Health Informatics Meets eHealth
D. Hayn and G. Schreier (Eds.)

doi:10.3233/978-1-61499-759-7-356

Biosignals, Standards and FHIR – The Way to Go?

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Abstract. Background: Standards have become available to share semantically encoded vital parameters from medical devices, as required for example by personal healthcare records. Standardised sharing of biosignal data largely remains open. Objectives: The goal of this work is to explore available biosignal file format and data exchange standards and profiles, and to conceptualise end-to-end solutions. Methods: The authors reviewed and discussed available biosignal file format standards with other members of international standards development organisations (SDOs). Results: A raw concept for standards based acquisition, storage, archiving and sharing of biosignals was developed. The GDF format may serve for storing biosignals. Signals can then be shared using FHIR resources and may be stored on FHIR servers or in DICOM archives, with DICOM waveforms as one possible format. Conclusion: Currently a group of international SDOs (e.g. HL7, IHE, DICOM, IEEE) is engaged in intensive discussions. This discussion extends existing work that already was adopted by large implementer communities. The concept presented here only reports the current status of the discussion in Austria. The discussion will continue internationally, with results to be expected over the coming years.

Keywords. Telemedicine, biosignal, interoperability.

1. Introduction

Biosignals play an important role in many medical fields, for example cardiology, sleep studies, orthopaedics, (tele-) rehabilitation, sports and fitness.

Many types of sources generate biosignal raw data:

- motion data like kinematic and kinetic measures, force and acceleration
- electrical biosignals like ECG, EMG, EEG, EOG, ENG
- body area sensors and networks, as used in the "quantified self"
- respiratory signals like airflow, pressure and temperature

Today no "golden standard" is available, to enable consistent acquisition, storage, presentation, analysis and sharing of biosignal data, while additionally conserving the

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meta data that is needed for further automated processing of the signals (semantic interoperability). A large number of standards for storing biosignals are available, for example SCP-ECG as standardised in the IEEE 11073 series [1], the European Data Format (EDF) [2] or DICOM waveforms [3]. Within IHE the profiles defined in the Patient Care Device (PCD) technical framework [4] enable sharing vital parameters from medical devices for example within a hospital. The HL7 Personal Healthcare Monitoring Report [5] enables to share data with healthcare providers in a summary report. The Personal Connected Health Alliance (PCHA) refers to these standards and profiles in their Continua implementation guidelines [6].

A review of biosignal file formats is available in [7], describing and considering the following requirements:

- single file format
- multiple sampling rates and scaling factors
- multiple binary data types (int16, int32, float, etc.), dynamic range
- events, annotations and markers, standardised terms
- support of demographics information
- support for quality control (i.e. who, when, where did the recording using which equipment)
- support for automated overflow (out-of-range) detection
- physical units, standardised
- random data access and streaming
- electrode positions

Based on this, in the year 2014 the requirements for storing biosignals in a standardised format were again raised by the authors in a meeting of the interoperability forum of the SDOs in Austria (Interoperabilitätsforum der Österreichischen SDOs). It was found that the status described in [7] did not change and existing standards still did not cover all the requirements.

Work therefore started in the "Medical Informatics" committee of the Austrian Standards Institute (ONK 238) to develop an Austrian standard based on the already available General Data Format (GDF) for Biomedical Signals [8], with substantial input from the authors. The standard [9] was published in the year 2015. The results and software tools from the BioSig project [10] were valuable for studying the feasibility in practice in this effort.

During the development of the standard, the authors, together with other experts in standardization from ONK 238 and DICOM, explored the feasibility of archiving standardised biosignal files into DICOM archives. It was found that additional standardisation efforts are needed, concerning the biosignal file format as well as further improvement of other standards e.g. HL7 CDA, and DICOM. Additionally, since 2015, Fast Healthcare Interoperability Resources (FHIR) [11] emerged within HL7, with the goal to support data transfer between software systems in healthcare, using state of the art IT protocols and technologies. The FHIR community raised substantial interest within the international standards community. For example, cooperations started between HL7, IHE, IEEE and PCHA to enable sharing medical device data on mobile platforms. The authors discussed biosignal file formats again in 2016, together with other experts in the Interoperabilitätsforum. It was found that a new review of the landscape of standards is necessary, considering FHIR and other recent developments, before starting further work on standards.

The funded project "INNOVATE" aims to investigate interoperability standards, but also design and implement "development kits", for example interoperable and modular IT-Framework components for the integration and exchange of data from eHealth, mHealth as well as open data applications and data sources, based on interoperability standards. This project builds on past work on the investigation, design, implementation and testing of interoperability standards for telemonitoring [12], [13]. These approaches were concerned with a Personal Health Device Setup in telemonitoring systems and EHR Systems measuring data and transmitting it via interoperability standards. In the initial phase of INNOVATE use cases from orthopaedics, biomechanics, clinical assessment, and rehabilitation were defined. Thereby, it became clear, that biosignals play an important role, and standards based solutions are needed for the ongoing work in the project.

This work therefore reconsiders the state of international standards development, in order to develop concepts for standards based end-to-end sharing, analysis, presentation of biosignal data in clinical practice and experimental work.

2. Methods

Within the INNOVATE project the following use cases from medical fields were defined together with bio-medical experts, for example in the field of cardiology, sleep studies, orthopaedics, (tele-)rehabilitation, sports and fitness:

- Basic use cases
  - Standardised storing of biosignal files
  - Archiving of biosignal files
- Advanced use cases
  - Management of multi-channel biosignal files from complex acquisition protocols
  - Analysis and presentation of raw and processed biosignal data, e.g. filtering, classification

Advanced use cases may occur in clinical settings, for example as a measurement is done on a patient in the hospital. It may alternatively be situated in research, as a large number of existing biosignal files are analysed, using different sets of analysis methods, in order to find the optimal setup for a given requirement. Similar use cases are described in more detail in [14]. In order to implement these use cases, IT systems are needed to address the requirements listed above.

The authors together with other experts discussed and developed a standards based draft IT architecture in a series of meetings in standards development organisations (SDOs):

- Interoperabilitätsforum der Österreichischen SDOs, Vienna, Austria, 17.1.2017
- At the HL7 Work Group Meeting San Antonio, USA, 16-20.1.2017:
  - HL7 Health Care Devices Work Group, including experts from the IHE Patient Care Devices Technical Work Group and from IEEE 11073 Standards Work Group
  - HL7 Imaging Integration Work Group

At these meetings, expert opinions on the following issues were collected and considered:

- Is there existing work that covers the requirements listed above (exchange protocols, nomenclatures, …)?
- Is there a working group that is currently developing standards or profiles for the requirements?
- Is there cooperation between SDOs to assure a consistent set of interoperability standards and profiles?
- Which existing working group seems best suited to define the specifications needed to address the requirements?
- When can results be expected, considering the workload and available resources?

The draft architecture was developed, incorporating the feedback from the discussions.

3. Results

3.1. Expert opinions on existing and emerging standards

The experts that were contacted in the workgroup meetings responded that there is no existing standard or profile that covers all the requirements from the biosignal use cases described in this work. There are however existing standards from HL7, the IEEE 11073 series, DICOM, and as well profiles from IHE that may be further developed. Many experts recommended especially the nomenclature and coding rules for medical device data, defined in the IEEE 11073 series of standards, as a valuable contribution.

Currently there are working groups within IEEE 11073, HL7, IHE and PCHA working towards standards for exchanging vital parameters (e.g. blood pressure and weight scale readings) in a strong effort. These working groups cooperate and most experts expect a set of consistent standards and profiles. Some work on biosignals has already started, also within DICOM. However, in the year 2017 no final results may be expected. Many experts suggested joining these existing efforts, with results not to be expected before the year 2018. Many provided feedback to the initial architecture that was presented to them.

3.2. Basic use case

Figure 1 shows the first steps of the simple case, where a device is able to store a biosignal in GDF format. Tools e.g. from the BioSig project [10] then export the structured header from the GDF file in JSON format.

Figure 2 shows the case where a device stores the biosignal in a file of another format, and the further processing steps. The BioSig project [10] provides converters for more than 100 file formats that enable to generate a GDF file. A FHIR resource, called Type A within this work, may then be defined that consumes the biosignal data as a GDF file and additionally the header information in JSON format, and stores it on a FHIR server. Alternatively, a FHIR resource of a Type B may be defined that consumes the same GDF file and JSON header as Type A, but stores the biosignal file in a DICOM Picture Archiving and Communication System (PACS) as a DICOM information object. The DICOM object generated by a Type B resource may include the GDF file as it was provided.

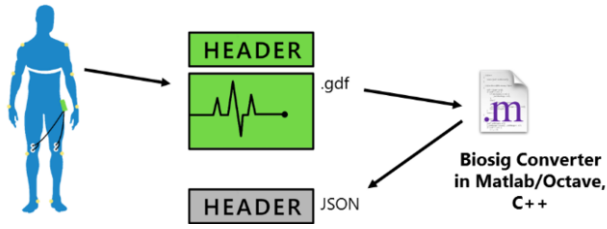

Figure 1: Data from biosignal measurement is stored in GDF format. The header information may then be exported in JSON format e.g. using tools from the BioSig project [10]

A third FHIR resource of a Type C may be defined that consumes the same GDF file and JSON header as Type A and B. However, it converts the incoming GDF file into a DICOM Waveform and stores it in the PACS. The expected advantage of this approach is that existing DICOM viewers may display the biosignal on the screen.

All FHIR Resources Type A, B and C may also read the archived files back, and provide them as a GDF file.

3.3. Advanced use case

In the discussion with the standardisation experts, it was suggested to define further types of FHIR resources that provide additional functions, which the advanced use case requires:

- Acquisition of biosignals
- Analysis of biosignals (filtering, integration, annotation, FFT, …)
- Presentation of raw and analysed biosignals and of the derived parameters
- Control of multiple FHIR resources to orchestrate the above FHIR resources within a multi-step protocol

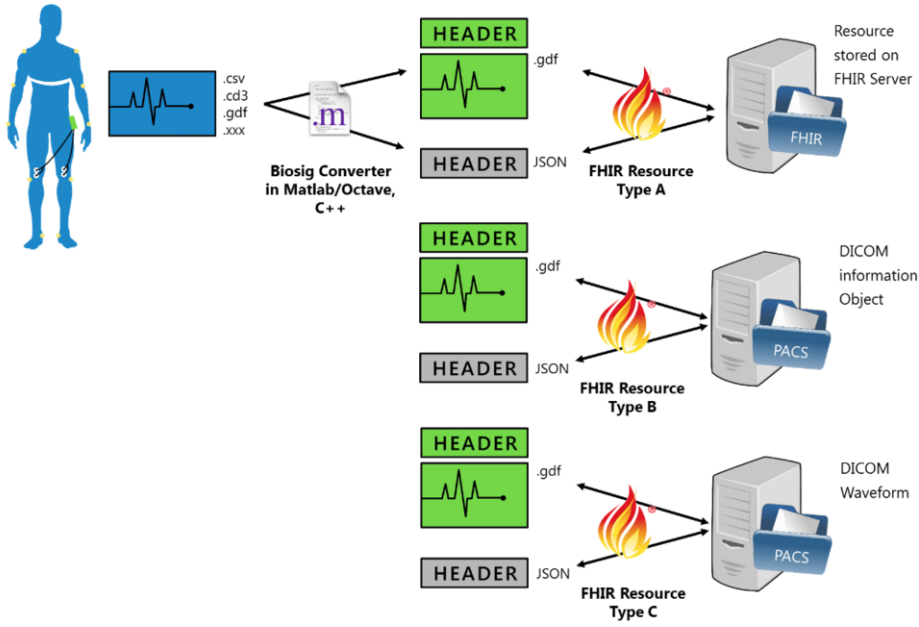

Figure 2: Proposal for standardized data transfer architecture using GDF, FHIR and DICOM

Many experts agreed that it may well be feasible to define and implement these use cases by defining and implementing additional FHIR resources. It was however noted that the available teams will be engaged within existing plans in the near future. Many experts reported that work on biosignal standards may likely start later in the year 2017, and that standards for the basic use cases may be expected over the year 2018. The experts also reported that work on the advanced use cases will only start when the basic use cases has provided first tangible results and implementations.

4. Discussion

In this work a draft standards based architecture for basic biosignal use cases was developed and discussed with standard experts in Austria and internationally. It was found that existing standards and profiles do not cover the requirements from the biosignal use cases. Working groups within IEEE 11073, HL7, DICOM, IHE and PCHA were identified that have great potential to successfully cover the requirements of the basic biosignal use cases described in this work.
DICOM experts suggested to convert biosignal data into DICOM waveforms, as described in the results, see Figure 2. This will enable users to use existing DICOM viewer tools to display the biosignals on the screen. On the other side, DICOM waveform only supports a single sampling rate for all channels. The storage size of DICOM waveforms may be substantially larger, e.g. if channels with different sampling rates are stored in the same file.

The discussions with experts revealed many open issues. For example there is strong evidence that binary biosignal file formats (e.g. GDF) are to be preferred to (semi)structured file formats like XML: Structured formats introduce substantial overhead and severely increase file size, which reduces efficiency and speed when storing and loading data to and from files. Although the authors conclude that binary formats are essential for biosignal raw data, this issue remains for discussion in the context of different use cases: Header information that is included in the biosignal file may for example be provided both in structured and in binary formats to enable registration of biosignals e.g. for fast and efficient search.

Further work will now engage with the existing standardisation efforts identified in this work. A first effort will address the basic use cases. In later phases, additional FHIR resources may then extend the architecture for advanced use cases like clinical protocols and experimental work.

Acknowledgment

This project (project-number 19-06) is funded by the City of Vienna Municipal department 23 “Economic Affairs, Labour and Statistics” within the program “Research at Viennese Universities of Applied Sciences”.

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