

Using electronic data capture for cardiovascular electrophysiology invasive procedures: An important step towards interoperable clinical registries

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Article Info	ABSTRACT
Article type: <i>Research</i>	Introduction: The capture and integration of structured data from point of care into clinical registries has been a challenge. However, this effort is very important toward a qualitative patient care and research. Collection, organization and interpretation of clinical data can help to improve evidence-based medicine practices. Worksheets data capture are prevalent, but, not flexible, protected, workflow pleasant, and user friendly and do not support the creation of standardized and interoperable data. The aim of this study was to design and implement an electronic data capture (EDC) instrument to be use in context of cardiovascular electrophysiology invasive procedures.
Article History: <i>Received: 2020-08-27</i> <i>Accepted: 2020-10-13</i> <i>Published: 2020-10-21</i>	
* Corresponding author: <i>Hadi Kazemi-Arpanahi</i> <i>Assistant Professor, Department of Health Information Technology, Abadan faculty of Medical Sciences, Abadan, Iran</i> <i>Email: H.kazemi@abadanums.ac.ir</i>	Material and Methods: This descriptive and developmental study conducted in three phases as follows. 1) data standardization according national and international data element templates published by specialized societies; 2) developing of an initial data collection and clinical research workflow 3), establishing of electronic case reports using Research Electronic Data Capture (REDCap) in accordance with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule.
Keywords: <i>Electronic Data Capture</i> <i>EDC</i> <i>Clinical Registry</i> <i>Electrophysiology</i> <i>REDCap</i>	Results: Three case report forms was developed that included demographics, medical history, physical examination, laboratory tests, imaging procedures, electrophysiology (EP) procedures, as well as medications and follow-up information. Data-entry validation criteria have been implementing in electronic data collection instrument to assure validity and precision when data enter in electronic form.
	Conclusion: This paper describes the process used to create an EDC application. Data collection applications were successfully develop as an a priori step in a clinical research for assisting data collection and management in a case of cardiovascular EP invasive procedures.

Cite this paper as:

Shanbehzadeh M, Kazemi-Arpanahi H, Bostan H, Nopour R. Using Electronic Data Capture for Cardiovascular Electrophysiology Invasive Procedures: An Important Step Towards Interoperable Clinical Registries. *Front Health Inform.* 2020; 9: 48. DOI: [10.30699/fhi.v9i1.236](https://doi.org/10.30699/fhi.v9i1.236)

INTRODUCTION

Quality of medical researches is fully dependent on accuracy and reliability of collected data. Data integration in to clinical research systems in proper way can be a considerable challenge. Clinical research often poorly integrated with clinical care practice and it resulting in redundant repetition of work and limits learning from clinical practice [1, 2].

One important step in medical research is accurate and reliable collection of data to ensure valid results. The validity and reliability of any research project depends on accuracy of collected data [3, 4]. Manual Data entry in clinical registry can be a time consuming, resources intensive and possible error prone process. Furthermore, design a data management solution is often a significantly

challenge [5].

As a special kind of clinical research systems, clinical registries have been consideration in this study. Investigations conducted based on high quality clinical registries can present an actual assessment of clinical practice, difference in treatment and consequences, describe patterns of care, and examine factors that influence prognosis and quality of life [6, 7]. Irrespective of its huge potential for both biomedical research as well as the potential to affect clinical practice and healthcare strategies, clinical registries frequently bounded by process problems that significantly lessening their importance [8, 9]. These include missing data and poor data quality, which related to how the research component of the registry aligned with clinical workflow and how personnel involved in the data collection trained [10, 11].

Lack of coordination between the clinical and research workflows is time consuming for clinical staff, healthcare policy maker and researcher. In addition, many hospitals and healthcare facilities that participate in studies, present different data capture systems for both healthcare and research settings resulting in island performance, effort duplication, and ultimately leading to data inconsistency [12-14].

To improve the quality of data in clinical registry and decrease the percentage of errors, healthcare organizations should follow certain structured measures to decrease inaccurate and incomplete data [15-17]. Therefore, in order to alignment the clinical data collection with the medical researches, EDC software is required to improve the efficiency and quality of data. It is a way to enter data from point of care electronically, instead use of traditional paper forms [18, 19].

REDCap software (<https://projectredcap.org>), is widely available under an authorization provided by Vanderbilt University [20, 21]. This software meets the requirements of HIPAA [22]. In addition, export data for analysis and reporting is compatible with several statistical packages, and easy to use are some features of REDCap software [23]. Besides, REDCap data validation measures can prevent data entry errors and non-integration through define standard data format and content normal ranges [24]. REDCap also supports detailed user permission controls so that study personnel can be limited in how they interact with the data [25]. For statistical analyses, data stored in REDCap can export into a variety of statistical software formats. This feature improved the study team's efficiency when automatic data entering into Statistical Package for the Social Sciences (SPSS) by independence to error-prone manual data entry [26].

As increasing data quality is a remaining concern in

healthcare researches and accurate, structured and automatic data entry process is essential for carrying out high-quality research; hence the aim of this study is to design an instrument that can serve as a convenient and reliable tool in data collection, storage, management, and interpretation to facilitate clinical research. We sought to implement a web-based EDC system for routine clinical care, using structured data entry to improve the ease of clinical documentation, and simultaneously establish a population based EPS database to facilitate outcomes reporting.

MATERIAL AND METHODS

In this study, we are creating EDC template to gathering and analysis data of cardiovascular invasive EP procedures (pacemaker, Implantable Cardioverter-Defibrillator (ICD), and catheter ablation). Patients who are undergoing cardiovascular invasive EP procedures are qualified to be included in this registry. To create these instruments, the following steps were undertaken:

Data element standardization

The first task was determining key clinical data element through standard, available, and approved national or international data element templates. To begin, in cooperate with two cardiologists the data dictionaries of the National Cardiovascular Data Registry (NCDR) and Adult Cardiac Surgery Registry (ACRF) examined. Then methodically studied all of the current existing cardiovascular data dictionaries and standards documents published by specialized societies such as the American Heart Association (AHA), American College of Cardiology (ACC), NCDR and the Iranian cardiovascular registries [27, 28].

Development data collection and research workflows

At first based on consulting with cardiologist and other employees, data flow and collection intervals in EP department extracted. For this ends, the registry forms designed based on standard categories for each cardiovascular invasive intervention in EP department. Data elements were grouping into nine demographics, medical history, physical examination, laboratory tests, imaging procedures, EP procedures, medical / surgical procedures, medications and follow-up categories. This categories indicate clinical context in which the data elements is expected to be obtained or collected and reflect the usual workflow organization of information in typical clinical settings for single episode of care. Three data capture case report forms where designed and implemented on the REDCap platform to allow the management of data for clinical registries of cardiac invasive EP procedures.

RESULTS

EDC forms structuring

Each data capture form developed in this study consists of demographic characteristics, medical history, physical examinations, laboratory tests, radiology examinations, EP procedures, medications administered before- during- and after procedure, procedure complications, and follow-up information. The data collection process is done in four time

interval including during admission, preoperative, intraoperative and discharge. We observed the changing state of their diseases in one, six, 12 month and then annually after admission (Fig 1). We created a large, prospective, non-interventional database in the registry to collect data describing the management and outcomes of patients who underwent evaluation, intraoperative, discharge from hospital. Then type of data that need to capture in clinical practice and research were determined (Table 1).

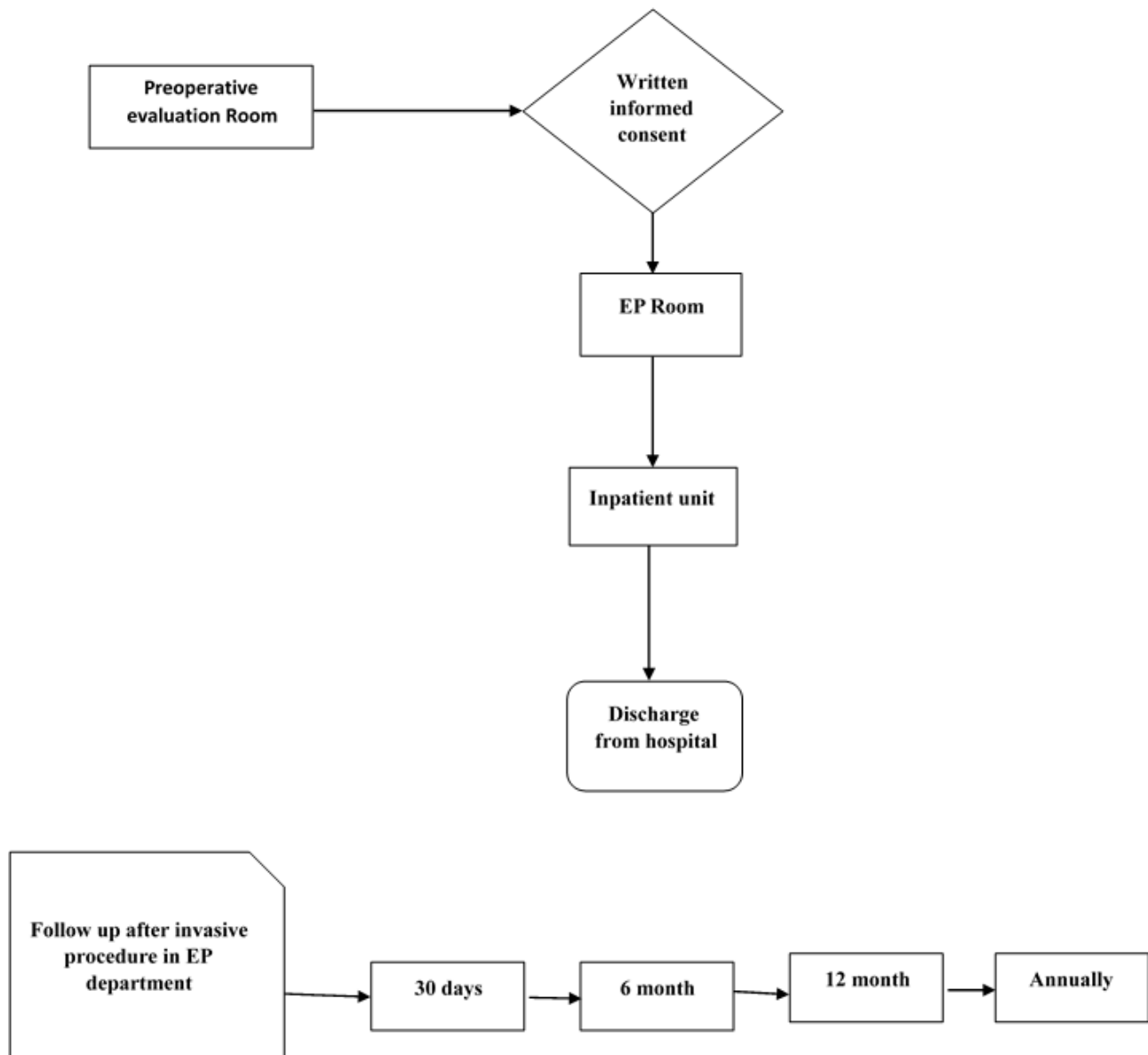


Fig 1: Flow of data collection for the cardiovascular invasive procedures registries

Table1: Data collection place, interval, corresponding data elements, and their research variables

Data collection place	Data collection interval	Data elements	Research variables
Preoperative Evaluation Room	Admission	Demographic data, treatment and surgery consent	Inclusion / exclusion criteria, ID, screening , consent to participating in clinical research
	Preoperative evaluation	Clinical evaluation Preoperative history Laboratory tests Echocardiogram Electrocardiogram Chest X-ray physical examinations Drug administration prior to procedure Qol assessment	Data capture based research profiles
EP department Room	Intraoperative procedures	Procedure information Drug administration during procedure	Data capture based research profiles
Inpatient unit	Discharge from hospital	Cardiac evaluation, pulmonary, renal, vascular and other complications following procedure discharge, Medications in use, discharge instructions	Data capture based research profiles
Clinical registries department	Follow up at 30 days, 6 month, 12 months, and annually	Living status, cardiovascular events, medications in use,	Data capture based research profiles

Development of EDC forms using REDCap

The REDCap user interface provides an instinctive method for securely and accurately record of data to research studies. It captured structured data by maximizing the use of drop-down menus, selection boxes, and radio buttons while minimizing catchall fields labeled "Other" with corresponding free-text. Each case report form is accessible only to users who have sufficient access rights set by the research team. Case report forms contain field-specific validation code sufficient to ensure strong data integrity. In addition to checking for obligatory field type (e.g. numeric entry for systolic blood pressure), surrounded functions also check data ranges (e.g. 70–180 mmHg) and aware the end-user whenever entered data disrupts specified confines. Data fields may be populated using text fields or through embedded pull-down boxes or radio buttons where the end-user is shown one value and a separate code is stored in the database for later statistical analysis (e.g. 0=No, 1=Yes).

With REDCap, we controlled data format/type, set ranges for date and numeric fields, and permitted data validation. Data consistency problems such as incorrect data type, values out of range, and outliers for numerical fields can be report using the data quality module. Further, we applied pre-defined rules that facilitated determination of whether a

specific data value might be discrepant, which is very important because our project contains many fields and has many records. Infrastructural requirements such as a web server that supports PHP Hypertext Preprocessor (PHP), a MySQL database server, and Secure Sockets Layer (SSL) connections need to be satisfied (Fig 2 and 3).

Security technical requirements

The clinical data preserve full patient confidentiality since they are SSL encoded and using Secure Hypertext Transfer Protocol (SHTTP) and Virtual Private Network (VPN) platform and kept on a protected server. All system transactions (documentation, content edition, deleting etc.) supported with the audit trail capabilities. The project administrative can also lock the data after all finalization checks have been complete. Researchers can access the database from multiple sites and institutions only with their own unique usernames and passwords. The project administrator can also allocate different levels of data access privileges to different users, depending on their roles in the project. These rights include logging, data entry rights, managing survey participants, calendar, data export/ import tools, file repository, data quality, project design, and setup.

Start date/ time Procedure	<input type="text"/> Now D-M-Y H:M
End date/ time Procedure	<input type="text"/> Now D-M-Y H:M
Procedure type	<input type="text"/>
ICD Indication	<input type="text"/>
Premarket clinical trial	<input checked="" type="radio"/> Yes <input type="radio"/> No
Reason for defibrillation implantation	<input type="text"/>
Specify type of defibrillator implanted	<input type="text"/>
Current ICD Mode	<input type="text"/>
Capability of ICD	<input type="text"/>
Generator therapy Mode	<input type="text"/>
Generator site of implantation	<input type="text"/>
Implant Device ID	<input type="text"/>
Device Manufacturer	<input type="text"/>
Device Model Name	<input type="text"/>
Device Model Number	<input type="text"/>
Implant Device Serial Number	<input type="text"/>

Fig 2: Sample of ICD registry case report form

Date of procedure	<input type="text"/> Today D-M-Y
Sedation /anesthesia	<input type="text"/>
Indication of pacemaker	<input type="text"/>
type of pacemaker implanted	<input type="text"/>
Venous access	<input type="text"/>
capable of pacemaker	<input type="text"/>
Endocardial Lead Positions	<input type="text"/>
Epicardial lead positions	<input type="text"/>
Generator manufacture	<input type="text"/>
Generator serial number	<input type="text"/>
Generator model	<input type="text"/>

Fig 3: Sample of pacemaker registry case report form

Data entry and quality control

It took a trained medical worker approximately 30 minutes per subject to convert clinical data to the eCRF format used in the REDCap platform. The frequent collection ensured timely and efficient acquisition of the clinical data of the patients of interest, significantly reducing the traditional data

collection workload and facilitating future clinical researches. Moreover, since the data collected can easily convert to formats used by Microsoft excel, Microsoft access, SPSS, and Statistical Analysis System (SAS), they are appropriate to transfer and share. For each user determined an electronic signature and nontransferable password, and defined different levels of access for insertion, query and exportation of data. Access to the software could

be performing from any computer, tablet or smartphone connected to the internet or using the offline version of REDCap.

DISCUSSION

Health information interoperability is defined the ability to capture, review, share, and reuse electronic health data seamlessly across health system, thus capture of data is important step to design interoperability framework between healthcare systems [29-31]. The preliminary effort to create these three electronic data capture forms is part of a larger program to address the lack of data interoperability between the clinical information systems and clinical registries in field of cardiac EP invasive procedures [32, 33].

In this paper, we describe the infrastructure required for interoperability between clinical information systems with clinical registries in the field of cardiac EP that involving a diversity of steps such as the alignment between research and clinical workflows, the adoption of clinical data management techniques, the development of electronic data capture using REDCap. This implemented web-based EDC systems, capture structured data from point of care, that leading to improving the efficiency of clinical documentation and prospectively populating clinical registries. These applications are practical for routine clinical use, and estimated a reduction in total documentation time per patient, during a standard course of procedure in cardiac EP department [34-36].

A high quality clinical registry can help to accurate monitoring and improve the efficiency of invasive EP procedures. To reach this, these applications can enable the researchers in data management on the context of cardiac EP invasive procedures, because data management is very important in clinical researches [37-39].

The main finding of this paper was that less time and effort is required to collect data than traditional tools e.g. spreadsheet. Setting up ranges and automatic calculations can prevent data entry errors and inconsistencies.

The major advantage of electronic Case Report Forms (CRF) over spreadsheets is that the former can be design to present only with certain acceptable choices for an item or to check the syntax and range of data that entered. This reduces the likelihood of data entry errors [40].

Moreover, in this paper we propose an electronic data capture application for enhancing health information systems potential to collect structured and standard based clinical research data during clinical encounters. This application integrates data

entry for clinical research into existing clinical documentation workflows, leveraging executable documentation management module to support harmonized, consistent data gathering for both patient care and clinical research.

Traditional data collection for clinical and scientific trials has focused on paper-based CRFs followed by double data entry into a Relational Database (RDB). Recent technological advances and considerable reduction in size, price and efficiency for portable computers (microcomputers e.g. Physician Device Assistant (PDA)) make EDC an intriguing alternative. The major advantages of EDC would be the ability to enter, review and analyze data in real-time and to implement online data validation checks to assure data quality more effectively at the point of entry [21, 40].

REDCap had a very clear advantage due to its extensive tutorials and online training materials [41, 42]. The benefits of EDC include direct data entry at the Point of care leading to greater accuracy, fewer queries, declined paper record storage, and timelier population of the study database. Direct data capture improves the accuracy of collected data [43].

Electronic documentation improves legibility and availability of documentations, and it facilitates the collection of structured data for purposes such as quality improvement and research. However, implementing electronic documentation has been reported to adversely impact clinicians' perceptions of documentation quality, workflow, professional communication, and patient care [44].

Data collection in clinical practice and biomedical research domain changed due to emergence of electronic medical record and automatic data capture [45]. These electronic forms lessen inaccurate data entry and study costs because the data entered in parallel to their clinical activities. Also EDC solution remove the limitations of paper-based data collection and increase the quality of data [40].

This development stands to be a huge benefit to researchers, as it will enable them to undertake increasingly sophisticated investigations more easily. However, in order to take advantage of improved data availability, we must first create effective systems to extract, store, utilize, and protect information with thoughtfully designed disease-specific databases and informatics infrastructures [46]. Proposed work for enhancing health information systems to support clinical research builds on the data management solutions, bridging the adoption gap by incorporating them directly into electronic documentation tools [47, 48]. The approach facilitates reuse of routinely collected data and seamless inclusion of data capture specific to a patient's research studies while minimizing the

impact on clinician effort [49, 50].

CONCLUSION

This paper represents the required infrastructure of cardiovascular EP invasive procedures registries and the approach taken to its construction and management. Construction of EDC template for cardiovascular EP invasive procedures facilitates better conversion from clinical practice to scientific research. In this way, REDCap offer users a strong data management platform for their study projects. It has enjoyed tremendous growth over the past few years because of its popular design, which facilitates research data collection needs. Such an effort can be widespread to other medical registries.

ACKNOWLEDGEMENTS

The authors thank the deputy dean of research affairs, Abadan Faculty of Medical Sciences for

financially supporting this project.

AUTHOR'S CONTRIBUTION

The authors agree on this final form of the manuscript, and attested that all authors contributed in the final draft of the manuscript.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this study.

FINANCIAL DISCLOSURE

This article extracted from a research project supported by Abadan Faculty of Medical Sciences and approved by ethical committee (IR. ABADANUMS.REC.1399.90).

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