eHealth Suisse

Swiss eHealth Exchange Format Handbook
Part I: Service Requests

(such as Orders and Referrals, Transition of Care and Request for Communication/Second Opinion)

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Content

1   Overview

With the electronic patient record (EPR) a first national health network is established. The EPR is a collection of patient related healthcare documents. These documents are available online and can be accessed at any time by patients and authorised health professionals, thus providing a "non-directional communication".

But health professionals have the need to digitally exchange orders, referrals reports etc. directly from the primary systems with other health care providers by means of a "directional communication" (of course with the consent of the patients). For this, interoperable supplementary services ("*Zusatzdienste*" in German) to the EPR are a necessary prerequisite. The eHealth strategy 2.0 speaks in this context of "EPR-related applications"[1].

As a result of the digital transformation of health care[2], documents and information exchange/sharing move whenever possible away from narrative text towards structured and coded content in order to allow machine processing. This applies for both, the EPR as well as directional communication.

In order to ensure the necessary syntactical and semantic interoperability of structured information, eHealth Suisse defines so called exchange formats. Exchange formats define syntax and semantics to be used for structured documents and are intended to be used for directional AND non-directional communication (e.g. a referral document sent by a doctor to the hospital may be made available for the patient by upload to his EPR). The concerning ordinance will declare these exchange formats as binding for the use in the EPR[3].

It has to be clarified that the exchange formats discussed here refer to documents and not to messages[4]. Although messaging has been used for ordering in the past, legal constraints require more and more patient related communication (including orders, referrals etc.) to be audit-proof. This requires legal valid signatures, which is in turn supported by a document-oriented approach rather than with messaging.

There is a major difference between the EPR and directional communication when looking at the interactions between engaged systems and thus the technical interoperability: Swiss EPR is based on IHE XDS and – soon – IHE MHD; details are defined in the concerning ordinances. For directional communication, there are no legal prerequisites for IHE profiles.

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[1] Supplementary services ("*Zusatzdienste*") may also cover other services than directional communication (e.g. invoicing), but directional communication is the one with the highest priority.

[2] Digital transformation defined by Wade und Marchand as: "Digital business transformation is organisational change through the use of digital technologies to materially improve performance"

[3] Because directional communication is not part of the EPR legal framework, exchange formats are legally binding for EPR use only; but their use for directional communication is strongly recommended.

[4] HL7 messaging is usually a real-time flow of patient and clinical information. They convey current information about a patient, including updates to admissions or discharges […], orders for tests […], and test results […]. HL7 documents are static – accurate given the point-in-time in which the information was captured. HL7 documents contain important information, but it is a snapshot. The documents are useful in providing relevant information in referrals to other physicians or healthcare organizations. Accordingly, it provides a starting point for the next step in patient care. (Source: https://healthstandards.com/blog/2008/01/25/comparing-hl7-messages-to-hl7-documents/)

2   Intended audience

This handbook addresses a technical oriented (international) readership involved in developing the specification of the exchange formats. It is expected that the specifications shall reference this handbook and/or reuse parts of it.

3   Objectives

eMedication, Ordering, Referral, Transition of Care and Requests for Communication[5] are the first exchange formats which will be defined by eHealth Suisse in FHIR format, others will follow. eHealth Suisse adheres to the principle of modularity: parts of an exchange format serving the same purpose shall look the same thus facilitating reuse of code.

One of the aims of this handbook is therefore to define what attributes in a structured document are generic elements in the sense that they look the same in all sorts of orders, referrals etc. Healthcare domain specific elements are in contrast dependent on the use case and to be defined in the specific implementation guide for this use case.

Furthermore, this handbook covers considerations about encryption and – in case of directional communication – document transport.

This handbook will provide guidance for specifying FHIR implementation guides[6] for ordering and referral documents as well as requests for communication, in particular for radiology, laboratory orders and transition-of-care documents.

In particular, the handbook …
… defines a basic foundation on which the implementation guides shall build on;
… points to legal and technical prerequisites;
… outlines the use cases;
… defines a common data model;
… defines the principle approach for security and privacy considerations.

4   Forms / Questionnaires

Further considerations require a discussion about what is exactly meant with the word "form" and "questionnaire". A bunch of definitions exist for both terms:

- "A form is a document with spaces (also named fields or placeholders) in which to write or select, for a series of documents with similar contents. The documents usually have the printed parts in common, except, possibly, for a serial number. Forms, when completed, may be a statement, a request, an order, etc."[7]

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[5] E.g. a request for results or a discharge letter from the past.

[6] An implementation guide (IG) is a set of rules about how to solve a particular problem, with associated documentation to support and clarify the usage. The term is used interchangeably with "Specification".

[7] https://en.wikipedia.org/wiki/Form_(document)

- "A form is a structured document with a fixed arrangement. Forms are used to collect the required information in a logical, meaningful fashion for communication and pass to another entity."[8]
- "Questionnaire: A form containing a list of questions; a means of gathering information for a survey."[9]
- "A questionnaire is a research instrument that consists of a set of questions or other types of prompts that aims to collect information from a respondent."[10]

The definition of "questionnaire" focusses rather on the purpose than on the nature of the document but it is quite obvious that both terms refer basically to the same thing: what is meant is a structured document with a set of fields, each with a corresponding prompt and possibly with additional remarks/explanations.

This notion applies originally to paper-based documents but can be transferred easily to electronic documents. This leads us to the term "electronic form" or "eForm" which includes not only structuredness of information but also the user interface in terms of screen layout, sequence of items, etc.

Structuredness of information is addressed since ever in IT; in eHealth it has been subsumed under the well-known term "semantic interoperability" (in fact there is syntactical interoperability as well). What has been neglected so far is the problem of uniform representation of the document at sender and receiver site. This aspect however is of crucial importance because differences in representation may alter the meaning of a statement (an example is "same as above" which may change in meaning in case statements are displayed in altered order).

In FHIR, almost everything is a resource, understood as an entity that contains a set of structured data items as described by the definition of the resource type. FHIR provides a so called Questionnaire Resource which allows an organized collection of questions intended to solicit information.

It is important to be aware of the fundamental difference between Questionnaire Resources and all other resource types: Questionnaire Resources describe specific questions and include information such as in what order questions should be displayed, what number/label should be displayed beside each question, conditions in which questions should be displayed (or not), what instructions should be provided to the user, what choices for answers were, etc. In a paper-based world, one would speak of an empty (not yet filled in) form. In this way, the Questionnaire Resource provides a means to standardize the information gathering process (how information is captured). A questionnaire guides the user through a data collection process that ensures appropriate information is collected based on answers to particular questions. It is focused on user-facing data collection.

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[8] https://www.123formbuilder.com/blog/what-is-a-form/
[9] https://en.wiktionary.org/wiki/questionnaire
[10] https://www.questionpro.com/blog/what-is-a-questionnaire/

All other resources merely define data structures with no guidance on display or rules around capture mechanism, only what data should exist in the end. They depict information models (logical models) and are not intended to capture data directly.

Such logical models are crucial for interoperability[11] and therefore FHIR based exchange formats will always rely on resources other than questionnaires. However, adding a Questionnaire Resource leverages the "machine interoperability" towards "interoperability between human users" by defining the captions (=specific questions) and the order questions should be displayed, etc.

Of course, all this requires a mapping between questionnaire items and the corresponding items in the other resources. The CH-ORF Profile as well as the underlying Structured Data Capture Profile give advice for extracting information from a completed questionnaire (=QuestionnaireResponse Resource) to generate other FHIR resources such as Observations, MedicationStatements, etc.

For the discussion of the question which exchange formats may benefit from a questionnaire refer to section 14.2.

5 Use cases

5.1 General considerations

The authors are aware of the fact that real world is not as simple as that the doctor orders and the nurse takes the blood sample. However, in this section, we adhere to this stereotype in order to make the use cases memorable. From the conceptual view, job descriptions and professional degrees happen to be independent from the user roles: e.g. who can make an order is solely dependent from the setting and legal permissibility. Furthermore, the use cases are not limited to communication between practices and hospitals: practice-to-practice communication (e.g. general practitioner (GP) to specialist, hospital to hospital, hospital to retirement home, etc., are meant, too). In short: the scope of consideration is the communication between any sort of institutions in healthcare, including legal bodies as well as insurances.

With regard to orders, referrals, transition of care, etc. wording is usually quite straightforward and terms have a broad, often overlapping meaning, particularly in German: if the patient is sent to a radiology institute, one speaks of "*Zuweisung*"; if the radiology is an inhouse department, "*Röntgenauftrag*" and "*Röntgenverordnung*" are common. From a legal perspective, a "*Röntgenverordnung*" (meaning a doctor's order) is mandatory also if the patient is "zugewiesen" from another institution. "*Röntgenverordnung*" is furthermore the German term for the "*Verordnung des*

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[11] Oemig F. Brauchen wir Informationsmodelle. HL7-Mitteilungen Nr. 43/2019. https://hl7.de/wp-content/uploads/hl7m432019.pdf

EDI über den Strahlenschutz bei medizinischen Röntgensystemen"[12]. Last but not least, "*Zuweisung*" is the preferred term for a transition of care process.[13]

The current FHIR Version 4.0.1 subsumes all under the ServiceRequest Resource: Service-Request is a record of a proposal/plan or order for a service to be performed that would result in a Procedure, Observation, DiagnosticReport, ImagingStudy or similar resource.[14]

In addition to ordering new procedures, imaging studies, etc., results of procedures which happened in the past (or happen now or in future[15]) are very often important but not present and have thus to be requested. From a conceptual point of view, the use cases of requesting results can also be covered by service requests: communicating something can be regarded as a kind of service.

5.2   Radiology order

We have the following players:

- Order placer: Health professional Dr. O. Rderplacer who is a GP in group practice "Happy Doctors"
- Order filler: Radiology department of "Happy Hospital"
- Patient: Mr. S. Ufferer who needs a radiological exam

We start at the point where patient S. Ufferer has an appointment with Dr. O. Rderplacer: he agrees with the patient that a chest x-ray is necessary which will be made at the x-ray department of "Happy Hospital". Dr. O. Rderplacer writes a radiology order, which contains all necessary information and sends it to the radiology department of "Happy Hospital". For comparison purposes, Dr. O. Rderplacer attaches images and reports made in the past.

For various reasons, scheduling of the appointment is tricky:
- Patient S. Ufferer does probably not know the possible dates, e.g. because he is dependent of his daughter who will bring him by car.
- Neither the patient nor the doctor knows which slots are available in the radiology department.
- Availability of slots and availability of transport etc. may change in time.
- Eventually, the patient may need other appointments that in turn cause collisions.
- Etc.

It is not easy to cover all this in a slim application. For this reason, scheduling is currently out of scope. What however will be provided is the possibility to propose a desired date and time; the latter has to be communicated to the order filler as well as to the patient.

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[12] https://www.admin.ch/opc/de/classified-compilation/20163023/index.html

[13] The Joint Commission has defined a "transition of care" as the movement of a patient from one health care provider or setting to another. (Source: The Joint Commission: Transition of Care Document - 2013, p.2; http://wiki.hl7.org/index.php?title=Referral_and_Transition/Transfer_of_Care)

[14] http://hl7.org/fhir/servicerequest.html

[15] In some situations, work flow prerequisites enforce explicit request for results.

In addition to the use case above, the radiology order covers additionally the request for second opinions or for reporting (e.g. images made in a small hospital without a radiologist on duty are sent to a remote radiology department).

5.3   Lab order

The use case is close to the one above; we just replace the radiology department by the lab of "Happy hospital":

- Order placer: Health professional Dr. O. Rderplacer who is a GP in group practice "Happy Doctors"
- Order filler: Laboratory of "Happy Hospital"
- Patient: Mr. S. Ufferer who needs a lab exam

However, there is a major difference to radiology insofar as the lab will need some specimen (blood, urine, saliva, etc.) for analysis; certain services offered by labs require devices to be worn by the patient in order to record data (e.g. heart rhythm analysis).

There are various settings:

1. Sampling takes place at the site of Dr. O. Rderplacer at the same encounter when the order is placed.
2. Sampling takes place at the site of Dr. O. Rderplacer at another time than the encounter where the order is placed.
3. Sampling takes place at patient site by staff of Dr. O. Rderplacer; other time than order is placed.
4. Sampling takes place at patient site by the patient himself or somebody close to him; other time than order is placed.
5. Sampling takes place at the patient site by staff of the lab; other time than order is placed.
6. Sampling takes place at the patient site by third party; other time than order is placed.
7. Sampling takes place at the site of the lab; other time than order is placed.
8. Sampling takes place at third party site; other time than order is placed.
9. …

Sampling is not always a procedure at one point in time: some diagnostic procedures (e.g. a heart rhythm analysis) span over a certain time period and/or require special apparatus. In such cases, two or more encounters will be necessary.

Workflow and communication considerations inside an institution (e.g. between Dr. O. Rderplacer and his staff or communication between different departments/employees in the lab) are out of scope.

In case of sampling at the site of the order placer, sampling and subsequent transfer to the lab is straightforward.

The other settings have their own workflow and thus flow of information. High variability is to be expected and a generic approach to cover everything is not realistic. However, the following landmarks can be defined:

- All cases have in common that a dedicated Identifier for the sample (series of samples) is needed in order to link order, sample, result and patient.
- All cases but (1) need some sort of scheduling for the sampling (e.g. proposed date and time).
- In case of involvement of a third party, proposed scheduling has to be communicated to the order filler, to the third party as well as to the patient. Responsibilities for sampling (including confirmation/update of the schedule) have to be stated.

5.4   Transition of care letter

The use case is close to the radiology use case: we just replace the radiology department by e.g. the surgery department of "Happy hospital". Although one might prefer a name change for the GP (e.g. Dr. R. Eferrer; paying tribute to the fact that in general language it is a referral rather than an order), we stay with the name of the GP as Dr. O. Rderplacer: as already mentioned before, with regard to the communication, there is no conceptual difference between referral and order.

The players are:

- Order placer: Health professional Dr. O. Rderplacer who is a GP in group practice "Happy doctors"
- Order filler: Surgery department at "Happy Hospital"
- Patient: Mr. S. Ufferer who needs a surgical intervention

We start at the point where patient S. Ufferer has an appointment with Dr. O. Rderplacer: He agrees with the patient that some surgery is necessary which will be made at the surgery department of "Happy Hospital". Dr. O. Rderplacer writes a referral which contains *all necessary information* and sends it to the surgery department of "Happy Hospital". This includes existing x-rays and reports as well as lab results.

For various reasons, scheduling of the appointment is again tricky:

- Patient S. Ufferer does probably not know the possible dates, e.g. because he is dependent of his daughter who will bring him by car.
- Neither the patient nor the doctor knows which slots are available in the surgery department.
- Availability of slots and availability of transport etc. may change in time.
- Eventually, the patient may need other appointments, which in turn cause collisions.
- Etc.

It is not easy to cover all this in a slim application. For this reason, scheduling is currently out of scope. What however will be provided is the possibility to propose a desired date and time.

5.5   Requesting results

Results of procedures are often not present but of crucial importance. They have therefore to be **requested.**

The players are:

- Order placer: Health professional Dr. O. Rderplacer who is a GP in group practice "Happy doctors"
- Order filler: Surgery department at "Happy Hospital"
- Patient: Mr. S. Ufferer who was in "Happy Hospital" for surgery 2 or 3 years ago

Although one might prefer a name change for the GP (e.g. Dr. R. Equester; paying tribute to the fact that in general language it is a request rather than an order), we stay with the name of the GP as Dr. O. Rderplacer: with regard to the author, there is no conceptual difference between communication request, referral and order.

The use case is agnostic to the nature of service: A request for information may concern radiological results, lab results, results of medical or diagnostic procedures, a discharge letter, etc.

In contrast to the preceding use cases there are no scheduling issues.

5.6   Second opinion

The second opinion use case is most frequent within radiology but also appears in other healthcare domains. It can be considered as a special case of an order. Conceptually, the use case is like a lab order: some "material" is sent, e.g. images (instead of urine, blood etc.) and – same as with the lab order – a result is expected which will be an interpretation/diagnosis rather than a lab figure.

The second opinion as described above has to be distinguished from real-time remote reporting and case presentation such as provided by various teleradiology solutions. The latter requires however a technical infrastructure which is beyond what is necessary for directional communication such as discussed here.

6   Service request process

This section describes the process of **generating** a service request. Everything said here applies in principle for all sorts of service requests including transition of care letters, although some use cases of transition of care may not use the feedback mechanism described below. For this reason, this section describes things based on an order (e.g. radiology order).

The use cases outlined in the preceding sections depict the current way how orders are done today but they neglect a particular problem which becomes more and more important. We do have basically these two settings:

- The requesting clinician has and wishes to exercise the authority (and expertise) to decide exactly what action will be done.
- The requesting practitioner is seeking another practitioner or organization to use their own expertise and/or authority to determine the specific action to take.

Unfortunately, specialist at order filler site do not always agree upon the self-assessment of the referring clinician: meaning that they very often do not consider the ordered procedure as adequate for a given diagnostic question.

Currently, such discrepancies cause two problems: consultations with the order placer are time consuming, and sometimes, order placers are not happy when confronted with questions about appropriateness of ordered procedures.

Mitigation of these problems can be achieved by establishing a structured process of feedback from the order filler towards the order placer: such feedback may contain a proposal for alternative diagnostics (e.g. ultrasound instead of MRI, more suitable lab analysis, etc.) including the reason why. The process is not limited to a single response: a proposal of an alternative diagnostic procedure may rise new issues to be discussed, etc. In short, the next generation ordering process will include a ping-pong of request and response (see Figure 1) by the order placer and the order filler facilitating the strive for the most adequate procedure.
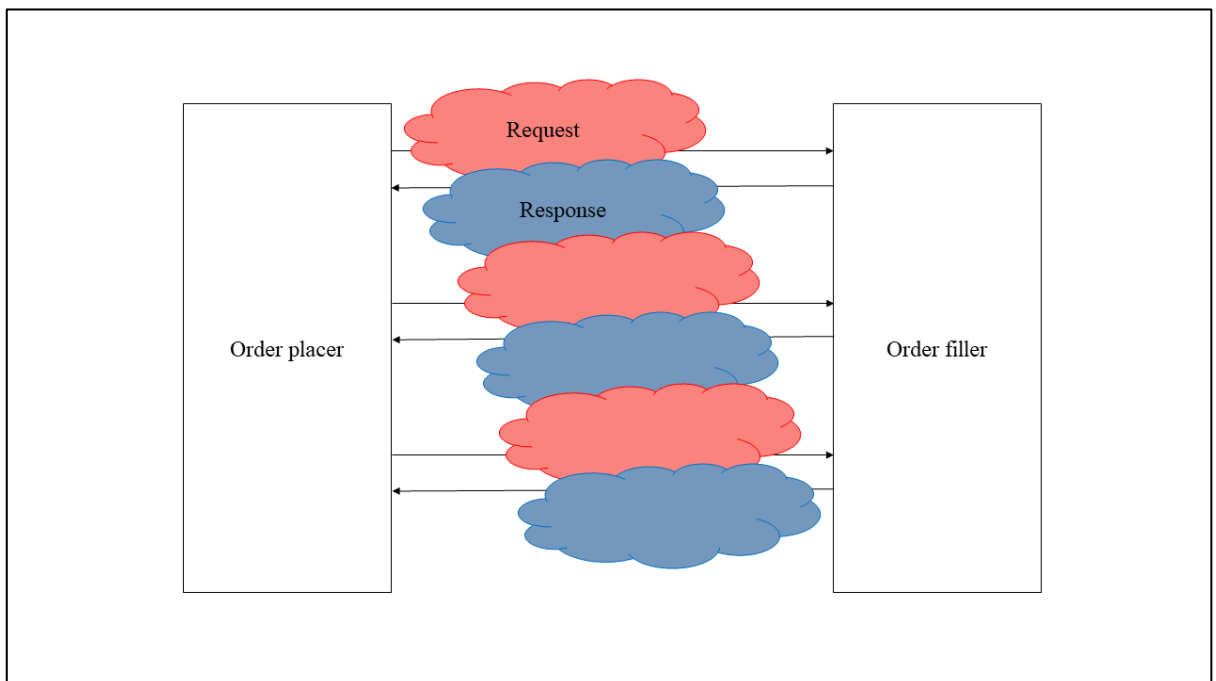

Figure 1: Service request process with feedback (ping-pong). Further description see text.

For the time being such feedback will be given by a human, but it is quite clear that the final aim is to implement machine generated feedbacks, or with other words: the order placer will be supported by a clinical decision support system (CDSS)[16]. It is important to notice that the CDSS discussed here is at the site of the order filler.

The setting requires bidirectional communication (e.g. the ping-pong described above) irrespective of whether a CDSS or a human provides feedback.

This handbook and the specifications of exchange formats and directional communication don't go neither into the mechanism of feedback generation nor the CDSS itself.

A request for results may usually not need a feedback mechanism in order to find the best suited proceeding. However, the answer to the request (e.g. sending the requested information) can be sent in the same way as a feedback. Thus, from a technical perspective, the ping-pong paradigm also applies.

7   Adaptive forms

From a generic point of view, adaptive forms allow tailoring and thus provide additional comfort to the user by omitting unnecessary questions. For a technical description refer to section 14 which explains FHIR Structured Data Capture and the Order and Referral by Form (CH-ORF) Implementation Guide.

Adaptive forms shall not be confused with the feedback feature described in section 6. Whereas feedback requires a deep healthcare domain specific knowledge, adaptability in forms is quite straightforward in that questions are displayed context dependent. An example is the question about pregnancy which will appear in a service request only in case the gender (asked first) is female.

8   Meeting new requirements

Evolution in diagnostics and therapies imposes frequently new requirements for service requests. This contradicts to a certain extent with interoperability, requiring well-defined structures (syntactics) and codes (semantics), which makes changes time consuming.

In order to provide both – interoperability AND flexibility – service requests and communication requests shall be implemented based on FHIR Structured Data Capture Implementation Guide (SDC) and the Order and Referral by Form (CH-ORF) Implementation Guide respectively.

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[16] A clinical decision support system (CDSS) is a health information technology system that is designed to provide physicians and other health professionals with clinical decision support (CDS), that is, assistance with clinical decision-making tasks. A working definition has been proposed by Robert Hayward of the Centre for Health Evidence: "Clinical decision support systems link health observations with health knowledge to influence health choices by clinicians for improved health care."

The reason behind this decision is illustrated in the following example: let's assume that a new diagnostic radiology procedure requires an additional lab parameter so far not used in radiology orders. It may take some time to implement this with the necessary changes in conventional GUI's, interfaces, etc. However, adding this lab item in the questionnaire is quite simple. As the whole questionnaire response shall be rendered as PDF/A document, the new lab value can be transmitted to the receiver. This is far from perfect but better than nothing for the time it takes for a full implementation in a new version of the exchange format.

For a technical description of structured data capture (SDC) refer to section 14.

It is however important to notice that flexibility does not mean that the structure and coding of service requests can be negotiated by individual service providers and their partners because this would lack interoperability.

The idea is that service requests in a particular healthcare domain (e.g. radiology) are well defined at a certain point in time; however, that new requirements can be met in short time.

The envisaged general setting (see Figure 2) is that an authority (e.g. society of radiology) defines structure and semantics of service requests in its healthcare domain. The resulting forms are then made available in a repository for form definitions.

Service providers may download the forms which are suitable for their services; they may enrich them with brandings (e.g. headers and/or footers with logos, staff coordinates, etc.) but they shall not otherwise alter these forms.

Order placers can then receive such forms and fill them in as required by the particular order placement. The same paradigm applies for feedbacks.
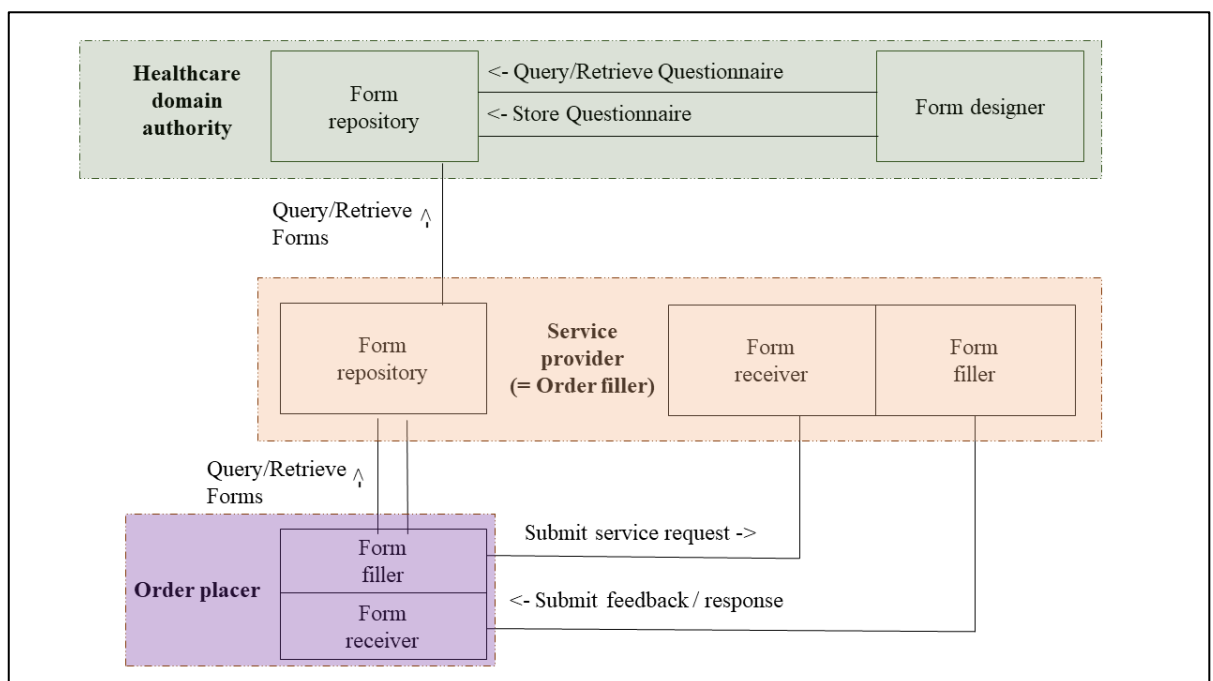

Figure 2: High-level view of envisaged setting for service requests. Description see text.

In comparison with the corresponding graphic in the FHIR Structure Data Capture Implementation Guide (SDC)[17], Figure 2 focuses on the broad concept and does for instance not show a SDC Form Archiver (write-only system responsible for archiving completed forms as well as works in progress). Furthermore, pre-population of forms by a form manager is not depicted in Figure 2 but subsumed under the Form filler (prepopulating e.g. patient demographic data from the PIS) and Form repository (prepopulating the branding as described above).

9 Form representation (e.g. graphical user interface)

9.1 Challenges

Form representation/graphical user interface (GUI) includes questions about adaptive behavior (refer to section 7) and flexibility for new requirements (refer to section 8).

However, what shall be discussed here is the content representation for the user which brings two questions forward:

1. Wholeness of a document
2. Order of the content

Ad 1) In order to achieve wholeness, it must be ensured that the receiver can percept everything that the sender has sent. This principle however contradicts use cases which imply partial information display. Examples for this are cockpits which display only key information in order to give a quick overview, exclusion of sensible information for certain user roles due to privacy obligations etc.

Another issue is that full adherence to wholeness is barely feasible: strictly speaking, altering page brakes (e.g. due to different screen sizes) can already affect perception.

Ad 2) Changing the order of the content (e.g. the order of sections in text) can alter the meaning because of wordings like "as mentioned above" or "same as above", etc.

Another question is what attributes are part of a specific exchange format. Generic elements (see section 14.3.1) are basically defined in this handbook. Healthcare domain specific elements (see section 14.3.2) are dependent by the use case; therefore they are defined by the specific implementation guide and correspondingly in EPRO-FDHA, Annex 4 (*Anhang 4 EPDV-EDI*).

It is however not considered to be a good practice to constrain attributes by means of CDA closed templates because this hinders development of new versions: open templates make piloting of new versions with additional attributes much easier.

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[17] http://hl7.org/fhir/uv/sdc/2019May/workflow.html

9.2 Feasible approach

The following principles may be sufficient in practice:

1) Wholeness: The order placer application is obliged to assure that the whole content is accessible for a human receiver by providing a PDF/A containing all content correctly rendered.[18]
2) Order of the content: The order of content representation must match between sender and receiver in terms of left to right and top to bottom.
3) Responsibility for partial display of content (e.g. after forwarding to further applications) lies with the responsibility of the receiving application.

Ad 1) Compared to a CSS/HTML approach (or similar technology) the PDF/A solution has two advantages: a) verification of correct operation (e.g. in terms of certification) is necessary only at sender site; b) ability to display PDF/A is usually anyplace.

The discussion about wholeness must also include the question which attributes shall be part of a particular exchange format and if an implementer may add custom attributes.

Ad 2) This is considered as a feasible compromise between truth of representation and conflicting interests such as e.g. ergonomic requirements to GUI's.

Ad 3) It must be granted that there is no change in clinical meaning.

10 Technical prerequisites

10.1 EPR

The Swiss EPR is document-oriented and bases on HL7 CDA but support of the FHIR based IHE profiles for mobile health is under way. Although these profiles carry "mobile health" in the name, they are not limited to mobile devices but also suitable to be implemented in primary systems.

10.2 Exchange formats

The exchange formats for structured information developed so far are CDA documents and cover these domains[19]:

- *eImpfdossier* (eVaccination record)
- *eLaborbefund* (eLaboratory findings)
- *eMedikation* (eMedication)

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[18] PDF is not free of display errors and ambiguities; however, they are generally considered to have less impact than CSS and HTML (or comparable technologies). Furthermore, PDF/A is accepted broadly in document management systems including audit-proof archiving.

[19] https://www.e-health-suisse.ch/technik-semantik/semantische-interoperabilitaet/austauschformate.html

- *Laborbefunde im Transplantationsprozess* (Laboratory findings in the transplantation process)
- *Laborbefunde für Qualitätskontrolle* (Laboratory findings for quality control)

However, transition to FHIR has started and the eMedication exchange formats are defined as CDA documents as well as FHIR documents. Future exchange formats will be developed presumably in FHIR only.

11 Security and privacy considerations

11.1 EPR

Security considerations for the Swiss EPR are not subject of this paper, because they are subject to strong legislation and therefore covered by law and ordinance.

11.2 Directional communication

The term "directional communication" points to the fact that there is one sender and one or many recipients of a particular message; all of them are well known at the moment a document is sent. This is in contrast to "document sharing" where a document is provided to a repository; at time of providing the document, nobody knows if, and if yes by whom and when, the document will be retrieved.

Whereas it is nearby impossible to sensibly implement end-to-end encryption (E2EE) with document sharing, E2EE is feasible for directional communication, because the receiver and his public key for decryption is known.

Swiss data protection law already considers the fact of a hospital stay as particularly worth protecting, which means that nearby all patient related directional communication is particularly worth protecting. As a consequence, exchange of sensitive content needs encryption as well as all data allowing conclusion of the patient such as name, surname, PID, etc.

Although not every provider of communication solutions in healthcare has implemented their services in this way (2020), the Swiss Federal Data Protection Commissioner requires that future implementations of directional communication solutions shall not allow access to the content of a document but for the sender and the recipient.[20]

It has to be stated clearly that the authors do not consider a general requirement for E2EE at the level of individual persons as sensible for directional communication. However, there may

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[20] Personal communication: *Burkhard Schwalm. Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter EDÖB. 29 Jul 2014: «Röntgenbilddaten von Menschen und begleitende Texte sind gemäss Bundesgesetz über den Datenschutz (DSG, SR 235.1) besonders schützenswerte Personendaten (Art. 3 Buchstabe c, DSG). Da es nicht notwendig ist, dass die Intermediäre Kenntnis des medizinischen Inhalts der übermittelten Daten haben, müssen diese mit den notwendigen technischen und organisatorischen Massnahmen gegen Einsichtnahme geschützt sein. Konkret sollen die Bilder und Befundberichte nicht unverschlüsselt bei den Intermediären vorliegen und die Intermediäre selbst dürfen keinen Zugang zu den Schlüsseln haben.»*

be certain use cases where an E2EE between persons might be desirable and/or enforced by law.

11.3   Patient consent

Depending on the topic, documents may need to document a patient consent. FHIR covers this requirement by means of the resource Consent – Content[21] which is used to express consent for advanced care directive, research treatment as well as privacy consent. Details must be discussed in a future version in the light shed by a particular use case.

11.4   Document signature

FHIR recommends the use of W3C Digital Signatures or JSON Digital Signatures for digital signatures[22]. If the document has to be signed it is recommended to use the specification for enveloped signature as profiled in the IHE DSG Profile.[23]

12   Real world model of the service request

Figure 3 shows a real-world model of the service request, analogous to the DICOM Model of the real world[24], but focusing on the communication between institutions. Information pathways and processes inside institutions (e.g. communication between the GP and his assistant, specimen handling and information flow at the lab, etc.) are not depicted with the following exception: sampling of specimens (such as blood, urine etc.) can take place at the site of the order placer or the order filler, but may also be done by third parties (e.g. Spitex). This is addressed by means of the items "Order placer task", "Order filler task" and "Third party task" which are depicted because the service request may relate to them via Specimen ID; furthermore, the Service Request may contain desired dates and places for appointments (not depicted in Figure 3).

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[21] https://www.hl7.org/fhir/consent.html

[22] https://www.hl7.org/fhir/signatures.html

[23] https://wiki.ihe.net/index.php/Document_Digital_Signature

[24] DICOM Model of the real world: http://dicom.nema.org/dicom/2013/output/chtml/part03/chapter_7.html
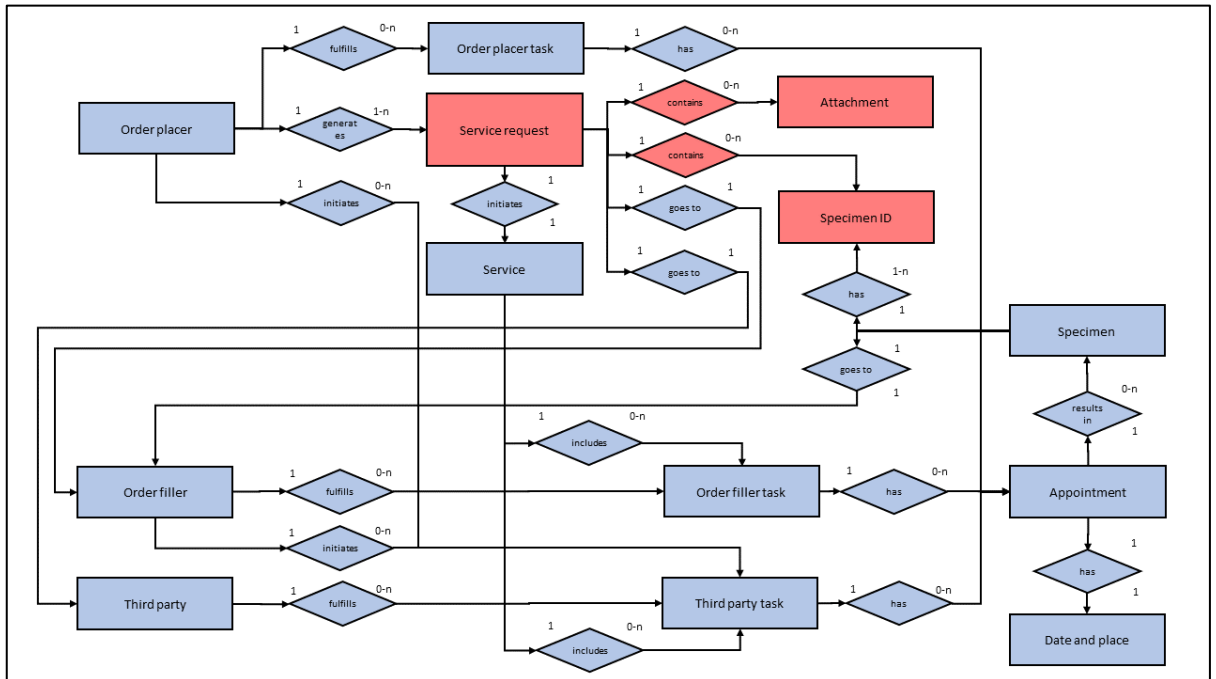
Figure 3: Service request real word model. Description see text.

Requests for results follow in principle the same model but do not make use of the appointment because they do not initiate new tasks related to specimen sampling. Figure 4 depicts the request for results.
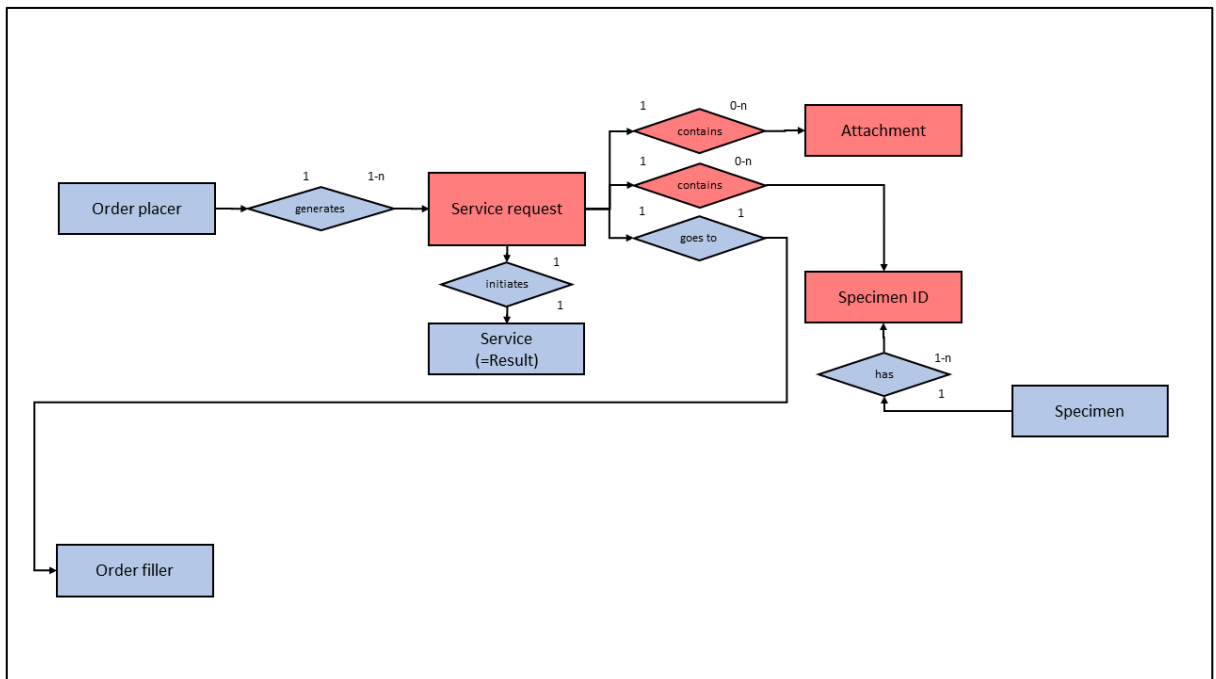

Figure 4: Request for results real word model. Description see text.

13   Content of the service request

The content of the service request must…

1) … correspond to the real world model depicted in Figure 3.
2) … allow structured representation of additional information such as patient demographic data, insurance coverage, relevant contact data concerning the personnel involved, etc.
3) … contain data necessary for service request handling on the application level, e.g. linking between requests and belonging feedbacks in order to depict the bidirectional communication (ping-pong) as a thread.
4) … contain adequate metadata.

Content of the generic service request is distinguished into two categories such as generic elements and healthcare domain specific elements. "Generic elements" refer to a well-defined set of content items which are part of each and every service request irrespective of the health care domain of the use case. "Domain specific elements" refer in contrast to a set of content items which varies according to the specific use case in different health care domains such as laboratory, radiology, transition of care, etc.

Section 14.3.1 lists all generic elements with their FHIR representation (corresponding FHIR resource) and the HL7 V3 equivalent.

An additional DocumentReference Resource refers to the healthcare specific content (see section 14.3.2).

14   Implementation based on FHIR structured data capture (SDC)

14.1   Principle

A service request shall base on the CH-ORF Implementation Guide[25] which in turn is based on the SDC Implementation Guide[26].

FHIR questionnaires use the Questionnaire Resource defining the empty form and the QuestionnaireResponse Resource which represents the form with the filled-in information.

The basic principle is to capture data on order placer site by forms (FHIR questionnaires) and to render the resulting QuestionnaireResponse to a PDF/A document. In parallel all resources such as Patient Resource, ServiceRequest Resource etc. must be populated in accordance to the implementation guide for the particular exchange format and the CH-ORF Profile respectively. Resources and PDF/A document are then packed in a bundle and sent to the order filler.

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[25] http://build.fhir.org/ig/ehealthsuisse/ch-orf/
[26] http://hl7.org/fhir/uv/sdc/2019May/

Using SDC has various advantages:

- Representation via the user (GUI, print) can be defined thus to ensure same content and appearance at sender and receiver site.
- SDC enables adaptive forms (see section 7)
- Changes to forms are easy; if newly introduced attributes are not yet handled by interfaces to other systems, they can at least be filled in and displayed at order placer and order filler site respectively.

Annotation: There has been a discussion whether population of the resources such as Patient Resource, ServiceRequest Resource etc. with the content of the QuestionnaireResponse Resource should be done by the order placer application or rather by the order filler application. The argument for assigning the task to the order placer is a result of the following consideration: as stated in section 14.2, the authors of a particular implementation guide may decide to define a questionnaire and its rendering but to leave it open if in a particular implementation the questionnaire is implemented or if the representation towards the user is made (in accordance to the questionnaire definition) by other technical means. In such a case, there would be no QuestionnaireResponse Resource in the bundle because all content is already in concerning resources. In order to handle all FHIR exchange formats equal (as far as sensible), the authors decided to mandate the order placer application with the task.

14.2 Using questionnaires

Structured Data Capture (SDC) describes how questionnaires can be used, see also the description in the CH-ORF section:

1. Finding a questionnaire describes expectations for systems serving as form repositories as well as clients who will need to search for forms.
2. Advanced Rendering describes how to use various questions and the base capabilities of Questionnaire to render different types of form elements.
3. Form Behavior describes how to design 'active' forms that adjust what information is displayed and/or that perform calculations based on user input.
4. Adaptive Forms describes an architecture to support completing forms where the questionnaire is not pre-defined and instead is dynamically developed based on the user's answers.
5. Questionnaire Population describes how to design questionnaires to support pre-population of answers and how to use services that support pre-populating forms.
6. Data Extraction describes how to design questionnaires to support converting completed forms into a FHIR resource or Bundle of FHIR resources for subsequent analysis.

There remains however the question which exchange formats may benefit from a questionnaire. Given the fact, that questionnaires are the means of choice to assure homogenous representation towards the content provider and the content receiver, one might argue to include such a questionnaire in general.

However, there are a number of exchange formats being developed elsewhere which do not follow the SDC approach. Another consideration refers to use cases where an application populates almost all items of a structured document. In such cases, population of the concerned resources may be more attractive than a detour via a questionnaire.

For further discussion, it may be helpful to be aware that defining a questionnaire and its implementation are two separate things. In other words: authors of a particular implementation guide may decide to define a questionnaire and its rendering but to leave it open if in a particular implementation the questionnaire is implemented or if the representation towards the user is made (in accordance to the questionnaire definition) by other technical means. In such a case, there would be no QuestionnaireResponse Resource in the bundle because all content is already in concerning resources.

Having said this, the authors of this handbook conclude:

Exchange formats which use the ServiceRequest Resource SHALL define a questionnaire as well as its rendering to the PDF/A document. In order to be able to react quickly to new requirements (see section 8), questionnaires shall be implemented (SDC approach).

For other implementation guides, this decision remains open for discussion.

Annotation: There has been a long discussion if transition of care shall be included in the requirements stated above. The discussion has been driven by its proximity to the International Patient Summary (IPS) which does not follow the SDC approach.

However, transition of care differs from the IPS in the fact, that the latter is a snapshot of the patient's health condition without any current question, order, etc.; the IPS does not contain any service request whereas the service request is the main element of a request for transition of care. This justifies inclusion of transition of care in the requirement regarding the use of questionnaires.

14.3 FHIR resources for content

14.3.1 Generic elements

Generic elements of a Questionnaire: See [Table in the CH-ORF Implementation Guide](#).

14.3.2 Healthcare domain specific elements

Healthcare domain specific elements shall be defined for each use case. CH-ORF currently defines a linkage between particular files or between a particular file and an imaging study (e.g. a link between a PDF-File, advanced care directive, research consent, privacy consent, treatment consent, a report and a DICOM study). Such links shall be expressed with a DocumentReference.

15 Codes and value sets

Value sets and thus all codes used in a specific exchange formats have to be defined in the concerning implementation guide. In particular, value sets for generic elements will be defined in the CH-ORF Implementation Guide. Value sets for health care specific value sets shall be defined in the implementation guide defining the specific exchange format (e.g. radiology-order).

Glossary

EPR	Swiss Federal Electronic Patient Record
GP	General practitioner, family doctor
Order	A request to perform examination […]. The Order is the focal object of the transactions between Order Filler and Order Placer […].[27]
Order placer	see "order"
Order filler	see "order"
PIS	Practice Information System
Procedure request	Procedure request is a record of a request for a procedure to be planned, proposed, or performed, as distinguished by the ProcedureRequest.intent field value, with or on a patient.[28]
Referral	Referral is the process, with the intention of initiating care transfer, from the provider making the referral to the receiver.[29]
ServiceRequest	ServiceRequest is a record of a proposal/plan or order for a service to be performed that would result in a Procedure, Observation, DiagnosticReport, ImagingStudy or similar resource.[30]
Transition of care	Movement of a patient from one health care provider or setting to another.[31]

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[27] Source: https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_GenIntro_AppD_Glossary_Rev2.0_2018-03-09.pdf (The full text refers to lab only; as we use the terms order, order placer, order filler in a more general way including lab, radiology, transition of care, etc., the lab specific part of the definition is omitted.)

[28] Source: https://www.hl7.org/fhir/procedurerequest.html

[29] https://wiki.hl7.org/index.php?title=Referral_and_Transition/Transfer_of_Care

[30] http://hl7.org/fhir/servicerequest.html

[31] Source: The Joint Commission: Transition of Care Document - 2013, p.2; http://wiki.hl7.org/index.php?title=Referral_and_Transition/Transfer_of_Care)