



## iCARDEA

“An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices”

### SPECIFIC TARGETED RESEARCH PROJECT

**PRIORITY Objective ICT-2009.5.1: Personal Health Systems - a) Minimally invasive systems and ICT-enabled artificial organs: a1) Cardiovascular diseases**

## iCARDEA – D5.2.1 Patient Education Mechanisms for the PHR

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## iCARDEA Consortium Contacts:

Organization	Name	Phone	Fax	E-Mail
SRDC	Asuman Dogac	+90-312-2101393	+90(312)2101837	asuman@srdc.com.tr
OFFIS	Wilfried Thoben	+49-441-9722-131	+49-441-9722-111	thoben@offis.de
SRFG	Manuela Plößnig	+43-662-2288-402	-	manuela.ploessnig@salzburgresearch.at
FORTH	Catherine Chronaki	+30-2810391691	+30-2810391428	chronaki@ics.forth.gr
SALK	Bernhard Strohmmer	+43-6624482-3481	+43-6624482-3486	b.strohmer@salk.at
SJM	Karl Eberhardt	+43-16073067	-	keberhardt@sjm.com
Medtronic	Alejandra Guillén	+34-916250361	+34-913346453	alejandra.guillen@medtronic.com
HCPB	Josep Brugada	+34-932275703	+34-932275459	jbrugada@clinic.ub.es

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## 1 INTRODUCTION

### 1.1 Purpose

This document describes the patient education material developed for the cardiac arrhythmia patients with an implanted cardiovascular implantable electronic device (CIED) in order to provide relevant education material that will be provide standard, optimal healthcare based on most recent evidence/clinical trials in the field.

In this regard, static and dynamic educative materials have been developed and are available for patients through the PHR system. Through the web the patient will be able to view this material and could improve self-care. The education material is being presented in this deliverable as an important tool for patient empowerment by helping him to better understand the disease and the way to live with CIEDs, subsequently reducing the burden of patient education for the healthcare givers.

### 1.2 Scope

This document provides detailed information about the patient education material developed within the scope of “Task 5.2.1 Patient Education” and will contribute to the milestone “M5: “iCARDEA Patient Empowerment Framework, Interoperability Layer and Personalized Follow-up Parameter Assistant”.

### 1.3 Definitions, acronyms and abbreviations

**Table 1 List of Abbreviations and Acronyms**

Abbreviation/Acronym	DEFINITION
CIED	Cardiovascular implantable electronic device
EHRA	European Heart Rhythm Association
EP	Electrophysiology
ESC	European Society of Cardiology
ER	Emergency department
HF	Heart failure
HIS	Hospital information System
ICD	Implantable Cardioverter Defibrillator
PHR	Personal Health Records
PM	Pacemaker
SCD	Sudden cardiac death

## 2 OVERALL DESCRIPTION OF ICARDEA PROJECT

Management of cardiac arrhythmia abnormalities that are not transient or reversible require constant clinical monitoring as a chronic condition. Delays on diagnosis or medical assistance increase risks of adverse outcomes such as heart failure (HF), stroke or sudden cardiac death. Therefore, CIEDs have become a part of the standard therapy in patients who are at the risk of life-threatening cardiac arrhythmias.

CIEDs with remote monitoring capabilities can store and transmit cardiac status and device function data. Remote sensor devices are located in patients’ homes to transfer stored data from the cardiac implant to a remote monitoring service centre. These remote monitoring service centres, operated by device manufacturers, receive, store, analyze and translate transmitted data into patient-specific reports and allow healthcare professionals to access patient data or to receive alerts in case of unusual persisting data variations. These systems are also capable of providing this valuable information in machine processable form. iCARDEA project has set out to use this information to semi-automate the follow-up of cardiac arrhythmia patients with

the care plans based on computer interpretable clinical guideline models by also personalizing the guidelines with the data obtained from patient EHRs.

Clinical guidelines include plans for treatment and aim to reduce inter-practice variations and the cost of the medical services, improve the quality of care and standardize clinical procedures. A variety of government and professional organizations are producing and disseminating clinical guidelines<sup>1,2</sup>. Several computer interpretable models of Clinical Guidelines have also been proposed such as GLIF<sup>3</sup>, ASBRU<sup>4</sup>, and ARDEN<sup>5</sup>. Additionally, there are several guideline execution engines processing these models, such as GLEE<sup>6</sup>, GLARE<sup>7</sup> and DeGel<sup>8</sup> demonstrating that the guideline definitions can be executed to automate the decision making process. In the iCARDEA system, GLIF is used for the definition of the care plans and an engine is developed to execute them. In this respect, the care plans presented in this deliverable are defined using GLIF Notation.

Currently the CIED data is available from two different sources. The patient may be at the clinic during an in-clinic follow-up, so the data from the CIED can be directly accessed using the CIED Programmer of the vendor. The CIED Programmer is able to export the data into PDF file(s) stored in a configurable directory. Alternatively, the patient may be at home and the data is transmitted (semi-) automatically into the CIED Data Centre of the vendor for a remote follow-up. The physicians then can access the CIED Portal of the vendor that functions as frontend of the CIED Data Centre. It is also possible to export the CIED Data to the clinic, however right now this export has to be triggered manually in the CIED Portal. The data is then either exported using the IHE IDCO/HL7 v2.5 message or it is exported to a vendor system that has to be installed in the clinic. Currently the v2.5 messages transferred by the CIED Vendors usually contain limited information; however the PDF reports that contain the detailed data are embedded in the message. The vendor system in the clinic then automatically stores the data in a single PDF file using a configurable filename and the filename includes additional information such as the Patient name, Patient ID, and the timestamp.

iCARDEA uses "IHE Implantable Device Cardiac Observation Profile (IDCO)"<sup>9</sup> to automatically expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. There are different CIED vendors each with its own device and data centre interfaces. On the other hand, IHE has defined this profile in order to standardize transferring information from an interrogated implantable cardiac device to the healthcare enterprise information management systems. The implant device is interrogated in clinic or home environment using vendor proprietary equipment and the information is transferred to clinic system as structured HL7 v2.5 ORU message using IEEE 11073 IDC nomenclature<sup>10</sup>.

In iCARDEA, a care plan is personalized to a patient by also accessing his medical history from the EHR systems. For example, in executing iCARDEA care plans for monitoring CIED patients with Atrial

<sup>1</sup> US National Guideline Clearinghouse, <http://www.guideline.gov/>

<sup>2</sup> National Institute for Clinical Excellence- England/Wales (NICE) Published Guidelines, <http://www.nice.org.uk/page.aspx?o=guidelines.completed>

<sup>3</sup> Boxwala AA, Peleg M, Tu S et al. GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines. *Journal of Biomed Inform.*, 2004, 37(3), 147-61

<sup>4</sup> Shahar, Y., Miksch, S., and Johnson, P. The Asgaard project: A task-specific framework for the application and critiquing of time-oriented clinical guidelines. *Artificial Intelligence in Medicine*, 1998, 14: 29-51.

<sup>5</sup> Jenders RA, Corman R, Dasgupta B. Making the standard more standard: a data and query model for knowledge representation in the Arden syntax. *Proceedings of AMIA Annual Symp.*, 2003, 323-30.

<sup>6</sup> Wang D, Shortliffe EH. GLEE - a model-driven execution system for computer-based implementation of clinical practice guidelines. *Proceedings of AMIA Symp.*, 2002, 855-9.

<sup>7</sup> Terenziani P, Montani S, Bottrighi A et al. The GLARE approach to clinical guidelines: main features. *Studies in Health Technology and Informatics*, 2004. 101, 162-6.

<sup>8</sup> Shahar Y, Young O, Shalom E, Mayaffit A, Moskovitch R, Hessing A, and Galperin M. DeGeL: A Hybrid, Multiple-Ontology Framework for Specification and Retrieval of Clinical Guidelines. *Proceedings of the 9th Conference on Artificial Intelligence in Medicine*, Springer-Verlag Heidelberg, 2003, 122 - 131.

<sup>9</sup> IHE Implantable Device - Cardiac - Observation Profile, [http://www.ihe.net/Technical\\_Framework/upload/IHE\\_PCD\\_TF\\_Supplement\\_IDCO\\_2009-08-10.pdf](http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Supplement_IDCO_2009-08-10.pdf)

<sup>10</sup> ISO/IEEE 11073-10101:2004, Point-of-care medical device communication -- Part 10101: Nomenclature, [http://www.iso.org/iso/catalogue\\_detail.htm?csnumber=37890](http://www.iso.org/iso/catalogue_detail.htm?csnumber=37890)

Fibrillation (AF), the history of the non-cardiac conditions, detailed information about severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition), the medications being taken at the time of spontaneous arrhythmia occurrence or the non-cardiac conditions denoting contraindications to the proposed therapies need to be accessed from the patient EHRs. The major challenge addressed in accessing the EHR systems is the interoperability problem of communicating with very many heterogeneous EHR systems. It should be noted that the care plans in this deliverables are generic in that they are not personalized to a specific patient.

To be able to avoid routinely monitoring a wide variety of clinical data from disparate systems, and developing ad hoc interfaces to access heterogeneous systems, IHE has specified the “Care Management Profile”<sup>11</sup> and this profile is used in the iCARDEA system.

## 2.1 iCARDEA System Architecture

The iCARDEA system aims to automate and personalize the follow-up of cardiac arrhythmia patients with implanted CIED devices with computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs. Figure 1 shows the overall architecture and the environment in which iCARDEA needs to provide interoperation services. The major components of the system are as follows:

1. **Personalized Adaptive Care Planner for the CIED Recipients:** In the iCARDEA project, the personalized follow-up of CIED patients is coordinated through a “care plan” which is an executable definition of computer interpretable clinical guideline models. The care plans are represented in GLIF, and the Care Plan Engine is capable of semi-automatically executing the care plan by processing its machine processable definition. The control flow of the care plan is dynamically adapted based on the patient’s context derived from the data coming from CIEDs and the medical context obtained from the EHRs. Through a graphical monitoring tool, the physicians are allowed to follow the execution of the care plan in detail, and coordinate the flow of actions when consultations to physicians are required.
2. **The CIED Data Exposure Module** uses “IHE Implantable Device Cardiac Observation Profile (IDCO)” to expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. For this, it has a component that allows accessing the CIED Portal of the vendor and triggers the CIED data export automatically from the CIED Data Centre (periodically every x hours or each morning at a defined time). The CIED Data Listener Component waits for the exported data. For this it either scans a configurable directory in case of the data is exported directly to a vendor system in the clinic, alternatively it listens a pre-configured port for the exported data using the IHE IDCO/HL7 v2.5 protocol in case of direct network retrieval. In both cases the PDF file(s) need to be processed to extract the CIED data and the Data Translation Service sub-system creates a valid IHE IDCO format (HL7 v2.5 ORU Message) and makes the CIED data available to the iCARDEA Adaptive Care Planner through PCD-09 Send Observation message.
3. **EHR Interoperability Infrastructure:** To execute the clinical guidelines, it is also necessary to have access to medical history of the patients in the EHR systems. Considering that there are very many EHR systems with proprietary interfaces, in iCARDEA, “IHE Care Management (CM) Profile” is used. In our system, the proprietary hospital information systems export “Discharge Summary” and also “Laboratory Report Summary” CDA documents in conformance to IHE CDA Document templates<sup>12</sup> to an EHR Server which is implemented as an IHE XDS Repository<sup>13</sup>. This EHR Server also acts as a “Clinical Data Source” by implementing the IHE CM Profile. In this way, Adaptive Care Manager can subscribe to receive update notifications for the clinical data that is necessary to

<sup>11</sup> IHE Patient Care Coordination (PCC) Technical Framework Supplement, 2008-2009, Care Management (CM), Draft for Trial Implementation, August 22, 2008

<sup>12</sup> IHE Care Coordination Framework, Content Modules, [http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical Documents Specification 1.3.6.1.4.1.19376.1.5.3.1.1.1](http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical_Documents_Specification_1.3.6.1.4.1.19376.1.5.3.1.1.1)

<sup>13</sup> IHE Cross Enterprise Document Sharing (XDS) Profile, [http://www.ihe.net/Technical\\_Framework/index.cfm#IT](http://www.ihe.net/Technical_Framework/index.cfm#IT)

execute the care plans. IHE Care Management Profile specifies standard interfaces to extract this data that is needed by the care plans from the EHR systems. The two standardized transactions used in the iCARDEA system are as follows:

- “PCC-09 Care Management Data Query” allows querying the clinical data sources such as the EHR systems for the data required to execute the care plan.
- “PCC-10-V3 Care Management Update” allows the clinical data sources (EHR systems) to send the updated clinical data to the subscribed Care management systems as an HL7 V3 messages.

Additionally, IHE has specified “Content Modules” to be used as the payloads of these transactions to transfer clinical data in terms of CDA Sections and Entries. The HL7 Clinical Document Architecture (CDA)<sup>14</sup> is a document mark-up standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange and each CDA document is made up of CDA Sections and each Section is made up of CDA Entries.

Different content module templates for CDA Documents such as Discharge Summary, Referral Summary; CDA Sections such as History of Present Illness, Medications, and CDA Entries such as Problem Entry, Vital Signs Observation have been specified.

While a Care manager queries a clinical data source, it specifies the type of the clinical data required through a code specified in the “careProvisionCode” field, such as “LABCAT”, meaning all lab results. For each code specified in this controlled code list, the IHE content module template (for example “Simple Observations” template is specified for reporting lab results) is also specified through which the clinical data update is sent. The clinical data sources send the updated clinical data to the iCARDEA care plan engine by conforming to these content module templates. In this way the interoperability of the transactions among clinical data sources and care managers is guaranteed.

4. Additionally, iCARDEA includes the Patient Empowerment Framework aiming to provide an active and informed involvement of patients in management of their own health. Through this PHR portal patients are able to have an overview about their own health data and to add additional personal health data such as the daily recorded blood pressure, body weight or upcoming problems related to their heart disease. Another important feature of the PHR portal is recording medication compliance indicating changes in e.g. dosage or change of drugs. Finally, the PHR portal allows the patient to have access to the education material provided by iCARDEA project.

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<sup>14</sup> HL7 Clinical Document Architecture (CDA), <http://hl7.org/library/Committees/structure/CDA.ReleaseTwo.CommitteeBallot03.Aug.2004.zip>

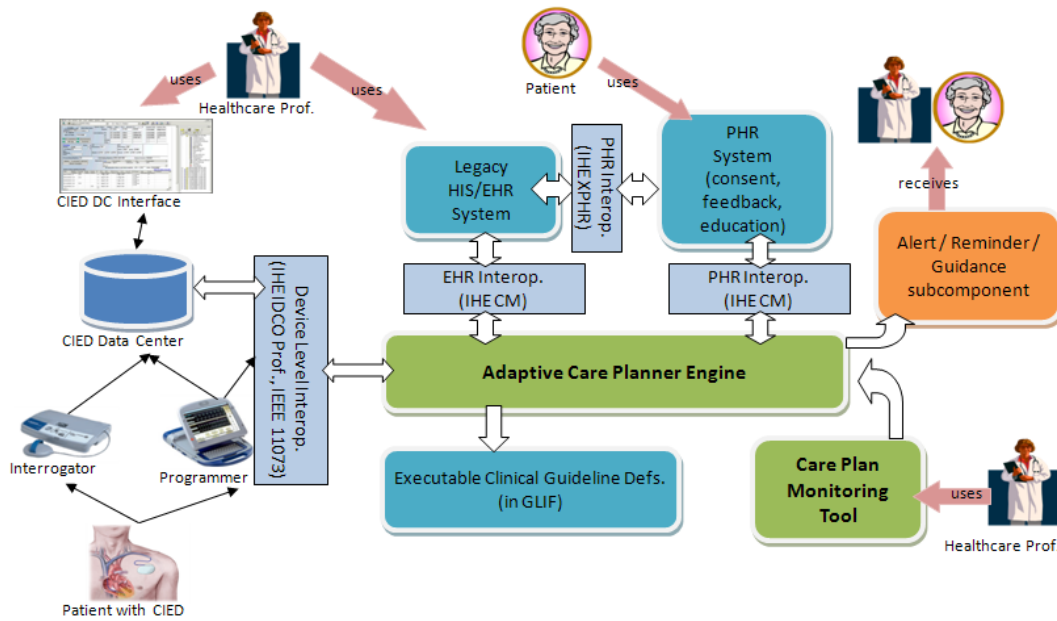


Figure 1 iCARDEA Architecture Overview

### 3 ICARDEA PATIENT EDUCATION MATERIAL

Personal Health Systems are innovative disruptive health solutions so that, in order to satisfy high acceptance of the patients with these new systems and gain the maximum clinical and social benefit, patient education is unavoidable

In iCARDEA Project, the following main aspects are contemplated in the patient education:

1. Static Educative Material.
2. Dynamic Educative Material.
3. Patient feedback (this section will be presented in deliverable D.5.3.1 “Patient Feedback Mechanisms for the PHR).

In the following subsections, the task is described emphasizing the mechanisms of patient education. For organizational purposes, the following patient education material has been classified into a Google portal and it will be served as wiki over the PHR System to the patients. We will submit a friendly presentation of education material in the next period and we are going to send an update.

It is known that access to health information empowers patients and fosters the physician-patient relationship by facilitating the patient to become a more qualified partner in his health care process. Access to information increases the control that patients can have in their healthcare. The challenge for Patient Empowerment is to improve patient’s access to good health information and their capacity to use it effectively. Typical patient education generally focuses on imparting knowledge to the patient that is disease-specific. Patient empowerment also means that the patient is educated in making good decisions about his/her health going beyond “medical” decisions. It also means that he/she is got to know how the disease affects his/her role in

life (e.g. such as performing hobbies or the way to participate in favourite sport) as well as knowing the emotional impact of the disease.<sup>15</sup>

### 3.1 Patient Education Mechanisms

HCPB has identified and produced the relevant patient education mechanisms that will be implemented in the PHR portal once fully developed. Both static and dynamic educative materials have already been designed and are currently being included in a Google Site. Accessing the already existing material is also facilitated through external webpage links and uploaded documents (those available for public use). Through the web, patient will be able to view this material. These resources will likely decrease the work load on the healthcare professionals since they will not have to spend enormous amount of time informing the patients about the new devices and systems. In addition, it will assist the patient to control their health status by informed decisions.

The objectives are to increase the patient's knowledge of their disease, to decrease the level of anxiety and to provide sufficient tools to improve their self-care through in person information and education, giving access to explanatory material, multimedial material and forums.

The platform allows you to add new information and provide continuous actualization for the patient's needs.

#### 3.1.1 Timing of patient education

There are different times in the patient education and different ways to inform the patient about their own health, all of them are needed to improve the way to understand the self-care. We can divide the opportunities to provide patient education in three parts: the hospitalization time, the follow up in the visit and the home monitoring time (figure 2). Each of them is important and essential and will improve the medical care.

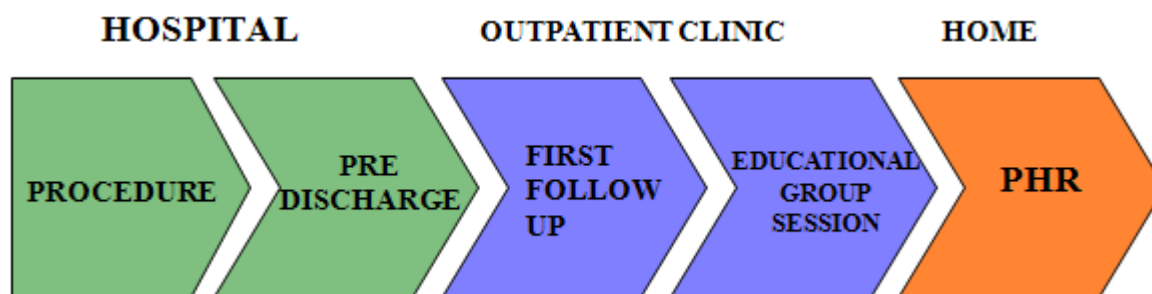


Figure 2. Different moments in patient education.

*PHR: Personal Health Record*

Before implantation, a doctor from the Arrhythmia Unit is responsible for informing the patient about the functioning of the device, indications, implantation technique, duration, and anesthesia risks. The healthcare provider also introduces the iCARDEA PHR system to the patient which will support his/her self-care.

<sup>15</sup> Santurri L: Patient Empowerment: Improving the Outcomes of Chronic Diseases Through Self-Management Education, [http://www.cwru.edu/med/epidbio/mphp439/Patient\\_Empowerment.htm](http://www.cwru.edu/med/epidbio/mphp439/Patient_Empowerment.htm)

At pre-discharge, once device is implanted, the nurse responsible for the patient will give to the patient immediate care information and basic recommendations on new habits: (Figure 2).

- Information about the wound: the patient discharged with a hydrocolloid dressing, sterile, which promotes wound healing. It's placed in the operating room at the end of the implant. The apposite is not to be removed until the day of the withdrawal of the suture clips (15 days). But in case of accidental removal of the dressing prior to the visit, if the wound shows good healing it should be cleaned with soap and water without rubbing too much. The nurse will inform the patient of the signs of infection (edema, redness, pain in the incision area, local heat, fever, etc.). If these appear, the patient is instructed to go to his reference center for evaluation. The nurse will also inform him of the possibility of occurrence of a slight hematoma at the incision site due to handling during the implant; this is not a sign of warning and it will disappear within a few weeks.
- Information about the mobilization of the limb: the tip of the implant must remain immobilized for 24 hours post implant. They inform the patient that they should not make sudden movements, lifting, or lift it until one month after the implant.
- Delivery of written support material: manual for patients with a Pacemaker (PM), manual for patients with an ICD, manual for patients with heart failure (HF), Brochures, fridge magnets warning signs and symptoms of HF, others.

PROCEDURE	PRE DISCHARGE
<ul style="list-style-type: none"> <li>•Physician / Nurse/ Technician</li> <li>•Information about: device, guidelines, procedure, ...</li> <li>•Information about Remote Monitoring</li> </ul>	<ul style="list-style-type: none"> <li>•Nurse</li> <li>•Information about wound, upper extremity movility</li> <li>•Handing of educational materials such as ICD manual, others</li> </ul>

Figure 2. Patient education during hospitalization.

In first visit at day 15, the following tasks are performed, usually by a nurse of arrhythmia department. The medical professional checks that the patient has understood the information given during hospitalization and whether he has received the written support material (Figure 3).

- Education: the patient is instructed that, if significant symptoms occur like a large clinical deterioration and/or the presence of  $\geq 2$  shocks occur, he should go to an emergency room. On the other hand, in case of shock or worsening of symptoms, phrenic nerve stimulation or activation of a warning, the patient needs to contact the Arrhythmia Unit for preferential assessment.
- Delivery of the provisional license and explanation that the device bearer should always carry the card which provides proof of the CIEDs.
- Using the PHR portal: additional to basic medical instructions the physician will suggest how the PHR portal can support the self-management for the patient, e.g. recording the daily weight or the blood pressure, medication changes or the appearance of symptoms. The physician will also refer to the education material and maybe recommend specific articles which are in particular of interest for the patient. The patient will be indicated that detailed information about using the PHR portal can be found in the user manual.

- Patient forums: The PHR portal includes the possibility for forums allowing patients to pose questions or to exchange their experiences with other patients which are sharing similar situations. A forum is either a link to an existing forum for CIED patients or a forum coordinated in the PHR portal.

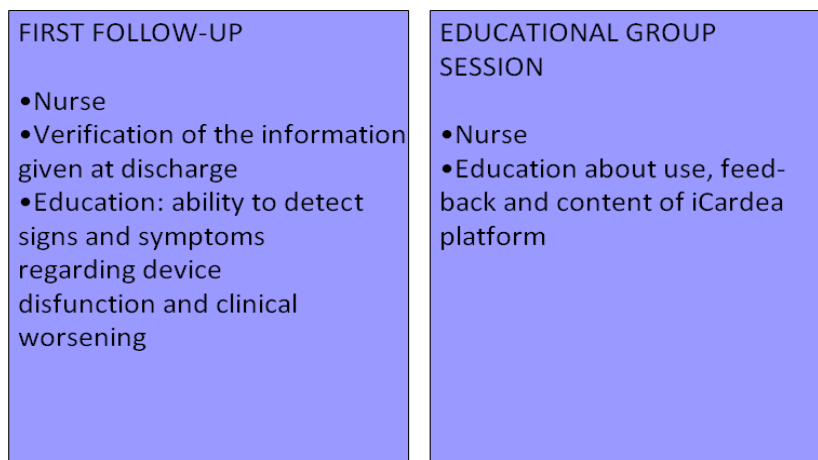


Figure 3: Follow up timing in patient education.

At the moment of follow up by the home monitoring start the personal health record in which the patient could interact and receive feedback for the professional health care (Figure 4).

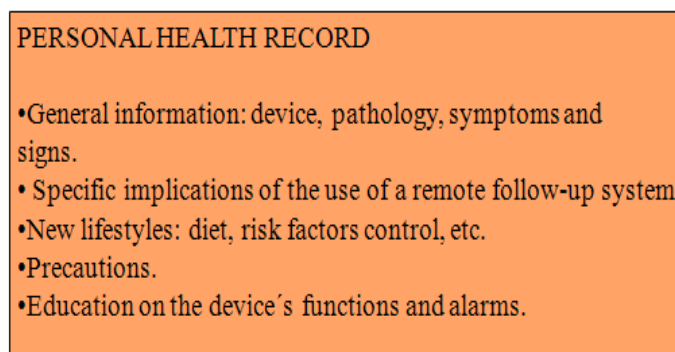


Figure 4: Home monitoring timing in patient education.

### 3.1.2 Static Educative Material

The static educative materials are documents prepared to give passive information to the patient and doctors for improve the care plan and self care. (Figure 5)

The screenshot shows a web browser window with the address bar displaying <https://sites.google.com/site/ciedpatient/basic-information>. The page layout includes a left-hand navigation menu under the heading 'Patient Education' with links for Home, Basic Information (highlighted), New Habits, Precautions, Warning Signs, Useful Links (Communities, etc.), CIED Health Resources, Test for playing..., and Sitemap. The main content area is titled 'Basic Information' and contains the following sections:

- What is a pacemaker?** (Placeholder: *Insert a text*)
- What is an ICD?** (Placeholder: *Insert a text*)
- What is cardiac resynchronization?** (Placeholder: *Insert a text*)
- What kind of follow-ups are made and why?** (Placeholder: *Insert a text*)
- What is remote monitoring? How does it work?** (Placeholder: *Insert a text*)
- What is heart failure?** (Placeholder: *Insert a text*)
- What is atrial fibrillation?** (Placeholder: *Insert a text*)

At the bottom, an 'Attachments (9)' section lists three documents:

- GENERAL INFORMATION. function of the heart.doc - on Aug 25, 2011 2:01 AM by silvia vidorreta (version 1) - 436k [View](#) [Download](#)
- GENERAL INFORMATION What is Atrial Fibrillation.doc - on Aug 25, 2011 2:00 AM by silvia vidorreta (version 1) - 89k [View](#) [Download](#)
- GENERAL INFORMATION What is an ICM.doc - on Aug 25, 2011 2:01 AM by silvia vidorreta (version 1) - 37k [View](#) [Download](#)

Figure 5: Google site.

The following table summarizes the currently available passive information documents on:

- **General information:** What is a pacemaker?, what is an ICD?, what is cardiac resynchronization?, what kind of follow-ups are made and why?, what constitutes remote monitoring or home monitoring?, how does it work?, what is HF?, what is atrial fibrillation?, etc.
- **New habits after implantation:** Wound care, movement and physical activity, food and nutrition, physical activity, travelling, driving, etc.
- **Precautions:** Magnetic fields, electromagnetic fields, alarm detection systems, mobile phones, laser, radiotherapy, etc.
- **Warning signs and symptoms – how to act:** What to expect and how to act in case of shock, how to proceed in case of activation of an audible alert, action in case of decompensation, etc.
- **Patient forums and patient feedback:** Contact addresses and phone numbers, links to other educational material, query section. This section will be further developed in D.5.3.1.

The following table is an abstract of the documents provided by iCARDEA, part of them are pre-existing material made by international official organisms and commercial houses available in the web and a part of them are newly created for iCARDEA by HCPB.

	NEWLY CREATED	EXISTING DOCUMENTS	WEB LINK
What is a pacemaker?	—	YES (Medtronic, AHA/ASA, SEC)	YES (Medtronic, US National Heart Lung and Blood Institute, Medicine Plus) <a href="http://www.medtronic.com/your-health/bradycardia/device/what-is-it/">http://www.medtronic.com/your-health/bradycardia/device/what-is-it/</a> <a href="http://www.nhlbi.nih.gov/health/dci/Diseases/pace/pace_all.html">http://www.nhlbi.nih.gov/health/dci/Diseases/pace/pace_all.html</a> <a href="http://www.nlm.nih.gov/medlineplus/ency/article/007369.htm">http://www.nlm.nih.gov/medlineplus/ency/article/007369.htm</a> <a href="http://www.americanheart.org/presenter.jhtml?identifier=4676">http://www.americanheart.org/presenter.jhtml?identifier=4676</a> <a href="http://www.americanheart.org/presenter.jhtml?identifier=33">http://www.americanheart.org/presenter.jhtml?identifier=33</a> <a href="http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Living-With-Your-Pacemaker_UCM_305290_Article.jsp">http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Living-With-Your-Pacemaker_UCM_305290_Article.jsp</a>
What is an ICD?	—	YES (Medtronic, AHA/ASA, SEC)	YES (Medtronic) <a href="http://www.medtronic.com/your-health/tachycardia/device/what-is-it/">http://www.medtronic.com/your-health/tachycardia/device/what-is-it/</a> <a href="http://www.nhlbi.nih.gov/health/dci/Diseases/icd/icd_what.html">http://www.nhlbi.nih.gov/health/dci/Diseases/icd/icd_what.html</a> <a href="http://www.nlm.nih.gov/medlineplus/ency/article/007370.htm">http://www.nlm.nih.gov/medlineplus/ency/article/007370.htm</a> <a href="http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_300449.pdf">http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_300449.pdf</a>
What is an ICM (Implantable Cardiac Monitor)?	—	YES (Medtronic)	—
What is the function of the heart?	—	YES (Medtronic, AHA/ASA)	—
What is cardiac resynchronization?	—	YES (Medtronic, SEC)	—
What kind of follow-ups are made and why?	YES	YES (Medtronic, AHA/ASA, SEC)	—
What is remote monitoring? How does it work?	YES	YES (Medtronic)	—
What is heart failure?	—	YES (Medtronic, SEC)	YES (Illumistream, Medline Plus, ASKvisualscience) <a href="http://www.heart.org/HEARTORG/Conditions/HeartFailure/Heart-Failure_UCM_002019_SubHomePage.jsp">http://www.heart.org/HEARTORG/Conditions/HeartFailure/Heart-Failure_UCM_002019_SubHomePage.jsp</a> <a href="http://www.nlm.nih.gov/medlineplus/heartfailure.html">http://www.nlm.nih.gov/medlineplus/heartfailure.html</a> <a href="http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000114.htm">http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000114.htm</a> <a href="http://www.nlm.nih.gov/medlineplus/tutorials/congestiveheartfailure/htm/no_50_no_0.htm">http://www.nlm.nih.gov/medlineplus/tutorials/congestiveheartfailure/htm/no_50_no_0.htm</a>
What is atrial fibrillation?	—	YES (Medtronic)	YES (Medtronic, Medline Plus) <a href="http://www.heart.org/HEARTORG/Conditions/Arrhythmia/Arrhythmia_UCM_002013_SubHomePage.jsp">http://www.heart.org/HEARTORG/Conditions/Arrhythmia/Arrhythmia_UCM_002013_SubHomePage.jsp</a> <a href="http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000237.htm">http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000237.htm</a> <a href="http://www.nlm.nih.gov/medlineplus/tutorials/atrialfibrillation/htm/no_50_no_0.htm">http://www.nlm.nih.gov/medlineplus/tutorials/atrialfibrillation/htm/no_50_no_0.htm</a>
New habits after device implantation	YES	YES (Medtronic, AHA, Circulation, SEC)	YES (Medtronic, AHA)
Precautions	YES	YES (Medtronic, AHA/ASA, SEC)	—
Warning signs and symptoms – how to act	YES	YES (Medtronic, Circulation, SEC)	—
Patient	—	—	YES

<b>forums</b>			(Forums)
			<a href="http://www.pacemakerclub.com/public/epage/1/p/Home/content.do">http://www.pacemakerclub.com/public/epage/1/p/Home/content.do</a>
<b>Patient feedback</b>	YES	—	YES (Links)
			<a href="http://www.thepacemakerforum.com/">http://www.thepacemakerforum.com/</a> <a href="http://www.implantable.com/">http://www.implantable.com/</a>
<b>AHA: American Heart Association; SEC: Spanish Society of Cardiology (Sociedad Española de Cardiología)</b>			

### 3.1.3 Dynamic Educative Material

Patient decision aids are interventions designed to help people make specific and deliberate choices among options by providing information on the options and outcomes relevant to the person's health status. This may include information on the disease/condition, probabilities of outcomes based on risk factors, information in other's options, guidance in the steps of decision making.<sup>16</sup>

There are 5 Steps for implementing patient decision support in clinical practice. The following highlights these steps and identifies resources that have been used to accomplish each step (Table 2).

Steps
<b>1. Step 1: Assessment</b>
<b>2. Step 2: Decision Support Tools</b>
<b>3. Step 3: Education and Training</b>
<b>4. Step 4: Implementation</b>
<b>5. Step 5: Quality Monitoring Tools</b>

#### Step 1: Assessment

The purpose is to assess patient's and practitioner's information and decision making needs.

- **Patients' learning needs:** Survey patients to determine their health information needs for common health issues.
- **Patients' decision making needs:** Conduct a population needs assessment to identify patients' and practitioner's perception of patients' decision making needs
- **Factors influencing practitioners' providing decision support:** Survey practitioners to determine barriers and facilitators influencing their practice in providing decision support to patients facing: symptom management and triage decisions using a standardized tool values-sensitive decisions using a standardized tool

#### Step 2: Decision Support Tools

In this time it is useful to make a review decision support tools to find those relevant to the identified needs.

- Identify current patient education materials
- Audit the quality of patient education resources currently used within the practice.
- Audit the quality of patient decision aids

#### Step 3: Education & Training

In this moment it is important to provide opportunities for practitioners to enhance their support skills.

#### Step 4: Implementation

<sup>16</sup> [http://decisionaid.ohri.ca/docs/develop/Develop\\_DA.pdf](http://decisionaid.ohri.ca/docs/develop/Develop_DA.pdf)

Now it is the time of implementing patient decision support using strategies tailored to the setting.

### Step 5: Quality Monitoring Tools

With all the information and assessment, it helps to monitor the quality of decision support provided.

Physicians and patients can be involved to different degree into a medical decision making process. iCARDEA aims to involve the patients in a more active way by offering him decision aids for typical and critical decision situations. With regards to helping the patient to make an informed decision, HCPB has developed a Decision Aid on **Telemonitoring** in order to help patients with a CIED to decide whether or not being included in a telemonitoring system. Further Decision Aids will be developed, including **anticoagulation, driving** and **catheter ablation of arrhythmias**.

#### 3.1.3.1 Telemonitoring Decision Aid

Trends in healthcare policy emphasize involvement of community and patients in many aspects of their care. In particular, self-care initiatives cannot be imagined without such involvement and authentic involvement also requires participation in decision-making. A key approach for patient-centred care is Shared Decision Making where physicians and patients communicate together using the best available evidence when faced with the task of making decisions, where patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a determination about the best action and which respects patient autonomy, where this is desired, ethical and legal.<sup>17</sup>

A key characteristic of shared decision programs is the competence of patients for decision making about their healthcare options. Patient decision aids are interventions preparing patients for decision making about professional care options. Decision aids can be e.g. information combined with advices or advices from the attending physician. Patients may use decision aids to prepare for talking with a physician, or a physician may provide them at the time of a visit to facilitate decision making. Additionally, different types of materials can be used for patient decision aids. Decision aids can be leaflets, interactive media, video or audio materials and they can also be enriched information material provided via the Internet.

Generally, Decision Aids support persons with chronic diseases in their day-to-day decisions which they have to make in response to changes in disease conditions. Patient decision aids are designed to complement, rather than replace, counseling from a health practitioner. It can help people to assess their decision making needs, plan the next steps, and track their progress in decision making.

The aim of this decision aid is to help patients with a Cardiovascular Implantable Electronic Device (CIED) to decide whether or not being included in a telemonitoring system.

Definitions:

CIED, Cardiovascular implantable electronic device (CIED) (from the HRS\_ERA Expert Consensus of CIEDs<sup>1</sup>): Cardiovascular implantable electronic devices include the pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization device (CRT), implantable loop recorder (ILR) and implantable cardiovascular monitor (ICM). PM, ICD and CRT devices have been described in detail in the google site and will be implemented in the PHR and all of these devices collectively have been termed cardiovascular implantable electronic devices (CIEDs).

Alerts: Some CIED have alert capabilities.

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<sup>17</sup> [http://en.wikipedia.org/wiki/Shared\\_decision\\_making](http://en.wikipedia.org/wiki/Shared_decision_making)

Home monitor/communicator (from the HRS\_ERA Expert Consensus of CIEDs<sup>1</sup>): A device designed to receive telemetry from a specific CIED and transmit the encrypted data using telephone technology to a remote-secure monitoring center or file server. Often the home monitor/communicator is stationary and connected to the Internet through an analog telephone line in a patient's home, but it can also be mobile/portable unit and connected via cellular technology

In-Clinic Follow-up: Patients with a CIED must be followed-up in an out-patient clinic (include follow up guidelines), where the physicians can assess the device is working properly (Table 3).

A CIED collects a large amount of information such as technical device parameters and clinical relevant data. All this information may help:

- Assess whether the device is working properly
- Detect present or anticipate future device dysfunction
- Keep track of the disease progress
- Help taking medical actions

<b>Table 3. Goals of monitoring CIEDs (HRS-ERA Expert Consensus of CIEDs)</b>	
<b>Goals</b>	
<b>Patients related</b>	<ul style="list-style-type: none"> <li>• <b>Optimize the patient`s quality of life.</b></li> <li>• <b>Optimized pacemaker/ICD system function to meet the patient`s clinical requirements.</b></li> <li>• <b>Identify patients at risk and initiate appropriate follow-up with field safety corrective action and safety alerts.</b></li> <li>• <b>Triage non CIED related health problems and make appropriate referrals.</b></li> </ul>
<b>CIED related</b>	<ul style="list-style-type: none"> <li>• <b>Document appropriate CIED function.</b></li> <li>• <b>Identify and correct abnormal CIED behavior.</b></li> <li>• <b>Maximize pulse generator longevity while maintaining patient safety.</b></li> <li>• <b>Identify CIEDs approaching end of battery life, to identify leads at risk of failure, and to organize CIED replacement in a non-emergent manner.</b></li> </ul>
<b>Disease related</b>	<ul style="list-style-type: none"> <li>• <b>Documented the nature and frequency of arrhythmias over time and correlate with patient symptoms and determine the appropriateness of CIED response to these arrhythmias.</b></li> <li>• <b>Documented hemodynamic status, transthoracic impedance, patient activity and other physiologic parameter over time as part of chronic disease monitoring in heart failure.</b></li> <li>• <b>Monitor response to therapy.</b></li> </ul>
<b>Communication</b>	<ul style="list-style-type: none"> <li>• <b>Maintain a patient database.</b></li> <li>• <b>Timely documentation to the patient and relevant health care providers of CIED and disease related information.</b></li> <li>• <b>Provide technical expertise and education to colleagues, patients and community.</b></li> </ul>

These follow-up sessions must be conducted with a certain frequency, as shown in table 4. As noted in the table, it is also the possibility to perform a CEID follow-up with remote monitoring (Telemonitoring).

Table 4. Minimum frequency of CIEDs control (HRS_ERA Expert Consensus of CIEDs)	
Type of CIEDs	
Pacemakers/ICDs/CRT	<ul style="list-style-type: none"> <li>• Within 72 hours of CIED implantation (In Person).</li> <li>• 2-12 weeks post implantation (In Person).</li> <li>• Every 3-12 months pacemaker/CRT-P (In Person or Remote).</li> <li>• Every 3-6 months ICD/CRT-D (In Person or Remote).</li> <li>• Annually until battery depletion (In Person).</li> <li>• Every 1-3 months at signs of battery depletion (In Person or Remote).</li> </ul>
Implantable loop recorder	<ul style="list-style-type: none"> <li>• Every 1-6 months depending on patient symptoms and indication (In Person or Remote).</li> </ul>

**TELEMONITORING**

Telemonitoring is a system which transmits the information contained in the device to a secure server so that the medical centre can monitor this information remotely.

This means that, with telemonitoring, remote follow-ups may be conducted:

- When the medical team considers it necessary
- Automatically, when an alert is triggered



Figure5. Telemonitoring system diagram (UC200801131 ES, © Medtronic 2007)

**3.2 Patient Feedback**

Basically, Patient Feedback mechanisms are described in D5.3.1 “Patient Feedback Mechanisms for the PHR”. This section summaries those issues which are of relevance for patient education. Patient feedback mechanisms include features that should either be integrated into the PHR system or made available via PHR interoperability services. Several social software components have identified and will be implemented:

- Support feedback and communication among patients using social software components such as forums, blogs, wikis or tagging.
- Support the exchange of patient data from and for external applications to support communications between patients and medical professionals. This interoperability is based on IHE CM Profiles.
- Extend patient profile information to include contact information of their healthcare providers

There are normally existing and established communication services and protocols to ensure patient safety and conform to established policies e.g. hospital, legal policies. The PHR system does not attempt to compete or replace those services, but offers alternatives that might be utilized during the patient-physician relationship:

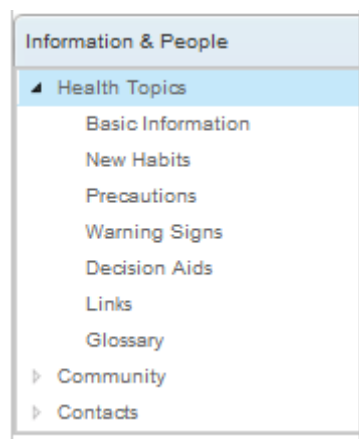
- Contact addresses and phone numbers
- Links to other educational material

Finally, it is essential to make clear that patient feedback mechanism supported by the PHR portal are NOT for medical assistance.

#### 4 USING THE EDUCATION MATERIAL WITHIN THE PHR PORTAL

Preparing information and education material for CIED patients requires expertise in the medical field in order to select the right material and to prepare answers for questions in particular for those which are frequently asked or which are essentials for CIED patients. For this reason the consortium decided to use a staging platform (a Google Site) for authoring allowing medical partners to prepare the education material independently from the PHR portal. This is imported and formatted into the PHR wiki.

The user can access the education material in the PHR portal through the menu items under “Health Topics (see Figure 4). If the information material should be modified this can easily be done by editing the PHR wiki.



**Figure 2 - Menu items for Health Topics**

The menu item “Health Topics” include several categories:

- Basic Information – answering basic questions for CIED patients (see Figure 3)
- New Habits – describing how a CIED implant may influence the patients way of living (see Figure 4)
- Precautions – indicating about what a patient should take care of (see Figure 5)
- Warning Signs – describes how to act in case of warnings and symptoms (see Figure 6)
- Useful Links – refers to external websites and information material (see Figure 8)
- Decision Aids – supports CIED patients in typical decision situations (see Figure 7)
- Glossary – explains important terms (see Figure 9)

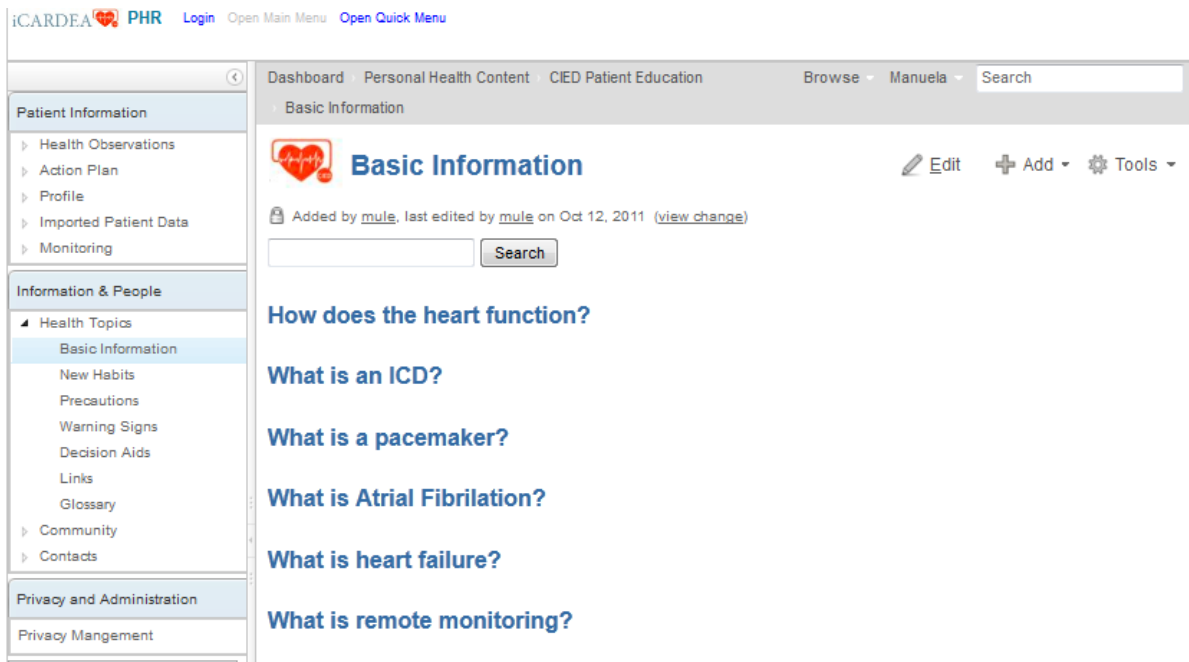


Figure 3 - Menu item "' Basic Information'

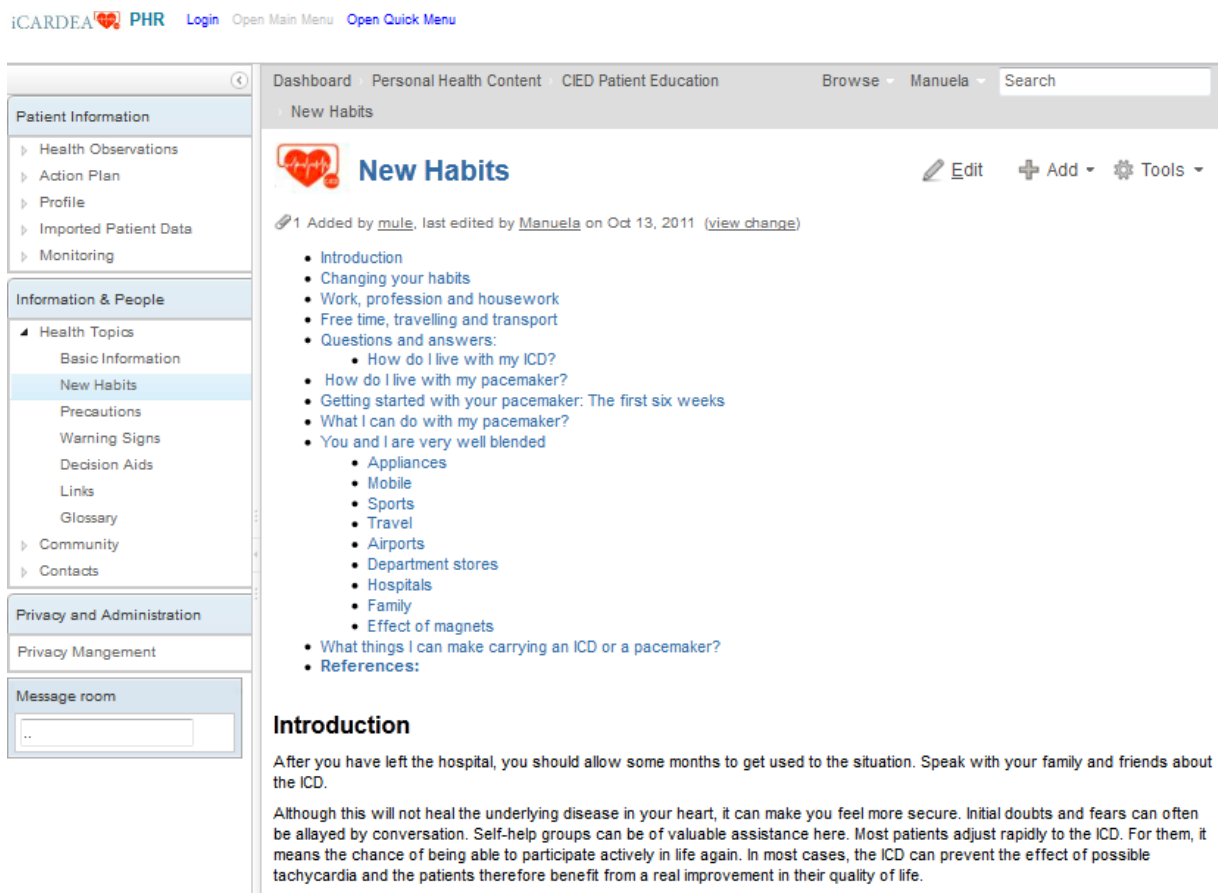


Figure 4 - Menu item "New Habits"

Dashboard Personal Health Content CIED Patient Education Browse Manuela Search

Precautions

Added by [mule](#), last edited by [Manuela](#) on Oct 13, 2011 ([view change](#))

### PRECAUTIONS

**With certain equipment, you should keep a minimum safety distance of one arm's length. These include:**

Combustion engines with sparking plugs, e.g. in lawnmowers; electrical tools, such as drills and table saws; strong magnets; ignition coils, e.g. in cars: Stereo loudspeakers; metal detectors, as in the security controls in airports Arc and resistance welding equipment; amateur and CB radio transmitters. When working at industrial plants, large generators, power stations or induction ovens, it is essential to pay attention to this warning:

**ICD wearers should check with their doctors before starting work.**

In principle, the following conditions must be met: All equipment in the plant is in good working order and properly grounded to prevent shocks; Hand-held appliances and machine shop tools should be kept at least 30 cm away from the implant site to prevent electromagnetic interference with your defibrillator; As far as possible, you should not work alone with tools that carry electrical current; All equipment must be properly grounded according to the regulations and Avoid using a power tool in the locked "on" position. This would prevent you from quickly turning off the equipment. A defibrillator can set off an alarm in security systems at airports. Do not allow yourself to be examined with the hand-held metal detector. Although the risk is very low, this equipment can temporarily interrupt the ability of your ICD to recognize arrhythmias or even cause a false alarm. Show the security men your ICD pass. They will then examine you by hand.

Figure 5 - Menu item "Precautions"

Dashboard Personal Health Content CIED Patient Education Warning Signs Browse Manuela Search

Warning Signs

Added by [mule](#), last edited by [Manuela](#) on Oct 13, 2011 ([view change](#))

- Warnings and symptoms - how to act
- How to Respond to ICD Shock
- Preparing for Shock
  - Information control
  - Action plan
- Postshock Coping
- Strategies for Coping with ICD Shock
  - Relax and Focus
  - Positive Thinking
  - Debriefing
- When should consult your cardiologist?
  - When do I get in touch with the pacemaker follow-up visit?
  - How can such incidents?
- References

**Warnings and symptoms - how to act**

If **tachycardia occurs**, the ICD will first try to stop it as gently as possible. If this is not successful, cardioversion or defibrillation will be carried out. In this case you should note the following:

- Look for a place where you can either stay comfortably seated or lie down comfortably.
- Ask someone to stay near to you, who could call an ambulance should problems arise.

Figure 6 - Menu item "Warning Signs"

**Decision Aid for Telemonitoring**

The aim of this decision aid is to help patients with a Cardiovascular Implantable Electronic Device (CIED) to decide whether or not being included in a telemonitoring system.

**Definitions**

**CIED**, Cardiovascular implantable electronic device (CIED) (from the HRS\_ERA Expert Consensus of CIEDs<sup>1</sup>): Cardiovascular implantable electronic devices include the pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization device (CRT), implantable loop recorder (ILR) and implantable cardiovascular monitor (ICM). PM, ICD and CRT devices have been described in detail in the google site and will be implemented in the PHR and all of these devices collectively have been termed cardiovascular implantable electronic devices (CIEDs).

**Alerts:** Some CIED have alert capabilities.

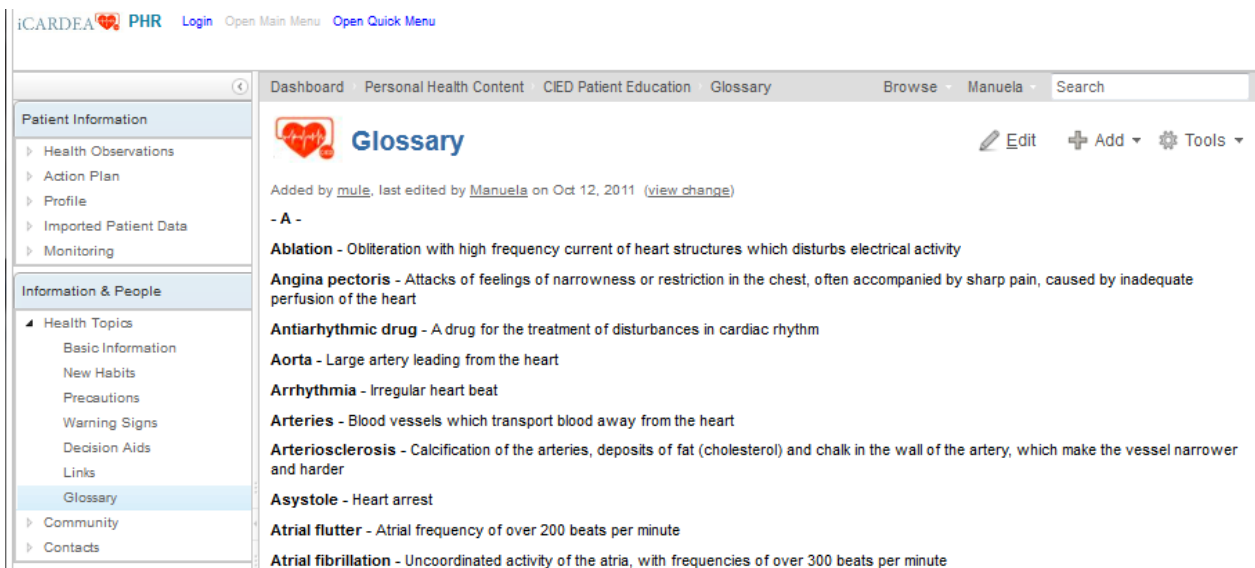
Home monitor/communicator (from the HRS\_ERA Expert Consensus of CIEDs<sup>1</sup>): A device designed to receive telemetry from a specific CIED and transmit the encrypted data using telephone technology to a remote-secure monitoring center or file server. Often the home monitor/communicator is stationary and connected to the Internet through an analog telephone line in a patient's home, but it can also be mobile/portable unit and connected via cellular technology.

Figure 7 - Menu item "Decision Aids"

**Links**

CIED	<a href="http://www.medtronic.com/your-health/bradycardia/device/what-is-it/">http://www.medtronic.com/your-health/bradycardia/device/what-is-it/</a>	Pacemaker - What is it?
CIED	<a href="http://www.nhlbi.nih.gov/health/dci/Diseases/pace/pace_all.html">http://www.nhlbi.nih.gov/health/dci/Diseases/pace/pace_all.html</a>	pacemaker
CIED	<a href="http://www.nlm.nih.gov/medlineplus/ency/article/007369.htm">http://www.nlm.nih.gov/medlineplus/ency/article/007369.htm</a>	pacemaker
CIED	<a href="http://www.americanheart.org/presenter.jhtml?identifier=4676">http://www.americanheart.org/presenter.jhtml?identifier=4676</a>	pacemaker
CIED	<a href="http://www.americanheart.org/presenter.jhtml?identifier=33">http://www.americanheart.org/presenter.jhtml?identifier=33</a>	Living with your pacemaker
CIED	<a href="http://www.medtronic.com/your-health/tachycardia/device/what-is-it/">http://www.medtronic.com/your-health/tachycardia/device/what-is-it/</a>	Implantable Cardioverter Defibrillator
CIED	<a href="http://www.nhlbi.nih.gov/health/dci/Diseases/icd/icd_what.html">http://www.nhlbi.nih.gov/health/dci/Diseases/icd/icd_what.html</a>	Implantable Cardioverter Defibrillator
CIED	<a href="http://www.nlm.nih.gov/medlineplus/ency/article/007370.htm">http://www.nlm.nih.gov/medlineplus/ency/article/007370.htm</a>	Implantable Cardioverter Defibrillator
CIED	Heart	what is an Implatable Defibrillator

Figure 8 - Menu item "Useful Links"



iCARDEA PHR Login Open Main Menu Open Quick Menu

Dashboard Personal Health Content CIED Patient Education Glossary Browse Manuela Search

**Glossary** Edit Add Tools

Added by [mule](#), last edited by [Manuela](#) on Oct 12, 2011 ([view change](#))

- A -

**Ablation** - Obliteration with high frequency current of heart structures which disturbs electrical activity

**Angina pectoris** - Attacks of feelings of narrowness or restriction in the chest, often accompanied by sharp pain, caused by inadequate perfusion of the heart

**Antiarrhythmic drug** - A drug for the treatment of disturbances in cardiac rhythm

**Aorta** - Large artery leading from the heart

**Arrhythmia** - Irregular heart beat

**Arteries** - Blood vessels which transport blood away from the heart

**Arteriosclerosis** - Calcification of the arteries, deposits of fat (cholesterol) and chalk in the wall of the artery, which make the vessel narrower and harder

**Asystole** - Heart arrest

**Atrial flutter** - Atrial frequency of over 200 beats per minute

**Atrial fibrillation** - Uncoordinated activity of the atria, with frequencies of over 300 beats per minute

**Figure 9 - Menu item "Glossary"**

## 5 CONCLUSION

In the recent years, interesting both global health and health care innovation has grown tremendously, and there has been increasing recognition of the importance of medical devices other health related technologies to all aspects of health care. Patient education is the process by which health professionals and others impart information to patients that will alter their health behaviors or improve their health status. Important elements of patient education are skill building and responsibility: patients need to know when, how, and why they need to make a lifestyle change. Group effort is equally important: each member of the patient's health care team needs to be involved. Professional health care givers have traditionally borne the responsibility for patient education. In recent time, however, patients independently have easy access to a wide range of health information. However, many patients cannot easily obtain information.

In the section of the patient education, the patient will find information related to the disease and the device and ask questions. For these we had identified and produced the relevant patient education mechanisms that will be implemented in the PHR. Both static and dynamic educative materials have already been designed and are currently being included in a Google Site. Already existing material is also facilitated through external webpage links and uploaded documents (those available for public use). Through the web, patient will be able to view this material.

These resources will likely decrease the work load on the healthcare professional's. Patient adherence is critical to the success of treatment, and ongoing patient education can help your patients understand and work with they own health, improving clinical outcomes. Being informed about one's health care options is essential to a patient's health and well-being. Especially with the increase in managed care, in which economics and efficiency is sometimes paramount, patients may be able to obtain better health care if they are knowledgeable and assertive about their needs and wishes. Informed patients may benefit, for example, by realizing they have a choice of different medications, different treatments, or what lifestyle patterns may affect their condition.