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Challenges of a HL7 CDA Guideline for Telehealth Based DMP Systems

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Abstract. Background: Disease management programs (DMP) are a modern way of treating health conditions and are becoming a part of standard care. One telehealth DMP service has been in regular operation since 2017, named "HerzMobil Tirol". Objectives: This paper investigates, if the electronic health record standard HL7 CDA, which is widely accepted in the health care industry, could be used for telehealth DMP services as well. It is already in use in a legally required integrated element of healthcare in Austria called ELGA. An official guideline from the Austrian Ministry of Health sets the standard for telemonitoring with data logging. Methods: After the background knowledge was built up, requirements have been gathered through existing official guidelines and interviews and existing documentation by "HerzMobil Tirol". Results: Twenty-five requirements were collected, categorized and analyzed to determine if the existing CDA guidelines are suitable or a new standard must be designed. Conclusion: Based on the requirements, it was established that seven specific sections and two different CDA documents are needed.

Keywords. Disease Management, Health Level Seven, Electronic Health Records, Computerized Medical Record System, Telemedicine, Patient Generated Health Data

1. Introduction

Within disease management programs (DMP) healthcare professionals (HP) interact and communicate with patients in a coordinated way, to treat a condition over a defined period of time where patient self-care is also highly essential for the therapy [1]. Such DMPs can also be supported by electronic medical devices and webservices, to make a remote medical treatment possible [2].

One of such telehealth services has been in regular operation since 2017 in the Austrian state of Tyrol and is named "HerzMobil Tirol". HerzMobil Tirol is a multidimensional post-discharge disease management program for Heart Failure (HF) patients employing a telemedical monitoring system incorporated in a comprehensive network. This network includes specialized HF nurses, private practice physicians and primary and tertiary referral centers [3]. The HerzMobil Tirol telehealth services collect vital signs on a regular basis like weight, blood-pressure, heart frequency, blood sugar levels, steps and wellbeing through questionnaires, to name a few. They also collect medication intake data, used medical devices and written communication [4]. There is

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no way to get access to the data outside of the HerzMobil Tirol network. Due to the fact of the scientific context it grew out of, and also the possibility of accessing intern information, the HerzMobil system therefore is taken as the reference system for Austrian telehealth DMPs.

The Ministry of Health Affairs in Austria has published a general IT-infrastructure guideline for telemonitoring with data logging [5]. It is describing, how a standardized base for the interfaces between the components could connect different DMP modules and make use of the synergy. For example, patients with more than one chronic disease. It is also mentioning the HL7 CDA Personal Healthcare Monitoring Report (PHMR) [6], that is created with the goal to contain monitoring information on personal healthcare, specifically patient measurement data taken by consumer medical devices. This PHMR is in use in an ongoing telemedicine project in Denmark [7].

ELGA ("ELektronische GesundheitsAkte") in Austria is on its way, to create a connection between patient record systems, that are mandatory for every health care provider. Specific documents from different healthcare professionals currently being registered on a centralized server and the actual data is hosted by the health care provider in their own ELGA domain. The patient can access all uploaded documents from a web based application. Other HPs can get access to the data of all uploaded documents concerning the patient by inserting the patients social security card. All documents in the ELGA must use the standardized document profile HL7 Clinical Document Architecture (CDA) [8].

In this paper the authors address the following questions: Is it possible to make the telehealth DMP data accessible for HP outside the DMP via standardized documents? Will the requirements of the main stakeholders from a reference telehealth DMP fit the given CDA Standard? Is it also possible to make this DMP document comply with the requirements of the ELGA and the Ministry of Health Affairs?

2. Methods

First the general background knowledge was built up which was summarized in the introduction. From this knowledge it was clear which different stakeholders had to be interviewed for further analysis. Before the needed interviews with telehealth service experts, individual recaps and interview guides, that match their profession, were created. The recaps were given a brief overview over the situation and were sent before the interview to the interviewee. The interview started with a short presentation of the recap followed by questions from the interview guide being asked. During questioning answers were written down and repeated to the interviewee, so that a correction from the interviewee was possible.

Some requirements were collected through analysis of the interviews with the stakeholders from the reference telehealth DMP service. The three main stakeholders regarding a telehealth DMP service, as seen on figure 1 in the orange box, include: the experts who are also the system designers in the collaborative heart-failure network, the healthcare professionals that are using the DMP inside the network and the healthcare professionals outside the DMP network, that will read the document. Each group offered one stakeholder representative to be interviewed. The requirements were extracted from the given answers. Additionally, the existing internal documentation of the design team was analyzed and the requirements relevant to the DMP document were collected as well.

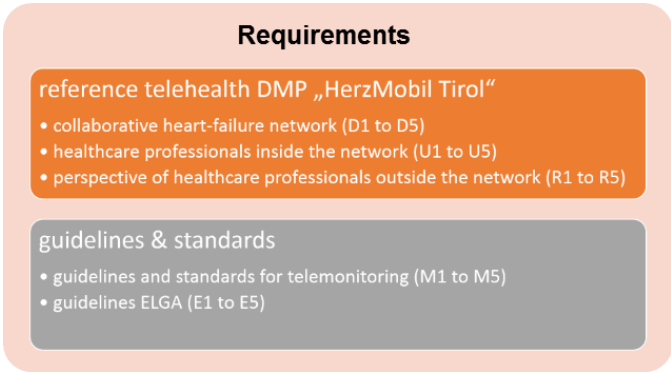

Figure 1. The stakeholder requirements are in two main groups, as shown. The identifiers D1 to D5, U1 to U5 and so on are analogues to the later defined requirements and their IDs.

Beside the DMP stakeholders, there are also two organizations with official guidelines that must be considered, as seen in the grey box on figure 1. From the Ministry of Health Affairs there was published a general IT-infrastructure guideline for telemonitoring with data logging [5]. Inside of this a guideline of HL7 International was referenced [6], that is affecting this work. The ELGA has CDA guidelines already in use for Austrian purposes that need to be considered also [8]. The official guidelines from these two organizations were analyzed and requirements were extracted. The purpose of the found guidelines for standardized records has been compared with the targets of this work.

After the requirements were collected, a categorization was made regarding the depth of the impact of the requirement on the guideline for the DMP CDA record. Because some requirements were targeting the same topic, a grouping inside the categories was also made. By the end of the results every requirement group was being considered and finally important aspects were suggested for a DMP document.

3. Results

In 3.1 the requirements are being listed. In 3.2 the requirements are being divided into categories. In 3.3 the possible solutions are being described. In 3.4 the potential guideline for telehealth DMPs is being summarized.

3.1. Requirements

In the following table, the requirements have been listed and given an ID. The letter in the ID stands for a stakeholder, see figure 1.

3.2. Categorization

In the following section, the requirements are categorized and grouped as seen in figure 2. Three categories were established. “General” requirements are requirements that are affecting the whole document. The requirements in the category “sections” are influencing the individual sections that will include the information in the document. The

Table 1. The individual requirements with their ID

ID	Requirement
D1	For all used data exports, imports and interfaces, only known standards out of the common practice should be used.
D2	There should be a summary of the DMP after it is finished, with all the relevant data for the treatment validated and signed by the supervising physician.
D3	The new document standard should be used as a more detailed and standardized backup file for the HP, to still have access to the data of their patient after the telehealth DMP service has been shut down or if the HP is not active in the DMP network.
D4	The document should be an easy way to pass on the data when the patient or another entitled person like a lawyer of the patient is demanding it.
D5	There should be a way to add diagrams in a widely-used picture-format to the document. Normally one diagram per section should be enough, but the chance of having more than one should be considered.
U1	There are types of comments and notes that are only meant for the HP themselves or among each other, these should not be included in that form in any official document.
U2	Attention should be paid, that for every chronic condition, the common practice is different and changes over time. This is primarily affecting the needed monitoring data.
U3	A fundamental question at the beginning of the document should show a brief overview, what condition caused to start this treatment. This is essential when more than one condition is known and this must be kept in mind while treating the patient.
U4	When written text is required, there should be an option to write various text elements, which should be reusable and combinable.
U5	Laboratory results and other documents should be able to be added to a DMP document.
M1	In the long-term the telemonitoring with data logging guideline will create a homogenous, communicating IT system landscape, that supports telemonitoring for health applications. It will also create a base for the international accordance of these IT standards.
M2	Specifying and further developing of standards for the IT architecture for telemonitoring and making the availability of compliant devices on the market better is also defined as a target in their guideline.
M3	Another goal is the creation of a technically binding base for patient care, especially for patients with multimorbidity, to add medical devices independently from the manufacturer for any requirements and course of diseases. This will be specified in the spirit of a rough concept, that will serve as a base for designing a detailed concept in ongoing planning phases.
M4	They are also specifically defining non-objectives. One worth mentioning for this work is, not defining quality standards or recommendations for the medical aspects of disease management programs, knowing that the existence of a DMP is essential for telemonitoring.
M5	For the data transfer between various interfaces, the guideline is specifically mentioning that the usage of HL7 CDA analogous to the HL7 CDA PHMR is binding.
E1	In the official law in the “ELGA-Verordnung 2015” it is defined that starting from 1.1.2018 the main documents can only be uploaded in “EIS Full Support”, that is analogues to HL7 CDA Level 3, which provides full machine readability.
E2	The data in the CDA header must be consistent to all specifications for headers of the general ELGA CDA guideline “Allgemeiner Implementierungsleitfaden” in its version 2.06.2 [8]. This also includes the correct referencing of the patient and the defaults for automatically generated documents.
E3	If the vital sign components (section, group and entry) are used, it should be considered that the ELGA is already specifying these vital sign components in the ELGA discharge summary [8] for the measurements recorded during an inpatient treatment.
E4	There are already defined code-systems and value sets in other ELGA document standards. These should be reused. If an expansion is needed, the request process has to be investigated.
E5	If medication components (sections, groups or entries) are needed, these should be reused from other ELGA guidelines like from the “eMedikation” [8], a standard for electronic medication CDA documents.
R1	Values outside of a range, that was set by the network physician, can be much more interesting than the standard values. These should be somehow summarized or highlighted.
R2	All the data in the document should be tagged with a timestamp. This is especially important in a DMP document because a treatment in HerzMobil Tirol normally last for 3 months or more.
R3	The additional information of the used measurement device is useful but should not be mandatory.
R4	The chronological order should be ascending, meaning that the oldest value is also the first one on the list.
R5	The details of a contact person should be included in every document, who can answer questions regarding the treatment of the specific patient.

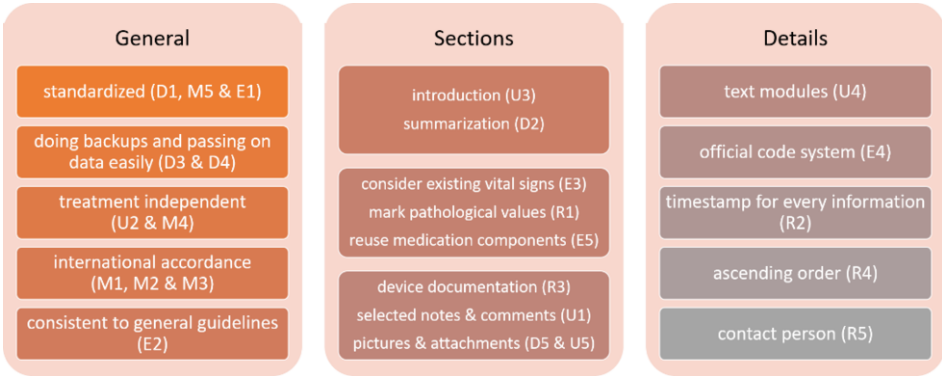

Figure 2. The requirements categorized and grouped by topics.

requirements in the category "details" will only change specifics in the record. Requirements with equal topics were discussed together under one title, followed by the requirement IDs in brackets. Requirements were grouped when the topics were similar but not the same, as seen in the first block in "sections" in figure 2.

3.3. Consideration of every requirement

The data standards for D1 are already limited by E1 and M5. This work has to use the widely-known document standard CDA from HL7 CDA Level 3, meaning that information is fully machine readable. M5 is even restricting it to a document that is analogous to the existing HL7 CDA PHMR standard. If designing a new standard is really needed it is beneficial to compare it to a similar existing standard.

D3 and D4 are both accomplished, because the HL7 CDA Standard is based on single XML document for every treatment. It can even be displayed in a simple browser, when an official XSL stylesheet has been added. Patients have the possibility to get the documents that were created out of the DMP directly in their ELGA portal.

U2 is stating, that different diseases are demanding different treatments and that treatments are evolving over time. The official document from the Ministry of Health Affairs is stating with M4, that they don't want to make a standard for the DMP treatment itself, so that a doctor has to follow a specific standard operation procedure when a disease is diagnosed. This is also not the objective for this work.

M1 is satisfied, providing that the HL7 CDA standard is an international accepted standard, used in many variations over the world. The more specific HL7 CDA PHMR standard is designed for medical devices generating a HL7 CDA document and sending it directly to the patient record folder. This fact is supporting M2 and M3, so that the devices could speak a common document export language and be used in different DMPs.

E2 demands that the document is consistent to the general ELGA CDA guideline. The interesting aspect is, that the standard should be like the HL7 CDA PHMR, which is automatically generated without any user interaction. Such a document is not having a human validation, that is required in most of the ELGA documents. Also required is the versioning of the ELGA document. It could add values to an existing document with every measurement, creating a new version number and extending the treatment-timespan of the document.

Regarding the sections U3 clarifies that a brief introduction into the DMP document is needed. Normally, a title can be insightful and clearly state the targeted disease. However, the possible condition with more than one chronic disease, which are influencing each other, demands to be stated first in documents like these. It would be too much information to be stated in a simple title. D2 is asking for a summarization of the treatment. This could be written continuously while treating or once at the end. A document could be used that is similar to the ELGA discharge summary "Ärztlicher Entlassungsbrief", that is meant as a discharge summary after an inpatient treatment. It could be a signed document and would include the data of the DMP.

E3 requires that the vital signs section in the PHMR is adapted to the vital signs section in the general ELGA guideline, that is demanding that every parameter in the vital signs is specified with their official name, unit and code in the value set "ELGA_Vitalparameter". The PHMR is also defining, that the vital signs are specific parameters, that are been standardized in health care. Non standardized parameters are being collected in the results section. R1 is demanding that parameters that are out of a specific range, get highlighted or summarized somehow. The HL7 CDA standard itself is limiting the formatting possibilities. The E2 with its general ELGA CDA guideline is adding more possibilities for formatting with extended style-codes, that a ELGA CDA stylesheet can realize. Aside from headings and table formatting, they also added xELGA_blue for highlighting text sections and xELGA_red for highlighting a whole row of pathological data of laboratory measurements. Aside of formatting, the table can be made collapsible with the given stylesheet, summarizing only the pathological or out-of-range data at first. With a click the table can expand and show all the data. E5 is similar to the usage of medication components that the ELGA discharge summary "Ärztlicher Entlassungsbrief" is using. The one big difference for the DMP document standard is, that it also needs to record the intake of the medication. This should be a machine-readable entry itself. Because such a medication intake entry is not existing in the ELGA guidelines at the time of this work, one has to be created, similar to the existing ELGA medication components.

R3 is weakening the mandatory medical equipment section in the PHMR from M5, because its stating that the added medical equipment information is not of high value. The design-purpose of a PHMR is that a device itself would create such a document. Because of this, the medical equipment section in the PHMR should be filled with the information of the device itself. The purpose of writing a document out of a DMP system whereby one or more devices are delivering vital parameters is making this section optional, to not overcomplicate the implementation of such a document. U1 could be simply solved through selecting the notes and comments at the exact moment a document is generated. Also, the option of categorization of comments and notes beforehand would be a practical solution. That would support the automatic generation of the document without any user interaction. Just the categories of notes and comments that can be uploaded needs to be set beforehand. D5 is requiring an option to add pictures to a section. The general ELGA CDA guideline is offering "observationMedia"-entries. These are embedding one or more attachments in a CDA as a base64 coded block of text to a section directly. Defined in the "ELGA_Medientyp" valueset there are PDF, MPEG, XML and the appropriate image types GIF, JPEG and PNG. Within this requirement, U5 also got answered, which demands the option to add whole documents as XML or PDF to a CDA.

The detail requirement U4 is not directly influencing the document standard. The text modules could offer one big text block or single paragraphs.

Table 2. recommended CDA sections for a DMP record

name	explanation
fundamental question	As a mandatory section the fundamental question could briefly show details about the reasons for starting the DMP treatment with adjustments on the patient.
summary	The summary outlines the whole DMP treatment. Every time a significant observation or change in treatment has been made, a few sentences should be added.
vital signs	The vital signs section is the observation section for clinical defined parameters. Like in the HL7 CDA PHMR, the DMP document should require both observation sections or at least one of these two to be valid.
results	The results section is the other observation section for non-clinical defined parameters. The medication intake can be documented in the result section as well. For this a CDA entry must be specified, so that that data is standardized for machine readability.
medical devices	The medical devices, unlike in the PHMR, should be optional, but when used it should support full machine readability.
feedback	The feedback contains all the notes and comments that were selected to share with HP outside of the DMP network.
attachment	In the attachment, whole documents like laboratory results (e.g. as PDF) can be appended.

E4 is saying that codeable parameters should be machine readable through a code system. There is the possibility that even in the good cultivated database there may not be a parameter that could be measured by a medical device. For those rare cases a publicly available value set from the HP or medical device manufacturer themselves could be created or updated with these missing values.

R2 is a point that could be specified as a rule in the specific standard guideline, that every data, even simple text passage, should have a timestamp or at least the date.

R4, with its ascending chronological order, should be standardized in the guideline. It would ensure that every document has been written and can be read the same way.

R5 is even matching to the CDA HL7 standard, that gives every document a contact person, who can be asked regarding questions to the document. This should be decided for every DMP separately, but at least one contact person should be given.

3.4. Suggested guideline for telehealth DMPs

From the above collected and discussed requirements, a guideline for a DMP record can be proposed. A standardized document for DMPs could have, besides fulfilling the header requirements of the overall ELGA CDA guideline, seven different CDA sections in their body, presented in table 2.

There needs to be distinction between the two documents. One is being created while treatment is ongoing. This could be automatically generated and therefore not be specifically signed. The second document is summarizing the whole treatment at the end of a DMP, signed by the supervising physician. Two different CDA subclass standards would be useful. The document that is used during treatment would contain the above specified sections. This could be created by the telehealth DMP system automatically on a daily basis. It could be called DMP report or short DMPR. The discharging document could be a subclass of the official ELGA discharge summary. In addition of being compliant to the ELGA discharge summary, it could contain the last DMP report itself as an attachment or include all the sections of the last report solely. This document type could be called DMP discharge summary, short DMPDS.

4. Discussion

The requirement analysis is showing, that the HL7 CDA is the right match for a base standard for such a DMP document standard. The HL7 CDA PHMR could be used as a template to create an ELGA guideline for the DMPR that is compliant to the general CDA guideline of the ELGA. Besides this, a DMPDS must be specified and that could be an adjusted version for the DMP of the actual ELGA discharge summary. It should be investigated if a third DMP document type is needed, however it is not specified or asked in the collected requirements. It would summarize a DMP treatment and be signed by a physician while the treatment is ongoing. This could be called a DMP situation summary or a DMP situation report.

In the future, the requirement for writing selectable text modules could be the reason for bringing up a code system for whole text blocks. Therefore, the meaning of the text block could be coded. For further discussion on the requirement to add diagrams to the document, SVG should be considered. This is due to the fact that most of today's browsers are compatible with such vector graphics. They would show its advantages in small storage spacing and enlarging without getting grainy, especially for diagrams. Additionally, ongoing work from other countries, like the discussion in Denmark about the addition of methodCodes for every measurement [7], should be considered in the ultimate implementation guideline for DMP documents.

It also should be noted, that this requirement analysis, made with the tools described, could be incomplete. All of the found requirements and their analysis stated in this work should be an appropriate start for designing the two needed CDA documents that keep record on a DMP, especially on a telemonitoring supported DMP.

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