SwissPedData: Standardising hospital records for the benefit of paediatric research

Jaboyedoff, Manon ; Rakic, Milenko ; Bachmann, Sara ; Berger, Christoph ; Diezi, Manuel ; Fuchs, Oliver ; Frey, Urs ; Gervaix, Alain ; Glücksberg, Amalia Stefani ; Grotzer, Michael ; Heininger, Ulrich ; Kahlert, Christian R ; Kaiser, Daniela ; Kopp, Matthias V ; Lauener, Roger ; Neuhaus, Thomas J ; Paioni, Paolo ; Poslay-Barbe, Klara ; Ramelli, Gian Paolo ; Simeoni, Umberto ; Simonetti, Giacomo ; Sokollik, Christiane ; Spycher, Ben D ; Kuehni, Claudia E

Abstract: 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.

DOI: https://doi.org/10.4414/smw.2021.w30069

Posted at the Zurich Open Repository and Archive, University of Zurich
ZORA URL: https://doi.org/10.5167/uzh-212946
Journal Article
Originally published at:
Jaboyedoff, Manon; Rakic, Milenko; Bachmann, Sara; Berger, Christoph; Diezi, Manuel; Fuchs, Oliver; Frey, Urs; Gervaix, Alain; Glücksberg, Amalia Stefani; Grotzer, Michael; Heininger, Ulrich; Kahlert, Christian R; Kaiser, Daniela; Kopp, Matthias V; Lauener, Roger; Neuhaus, Thomas J; Paioni, Paolo; Posfay-Barbe, Klara; Ramelli, Gian Paolo; Simeoni, Umberto; Simonetti, Giacomo; Sokollik, Christiane; Spycher, Ben D; Kuehni, Claudia E (2021). SwissPedData: Standardising hospital records for the benefit of paediatric research. Swiss Medical Weekly, 151:w30069.
DOI: https://doi.org/10.4414/smw.2021.w30069
SwissPedData: Standardising hospital records for the benefit of paediatric research

Manon Jaboyedoff**, Milenko Rakic**, Sara Bachmann†, Christoph Bergr, Manuel Diezl, Oliver Fuchs†, Urs Frey†, Alain Gervaix†, Amalia Stefani Glücksberg‡, Michael Grotzer‡, Ulrich Heining‡, Christian R. Kahler‡, Daniela Kaiser‡, Matthias V. Kop², Roger Launér‡, Thomas J. Neuhäusl, Paolo Paioni*, Klara Posfay-Barbe³, Gian Paolo Ramelli³, Umberto Simeoni³, Giacomo Simonetti³, Christiane Sokollik², Ben D. Spycher⁴, Claudia E. Kuehni⁵

* Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland
† Service of Pediatrics, Department Women-Mother-Child, Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland
‡ University of Basel Children's Hospital Basel (UKBB), University of Basel, Basel, Switzerland
§ University Children's Hospital Zurich, University of Zurich, Zurich, Switzerland
© Department of Pediatrics, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland
¶ Department of Woman, Child and Adolescent, Geneva University Hospitals and Faculty of Medicine, Geneva, Switzerland
† University of Basel Children's Hospital Basel (UKBB), University of Basel, Basel, Switzerland
* Pediatric Department of Southern Switzerland, Ete Ospedaliero Cantonale, Bellinzona, Switzerland and Università della Svizzera Italiana, Lugano, Switzerland
¶ Children's Hospital of Eastern Switzerland, St. Gallen, Switzerland
† Children's Hospital of Lucerne, Cantonal Hospital Lucerne, Lucerne, Switzerland
* Contributed equally as first authors
** Contributed equally as last authors

**Correspondence:**
Prof. Dr. med. Claudia Kuehni
Institute of Social and Preventive Medicine
University of Bern
Mittelstrasse 43
3012 Bern
claudia.kuehni[at]ispn.unibe.ch

---

**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 high-quality nationwide retrospective and prospective observational studies. 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,
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.

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 (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 ISPMBern 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-
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

| Preparatory steps | Delphi process |
|-------------------|----------------|
| **I. Source of variables** | **Round 1:** Online survey (1 per subspecialty) |
| a) Clinical forms used currently in the Swiss Children’s hospitals | - Decision for inclusion or exclusion of candidate CDEs, according to relevance for research and clinical work. Inclusion if > 80% agreed, exclusion if >80% agreed. The others were classified as controversial. |
| b) Existing clinical cohort studies and registries in Switzerland | - Included variables classified as mandatory, recommended or optional. |
| c) Published datasets from similar initiatives, in particular PEDSnet | - Suggestion of new variables (classified all as controversial) |
| d) Suggestions from taskforce members |  |
| **II. Selection of candidate CDEs** | **Round 2:** Face-to-face meeting (1 per subspecialty) |
| General paediatrics: Initial list (based on sources a, b and c) (n=150) was refined during a 2-days interdisciplinary retreat of paediatricians, epidemiologists and registry managers. | - Discussion of all controversial CDEs (< 80% agreement or variables newly suggested in first round) until a group consensus was reached |
| Subspecialty modules: The core team drafted a list of candidate variables using existing datasets specific to each subspecialty (sources a, b and c) in collaboration with one representative per subspecialty. | - Definition of answer choices of included variables |
| **III. Set up of the Delphi process** | **Round 3:** Online survey (1 per subspecialty) |
| Eleven working groups: | - Experts received excel file containing all the CDEs |
| - One group for general paediatrics | - They could propose to add new CDEs, delete CDEs, and define answer choices where they were missing |
| - One group per subspecialty: cardiology, endocrinology, gastroenterology, immunology, dermatology, oncology, metabolic diseases, nephrology, neurology, pulmonology, rheumatology |  |
| - Neonatology and paediatric oncology had already defined standard dataset prior to this project | **Round 4:** Online survey (all participants) |
| - Paediatric emergency medicine is currently going through the procedure. | - All experts received the excel file containing the paediatric core CDEs and all subspecialty CDEs |
| Experts were invited to each round, independent of their participation in previous rounds. | - Last input (minor suggestions) and final approval of entire dataset |

**SwissPedData, Version 1.0**

**General paediatrics:** 76 CDEs; **Cardiology:** 11 CDEs; **Endocrinology:** 59 CDEs; **Gastroenterology:** 17 CDEs; **Allergy/Immunology:** 29 CDEs; **Infectious diseases:** 47 CDEs; **Metabolic diseases:** 20 CDEs; **Nephrology:** 34 CDEs; **Neurology:** 17 CDEs; **Pulmonology:** 31 CDEs; **Rheumatology:** 16 CDEs; **Neonatology** (SwissNeoNet); **Oncology** (Childhood Cancer Registry); **Paediatric Emergency care:** ongoing
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 subspeciality 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]. 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                | cdos           | E                        | E + P                    | E                        | E                | E           |
| Geneva              | DPI            | E                        | E                        | E                        | E                | E           |
| Lausanne            | Soarian        | E                        | E                        | E                        | E                | E           |
| Luzern              | Epic/LUKS      | 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 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.

Acknowledgements

We thank all the experts who participated in the Delphi process, SwissPedNet, College A, the Swiss Personalized Health Network (SPHN), and ISPUn Bern staff: Alexander Laemmle, Alexander Moeller, Alexandra Wilhelm-Bals, Alexandre Data, Alice Kochli, Andrea Dupperenthal, Andreas Nydegger, Andreas Wonner, Anita Rauch, Anna Wefers, Anne Tischerer, Arnaud Merglen, Barbara Goeggel Simonetti, Juerg Barben, Birgit Donner, Caroline Roduit, Christian Braegger, Christian Kahler, Christian Korff, Christian Huemer, Christian Lovis, Christina Schindera, Christoph Aebi, Christoph Berger, Christophe Folly, Christophe Rudin, Christian Balmer, Cristina Ardura, Claudia Boettcher, Constanze Barazzo-Angiroff, Corinna Leon Foegi, Dagmar L’Allemann, Daniel Konrad, Daniel Trachsel, Daniela Marx-Berger, Diana Ballhausen, Dirk Fischer, Dominik Stambach, Eliane Roulet, Elvira Cauanzzaro, Emanuela Valsangiacomo, Eva Pedersen, Federica Vacchini, Felicitas Bellutti, Florian Bauder, Florence Barbey, Florian Singer, François Cachat, Franziska Kunz, Gabor Szinnai, Georg Marx, Giovanni Ferrari, Gianluca Gualco, Guido Laube-Bless, Hans Peter Kuen, Hassib Chelade, Ilse Kern, Isabel Bolte, Isabelle Rochat, Jana Pachlomnik Schmid, Jean-Baptiste Armengaud, Jean-Christoph Caubet, Joanne Carles Suris Granell, Joel Fluss, Johannes Spaling, Julien Caccia, Jürg Hammer, Ketaneth Bossip, Katrin Heldt, Katharina Flander, Kristina Keitel, Laetitia Marie Petit, Lisa Kottanattu, Lorenzo Zgraggen, Luca Garzonni, Matthias Horn, Maria Orth, Matthias Baumgartner, Matthias Gauthier, Maura Zanolari-Calderari, Maurice Beghetti, Melanie Hess, Michael Hauschild, Michael Boettcher, Michael Hofer, Mirjam Dirlewanger, Myrofora Goutaki, Nicolas Regamey, Nicolas Wauespe, Nicole Sekarski, Nicole Ritz, Noémie Wagner, Oliver Niesse, Oswald Hasselmann, Paloma Parvex, Paolo Tonella, Paola Papi, Pascale Wenger, Peter Weber, Philipp Broser, Philipp Agyman, Philipp Do Canto, Philippe Steenhout, Philippe Eigenmann, Pierre Balice, Pierre-Alex Cressoul, Raul Farlan, Rebeca Mozun, Regula Laux, Regula Locatelli, Robert Steinfeld, Sabine Pallivathukal, Sandra Asner, Sebastian Grunt, Sébastien Lebon, Sébastien Papis, Selina Pinosch, Silbyle Tschumi, Stefano di Bernardo, Sylvain Blanchon, Thomas Schmitt-Mechelke, Ulrike Halbguth, Urs Zumtobel, Valérie Schwitzgebel, Valérie McLin, Verena Pfeiffer and Yvonne Aggoun.

Financial disclosure

This study is funded by the Swiss Personalized Health Network (SPHN) [2017DEV14] and by the University of Bern (matched funding).

References

1. Calif RM, Robb MA, Bindman AB, Briggs JP, Collins FS, Conway PH, et al. Transforming Evidence Generation to Support Health and Health Care Decisions. N Engl J Med. 2016 Dec;375(24):2395–400. http://dx.doi.org/10.1056/NEJMc1610182. PubMed. 1533-4406.
2. Klooin S, Blumenthal GM, Pauhu R; Real-World Data for Clinical Evidence Generation in Oncology. Real-world Data for Clinical Evidence Generation in Oncology. J Natl Cancer Inst. 2017 Nov;109(11). http://dx.doi.org/10.1093/jnci/djx187. PubMed. 1460-2105.
3. Wensing M, Grof R. Knowledge translation in health: how implementation science could contribute more. BMC Med. 2019 May;17(1):88. http://dx.doi.org/10.1186/s12913-019-1322-9. PubMed. 1741-7015.
4. Kern SE. Challenges in conducting clinical trials in children: approaches for improving performance. Expert Rev Clin Pharmacol. 2009 Nov;2(6):609–17. http://dx.doi.org/10.1586/ercp.09.40. PubMed. 1751-2441.
5. The Lancet Diabetes Endocrinology. Spotlight on rare diseases. Lancet Diabetes Endocrinol. 2019 Feb;7(2):75. http://dx.doi.org/10.1016/S2213-8587(19)30006-3. PubMed. 2213-8595.
6. Davis MM. Shunting the growth of child health research: a need to reframe “children are not small adults”. JAMA Pediatr. 2013 Jul;167(7):598–9. http://dx.doi.org/10.1001/jamapediatrics.2013.165. PubMed. 2168-6211.
7. Polnazz B, Gilmore-Bykovskii A, Hovanes M, Rolland R, Ferguson F, Brown R, et al. Overcoming the Challenges of Unstructured Data in Multisite, Electronic Medical Record-based Abstraction. Med Care.
16. Michel G, von der Weid NX, Zwahlen M, Adam M, Rebholz CE, Jones J, Hunter D. Consensus methods for medical and health services research. Cochrane Database Syst Rev. 2011 Feb;11(1):1-11. PubMed. 1472-9497

17. Jones J, Hunter D. Consensus methods for medical and health services research. Cochrane Database Syst Rev. 2011 Feb;11(1):1-11. PubMed. 1472-9497

18. Dalkey NC. The Delphi method: a useful tool for the allied health professions. J Adv Nurs. 2000 Oct;32(4):1008-15. PubMed. 1098-4275

19. Ingham T, Cullen B, Aisner J, McGinnis J. Methods for consensus development in the health professions. J Adv Nurs. 2000 Oct;32(4):1008-15. PubMed. 1098-4275

20. Walker MA, Selfe MJ. The Delphi method: a useful tool for the allied health professions. Br J Ther Rehabil. 1996;3(12):677-81. PubMed. 1098-4275
## 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 (JIRcohort)             | 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  |
| Registry                                                                 | Scope          |
|------------------------------------------------------------------------|----------------|
| 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 | 1st round | Delphi process, number of experts involved |
|----------------------|---------------------------|-----------|------------------------------------------|
|                      |                           | 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                                                                                  | Recommende d | 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 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       | Ethnicity of the patient                         | standardized options    | See comments                            | Optional   | 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          |                                                                                               |                   | 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  | Mother's height                            | number          | Mandatory                                                                                     | Height of the mother in cm |
| Nephrology     |                                             |                 |                                                                                               |                   | Height of the father in cm                                                             |
| Endocrinology  | Father's height                            | number          | Mandatory                                                                                     |                   | Age of the mother at menarche in years                                                 |
| Endocrinology  | Mother's age at menarche                   | number          | Mandatory                                                                                     |                   |                                                                                        |
| Endocrinology  | Father's puberty                           | standardized options | Normal, Early, Late                                                                            | Mandatory        | Any type of diabetes in a first degree relative                                         |
| Endocrinology  | Diabetes in first degree relatives         | standardized options | No, Yes, Type 1, Yes, Type 2, Yes, Monogenic, Unknown                                         | Mandatory        | Presence of thyroid disorder in a first degree relative                                 |
| Endocrinology  | Thyroid disorder in first degree relative  | yes/no           | Mandatory                                                                                     |                  |                                                                                       |
| 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, 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 rhinoconjunctivitis                           | 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   | Yes, reported Yes, documented No                       | Recommende | 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| Documented food allergy by oral food challenge           | yes/no          |                                                        | Mandatory  | Presence of any documented food allergy (diagnosed by physician)                       |
| Gastroenterology  | Hymenoptera venom allergies                               | standardized   | Yes, reported Yes, documented No                       | Mandatory  | Known documented hymenopter allergies                                                  |
| Allergy/Immunology| History of anaphylaxis                                   | standardized   | 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     | No, acute and dry Yes, acute and wet Yes, chronic and dry Yes, chronic and wet                   |            | Recommend Cut-off for acute/chronic 4 weeks                                             |
| Rheumatology              | Recurrent fever                                 | yes/no           | yes/no                                                                                         | Mandatory  | History of recurrent fever                                                             |
| Rheumatology              | History of uveitis                              | yes/no           | yes/no                                                                                         | Mandatory  | Presence of active uveitis                                                             |
| Rheumatology              | History of inflammatory skin disease            | yes/no           | yes/no                                                                                         | Mandatory  | Presence of skin involvement                                                            |
| Rheumatology              | Family history of inflammatory rheumatic disease| standardized     | No, without spondyloarthropathy Yes, with spondyloarthropathy                                    | Mandatory  | Presence of any rheumatic disease in the family                                         |
| Rheumatology              | Family history of inflammatory skin disease     | standardized     | No, without psoriasis Yes, with psoriasis                                                       | Mandatory  | Presence of any skin disease in the family                                              |
| Rheumatology              | Family history of chronic intestinal diseases    | yes/no           | yes/no                                                                                         | Mandatory  | Presence of any chronic intestinal disease in the family                                |
| Rheumatology              | Family history of recurrent fever               | yes/no           | 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 stretched 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           | 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        | 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 | | | |
| Endocrinology | Tanner pubic hair stage | number | | | |
| Endocrinology | Tanner axillary hair stage | number | | | |
| Endocrinology | Tanner genital stage | number | | | |
| Endocrinology | Breast size | number | | | |
| Endocrinology | Female genital examination | normal/abnormal | | | |
| Endocrinology | Penis length | number | | | |
| Endocrinology | Chovstek sign | yes/no | | | Twitching of facial muscles in response to tapping over the area of the facial nerve |
| Endocrinology | Trousseau sign | yes/no | | | Carpopedal spasm that results from ischemia |
| Endocrinology | Thyroid nodule | yes/no | | | Presence of thyroid nodule |
| Infectious diseases | Hepatomegaly noted at physical examination | yes/no | | | |
| Metabolic diseases | Splenomegaly noted at physical examination | yes/no | | | |
| Rheumatology | Meningeal signs noted at physical examination | yes/no | | | |
| Rheumatology | Skin lesion noted at physical examination | yes/no | | | |
| Rheumatology | Irritability noted during physical examination | yes/no | | | |
| Rheumatology | Adenopathy noted at physical examination | standardized options | No Yes, localized Yes, generalized | | |
| Rheumatology | Respiratory distress noted at physical examination | yes/no | | | |
| Rheumatology | Conjunctivitis noted at physical examination | yes/no | | | |
| Rheumatology | Prolonged capillary refill time (> 2 sec) noted at physical examination | yes/no | | | |

Published under the copyright license “Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0)”. No commercial reuse without permission. See https://smw.ch/permissions.
| 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 abnormalities                                             | yes/no                            |                                | Mandatory | Presence of skin abnormalities                                                        |
| Metabolic diseases  | Abnormal body proportions                                      | yes/no                            |                                | Recommende d | 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 | Measured MAP in mmHg                                                                  |
| Nephrology         | Mean Arterial Pressure (MAP)                                  | 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 | The shape of the thorax                                                               |
| Pulmonology        | Thorax shape                                                  | normal/abnormal                   |                                | Mandatory | Presence of active arthritis                                                         |
| Rheumatology       | Active arthritis                                               | yes/no                            |                                | Mandatory | Number of joints involved in active arthritis                                         |
| Rheumatology       | If active arthritis: number of joints involved                 | number                            |                                | Mandatory | Maximal mouth opening in mm                                                          |
| Rheumatology       | Maximal mouth opening                                          | number                            |                                | Mandatory |                                                                                      |
| Rheumatology       | Muscle strength                                                | normal/abnormal                   |                                | Recommende d | 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                             | Mandatory  | Name of the triage scale used                                                        |
| General paediatrics    | Triage scale (ED), value                                                              | number                  | Canadian Triage Scale Other                           | 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| 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 | Developmental delay as assessed by treating physician                                 |
| 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      | 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     | Use of continuous glucose monitoring                      | yes/no            |                                                                     | Recommende d| 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      | 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 < 3.9 mmol/l in %                                                                |
| Gastroenterology  | Type of gastrointestinal endoscopy                       | standardized      | Upper, Lower, Upper and lower, Other                                | Mandatory  | Date of study should be recorded                                                      |
| Gastroenterology  | Indication for gastrointestinal endoscopy                | standardized      | 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   | 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| sIgE performed                             | yes/no         |                                                   | Mandatory  | sIgE stands for specific serum immunoglobulin E. Date of study should be recorded      |
| Pulmonology       | sIgE performed                             | yes/no         |                                                   | Mandatory  | Date of study should be recorded                                                        |
| Allergy/Immunology| Result of sIgE                             | positive/negative | sIgE stands for specific serum immunoglobulin E | Mandatory  | Date of study should be recorded                                                        |
| 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  | Date of study should be recorded                                                        |
| Infectious diseases| Urine collection method                    | standardized   | 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   | 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       | 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                 | Date of study should be recorded                          | Mandatory    |                                                                                       |
| Nephrology       | Renal MRI result                                                                     | normal/abnormal                 | Date of study should be recorded                          | Mandatory    |                                                                                       |
| 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                          | Date of study should be recorded                          | Mandatory    |                                                                                       |
| Nephrology       | Renal scintigraphy results                                                           | standardized options            | Normal, Hypoplasia, Scars, Other                          | Mandatory    |                                                                                       |
| Nephrology       | Estimated GFR by Schwartz formula                                                    | number                          | GFR [ml/min]                                              | Mandatory    |                                                                                       |
| Nephrology       | Proteinuria                                                                          | number                          | In mg/mmol (spot urine) or mg/m2/h for 24h Urine          | Mandatory    |                                                                                       |
| Nephrology, Neurology, Pulmonology | Genetic test performed                                                             | yes/no                          | Mandatory for nephrology, recommended for neurology and pulmonology | Mandatory    |                                                                                       |
| 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| 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| Hearing test: Result                                                               | normal/abnormal         |                                                                                                | Mandatory  |                                                                                        |
| Neurology         | Vision test: Performed by                                                           | standardized options    | Ophtalmologist, Optometrist, Paediatrician, Other                                            | Recommended| Health professional who tested vision                                                  |
| Neurology         | Vision test: Result                                                                | normal/abnormal         |                                                                                                | Recommended| Date of study should be recorded                                                       |
| 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                  | RV: Residual volume.                                                                         | Recommended|                                                                                       |
| 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 | Bodypelethysmography 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 |                                        | 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  |                                                                                       |
| 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                              | Recommende d | OMIM: Online Mendelian Inheritance in Man                                            |
| Neurology                 | HPO code                                   | standardized options | HPO code                               | Optional   | HPO: Human Phenotype Ontology                                                        |
| 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<br>Ergotherapy<br>Social assistance<br>Other | Mandatory | |
| Endocrinology | Type of insuline therapy | standardized options | MDI<br>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<br>Metabolic diseases | Therapeutic diet | yes/no | | Mandatory | Therapeutic diet prescribed by physician |
| Metabolic diseases | Type of therapeutic diet | standardized options | Low-protein<br>Ketogenic<br>Low-fat<br>Frequent meals<br>Nocturnal feed<br>Medical food<br>Other | Mandatory | Type of therapeutic diet prescribed |
| Allergy/Immunology | Epinephrine Pen prescribed | yes/no | | Mandatory | |
| Infectious diseases | BCG immunization | standardized options | Yes<br>No<br>Unknown | Mandatory | |
| Neurology | Rehabilitation supportive devices: Type | standardized options | Upper limb orthoses<br>Lower limb orthoses<br>Corset<br>Standing frame<br>Walking aid (crutches NF-walker, rollator etc.)<br>Wheelchair: Manual<br>Wheelchair: Electric powered<br>Other | Recommended | |
| Pulmonology | Pulmonary rehabilitation | yes/no | | Recommended | |

**Domain: Equipment and procedures**

| Module(s) | Equipment type | Format | Standardized response options | Importance | Comment / Description |
|----------|----------------|--------|-------------------------------|------------|-----------------------|
| 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 | IPCC Code                                                                                       | Mandatory  | IPCCCC: 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, 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  |                       |
| 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  |                       |
| 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  |                       |