

SwissPedData: Standardising hospital records for the benefit of paediatric research

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Summary

BACKGROUND: Improvement of paediatric healthcare is hampered by inefficient processes for generating new evidence. Clinical research often requires extra encounters with patients, is costly, takes place in an artificial situation with a biased selection of patients, and entails long delays until new evidence is implemented into health care. Electronic health records (EHR) contain detailed information on real patients and cover the entirety of patients. However, the use of EHR for research is limited because they are not standardised between hospitals. This leads to disproportionate amounts of work for extracting data of interest and frequently data are incomplete and of poor quality.

AIMS: SwissPedData aims to lay the foundation for a paediatric learning health system in Switzerland by facilitating EHR-based research. In this project, we aimed to assess the way routine clinical data are currently recorded in large paediatric clinics in Switzerland and to develop a national EHR-based set of common data elements (CDEs) that covers all processes of routine paediatric care in hospitals.

METHODS: A taskforce of paediatricians from large Swiss children's hospitals reviewed the current status of routine data documentation in paediatric clinical care and the extent of digitalisation. We then used a modified Delphi method to reach a broad consensus on a national EHR-based set of CDEs.

RESULTS: All Swiss children's hospitals use EHR to document some or all aspects of care. One hundred and nineteen paediatricians, representing eight hospitals and all paediatric subspecialties, participated in an extended Delphi process to create SwissPedData. The group agreed

on a national set of CDEs that comprises a main module with general paediatric data and sub-modules relevant to paediatric subspecialties. The data dictionary includes 336 CDEs: 76 in the main module on general paediatrics and between 11 and 59 CDEs per subspecialty module. Among these, 266 were classified as mandatory, 52 as recommended and 18 as optional.

CONCLUSION: SwissPedData is a set of CDEs for information to be collected in EHR of Swiss children's hospitals. It covers all care processes including clinical and paraclinical assessment, diagnosis, treatment, disposition and care site. All participating hospitals agreed to implement SwissPedData in their clinical routine and clinic information systems. This will pave the way for a national paediatric learning health system in Switzerland that enables fast and efficient answers to urgent clinical questions by facilitating high-quality nationwide retrospective and prospective observational studies and recruitment of patients for nested prospective studies and clinical trials.

Introduction

The creation of new evidence in medicine and the improvement of patient care are hampered by inefficient and laborious processes [1, 2]. Most evidence is gathered through stand-alone research projects that are costly, time-consuming, and conducted in an artificial research setting with a selected sample of patients. It also takes a long time for evidence to be implemented in health care [3]. Delays of many years are common, caused by the need to acquire research grants, recruit staff, obtain ethical approval, set up the study, recruit participants, collect and analyse data,

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write up and publish the results, and integrate these results into current standards of care. Paediatric research lags behind adult research for various reasons, including that the paediatric population is small, many paediatric health conditions are rare and ethical requirements are high. Given these constraints, results from studies in adults are often extrapolated to children [4, 5]. However, because of the important changes that occur during their development, children differ fundamentally from adults in many aspects. These include large age-related differences in susceptibility to environmental influences, in disease manifestations, in the adequacy and performance of diagnostic tests, in drug disposition, and in responses to treatment [6].

The digitalisation of health records could significantly improve the evidence for paediatric medicine and rare diseases as it potentially allows easy and fast access to clinical data from routine patient encounters. It could make clinical research faster and cheaper and make its results more representative of the patients typically seen in health care. Electronic health records (EHR) are widely used in hospitals to document clinical and administrative information about patient encounters. Unfortunately, EHR are rarely standardised within and between institutions and data are often entered into open text fields, resulting in unstructured data. Research on rare diseases relies on data from multiple centres and is limited by the time and costs required to extract and recode these data into a common format. Such data abstraction is particularly challenging when the original data are unstructured [7, 8]. Natural language processing and machine learning methods are increasingly being used to process unstructured data and make them available to research; however, many challenges remain [9]. Furthermore, retrospective standardisation often leads to a loss of information and impairment of data quality. These limitations could largely be circumvented if the original data were recorded in a structured and standardised way [10, 11]. A common EHR architecture allowing structured data capture during routine medical encounters could enable rapid analysis of healthcare data followed by speedy feedback of the knowledge generated into the same health care settings, a process called a learning health system [12, 13]. The aim of our project, which we have named SwissPedData, is to facilitate paediatric clinical research by improv-

ing and standardising the quality of data generated by paediatric health care in Switzerland. To achieve this, we first assessed the status quo, i.e., the relevant aspects of paediatric care for which data are collected, the way these data are recorded, and the data management systems used in the participating paediatric hospitals in Switzerland. Second, we developed and approved a standardised paediatric set of common data elements (CDEs) for EHR across Switzerland by conducting a multi-stage consensus finding process among general paediatricians and paediatric subspecialists of university and cantonal children's hospitals. This paper describes the status quo of the project, the process of standardisation and the resulting set of CDEs: SwissPedData, Version 1.0.

Methods

SwissPedData taskforce

SwissPedNet, the research network of Swiss Children's hospitals (<https://www.swisspednet.ch/home/>), received an infrastructure grant from the Swiss Personalized Health Network (SPHN) to develop a common data structure in paediatric hospitals and launched SwissPedData with the support of the Swiss Society of Paediatrics (<https://www.paediatricschweiz.ch>). SPHN, an initiative of the Swiss Federal Government, aims to achieve a nationwide interoperability of health data produced in university hospitals (<https://sphn.ch>). SPHN funds the development of infrastructures that make health data shareable for research, following a decentralised approach where data remain in each hospital. Data sharing should become possible either through the direct transfer of individual health data or through distributed analyses, whereby the data do not travel, but are processed decentrally by algorithms and then only data summaries and results are transferred to a central location [14]. SwissPedData is coordinated by a taskforce that consists of a core team at the Institute of Social and Preventive Medicine, University of Bern (ISPM Bern) and representatives from all participating hospitals (fig. 1). All the university hospitals (Basel, Bern, Geneva, Lausanne and Zurich) and three cantonal children's hospitals (Lucerne, St Gallen and Ticino) participated. The clinical directors of each hospital proposed one senior physician to represent the hospital's management board and one junior physician to represent the house officers and registrars who enter the most data into the EHR. The directors also suggested senior physicians representing general paediatrics and all major paediatric subspecialties for collaboration as experts on the Delphi panel. Each hospital suggested at least one expert for general paediatrics and one for each subspecialty. These were then contacted by the core team. Distinct panels were set up for the following subspecialties: paediatric cardiology, endocrinology, gastroenterology, allergy/immunology, infectious diseases, metabolic diseases, nephrology, neurology, pulmonology and rheumatology. Paediatric oncology and neonatology were considered separately because standardised datasets for these subspecialties have already been developed by the Swiss Neonatal Network & Follow-Up Group (Swiss-NeoNet, <https://www.neonet.ch/swissneonet>) [15] and the Childhood Cancer Registry (<https://www.childhood-cancerregistry.ch>) [16]. Both datasets have been in use for

LIST OF ABBREVIATIONS

CDE	Common data element
EHR	Electronic health record
ISPM Bern	Institute of Social and Preventive Medicine, University of Bern
PEDSnet	A multi-specialty network that conducts observational research and clinical trials across multiple children's hospital health systems in the US (www.pedsnet.org)
PECARN	Pediatric Emergency Care Applied Research Network
SPHN	Swiss Personalized Health Network (https://sphn.ch/)
SwissPedData	"Harmonizing the collection of health-related data and biospecimens in pediatric hospitals throughout Switzerland", an infrastructure development project of the SPHN funded in 2017
SwissPedNet	Swiss Research Network of clinical Pediatric Hubs (www.swisspednet.ch)

many years and have been continuously refined and thus could be included directly in SwissPedData without further discussions. A related project is developing a set of CDEs for paediatric emergency medicine using the same approach. The results of that effort will be reported separately.

SwissPedData scope

SwissPedData focuses on the standardisation of the documentation of clinical encounters by paediatricians in children's hospitals. This documentation encompasses medical history, physical examination, investigations, diagnosis, treatment and procedures. It excludes laboratory data and biospecimens, as these types of data are usually not entered into EHR by the clinicians themselves. Other SPHN-funded projects are working towards the harmonization of laboratory data in Switzerland (<https://sphn.ch/fr/network/project-overview/>).

Preparatory steps

To prepare the ground for determining the new set of CDEs, the core team assessed the current status of clinical data documentation during routine encounters in participating hospitals and in ongoing clinical registries and cohort studies. They then searched the literature for other initiatives aiming to standardise paediatric EHR (fig. 2). The core team visited each participating hospital and collected clinical data entry forms and information on the EHR system used and on the degree of digitalisation of health records. The team identified any large existing national or regional clinical paediatric registries and cohort studies via the registry centre (<https://www.paediatrieschweiz.ch/swisspedregistry/>) and the clinical hubs of SwissPedNet and through information obtained from the task force members of the participating hospitals. The core team collected metadata describing the datasets collected in these

registries and cohort studies and investigated the content and format of the variables.

The core team also conducted a non-systematic, focused literature search to identify approaches to standardising paediatric data across multiple centres in other countries. The reference lists of the relevant publications identified were also scanned.

Selection of candidate common data elements for SwissPedData

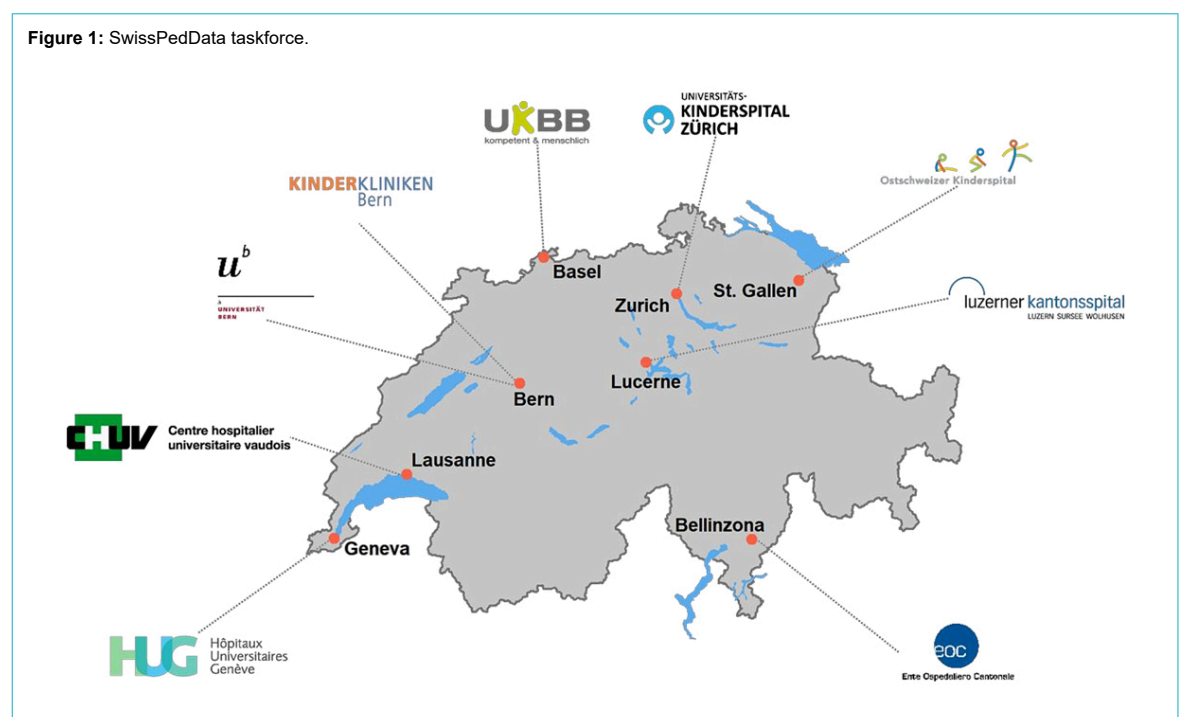
Based on the information gained in the preparatory phase, the core team defined an initial list of CDEs to be considered for inclusion in the main module (general paediatrics) of SwissPedData. This was done based on an overview of the clinical data routinely documented in the hospitals; the variables collected in ongoing clinical cohort studies and registries; and the datasets of similar international initiatives. The initial list of CDEs was further refined during a two-day retreat held at the ISPM Bern with an interdisciplinary group including six paediatricians, three paediatric epidemiologists and two paediatric registry managers.

For each paediatric subspecialty, the initial list of candidate CDEs was drafted by the core team together with one hospital paediatrician who represented the subspecialty. This first draft was based on existing datasets specific to each subspecialty, such as large cohort studies or clinical registries, and/or on expert opinion (fig. 2, selection of candidate CDEs).

Reaching a consensus: the Delphi process

The consensus finding process aimed to reach agreement on 1) a list of CDEs for SwissPedData, 2) a standardised answer format for each CDE and 3) a classification of each CDE as either mandatory, recommended or optional. Starting with the initial selection of candidate CDEs, we implemented four Delphi rounds, consisting of one face-to-

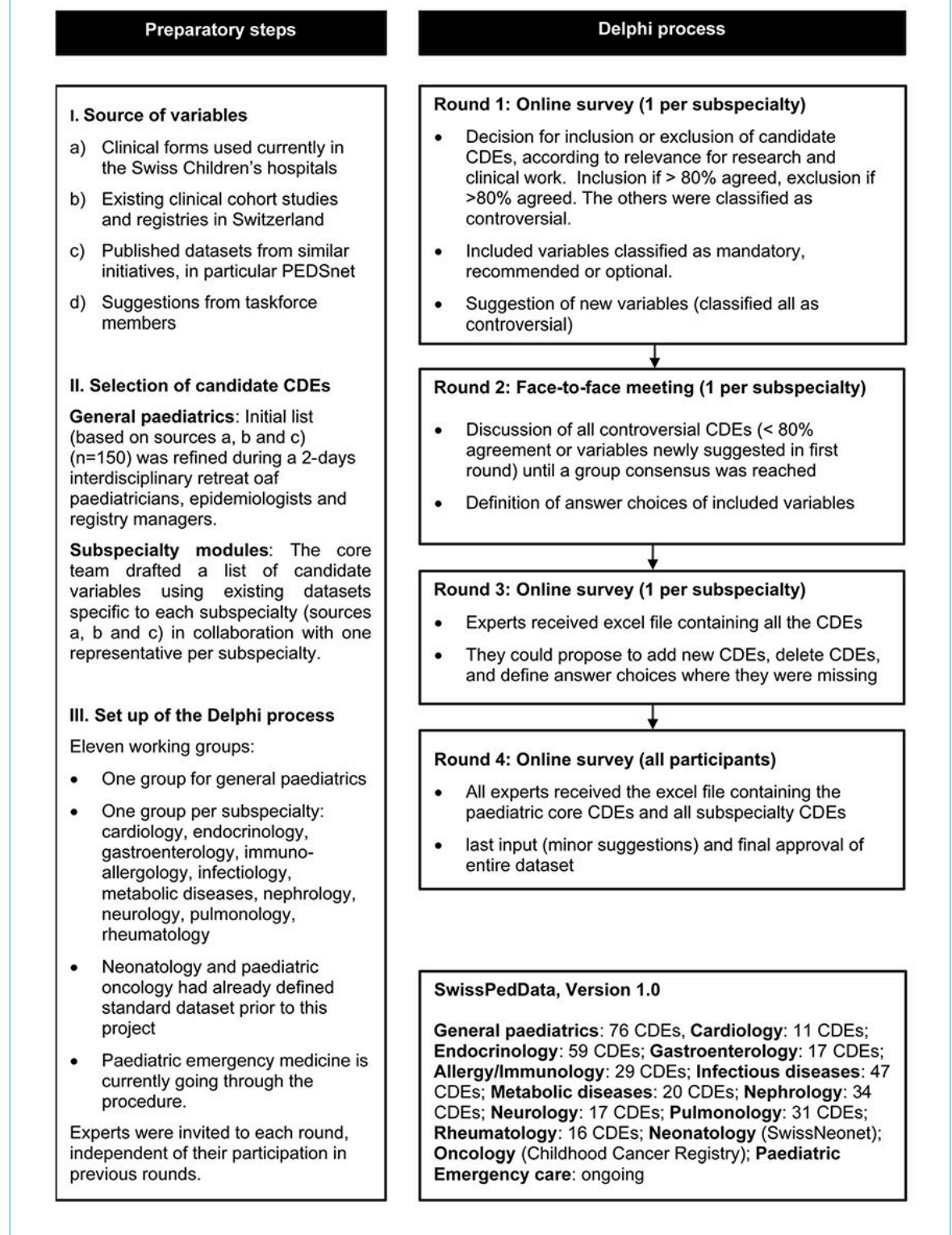
Figure 1: SwissPedData taskforce.



face meeting and three online surveys, to obtain a final set of CDEs based on a broad consensus (fig. 2). The Delphi method achieves consensus through a multi-round iterative process that involves eliciting opinions from experts and controlled feedback from the coordinating team [17, 18]. The same basic scheme was followed for the main general paediatric module and for each of the subspecialty mod-

ules. All experts were invited to each round, irrespective of whether or not they had given inputs in the previous rounds. For each online survey, the experts were asked to complete the questionnaire within two weeks. Those who had not responded within one week received a reminder e-mail. The online surveys were programmed with the soft-

Figure 2: Consensus finding process followed to define SwissPedData, a set of CDEs for recording routine encounters in children's clinics in Switzerland. CDE: Common Data Element



ware SurveyMonkey Inc., San Mateo, California, USA and analysed using Microsoft Excel.

In the first round, the experts evaluated the candidate CDEs according to their relevance for research and clinical work (fig. 2, round 1). Each expert was asked to vote for the inclusion or exclusion of each candidate CDE and to suggest any additional CDEs. The questions were: “please state for each of the proposed variables (CDEs) below whether you think they should be included in this subspecialty module of SwissPedData” and “would you add other variables (CDEs)?”. When opting for inclusion of a CDE, experts were further asked to classify the CDE as “mandatory”, “recommended” or “optional”. We retained CDEs that reached 80% for inclusion (designated as agreed) and excluded CDEs for which 80% of experts voted for exclusion. All other CDEs, including the additional CDEs suggested by the experts, were classified as “controversial”. There is no standard level of consensus in the literature, but levels ranging from 50% to 80% are commonly used [19, 20].

The second round consisted of face-to-face meetings, which were moderated by the core team and held at the ISPM Bern. During the face-to-face meetings, participants discussed all controversial CDEs and the additional CDEs suggested in the first online survey. They also agreed on standardised answer formats for the included CDEs. Eligible answer formats were a date, a date and time, a number, a binary response (e.g., yes/no), standardised response options or free text. When the discussions did not lead to a consensus, we used majority voting. Each face-to-face meeting lasted about three hours.

The third round was another e-Delphi survey, with participants being asked to check if key CDEs for their discipline were missing and to propose standardised answer formats or response options where these were missing.

In the **fourth and final round**, the agreed CDEs and answer formats were sent by email to all the experts for any last inputs and final approval.

Ethical approval was not required for this study, which did not involve the collection or use of patients' data.

Results

Current status of EHR in participating hospitals and existing initiatives aiming to standardize paediatric data

The eight participating hospitals were using different clinical systems for EHR from various vendors (table 1). Their degree of digitalisation varied: while some hospitals were using EHR for all care processes, others were only doing so for some. For example, all hospitals were recording clinical notes relating to inpatients electronically, but only half of them were using electronic drug prescriptions at the time of the survey.

We identified 5 paediatric cohort studies and 25 paediatric clinical registries with a nationwide or multiregional reach (appendix 1). The focused literature search identified four projects with similar goals in other countries, namely PECARN (Pediatric Emergency Care Applied Research Network), PHIS+ (Pediatric Health Information System), PROS (Pediatric Research in Office Settings) and PEDSnet. The initiative most similar to ours was PEDSnet, an American national paediatric learning health system that was founded in 2014 by eight children's hospitals, primarily to obtain child-specific data on the efficacy and safety of new and approved drugs [21] (<https://pedsnet.org/data/>). Currently, PEDSnet hosts analysis-ready, standardised longitudinal data from the primary, secondary and tertiary care of over 6.5 million patients. PEDSnet uses a common interoperable data platform that optimises the use of EHR, ensuring that data are entered once only. The collected data include demographics, vital status, encounters, diagnoses, vital signs, treatment and immunisations, among others (<https://pedsnet.org/data/common-data-model/>).

Consensus finding process (Delphi method)

Clinical directors proposed 121 experienced general paediatricians and subspecialists for the Delphi process, of whom 119 agreed to participate. Of these, 73 took part in the first round (online survey), 45 attended the second round (face-to-face meetings), 58 commented in the third round of the Delphi process and 68 gave their final approval of the dataset (appendix 2). The working groups contained between 7 and 14 members. All disagreements could be settled during the process through majority voting or through discussions. Most disagreements were about answer format rather than about which CDEs should be included in SwissPedData.

Table 1:

Electronic health records systems used in Swiss children's hospitals and digitalization of clinical documentation.

Children's hospital	Main IT system	Emergency clinical notes	Outpatient clinical notes	Inpatient		
				Clinical notes	Drug prescription	Vital signs
Basel	Phoenix	E	E + P	E	P	E
Bellinzona	DPI	E	E	E	E	E
Bern	ipdos	E	E + P	E	E	E
Geneva	DPI	E	E	E	E	E
Lausanne	Soarian	E	E	E	E	E
Luzern	Epic/LUKIS	E	E	E	E	E
St.Gallen	KISIM	E	E	E	P	E + P
Zürich	Phoenix	E	E	E	E	E

E: Electronic, P: Paper

SwissPedData (Version 1.0)

SwissPedData consists of 336 CDEs: 76 in the main module on general paediatrics and between 11 and 59 in each of the 10 subspecialty modules (table 2 and appendix 3). The main module covers aspects concerning all paediatric patients, whether they are outpatients or inpatients. The subspecialty modules cover aspects specific to paediatric subspecialties that are not already covered by the main module. Each module is formally structured into the same nine domains representing all care processes: 1. Care Site, 2. Demographics, 3. Medical History, 4. Physical Examination, 5. Clinical Scores, 6. Investigations, 7. Diagnosis, 8. Treatment, and 9. Equipment and Procedures. These represent domains commonly covered by EHR. The Care Site domain contains administrative data related to the hospital and to patient encounters. It includes type of admission, length of stay and scheduled follow-up. The Demographics domain contains demographic data, for example date of birth, gender, address, and country of birth. The Medical History and Physical Examination domains include clinical information such as birth history, family history, symptoms, medications and vital signs. The Clinical Scores domain contains specific scores, for example triage scale for emergency department patients or developmental tests. The Investigations domain contains data on investigations performed, such as lung function, renal ultrasound or blood glucose monitoring for patients with diabetes. The Diagnosis domain includes diagnosis and date of diagnosis, as well as diagnosis classifications such as Online Mendelian Inheritance in Man (OMIM) codes. The Treatment domain contains data on medications prescribed and administered in hospital, treatment adverse events and reasons for discontinuation of treatment. The Equipment and Procedures domain contains data on procedures performed on the patient, such as dialysis.

The full set of CDEs is shown in appendix 3, which provides a complete list of all agreed CDEs along with their description, answer format and standardised response options, and importance (mandatory, recommended or optional). Answer choices are number, binary or standardised options, or free text. When the “standardised option” format is used, specific value sets are defined. The CDEs will be implemented in children’s hospital EHR depending on their importance, categorised as mandatory, recommended or optional. Mandatory CDEs must be implemented in EHR by all participating hospitals. Recommended CDEs

should be implemented and optional CDEs may be implemented at the discretion of each hospital.

Examples of mandatory CDEs are vital parameters in the main module (general paediatrics) or “route of feeding” in the gastroenterology module. In the latter case, “route of feeding” will be recorded with standardised response options (oral, gastrostomy, naso/orogastric tube, intravenous, other). An example of a recommended CDE is “seizure type according to the ILEA 2017 classification of seizures” in the neurology module. “Opening pressure at lumbar puncture” is an optional CDE in the same module (appendix 3).

Discussion

We developed SwissPedData, a standardised national set of CDEs designed to collect clinical data during paediatric routine encounters in a harmonised way. It is the result of a broad consensus between general paediatricians and paediatric subspecialists from eight university and cantonal children’s hospitals in Switzerland. It describes all processes of paediatric medical care including clinical and paraclinical assessment, diagnosis, treatment, disposition and care site. Each part of the dataset follows the usual structure of the EHR to allow easy implementation.

Clinical data standardisation for a Swiss paediatric learning healthcare system

SwissPedData aimed to standardise items up-front at the point of data entry. Prospective, standardised recording of routine clinical encounters avoids duplicate entry into research databases. However, this should not happen at the expense of an increase in documentation time by clinicians, a concern raised during our Delphi process. To avoid this pitfall, we focused primarily on data elements that are not only useful for research, but also for clinical work, and included CDEs that are routinely documented in paediatric EHR. SwissPedData is not comprehensive and much of the clinical documentation will remain unstandardised to preserve the rich narrative details that are difficult to capture in standardised fields but are nevertheless important for daily clinical work. These narrative data could be used by researchers applying text-mining approaches. SwissPedData could also be supplemented by questionnaires to patients and their families. The implementation of SwissPedData in EHR will include careful attention to clinician workflow to minimise potential negative consequences of standardisation.

Table 2:
Examples of common data elements (CDEs) of the core module (general paediatrics) of SwissPedData.

Common data element	Format	Standardized response options	Importance	Comment / description
Follow-up after discharge / consultation	Standardised options	General paediatrician, General practitioner, Subspecialist, Nurse, None	Mandatory	Scheduled follow-up at discharge
Country of birth	Standardised options	Swiss Federal Statistical Office: ISO code of the country of origin	Mandatory	Country of birth of the patient
Birth weight	Number		Mandatory	Weight at birth in kg
Heart rate	Number		Mandatory	Heart rate in beats per minute
Glasgow Coma Scale	Number		Mandatory	
Indication for imaging study	Free text		Mandatory	Medical reason for the radiological study
Drug name	Standardised options	International non-proprietary name	Mandatory	Name of the drug(s) received as inpatient
Equipment date of insertion	Date	YYYY-MM-DD	Mandatory	

SwissPedData is designed to provide a basis for a paediatric learning health system in Switzerland in which clinical data from different children's hospitals can be combined to rapidly generate new knowledge relevant for day-to-day practice and translate it into improved health care for children. Existing learning health systems in other countries, such as PEDSnet in the US, have demonstrated that a paediatric learning health system can improve the health outcomes of children [22, 23]. Examples include the rapid identification of children suffering from glomerular diseases for clinical trials [24], comparing weight loss and safety among bariatric procedures using EHR data [25] and, recently, describing the epidemiology of paediatric patients infected by SARS-CoV-2 [26].

Strengths and limitations

The main strength of SwissPedData is that it is based on broad agreement between paediatricians from all university and cantonal paediatric clinics in Switzerland. The project received strong support from all clinical directors of Swiss children's hospitals, from the paediatric research network SwissPedNet and from more than 100 experienced paediatricians who participated in its development. SwissPedData emphasises the prospective collection of standardised data, which can greatly reduce the time and costs needed for data preparation and analysis as it avoids the need for retrospective standardisation or double entry. Our consensus finding approach could be adapted for use by other medical specialties that wish to define CDEs in the future.

SwissPedData has a number of omissions that are intentional. First, we focused on standardising a minimal set of items that are particularly relevant and specific to paediatric routine care. SwissPedData will thus not replace existing terminologies for clinical health care such as SNOMED-CT. Rather, standardised data from SwissPedData can in the future be mapped to SNOMED-CT. Second, SwissPedData does not include laboratory data or detailed radiological data. However, other projects within the SPHN are working on the standardisation of these domains. The goal is to link the standardised paediatric data extracted from EHR with laboratory data standardised thanks to other SPHN projects like L4CHLAB. Such linkage can be done through hospital patient IDs, or with birth dates and names. Third, SwissPedData will need to be translated into the Swiss national languages before implementation in children's hospital EHR.

SwissPedData is adapted to the Swiss context

The Swiss healthcare system is decentrally structured, with cantons being responsible for the organisation of local health care, and therefore is highly heterogeneous. As a consequence, children's clinics are relatively small, with catchment areas of a few 100,000 children. Obtaining sufficient patient samples for research is only possible by combining data from multiple hospitals, especially for rare conditions. However, given the differences in EHR and IT systems between hospitals, this results in long delays and huge costs for obtaining, extracting, standardising and cleaning the heterogeneous data. SwissPedData, once implemented in all children's clinics, will allow researchers to identify and recruit patients for clinical trials in real time,

to conduct retrospective studies with high-quality data, and to conduct nested prospective studies. As examples, participants of the "Clinical Data for Paediatric Research: the Swiss Approach" symposium held in 2019 drafted sketches of the following research projects based on SwissPedData: a diagnostic study on the validity of the tests used for auditory screening in newborns; a benchmarking study assessing the quality of treatment for bronchiolitis across different children's hospitals; a cohort study on the incidence of hearing loss after treatment with aminoglycosides in infancy; a cohort study on kidney injury after treatment with acyclovir; and a randomised clinical trial comparing the effectiveness of different treatment regimens for type 1 diabetes. Some of these project sketches suggested complementing the hospital dataset with available data from other sources such as the federal statistical office or laboratory data, or through the collection of additional data through questionnaires or specific examinations.

Comparison with other projects

SwissPedData is closely aligned with PEDSnet, a US-based paediatric clinical data research network [21]. PEDSnet includes eight children's hospitals that provide care for 2.8% of the paediatric population in the USA (2.1 million patients) [21]. The database contains standardised clinical data from EHR covering 6.5 million children (<https://pedsnet.org/>) and forms the basis of a high-quality research programme and learning health system. Studies based on PEDSnet data cover a wide range of research topics and study designs in paediatrics, including descriptive epidemiology [27], computable phenotyping [24], longitudinal observational studies [28] and comparative effectiveness [29]. PEDSnet established a common data model (PEDSnet CDM) from the beginning of their network, based on the Observational Health Data Sciences and Informatics collaborative's OMOP common data model. With SwissPedData, we defined a list of priority CDEs that can be mapped to SNOMED-CT in the future.

PEDSnet may also serve as a role model for the implementation of SwissPedData and has already demonstrated its usefulness for observational and interventional research and for the standardisation of care processes. Each hospital that participates in PEDSnet regularly extracts the standardised data from its EHR in a predefined way [21].

Another notable example of harmonised clinical datasets in paediatrics is the Pediatric Emergency Care Applied Research Network (PECARN), an EHR-based registry that has harmonised data in the paediatric emergency setting in seven American paediatric emergency departments to make it usable for paediatric research. PECARN uses data resources from seven paediatric emergency departments of four hospitals [30].

Outlook and next steps

All participating hospitals are committed to implementing SwissPedData in their EHR by 2024. A committee of clinicians and IT specialists in each hospital will supervise the implementation process. The EHR of children's hospitals will be restructured at the front-end to include SwissPedData CDEs. Practically, this means that EHR as seen by their users (physicians) will include the CDEs of Swis-

sPedData. For some hospitals, where this is not possible in the short term, we will also offer the possibility of transforming the source data to the CDEs and contributing it to the common dataset. SwissPedData is intended to evolve and be adaptive to existing needs. The set of CDEs can be expanded to cover more domains or to include more CDEs per domain. Temporary CDEs can be added for nested research projects. Self-completed or parent-completed questionnaires can add information relating to a child's family and home environment, which is not routinely recorded in EHR. Data from primary care encounters could also be integrated in the future.

In ongoing work, other prerequisites for the implementation of SwissPedData are being put into place: a general consent form for use of the data from patients and caregivers, a data transfer and use agreement (DTUA) between the clinics, and protocols for obtaining ethics approval for SwissPedData overall and for individual research projects. Some aspects are being dealt with within other infrastructure development projects of the SPHN network (www.sphn.ch), namely the C3-Study (citizen centred consent) project and the E-General Consent project. Furthermore, the SPHN provides legal agreement templates, including a DTUA and an ethical framework for all its projects. It is important to stress that only data useful for the clinical management of the patient will be recorded and that these data will always be stored by each children's hospital as part of the patient's file. The only difference to the previous procedure is that some of these clinical data will be recorded in a standardised way. To have access to these data for research, researchers will have to get ethical approval as usual.

It is planned that SwissPedData will be implemented as a project on the SPHN infrastructure for data exchange, so that data can in future be accessed through a central portal. The SPHN Data Coordination Centre and BioMedIT (<https://sphn.ch/network/projects/biomedit/>) can provide assistance and the infrastructure for this. The aim is to keep SwissPedData CDEs harmonized with the future releases of the SPHN dataset (<https://sphn.ch/services/documents/technical-documents/>). An additional central coordination center for paediatric research should facilitate communication between children's clinics, international research partners and funders, and also assist researchers in writing grant applications, obtaining ethical approval and accessing the necessary datasets. The resources needed to maintain SwissPedData will require the support of a central coordination center encompassing an experienced researcher ideally with a background in paediatrics, an IT specialist, and local support of the responsible clinicians and IT specialists in each hospital. Funding for the implementation and maintenance of SwissPedData will need to be secured. Potential funding sources are participation in suitable calls for proposals, charging cost-covering fees for services provided by SwissPedData and collaboration with industry, for example for post-marketing studies. Collaborations with international partners such as PEDSnet are foreseen, and first exchanges have occurred.

In conclusion, SwissPedData defines a set of common data elements (CDEs) for clinical paediatric care based on a broad agreement among university and cantonal paediatric hospitals in Switzerland. With SwissPedData, Swiss chil-

dren's hospitals will be able to provide researchers with standardized, high-quality routine clinical paediatric data in the near future. SwissPedData will provide the basis for a learning health system for paediatric care in Switzerland.

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