Common data elements for epilepsy mobile health systems

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Abstract

OBJECTIVE—Common data elements (CDE) are currently unavailable for mobile health (mHealth) in epilepsy devices and related applications. As a result, despite expansive growth of new digital service for people with epilepsy, information collected is often not interoperable or directly comparable. We aim to correct this problem through development of industry-wide standards for mHealth epilepsy data.

METHODS—Using a group of stakeholders from industry, academia and patient-advocacy organizations, we offer a consensus statement for the elements that may facilitate communication among different systems.

RESULTS—A consensus statement is presented for epilepsy mHealth CDE.

SIGNIFICANCE—While not exclusive, we believe that the use of a minimal common information denominator, specifically these CDEs, will promote innovation, accelerate scientific discovery, and enhance clinical usage across applications and devices in the epilepsy mHealth space. As a consequence, people with epilepsy will have greater flexibility and ultimately more powerful tools to improve their lives.

Keywords

common data elements; seizure diary; standards; epilepsy; mHealth; devices

1. Introduction

Epilepsy affects 1.2% of the US population[1], and as many as 1 in 3 people with epilepsy (PWE) have drug-resistant seizures[2]. Many PWE use mobile and online health (mHealth) solutions to monitor their disease. These mHealth applications take many forms, including alerting devices[3–6], therapy devices[7–9], and mobile self-management apps[10–14]. Unfortunately, as various mHealth solutions have arisen independently, they lack common standards. As a result, systems are often not interoperable, and PWE who use multiple tools or transition between tools are required to enter information for each tool separately and redundantly. In addition, organizations or companies developing a new device or app have often built a new mHealth solution in isolation, despite availability of existing and well-tested software packages. These tools have considerable overlap in terms of the types of information they record (e.g. time of seizure, duration of seizure, background demographics, etc.), yet there has not been any industry standard developed, so many differences exist between tools. Indeed, mHealth diary studies [12,15–23] suggest that standardization will help further facilitate data interpretation and clinical implementation. Given the potential advantages that patients, caregivers and researchers might receive when using mHealth solutions, the lack of standardization is no longer sustainable.

PWE and caregivers use mHealth tools in epilepsy for a number of reasons. One common reason is to facilitate communication with clinicians. In the case of PWE who have frequent seizures, graphical summaries are much more helpful than paper and pencil seizure diaries. Another common situation applies to PWE who have some degree of memory impairment, and remembering to bring a mobile device (e.g. cellphone) is much easier than remembering to bring a paper calendar to clinic. Knowing how many seizures patients have and when they occur is the cornerstone of determining if a therapy (drug, device, diet, etc.) is effective; therefore, this information is of vital importance to the treating physician. Some mHealth devices are designed to detect seizures, which can improve the accuracy of seizure diaries. Other mHealth devices include a therapy (such as the RNS System from Neuropace) delivered in response to recorded data. An important use for mHealth systems is to empower PWE and their caregivers with knowledge of seizure patterns, such as time of day when seizures are more likely[24], which could lead to more tailored treatment options. It is likely that all of these uses could be enhanced if the various mHealth tools were able to import/export common data between them, because many synergies are possible.

Currently, no common data elements (CDEs) exist between mHealth tools for epilepsy. This can lead to inefficiencies for PWE in several situations. First, transitioning from one tool to another currently requires all data to be re-entered in the new tool. Also, there is no easy way to maintain multiple diary tools simultaneously without excessive redundant entries. Moreover, lack of CDEs precludes interoperability between tools with different niche capabilities (e.g. seizure detector devices and independent online diary systems).

Lack of CDEs also creates a financial inefficiency for industry. For example, devices designed to record, detect and/or treat seizures in a non-hospital setting all require some kind of seizure diary interface to collect patient-reported data. Unfortunately, each device manufacturer currently must re-invent a seizure diary or data collection system that connects

with their specific device. All the expertise, patient and caregiver input and dedicated software development time that went into the current generation of widely used seizure diary systems would need to be replicated before a refined product could be delivered with the new device. Clearly, industry inefficiencies will add up in a market that now has multiple seizure devices either already approved or in the development process.

We endeavored to fill the gap in epilepsy mHealth data standards in order to improve the situation of PWE, clinicians, academics and members of industry.

2. Methods

A consortium of key stakeholders in industry, patient advocacy groups, and clinician scientists was formed in 2016. This consortium met on December 5, 2016 at the Annual Meeting for the American Epilepsy Society, and discussed strategies for moving forward with a set of CDEs for epilepsy mobile health solutions (see Table 1 for definitions). Feedback from the initial meeting and subsequent communication with additional stakeholders over the following year was developed into the final document. The goal of this document was to develop a common language that mHealth tools would communicate with on the "back-end," creating inter-operable solutions, without limiting innovation in user-interface elements or fundamental technology.

The working document was sent to authors and stakeholders of the Seizure Diary Group multiple times during 2017 for feedback including edits for deletions, additions, and revisions. Consensus was determined to be reached when all of the Seizure Diary Group agreed on the CDEs.

3. Results

3.1. Basic terminology

The group agreed by consensus that an a priori determination of the "front-end" user interface was not within the scope of this project. The CDEs described here were chosen only as common descriptors of data collected and recorded by the devices and apps in the "back-end" of the software. Developers should have the freedom and flexibility to develop their own user interfaces. We are concerned with how these applications and devices communicate with each other, rather than how they communicate with PWE and care providers.

Some basic definitions of terminology, including "mHealth epilepsy tool", "CDE" and "CDE Compliant", are offered in table 1. Of note, to achieve "CDE compliant" status, a tool is not required to present all the CDEs in the user interface. Rather, it must be capable of import, export and "pass through" (meaning that unused CDEs will be unchanged if imported and then exported from any given tool).

3.2. File Format

The group recommended JSON as the preferred file format for import and export, as this format allows maximal portability of data across operating systems and programming

environments. Moreover, the specific digital names of elements are specified in the Appendix; this requirement simplifies the communication between tools.

3.3. Common Data Elements

The overall structure of the CDE is divided into two broad sets: "frequent" and "less frequent" inserts/updates, along with categories of elements within each set (Table 2). The meaning of these broad sets is loosely defined. It is expected that PWE and/or caregivers will enter the "less frequent" type information perhaps once or infrequently, though this may not always be the case. An example of such data might be demographic information. The "more frequent" set represents information expected to be added multiple times, such as records about individual seizures.

The complete specification of the standard is provided in the Appendix, while Table 2 provides a summary format of the CDE standard. In addition, individual elements independently labelled either "Essential", "Recommended" or "Optional":

1.   Essential: These are determined by consensus to be essential ingredients of any epilepsy mHealth solution. Examples of "Essential" CDE includes things like gender and seizure type.

2.   Recommended: Additional CDEs determined to be very helpful, but not always useful, depending on the purpose of individual tools. The Seizure Diary Group encourages mHealth elements listed in the "Recommended" category to be included when relevant and if appropriate to the tool.

3.   Optional: These elements include items that are sometimes helpful in certain specific use cases. For example, devices that use reflected light from the skin (such as photoplethysmography or near infrared spectroscopy) may record Fitzpatrick skin type. This final category is not expected to be used from all tools, however, all tools should be able to share the contents of these elements in the back-end via the common elements.

3.4. Additional technical considerations

There are several technical considerations for the CDEs. Some CDEs were considered important but may be protected health information (PHI), such as patient name. Whenever PHI is involved, we recommend using encryption to prevent the PHI from being released. Thus, for example, if the patient's name is included in a data export to a new tool, the new tool would not "know" the patient's name without possession of the decryption technique and password. Elements that involve PHI are specially marked on in the Appendix as "encoded". By encoding this data, the PHI can be transported from one tool to another, but privacy can be maintained.

In addition, seizure "nicknames" could be used internally by individual seizure diary systems, but these "nicknames" should be translated for communication between apps/devices whenever possible into clinically diagnosed seizure types. It is easy to imagine that a software tool might want to simplify data entry for users and help them define such "nicknames" for their 4–5 most common seizure types. The canonical definition of each

nickname is not required in this CDE standard, and would not need to be transported from one tool to another. Since the emphasis of this endeavor is on data of actual reported events, relevant details for each recorded seizure must be included in data exports. Nevertheless, nickname information can optionally be included, along with the standard seizure type information.

One of the CDE items is "history of status epilepticus." For the purposes of this document, an operational definition of status based on the recent ILAE recommendation was adopted[25]. One seizure (or a group of seizures) would be defined as status if: (1) the active part of a tonic-clonic seizure lasts 5 minutes or longer, or (2) a person has a second seizure without recovering consciousness after the first one, or (3) a person has repeated seizures for 30 minutes or longer.

Labelling seizure type is another challenging consideration. A recent recommendation from the ILAE[26,27] describes a framework for classifying seizure types that could decrease confusion and increase uniformity in reporting. Unfortunately, these are not yet in widespread use and are not known to many patients or their physicians. As a group of patient advocates, physicians, clinical investigators, and industry leaders, we are in an unusual position with regard to the ILAE recommendation. Some of the developers already have substantial databases of seizures recorded in the nomenclature that predates the 2017 ILAE framework. Moreover, it is believed that at least some members of the clinical and patient community have not yet accepted the new ILAE nomenclature. The preferred solution is to allow front-end user selections to use any terminology at the discretion of developers, but recommend that all tools map names for seizure types into the common 2017 ILAE seizure classification in the back-end. We elected to use the 2017 classification both because of the ILAE endorsement, but also because the nomenclature fully encompasses the more common terminology, so it is flexible enough to support translation from other systems to it. To accommodate multiple nomenclature approaches and simplify mapping, a translation table in the Appendix may allow developers to use whichever framework they feel appropriate within their own software, while using the ILAE 2017 nomenclature for the implementation of CDEs. The effort will accommodate both past and future practice, while the epilepsy community works toward one standard set of terminology that is widely adopted.

4. Discussion

Implementing these CDEs will empower patients, care providers, clinicians and researchers. Patients will gain the ability to import and export records from one tool to another, allowing greater flexibility in choosing the best tool for their needs. Developers will have the opportunity to connect diverse applications and/or devices in novel combinations. For example, a seizure detector device could automatically populate one of several cloud-based diary systems, or perhaps several independent seizure detection devices could combine their detections in new ways. Furthermore, data from multiple platforms could be integrated for large-scale analyses, which could help bring new insights about seizure patterns. The end product offers a minimal set of CDEs for epilepsy mHealth tools as well as additional elements to consider depending on purpose and design. Tools may include more elements than those proposed, without risking non-compliance with the standard.

4.1. An evolving standard

It is worthwhile to point out that the rapidly evolving nature of mHealth requires that a CDE framework be flexible enough to accommodate new changes in technology, scientific understanding, and communities. To that end, we have posted the "live" version of the current mHealth in epilepsy CDE on the International Seizure Diary Consortium website. In this way, if the stakeholders find it valuable to update the elements, there will be a low latency between the change and the ability for developers to become aware of them. The website is https://sites.google.com/site/isdchome/home/cde.

The developers included in this consensus document have agreed to implement these CDE standards in their future deployment of mHealth products for epilepsy, specifically for the import and export feature. There will be continuity of partners in the ongoing development of these standards, because all the developers in this community have a vested interest in the successful implementation of these CDE. This implementation alone can have dramatic effects for patients, industry and academia. Moreover, as the field of epilepsy mHealth advances, the field is expected to grow in terms of new technologies, new startups, and new academic partnerships. The International Seizure Diary Consortium will continue to provide a common framework for these various entities to connect to standardized CDE in order to provide maximum benefit to patients, but also to allow flexibility in the standard as new developments arise in epilepsy.

4.2. Conclusions

The CDEs for epilepsy mHealth presented in this consensus document represents a first step towards a collaborative approach to improving the utility and value of patient-entered data in communications, health care delivery systems, and clinical research in epilepsy. By providing a common language for mHealth apps and devices in epilepsy, the door is opened to inter-operability, synergy of tools, accelerated scientific discovery and streamlined clinical management.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Key points

1. Common data elements (CDEs) for mHealth in epilepsy are urgently needed.

2. We formed a wide collaboration across industry, academia, and patient-advocacy to build a consensus on CDEs.

3. Use of these CDEs will facilitate software interoperability, accelerate research and enhance clinical usage.

Table 1

Definition of terms.

mHealth epilepsy tool	Any digital hardware or software (e.g. via the internet, mobile device, wearable, or desktop platforms) capable of collecting, tracking, or sharing data, while interacting with patients about their epilepsy health information
Common Data Element (CDE)	Category of information that is common across multiple tools, using a shared definition of data headings, data format and possible values the data can take.
CDE Compliant	An mHealth tool that can import and export all portions of the common data elements (see Appendix). Of note, the tool itself need not necessarily generate every kind of CDE item, but must be capable of import and export of each element, including the ability to "pass through" elements from import to export regardless of if the tool itself does uses any given element.

Table 2

Overall structure of the common data elements. More detail is provided in the Appendix.

Frequency	Category
Less Frequent Inserts /Updates	Demographics
	Social history
	Other history
	Review of systems
	Seizure history
	Medication side effects
	Past seizure medications
	Diet as treatment
	Mood
	Social Support
Frequent Inserts/Updates	Medication use
	Non-seizure medications
	Supplements/Vitamins
	Rescue medications/therapies
	VNS magnet swipes
	Seizure event