Mini Review

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Using HL7 CDA and LOINC for standardized laboratory results in the Austrian electronic health record

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Abstract: With the implementation of the Austrian electronic health record (ELGA), laboratory results are formally standardized for the first time throughout Austria. The nomenclature of the lab analyses, their sequence and structure as well as the display of laboratory results are unified with ELGA. One of the most significant steps is using Logical Observation Identifiers Names and Codes (LOINC) as a reference terminology for lab analyses. Thereby laboratory results can be reused semantically interoperable all over Austria.

Keywords: electronic health record; LOINC; nomenclature.

Introduction

Results from medical laboratory examinations are one of the most fundamental tools of clinical diagnostics for therapy decisions and for the surveillance and prevention of diseases. The medical analysis of blood and other body fluids provide necessary and essential information for efficient, safe and evidence-based clinical decisions. Laboratory reports are therefore the most common diagnostic measures and the most common healthcare documents [1, 2]. Laboratory reports are usually provided by clinical-chemical laboratories in the form of paper documents; in many cases, electronic transmission has also become established.

The Austrian electronic health record (ELGA) connects general practitioners, pharmacies, infirmaries, care facilities, ambulances and institutes throughout Austria. Latest information on the medication of a patient and medical reports can be obtained using ELGA. Only the patient himself and organizations who are directly involved in his treatment have access to the patient’s data [3].

ELGA was conceived, built up and gradually put into operation as an Austrian IT infrastructure since 2015 with laboratory reports as one of their most important documents.

Alongside laboratory reports, other clinical documents are provided in ELGA such as medical discharge letters and radiology reports; additional document classes are in preparation. By the end of June 2018, 8.1 million laboratory reports had been available through ELGA.

ELGA health data can be accessed directly from the IT systems of doctors and hospitals. The data can be reused without media discontinuity. In order to easily retrieve, display and store data platform independently, the reports must be provided in a standardized manner. Hence, ELGA relies on the international standard HL7 CDA® [3].

HL7 CDA® (or Health Level Seven® Clinical Document Architecture®, Release 2) is an XML-based standard, which could be used for all types of medical reports. CDA can not only transport text and images, but also offers the possibility to embed data in machine-readable form; it enables the recipient to reuse the data without having to type or transcribe any of it. These data can either be used for calculations, comparisons and statistics or can be used in clinical decision support systems (CDSS), e.g. for warnings [4].

The hospital discharge letter, for example, may contain discharge medications in machine-readable form, which a general practitioner in his private practice can now automatically convey to the subsequent electronic prescription.

The so-called “implementation guides” regulate the concrete requirements for implementing the CDA standard for a specific area of application. For the laboratory report in the Austrian health service, a corresponding guideline has been harmonized, which is mandatory for ELGA within federal ministerial regulations [5].

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The working group for the laboratory report developed the ELGA CDA implementation guideline for the laboratory report in two phases from 2008 to 2012, followed by several updates, the last major ones in 2015 and 2017. The open working group consisted of not only specialists in laboratory medicine (private laboratory facilities and hospital laboratories), the Austrian medical chamber and the Austrian Medical Association for Laboratory Medicine and Clinical Chemistry (ÖGLMKC) but also laboratory IT vendors, experts for medical informatics and HL7 experts.

In total, over 70 people were actively involved in the harmonization process of the specification; many more received the progress reports of the working group via e-mail. The aim was to come to an agreement throughout Austria to reach the highest possible standardization of the laboratory and microbiology reports. In addition, these reports should be interchanged in a “unified presentation format” based on international standards such as HL7 CDA and Logical Observation Identifiers Names and Codes (LOINC) to reach semantic interoperability. The specifications were harmonized by consensus of all parties involved so that all laboratories can provide laboratory findings via ELGA without having to change existing laboratory processes. The guidelines drawn up by the working group were formally adopted as the new national standard in subsequent public technical commentary procedures of HL7 Austria (“normative ballot”) [6].

For the graphical visualization of CDA XML documents, ELGA provides a so-called “reference stylesheet” – free of charge and license. The reference stylesheet converts the ELGA CDA documents into a usability-optimized and accessible (barrier-free) layout that can be displayed in all standard web browsers without additional viewers. Moreover, a free PDF conversion tool is available [9].

The ELGA laboratory report contains all the necessary general information for processing the document (“metadata”) such as the patient’s basic data, admission, recipient, signer, document date, etc., which are contained in the so-called “CDA header”. Metadata have been standardized for all documents in ELGA, allowing automated document management and consistent filtering criteria. The CDA header and its metadata are described in detail in the ELGA Basic Implementation Guidelines [10].

Below, only the ELGA-specific medical content of laboratory reports is discussed.

### Order

Ordering provider (“order placer”), order date and order number are contained in every laboratory report. Additionally, the medical problem or reason for the referral can be indicated. A unique identifier assigned by a national healthcare provider registry can unambiguously identify ordering providers.

### Specimen information

For each laboratory report, the analyzed samples must be stated. A complete specification of the sample information includes the specimen identifier, the collection time, the specimen type (in unified HL7 nomenclature) and the specimen receiving time. The lab can add a commentary (“sample slightly hemolytic”). In addition, the person performing the sampling procedure and the anatomical region from which the sample originates can be documented. An example is shown in Figure 1. The currently used HL7 nomenclature for the specimen type will be supplemented by the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) in the near future.

### Human-readable content of the standardized ELGA laboratory report

The ELGA laboratory report contains all information needed for conventional printed laboratory results [7]. The presentation of the findings is standardized for ELGA throughout Austria; Not only the graphic appearance is standardized in ELGA, but also the naming of the laboratory parameters and their grouping and order of findings [8]. This should make it much easier for users of ELGA to read and compare laboratory results from different laboratories.

#### Specimen Information

<table>
<thead>
<tr>
<th>Specimen-ID</th>
<th>Collection time</th>
<th>Specimen</th>
<th>Collected by</th>
<th>Specimen received</th>
<th>Annotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL-121201-02</td>
<td>01.12.2016 06:34</td>
<td>BLOOD</td>
<td>Dr. Hofer</td>
<td>01.12.2016 06:15</td>
<td>Hemolytic</td>
</tr>
<tr>
<td>PL-121201-01</td>
<td>01.12.2016 06:34</td>
<td>PLASMA</td>
<td>Dr. Hofer</td>
<td>01.12.2016 06:15</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1:** Complete sample information. The columns for “Specimen-ID” and “Collected by” may be omitted. The “Collection time” can be “unknown”.

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Structure and sequence

The ELGA laboratory report has a defined hierarchy and order. All laboratory parameters have a specifically defined sequence in which they appear on the report. The grouping of the laboratory parameters is fixed to two hierarchical levels (category and group/"Bereich" und "Gruppe"). These structured levels as well as the laboratory parameters themselves are defined in the value set (a value set is a collection of codes for a particular application) of ELGA laboratory parameters.

Laboratory results

Laboratory results are shown in the common table format in the ELGA laboratory report: a line begins with the name of the laboratory parameter, followed by the result (measured value), the unit, the locally defined reference range ("normal values") and an interpretation indicator. Comments on analyses can be added as a footnote at the end of the group or in the line below the analysis. Wording and syntax of laboratory parameters originate in a controlled vocabulary (Figure 2).

Test results outside of reference ranges are marked by standardized flags for numerical ("+", "−") and non-numerical values ("*"). For results exceeding the normal reference range, additional flags are shown ("−−", "++" or "***"). All test results outside normal reference ranges are displayed in bold and in color. If an analysis was performed by an external laboratory, an "E" will be displayed in an additional column at the end of the report.

As LOINC codes are only necessary for machine processing, they are not displayed on the report, but they allow the display of an "infobutton" via the style sheet, which links precise additional information to the respective laboratory parameters.

Microbiological results

Microbiological culture results can be tabulated in a separate section of the laboratory report. Each row of this table contains the name of the pathogen, the methodology of the investigation and the germ count (Figure 3).

Observations can be coded with LOINC as in the clinical chemistry lab the terms for semi-quantitative results of the germ count have also been standardized.

A particular challenge is the specification of the identified microorganisms for later evaluation and further processing. Coded information is required as free-text information is notoriously untrustworthy: spellings vary, new research findings may lead to the renaming of taxa. SNOMED CT turned out to be the most complete and reliable collection of concepts for microorganisms and is one of the most important computer-readable terminologies in medicine, currently containing more than 340,000 concepts, including over 21,000 entries for microorganisms with taxonomic and pragmatic groupings. For the application of SNOMED CT in Austria, the national license is currently missing. However, it is intended to make SNOMED CT available in 2019 and to use it in definite areas like the coding of microorganisms.

Antibiotic susceptibility testing is presented in ELGA lab reports as a compact pivot table (Figure 4)
which gives a clear and comprehensive overview of the sensitivity of several pathogens to several antibiotics. The sensitivity or resistance is expressed with unified letters. In addition to the letters, the respective minimum inhibitory concentration (MIC) can also be stated numerically.

The different antibiotic susceptibility tests are shown alongside following respective LOINC compatibility.

Illustrations

Illustrations, for example, for diagrams, may be embedded as graphics in every section. The section text may contain further image description and possible meta information. Currently, only raster graphics are supported (JPG, PNG); however, it is planned to support vector graphics (SVG) for a high-resolution representation in the future.

Machine-readable content or: semantic interoperability

In order to read out and further process individual laboratory results from laboratory reports, data must be available in uniform structure and semantics. An appropriate standard is the IHE Laboratory Integration Profile XD-LAB that was used as a basis for the ELGA implementation guidelines [8].

One of the challenges here is the standardized coding of laboratory parameters and the notation of the units of measurement. The same laboratory parameters have to be documented in all laboratory reports with the same code. A value set based on the LOINC standard was introduced, as described further below.

However, the working group could not agree on a standardization of the units of measurement. As they are given in uniform notation according to UCUM the (Unified Code for Units of Measure) standard, the interoperability of laboratory values with different units of measurement remains possible [11].

UCUM is a rule-based nomenclature for units of measure. Due to the fact that UCUM does not represent an enumeration of expressions (no countable “code list”), there is no “conversion table”, and every expression has to be analyzed. The U.S. National Library of Medicine provides a conversion service free of charge [12].

Additionally, reference ranges are also machine-readable. Open intervals (“>10”) can be represented as well. Furthermore, all kinds of interpretation flags for measurement results have to be coded too.

The process of exchanging laboratory results between laboratories or between a lab and a recipient via ELGA laboratory reports is shown in Figure 5.

The ELGA GmbH maintains all necessary terminologies (code lists and value sets) of the ELGA CDA laboratory report and provides them through a central terminology server [13].

This terminology server can be accessed through a website to browse and download terminologies, and if web services are in use, new and updated terminologies can be accessed automatically [14].

LOINC for communication of laboratory data

LOINC (“Logical Observation Identifiers Names and Codes”) is a standard for identifying health measurements, observations and documents, established by
LOINC includes a list of unique identifiers whose specific feature is the LOINC code (an alphanumeric string). On the one hand, LOINC codes can be used to request clinical reports (so-called “order codes”). On the other hand, LOINC codes are mainly used for coding the medical test results (“Observation-Codes”, e.g. glucose [mass per unit volume] in serum or plasma) [15].

The LOINC standardization draws on the following six semantic axes, which thus form the basis for every single codeable medical-clinical examination (laboratory services, laboratory measurements, etc.):

1. Description of a component (laboratory service)
2. Property of a component (e.g. mass or substance concentration)
3. Timing (sampling time or period of the material)
4. System (e.g. plasma, serum, urine)
5. Scale of the measurement (qualitative or quantitative analysis)

Out of these six semantic axes, only the last one (method of examination) is optional. The reason for this concept lies in the fundamental decision of the LOINC editors to avoid an uncontrollable proliferation of codes by considering all possible analytical methods. Therefore, examination methods are only to be taken into account in measurement methods with significantly different reference ranges or different sensitivities of the test systems used when implementing the LOINC model, i.e. if the examination procedure is relevant for the clinical interpretation of test results [15].

Another special feature of the LOINC model in this context is the fact that based on the six semantic axes stated above the individual LOINC entries are not bound to a specific unit. The reason for this as well as for the possibility of the examination method is that in the context of electronic data exchange of reports, for example, in HL7, alternative containers (file formats) for the communication of units or examination methods exist and therefore are not necessarily to be considered at the level of LOINC.

The use of LOINC in Austria

The decision to implement LOINC in Austria began in 2005 in the Vienna Hospital Association (KAV – “Krankenanstaltenverbund”), a public-sector association of healthcare facilities comprising 10 hospitals, two geriatric centers and eight nursing homes [19]. At this time, the KAV operated 13 medical diagnostic laboratories. However, the laboratory management of these facilities
together with the KAV directory board and the KAV IT departments set LOINC as the standard for the exchange of electronic lab findings (clinical chemistry, immunology, hematology, hemostaseology, infectious serology, molecular diagnostics and human genetics. Blood group serology, transfusion medicine, microbiology and pathology were not part of this standardization at that time).

The complexity of this project, anyhow, is reflected in the fact that it took longer than expected – 9 years in total – until the final implementation of a common LOINC-based laboratory catalog took effect in June 2014. In the meantime, Austria has set the course for the setup of the nationwide electronic health record (ELGA – Go-Live December 2015), by which the unified electronic laboratory test, which is also based on the LOINC model, was one of the first objectives to be implemented.

The difficulties in the practical implementation of standardization projects on a large scale are also shown in the studies by McDonald et al. [20] and Vreeman et al. [21]. They demonstrated by the examination of approximately 49 million test results that only a small percentage of individual measurements make up a large percentage of the entire data collective. This Pareto principle (so-called 80/20 rule) was also observed in the context of this study: 80% of the total recorded results accounted for no more than 80 clinical individual examinations (corresponding to 2% of the codes). On the other hand, 784 codes (19% of all codes) represented 99% of the total volume of test results.

**ELGA value set for laboratory parameters**

The empirical experiences of the Pareto principle can also be seen within the implementation of the standardized laboratory report within the framework of the Austrian ELGA project. Thus, based on the experience gained at KAV, not the whole LOINC database was translated into German for the ELGA laboratory report, but only a limited subset of the overall list (“ELGA_Laborparameter”) [22].

Therefore, the current scope of the ELGA value set of laboratory codes comprises only 5996 (6.8%) data records translated from the original source terminology (LOINC) into German. Now, only a part of the *in vitro* diagnostics is currently included in the value set, and the completion of the standardization efforts in this context is still not finished yet.

**The omission of the 6th axis**

Almost 70% of the selected LOINC terms do not state a certain method (which would be indicated in the 6th LOINC axis). This is a much higher percentage compared to the complete LOINC terminology, where the percentage of such codes lies under 50% (ELGA, n=4205 or 69.5%; LOINC, n=42,099 or 479%).

The main argument for the approach of “method neutrality” in the ELGA value set laboratory parameters is that the examination procedure should only be taken into account if it is of significant importance for the clinical interpretation of test results. It is extremely difficult to compare different LOINC in later evaluations; therefore, common LOINC terms should be used wherever possible. In modern laboratory information systems, there are quite a few possibilities to record test procedures and methods (such as, for example, generation changes in immunoassays) and, if necessary, to communicate this information in the context of electronic lab data exchange. The additional information can be placed in the line below the test result or as a footnote.

**ELGA GmbH as LOINC terminology authority**

For the ongoing maintenance and clearing of the Austrian ELGA value set of laboratory parameters, a terminology authority was set up under the aegis of the ELGA GmbH (“Clearingstelle”), which has been in operation since 2014. The terminology authority is responsible for the coordination throughout Austria with the ongoing data maintenance of the current databases, including error corrections, new admissions (including a conclusive translation into German) of examination procedures as well as structuring and classification of specific laboratory tests [13].

Another activity of the Austrian terminology authority is the submission of examination procedures, which are still missing in the source terminology. For this purpose, a system of temporary codes (so-called ELGA “V codes” – provisional codes) has been created. They can be used until Regenstrief Institute, Inc. has granted approval and the assignment of a regular LOINC code is completed.

Prior experiences with the LOINC submission process have shown that a greater number of provisional codes were not approved. For this reason, the ELGA value set laboratory parameter currently contains 518 (7.8%) V-codes. On the one hand, this underlines the enormous importance of the national terminology authority. On the other hand, these experiences also confirm the enormous complexity of the task to create comprehensive
compatibility in the development of a global uniform laboratory standard.

As an exception of the overall rules, codes for “local laboratory parameters” (for special and non-standardized tests) can be used without approval of the Austrian terminology authority. These local codes may also be used in the ELGA laboratory report communication, but they have to be explicitly marked.

Discussion

Laboratory reports are highly specialized and contain highly compressed information that is difficult to understand for untrained people. It is known that format and presentation of the values significantly affect the perception and interpretation by clinicians. Another source of misinterpretation is the wording of laboratory analyses on respective reports. Notations are often provided with idiosyncratic abbreviations, which may be different for each laboratory [23].

Generally, the layout of laboratory reports varies from laboratory to laboratory, as well as hierarchy and order of laboratory parameters on the printed report.

Therefore, a significant breakthrough in standardization was the decision of the incorporated company to standardize both the wording of the laboratory parameters and their hierarchy and order within the lab reports. For the first time, laboratory observations in Austria could be standardized in appearance, structure and semantics. For end users of the standardized lab reports, we therefore postulate several advantages:

1. The reading of reports from different laboratories will be easier due to the unified structure.
2. The comprehension of laboratory reports will increase because the wording of the same tests is harmonized.
3. The comparability of lab reports from different laboratories will be facilitated.
4. Due to the fact that ELGA laboratory reports always use the same semantics, the import and automatic usage will increase.
5. The error rate when importing the laboratory findings into medical office systems is reduced on the long run as the hitherto manually maintained mapping tables can be omitted or reduced to a single mapping.
6. Patients will find it easier to gain relevant information on the laboratory results by allowing a direct link with public independent, quality-assured information on laboratory testing (Gesundheitsportal Österreich) [24].

7. CDSS can easily access laboratory parameters from different sources and therefore will be able to generate a higher benefit. For example, radiographic examinations with contrast agents may be automatically screened for conspicuous creatinine or glomerular filtration rates.
8. Longitudinal displays over long periods are easily possible. Subtle progressions of, e.g. hormone, liver or kidney parameters can be automatically analyzed, or a general overview of the course of the glycated hemoglobin (HbA\textsubscript{1c}) value of diabetics can be displayed.
9. Eventually, the unification of laboratory reports also generates a benefit for the laboratories themselves. ELGA now also provides preliminary values from other laboratories, which can be accessed automatically or on demand by the laboratory information system.
10. Clinical studies and evaluations of laboratory data will be simplified.
11. As the same semantics are available throughout Austria, short-term projects for electronic laboratory requirement should also be facilitated.
12. The use of international standards allows cross-border exchange of laboratory data.

The majority of laboratories in Austria’s hospitals have already mastered the challenges of implementing the ELGA laboratory concepts brilliantly. Although the mapping of the heretofore used local codes to LOINC worked well so far, the biggest obstacle on the way to interoperable and uniform laboratory reports remains the LOINC mapping. Overall, from the experience of the projects of Vienna Hospital Association and ELGA in the LOINC-based standardization of laboratory findings, it has to be stated that data standardization in these dimensions (nationwide as well as globally) is not representing a definite task, but rather a long-term endeavor. The implementation of semantic interoperability is a continuous and dynamic process that must be adapted to technical and medical progress.

The accomplishments achieved so far in the standardization of laboratory findings in Austria are being followed with great interest in German-speaking countries. Several parties have already shown interest in cooperating and adopting the model.

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