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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.

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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,

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 improving 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.

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)

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.paediatrieschweiz.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 (SwissNeoNet, https://www.neonet.ch/swissneonet) [15] and the Childhood Cancer Registry (https://www.childhoodcancerregistry.ch) [16]. Both datasets have been in use for

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

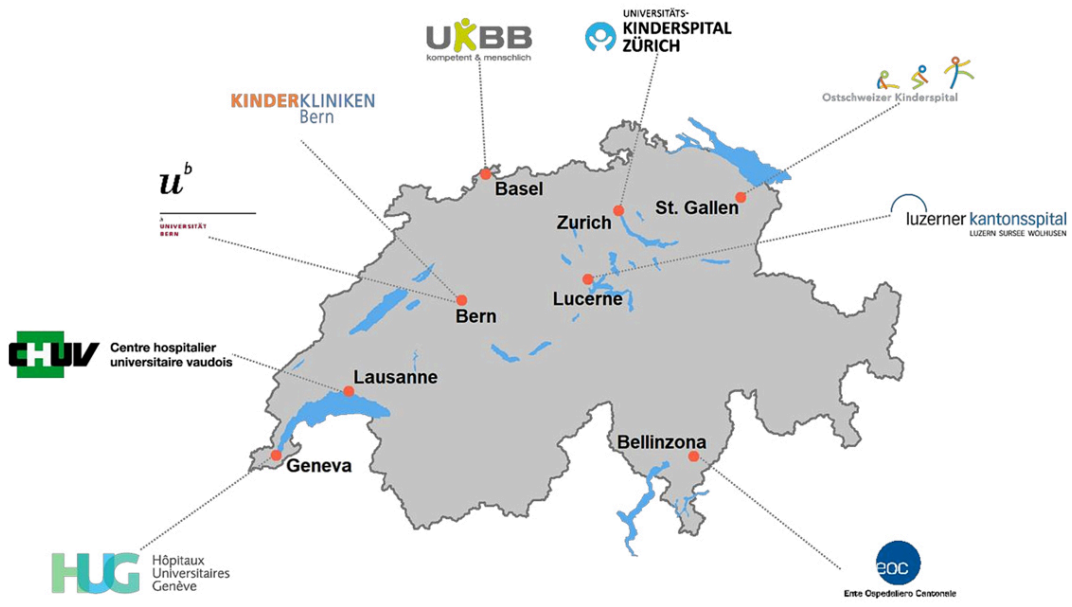
Based on the information gained in the preparatory phase, the core team defined an initial list of CDEs to be considered for inclusion in the main module (general paediatrics) of SwissPedData. This was done based on an overview of the clinical data routinely documented in the hospitals; the variables 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

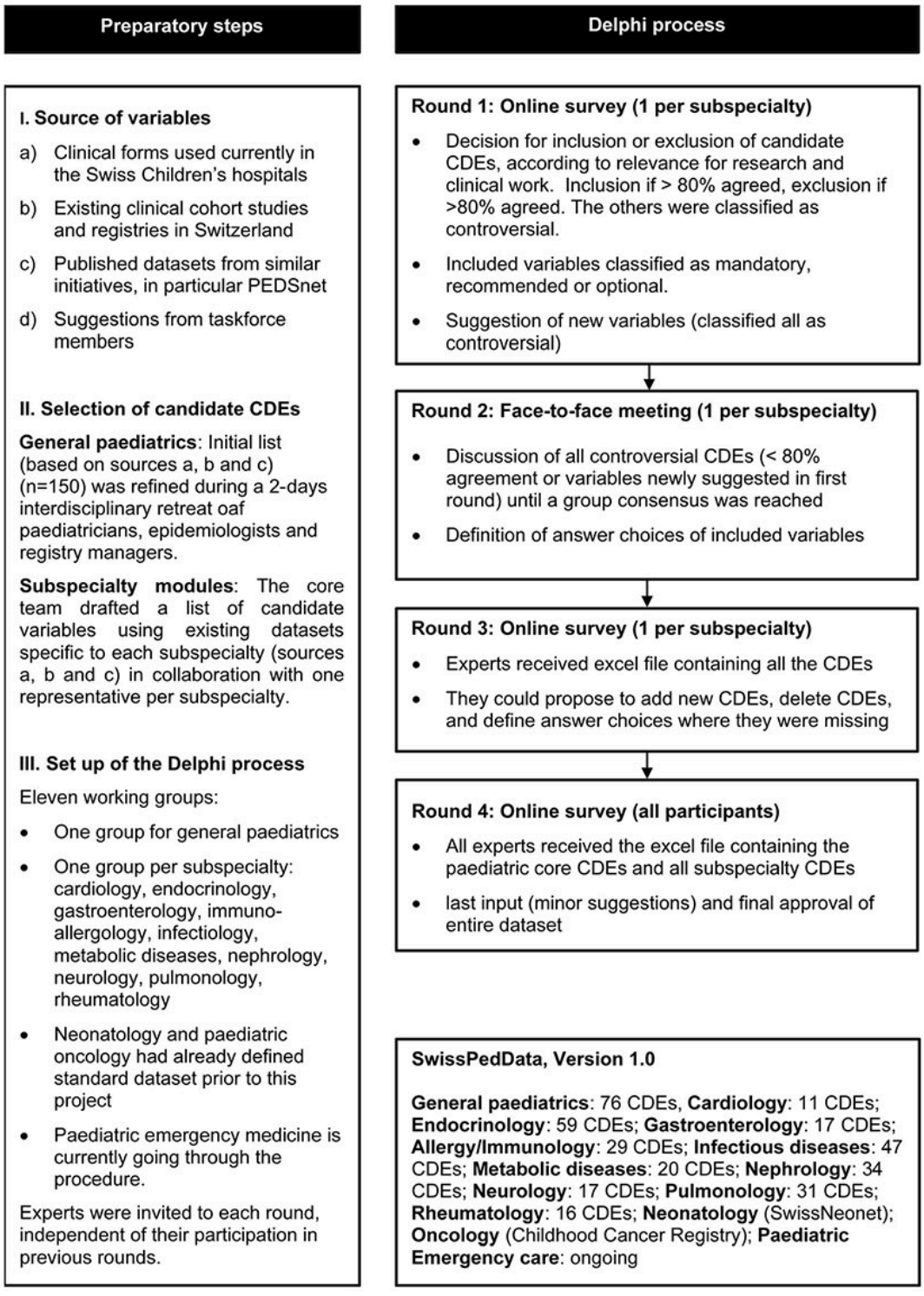
The consensus finding process aimed to reach agreement on 1) a list of CDEs for SwissPedData, 2) a standardised answer format for each CDE and 3) a classification of each CDE as either mandatory, recommended or optional. Starting with the initial selection of candidate CDEs, we implemented four Delphi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

Appendix 1: Paediatric registries and cohort studies in Switzerland

Registry / Cohort Study	Coverage
Childhood Cancer Registry ChCR	National
Swiss Primary Ciliary Dyskinesia Registry (SPCDR)	National
Swiss Cerebral Palsy Registry (Swiss-CP-Reg)	National
Swiss Growth Registry (SGR)	National
Swiss Paediatric Airway Cohort (SPAC)	National
Swiss Paediatric Renal Registry (SPRR)	National
Swiss Rare Disease Registry (SRDR)	National
Swiss Registry for Neuro-Muscular Disorders (Swiss-Reg-NMD)	National
Cystic Fibrosis (CF) newborn screening	National
Juvenile Inflammatory Rhumatism cohort (JIRcohorte)	European
SwissNeoNet Minimal Neonatal Data Set (MNDS)	National
SwissNeoNet National Asphyxia and Cooling Registry (ASP)	National
SwissNeoNet Follow-Up (FU)	National
Swiss NeuroPaediatric Stroke Registry (SNPSR)	National
Swiss Congenital Lung Anomalies (CLA) Registry	National
Swiss Mother and Child HIV Cohort Study (MoCHiV)	National
Swiss Cystic Fibrosis Infant Lung Development (SCILD) cohort	National
Swiss Pediatric Surveillance Unit (SPSU)	National
Swiss Hemophilia Registry (SHN)	National
COST Action BM1105 Patient Registry - GnRH Network	European
Registry of congenital anomalies in the canton of Vaud	National
Swiss Cleft lip and Palate Registry	National

Swiss Biliary Atresia Registry	National
Swiss registry on Autoimmune Hepatitis	National
European Registry for Primary Immunodeficiencies (ESID registry)	European
European Cystic Fibrosis Patient Registry (ECFSPR)	European
European Childhood Interstitial Lung Disease (chILD-EU) Registry	European
Swiss Inflammatory Bowel Disease Pediatric Cohort Study (Swiss IBD Pediatric Cohort Study)	National
Splenectomy Registry	Global
Pediatric and Adult Intercontinental Registry on Chronic ITP (PARC-ITP registry)	Global
Diabetes Patienten Verlaufsdokumentation Registry (DPV)	European

Appendix 2: Number of experts involved at each stage of the Delphi process

Paediatric specialty	Number of experts invited	Delphi process, number of experts involved			
		1st round	2nd round	3rd round	4th round
General paediatrics	14	8	4	4	5
Cardiology	13	10	4	7	8
Endocrinology	12	7	6	8	9
Gastroenterology	10	8	4	4	6
Allergy/Immunology	12	6	4	8	7
Infectiology	11	8	5	6	9
Metabolic diseases	8	7	2	4	3
Nephrology	12	3	4	5	4
Neurology	14	5	4	3	5
Pulmonology	11	8	5	4	6
Rheumatology	8	3	3	5	6

Appendix 3 : SwissPedData Common Data Model (CDM), Version 1.0

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Domain: Care site					
General paediatrics	**Type of admission**	standardized options	Elective admission Emergency admission	Mandatory	
General paediatrics	**Provenance**	standardized options	Other hospital Emergency department Home Other	Mandatory	
General paediatrics	**Care Handling Type**	standardized options	Inpatient Outpatient	Mandatory	
General paediatrics	**Visit start date and time**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Datetime at which the interaction between individual and the care provider institute started
General paediatrics	**Visit end date and time**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Datetime at which the interaction between individual and the care provider institute stopped
General paediatrics	**Datetime of admission**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Datetime of patient's admission to the care provider institute
General paediatrics	**Discharge destination**	standardized options	Home Other hospital Institution Other	Mandatory	Location to which the patient is discharged
General paediatrics	**Follow-up after discharge / consultation**	standardized options	General paediatrician General practitioner Subspecialist Nurse None	Mandatory	Scheduled follow-up at discharge
General paediatrics	**Translator needed**	standardized options	Yes No Unknown	Recommended	Translator needed for communication between patient and healthcare team
General paediatrics	**Hospital**	standardized options	See comments	Mandatory	Standardized response options will be name of participating children's hospitals

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
General paediatrics	**Department**	standardized options	See comments	Mandatory	Standardized response options will be name of departments of participating children's hospitals
General paediatrics	**Unit**	standardized options	See comments	Mandatory	Standardized response options will be name of units of participating children's hospitals
Infectious diseases	**If coming from another hospital: Country**	standardized options	Swiss Federal Statistical Office: ISO code of the country of origin	Mandatory	Country of originating hospital
Domain: Demographics					
General paediatrics	**Patient Datetime of birth**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Datetime of birth of the patient
General paediatrics	**Country of birth**	standardized options	Swiss Federal Statistical Office: ISO code of the country of origin	Mandatory	Country of birth of the patient
General paediatrics	**Place of birth (CH)**	number	Postal code (PLZ/NPA)	Mandatory	Municipality of birth of the patient if in Switzerland, coded by postal codes (PLZ/NPA).
General paediatrics	**Patient administrative gender**	standardized options	Male Female Other	Mandatory	
General paediatrics	**Address (postal code)**	number	Postal code (PLZ/NPA)	Mandatory	Current address of the patient, coded by postal codes (PLZ/NPA). Exact address should also be recorded
General paediatrics	**Nationality**	standardized options	Swiss Federal Statistical Office: ISO code of the country of origin	Mandatory	Current nationality of the patient
General paediatrics	**Date of immigration**	date	YYYY-MM-DD	Mandatory	Date of first immigration to Switzerland if born abroad

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Infectious diseases	**If immigrant: Type of residency permit**	standardized options	B C G L F N S undocumented	Optional	
Metabolic diseases	**Ethnicity of the mother**	standardized options	See comments	Optional	Standard classification to be defined
Metabolic diseases	**Ethnicity of the father**	standardized options	See comments	Optional	Standard classification to be defined
Rheumatology Pulmonology	**Ethnicity of the patient**	standardized options	See comments	Optional Recommended	Standard classification to be defined. Optional for rheumatology, recommended for pulmonology.
Domain: Medical history					
General paediatrics	**Reason for consultation / for admission**	free text		Mandatory	Main reason for consultation or for admission. Standard classification not defined.
General paediatrics	**Current medications: Drug name**	standardized options	International non-proprietary name	Mandatory	Name of the drug(s) received as inpatient
General paediatrics	**Current medications: Route of administration**	standardized options	Oral Intravenous Subcutaneous Intramuscular Intrathecal Rectal Inhalation Cutaneous Ocular Nasal Otic Other	Mandatory	
General paediatrics	**Current medications: Frequency of administration**	number		Mandatory	Number of administrations per 24 hours

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
General paediatrics	**Current medications: Dose**	number		Mandatory	Dose given at each administration of the drug
General paediatrics	**Current medications: Dose unit**	standardized options		Mandatory	List of possible units to be defined
General paediatrics	**Use of complementary medicine**	yes/no		Optional	Patient treated with complementary medicine at home or in hospital
General paediatrics	**Birth weight**	number		Mandatory	Weight at birth in kg
General paediatrics	**Birth length**	number		Mandatory	Length at birth in cm
General paediatrics	**Birth's head circumference**	number		Mandatory	Head circumference at birth in cm
General paediatrics	**Delivery mode**	standardized options	Caesarean section Instrumental vaginal delivery Spontaneous vaginal delivery	Mandatory	Birth delivery mode
General paediatrics	**Gestational age**	number		Mandatory	Post-menstrual age at birth in week and days
General paediatrics	**Apgar score 1 min**	number		Recommended	Apgar score 1 min after birth
General paediatrics	**Apgar score 5 min**	number		Recommended	Apgar score 5 min after birth
General paediatrics	**Apgar score 10 min**	number		Recommended	Apgar score 10 min after birth
General paediatrics	**Mother's year of birth**	number		Mandatory	Year of birth of the mother
General paediatrics	**Father's year of birth**	number		Mandatory	Year of birth of the father
General paediatrics	**Year(s) of birth of sibling(s)**	number		Mandatory	Year of birth of sibling(s) if any
General paediatrics	**Drug allergies**	standardized options	International Nonproprietary Name of drug	Mandatory	Known drug allergies
General paediatrics	**Documented food allergies**	yes/no		Mandatory	Presence of any documented food allergy
Endocrinology	**Age at menarche**	number		Mandatory	Age at menarche in years
Endocrinology	**Age at thelarche**	number		Mandatory	Age at thelarche in years
Endocrinology	**Age at pubarche**	number		Mandatory	Age at pubarche in years

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Endocrinology	**Single/Multiple birth**	number		Recommended	Number of children born from the same pregnancy as the patient's
Endocrinology	**Neonatal hypoglycaemia**	standardized options	No Yes, confirmed Yes, reported by patient/family	Recommended	History of hypoglycaemia in the neonatal period
Endocrinology	**Neonatal hyperbilirubinemia**	standardized options	No Yes, confirmed Yes, reported by patient/family	Recommended	History of hyperbilirubinemia in the neonatal period (only hyperbilirubinemia treated with phototherapy)
Endocrinology Nephrology	**Mother's height**	number		Mandatory	Height of the mother in cm
Endocrinology Nephrology	**Father's height**	number		Mandatory	Height of the father in cm
Endocrinology	**Mother's age at menarche**	number		Mandatory	Age of the mother at menarche in years
Endocrinology	**Father's puberty**	standardized options	Normal Early Late	Mandatory	
Endocrinology	**Diabetes in first degree relatives**	standardized options	No Yes, Type 1 Yes, Type 2 Yes, Monogenic Unknown	Mandatory	Any type of diabetes in a first degree relative
Endocrinology	**Thyroid disorder in first degree relative**	yes/no		Mandatory	Presence of thyroid disorder in a first degree relative
Endocrinology	**Other auto-immune disorders in first degree relative**	yes/no		Recommended	Presence of auto-immune disorder in a first degree relative. With added box for free text to specify the disease.
Endocrinology	**Other endocrinopathy in first degree relative**	yes/no		Mandatory	Presence of endocrinopathy in a first degree relative. With added box for free text to specify the disease.

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Endocrinology	**Fertility problems in first degree relative**	yes/no		Recommended	Presence of fertility problems in first degree relatives. With added box for free text to specify the disease.
Endocrinology	**Severe hypoglycaemia (requiring assistance OR coma)**	number		Mandatory	Number of events since last visit
Endocrinology	**Mild hypoglycaemia (BG < 3.9mmol/l)**	number		Mandatory	Number of events per month
Endocrinology	**Ketoacidosis**	standardized options	No Yes, managed ambulatorily Yes, with hospitalization	Mandatory	History of ketoacidosis
Endocrinology	**Diagnostic of obesity in first degree relative**	yes/no		Recommended	Diagnostic of obesity in a first degree relative
Gastroenterology	**Nutrition habits**	standardized options	No specific diet Vegetarian Vegan Other	Recommended	Nutrition habits of the patient
Gastroenterology Metabolic diseases	**Route of feeding**	standardized options	Oral Gastrostomy Naso/orogastric tube Intravenous Other	Mandatory	The route(s) by which the patient is fed
Allergy/Immunology	**History of rhinoconjonctivitis**	standardized options	Yes, reported Yes, documented No	Mandatory	
Allergy/Immunology	**History of atopic dermatitis**	standardized options	Yes, reported Yes, documented No	Mandatory	
Allergy/Immunology	**History of wheezing**	standardized options	Yes, reported Yes, documented No	Mandatory	
Allergy/Immunology	**History of asthma**	standardized options	Yes, reported Yes, documented No	Mandatory	
Allergy/Immunology	**Respiratory support during first hours of life**	standardized options	Yes, reported Yes, documented No	Recommended	Presence of any kind of respiratory support (non-invasive and invasive ventilation) during first hours of life

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Allergy/Immunology	**Supplemental O2 during first hours of life**	standardized options	Yes, reported Yes, documented No	Recommended	Supplemental oxygen administered during first hours of life
Allergy/Immunology	**Chronic diarrhea**	yes/no		Mandatory	
Allergy/Immunology	**Number of hospitalisations for IV antibiotherapy in life**	number		Mandatory	
Allergy/Immunology	**Maximal number of otitis media in one year**	number		Mandatory	
Allergy/Immunology	**Number of pneumonias in life**	number		Mandatory	
Allergy/Immunology	**Number of sinusitis in life**	number		Mandatory	
Allergy/Immunology	**Number of meningitis in life**	number		Mandatory	
Allergy/Immunology	**Family history of atopic diseases**	yes/no		Mandatory	Presence of atopic diseases in a first degree relative
Allergy/Immunology	**Family history of immunodeficiency**	yes/no		Mandatory	Presence of immunodeficiency in a first degree relative
Allergy/Immunology	**Family history of auto-immune disease**	yes/no		Mandatory	Presence of auto-immune disease in a first degree relative
Allergy/Immunology	**Family history of angioedema**	yes/no		Mandatory	Presence of angioedema in a first degree relative
Allergy/Immunology Gastroenterology	**Documented food allergy by oral food challenge**	yes/no		Mandatory	Presence of any documented food allergy (diagnosed by physician)
Allergy/Immunology	**Hymenoptera venom allergies**	standardized options	Yes, reported Yes, documented No	Mandatory	Known documented hymenopter allergies
Allergy/Immunology	**History of anaphylaxis**	standardized options	Yes, reported Yes, documented No	Mandatory	History of anaphylaxis
Allergy/Immunology	**Autoimmune or inflammatory diseases in the patient**	yes/no		Mandatory	Classification for type of autoimmunity (organ specific or systemic) and organ(s) involved will be further defined.
Infectious diseases	**History of fever (>38°C)**	yes/no		Mandatory	
Infectious diseases	**If history of fever: Number of days with fever**	number		Mandatory	
Infectious diseases	**History of cough**	yes/no		Mandatory	

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Infectious diseases	**History of running nose**	yes/no		Mandatory	
Infectious diseases	**History of diarrhea**	yes/no		Mandatory	
Infectious diseases	**History of vomiting**	yes/no		Mandatory	
Infectious diseases	**History of headache**	yes/no		Mandatory	
Infectious diseases	**Travel history in the last 6 months**	standardized options	Swiss Federal Statistical Office: ISO code of the country of origin (selection of >1 possible)	Mandatory	Country(ies) visited in the last 6 months
Infectious diseases	**History of tick bite**	yes/no		Recommended	
Infectious diseases	**If history of tick bite: Month of tick bite**	date	YYYY-MM	Recommended	
Infectious diseases	**History of contact with animals**	yes/no	No Yes	Optional	Standard animal list to be defined
Infectious diseases	**Pertussis immunization during pregnancy**	yes/no		Mandatory	For patients under 6 months of age
Infectious diseases	**Influenza immunization during pregnancy**	yes/no		Mandatory	For patients under 6 months of age
Infectious diseases	**Prolonged rupture of membranes**	yes/no		Mandatory	For patients under 1 month of age. Prolonged rupture defined as longer than 18h
Infectious diseases	**Maternal GBS colonization**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal HIV serology**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal HBsAg**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal HBsAb**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal HBcAb**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal HBeAg**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Infectious diseases	**Maternal HCV serology**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal CMV serology (IgG / IgM)**	standardized options	Positive Negative Unknown	Optional	For patients under 1 month of age
Infectious diseases	**Maternal syphilis serology**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal rubella serology**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Infectious diseases	**Maternal toxoplasmosis serology**	standardized options	Positive Negative Unknown	optional	For patients under 1 month of age
Infectious diseases	**Maternal Chagas serology**	standardized options	Positive Negative Unknown	Mandatory	For patients under 1 month of age
Metabolic diseases	**Self-monitoring of blood glucose**	yes/no		Optional	Regular self-monitoring of blood glucose done at home
Metabolic diseases	**Self-monitoring of ketone bodies**	yes/no		Optional	Regular self-monitoring of ketone bodies done at home
Nephrology	**Prenatal ultrasound**	standardized option	Normal An-/Oligohydramnios Polyhydramnios Megacystis Megaureter Bilateral renal pelvis dilatation > 10 mm Bilateral renal pelvis dilatation < 10 mm Unilateral renal pelvis dilatation > 10 mm Renal cysts Renal agenesis or ectopia Multicystic-dysplastic kidney and bladder extrophy	Mandatory	
Nephrology	**Family history of renal disease (1st-2nd degree)**	yes/no		Mandatory	
Neurology	**Seizure type (ILEA 2017 Classification of Seizures)**	standardized options	Focal Onset Generalized Onset Unknown Onset Unclassified	Recommended	Seizure type according to the ILEA 2017 classification of seizures
Neurology	**Family history of neurological diseases**	yes/no		Recommended	Family history of any type of neurological diseases

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Pulmonology	**Cough**	standardized options	No Yes, acute and dry Yes, acute and wet Yes, chronic and dry Yes, chronic and wet	Recommended	Cut-off for acute/chronic 4 weeks
Rheumatology	**Recurrent fever**	yes/no		Mandatory	History of recurrent fever
Rheumatology	**History of uveitis**	yes/no		Mandatory	Presence of active uveitis
Rheumatology	**History of inflammatory skin disease**	yes/no		Mandatory	Presence of skin involvement
Rheumatology	**Family history of inflammatory rheumatic disease**	standardized options	No Yes, without spondyloarthropathy Yes, with spondyloarthropathy	Mandatory	Presence of any rheumatic disease in the family
Rheumatology	**Family history of inflammatory skin disease**	standardized options	No Yes, without psoariasis Yes, with psoriasis	Mandatory	Presence of any skin disease in the family
Rheumatology	**Family history of chronic intestinal diseases**	yes/no		Mandatory	Presence of any chronic intestinal disease in the family
Rheumatology	**Family history of recurrent fever**	yes/no		Mandatory	Presence of recurrent fever in the family
Domain: Physical examination					
General paediatrics	**Heart rate**	number		Mandatory	Heart rate in beats per minute
General paediatrics	**Systolic blood pressure**	number		Mandatory	Value of the systolic blood pressure in mmHg
General paediatrics	**Diastolic blood pressure**	number		Mandatory	Value of the diastolic blood pressure in mmHg
General paediatrics	**Respiratory rate**	number		Mandatory	Respiratory rate in breaths per minute
General paediatrics	**Oxygen saturation**	number		Mandatory	Measured oxygen saturation in %
General paediatrics	**Temperature**	number		Mandatory	Measured temperature of the patient in Celsius degrees
General paediatrics	**Weight**	number		Mandatory	Measured weight of the patient in kg

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
General paediatrics	**Height**	number		Mandatory	Measured height of the patient in cm
General paediatrics	**Head circumference**	number		Mandatory	Measured head circumference of the patient in cm
Endocrinology	**Sitting height**	number		Recommended	Sitting height measured sitting with straight back in in cm
Endocrinology	**Arm span**	number		Recommended	Arm span: arms streched horizontally, measurement from fingertip to fingertip in cm
Endocrinology	**Waist circumference**	number		Recommended	In cm
Endocrinology	**Hip circumference**	number		Recommended	In cm
Endocrinology	**Goiter**	yes/no		Recommended	Presence of goiter
Endocrinology	**Gynecomastia**	standardized options	No Yes, unilateral Yes, bilateral	Recommended	Presence of gynecomastia
Endocrinology Metabolic diseases	**Dysmorphic signs**	yes/no		Recommended	Presence of dysmorphic features. If answer is yes, specification with standardized classification to be defined.
Endocrinology	**Cryptorchidism**	standardized options	No Yes, unilateral Yes, bilateral	Mandatory	Presence of cryptorchidism
Endocrinology	**Insulin injection site**	standardized options	Normal Abnormal, lipoatrophy Abnormal, lipohypertrophy	Optional	Inspection of insulin delivery sites
Endocrinology	**Retinopathy screening**	normal/abnormal		Optional	
Endocrinology	**Neuropathy screening performed**	standardized options	No Yes, vibration Yes, monofilament	Optional	
Endocrinology	**Testis volume right side**	number		Mandatory	Volume of right testis in ml
Endocrinology	**Testis volume left side**	number		Mandatory	Volume of left testis in ml

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Endocrinology	**Tanner breast stage**	number		Mandatory	
Endocrinology	**Tanner pubic hair stage**	number		Mandatory	
Endocrinology	**Tanner axillary hair stage**	number		Mandatory	
Endocrinology	**Tanner genital stage**	number		Recommended	
Endocrinology	**Breast size**	number		Optional	In cm
Endocrinology	**Female genital examination**	normal/abnormal		Mandatory	
Endocrinology	**Penis length**	number		Recommended	In cm
Endocrinology	**Chovstek sign**	yes/no		Recommended	Twitching of facial muscles in response to tapping over the area of the facial nerve
Endocrinology	**Trousseau sign**	yes/no		Recommended	Carpopedal spasm that results from ischemia
Endocrinology	**Thyroid nodule**	yes/no		Recommended	Presence of thyroid nodule
Infectious diseases Metabolic diseases Rheumatology	**Hepatomegaly noted at physical examination**	yes/no		Mandatory	
Infectious diseases Metabolic diseases Rheumatology	**Splenomegaly noted at physical examination**	yes/no		Mandatory	
Infectious diseases	**Meningeal signs noted at physical examination**	yes/no		Mandatory	
Infectious diseases Rheumatology	**Skin lesion noted at physical examination**	yes/no		Mandatory	
Infectious diseases	**Irritability noted during physical examination**	yes/no		Mandatory	
Infectious diseases Rheumatology	**Adenopathy noted at physical examination**	standardized options	No Yes, localized Yes, generalized	Mandatory	
Infectious diseases	**Respiratory distress noted at physical examination**	yes/no		Mandatory	
Infectious diseases	**Conjunctivitis noted at physical examination**	yes/no		Mandatory	
Infectious diseases	**Prolonged capillary refill time (> 2 sec) noted at physical examination**	yes/no		Mandatory	

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Infectious diseases	**Signs of dehydration noted at physical examination**	standardized options	No Yes, < 5% Yes, 5-10% Yes, >10%	Mandatory	
Metabolic diseases	**Skin abormalities**	yes/no		Mandatory	Presence of skin abnormalities
Metabolic diseases	**Abnormal body proportions**	yes/no		Recommended	Presence of abnormal body proportions
Nephrology	**Average 24-hour arterial pressure, systolic**	number		Mandatory	In mmHg
Nephrology	**Average 24-hour arterial pressure, diastolic**	number		Mandatory	In mmHg
Nephrology	**Average daytime systolic BP**	number		Mandatory	In mmHg
Nephrology	**Average daytime diastolic BP**	number		Mandatory	In mmHg
Nephrology	**Average night-time systolic BP**	number		Mandatory	In mmHg
Nephrology	**Average night-time diastolic BP**	number		Mandatory	In mmHg
Nephrology	**Mean Arterial Pressure (MAP)**	number		Mandatory	Measured MAP in mmHg
Nephrology	**Blood pressure dipping pattern**	number		Mandatory	Difference between daytime mean systolic pressure and night-time mean systolic pressure expressed as a percentage of the day value
Neurology	**Walking ability**	standardized options	Community ambulator Household ambulator Non-ambulatory	Mandatory	
Pulmonology	**Auscultation**	normal/abnormal		Mandatory	
Pulmonology	**Thorax shape**	normal/abnormal		Mandatory	The shape of the thorax
Rheumatology	**Active arthritis**	yes/no		Mandatory	Presence of active arthritis
Rheumatology	**If active arthritis: number of joints involved**	number		Mandatory	Number of joints involved in active arthritis
Rheumatology	**Maximal mouth opening**	number		Mandatory	Maximal mouth opening in mm
Rheumatology	**Muscle strength**	normal/abnormal		Recommended	Overall muscle strength

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Domain: Clinical scores					
General paediatrics	**Triage scale (ED), type**	standardized options	Australasian Triage Scale Canadian Triage Scale Other	Mandatory	Name of the triage scale used
General paediatrics	**Triage scale (ED), value**	number		Mandatory	Value of the triage scale
General paediatrics	**AVPU score**	standardized options	Alert Voice Pain Unresponsive	Mandatory	
General paediatrics	**Glasgow Coma Scale**	number		Mandatory	
Cardiology	**Modified Ross heart failure classification for children**	standardized options	Class I Class II Class III Class IV	Mandatory	Class I: Asymptomatic Class II: Mild tachypnea or diaphoresis with feeding in infants, dyspnea on exertion in older children Class III: Marked tachypnea or diaphoresis with feeding in infants, marked dyspnea on exertion, prolonged feeding times with growth failure Class IV: Symptoms such as tachypnea, retractions, grunting or diaphoresis at rest

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Cardiology	**NYHA classification for adults**	standardized options	Class I Class II Class III Class IV	Mandatory	Class I: No symptoms and no limitation in ordinary physical activity Class II: Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. Class III: Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest. Class IV: Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.
Endocrinology	**Endocrinology clinical score type**	standardized options	Crook score Billewicz score Ferriman-Gallway score Prader stage External genitalia score	Optional	Type of score
Endocrinology	**Endocrinology clinical score result**	number	number	Optional	Result of score
Gastroenterology	**PCDAI**	number		Mandatory	Paediatric Crohn's Disease Activity Index
Gastroenterology	**PUCAI**	number		Mandatory	Paediatric Ulcerative Colitis Activity Index
Gastroenterology	**PYMS score**	number		Mandatory	Paediatric Yorkhill Malnutrition Score
Gastroenterology	**Bristol stool scale**	number		Mandatory	
Allergy/Immunology	**SCORAD index**	number		Mandatory	SCORing Atopic Dermatitis Index
Metabolic diseases Neurology	**Developmental test: Type**	standardized options	Bayley II Bayley III Griffith Other	Mandatory	Type of developmental test performed

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Metabolic diseases Neurology	**Development test: Results**	normal/abnormal		Mandatory	Result of developmental test performed
Metabolic diseases	**Developmental delay**	yes/no		Mandatory	Developmental delay as assessed by treating physician
Nephrology	**CKD stage**	number		Mandatory	Chronic Kidney Disease stage
Pulmonology	**Epworth Sleepiness Scale**	number		Mandatory	
Pulmonology	**Lung-to-Head-Ratio**	number		Mandatory	Congenital diaphragmatic hernia
Pulmonology	**PICADAR**	number		Mandatory	PrImary CiliARy DyskinesiA Rule
Domain: Investigations					
General paediatrics	**Type of radiological study (detailed)**	standardized options	See comments	Mandatory	Standard classification to be defined
General paediatrics	**Date and time of imaging study**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Date and time of the radiological study
General paediatrics	**Radiation dose**	number		Mandatory	If applicable, dose of radiation in mSv
General paediatrics	**Indication for the imaging study**	free text		Mandatory	Medical reason for the radiological study
Cardiology	**ECG performed**	yes/no		Mandatory	Date of study should be recorded
Cardiology	**Holter-ECG**	yes/no		Mandatory	Date of study should be recorded
Cardiology	**Ergometry**	yes/no		Mandatory	Date of study should be recorded
Cardiology	**Echocardiography performed**	yes/no		Mandatory	Detailed standardized echo measurements will be discussed in the future. Date of study should be recorded
Cardiology	**Cardiac electrophysiology study performed**	yes/no		Mandatory	Date of study should be recorded
Cardiology	**Diagnostic cardiac catheterization (hemodynamic study) performed**	yes/no		Mandatory	Date of study should be recorded

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Endocrinology	**Bone age: method**	standardized options	Greulich & Pyle BoneXpertR Tanner Whitehouse	Mandatory	Method used to assess radiographic bone age. Date of study should be recorded
Endocrinology	**Bone age: result**	number		Mandatory	Bone age result in years
Endocrinology Metabolic diseases	**Use of continuous glucose monitoring**	yes/no		Recommended	Use of glucose sensor
Endocrinology	**Number of days per week with continuous glucose monitoring**	number		Mandatory	Days per week
Endocrinology	**Continuous glucose monitoring: Device**	standardized options	Freestyle libre Freestyle libre 2 Dexcom G5 Dexcom G6 Medtronic Guardian Medtronic Enlyte	Mandatory	
Endocrinology	**Blood glucose self-measurement**	number		Mandatory	Number of measures per week
Endocrinology	**Scans per day**	number		Mandatory	If Flash Glucose Monitoring (FGM) is used
Endocrinology	**Blood ketone measurement**	number		Mandatory	Number of measures per week
Endocrinology	**Mean glucose**	number		Mandatory	mmol/l
Endocrinology	**Glucose variability**	number		Mandatory	%
Endocrinology	**Time in range**	number		Mandatory	Time between 4.0 and 10.0 mmol/l in %
Endocrinology	**Time in hypoglycemia**	number		Mandatory	Time < 3.9mmol/l in %
Gastroenterology	**Type of gastrointestinal endoscopy**	standardized options	Upper Lower Upper and lower Other	Mandatory	Date of study should be recorded
Gastroenterology	**Indication for gastrointestinal endoscopy**	standardized options	Rectal bleeding Abdominal pain Dysphagia Diarrhea Other	Mandatory	Medical reason for the endoscopic study. Other include for example oesophageal atresia or other anatomical abnormality, food impaction

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Gastroenterology	**Gastrointestinal endoscopic biopsy**	yes/no		Mandatory	Gastrointestinal endoscopic biopsy performed. Date of study should be recorded
Gastroenterology	**Impedance-pHmetry**	yes/no		Mandatory	Date of study should be recorded
Gastroenterology	**Type of breath test**	standardized options	Lactose Lactulose Fructose Urea Other	Mandatory	Type of breath test. Date of study should be recorded
Gastroenterology	**Capsule endoscopy**	yes/no		Mandatory	Date of study should be recorded
Gastroenterology	**Endoscopic ultrasound**	yes/no		Mandatory	Date of study should be recorded
Gastroenterology	**Liver biopsy**	yes/no		Mandatory	Date of study should be recorded
Allergy/Immunology	**Prick-test performed**	yes/no		Mandatory	Date of study should be recorded
Allergy/Immunology Pulmonology	**sIgE performed**	yes/no		Mandatory	sIgE stands for specific serum immunoglobulin E. Date of study should be recorded
Allergy/Immunology	**Result of sIgE**	positive/negative		Mandatory	sIgE stands for specific serum immunoglobulin E
Allergy/Immunology	**Result of prick-test**	positive/negative		Mandatory	Date of study should be recorded
Allergy/Immunology	**Allergen challenge performed**	yes/no		Mandatory	Date of study should be recorded
Allergy/Immunology	**Allergen challenge result**	positive/negative		Mandatory	
Infectious diseases	**Urine collection method**	standardized options	Urethral catheterization Clean catch void Urine collection bag Mid-stream urine Suprapubic aspiration	Mandatory	Method of collection of urine for culture. Date of study should be recorded
Infectious diseases	**Mantoux test**	number		Mandatory	In mm. Date of study should be recorded
Infectious diseases	**Mantoux test: interpretation**	standardized options	Positive Negative Doubtful Unknown	Mandatory	Healthcare provider's interpretation of Mantoux test

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Infectious diseases	**IGRA result**	standardized options	Positive Negative Indeterminate	Mandatory	IGRA stands for Interferon-Gamma Release Assay. Date of study should be recorded
Nephrology	**Renal ultrasound result**	normal/abnormal		Mandatory	Date of study should be recorded
Nephrology	**Renal MRI result**	normal/abnormal		Mandatory	Date of study should be recorded
Nephrology	**Voiding cystourethrography or kidney microbubble ultrasound results**	standardized options	No vesicoureteral reflux Vesicoureteral reflux, unilateral – Grade I Vesicoureteral reflux, unilateral – Grade II Vesicoureteral reflux, unilateral – Grade III Vesicoureteral reflux, unilateral – Grade IV Vesicoureteral reflux, bilateral – Grade I Vesicoureteral reflux, bilateral – Grade II Vesicoureteral reflux, bilateral – Grade III Vesicoureteral reflux, bilateral – Grade IV	Mandatory	Date of study should be recorded
Nephrology	**Posterior urethral valves**	yes/no			
Nephrology	**Renal scintigraphy results**	standardized options	Normal Hypoplasia Scars Other	Mandatory	Date of study should be recorded
Nephrology	**Estimated GFR by Schwartz formula**	number		Mandatory	GFR [ml/min]
Nephrology	**Proteinuria**	number		Mandatory	In mg/mmol (spot-urine) or mg/m2/h for 24h Urine
Nephrology Neurology Pulmonology	**Genetic test performed**	yes/no		Mandatory Recommended	Mandatory for nephrology, recommended for neurology and pulmonology
Neurology	**Neurologic electrophysiologic study: Type**	standardized options	EEG EMG AEP SEP VEP Other	Mandatory	EEG: electroencephalogram, EMG: electromyography, AEP: auditory evoked potentials, SEP: somatosensory evoked potentials, VEP: visual evoked potential Date of study should be recorded

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Neurology	**Neurologic electrophysiologic study: Result**	normal/abnormal		Mandatory	
Metabolic diseases Neurology	**Hearing test: Type**	standardized options	OAE AEP Pure tone audiometry	Mandatory	OAE: otoacoustic emissions, AEP: auditory evoked potentials Date of study should be recorded
Metabolic diseases Neurology	**Hearing test: Result**	normal/abnormal		Mandatory	
Neurology	**Vision test: Performed by**	standardized options	Ophtalmologist Optometrist Peadiatrician Other	Recommended	Health professional who tested vision
Neurology	**Vision test: Result**	normal/abnormal		Recommended	
Neurology	**Lumbar puncture performed**	yes/no		Mandatory	Date of study should be recorded
Neurology	**Opening Pressure at Lumbar Puncture**	number		Optional	Opening pressure in cmH2O
Pulmonology	**Spirometry performed**	yes/no		Mandatory	Date of study should be recorded
Pulmonology	**Lung function: RV**	number		Recommended	RV: Residual volume. In L
Pulmonology	**DLCO**	number	Diffusion capacity of the lung for carbon monoxide	Recommended	DLCO: diffusing capacity of the lungs for carbon monoxide. In ml CO/min/mmHg
Pulmonology	**Lung function: Bronchodilator administered**	yes/no		Mandatory	
Pulmonology	**Bronchoscopy performed**	yes/no		Mandatory	Date of study should be recorded
Pulmonology	**Lung function: Challenge test performed (treadmill, methacholine challenge test)**	yes/no		Mandatory	
Pulmonology	**Broncho-alveolar lavage performed**	yes/no		Mandatory	
Pulmonology	**Sweat test results**	standardized options		Mandatory	Chloride in mmol/l (Macroduct) Conductivity in mmol/l eq NaCl (Nanoduct) Date of study should be recorded

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Pulmonology	**Sleep studies**	standardized options	Polysomnography Respiratory Polygraphy Oximetry	Mandatory	Sleep studies performed Date of study should be recorded
Pulmonology	**Lung function: FEV1**	number		Mandatory	FEV1: forced expiratory volume-one second. pre/post absolute number in L
Pulmonology	**Lung function: FVC**	number		Mandatory	FVC: forced vital capacity. Pre/post. In L
Pulmonology	**Lung function: TLC**	number		Recommended	TLC: Total lung capacity. In L
Pulmonology	**Lung function: LCI**	number		Recommended	LCI: Lung clearance index. Equipment / gas currently in use in each center
Pulmonology	**Lung function: Nasal NO**	number		Recommended	Nasal NO: Nasal nitric oxide measurement. in ppb or nl/mn
Pulmonology	**Lung function: FeNO**	number		Recommended	FeNO: exhaled nitric oxide test. Online or Off-line method. absolute number in ppb
Pulmonology	**Lung function: CPET performed**	yes/no		Recommended	CPET: Cardiopulmonary Exercise Testing
Pulmonology	**Lung function: FEF 25-75**	number		Recommended	FEF25-75: Forced expiratory flow over the middle one half of the FVC (force vital capacity). in L/s
Pulmonology	**Lung function: FEV 0.75**	number		Recommended	FEV 0.75: forced expiratory volume in 3/4 of a second. pre/post. absolute number in L
Pulmonology	**Lung function: sRaw**	number		Recommended	sRaw: specific airway resistance. kPa/sec
Pulmonology	**Lung function: FRC**	number		Recommended	FRC: functional residual capacity. in L
Pulmonology	**Lung function: FRC: Test**	standardized options	Bodyplethysmography MBW	Recommended	MBW: multiple breath washout

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Domain: Diagnosis					
General paediatrics	**Diagnosis**	See comments	See comments	Mandatory	Inpatients diagnosis are ICD10 coded and outpatients diagnosis are free text.
General paediatrics	**Date of diagnosis**	date	YYYY-MM-DD	Mandatory	
General paediatrics	**Cause of death**	See comments	See comments	Mandatory	Standard classification to be defined
General paediatrics	**Date of death**	date	YYYY-MM-DD	Mandatory	
Cardiology	**IPCCC diagnosis**	standardized options	IPCCC Code	Mandatory	IPCCC: International Paediatric and Congenital Cardiac Code
Allergy/Immunology	**Allergic disease confirmation**	standardized options	Skin prick test Allergen challenge sIgE	Mandatory	
Infectious diseases	**If infectious diagnosis: Type of documentation**	standardized options	Clinically documented infection Microbiologically documented infection	Mandatory	
Infectious diseases	**If infectious diagnosis: Nosocomial**	yes/no		Mandatory	
Infectious diseases	**If nosocomial infection: Date of first symptom**	date	YYYY-MM-DD	Mandatory	
Infectious diseases	**If nosocomial infection: Site of infection**	standardized options	Respiratory tract Gastro-intestinal tract Urinary tract Surgical site Other	Mandatory	
Metabolic diseases	**Diagnosis confirmation**	standardized options	Clinical Biochemical Enzymatic Genetic	Mandatory	The way diagnosis has been confirmed
Metabolic diseases	**Diagnosis suspicion**	standardized options	Prenatal Newborn Selective	Mandatory	The type of screening that led to the diagnosis
Neurology	**OMIM code**	standardized options	OMIM code	Recommended	OMIM: Online Mendelian Inheritance in Man
Neurology	**HPO code**	standardized options	HPO code	Optional	HPO: Human Phenotype Ontology
Domain: Treatment					

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
General paediatrics	**Drug name**	standardized options	International non-proprietary name	Mandatory	Name of the drug(s) received as inpatient
General paediatrics	**Prescribed drug at discharge**	standardized options	International non-proprietary name	Mandatory	Name of the drug(s) prescribed at discharge
General paediatrics	**Route of administration**	standardized options	Oral Intravenous Subcutaneous Intramuscular Intrathecal Rectal Inhalation Cutaneous Ocular Nasal Otic Other	Mandatory	
General paediatrics	**Date and time of first administration**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Time of first administration of the drug
General paediatrics	**Date and time of last administration**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Time of last administration of the drug
General paediatrics	**Frequency of administration**	number		Mandatory	Number of administrations per 24 hours
General paediatrics	**Dose**	number		Mandatory	Dose given at each administration of the drug
General paediatrics	**Dose unit**	standardized options		Mandatory	List of possible units to be defined
General paediatrics	**Reason for discontinuation of treatment**	standardized options	Recovery Change to another medication No effect observable Adverse events Reducing polypharmacy Other	Mandatory	Reason why a treatment is stopped
General paediatrics	**Adverse events**	standardized options	MedDRA classification	Mandatory	MedDRA: Medical Dictionary for Regulatory Activities
General paediatrics	**Supplemental O2: Date and time of start**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Time at starting oxygen therapy
General paediatrics	**Supplemental O2: Date and time of interruption**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	Time at stopping oxygen therapy

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
General paediatrics	**Supportive services: Type**	standardized options	Physiotherapy Ergotherapy Social assistance Other	Mandatory	
Endocrinology	**Type of insuline therapy**	standardized options	MDI CSII	Mandatory	MDI: Multiple dose injection. CSII: Continuous subcutaneous insulin infusion
Endocrinology	**Total daily dose of insuline (long and short acting)**	number		Mandatory	units per kg per day
Endocrinology	**Basal insuline**	number		Mandatory	Percentage of basal insuline (%)
Gastroenterology Metabolic diseases	**Therapeutic diet**	yes/no		Mandatory	Therapeutic diet prescribed by physician
Metabolic diseases	**Type of therapeutic diet**	standardized options	Low-protein Ketogenic Low-fat Frequent meals Nocturnal feed Medical food Other	Mandatory	Type of therapeutic diet prescribed
Allergy/Immunology	**Epinephrine Pen prescribed**	yes/no			
Infectious diseases	**BCG immunization**	standardized options	Yes No Unknown	Mandatory	
Neurology	**Rehabilitation supportive devices: Type**	standardized options	Upper limb orthoses Lower limb orthoses Corset Standing frame Walking aid (crutches NF-walker, rollator etc.) Wheelchair: Manual Wheelchair: Electric powered Other	Recommended	
Pulmonology	**Pulmonary rehabilitation**	yes/no		Recommended	
Domain: Equipment and procedures					
General paediatrics	**Equipment type**	standardized options	See comments	Mandatory	Standard classification to be defined
General paediatrics	**Equipment date of insertion**	date	YYYY-MM-DD	Mandatory	
General paediatrics	**Equipment date of withdrawal**	date	YYYY-MM-DD	Mandatory	

Module(s)	Common Data Element	Format	Standardized response options	Importance	Comment / Description
Cardiology	**Cardiac procedures**	standardized options	IPCCC Code	Mandatory	IPCCC: International Paediatric and Congenital Cardiac Code
Cardiology	**Date of cardiac procedure**	date	YYYY-MM-DD	Mandatory	Date of intervention
Gastroenterology	**Therapeutic gastrointestinal endoscopic procedures**	standardized options	Haemostasis Oesophageal dilatation (Balloon/Savary) Percutaneous endoscopic gastrostomy (PEG) Endoscopic retrograde cholangiopancreatography (ERCP) Other	Mandatory	
Nephrology	**Type of dialysis (1)**	standardized options	Acute Chronic	Mandatory	
Nephrology	**Type of dialysis (2)**	standardized options	Haemodialysis Peritoneal dialysis Hemodiafiltration	Mandatory	If peritoneal dialysis, type of catheter and number of peritonitis should be specified
Nephrology	**Date of dialysis initiation**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	
Nephrology	**Date of dialysis termination**	datetime	YYYY-MM-DD hh:mm:ss	Mandatory	
Nephrology	**Dialysis: vascular access type**	standardized option	Central venous catheter Arteriovenous fistula Arteriovenous graft	Mandatory	If central venous catheter, its localization should be specified
Nephrology	**Renal transplantation, graft (1)**	standardized options	Deceased donor Living donor	Mandatory	
Nephrology	**Renal transplantation, graft (2)**	standardized options	Related donor Unrelated donor	Mandatory	
Nephrology	**Renal transplantation**	standardized options	Preemptive transplantation Nonpreemptive transplantation	Mandatory	
Nephrology	**Renal transplantation: Number of received grafts**	number		Mandatory	Number of grafts received including present one
Nephrology	**Plasmapheresis performed**	yes/no		Mandatory	
Nephrology	**Renal biopsy performed**	standardized options	No Yes, without complication in the following 24 hours Yes, with complications in the following 24 hours	Mandatory	
Nephrology	**Cystoscopy performed**	yes/no		Mandatory	
Nephrology	**Angiography performed**	yes/no		Mandatory	