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Developing a Minimum Data Set (MDS) for Cardiac Electronic Implantable Devices Implantation

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ABSTRACT

Background: There is no established minimum data set (MDS) for cardiovascular implantable electronic devices (CIEDs), which have led to a lack of standardized assessment criteria in this field to ensure access to a reliable and coherent set of data. **Objective:** To establish the minimum data set of CIEDs implantation that enables consistency in data gathering, uniform data reporting and data exchange in clinical and research information systems. **Methods:** This descriptive and cross-sectional study was conducted in 2018. That comprised a literature review to provide an overview of cardiovascular documents, registries, guidelines and medical record forms to extract an initial draft of potential data elements then asked from experts to review the initial draft of variables to score the items according to the importance perceived by them based on a five-point Likert scale. The items scored as important or highly important by at least 75% of the experts were included in the final list of minimum data set. **Results:** Initial dataset were refined by experts and essential data elements was selected in eight data classes including administrative data, past medical history, sign and symptoms, physical examinations, laboratory results, procedure session, post procedure complications and discharge outcomes. For each category required variables and possible respondents where determined. **Conclusions:** The minimum dataset will facilitate standardized and effective data management of CIEDs implantation; and presents a platform for meaningful comparison across contexts.

Keywords: Cardiovascular implantable electronic device, Pacemaker, Implantable cardioverter defibrillator, minimum data set.

1. INTRODUCTION

Cardiovascular implantable electronic devices (CIEDs) era began in 1958. Since then their use has become more widespread (1, 2). CIEDs are internal devices with the main purpose of correcting the irregular electrical activity of the heart (3). With growing indications these devices in the treatment of rhythm disorders, heart failure and prevention of sudden cardiac death, the implantations broaden and frequency of device utilization increases the supervision of these patients and their devices become in consideration (4-8). In Iran, history of these devices goes back to 1995 (9). For the purpose of this article, pacemakers and implantable cardioverter defibrillators (ICDs) will be the focus; however, implantable loop recorders are also considered CIEDs. Pacemaker and cardioverter defibrillators are increasingly recognized as efficient tools for management of cardiac rhythm disorders. Pacemakers, which are capable to send electrical impulses via intracardiac conductors to avoid Brady arrhythmias; the implantable cardioverter-defibrillator (ICD), which is effective in the inhibition of sudden cardiac death (SCD) through programmable anti-tachycardia pacing and/or DC shocks; and CRT devices, which are able to perform right and left ventricular pacing, usually in synchrony, to resynchronize ventricular contraction in patients with heart failure and conduction disturbances (10, 11). In this context, in order to establishing and maintenance a comprehensive information management system, existence of minimum dataset is essential. The most important step of any information management system is data collection; Disparity in data collection impedes the use of patient data for direct care and prevents data reuse for many other applications. Accordingly, there is a need

to move towards a unified dataset (12-14). Therefore, to facilitate standardized data entry and consistent data gathering, a minimum data set will suggest to uniform data reporting in the CIEDs field.

2. AIM

This paper represents the first attempt undertaken to develop minimum data set of cardiac implantable electronic devices (CIEDs) implantation. The specific goal of CIEDs-MDS is to establish a consistent, interoperable, and national framework as a basis for both clinical care and clinical research information systems.

3. MATERIALS AND METHODS

To design this dataset a combination of literature review and expert consensus approach was used. The research presented in this paper is a descriptive cross-sectional study that performed in 2018. The CIEDs minimum data set was developed via a three-stage process:

Assembly of the expert team

In view of the need for different types of knowledge, expertise, and skills, the team of working group of leading experts in the fields of cardiology and Health Information Management was convened to simplify our workflow and accomplish national consensus among all Electro physiologist clinicians. This five member team working group design study plan, determine initial draft of data element and construct the questionnaire.

Determination of initial draft MDS-CIEDs

There are a number of identified international cardiovascular databases with different contents and structures. Using existing registries and published data sources (Table 1) as a starting point, a preliminary list was collected and refined through consensus discussions steered by the work group. Consequently, variables for possible inclusion in the MDS import to questionnaire.

Title	Source
ACC-NCDR Registries	
CathPCI Registry	www.ncdr.com/webncdr/cathpci/home/datacollection
ICD Registry	www.ncdr.com/webncdr/icd/home/datacollection
CARE Registry	www.ncdr.com/webncdr/care/home/datacollection
Society of Thoracic Surgeons Adult Cardiac Surgery Data Registry	www.sts.org/national-database/database-managers/adult-cardiac-surgery-database
ACC/AHA Data Standards documents	
Adult cardiovascular EHR	Weintraub et al (15)
Cardiac imaging	Hendel et al.(16)
Electrophysiology	Buxton et al.(17)
ACS	Cannon et al.(18)

Table 1. Data source of preliminary list

Selection and Confirming of Variables in the minimum data set

In this phase, selection of data element from preliminary MDS-CIEDs was achieved by consensus of the group after review and discussion. A researcher-made questionnaire was created in order to validate data elements of the preliminary MDS-CIEDs. The experts participating in the study were asked to review the initial draft of variables to score the items according to the importance perceived by them based on a five-point Likert scale. In this scale, a score of 1 naturally represented the "lowest level of importance" and a score of 5 represented the "highest level of importance". Only the data elements with average score of 3.75 and higher were allowed into the MDS. Moreover, where asked from experts if intended to change, delete or add a variable for a specific purpose they should write an acceptable reason. The content validity of the questionnaire was done using the comments from2 cardiologists and 3 HIM experts. For the reliability of the questionnaire was used the test-retest method. The population of this study comprised 15 cardiologists with at least three years of work experience in medical centers performing EP procedures. Responses were received from 15 members. In the next step, the collected data were analyzed with IBM SPSS Statistics software (version 22).

4. RESULTS

We managed to collect 15 filled questionnaires out of 15 that had been distributed (100%). The CIEDs-MDS implantation data elements were divided into four categories, a first category is administrative data; that is included patient demographic and current episode of hospitalizations. The second category is clinical EP LAB visit that are included past medical history, sign and symptoms, physical examinations, lab-tests. Third category is data elements related to procedure session that included ICD insertion, Pacemaker Insertion, lead assessment, device identifiers, and fourth category is post procedure evaluation that includes post procedure complications, discharge outcomes and discharge drugs.

Patient demographics

There was consensus to include Name, Last name, father's name, gender, date of birth, place of birth, marital status, occupation, education level, National number, Home address and Phone number.

Current Episode of hospitalization

There was consensus to includeCare facility name, Physician name, admission date, Reason for admission, Insurance payers and medical record number.

Past medical history

The first section of the clinical EP LAB visit category is related to past medical history which was classified into four subsections of cardiovascular diseases history, non-cardiovascular diseases history, family history of cardiovascular diseases and prior history of cardiovascular procedures.

History of Cardiovascular diseases

That included Heart Failure, Heart Failure stage, Hypertrophic cardiomyopathy (HCM), Non-Ischemic Dilated Cardiomyopathy, Idiopathic dilated cardiomyopathy (DCM), Right ventricular cardiomyopathy (RVC), Restrictive cardiomyopathy (RCM), Pericarditis, Peripheral vascular disease, Stable Angina, Unstable Angina, NSTEMI, STEMI, Primary Valvular Heart Disease, Tetralogy of Fallout, Ventricular Sepal Defect, Common Ventricle, Epstein's Anomaly, Atrial Septal Defect (ASD), Amyloidosis, Chagas Disease, Giant Cell Myocarditis, Left Ventricular Aneurysm, Left Ventricular Non-compaction Syndrome, Right Ventricular Dysplasia (ARVD), Sarcoidosis.

History of Non-cardiac diseases

That included Stroke, Transient ischemic attack, chronic

Data classes	Data items	Data item subcategories	
Procedure general information	Date of procedure		yy/mm/dd
	Duration of procedure		In minutes
	Sedation type	1	Minimal Sedation
		2	Moderate Sedation
		3	Deep sedation
		4	General Anesthesia
	Procedure type	1	Initial device implant
		2	Generator change
		3	Lead displacement
		4	Lead Extraction
		5	Lead assessment
Cardioverter-Defibrillator Implantation	ICD type	1	Single chamber
		2	Dual chamber
		3	Biventricular
	Current ICD Mode	1	VVEV
		2	VVED
		3	DDED
		4	AAEV
		5	DDHD
		6	Other
	Generator site of implantation	1	Right Pectoral- subcutaneous
		2	Left Pectoral- subcutaneous
		3	Right Pectoral - sub muscular
		4	Left Pectoral - sub muscular
		5	Abdominal subcutaneous
Permanent pacemaker implantation	type of pacemaker	1	Single chamber (atrial)
		2	Single chamber (ventricular)
		3	Dual chamber (both atrial and ventricular)
		4	Biventricular of any type
	Current pacing mode	1	VVIR
		2	DDD
		3	DDDR
		4	DDI
		5	DDIR
		6	AAI
		7	Other
	Venous access	1	Subclavian
		2	Axillary
		3	Internal jugular
		4	External jugular
	Lead location	1	RA endocardial
		2	LV epicardial
		3	RV endocardial
		4	SVC/subclavian
		5	LV via coronary venous system
		6	Subcutaneous array (S-ICD)
		7	Other
	lead configuration	1	Unipolar
		2	Bipolar
Reposition/ Repair/Replacement/ Extracted procedure	Indications	1	Not applicable
		2	Normal EOL
		3	Premature EOL
		4	Upgrade to dual chamber
		5	Upgrade to biventricular / CRT
		6	Upgrade to atrial therapy
		7	Sensing/pacing failure
		8	Software (algorithm) failure
		9	Connector/header failure
		10	Recall
		11	Skin erosion/infection
		12	Systemic infection /endocarditis
		13	Malfunction
		14	Elective (patient request)
		15	Device relocation
	Extracted treatment recommendation	1	No, Re-implant
		2	Downgrade
	If upgrade , reason for upgrade	1	Single ICD to Dual ICD
		2	ICD to CRT-D
	Method of lead extraction	1	Laser sheaths
		2	Electrosurgical dissection sheaths (EDS)
		3	Mechanical sheaths
		4	Femoral extraction tools and/or snares
		5	Locking stylets
Lead assessment	Lead implant date		yy/mm/dd
	Lead Status	1	Extracted
		2	Abandoned
		3	Reused
	Lead Function	1	Normal
		2	Abnormal
		3	Not assessed
	Lead Extraction Indications	1	Infection
		2	Venous obstruction
		3	Lead dislodgment
		4	Perforation
		5	Erosion
		6	Conductor failure
		7	Insulation failure
		8	Venous obstruction
		9	Lead malfunction
		10	Returned to Manufacturer/recall

Table 2. Cardiac implantation electronic Devices MDS

renal failure, Currently on Dialysis, Chronic Lung Disease, Diabetes Mellitus, Hyperthyroidism, Hypothyroidism, cirrhosis disease, Obstructive Sleep Apnea, Patient Life Expectancy of >= 1 Year by physician estimate, Cancer, Hyperlipidemia, Hypertension, Cigarette smoker, Opium addiction.

Family History of Cardiovascular diseases

That included Family history of arrhythmias, Family history of recurrent syncope, Specific familial arrhythmia syndromes, Family history of sudden cardiac death, Family history of ischemic heart disease, Familial history of cardiomyopathy.

History of Invasive Cardiac Interventions/Surgery

That included previous pacemaker (pacemaker type, Indication), Previous ICD implant **(**ICD type, ICD Implant Site, ICD implants Date, Indication), Prior catheter ablation**,** Prior Diagnostic Coronary Angiography, Prior PCI, Prior CABG, Prior Heart Transplant and Prior Valve Surgery.

Sign and symptoms

This category was included of Asymptomatic, Fatigue, Palpitations, Dyspnea, Chest pain, NYHA functional classification, Presyncope, Syncope, Orthopnea, Paroxysmal Nocturnal Dyspnea *(PND***),** Cardiac arrest / aborted sudden death.

Physical examinations

This category was included of Heart rate, Blood pressure, Respiratory rate, Height, Weight, Third heart sound (S3), Fourth heart sound (S4), Lung examination, Waist circumference.

Laboratory data

This category include Blood urea nitrogen (BUN), Com-

Post procedure complications(19).					
Major complications	1	Cardiac Arrest	Minor complications	1	Device-related pain
	2	Myocardial infarction		2	Inappropriate shocks
	3	Transient ischemic Attack		3	Bleeding
	4	Drug reaction		4	Pericardial effusion
	5	pericardial Tomponad		5	Vascular damage
	6	Stroke		6	Arteriovenous fistula
	7	Ventricular tachycardia		7	Hematoma
	8	Ventricular fibrillation		8	Hemathorax
	9	Death		9	Air embolism
	10	Cardiac perforation		10	Pneumothorax
	11	Coronary venous dissection		11	Infection
	12	Lead dislodgement		12	Pulmonary vein injury
	13	Lead fracture		13	Sever PV stenosis
	14	Erosion of device through skin		14	Esophageal injury
	15	Urgent cardiac surgery			
	16	Deep venous thrombosis			
	17	Cardiac valve injury			
	18	Conduction block			
	19	Peripheral embolus			
	20	Peripheral nerve injury			
	21	Upper extremity edema			
	22	Set screw problem			
	23	Venous obstruction			
	24	Pulmonary embolism			
	25	AV fistula			

Discharge outcomes		
	1	Discharge Date
	2	Discharge Status
	3	If Deceased, Death During the Procedure
	4	If Deceased, Cause of Death
	5	Date of follow up
	6	Prescribed drug name
	7	drug dose

Table 2. continued. Cardiac implantation electronic Devices MDS

plete blood count (CBC), Hemoglobin, Platelet count, Hemoglobin, Hemoglobin A1c, Hematocrit, White blood count, Sodium, Creatinine, Potassium, Fasting blood sugar, Total cholesterol, HDL cholesterol, LDL cholesterol, Triglycerides, Protrombine Time(PT), PTT, Thyroid stimulating hormone (TSH).

Since the main focus of this paper is to present a minimum data set of cardiac implantation electronic devices, Table 1 classified these data elements.

5. DISCUSSION

This paper represents a developed MDS subsequent wide discussion with a range of related expertise over a period of time. This paper aims to design a minimum dataset to meet collection of data elements believed to be essential and sufficient to reflect a need for uniform reporting of cardiac Implantable electronic devices and additionally to improve efficiency and data quality in this field. Once selected, all data elements were clustered into standard classes (20). These classes specify the medical background in which the data element is anticipated to be obtained or collected and reflect the usual work low organization of information in typical clinical settings for a single episode of care. These Classes are Personal History and Family History, Physical Examination at the time of the encounter, Laboratory tests, Therapeutic Procedures, post procedure complications, Discharge Information and outcomes.

Lack of data standards has been the main obstacle to use of health care data for secondary purposes, such as research or quality monitoring. A basic dataset is a minimum, chosen, and complete agreed of elements related to each domain that could be used for investigation, strategy creating, and planning. One of the incentives for developing an MDS is to promote health through providing high quality information. Also, the MDS could be used for monitoring the patient's condition, health care provider or system assessment, and comparison in national and international levels, as well as serving as an indicator of health care provided by different institutes (21, 22). MDS also can support data sharing and interoperability in medical information systems (23).

While there is a growing interest in Iran to adopt MDS, no research has been undertaken so far in order to identify minimum data set for consistency reporting of CIEDs implantations. Therefore this paper represents our attempt to identify minimum data set for CIEDs. This MDS can be used as a basis for uniform data reporting in to electronic health record or clinical registries related to cardiac implantable electronic devises. We hope our MDS will enable and accelerate improvements in the outcomes of patients who undertaken to implant these devices, by providing consistent measurement of meaningful outcomes and allowing comparison between different care providers. This MDS also can be used as infrastructure for data interoperability between medical information systems in clinical and research domains related to cardiac implantable electronic devises.

We acknowledge that this work does have limitations. The proposed minimum dataset has not been widely consulted on and has been derived from consensus opinions of cardiologist physicians in Tehran heart center hospital. However, the working group has made these required data elements based on the best currently available appropriate evidence and a vast collective wealth of experience. Moreover it is not possible to comprehensively collect all the data items which limit the practicality of the MDS; however this will be outweighed by providing the most required data elements and possible subcategories.

6. CONCLUSION

This paper has highlighted the need for consistency in collecting and reporting data in healthcare environment. That could help to generate higher-quality data that would lead to better clinical decisions. In this regard a combination of experts-consensus and data-driven approaches was used to develop a Cardiac Implantable electronic devices implantation minimum dataset. This Minimum dataset can be also useful in designing electronic patient records or registry in this field toward integration of their fragmented records across continuum of the health care system and for the shared patient care.

- **Abbreviations:** MDS: Minimum Data Set; CIEDs: Cardiovascular implantable electronic devices; EPS: electrophysiology studies.
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- **Author's contribution:** All authors were included in all phases of preparing this article. Final proof reading was made by the first author.
- **Conflict of interest:** The authors declare there is no conflict of interest.

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