Electronic Protocol for Systematic Data Collection of Burn Patients: A Proposal to Standardize Burn Patient Data

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ABSTRACT

OBJECTIVES: **Burn patients usually present with a long medical history and require a prolonged management that makes the process of collecting and storing information complex and confusing. Electronic health records have been deployed to replace or supplement existing paper-based records and can improve the quality of health care. A system that completely addresses the needs of patient care providers and researchers probably does not exist, and this integration would reduce redundant data collection. Here, we share our experiences with a customizable and standardized electronic protocol with the ability to systematize, store, and analyze relevant information from burn patients that can be used worldwide since it contains a universal codification and can be easily adapted to any specific requirement by the user or legal/regulatory authorities.**

MATERIALS AND METHODS: **The database was developed based on medical literature searches on burn injuries. A web platform was designed using Microsoft.NET framework technology with C# and MVC programming languages. The data collection items were selected and grouped into 2 main categories that contained 7 subcategories each, with a unique code assigned to each customizable item for universal comparability in the collection, processing, categorization, and presentation of the data. An SQL server stored data to ensure encryption, protection, and invulnerability.**

RESULTS: **The system recognized the user by identifying a predefined security authorization and allowed the creation, storage, organization, combination/aggregation, analyses, exportation, and editing of collected information. The protocol has been successfully verified in a medical institution by the Benaim Burn Foundation.**

CONCLUSIONS: **A new validated electronic database protocol focusing on burn patients was successfully created, resulting in a substantial improvement of medical record standardization. This system has laid a solid foundation for future data mining, medical records sharing, and academic purposes.**

KEY WORDS: ***Burn injuries, Data management, Data standardization, Health information systems***

INTRODUCTION

The use of digital technologies is changing the health industry by facilitating efficient and effective health care delivery.[1] However, the concept of big data has been progressively affecting the industry because of the massive amounts of data that can be collected and the need to find the best strategies to use the information. Managing, storing, and extracting such unstructured and heterogeneous data are challenging issues because each source has a different schema and format. The appropriate use of big data analytics in health care can have many positive and life-saving outcomes.[2] Electronic health records have been deployed to largely replace or supplement existing paper-based records and have the potential to improve the quality of health care by offering a huge advantage of collecting and maintaining the patient's medical information in electronic formats, offering quick and easy access to information, the ability to monitor patients for better care, and the ability to establish decision-support mechanisms to reduce medical errors.[3]

Despite recommendations and guidelines from expert groups, no universally accepted standardized protocol

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currently exists for the acquisition, documentation, and evaluation of clinical data in burn patients.[4-6] In health care, standardization is a process for transforming data into a format that can be processed, understood, and compared across different systems, registries, and countries, and it helps to ensure the validity and reliability of clinical data. Through standard settings, a required service or outcome can be stated; standards can also be used to define the knowledge, skills, attitudes, and resources necessary for achieving a certain level of care and to identify the learning outcomes required to treat patients in a proper manner. Thereby, standard setting constitutes a crucial strategy for improving quality, strengthening the health systems, and enhancing patient outcomes.[7,8]

Burn patients are challenging as they usually present with a long medical history and require prolonged management, which makes the process of collecting and storing information complex and confusing. Severely burned patients usually experience systemic and local complications; burn injuries are dynamic and evolve over time, and the same patient can present multiple and different injuries with varying depths, each requiring a different treatment. The clinical judgment of the burn specialist is currently the standard on which diagnostic and therapeutic decision-making is based. Physicians spend most of their time providing direct care to patients, and the provision of care requires the documentation of clinical information as an intrinsic aspect of routine clinical activity and is essential from both professional and legal standpoints.[9,10]

Valid and reliable clinical data are essential for monitoring the course of patients. An ideal health data system would integrate itself within the patient care environment, and its use would become routine in the patient care process. In the burn field, a system that completely addresses the needs of both patient care providers and researchers probably does not exist, and this integration would reduce redundant data collection. For this reason, we share our experience using a customizable and standardized electronic protocol with the ability to systematize, store, and analyze relevant information from burn patients that can be used worldwide since it contains a universal codification and can be easily adapted to any specific requirement set by the user or legal/regulatory authorities.

MATERIALS AND METHODS

The development team consisted of programmer analysts (ElemSoft Desarrollos, Ushuaia, Argentina) and expected users. Ethical approval to construct and implement the system was obtained from the corresponding ethics committee. The patients and/or patients' legal guardians or representatives consented to their data being entered into the system during the testing period.

As a first step, extensive literature research was conducted taking in consideration Dr. Benaim and Dr. Haberal's experience in the field of burns (over 70 and 50 years dedicated to burns, respectively) to obtain consensus on registry objectives and data sets. Standard definitions and established instruments were used whenever possible to enable the registry data to be cross-referenced to other studies and to minimize the data collection burden.[4-6,11-27]

After the data elements were selected, the data map was created. The data collection items (Table 1) were grouped into 2 main categories: the fixed or permanent data are data that are entered once and not, under normal circumstances, subject to change; the dynamic data need continual updating according to the patient's health status progression (Table 2). Specific and unique alphabetic and alphanumeric codes were assigned to each data item and item group for universal comparability in the collection, processing, categorization, and presentation of the data (Table 3).

A web platform was designed rather than a local clinic model, which removed the need for local clinic infrastructure and enhanced data access and sharing at different levels since the server and data are hosted centrally and not by the individual clinic. To establish the web platform, the scientific database was digitized, the screen layout was developed (Figure 1), a software product was used to connect the database management system to the web site, the internet address and the domain name for the web site were obtained, and security measures were applied to ensure encryption, protection, invulnerability, and monitoring of the system users, with data stored in a Microsoft SQL server. To prevent data loss, 2 copies of backup of the

TABLE 1. Data Collection Items

Item	Code
Demographics	P
Event	S
Transfer	Tras
Comorbidities	O
Physical examination at admission	Pac
Injury	L
Status at discharge	Eg
Referrals	D
Reports	I
Discharge summary	Ep
Progress Note	Ev
Treatments	Tr
Complications	C
Laboratories and imaging	Ex

TABLE 2. Grouped Data Collection Items

Item	Code
Fixed data	
Demographics	P
Event	S
Transfer	Tras
Comorbidities	O
Physical examination at admission	Pac
Injury details	L
Status at discharge	Eg
Referrals	D
Reports	Inf
Discharge summary	Ep
Variable data	
Laboratories and imaging	Ex
Treatment Local treatment Surgical treatment General treatment Other treatments Rehabilitation	Tr Tr.5 Tr.6 Tr.7 Tr.8 Tr.9
Complications Local General	Co.10 Co.10.1 Co.10.2
Injury progression Local General	Ev.11 Ev.11.1 Ev.11.2

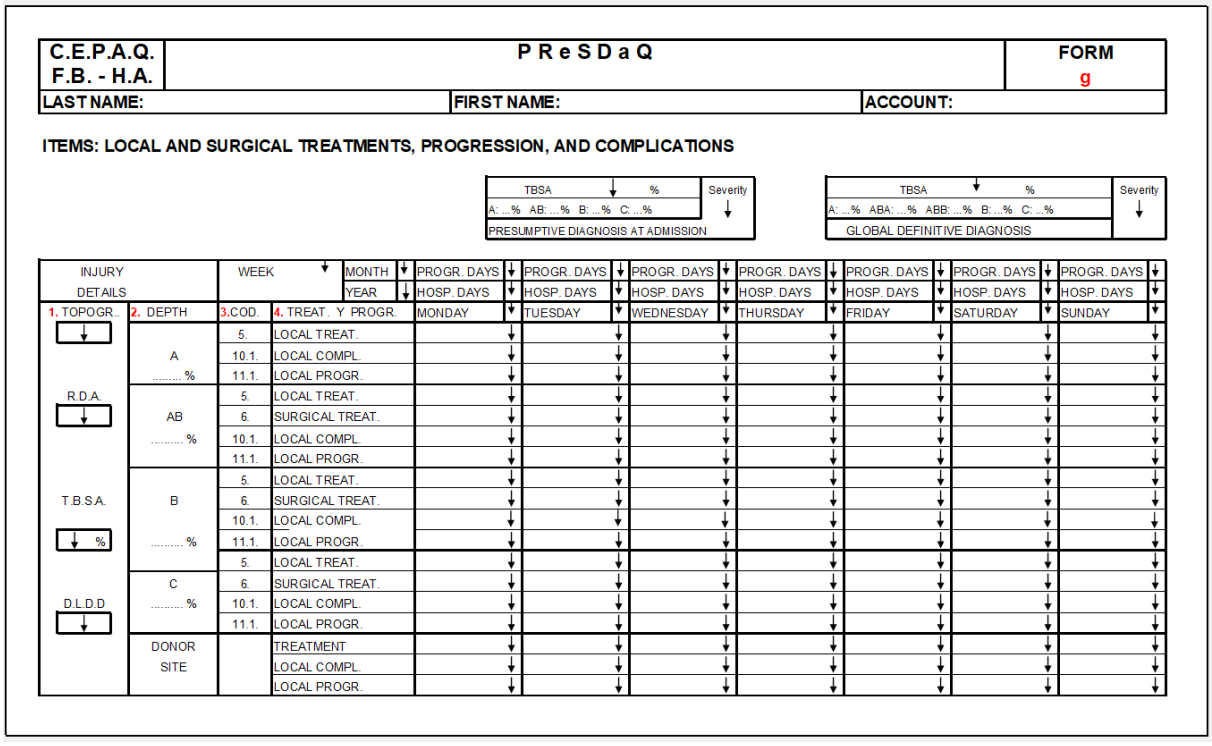
TABLE 3. Encoding of Data Item

Group	Code	Variable	Code
Treatment	Tr	Local	Tr.5
		Surgical	Tr.6
		General	Tr.7
		Others	Tr.8
		Rehabilitation	Tr.9

database are automatically created once a week. Microsoft. NET technology with C# and MVC programming languages were used. The system provides flexibility for future expansion, customization, and/or inclusion of additional data.

There are 2 user groups: the admin group, who can manage users, configure roles, and configure system-wide settings; and the regular user group. The data were organized in 8 sections using web-form (form-like web pages) style tabs; some sections were further divided into subsections (Figure 2). The menu bar at the top of the window provides the user with a place to find most of the program's essential functions (home screen, encodings, data export security settings, help, users manual). The field was defined by various field properties (field label, required field, note box for a large amount of text). There are multiple choices for data input: using the drop-down with predefined options, the yes/no toggle switch, and free-text input. Each field

FIGURE 1. Screen Layout Design



contains automatic data validation to warn the user if there are mistypes or meaningless data.

The system allows users to enter as many details as they wish related to the event and medical history (Figure 3); it calculates the time interval from injury date to important details related to first aid, first medical evaluation, hospitalization in a general hospital, and evaluation and/or admission to a burn center. Each injured area must be registered individually along with the details (etiology, topography, presumptive regional diagnosis at admission, total body surface area, and burn depth), and all of the information entered is listed in a table. For burn depth and severity, the system uses the Benaim classification.[25] This classification has been used in many Latin American countries for over 60 years, and it is directed to obtain a more accurate and comprehensive diagnosis ("presumptive diagnosis" for the admitting diagnosis and "definitive diagnosis" or discharge diagnosis). This classification can precisely identify the type of burns, with use of letters instead of numbers, and types instead of degrees, helping to avoid confusion compared with the degree classification. The global diagnosis allows complete information on extensions and depths of each case, whereas the regional severity according to depth and localization is also designated into 5 groups, depending on the localization, depth, and the possibility of sequelae of the injury.[25]

Every injury that has been recorded will allow the user to enter the treatment for each. It is shown on a weekly generated spreadsheet and divided into surgical and nonsurgical care according to the depth of injury. The

FIGURE 2. Tab Style Organization of Grouped Data (Indicated by Arrow)

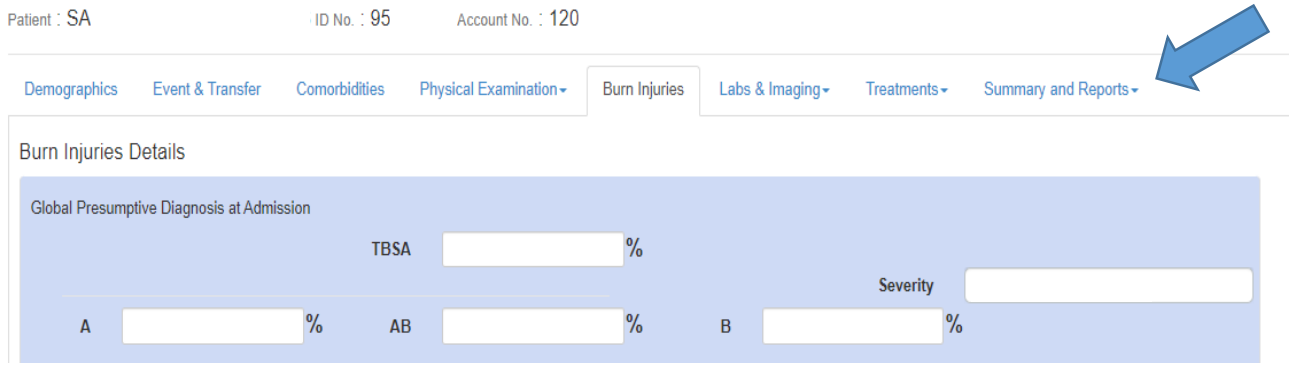


FIGURE 3. Entering Data Using the Drop-Down List Modality

spreadsheet includes a cell (one per day) with predefined options for the injury progression and complication. It also shows the time interval from injury date and the length of stay. Laboratory results, complementary treatment, and nutritional requirement forms were similarly designed.

The data export tool allows users with appropriate access permission to export data in Microsoft Excel format for all or selected fields.

Pilot tests were conducted by the Benaim Burn Foundation to determine the time needed to complete the form, the resulting subject/abstractor burden, and the rate of missing data and any validity issues with the data collection system. ElemSoft Desarrollos (Ushuaia, Argentina) offered web-based training and telephone support to users in need.

RESULTS

The protocol has been successfully verified in a medical institution by the Benaim Burn Foundation, and users expressed trust in the experts who created the system. Our system's dual functionality meets the patient care management needs of the physician and the data management needs of the clinical researcher. The system recognizes the user by identifying a predefined security authorization and allows the creation, storage, organization, combination, aggregation, analyses, exportation, and editing of the collected information. Most users found the system easy to log on, navigate, and accomplish the tasks required. All connection attempts to the server were logged and audited. During and after the pilot tests, feedback from users was sought, and the collected information was used to further improve the system to reach better usability. Overall, the protocol was proven to be user friendly.

DISCUSSION

The need for developing tools to make such human-machine interactions more human-like has grown significantly in recent years, and it is taking part in everyday processes. Web-based systems for data collection offer a range of benefits. In general, electronic data collection systems are not under the control of regulated entities; in most instances, these systems belong to health care providers, health care organizations, and health care institutions. However, the digitization of clinical and real-world data comes with regulatory, ethical, and data privacy challenges.[28] To minimize the risks and maximize the benefits of data digitization, those with interests in burns need to actively participate in the development of digital solutions for the routine care of patients.

Our model proposes a new vision of data collection and standardization. In our experience, this tool has significantly facilitated several issues surrounding the handling of data. Studies on well-designed and well-performed databases can provide a real-world view and can provide evidence on development and decision-making purposes.[28] Another benefit of this system is the automatic data monitoring; those defined as required fields must contain valid and complete information, which decreases the amount of human error and thus improves trial validity.

There is a need for effective education and training programs, especially in low- and middle-income countries; this need has been recognized by the International Society for Burn Injuries and the World Health Organization. There is also a need for e-learning modules, on-the-job training, and IT courses in undergraduate education curricula to enhance future health care professionals' readiness to use software platforms containing health-related information effectively. Most of the existing training and educational programs have been developed by and for high-income countries, so that they possess limited relevance and applicability in low- and middle-income countries, although burns can happen anywhere and at any time to any one. Unfortunately, burn injuries are a huge but preventable cause of morbidity and mortality in these countries, especially among the younger population.[29,30]

Standardization and digitization are essential to ensure the validity and reliability of clinical data to facilitate the comparison of data within 1 center over time or between different centers and health care professionals.[7,8] We found many depth classifications of burns in the literature, most of them using the word "degree" and numbers, and sometimes the same degree and number can mean different depths according to each classification. To avoid confusion, we decided to use the Benaim classification for a more precise identification of types of burns, giving the possibility to study separately each group and to obtain more specific scientific information.[25] Standards represent a crucial step in improving the quality of care and education, but cost can be a major factor when considering the incorporation of new or advanced technology. The burden of form collection is a major factor determining a registry's success or failure, and persuading health care workers to adhere to collect and register the data is very important.[7-10,31]

One of our primary goals was to reduce the effort required by physicians to enter data. Data integrity is another important factor to take into consideration when implementing electronic systems that contain sensitive data. Previous studies have described access-related security through login name/password as the most appropriate way to guard against unauthorized access and have suggested frequent password changes, setting a minimum number of letters, and prohibiting the reuse of passwords.[32,33] Unexpected system-related adverse events is a concern in

some institutions.[34] For this reason, our system has back-up policies destined to address system failure, including duplication of critical clinical data and implementation of comprehensive testing and monitoring strategies; we also recommend the use of generator-supported electronic systems.

Based on our time constraint and broad scope of our project, there is still work to be done to improve the system. One of the main limitations is that, in addition to an electronic device availability, internet connectivity is equally important; this could be a problem in places where the levels of technology, staff, and other resources are very different since all users need to have some connectivity to the server in order to access. If available, the speed of the internet connection can also be a limiting factor; a slow internet connection can be very frustrating for users. There is also an inherent dependency on the features and functions supported by the popular web browsers. Usability assessment resulted in a complex task, and we only used 1 method, which may not be comprehensive enough to thoroughly consider all relevant issues associated with the system. However, performing a complex usability study can be a very expensive process and not always applicable. Despite the limitations, we consider this proposal as a stepping-stone or foundation with the potential to improve data management and produce high-quality research and patient care in the field of burns.

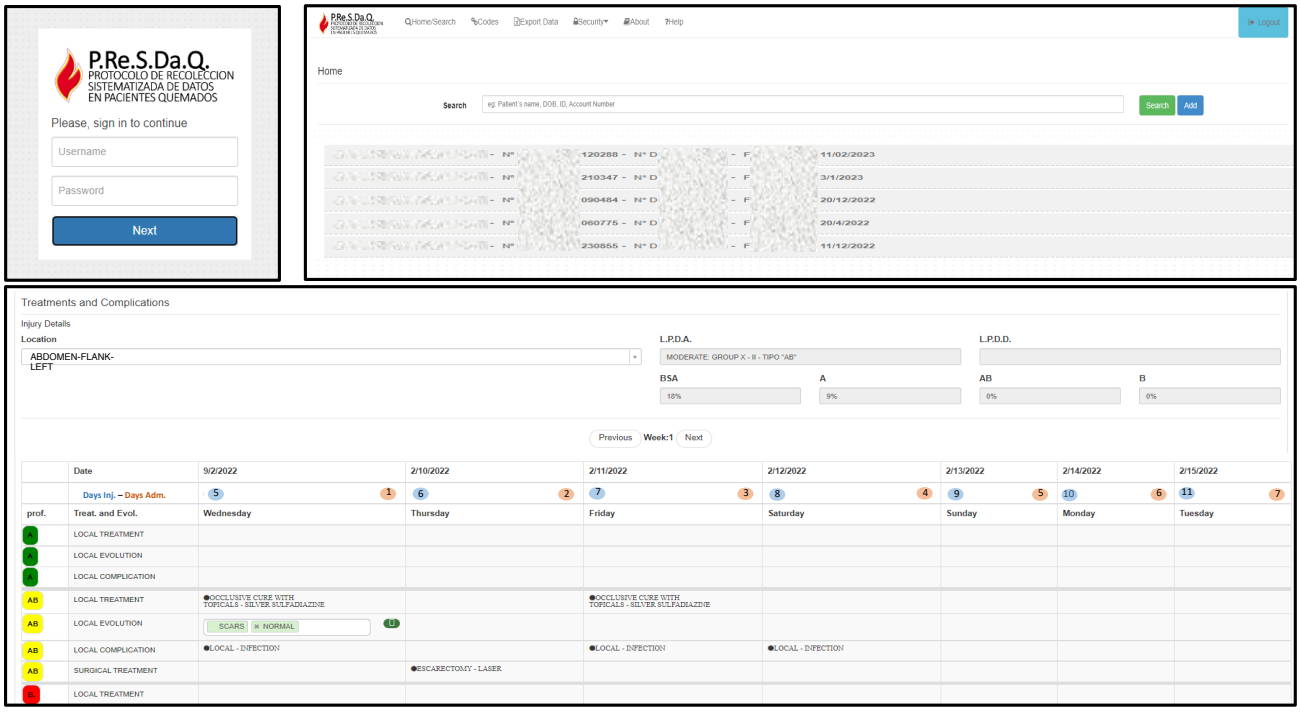
CONCLUSIONS

Our electronic data collection system allowed the collection, storage, and management of research data electronically in a secure central repository (Figure 4). The use of data standards will have a positive impact on continuity of care, quality of care, and population monitoring and will enable future opportunities for sharing or comparing data across registries for global research.

This tool significantly reduced research-related time, effort, and costs, allowing researchers time to focus on data analysis and their research activities. It can be used worldwide since it contains a universal codification that can be easily adapted to any specific requirement by the user or legal/regulatory authorities. We invite colleagues from all around the world, patients, and all those interested in burns to use the system.

With the consideration of burns as a global public health problem, we reemphasized the value of developing harmonized and semantically consistent standards developed through a recognized standards development process and based on good clinical practices, consensus, guidelines, and

FIGURE 4. Screenshot Showing Some of the Features of the System



(a) Login screen. **(b)** Home screen and patient search attributes. **(c)** Spreadsheet view of treatment, injury progression, and complications.

local and international regulations. We suggest academia, regulatory authorities, burn societies, and industry to work together at a global level to also redefine the regulatory framework in order to optimize patient safety and privacy without stifling innovation.

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