture (cf. Figure 4 in [12] and the depiction of ePA processes by Semler [13]), we identify possible routes of outpatient healthcare data

[2] https://simplifier.net/base1x0/ (retrieved on 30.03.2023)

[3] https://simplifier.net/pvs-archivierungs-undwechselschnittstelle/ (retrieved on 30.03.2023)

from the digital health infrastructure to a research data repository. We depicted those routes in a figure focused on data flows including technical aspects regarding employed information models.

To assess the organizational, technical and regulatory efforts, the identified routes are evaluated qualitatively. Evaluation criteria are compatibility of the information models with the defined and rated semantic groups, and the expected technical, organizational and regulatory effort to make the data available for the specific use case of general practitioners that want to conduct research on their patient data. Additionally, the timetable for the continuous future development of different data access routes as well as the researcher's perspective is taken into considered and discussed. We include previous experiences and available documentation in the management of research data provision into the evaluation.

3. Results

3.1. Comparison of information models on coverage of semantic groups

The comparison of the different information models resulted in an overall large coverage. Most overlap with all groups present was found with the MII CDS, 10 were found in the KBV AWS profiles while the KBV base profile covered 9 semantic groups. Table 1 shows the respective FHIR profiles where data items of the semantic groups are found.

In the MII CDS there are in principle corresponding counterparts for each semantic group. Most of them can be mapped to one profile, while in particular data items of the findings group are now found in five different profiles. Time and date data, cost unit and billing information are found in three profiles each. This is due to a more and more differentiated information model of the MII-CDS, that defines and standardizes subsequently different domain-specific modules. Different categories of findings are modeled as different profiles. Other than in BDT, information about time points of an event are stored within the respective event profile in FHIR.

In the KBV base profiles most semantic groups are found in one or two profiles, except time and date data which is again found in the respective event profiles, as reported for the MII CDS. It should be noted, that the base profiles are intended to be further profiled as MIOs and that some of them also serve as base profiles for AWS profiles. Due to their generic nature, they map more direct to the generic semantic groups. However, the last two semantic groups cost unit and billing could not be assigned to a counterpart of the KBV base profiles. This is related to the fact that billing and reimbursement exchange is realized by a different interface. As already mentioned, MIOs are based on KBV base profiles [14]. This means that wherever KBV base profiles have been used, it is likely that the associated semantic groups can be found again in the MIO, although constraints during profiling may remove items related to the semantic groups.

Comparison with the AWS profiles show that there are many profiles defined for similar content, e.g. for each billing type there is an individual profile that also contains information about the cost unit. There are also four different profiles for medication. Interestingly, there is no profile for laboratory results. This is related to the fact, that laboratory results are typically transferred through another interface, the laboratory data transfer interface LDT. As a replacement for BDT, AWS does as well not represent the

laboratory sector. In contrast, a MIO based on the KBV base profiles for laboratory data is currently being specified.

Table 1. FHIR profiles of the different information models that contain data items of the semantic group. Cf. [9] for individual data items within these groups. $, § and % replace the prefixes KBV_PR, AW_Abrechnung and AW_Rezept_Medication, respectively

Semantic group	MII CDS	KBV base	KBV AWS
diagnoses	diagnoses	$_Base_DiagnosticReport, $_Base_Condition_Diagnosis	$_AW_Diagnose
medication	medication	$_Base_Medication, $_Base_MedicationStatement	$_AW_Medikament, $_%_Compounding, $_%_FreeText, $_%_Ingredient, $_%_PZN
laboratory results	lab results	$_Base_DiagnosticReport	
findings	lab results, pathology results, molecular genetics, imaging	$_Base_DiagnosticReport	$_AW_Observation_Befund
therapies	procedures	$_Base_Procedure	$_AW_Therapie
other procedures	procedures	$_Base_Procedure	$_AW_Therapie
time and date data	treatment case, diagnoses, medication	$_Base_Condition_Diagnosis, $_Base_DiagosticReport, $_Base_Medication, $_Base_MedicationStatement	$_AW_Dauermedikation, $_AW_Impfung
patient's general and permanent data	person	$_Base_AllergyIntolerance, $_Base_Patient	$_AW_Patient, $_AW_Allergie
practice characteristics	structural data	$_Base_Organization	$_AW_Betriebsstaette
cost unit	treatment case, fee, cost data		$_§_BG, $_§_HzV_Besondere Versorgung_Selektiv, $_§_privat, $_§_vertragsaerztlich, $_§_Vorlaeufig, $_AW_Krankenhausversicherungsverhaeltnis
billing	treatment case, fee, cost data		$_§_BG, $_§_HzV_Besondere Versorgung_Selektiv, $_§_privat, $_§_vertragsaerztlich, $_§_Vorlaeufig, $_AW_Krankenhausversicherungsverhaeltnis

3.2. Access to health data for research use

In Figure 1, we depict different routes from the citizen with health data generated by a health service provider to secondary research use. Route 1 reflects the provision of data stored in the ePA as defined in the current legislation – SGB V. In general, two possible ways are envisioned: a) via a central German Research Data Center (FDZ) [15] in responsibility of Federal Institute for Drugs and Medical Devices (BfArM), where ePA data as well as routine data from the health insurance companies shall be provided for

research (defined in § 363 (1-7)); or b) through an arbitrary data provider by direct mandate by the citizen (defined in §363 (8)).

In Route 2, export from the health information system via any suitable interfaces is shown. This method resembles the data integration strategy of the MII, and has been employed by RADAR as well. Due to the close relation to the technical concept of the MII, option a) would be to consider a practice information system as one of the different health information systems to be integrated into a Data Integration Center. Consequently, the data needs to be mapped to the MII CDS but could then be made available through the established mechanism of the MII. Option b) is a separate route, where data is mapped to one to the healthcare standards and is made available by another data provider.

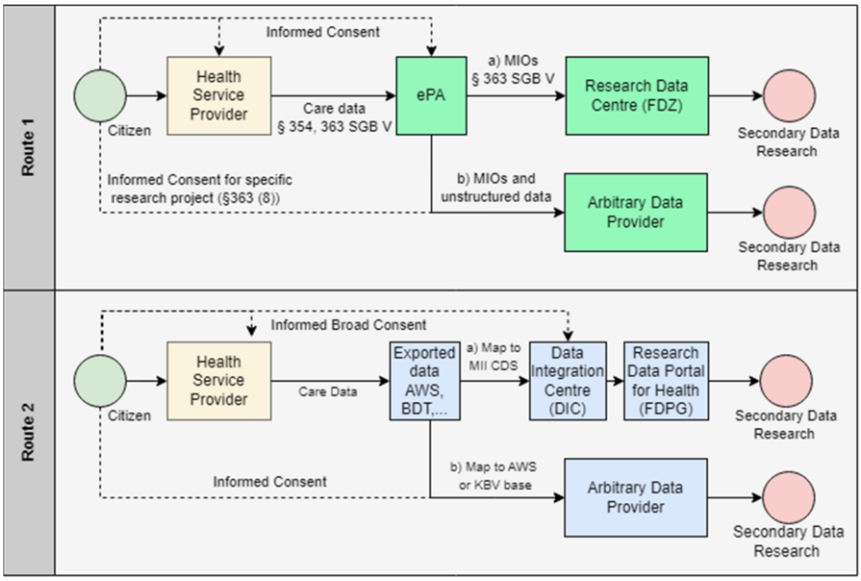

Figure 1. Routes of health data from routine care to research.

Regarding the efforts to make data available, in Route 1a) data transfer to the FDZ takes place on the basis of informed consent by citizens given towards the health insurer via the ePA frontend. The implementation started with the release of the defined MIOs [14]. The obligation for pseudonymization and encryption lies with the persons responsible for data processing in the ePA, which are the statutory health insurance funds [16]. The responsibility to provide and maintain the data within the FDZ is completely within the federal government, with a central portal to apply for the data. As per SGB V § 303e, applicants to the FDZ can be, among others, institutions of health care research, universities, clinics, non-university research institutions, self-help groups and institutions for quality assurance or reporting. Research-relevant purposes of use are improvement of quality of care, longitudinal analysis or analysis of treatment processes and care provision, or support of political decision-making processes in the context of health and fulfillment of tasks for health reporting. The provision takes place either in the form of aggregated and anonymized data, pre-analyzed data or, after the researcher has proven necessity, per release of pseudonymized data records [16]. General

practitioners or research networks are not explicitly mentioned, however currently all networks are with participation of a university that may serve as the formal applicant.

Route 1b) as defined in SGB V § 363 (8) allows direct, informed consent-based access to a citizen's ePA for specified research projects. As per specification, the technical path for this route is ready with expansion level 1 or 2 of the ePA [16]. However, specification regarding implementation and enforcement of data subject's rights according to GPDR for route 1b) were not finalized. With ePA level 2.6 the release of documents from the ePA of an insured person by consent is still limited to data in structured documents (MIOs) [17, p. 55]. See table 2 for an overview about the different comparison dimensions for route 1 and route 2 which is described below.

Table 2. Comparison of different data access routes depicted in figure 1 by different dimensions.

Dimension	Criterium	Route 1a	Route 1b	Route 2a	Route 2b
technical	data source	PMS -> ePA	PMS -> ePA	PMS Pipeline	PMS Export
	source information model	MIO (KBV base) documents	MIO (KBV base) documents	AWS (BDT) (proprietary)	AWS (BDT) (proprietary)
	target information model	MIO (KBV base)	arbitrary	MII-CDS	arbitrary
organizational	data provider	FDZ	arbitrary	DIC/MII	arbitrary
sovereignty	data holder	citizen	citizen	health service provider	health service provider
regulatory	legal basis	§ 363 (1-7) -> Consent or aggregated/ anonymized	§ 363(8) -> Specific Consent	Broad Consent	Specific Consent
timeframe	implementation due by law	ePA2.5: 1/2023*	ePA2.5: 1/2023*	AWS: 6/2021*	AWS: 6/2021*
	current availability for research	non	no provider known	in implementation by digihubs	projects using BDT or proprietary format
researcher's perspective	data richness	sparse	sparse	rich	rich

*not fully available or implemented by system vendors as of the time of writing

Route 2 in general is not addressed by specific legislation, therefore can currently only be employed by the citizen's informed consent, in analogy to the MII approach by a broad consent or a project specific consents, comparable to Route 1b). Route 2a) would imply efforts by the data integration centers, with building a path to data sources outside the university hospitals. If once integrated, the effort of data provision is within the DICs and the central Research Data Portal for Health (FDPG) maintained by the MII coordination site [18].

Route 2b) in contrast describes the route to an arbitrary data provider where exported healthcare data is made available within an information model used in routine care. Route

2b) correspond to the route currently employed by RADAR, except the fact, that the RADAR data is currently provided as table data. We would like to mention, that the arbitrary data provider in Routes 1b) and 2b) are considered as biomedical research data infrastructures that need to implement full functionality regarding subject's rights enforcement and FAIR data management. This might encompass different components, such as a trusted third party, the data management itself and a transfer office. This is a significant effort with long-term commitment beyond a specific project funding.

4. Discussion and Conclusion

As we find large overlap between the different information models and the identified semantic groups, we deduce that all three models would be candidates as a target format for data access for secondary use in research. While the model comparison on high semantic level allowed us to identify the scopes of different information models we see the need for more detailed comparisons on item level in case of practical application of data access.

Of specific interest is the profiles provided by the KBV as the envisioned standard interfaces to access the clinical content of a practice information system. We would like to note that not all data elements within the semantic groups could be matched, but on the other hand the new profiles contain much more structured data items which makes data curation including de-identification much easier. But it might be necessary for specific questions to access data within the practice information system through other interfaces, such as LDT or the respective MIO for laboratory results. The past has shown that in some cases even open interfaces have barriers to access implemented by providers. Free availability of these interfaces cannot be assumed in principle.

Regarding the ePA, the very limited scope of MIOs will only be useful a small number of research question in a short- to midterm perspective. Furthermore, from the consideration of the legal framework, it became clear that access to the TI and the ePA itself is limited for security reasons. In practice, the citizen, health service providers (with eHBA), health insurers and authorized system operators have access to the TI. Access to data from outside is only possible via consent by the citizen or in case of aggregated, anonymous data via the defined interfaces such as the FDZ, and the direct export of data for specific research questions is rather on a long-range perspective.

With the filling of the ePA in the form of a manual process between citizen and health service provider, a continuous and steady long-term collection of relevant research data is unlikely. With the digitalization strategy recently published by the Ministry of Health, the ePA might gain some more momentum due to an opt-out provision which would probably increase the usage and usefulness for the individual patients. But remains to be seen which data objects and items are regularly transferred to the ePA and made usable for research. Furthermore, it must be considered that data may be incomplete due to the right of citizens to delete or obfuscate parts of their personal health data.

Comparing the different routes, we first distinguish between the source system, i.e. the ePA or the practice information system. While the ePA has a huge conceptional advantage of being patient-centered. It can actually represent the intersectoral patient journey and is furthermore optimal to implement informational self-determination. On the other hand, on a short- to midterm perspective, the information that is provided in a structured way will be very limited and there are few healthcare providers that really can share data to the ePA already. However, it is plausible that within the funding of the

Digital Hubs: Advances in Research and Health Care [19], as part of the MII and some of the use cases of the consolidation and expansion phase of the MII, where intersectoral data exchange is explicitly targeted, also the challenge of compatibility between the KBV and MII profiles might be tackled. In terms of comprehensive data, the practice information systems are currently the data source of choice. As mentioned above, it can be regarded as a primary information system where the containing data must be made available to the researcher similar to the concept of a DIC. In principle, the established infrastructure of the DICs could be employed. However, it should be noted that integration of outpatient health information is not in the primary focus of the MII. In particular, if the citizens are not anyhow stationary patients, it would presumably require complex contractual structures connect a practice information system from another health care provider to a DIC.

We conclude, the Route 2 options seem to be more achievable considering the current situation. Especially for health services research with outpatient data, we see the need for access to rich data sets via practicable ways in the short to medium term. As already mentioned with regard to the MII CDS, there are several use cases that are to combine intersectoral health data within the MII. The choice between Route 2a) and b) might rather depend on the capabilities and self-conception as well as legal and organizational constraints of a DIC and an alternative arbitrary data provider which is easier to use - and which might be easier integrated into the upcoming research data structure of the European Health Data Space.

Declarations

Conflict of Interest: The authors declare, that there is no conflict of interest.

Author contributions: DK, JR, MK: conception of the work, development of results; DK, JR, MK, JH: writing the manuscript; JH, DK, revising of the manuscript. All authors approved the manuscript in the submitted version and take responsibility for the scientific integrity of the work.

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