



## 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 – D4.1.1 Clinical Guideline Definitions and Flowcharts for the Follow-up of CIED Patients

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# 1 INTRODUCTION

## 1.1 Purpose

This document describes the clinical care plans developed in the pilot applications of iCARDEA Project. Basically, three care plans are developed: the first care plan is for management of patients with atrial fibrillation, the second for the management of patients with ventricular tachycardia and the third for the monitoring of the risk of technical failure of cardiovascular implantable electronic devices.

## 1.2 Scope

This document provides detailed information about the care plans developed within the scope of “Task 4.1 Adaptable Computer Interpretable Clinical Guideline Models for Executable Personalized CIED Follow-up” and will contribute to the milestone “M7 iCARDEA Personalized Adaptive Care Planner for CIED Recipients”.

## 1.3 Definitions, acronyms and abbreviations

**Table 1 List of Abbreviations and Acronyms**

<b>Abbreviation/ Acronym</b>	<b>DEFINITION</b>
CIED	Cardiovascular Implantable Electronic Device
ICD	Implantable Cardioverter Defibrillator
AF	Atrial fibrillation
VT	Ventricular tachycardia
SR	Sinus rhythm
EGM	Endocardial electrogramm
HIS	Hospital information System

# 2 OVERALL DESCRIPTION

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, stroke or sudden cardiac. Therefore, Cardiovascular Implantable Electronic Devices (CIED) have become a part of the standard therapy in patients who are at the risk of life-threatening cardiac arrhythmias.

CIED devices 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 centers, 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

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

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 Center 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 Center. 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 center 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 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

<sup>2</sup> National Institute for Clinical Excellence- England/Wales (\uppercase{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)

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 Center (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 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:

<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)

- “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 markup 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. There is also a Patient Empowerment component that aims to provide active and informed involvement of patients in management of their own health. Through the web based PHR, patients will be able to view their medical history, CIED data, and manage their medication summaries, daily nutrition information.

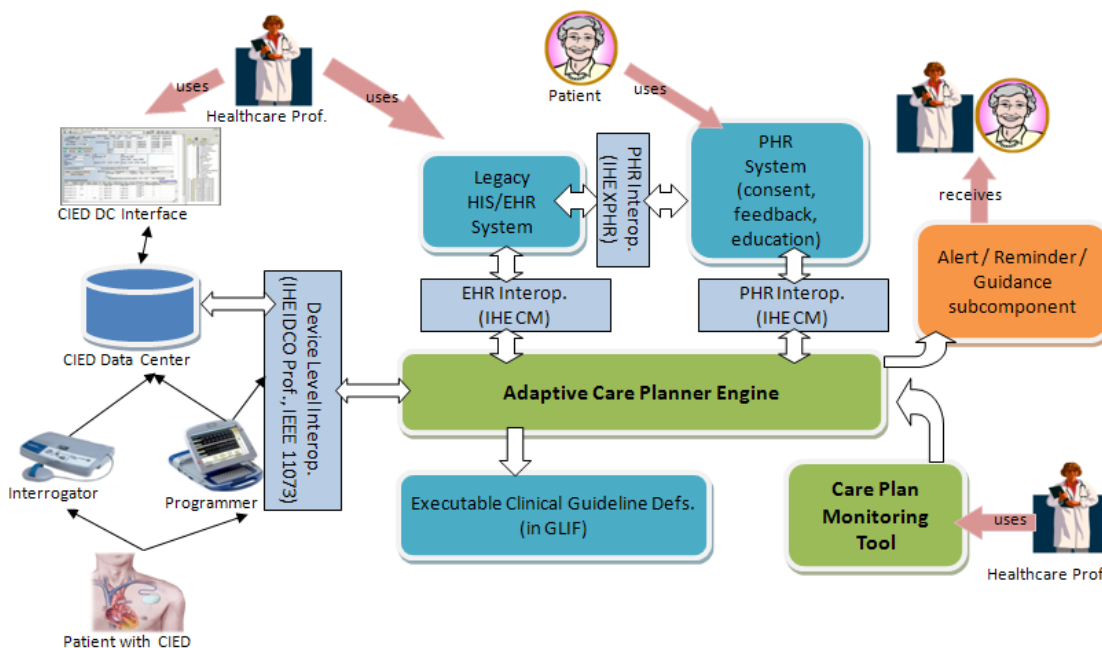


Figure 1 iCARDEA Architecture Overview

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

### 3 ICARDEA PILOT APPLICATION MEDICAL CARE PLANS

In iCARDEA Project, three care plans are developed for the pilot application:

1. AF Care plan: Management of patients with atrial fibrillation,
2. VT Care plan: Management of patients with ventricular tachycardia, and
3. Technical Care plan: Monitoring of the risk of technical failure of the cardiovascular implantable electronic devices.

In the following subsections, the care plans are described respectively. Furthermore, in the appendices the full definitions of the care plans together with their flowchart representations are presented. The information items needed for the execution of the care plans and the possible data sources from where the information items can be obtained is also provided in the appendices.

#### 3.1 Care plan for the Management of patients with atrial fibrillation

In this section, care plan defined for the management of Atrial Fibrillation (AF) is described. The care plan emphasizes the oral anticoagulation therapy for preventing thromboembolic events like stroke in patients with AF. Anticoagulation therapy is a basic point in the therapy of AF for the early recognition of this arrhythmia and its medical consequences and the remote monitoring creates an important advantage in this respect. The iCARDEA Personal Adaptive care plan engine continuously monitors the CIED patients and provides guidance to the physician for a reliable and fast decision on whether to start anticoagulation by checking the alerts provided by the CIED devices, together with the patient’s medical history, his current medications, his recent lab results, and the possible contraindications. The flowcharts of the care plan are specified based on the clinical expertise provided by the clinicians of Salzburg Clinic, and Hospital Clínic de Barcelona, and defined as a computer interpretable clinical guideline definition in GLIF.

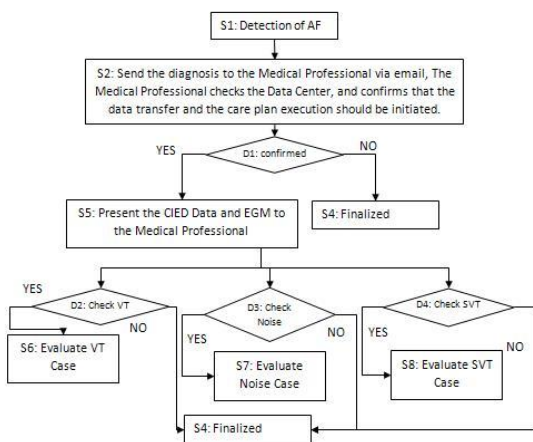


Figure 2 Triggering of the Care plan through an AF Event

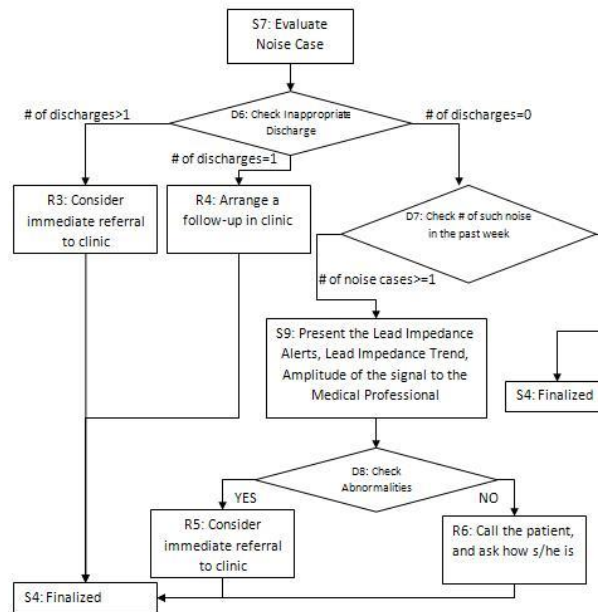


Figure 3 Evaluating the Noise Case

##### 3.1.1 Triggering of the Care Plan Execution through a CIED Event

In this example case after the CIED is implanted, the patient is sent to home, and his condition is continuously monitored through the iCARDEA system. As presented in Figure 2, the care plan is initiated whenever an AF event is detected by the CIED indicating that the AF daily burden has exceeded the specified threshold. Whenever such an event is detected, the physician is notified automatically through an SMS by the CIED system, and the physician checks the CIED Data Center Portal to see the current

measurements and the Endocardial Electrogram (EGM). If he finds it necessary, the execution of care plan is initiated. In the mean time, the recent CIED data together with Endocardial Electrogram (EGM) has already been transferred to the Adaptive Care Planner through the PCD-09 Send Observation transaction in conformance to IHE IDCO Profile as shown in Figure 4.

```

.....
PID||MODEL:XXX/SERIAL:YYY^^BSC^U~123-12-1234^^BSC^SS||DOE^JOHN||20070422153118|M||^12345-1234
PV1|1|R||||MWELBY|||||||12345
OBR|1||123456|REMOTE FOLLOW-
UP||20070422162958|20070422163006|||||||F|||||&OLSON&JANE||&ANDERSON&BOB
OBX|1|TX|514^MDC_IDC_SYS_SESSION_OBSERVATION_PRODUCER^MDC_IDC|Data Collector
123456|||||F||20070422170125|||DEV12345
OBX|2|DTM|513^MDC_IDC_SYS_SESSION_DATE_TIME^MDC_IDC|20070422170125|||||F||20070422170125|||DEV12345
OBX|3|DTM|515^MDC_IDC_SYS_SESSION_PREVIOUS_DATE_TIME^MDC_IDC|20070323170125|||||F||20070422170125|||DEV12345
OBX|4|CWE|516^MDC_IDC_SYS_SESSION_TYPE^MDC_IDC|Remote|||||F||20070422170125|||DEV12345
OBX|5|TX|257^MDC_IDC_SYS_STATUS^MDC_IDC|Normal|||||F||20070422170125|||DEV12345
.....
OBX|9|TX|1029^MDC_IDC_SYS_DEV_INFO_SERIAL_NUMBER^MDC_IDC|12345678|||||F||20070422170125|||DEV12345
OBX|10|CWE|1030^MDC_IDC_SYS_DEV_INFO_TYPE^MDC_IDC|CRT_D|||||F||20070422170125|||DEV12345
OBX|11|DTM|1025^MDC_IDC_SYS_DEV_INFO_IMPLANT_DATE^MDC_IDC|20060422170125|||||F||20070422170125|||DEV12345
.....
OBX|85|CWE|2821^MDC_IDC_SYS_DEV_EPISODE_TYPE^MDC_IDC|2|Afib|||||F||20100422170125|||DEV12370
OBX|86|TX|2820^MDC_IDC_SYS_DEV_EPISODE_IDENTIFIER^MDC_IDC|2|Afib-12345|||||F||20070422170125|||DEV12369
OBX|87|DTM|2817^MDC_IDC_SYS_DEV_EPISODE_DATE_TIME^MDC_IDC|2|20100215170125|||||F||20070422170125|||DEV12366
.....
OBX|89|NM|2819^MDC_IDC_SYS_DEV_EPISODE_DURATION^MDC_IDC|2|00:00:21|hr:min:sec|||||F||20070422170125|||DEV12368
.....
.....

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**Figure 4 An excerpt from an example PCD-09 Send Observation Message**

As an initial step, the care plan checks the computer interpretable CIED data received whether it is a “Ventricular Tachycardia case”, a “Supraventricular Tachycardia case” or it is in fact a “Noise”. All of these decisions are presented to the physician through a graphical interface to be confirmed by checking the Endocardial Electrogram (EGM) when necessary. Based on his decision, different treatment options are followed.

For example, in case of Ventricular Tachycardia (VT), the existence of appropriate discharge is controlled. If there is an appropriate discharge, the care plan recommends an immediate referral of the patient to clinic. Otherwise, it recommends to the doctor to call the patient and check his/her health status.

On the other hand, in the case of a “Noise” detection, by processing the CIED data, the care plan checks the “number of inappropriate discharges” and this is confirmed with the physician (Figure 3); if there has been several such inappropriate discharges, the care plan recommends “immediate referral to the clinic”; if there has been only one such inappropriate discharge, the care plan recommends “to arrange a follow-up in the clinic”; and if there has been no such inappropriate discharges, the care plan engine checks the occurrence of such noise cases in the past week for the abnormalities in lead impedance values, lead impedance trends and amplitude of the signal. If such abnormalities are detected, the care plan engine recommends “immediate referral to the clinic” to re-program the CIED Device.

In case of “Supraventricular Tachycardia (SVT) case”, the care plan engine evaluates the case of “Sinus Tachycardia”, “Real Supraventricular Tachycardia” and “Real AF” by also getting confirmation from the physician (Figure 5).

In the “Sinus Tachycardia” case, the existence of inappropriate discharge is controlled. If there is an inappropriate discharge, the care plan recommends a follow-up of the patient in the clinic. Otherwise, it recommends to the doctor to coordinate an urgent in person/remote or routine follow-up. On the other hand, in the “Real Supraventricular Tachycardia” case, the number of inappropriate discharges is controlled. If there is more than one inappropriate discharge, the care plan recommends an immediate referral of the patient to clinic, else if there is only inappropriate discharge is equal to 1, then a follow-up of the patient in the clinic is recommended. Otherwise (i.e. if there is no inappropriate discharge), it recommends to the doctor to coordinate an urgent in person/remote or routine follow-up.

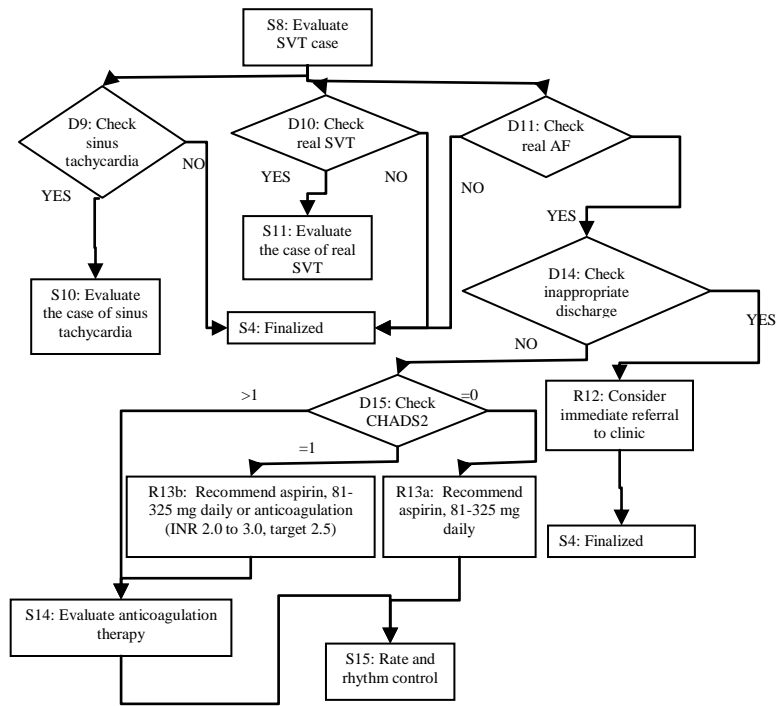


Figure 5 Evaluating the SVT Case

### 3.1.2 Accessing the Electronic Healthcare Records to Control the Flow of Action in the Care Plan

In the “Real AF” case, as shown in Figure 5, if there were no “inappropriate discharges”, the possibility of “Anticoagulation Therapy” is considered. For this decision, the care plan engine needs to access the Electronic Health Records of the patients. First of all, the CHADS2 Score of the patient is required to decide whether anticoagulation therapy is needed. The CHADS2 Score is a guideline approved risk score for thromboembolic events in patients with AF, which provides guidance to the physician about the necessity for oral anticoagulation therapy. CHADS2 is an acronym of the risk factors (Congestive heart failure, Hypertension, Age, Diabetes, Stroke in clinical history). Each risk factor is assessed with the value of one, whereas stroke is valued as 2. If the sum of these values is higher than 1, it indicates the oral anticoagulation therapy.

When the care plan is personalised for a specific patient and registered to the care plan engine, the machine processable care plan definition represented in GLIF is processed, and the clinical data that needs to be retrieved from the EHR server is identified. In our care plan, each such case is represented through a “GetDataAction” in the GLIF definition. In the “GetDataAction” definition, the required clinical data is coded both using the CDA Entry semantics (like specifying the SNOMED CT code for “Congestive Heart Failure” as “42343007”), and the CDA Section semantics (like specifying the LOINC code for “History Of Past Illness” as “11348-0”). The Adaptive care plan engine processes these definitions and creates a “PCC-09 Clinical Data Query” to be sent to the EHR Server. For instance, in the example case, the care plan engine first checks the IHE Content Module coded with the LOINC code “11348-0” which corresponds to “History of Past Illness Section” template<sup>15</sup>. This template contains a list of “Problem Concern Entry” CDA Entries, all of which must be retrieved from the EHR system. Therefore, the care plan engine creates a “Clinical Data Query” specifying the “careProvisionCode” as “PROBLIST” (as depicted in Figure 6) to retrieve the updates for “All of the Problem Concerns”.

<sup>15</sup> IHE History of Past Illness Section, <http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.8>

```

<QUPC_IN043100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
.....
<receiver typeCode="RCV">
...
</receiver>
<sender typeCode="SND">
.....
</sender>
<controlActProcess moodCode="RQO">
...
<queryByParameter>
  <statusCode code='new'/>
  <responseModalityCode code='R'/>
  <responsePriorityCode code='D'/>
  <parameterList>
    <careProvisionCode>
      <value code='PROBLIST' displayName='All Problem Concerns'
      codeSystem='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />
    </careProvisionCode>
    <patientId><value root='1.2.3.4.5.1000' extension='168760' /></patientId>
  </parameterList>
</queryByParameter>
</controlActProcess>
</QUPC_IN043100UV>

```

**Figure 6** An excerpt from a sample Care Management Data Query

As a response to this query, the clinical data source, the EHR Server in our case, presents an initial response, providing the registered Problem Concern List for this specific patient in conformance to the specified “Problem Concern” Entry Template. In Figure 7, an excerpt from a sample V3 Care Management Update is given where the history of Congestive Heart Failure is reported through a Problem Concern Entity Template<sup>16</sup>.

```

<QUPC_IN043200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
.....
<controlActProcess moodCode="EVN">
<code code='QUPC_TE043200UV' />
.....
<subject>
  <registrationEvent>
    <statusCode code='active'/>
    <custodian> ... </custodian>
    <subject2>
      <careProvisionEvent>
        <recordTarget>
          <patient>
            <id root='' extension='' />
            ...
          </patient>
        </recordTarget>
        <pertinentInformation3>
          <!-- Domain Content -->
          <act classCode='ACT' moodCode='EVN'>
            <templateId root='2.16.840.1.113883.10.20.1.27' />
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' />
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2' />
            <id root=' ' extension=' ' />
            <code nullFlavor='NA' />
            <statusCode code='completed' />
            <effectiveTime>
              <low value="20090412100000" />
              <high value="20090412150000 " />
            </effectiveTime>
            <entryRelationship type='SUBJ'>
              <observation classCode='OBS' moodCode='EVN' negationInd=' false|true ' >
                <templateId root='2.16.840.1.113883.10.20.1.28' />
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5' />
                <code code='55607006 ' displayName='Problem '
                codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT' />
                <statusCode code='completed' />
                <effectiveTime>

```

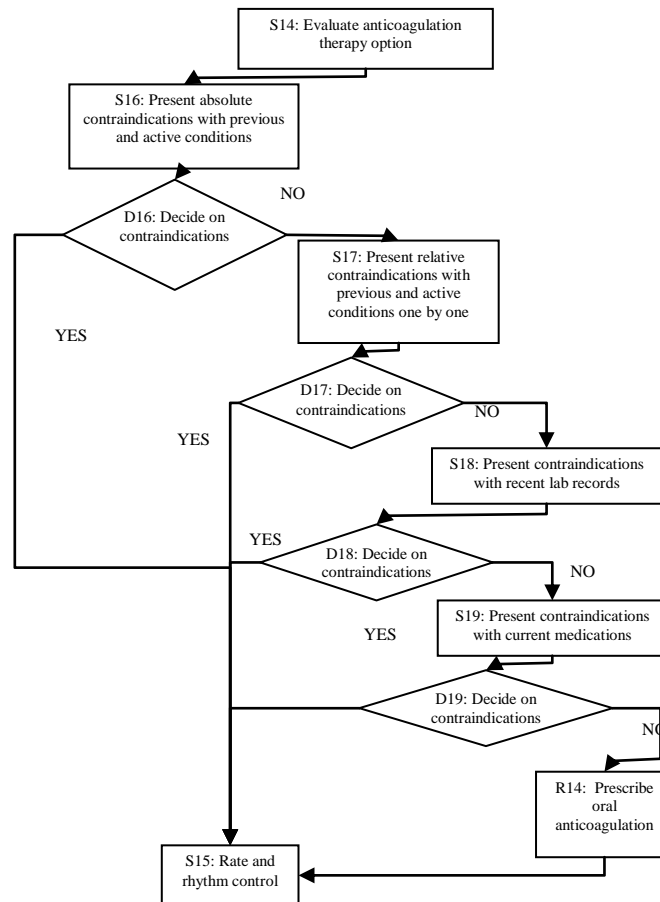
<sup>16</sup> IHE Problem Concern Entity Template, <http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.5.2>

```

        <low value="2009041210000"/>
        <high value="2009041215000 "/> </effectiveTime>
        <value xsi:type='CD' code= '42343007'
        codeSystem='2.16.840.1.113883.6.96' displayName='CHF' codeSystemName='SNOMED
        CT'>
        <originalText>The Patient had a CHF on 12.04.2009 /originalText>
        </value>
        </observation>
    </entryRelationship>
</act>
    ....
    ....
</pertinentInformation3>
</careProvisionEvent>
</subject2>
</registrationEvent>
</subject>
<queryAck>
    ....
</queryAck>
</controlActProcess>
</QUPC_IN043200UV>
    
```

**Figure 7 An excerpt from a sample V3 Care Management Update**

In this way, the adaptive care plan engine is kept up to date regarding the historical and current clinical problems of the patient. Whenever such “PCC V3 Care Management Update” messages are received, these are processed and stored in the database of the Care Plan Engine to be retrieved when the care plan is executed.



**Figure 8 Checking Contraindications for Anticoagulation Therapy**

After retrieving the problem concern entries from the EHR system as mentioned, the CHADS2 score is calculated, if it is greater than 1, the Care Plan Engine checks if it is appropriate to prescribe anticoagulation drugs for this particular patient. For this purpose, the contraindications of anticoagulation drugs with the previous and active conditions of the patient, with his active medications, and recent lab results need to be

checked (Figure 8). For example, prescribing anticoagulation drugs for patients with “Gastrointestinal bleeding” problem is not recommendable. Likewise, if in a recent lab result, “erythrocyte count” is out of specified thresholds indicating probable “Blood dyscrasia” problem, it would not be appropriate to prescribe anticoagulation therapy. Finally there are certain drug families such as “Hepatotoxic Drugs” which may be responsible for increased response to anticoagulation drugs, and if the patient is already on such medications, the prescription of anticoagulation drugs should not be considered. All such cases are coded into the guideline while it is being developed to be checked and during guideline execution, the required data is retrieved by subscribing to the EHR server through the “PCC-09 Care Management Data Query”. For this case, the careProvisionCode in the subscription request is specified as PROBLIST for problem concern list, as LABCAT for the lab results and as CURMEDLIST for the active medications. As a response, respective “PCC-10 V3 Care Management Update” messages are received and recorded by the care plan engine.

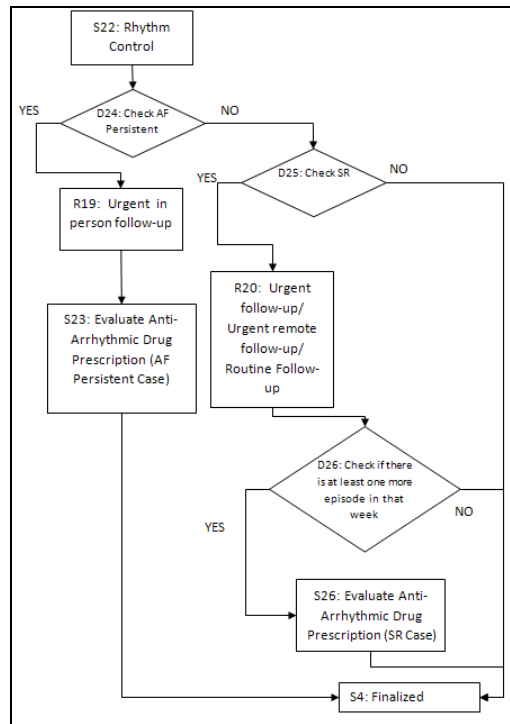
### 3.1.3 Recommendations and Consultations with the physician

As mentioned in the previous section, the care plan engine checks the contraindications by accessing the EHR of the patient based on the guideline specified in the care plan and if no such contraindication is encountered, the care plan engine presents the “Anticoagulation Drug Prescription” recommendation to the physician through a graphical interface. This interface provides detailed information to the physician about the execution steps of the care plan: patient’s initial diagnosis, information about the implanted device, and the link to the previous remote follow-up reports. Then, information about the triggering event for the care plan execution is presented by allowing the physician to check the Endocardial Electrogram and also the reports generated by the CIED devices about this triggering event. Brief information about care plan execution steps are provided, and a link is given to a graphical monitoring tool which shows the care plan workflow graphically where it is also possible to see the results of each decision step, such as the retrieved EHRs, and the lab results.

If CHADS2 Score is less than 1, then the care plan engine recommends “Prescription of 81-325 mg Aspirin daily”. If CHADS2 Score is equal to 1, either Anticoagulation therapy evaluation or Aspirin prescription can be chosen by physician. The care plan then continues with evaluating possible treatment options for “Heart Rate Problems”. The care plan engine checks the recently reported CIED data to evaluate the status of “AF Normofrequent”, “AF Bradycardia” and “AF Tachycardia”. If there is “AF Normofrequent”, then the Care Plan Engine enables the physician to access the patient’s latest CIED reports, EHRs and recommends “to coordinate an urgent in person/remote or routine follow-up” depending on the symptoms, the duration of the arrhythmia, the concomitant comorbidities and the medications of the patient. Likewise, if there is “AF Bradycardia” then the Care Plan Engine recommends “immediate referral to clinic” for reprogramming the device. If there is “AF Tachycardia” then the Care Plan Engine recommends “immediate referral to clinic” for reprogramming the device, and also provides guidance on the possible rate control drug prescription. If the patient does not have an active lifestyle, Digitalis is recommended. Otherwise, the patient’s associated diseases are controlled. If the patient has no associated disease or if s/he has hypertension, prescription of  $\beta$ -blocker Diltiazem Verapamil Digitalis is recommended. If the patient has history of heart failure, prescription of  $\beta$ -blocker Digitalis is recommended. If the patient has chronic obstructive pulmonary disease (COPD), prescription of Diltiazem Verapamil Digitalis  $\beta$ 1-selective blockers is recommended. Guidance on possible doses and major side effects is also presented to the physician.

After that, the care plan engine provides guidance to the physician to evaluate possible actions and therapies for Heart Rhythm problems, such as prescribing “Anti-Arrhythmic Drugs” after checking the current condition of the patient and possible contra-indications.

In this respect, (Figure 9) the care plan checks the “AF Persistent” parameter. If there is, an urgent in-person follow-up is recommended and then “Anti-Arrhythmic Drug Prescription for AF Persistent” case is evaluated by the care plan; else the sinus rhythm (SR) is controlled by examining the EGM of the patient. If there is an SR case, the care plan recommends “to coordinate an urgent in person/remote or routine follow-up” and if there is more than one such episodes in that week, “Anti-Arrhythmic Drug Prescription for SR” case is evaluated.



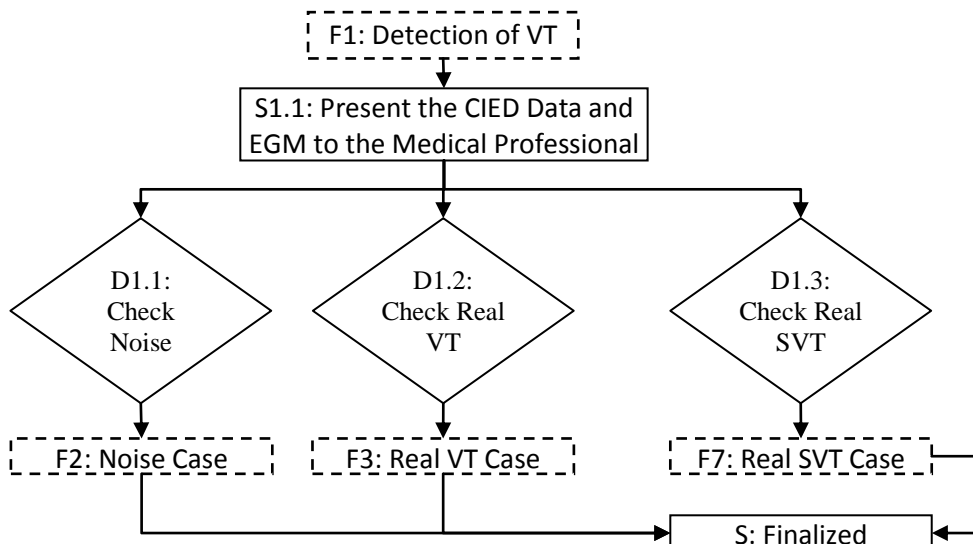
**Figure 9 Rhythm Control**

In the “Anti-Arrhythmic Drug Prescription for AF Persistent” case, suitable drugs are recommended according to the the duration of the atrial fibrillation. These drugs are presented in the “Flowchart 14” part of Appendix I.

It should be noted that all the decisions by the care plan engine need the physician’s approval.

### 3.2 Care plan for the Management of patients with ventricular tachycardia

In this section, care plan defined for the management of Ventricular Tachycardia (VT) is described.



**Figure 10 VT Care plan**

As shown in Figure 10, the care plan starts with detection of a VT event by the CIED device. An email is sent to the Medical Professional. S/he will check the Data Center to look at the alert. Then the Medical Professional decides whether to initiate the data transfer in order to run the care plan. If so, the CIED data

(along with the EGM) is transferred to the clinic; the CIED Data Exposure Service sends the data to the Care plan Engine and the care plan is started. After that, the Medical Professional examines the CIED data and the EGM of the patient. By examining the CIED data and EGM, the Medical Professional decides whether there is Noise, Real VT and Real SVT. If the Medical Professional decides that there is Noise, s/he basically checks electrode dysfunction, extern disturbances, impedance, trends and amplitude parameters (Flowchart 2). If the case is Real VT, then the Medical Professional controls the number of episodes within 24 hours and the care plan engine guides the Medical Professional whether the case is single/rare episode case or frequent episode case (Flowchart 3). Finally, if it is a Real SVT case, the Medical Professional checks the number of inappropriate discharges and then arranges a date and time for a follow-up according to the recommendations (Flowchart 7). All the flowcharts of this care plan are presented in Appendix II.

### 3.3 Care plan for the Monitoring of the risk of technical failure with cardiovascular implantable electronic devices

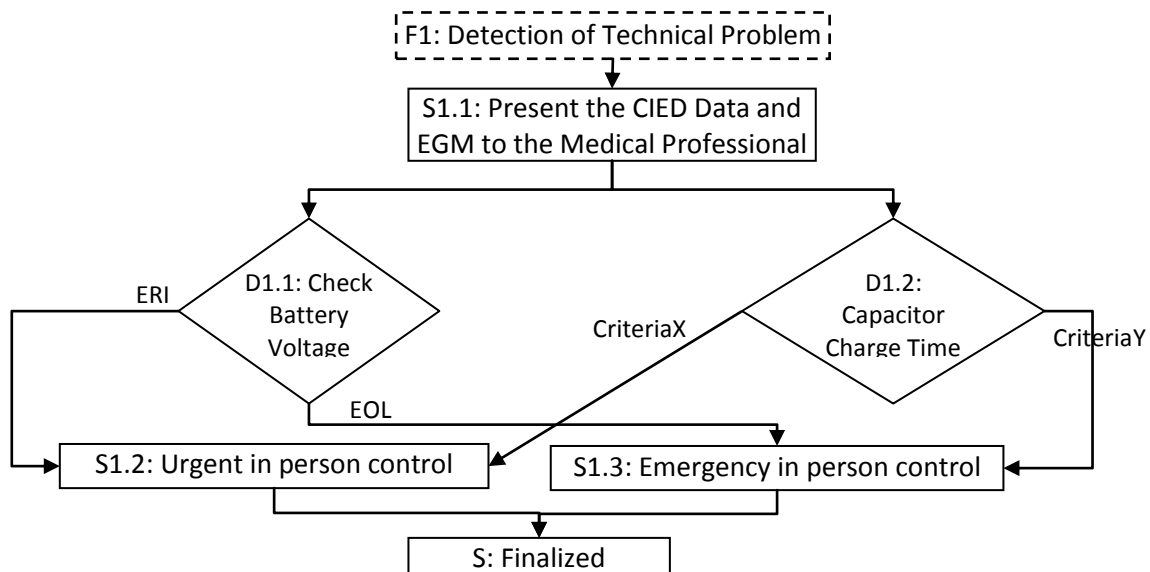
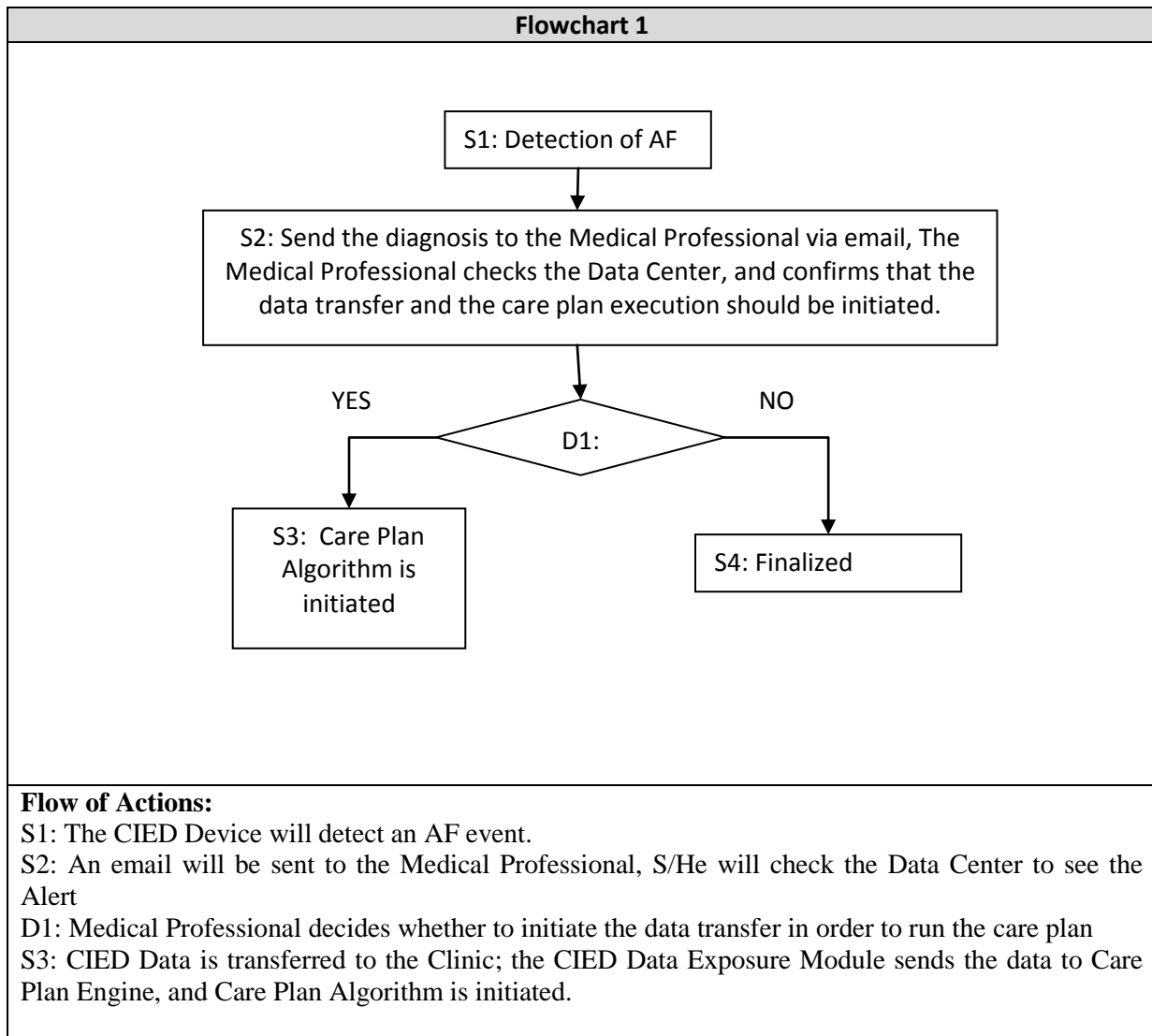
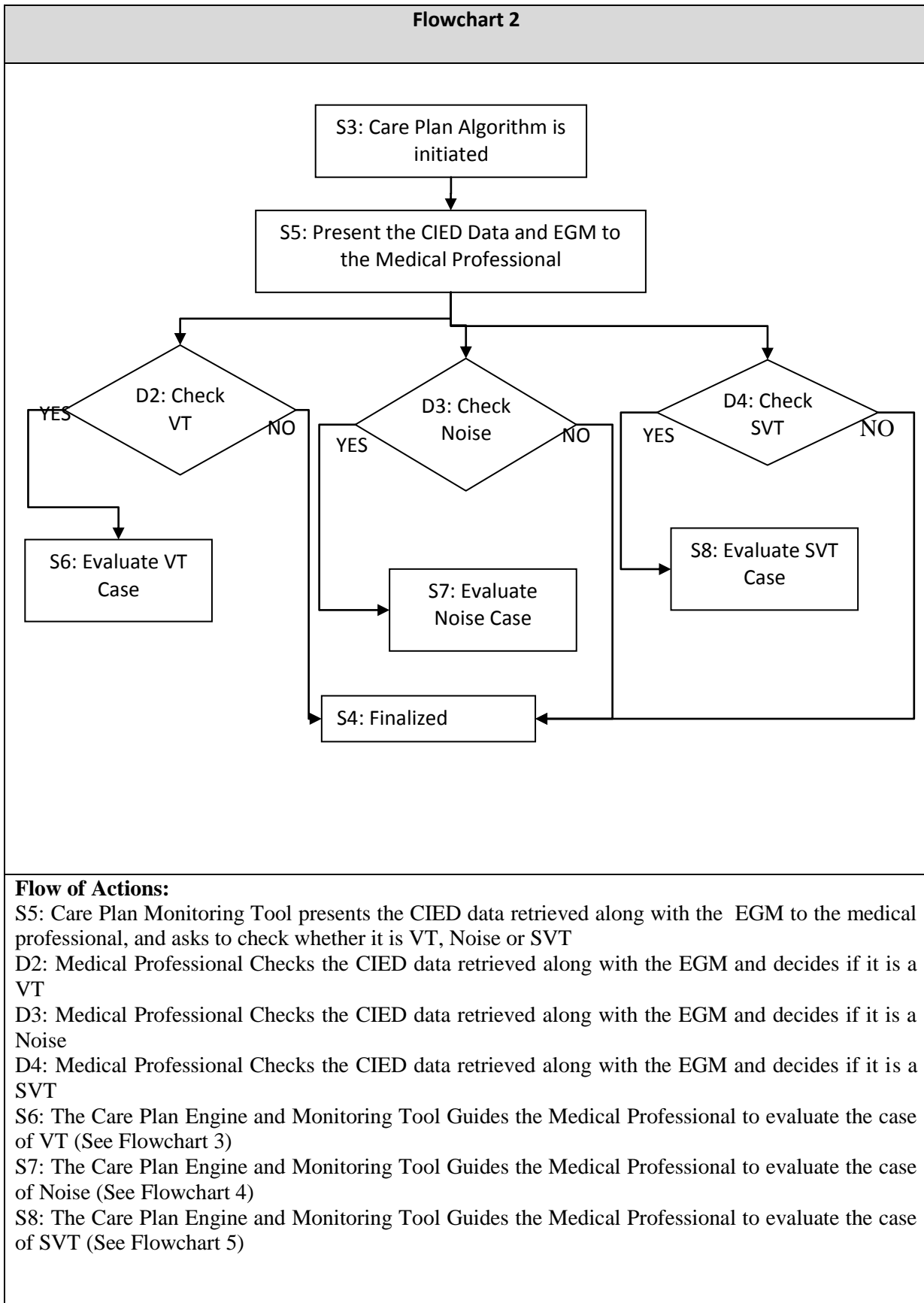


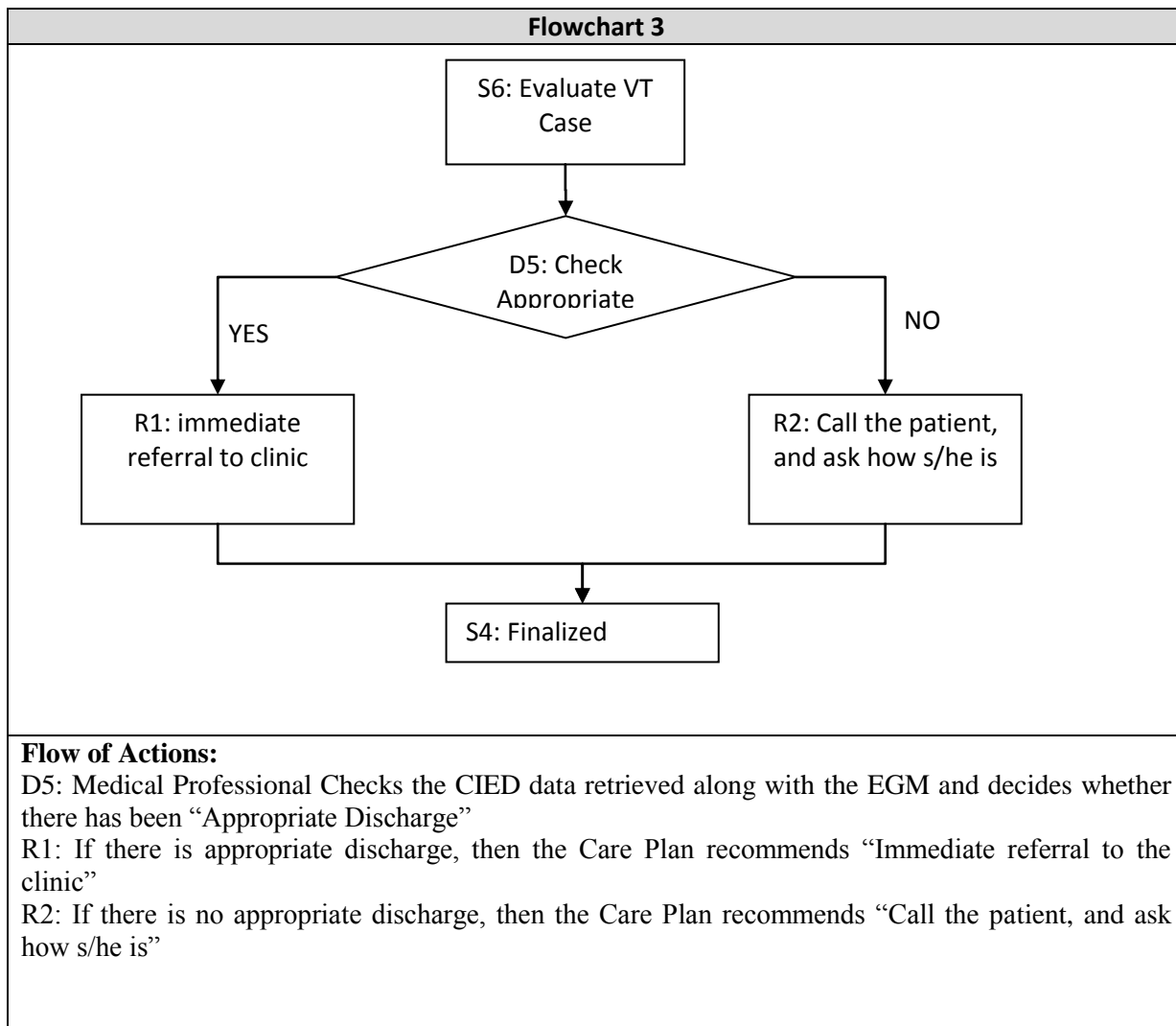
Figure 11 Technical care plan

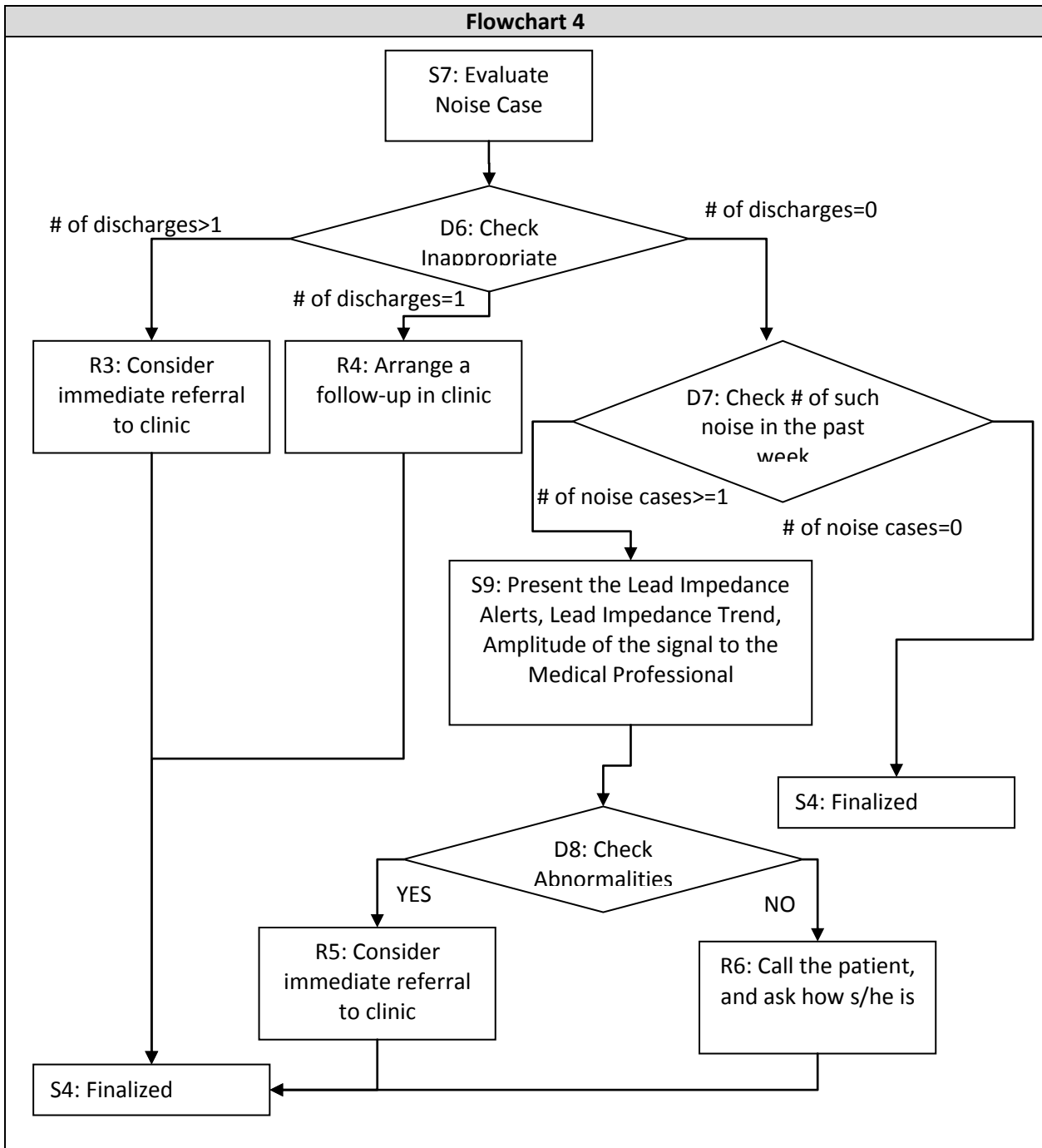
As shown in Figure 11, the care plan starts with the detection of a technical problem event by the CIED Device. An email is sent to the Medical Professional. S/he will check the Data Center to look at the alert. Then the Medical Professional decides whether to initiate the data transfer in order to run the care plan. If so, the CIED data (along with the EGM) is transferred to the clinic; the CIED Data Exposure Service sends the data to the Care plan Engine and the care plan is started. The Medical Professional logs into the Care plan Monitoring Tool and the tool presents the CIED data retrieved along with the EGM to the medical professional, and asks to check battery voltage and capacitor charge time. If the voltage is “Elective Replacement Indicator (ERI), an urgent in person control is recommended by the care plan. Otherwise, if the voltage is “End of Life (EOL) Indicator” then emergency in person control is recommended. The emergency means immediate action. In other words, the patient should go to and be seen in an emergency room immediately. On the other hand, urgent means as soon as possible; e.g. next day when the clinic is open. If the capacitor charge time is CriteriaX, an urgent in person control is recommended by the care plan. Otherwise, if it is CriteriaY then emergency in person control is recommended. The detailed flowchart of this care plan is presented in Appendix III.

## 4 APPENDIX I – AF CARE PLAN









**Flow of Actions:**

D6: Medical Professional checks the CIED data retrieved along with the EGM and decides whether there has been “Inappropriate Discharge”

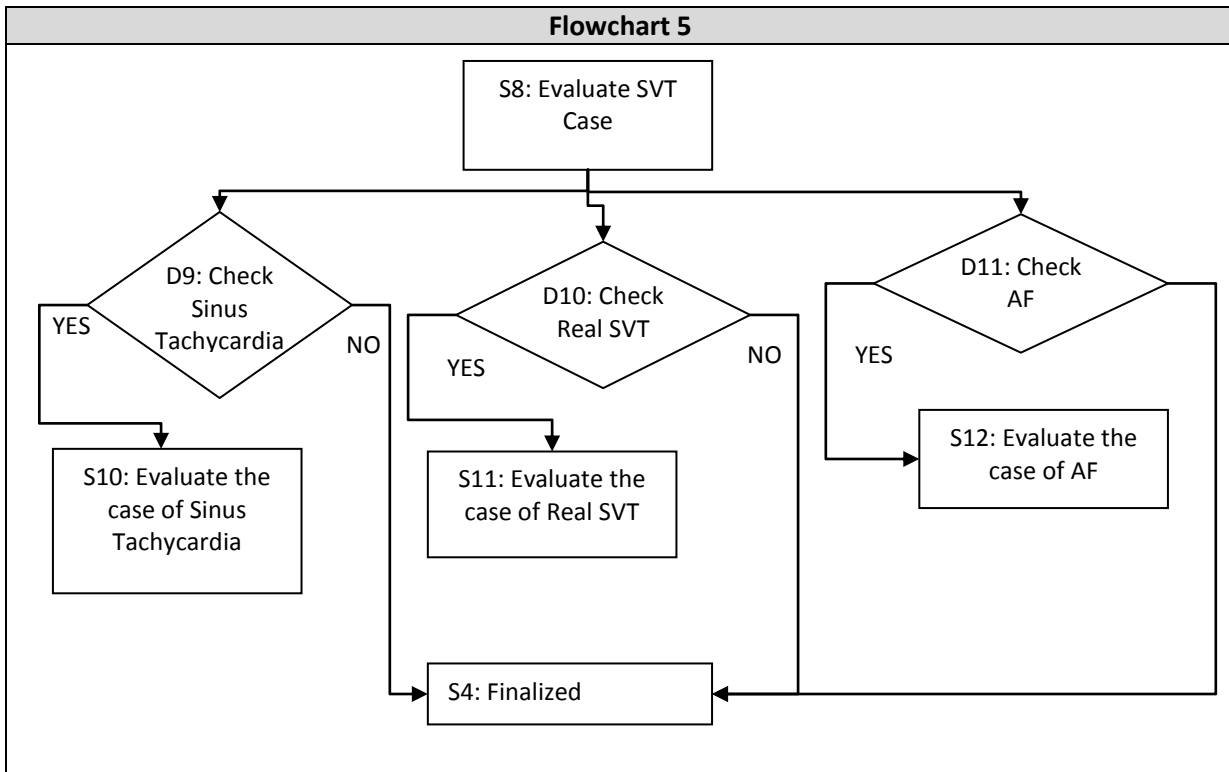
R3: If the # of Discharges is greater than 1, then the Care Plan recommends “Immediate referral to the clinic”

R4: If the # of Discharges is equal to 1, then the Care Plan recommends “Arranging a follow-up in clinic”

D7: If there is no discharge, then the care plan engine checks whether there has been other occurrences of such noise cases in the past week

S9: If there are other occurrences of such noise cases in the past week, then the care plan monitoring tool presents the recently retrieved Lead Impedance Alerts, Lead Impedance Trend report and the value of the Amplitude of signal to the Medical Professional, so that s/he can decide whether there is an abnormality

R5: If there are any abnormality, then the Care Plan recommends "Immediate referral to the clinic"  
R6: If there is no such abnormality, then the Care Plan recommends "Call the patient, and ask how s/he is"



**Flow of Actions:**

D9: Medical Professional Checks the CIED data retrieved along with the EGM and decides whether there is “Sinus Tachycardia”

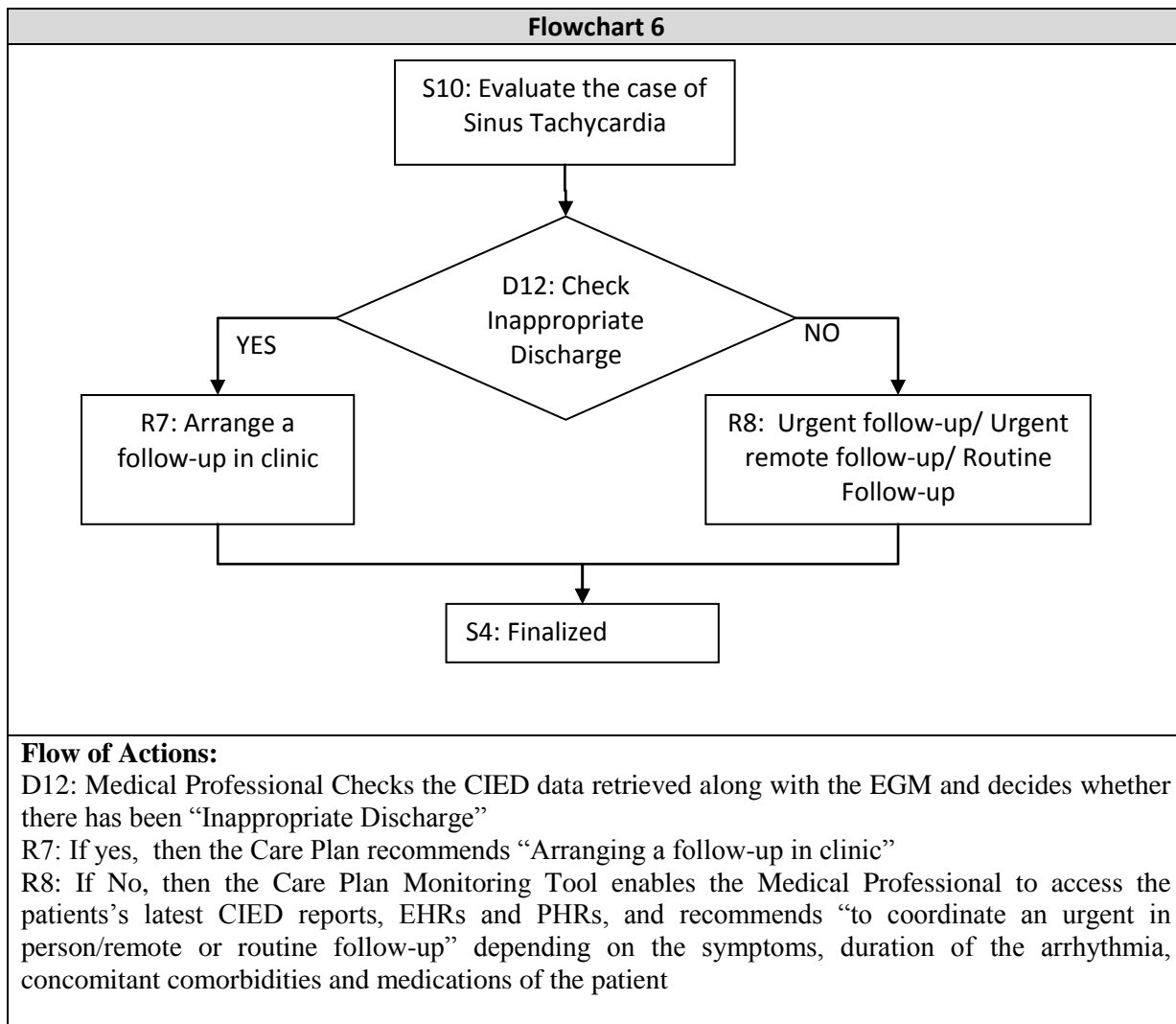
S10: The Care Plan Engine and Monitoring Tool Guides the Medical Professional to evaluate the case of Sinus Tachycardia (See Flowchart 6)

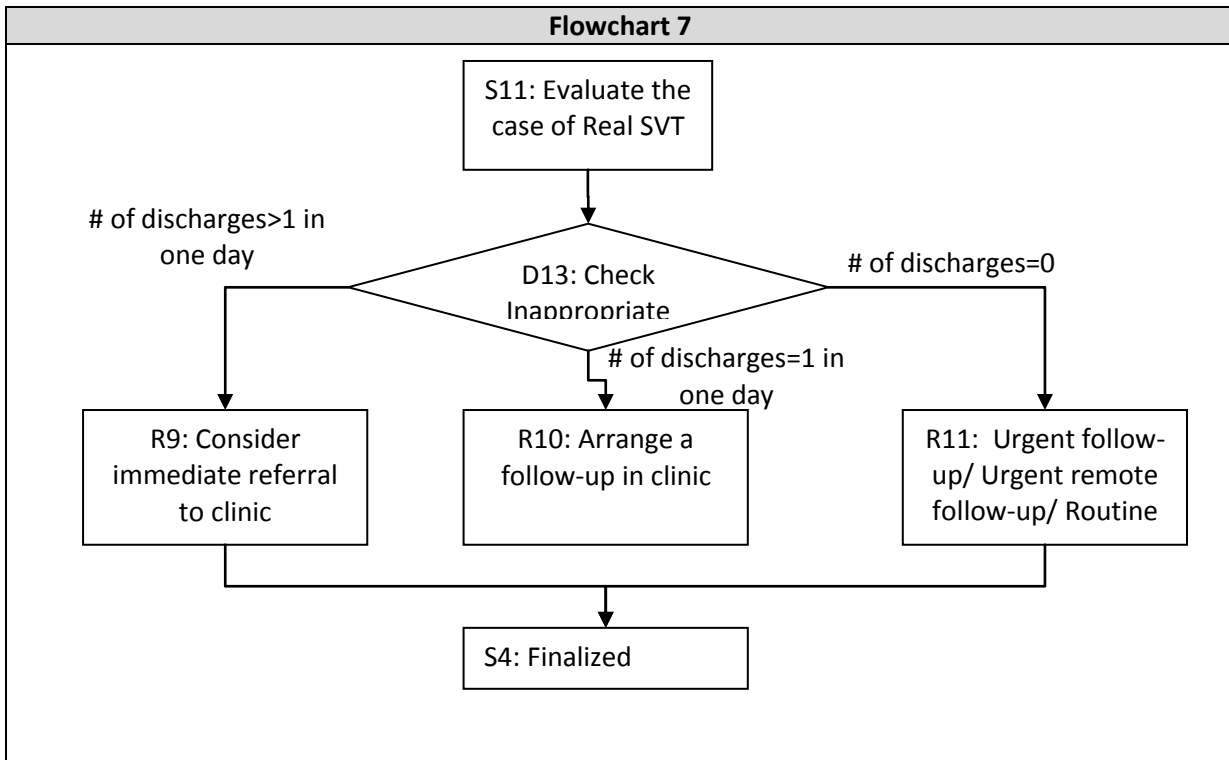
D10: Medical Professional Checks the CIED data retrieved along with the EGM and decides whether there is “Real SVT”

S11: The Care Plan Engine and Monitoring Tool Guides the Medical Professional to evaluate the case of Real SVT (See Flowchart 7)

D11: Medical Professional Checks the CIED data retrieved along with the EGM and decides whether there is “AF”

S12: The Care Plan Engine and Monitoring Tool Guides the Medical Professional to evaluate the case of AF (See Flowchart 8)





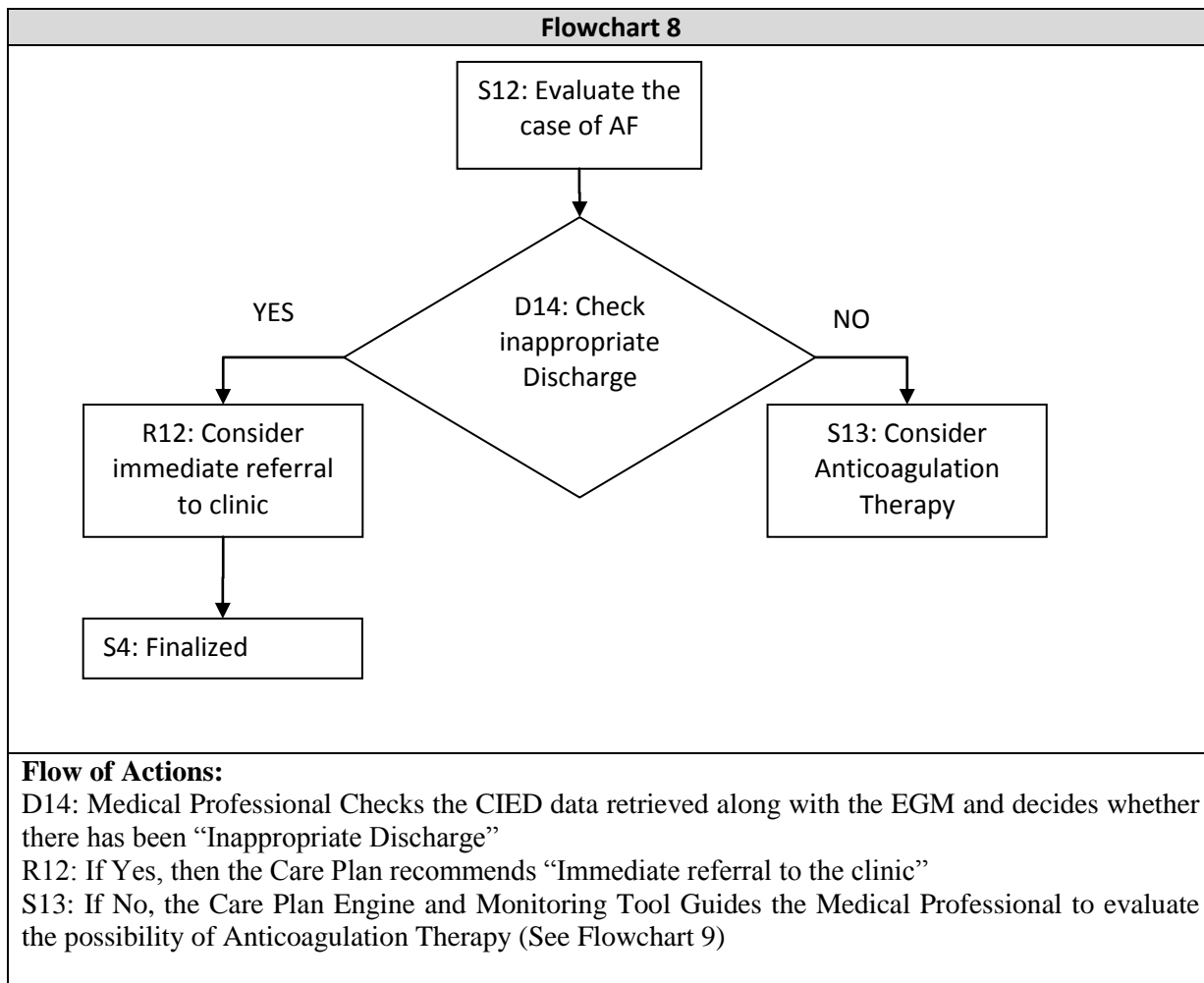
**Flow of Actions:**

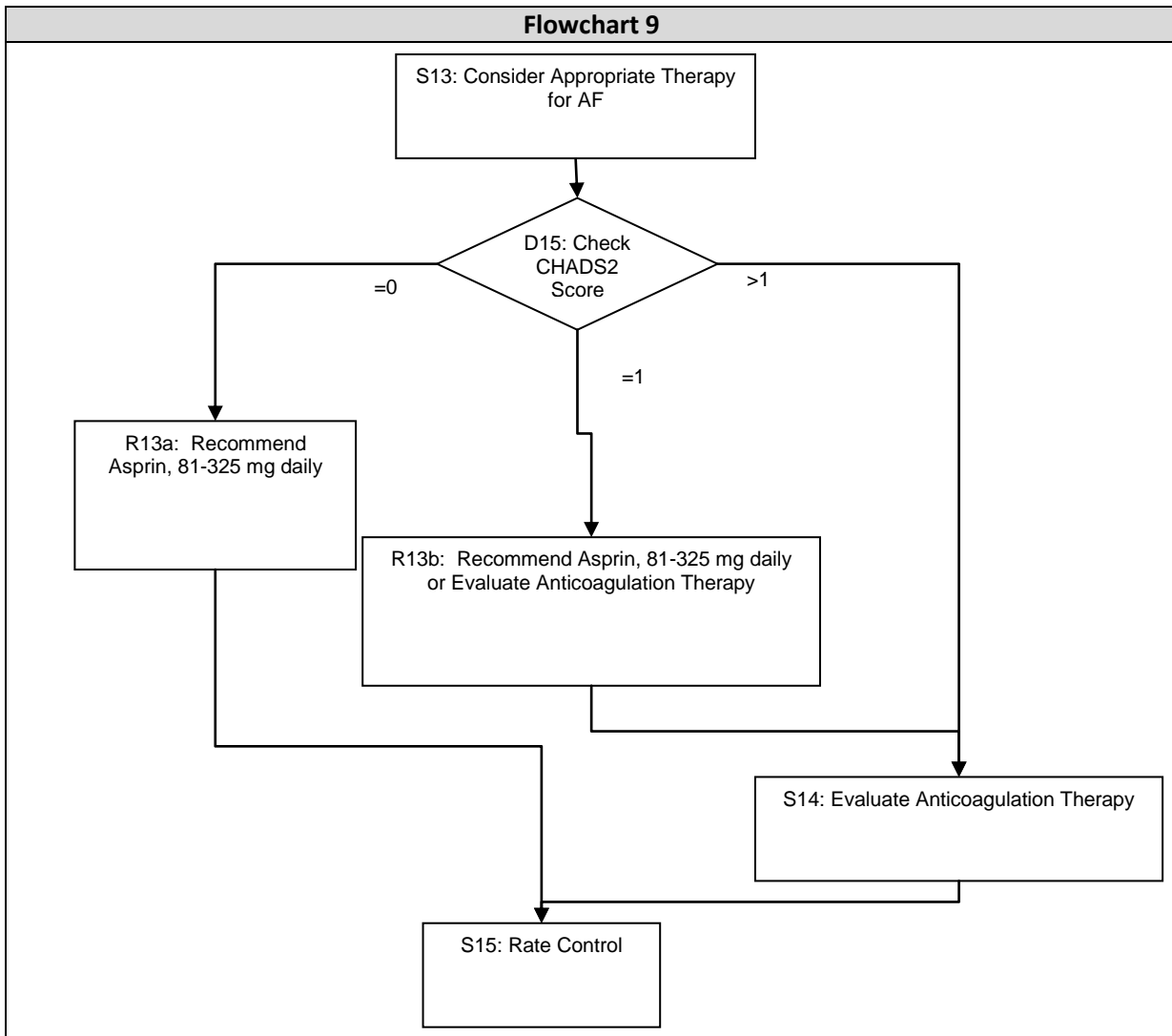
D13: Medical Professional Checks the CIED data retrieved along with the EGM and decides whether there has been “Inappropriate Discharge”

R9: If the # of Discharges is greater than 1 in that day, then the Care Plan recommends “Immediate referral to the clinic”

R10: If the # of Discharges is equal to 1, then the Care Plan recommends “Arranging a follow-up in clinic”

R11: If there is no discharge, then the Care Plan Monitoring Tool enables the Medical Professional to access the patient’s latest CIED reports, EHRs and PHRs, and recommends “to coordinate an urgent in person/remote or routine follow-up” depending on the symptoms, duration of the arrhythmia, concomitant comorbidities and medications of the patient





**Flow of Actions:**

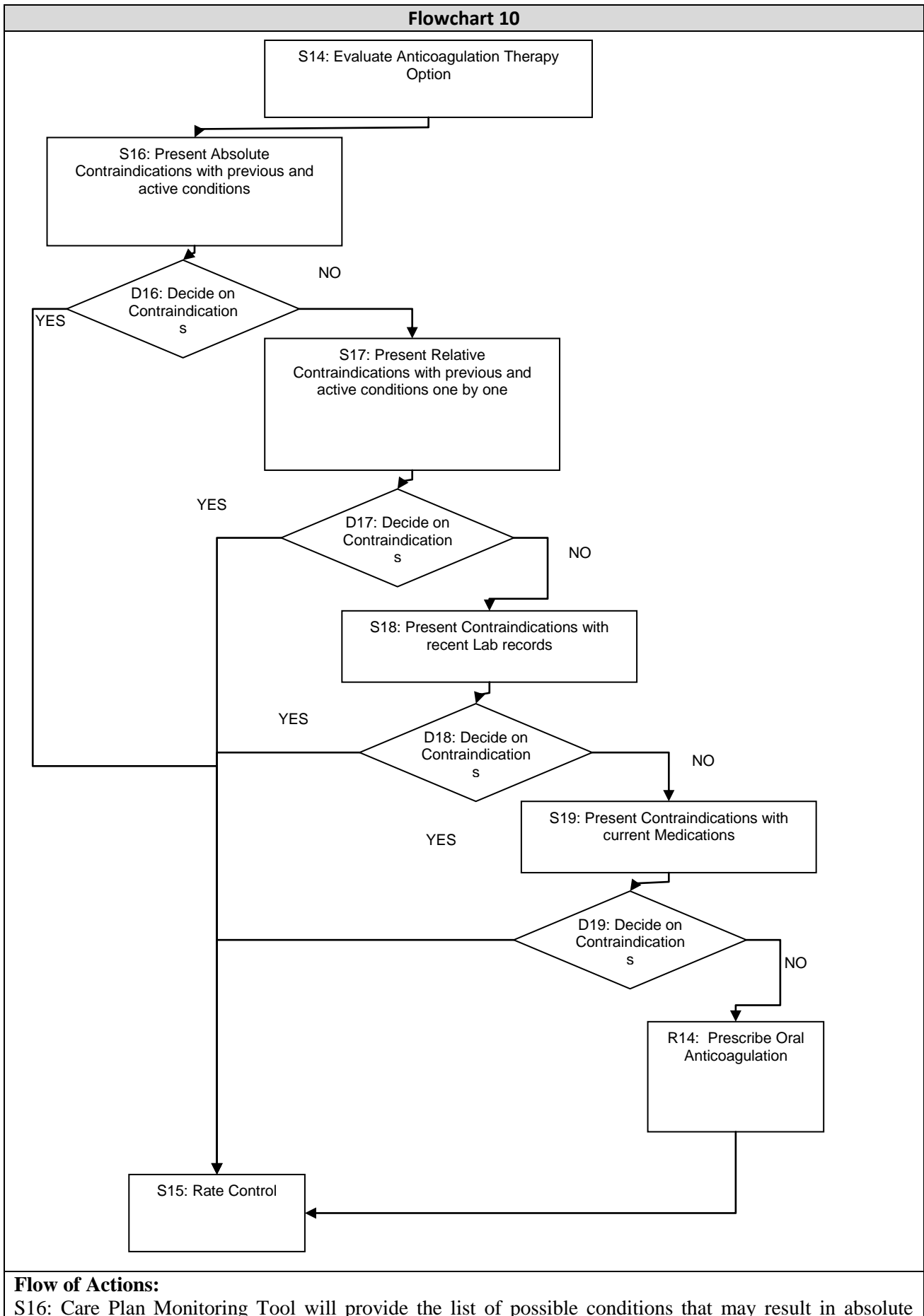
D15: Care Plan Engine Checks the History of Stroke, History of Congestive Heart Failure, History of Diabetes Mellitus, History of Hypertension, and Age of the Patient, and calculates the CHADS2 score

S14: If CHADS2 Score is greater than 1, then the Care Plan guides the Medical Professional for Evaluation the Anticoagulation Therapy Option (See Flowchart 10)

R13a: If CHADS2 score is equal to 0, care plan recommends against Oral Anticoagulation Prescription. Prescription of Aspirin , 81 to 325 mg daily is recommended.

R13b: If CHADS2 score is equal to 1, care plan recommends prescription of Aspirin , 81 to 325 mg daily or evaluating Anticoagulation Therapy (INR 2.0 to 3.0, target 2.5) (See Flowchart 11)

S15: Then the Care Plan guides the Medical Professional to evaluate Rate Control Therapy Option (See Flowchart 11)



contraindication with Anticoagulation drugs. For each of them, the EHR of the patient will be checked and if value is available, those will be presented to the Medical Professional.

D16: Based on the presented values retrieved from the EHR, and his/her knowledge of the patient, the Medical Professional decides whether there is contraindication.

The following conditions will be checked for Absolute contraindication:

ABSOLUTE CONTRAINDICATION
<ol style="list-style-type: none"> <li>1. Major bleeding in the previous six months</li> <li>2. Intracranial hemorrhage</li> <li>3. Intracranial aneurism</li> <li>4. Recent major trauma</li> <li>5. Gastrointestinal bleeding</li> <li>6. surgery performed or planned within one month</li> <li>7. Severe hepatic impairment</li> <li>8. Blood dyscrasia</li> <li>9. Severe uncontrolled hypertension</li> <li>10. Pregnancy (1<sup>st</sup> and 3<sup>rd</sup> trimester) or lactation</li> <li>11. Severe cognitive impairment (severe dementia or psychiatric disease)</li> <li>12. Severe chronic alcoholism</li> <li>13. Failure to comply</li> <li>14. Hypersensibility</li> <li>15. Patient rejection</li> </ol>

S17: If there is no absolute contraindication, The care plan monitoring tool guides the Medical Professional to check the possible relative contraindications one by one. It will also check the EHRs and PHR of the patient and if data is available, it will be presented to the Medical Professional.

D17: It is checked if any of the relative contraindications have been confirmed by the Medical Professional.

The following conditions will be checked for Relative contraindication:

RELATIVE CONTRAINDICATION
<ol style="list-style-type: none"> <li>1. Hemorrhagic retinopathy (depending on its degree it can be an absolute contraindication)</li> <li>2. Active gastroduodenal ulcer</li> <li>3. Chronic hepatic disease</li> <li>4. Active alcoholism</li> <li>4. Moderate cognitive impairment.</li> <li>5. Epilepsy</li> <li>6. Pericarditis with pericardial effusion</li> <li>7. Short life-expectancy</li> </ol>

S18: If none of the relative contraindications have been confirmed by the Medical Professional, then the Care plan Monitoring Tool will provide the list of possible recent lab results that may result in absolute contraindication with Anticoagulation drugs. These are:

- Hepatic impairment & chronic hepatic disease – GOT (AST), GPT (ALT), LDH, alk. Phosphatase, Gamma-GT
- Blood dyscrasia – Erythrocytenzahl (erythrocyte count), hämoglobin (hemoglobin) Thrombocyten (platelets), Leukocyten (leucocytes), PT, TZ, PTT, fibrinogen

The boundary values for these values are as follows:

KLINISCHE CHEMIE (ZL)		
Chlorid	97-108	mmol/l
Bicarbonat	21-28	mmol/l
Natrium	135-148	mmol/l
Kalium im Serum	3.9-5.4	mmol/l
Harnstoff	15-70	mg/dl
Kreatinin	0.5-1.1	mg/dl
eGFR		ml/min/KO
Calcium	2.13-2.63	mmol/l
Total-Protein/Serum	6.2-8.2	g/dl
Glukose	70-100	mg/dl
CRP	<0.6	mg/dl
Harnsäure	2.0-6.4	mg/dl
Phosphor	0.65-1.30	mmol/l
Magnesium	0.77-1.03	mmol/l
Bilirubin (gesamt)	0.2-1.1	mg/dl
Cholesterin	150-220	mg/dl
Triglyceride	50-200	mg/dl
HDL-Cholesterin	48-70	mg/dl
LDL-Cholesterin ber.	50-150	mg/dl
GOT (AST)	10-35	U/l
GPT (ALT)	10-35	U/l
LDH	135-225	U/l
Alk. Phosphatase	35-104	U/l
Gamma-GT	5-39	U/l
Cholinesterase	3.7-11.3	U/ml
Creatinkinase	26-140	U/l
CK-MB	<24	U/l
Eisen	60-140	µg/dl
Ferritin	14-233	µg/l
HbA-1c	3.4-6.1	%
HERZMARKER (ZL)		
Troponin I	<0.032	µg/l
Troponin T	<0.03	µg/l
GERINNUNG (ZL)		
PZ	70-130	%
TZ	14-20	Sekunde(n)
PTT	26-40	Sekunde(n)
Fibrinogen	150-450	mg/dl
HÄMATOLOGIE (ZL)		
Erythrocytenzahl	3.8-5.2	T/L
Hämoglobin	11.7-15.7	g/dl

Hämatokrit	35-47	%
MCV	83-103	fl
MCH	28.0-34.0	pg
MCHC	32.0-36.0	g/dl
Leukocyten	4.00-10.00	G/L
Thrombocyten	140-400	G/L

HARNANALYSE (ZL)		
pH im Urin	5-8	
Eiweiss im Urin		
Glukose/Urin		
Ketonkörper im Urin		
Urobilinogen im Urin		
Hämoglobin/Urin		
Nitrit im Urin		
Bilirubin im Urin		
Leukocyten im Urin		
Spez. Gewicht im Urin	1015-1035	

HARNSEDIMENT (ZL)		
Leukocyten		
Erythrocyten		
Rundepithelien		
Bakterien		

For each of them, the EHR of the patient will be checked and if value is available, those will be presented to the Medical Professional. It will be also possible to access the lab results through a link.

D18: Based on the presented values retrieved from the EHR, and his/her knowledge of the patient, the Medical Professional decides whether there is contraindication.

S19: If there is no contraindications with the recent Lab results, , then the Care plan Monitoring Tool will provide the list of possible drugs that may result in contraindication with Anticoagulation drugs. If Medical Professional is interested, for each of them, the EHR of the patient will be checked to see if the patient is using any of them and those will be presented to the Medical Professional.

The following drugs and classes of drugs will be checked:

#### Classes of drugs that may be responsible for increased response to anticoagulation

5-lipoxygenase Inhibitor	Antiplatelet Drugs/Effects	Leukotriene Receptor Antagonist
Adrenergic Stimulants, Central	Antithyroid Drugs†	Monoamine Oxidase Inhibitors
Alcohol Abuse Reduction Preparations	Beta-Adrenergic blockers	Narcotics, prolonged
Analgesics	Cholelitholytic Agents	Nonsteroidal Anti-Inflammatory Agents
Anesthetics, Inhalation	Diabetes Agents, Oral	Proton Pump Inhibitors
Antiandrogen	Diuretics†	Psychostimulants
Antiarrhythmics†	Fungal Medications,	Pyrazolones
Antibiotics†	Intravaginal, Systemic†	Salicylates
Aminoglycosides (oral)	Gastric Acidity and Peptic Ulcer Agents†	Selective Serotonin Reuptake Inhibitors
Cephalosporins, parenteral	Gastrointestinal	Steroids, Adrenocortical†
Macrolides	Prokinetic Agents	Steroids, Anabolic (17-Alkyl
Miscellaneous	Ulcerative Colitis Agents	

Penicillins, intravenous, high dose	Gout Treatment Agents	Testosterone Derivatives)
Quinolones (fluoroquinolones)	Hemorrhologic Agents	Thrombolytics
Sulfonamides, long acting	Hepatotoxic Drugs	Thyroid Drugs
Tetracyclines	Hyperglycemic Agents	Tuberculosis Agents†
Anticoagulants	Hypertensive Emergency Agents	Uricosuric Agents
Anticonvulsants†	Hypnotics†	Vaccines
Antidepressants†	Hypolipidemics†	Vitamins†
Antimalarial Agents	Bile Acid-Binding Resins†	
Antineoplastics†	Fibric Acid Derivatives	
Antiparasitic/Antimicrobials	HMG-CoA Reductase Inhibitors†	

**Specific drugs reported that may be responsible for increased response to anticoagulation**

acetaminophen	chlorpropamide	fenofibrate	levamisole	oxymetholone
alcohol†	cholestyramine†	fenoprofen	levofloxacin	pantoprazole
allopurinol	cimetidine	fluconazole	levothyroxine	paroxetine
aminosalicylic acid	ciprofloxacin	fluorouracil	liothyronine	penicillin G, intravenous
amiodarone HCl	cisapride	fluoxetine	lovastatin	pentoxifylline
argatroban	clarithromycin	flutamide	mefenamic acid	phenylbutazone
aspirin	clofibrate	fluvastatin	methimazole†	phenytoin†
atenolol	WARFARIN overdose	fluvoxamine	methyl dopa	piperacillin
atorvastatin†	cyclophosphamide†	gefitinib	methylphenidate	piroxicam
azithromycin	danazol	gemfibrozil	methylsalicylate	pravastatin†
bivalirudin	dextran	glucagon	ointment (topical)	prednisone†
capecitabine	dextrothyroxine	halothane	metronidazole	propafenone
cefamandole	diazoxide	heparin	miconazole	propoxyphene
cefazolin	diclofenac	ibuprofen	(intravaginal, oral, systemic)	propranolol
cefoperazone	dicumarol	ifosfamide	moricizine	propylthiouracil
cefotetan	diflunisal	indomethacin	hydrochloride†	quinidine
cefoxitin	disulfiram	influenza virus vaccine	nalidixic acid	quinine
ceftriaxone	doxycycline	itraconazole	naproxen	rabeprazole
celecoxib	erythromycin	ketoprofen	neomycin	ranitidine†
cerivastatin	esomeprazole	ketorolac	norfloxacin	rofecoxib
chenodiol	ethacrynic acid	lansoprazole	ofloxacin	sertraline
chloramphenicol	ezetimibe	lepirudin	olsalazine	simvastatin
chloral hydrate†			omeprazole	
			oxandrolone	
			oxaprozin	

**Classes of drugs that may be responsible for decreased response to anticoagulation**

Adrenal Cortical Steroid Inhibitors	Antithyroid Drugs†
Antacids	Barbiturates
Antianxiety Agents	Diuretics†
Antiarrhythmics†	Enteral Nutritional Supplements
Antibiotics†	Fungal Medications, Systemic†
Anticonvulsants†	Gastric Acidity and Peptic Ulcer Agents†
Antidepressants†	Hypnotics†
Antihistamines	Hypolipidemics†
Antineoplastics†	Bile Acid-Binding Resins†
Antipsychotic Medications	HMG-CoA Reductase Inhibitors†

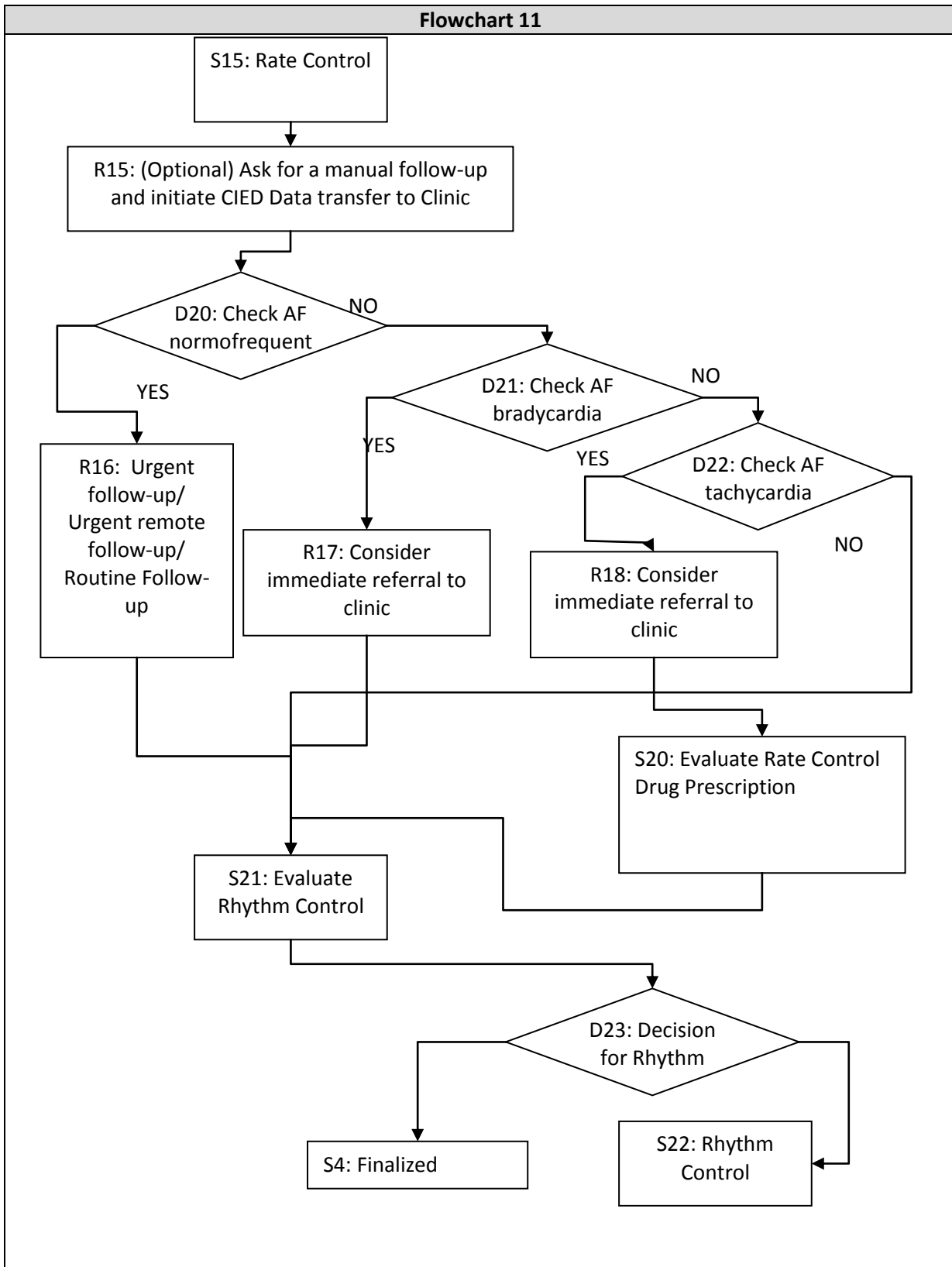
### Specific drugs reported that may be responsible for decreased response to anticoagulation

alcohol†	Warfarin under dosage	phenobarbital
aminoglutethimide	cyclophosphamide†	phenytoin†
amobarbital	dicloxacillin	pravastatin†
atorvastatin†	ethchlorvynol	prednisone†
azathioprine	glutethimide	primidone
butabarbital	griseofulvin	propylthiouracil†
butalbital	haloperidol	raloxifene
carbamazepine	meprobamate	ranitidine†
chloral hydrate†	6-mercaptopurine	rifampin
chlordiazepoxide	methimazole†	secobarbital
chlorthalidone	moricizine hydrochloride†	spironolactone
cholestyramine†	nafcillin	sucralfate
clozapine	paraldehyde	trazodone
corticotropin	pentobarbital	vitamin C (high dose)
cortisone		vitamin K

D19: Based on the presented values retrieved from the EHR, and his/her knowledge of the patient, the Medical Professional decides whether there is contraindication.

R14: The care plan recommends Oral Anticoagulation.

S15: If there is contra indication, or after Oral Anticoagulation recommendation, the Care Plan guides the Medical Professional to evaluate Rate Control Therapy Option (See Flowchart 11)



**Flow of Actions:**

R15: The Care Plan Engine recommends to ask to the patient for a manual initiation of a follow-up and initiate CIED Data transfer to Clinic. After this is achieved the most recent CIED Data is transferred to the Care Plan Engine.

D20: Care Plan Engine Checks the “AF NormoFrequent parameter”.

R16: If there is “AF NormoFrequent”, then the Care Plan Monitoring Tool enables the Medical

Professional to access the patient's latest CIED reports, EHRs and PHRs, and recommends "to coordinate an urgent in person/remote or routine follow-up" depending on the symptoms, duration of the arrhythmia, concomitant comorbidities and medications of the patient

D21: If there is no "AF NormoFrequent", then Care Plan Engine Checks the "AF Bradycardia parameter".

R17: If there is "AF Bradycardia" then the Care Plan Engine recommends "immediate referral to clinic" for reprogramming the device.

D22: If there is no "AF Bradycardia ", then Care Plan Engine Checks the "AF Tachycardia parameter".

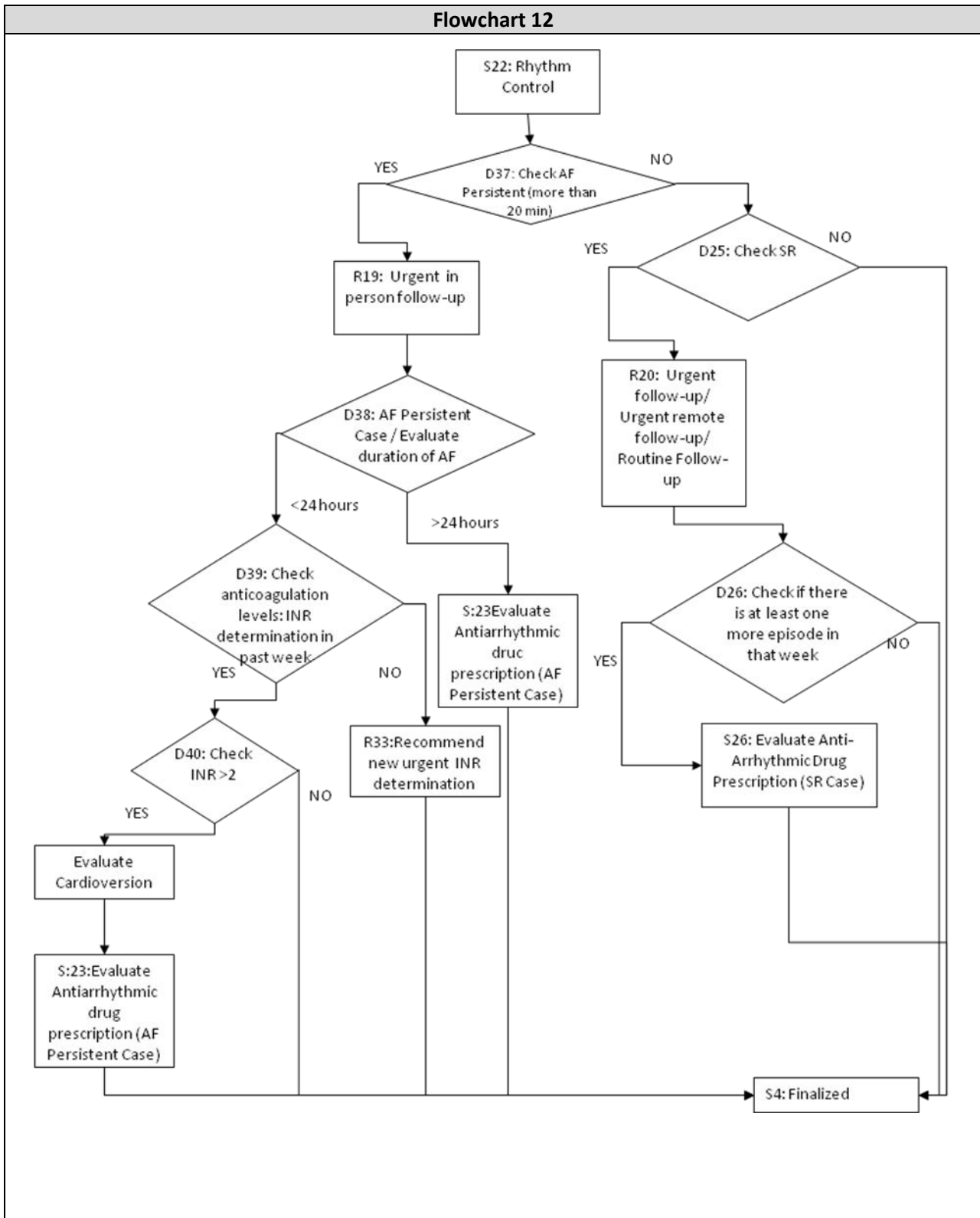
R18: If there is "AF Tachycardia" then the Care Plan Engine recommends "immediate referral to clinic" for reprogramming the device.

S20: The Care plan guides the Medical Professional for evaluation of Rate Control Drug Prescription Option (Check Flowchart 13).

S21: If there is no "AF Tachycardia", then the Care Plan Monitoring Tool will enable the Medical Professional to access the recent CIED reports, EHRs and PHRs of the patient, to be able to decide whether there is a need for "Rhythm Control".

D23: Based on the available data Medical Professional decides whether there is a need for "Rhythm Control".

S22: The Care plan guides the Medical Professional for evaluation of Rhythm Control options (Check Flowchart 12).



**Flow of Actions:**

D24: Care Plan Engine Checks the “AF Persistent parameter to see whether the duration is more than 20 minutes”.

R19: If there is “AF Persistent (i.e. duration is more than 20 minutes)”, then the Care Plan recommends “Urgent in Person Follow-up”

D38: Care Plan checks whether the duration of AF is more than 24 hours or not.

S23: If it is more than 24 hours the Care plan guides the Medical Professional for evaluation of Anti-Arrhythmic Drug Prescription Option (Check Flowchart 14).

D39: If it is less than 24 hours, it checks whether the INR determination exist in past week.

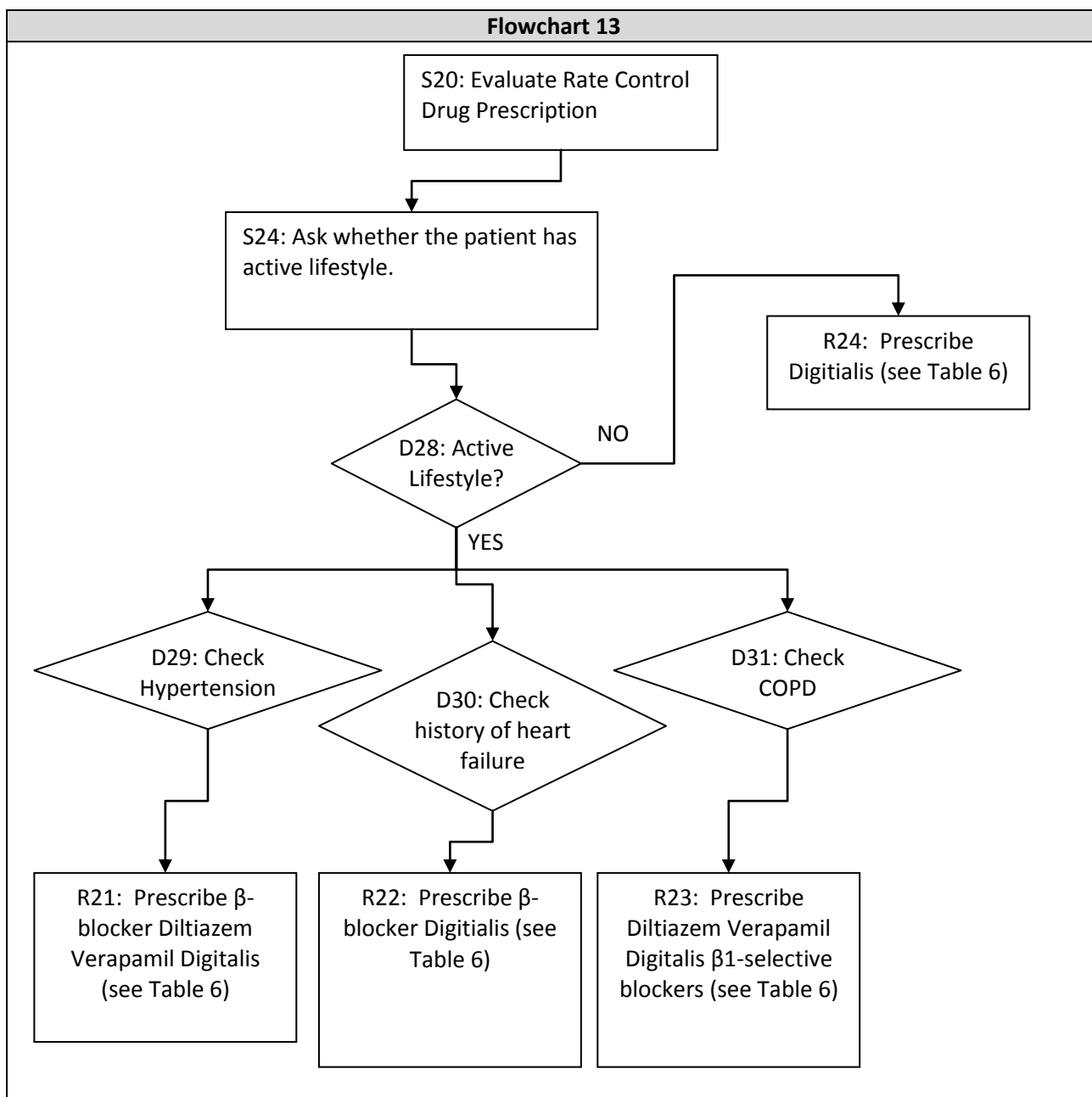
R33: If there is no INR determination in past week, Care plan recommends new urgent INR determination.

D40: If INR exists and its value is greater than 2, Care plan guides the Medical Professional for evaluation of Cardioversion.

D25: If there is no "AF Persistent", then Care Plan Engine checks the "SR".

R20: If there is "SR" then the Care Plan Monitoring Tool enables the Medical Professional to access the patient's latest CIED reports, EHRs and PHRs, and recommends "to coordinate an urgent in person/remote or routine follow-up" depending on the symptoms, duration of the arrhythmia, concomitant comorbidities and medications of the patient

D26: Care Plan Engine Checks whether there is at least one more episode in that week, if there is the care plan guides the Medical Professional for evaluation of Anti-Arrhythmic Drug Prescription Option (Check Flowchart 15).



**Flow of Actions:**

S24: Check with the physician whether the patient has an active lifestyle.

R24: If the patient does not have an active lifestyle, Digitalis is recommended as in Table 2. Otherwise, the patient's associated diseases are controlled.

D29: If the patient has no associated disease or if s/he has hypertension, prescription of  $\beta$ -blocker Diltiazem Verapamil Digitalis (as in Table 2) is recommended.

D30: If the patient has history of heart failure, prescription of  $\beta$ -blocker Digitalis (see Table 2) is recommended.

D31: If the patient has chronic obstructive pulmonary disease (COPD), prescription of Diltiazem Verapamil Digitalis  $\beta$ 1-selective blockers (as in Table 2) is recommended. Small doses of  $\beta$ 1-selective blockers may be used in COPD if rate control is not adequate with non-dihydropyridine calcium channel antagonists and digoxin. Amiodarone is also used for rate control in patients who do not respond to glycosides,

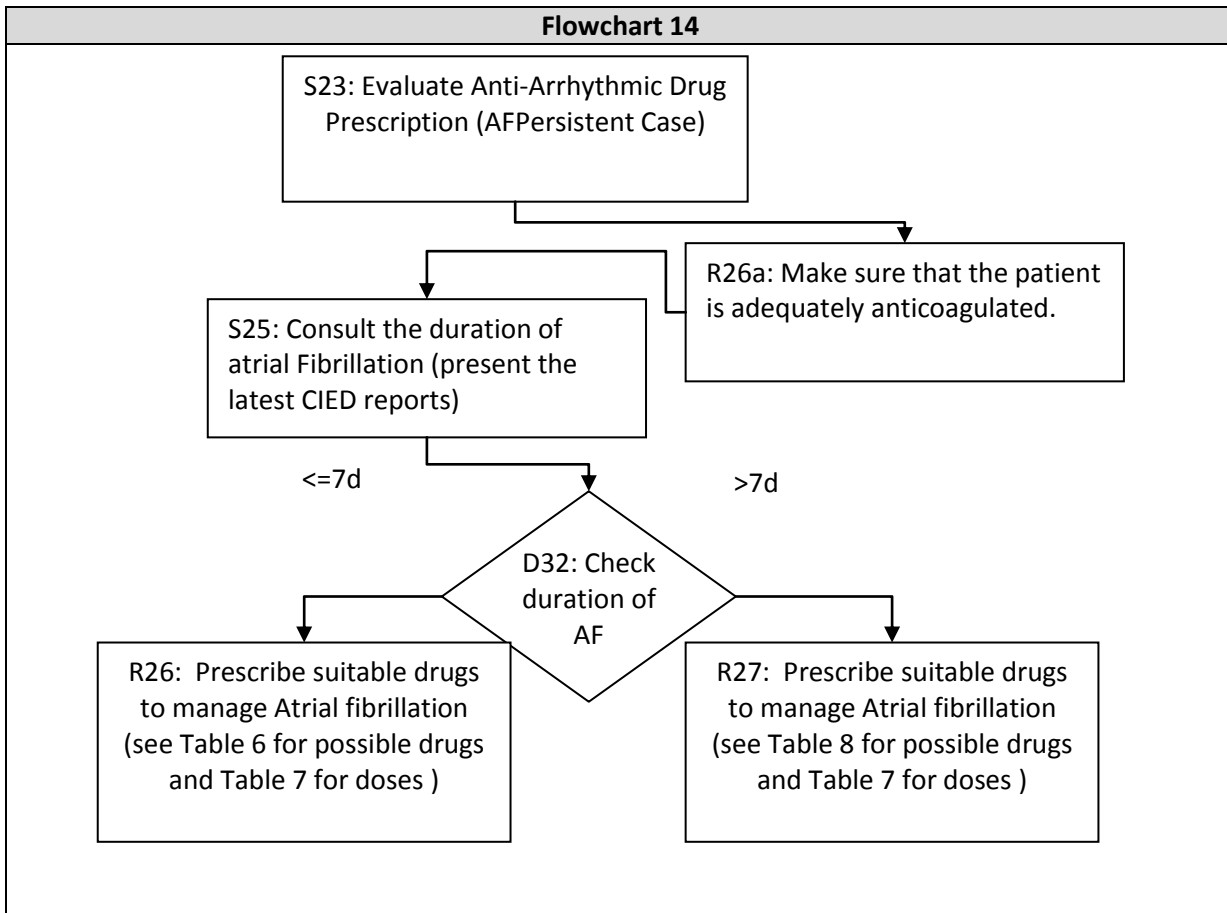
$\beta$ -blockers or non-dihydropyridine calcium antagonists. Dronedarone may also be used for rate control in patient with recurrent episodes of atrial fibrillation.

	Intravenous administration	Usual oral maintenance dose
<b><math>\beta</math>-Blockers</b>		
Metoprolol CR/XL	2.5–5 mg	100–200 mg o.d. (ER)
Bisoprolol	N/A	2.5–10 mg o.d.
Atenolol	N/A	25–100 mg o.d.
Esmolol	10 mg	N/A
Propranolol	1 mg	10–40 mg t.i.d.
Carvedilol	N/A	3.125–25 mg b.i.d.
<b>Non-dihydropyridine calcium channel antagonists</b>		
Verapamil	5 mg	40 mg b.d. to 360 mg (ER) o.d.
Diltiazem	N/A	60 mg t.d.s. to 360 mg (ER) o.d.
<b>Digitalis glycosides</b>		
Digoxin	0.5–1 mg	0.125 mg–0.5 mg o.d.
Digitoxin	0.4–0.6 mg	0.05 mg–0.1 mg o.d.
<b>Others</b>		
Amiodarone	5 mg/kg in 1 h, and 50 mg/h maintenance	100 mg–200 mg o.d.
Dronedarone <sup>a</sup>	N/A	400 mg b.i.d.

ER = extended release formulations; N/A = not applicable.

<sup>a</sup>Only in patients with non-permanent atrial fibrillation.

**Table 6**



**Flow of Actions:**

R26a: Before prescribing any anti arrhythmic drug in the case of persistent AF, send a recommendation to healthcare actor to make sure that the patient is adequately anticoagulated before starting the drug.

S25: Consult with the physician the duration of AF, allow the physician to see recent CIED reports

D32: Check the duration of AF

R26: If duration of AF is up to 7 days, then care plan suggests to prescribe drugs presented in Table 2. The doses information is also provided as specified in Table 3.

The physician is also enabled to check the recommendations about Amiodarone Monitoring (See Table 6).

R27: If duration of AF is more than 7 days, then care plan suggests to prescribe drugs presented in Table 4. The doses information is also provided as specified in Table 3.

The physician is also enabled to check the recommendations about Amiodarone Monitoring (See Table 6).

Recommendations for pharmacological cardioversion of atrial fibrillation of up to 7-d duration			
Drug <sup>a</sup>	Route of administration	Class of recommendation	Level of evidence

Agents with proven efficacy	Dofetilide	Oral	I	A
	Flecainide	Oral or	I	A
	Ibutilide	intravenous	I	A
	Propafenone	Intravenous	I	A
	Amiodarone	Oral or intravenous	IIa	A
Less effective or incompletely studied agents	Disopyramide	Intravenous	IIb	B
	Procainamide	Intravenous	IIb	B
	Quinidine	Oral	IIb	B
Should not be administered	Digoxin	Oral or	III	A
	Sotalol	intravenous Oral or intravenous	III	A
<i><sup>a</sup>The doses of medications used in these studies may not be the same as those recommended by the manufacturers. Drugs are listed alphabetically within each category of recommendation and level of evidence.</i>				

**Table 2**

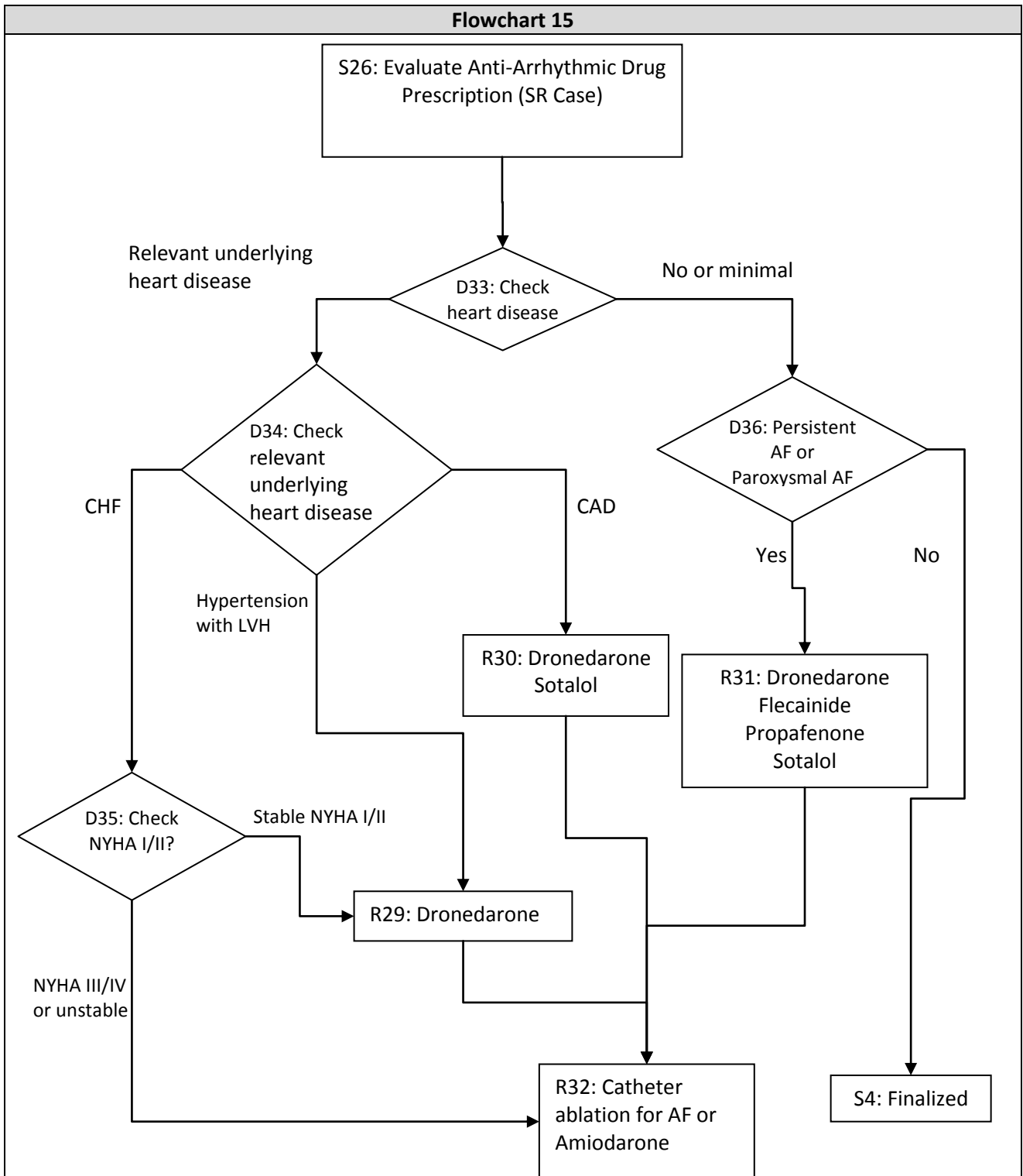
Recommended doses of drugs proven effective for pharmacological cardioversion of atrial fibrillation			
Drug <sup>a</sup>	Route of administration	Dosage <sup>b</sup>	Potential adverse effects
Amiodarone	Oral	<u>Inpatient</u> : 1.2 to 1.8 g per day in divided dose until 10 g total, then 200 to 400 mg per day maintenance or 30 mg/kg as single dose <u>Outpatient</u> : 600 to 800 mg per day divided dose until 10 g total, then 200 to 400 mg per day maintenance	Hypotension, bradycardia, QT prolongation, torsades de pointes (rare), GI upset, constipation, phlebitis (IV)
	Intravenous/oral	5 to 7 mg/kg over 30 to 60 min, then 1.2 to 1.8 g per day continuous IV or in divided oral doses until 10 g total, then 200 to 400 mg per day maintenance	
Dofetilide	Oral	Creatinine Clearance (mL/min) - Dose (mcg BID) > 60 - 500 40 to 60 - 250 20 to 40 - 125 < 20 - Contraindicated	QT prolongation, torsades de pointes; adjust dose for renal function, body size, and age
Flecainide	Oral	200 to 300 mg	Hypotension, atrial flutter with high ventricular rate
	Intravenous	1.5 to 3.0 mg/kg over 10 to 20 min <sup>c</sup>	
Ibutilide	Intravenous	1 mg over 10 min; repeat 1 mg	QT prolongation,

Propafenone	Oral	when necessary 600 mg	torsades de pointes Hypotension, atrial flutter with high ventricular rate
	Intravenous	1.5 to 2.0 mg/kg over 10 to 20 min <sup>c</sup>	
Quinidine <sup>d</sup>	Oral	0.75 to 1.5 g in divided doses over 6 to 12 h, usually with a rate-slowing drug	QT prolongation, torsades de pointes, GI upset, hypotension
<p><i>AF indicates atrial fibrillation; BID, twice a day; GI, gastrointestinal; IV, intravenous.</i></p> <p><i><sup>a</sup>Drugs are listed alphabetically.</i></p> <p><i><sup>b</sup>Dosages given in the table may differ from those recommended by the manufacturers.</i></p> <p><i><sup>c</sup>Insufficient data are available on which to base specific recommendations for the use of one loading regimen over another for patients with ischemic heart disease or impaired left ventricular function, and these drugs should be used cautiously or not at all in such patients.</i></p> <p><i><sup>d</sup>The use of quinidine loading to achieve pharmacological conversion of atrial fibrillation is controversial, and safer methods are available with the alternative agents listed in the table. Quinidine should be used with caution.</i></p>			

**Table 3**

Recommendations for pharmacological cardioversion of atrial fibrillation present for more than 7 d				
	<b>Drug<sup>a</sup></b>	<b>Route of administration</b>	<b>Class of recommendation</b>	<b>Level of evidence</b>
Agents with proven efficacy	Dofetilide	Oral	I	A
	Amiodarone	Oral or	IIa	A
	Ibutilide	intravenous Intravenous	IIa	A
Less effective or incompletely studied agents	Disopyramide	Intravenous	IIb	B
	Flecainide	Oral	IIb	B
	Procainamide	Intravenous	IIb	C
	Propafenone	Oral or	IIb	B
	Quinidine	intravenous Oral	IIb	B
Should not be administered	Digoxin	Oral or	III	B
	Sotalol	intravenous Oral or intravenous	III	B
<p><i><sup>a</sup>The doses of medications used in these studies may not be the same as those recommended by the manufacturers. Drugs are listed alphabetically within each category by class and level of evidence.</i></p>				

**Table 4**



**Flow of Actions:**

D33: Check history of Heart disease

D34: If there are relevant underlying heart diseases, check whether CHF, CAD or Hypertension with LHV exists.

D35: If there is CHF, check NYHA.

R29: If there is stable NYHA I/II or there is Hypertension with LVH, care plan suggests to prescribe Dronedaronone.

R30: If there is CAD, care plan suggests to prescribe Dronedaronone Sotalol.

D36: If there is no or minimal heart disease, check persistent or paroxysmal AF.

R31: If there is persistent or paroxysmal AF, prescription of Dronedarone, Flecainide, Propafenone and Sotalol is recommended. See Table 5 for doses.

R32: After that, Catheter Ablation for AF together with Amiodarone prescription is suggested. The physician is also enabled to check the recommendations about Amiodarone Monitoring (See Table 10)

Drug	Dose	Main contraindications and precautions	ECG features prompting lower dose or discontinuation	AV nodal slowing
Disopyramide	100–250 mg t.i.d.	Contraindicated in systolic heart failure. Caution when using concomitant therapy with QT-prolonging drugs.	QT interval >500 ms	None
Flecainide Flecainide XL	100–200 mg b.i.d. 200 mg o.d.	Contraindicated if creatinine clearance <50 mg/mL. In coronary artery disease, reduced LV ejection fraction. Caution in the presence of conduction system disease.	QRS duration increase >25% above baseline	None
Propafenone Propafenone SR	150–300 mg t.i.d. 225–425 mg b.i.d.	Contraindicated in coronary artery disease, reduced LV ejection fraction. Caution in the presence of conduction system disease and renal impairment.	QRS duration increase >25% above baseline	Slight
d,l-Sotalol	80–160 mg b.i.d.	Contraindicated in the presence of significant LV hypertrophy, systolic heart failure, pre-existing QT prolongation, hypokalaemia creatinine clearance <50 mg/mL. Moderate renal dysfunction requires careful adaptation of dose.	QT interval >500 ms	Similar to high-dose $\beta$ -blockers
Amiodarone	600 mg o.d. for 4 weeks, 400 mg o.d. for 4 weeks, then 200 mg o.d.	Caution when using concomitant therapy with QT-prolonging drugs, heart failure. Dose of vitamin K antagonists and of digtoxin/ digoxin should be reduced.	QT interval >500 ms	10–12 bpm in AF
Dronedarone	400 mg b.i.d.	Contraindicated in NYHA class III–IV or unstable heart failure, during concomitant therapy with QT-prolonging drugs, powerful CYP3A4 inhibitors, and creatinine clearance <30 mg/mL. Caution when using concomitant therapy with QT-prolonging drugs, heart failure. Dose of digtoxin/digoxin should be reduced. Elevations in serum creatinine of 0.1–0.2 mg/dL are common and do not reflect reduced renal function.	QT interval >500 ms	10–12 bpm in AF

AF = atrial fibrillation; AV = atrioventricular; bpm = beats per minute; CYP = cytochrome P; ECG = electrocardiogram; LV = left ventricular; NYHA = New York Heart Association.

**Table 5**

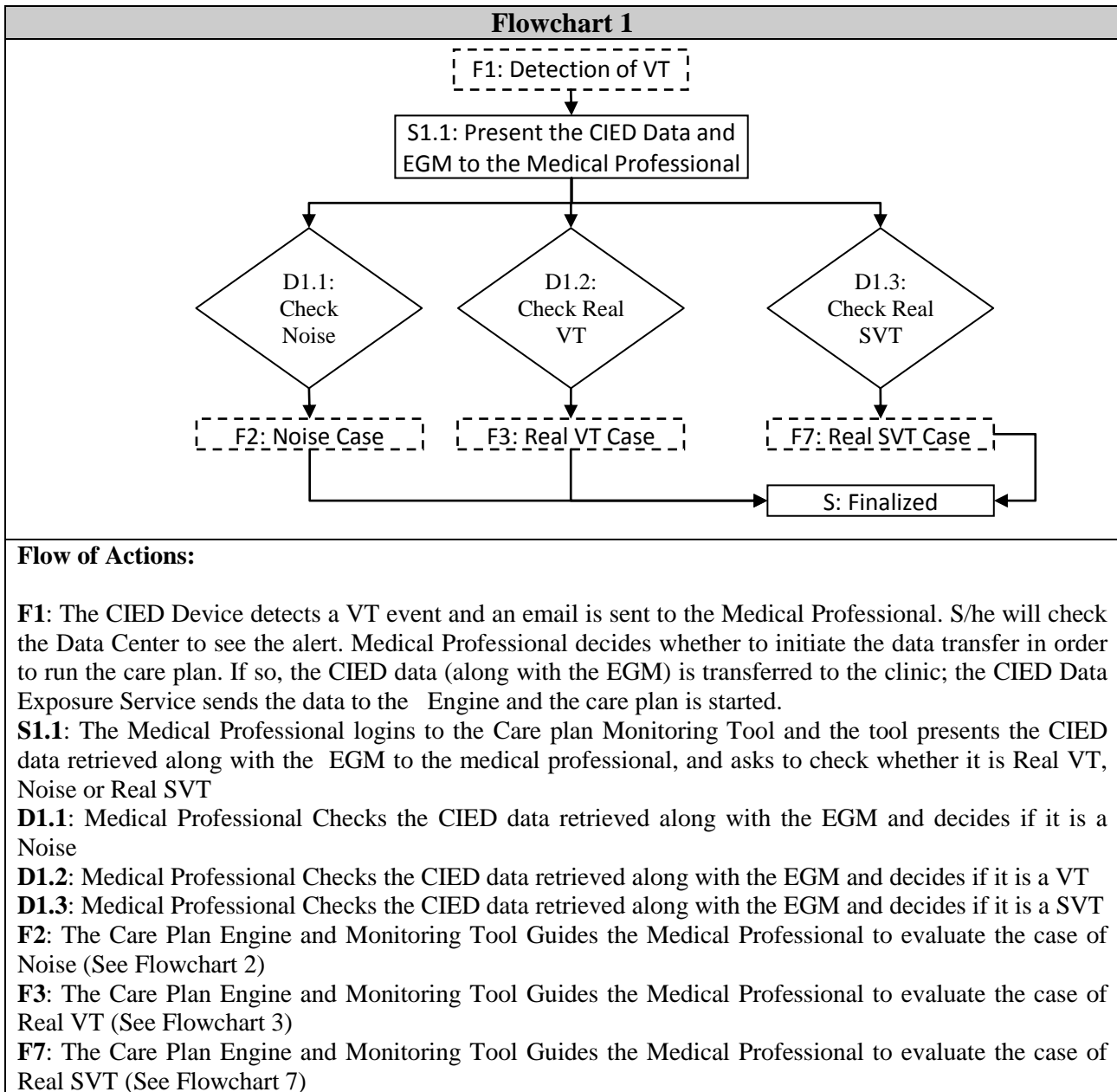
Amiodarone monitoring and recommendations\*

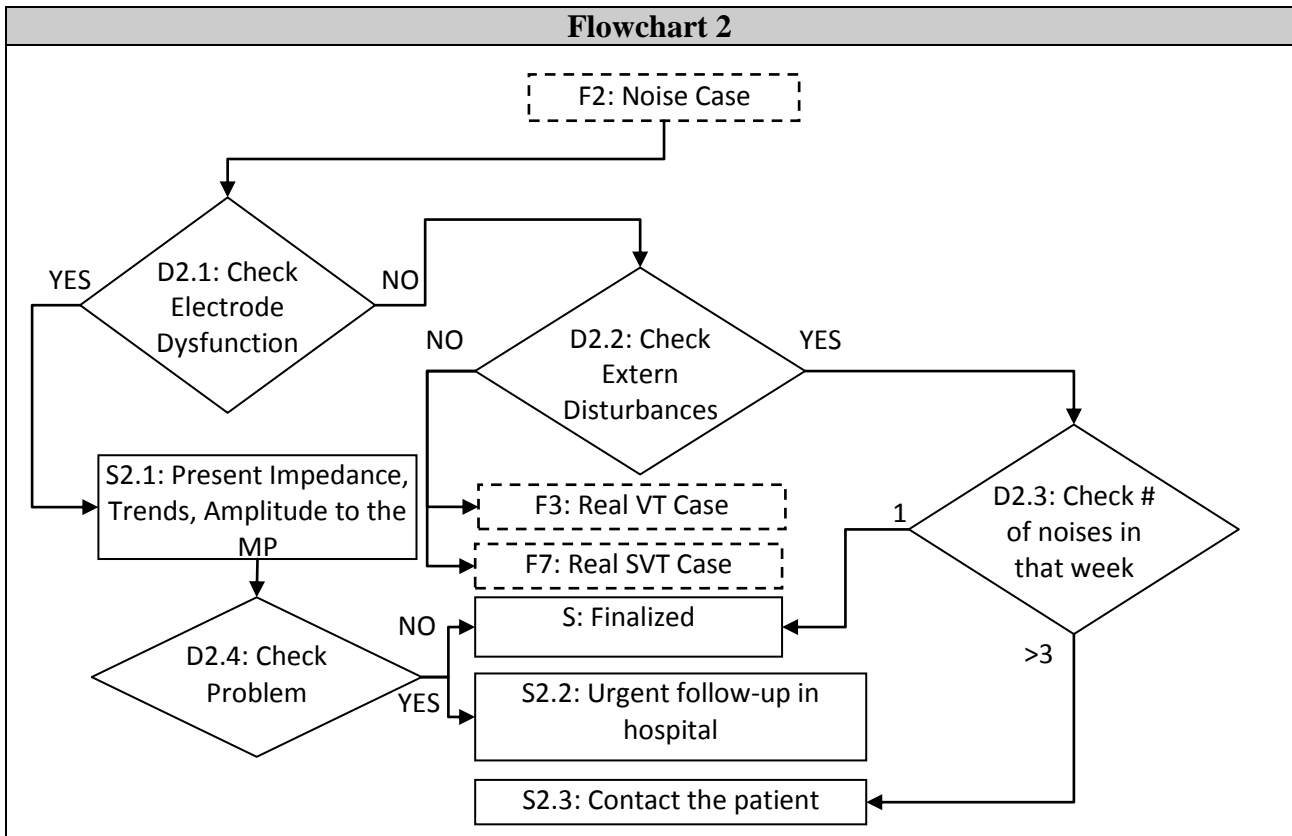
System	Monitoring		Possible Adverse Effect	Incidence	Recommendation
	Baseline	Follow-Up			
Cardiac	ECG (at baseline and during loading dose)	Yearly	QT prolongation; torsade de Pointes	<1%	Reduce amiodarone dose or discontinue use
			Symptomatic sinoatrial or conduction system impairment	5%	Reduce amiodarone dose or discontinue use
Dermatologic	Physical	As needed	Photosensitivity to	25-75%	Avoid sunlight; use

	examination	for signs / symptoms	UV light Blue-gray skin discoloration	4-9%	sunscreen Reduce amiodarone dose or discontinue use
Endocrine	Thyroid function tests	Every 6 months	Hyperthyroidism	3%	Discontinue amiodarone; refer to endocrinologist
			Hypothyroidism	20%	Treat with levothyroxine
Hepatic	Liver function tests	Every 6 months	AST or ALT elevation >x2 upper limit of reference range	15%	Reduce amiodarone dose or discontinue use
Neurologic	Physical examination	As needed for signs / symptoms	Tremor and ataxia, peripheral neuropathy, insomnia, memory disturbances, and delirium	3-30%	Reduce amiodarone dose or discontinue use
Ophtalmologic	Eye examination (if visual impairment or for symptoms)	As needed for signs / symptoms	Corneal microdeposits	>90%	Continue amiodarone treatment
			Optic neuropathy	<1%	Discontinue amiodarone
Pulmonary	Pulmonary function tests (including diffusion capacity of carbon monoxide DC <sub>L</sub> O)	As needed for signs / symptoms	Pulmonary toxicity (cough, fever, dyspnea)	<3%	Discontinue amiodarone immediately; consider corticosteroid treatment High resolution CT scan (if clinical suspicion of pulmonary toxicity)
	Chest radiograph	Yearly			

Table 6

## 5 APPENDIX II – VT CARE PLAN





**Flow of Actions:**

**D2.1:** By examining the CIED data and EGM, the Medical Professional decides whether there is Electrode Dysfunction.

**S2.1:** If there is, then the impedance, trends and amplitude is presented to the Medical Professional.

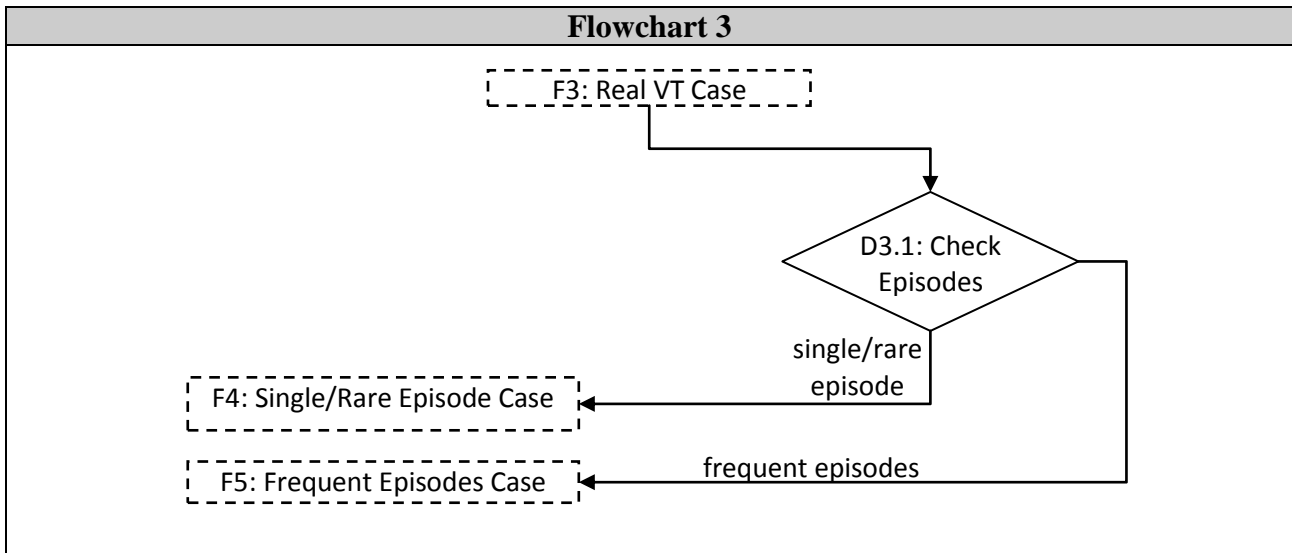
**D2.4:** By examining the presented CIED report (especially the alterations in the impedance (For SJM, Pacing impedance range: 200-2000Ω, Schock impedance: 20-200Ω), reduction/alteration of the amplitude of the signal and the recorded electrogram), the Medical Professional checks whether there is a problem.

**S2.2:** If there is a problem, the Care plan Engine recommends “Urgent follow-up in hospital”. Otherwise, the care plan is finalized.

**D2.2:** If there is no Electrode Dysfunction, the Medical Professional decides whether there is Extern Disturbances, by examining the CIED data and EGM. If there is not, the Care plan Engine and Monitoring Tool guide the Medical Professional to evaluate Real VT case (See Flowchart 3).

**D2.3:** If there are extern disturbances, the number of noises in that week is checked.

**S2.3:** If the number of noises is greater than three, the patient is contacted. Otherwise, the care plan is finalized.



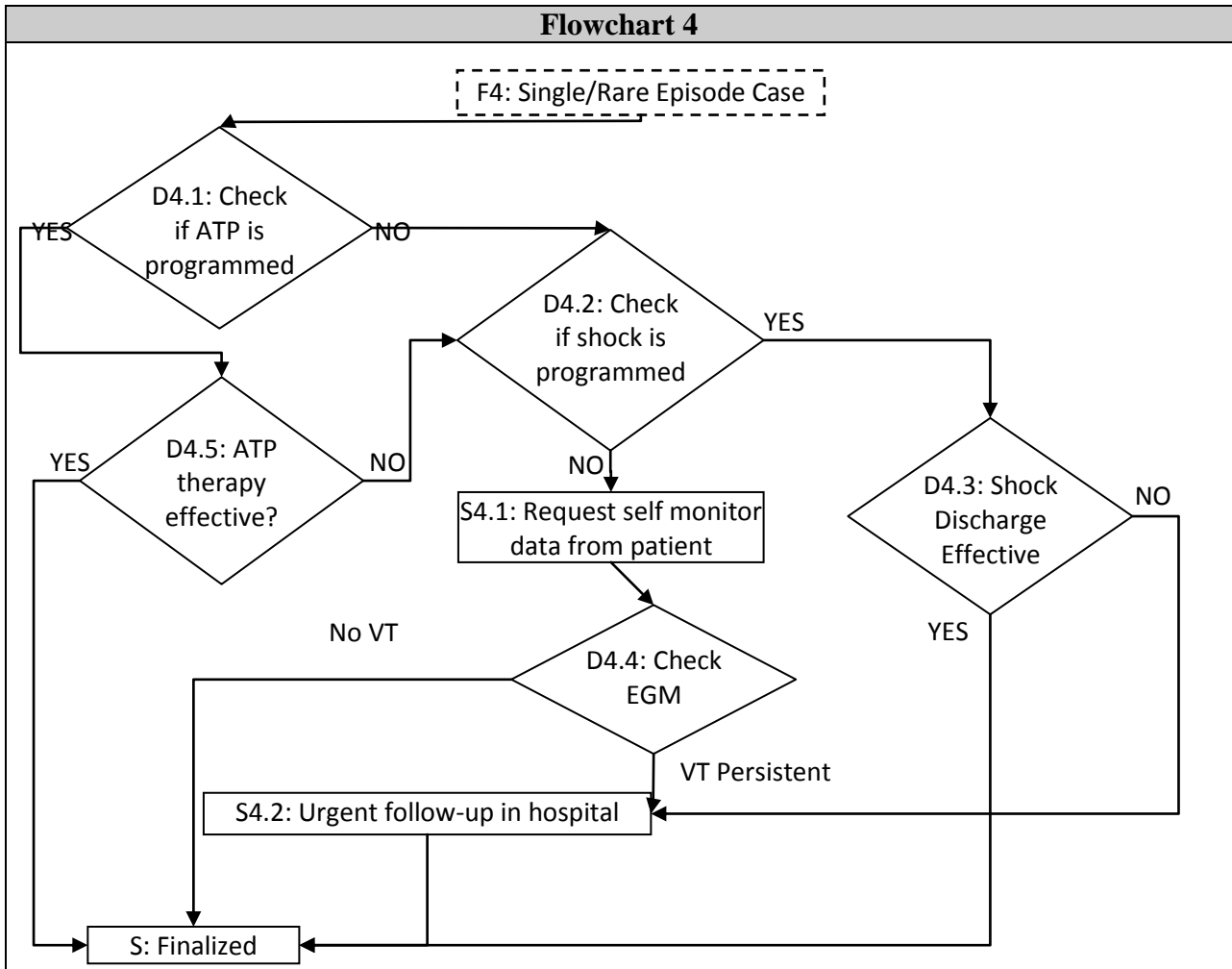
**Flow of Actions:**

**D3.1:** The VT episodes in CIED data are then checked.

**S3.1:** If the # of episodes is more than 3 within 24 hours then the Care plan Engine recommends “Urgent follow-up in hospital”.

**F4:** If there is a single episode (or the number of episodes are rare), then the care plan continues with controlling “Single/Rare Episode Case” (See Flowchart 4).

**F5:** If there are frequent episodes, then the care plan continues with controlling “Frequent Episode Case” (See Flowchart 5).



**Flow of Actions:**

**D4.1:** The Care plan Engine by examining the CIED Data, checks whether ATP is programmed.

**D4.5:** If it was, the engine by examining the CIED Data (by also consulting the Medical Professional) checks whether the ATP therapy is effective. If it is effective, the care plan is finalized.

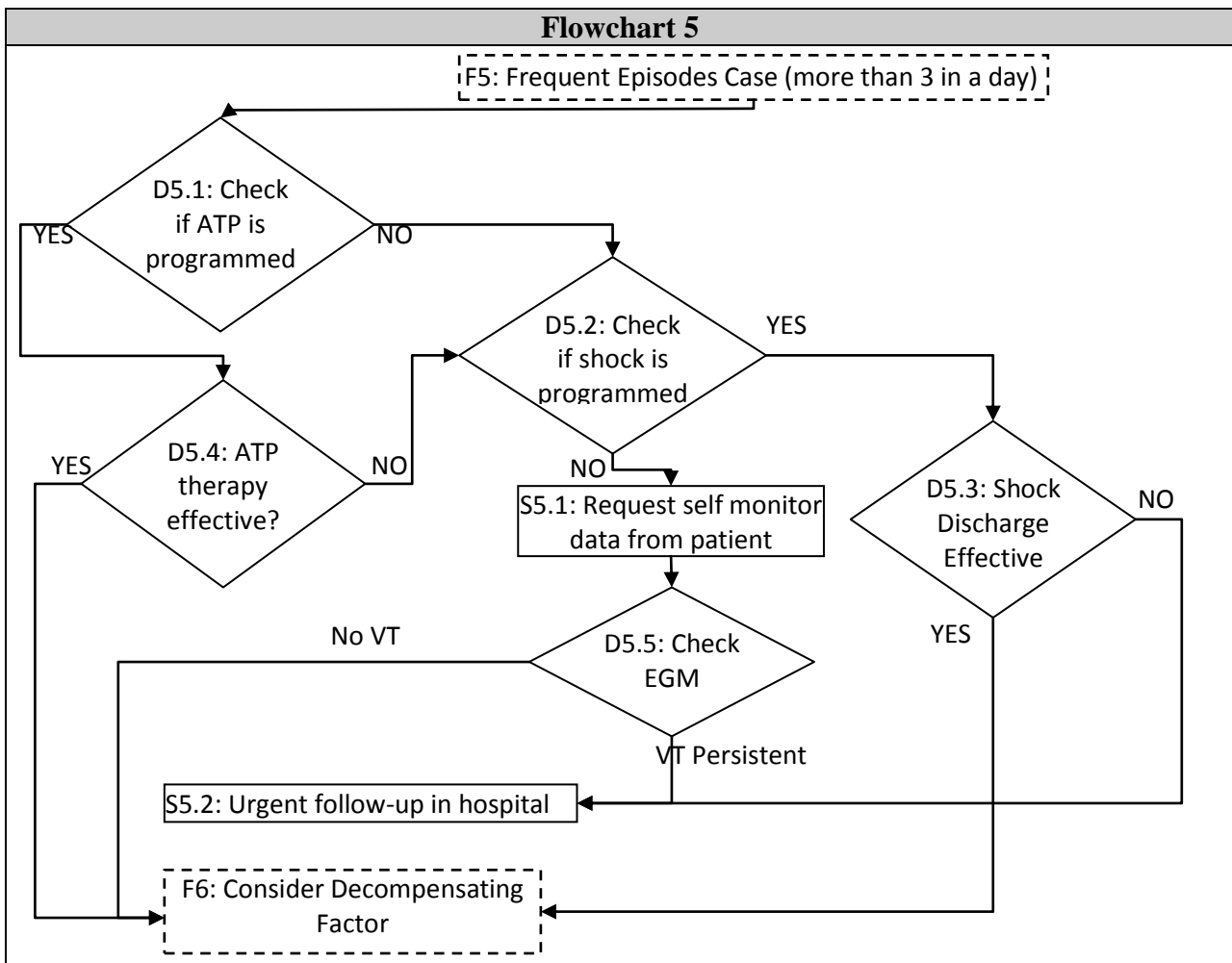
**D4.2:** Otherwise, if a shock is programmed is checked.

**D4.3:** If a shock is programmed and if the discharge is effective, then the care plan is finalized.

**S4.2:** If a shock is programmed and if the discharge is not effective, the Care plan Engine recommends arranging urgent hospital follow-up.

**S4.1:** If the shock is not programmed, the patient is requested to perform a self monitor.

**D4.4:** The EGM from the patient is checked whether there is VT or not. If there is no VT, then the care plan is finalized. Otherwise, the Care plan Engine recommends arranging an urgent hospital follow-up.



**Flow of Actions:**

**D5.1:** The Care plan Engine by examining the CIED Data, checks whether ATP is programmed.

**D5.4:** If it was, the engine by examining the CIED Data (by also consulting the Medical Professional) checks whether the ATP therapy is effective. If it is effective, the care plan recommends to consider decompensating factor.

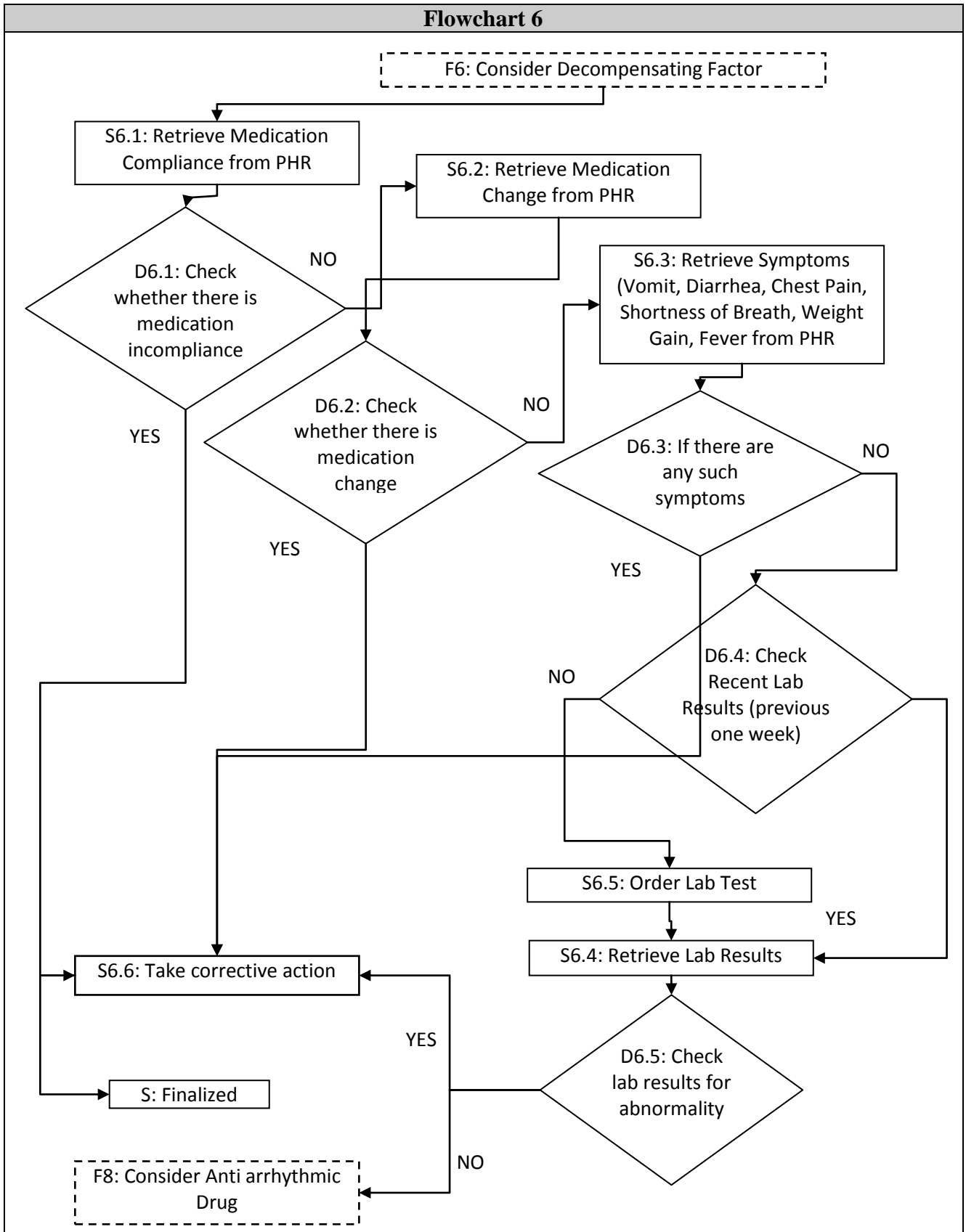
**D5.2:** Otherwise, if a shock is programmed is checked.

**D5.3:** If a shock is programmed and if the discharge is effective, then the care plan recommends to consider decompensating factor.

**S5.2:** If a shock is programmed and if the discharge is not effective, the Care plan Engine recommends arranging urgent hospital follow-up.

**S5.1:** If the shock is not programmed, the patient is requested to perform a self monitor.

**D5.5:** The EGM from the patient is checked whether there is VT or not. If there is no VT, then the care plan recommends to consider decompensating factor. Otherwise, the Care plan Engine recommends to arrange an urgent hospital follow-up.



**Flow of Actions:**

**S6.1:** The medication compliance is retrieved from the PHR of the patient.

**D6.1:** It is checked whether there is any medication incompliance, if there is any, then go to S6.6. If not then

go to S6.2.

**S6.2:** The medication change is retrieved from the PHR of the patient.

**D6.2:** It is checked whether there is any medication change. The doctor need to check to see if there were any changes s/he compares them to what s/he have documented and to what the patient says s/he is taking. If there is any, then go to S6.6. If not then go to S6.3.

**S6.3:** Symptoms (Vomit, Diarrhea, Chest Pain, Shortness of Breath, Weight Gain, Fever) of the patients are retrieved from PHR.

**D6.3:**It is checked whether there is any such symptoms, if there is any, then go to S6.6. If not then go to D6.4.

**D6.4:** The EHR of the patient is checked whether there are lab results within previous week.

**S6.4:** If there is, it is retrieved from the EHR.

**S6.5:** Otherwise, a lab test is ordered and the results of the lab test are waited.

**D6.5:** The parameters from the lab results are checked for possible corrective action. If there are any abnormalities then go to Step S6.6. If not then continue with F8.

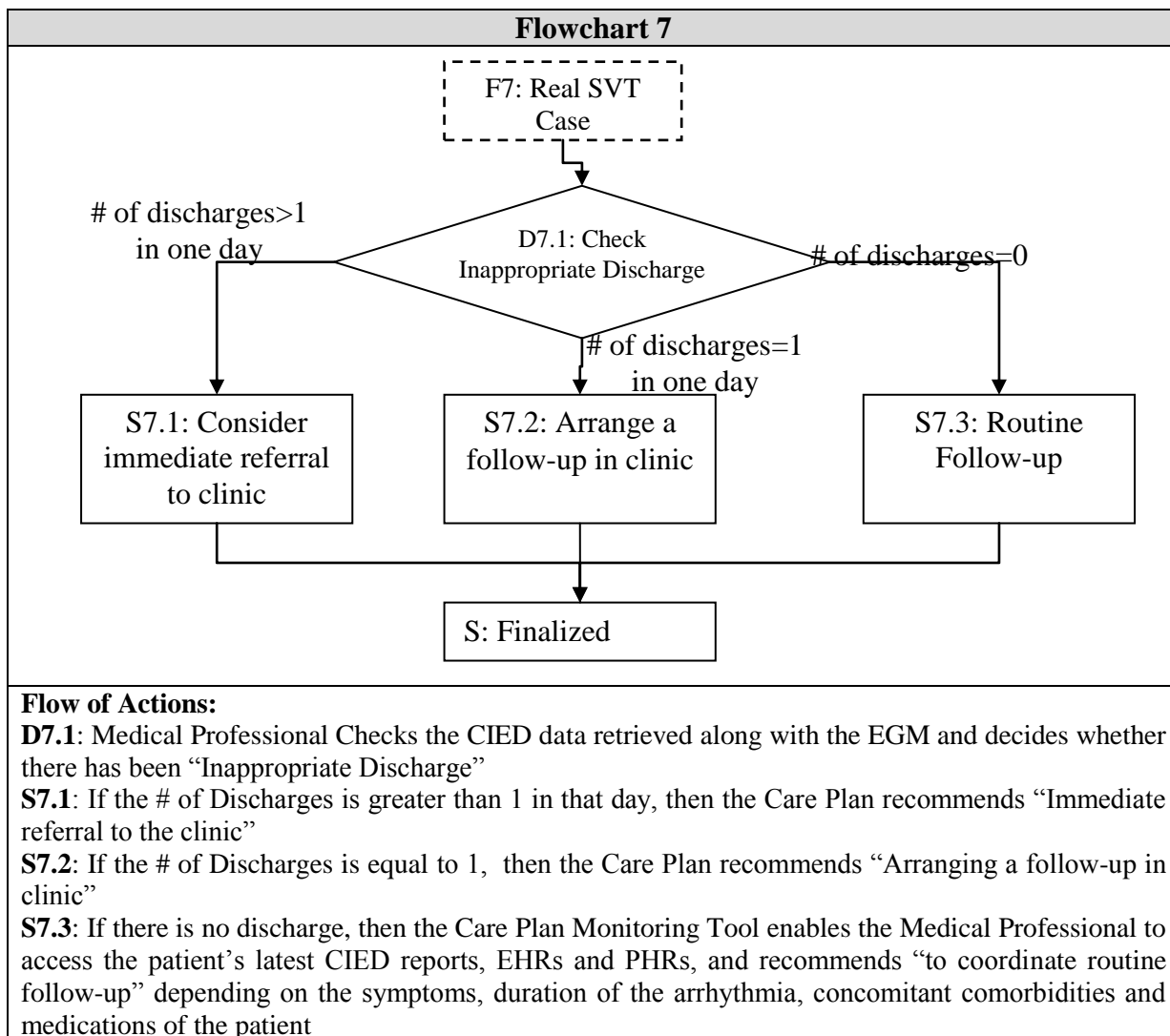
**S6.6:** Necessary corrective actions are taken. For example, the healthcare actor needs to speak with the patient to check whether they have a pill box to make sure that pills are put in so they do not forget to take pills. Furthermore, the healthcare actor can check whether the patients have a medication list to follow and update when there are changes and what pills have they missed.

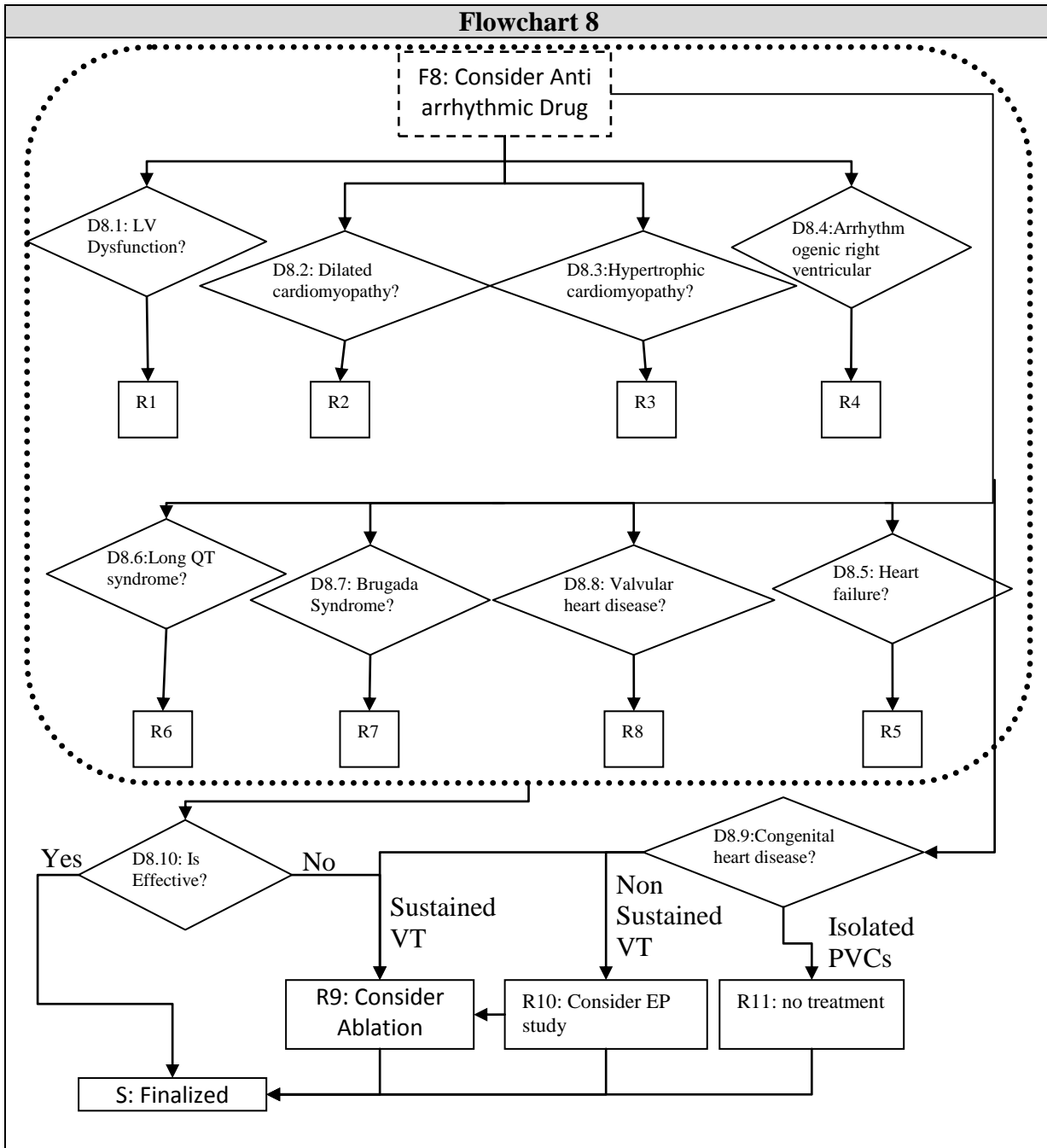
In addition to these, the following conditions of the patients should be controlled:

- If the patient is vomiting over 48 hours
- If the patient has Diarrhea over 48hours
- If the patient has chest pain and if s/he takes nitro and take it every 5 min x 3 and if there is no relief
- If there is shortness of breath and weight gain.

In such cases the patient need to have a follow-up in the hospital.

**F8:** The Care plan Engine recommends the Medical Professional to consider Anti arrhythmic Drug (See Flowchart 8).





**Flow of Actions:**

In this case, the problems of the patient are retrieved from EHR/PHR and depending on the problems; different anti arrhythmic drugs are suggested as follows:

**D8.1 & R1:** LV dysfunction due to prior myocardial infarction:

- a. amiodarone + / - beta-blockers (class IIa, level of evidence B)
- b. sotalol (class IIa, level of evidence C)
- c. Catheter ablation (class IIb, level of evidence B).

**D8.2 & R2:** Dilated cardiomyopathy (nonischemic)

- a. amiodarone + / - beta-blockers (class IIb, level of evidence C)

**D8.3 & R3:** Hypertrophic cardiomyopathy:

- a. Amiodarone (class IIa, level of evidence C)

**D8.4 & R4:** Arrhythmogenic right ventricular cardiomyopathy:

- a. Amiodarone (class IIa, level of evidence C).
- b. Sotalol (class IIa, level of evidence C).

**D8.5 & R5:** Heart failure:

- a. Amiodarone + / - beta-blocker (class I, level of evidence C).
- b. Sotalol (class I, level of evidence C).

**D8.6 & R6:** Long QT syndrome:

- a. Beta-blockers.

**D8.7 & R7:** Brugada Syndrome:

- a. Electrical storm: isoproterenol (class IIa, level of evidence C).
- b. Electrical storm: quinidine (class IIb, level of evidence C).

**D8.8 & R8:** Valvular heart disease:

- a. Candidate for valvular repair / replacement?
- b. No specific drug suggested by guidelines.

**D8.9:** In addition to the above decisions and recommendations, if the patient has congenital heart disease and if the CIED data reports “Sustained VT”, then ablation is recommended (**R9**). Otherwise, EP electrophysiology study is recommended (**R10**). If there is Isolated premature ventricular contraction then there is no need for treatment (**R11**).

**D8.10:** An action is requested from the patient to ask self monitoring within a week to see the results.

**R9:** If anti arrhythmic drug is not effective, ablation should be considered.

It should be noted that all of the recommendations are provided to the healthcare actor along with Table 1 showing the recommended doses of the drugs.

Table 1. Recommended doses of drugs

Drug <sup>a</sup>	Route of administration	Dosage <sup>b</sup>	Potential adverse effects
Amiodarone	Oral	<u>Inpatient</u> : 1.2 to 1.8 g per day in divided dose until 10 g total, then 200 to 400 mg per day maintenance or 30 mg/kg as single dose <u>Outpatient</u> : 600 to 800 mg per day divided dose until 10 g total, then 200 to 400 mg per day maintenance	Hypotension, bradycardia, QT prolongation, torsades de pointes (rare), GI upset, constipation, phlebitis (IV)
	Intravenous/oral	5 to 7 mg/kg over 30 to 60 min, then 1.2 to 1.8 g per day continuous IV or in divided oral doses until 10 g total, then 200 to 400 mg per day maintenance	
Quinidine <sup>c</sup>	Oral	0.75 to 1.5 g in divided doses over 6 to 12 h, usually with a rate-slowing drug	QT prolongation, torsades de pointes, GI upset, hypotension
<p><i>AF indicates atrial fibrillation; BID, twice a day; GI, gastrointestinal; IV, intravenous.</i>  <sup>a</sup>Drugs are listed alphabetically.  <sup>b</sup>Dosages given in the table may differ from those recommended by the manufacturers.  <sup>c</sup>The use of quinidine loading to achieve pharmacological conversion of atrial fibrillation is controversial, and safer methods are available with the alternative agents listed in the table. Quinidine should be used with caution.</p>			

Table 2. Typical doses of drugs

Drug <sup>b</sup>	Daily	Potential Adverse Effects
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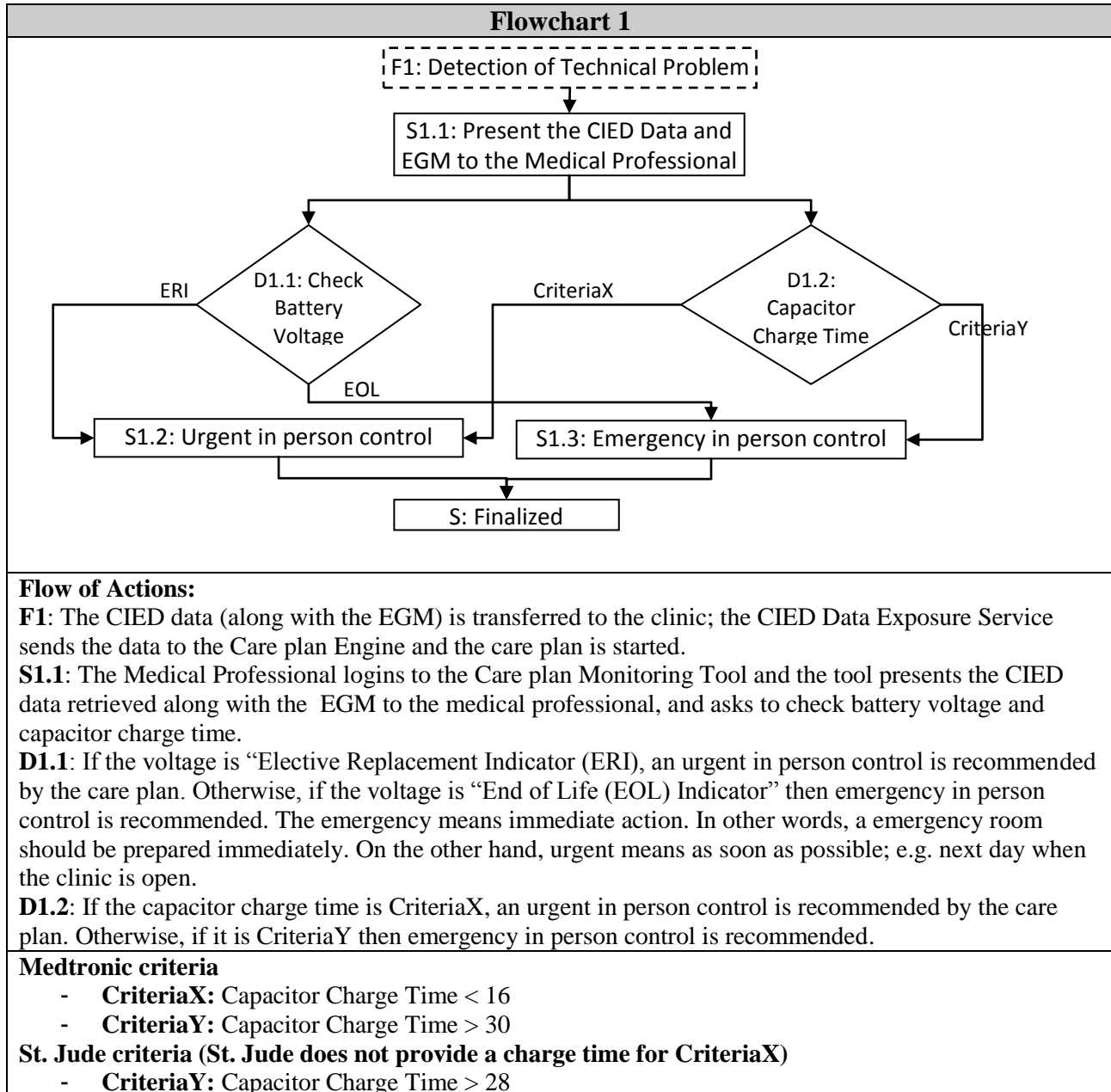
Dosage		
Amiodarone <sup>c</sup>	100 to 400 mg	Photosensitivity, pulmonary toxicity, polyneuropathy, GI upset, bradycardia, torsades de pointes (rare), hepatic toxicity, thyroid dysfunction, eye complications
Sotalol <sup>d</sup>	160 to 320 mg	Torsades de pointes, HF, bradycardia, exacerbation of chronic obstructive or bronchospastic lung disease
<p><i>AF indicates atrial fibrillation; AV, atrioventricular; GI, gastrointestinal; HF, heart failure.</i>  <i><sup>a</sup>Drugs and doses given here have been determined by consensus on the basis of published studies.</i>  <i><sup>b</sup>Drugs are listed alphabetically.</i>  <i><sup>c</sup>A loading dose of 600 mg per day is usually given for one month or 1000 mg per day for 1 week.</i>  <i><sup>d</sup>Dose should be adjusted for renal function and QT-interval response during in-hospital initiation phase.</i></p>		

Table 3. Amiodarone monitoring and recommendations

Monitoring					
System	Baseline	Follow-Up	Possible Adverse Effect	Incidence	Recommendation
Cardiac	ECG (at baseline and during loading dose)	Yearly	QT prolongation; torsade de Pointes	<1%	Reduce amiodarone dose or discontinue use
			Symptomatic sinoatrial or conduction system impairment	5%	Reduce amiodarone dose or discontinue use
Dermatologic	Physical examination	As needed for signs / symptoms	Photosensitivity to UV light	25-75%	Avoid sunlight; use sunscreen
			Blue-gray skin discoloration	4-9%	Reduce amiodarone dose or discontinue use
Endocrine	Thyroid function tests	Every 6 months	Hyperthyroidism	3%	Discontinue amiodarone; refer to endocrinologist
			Hypothyroidism	20%	Treat with levothyroxine
Hepatic	Liver function tests	Every 6 months	AST or ALT elevation >x2 upper limit of reference range	15%	Reduce amiodarone dose or discontinue use
Neurologic	Physical examination	As needed for signs / symptoms	Tremor and ataxia, peripheral neuropathy, insomnia, memory disturbances, and delirium	3-30%	Reduce amiodarone dose or discontinue use
Ophtalmologic	Eye examination (if visual impairment or for	As needed for signs / symptoms	Corneal microdeposits	>90%	Continue amiodarone treatment
			Optic neuropathy	<1%	Discontinue amiodarone

Pulmonary	<i>symptoms)</i>				
	Pulmonary function tests (including diffusion capacity of carbon monoxide DC <sub>L</sub> O)	As needed for signs / symptoms	Pulmonary toxicity (cough, fever, dyspnea)	<3%	Discontinue amiodarone immediately; consider corticosteroid treatment High resolution CT scan (if clinical suspicion of pulmonary toxicity)
Chest radiograph	Yearly				

## 6 APPENDIX III – TECHNICAL CARE PLAN



## 7 APPENDIX IV – AF CARE PLAN INFORMATION ITEMS AND THEIR DATA SOURCES

Flowchart No	Box identifier	Information Item	Source Type	Source Description
Flowchart 2	S5	EGM	Latest CIED Data	IDCO Message's OBX Segment with ED Datatype: It is assumed that the EGM is in the CIED data and it is in PDF format. Electrocardiogram [C0013798]
Flowchart 2	D2	VT	Latest CIED Data	The following are used: - MDC_IDC_EPISODE_TYPE: The value will be Epis_VT or - MDC_IDC_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_VT or MDT-Epis_VT or
Flowchart 2	D3	Noise	Latest CIED Data	EGM in the IHE IDCO Message.
Flowchart 2	D4	SVT	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_SVT or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_SVT or MDT-Epis_SVT
Flowchart 3	D5	Appropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT
Flowchart 4	D6	Inappropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT
Flowchart 4	D7	# of noise case in the past week	Care Management DB	The noise cases are kept in the Care Management DB component of iCARDEA. The "Problem entry" ( <a href="http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.5">http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.5</a> ) is used to store these noise events in the Care Management DB by EHR/PHR components through the use of IHE CM profile. The code will be "Noise [C0028263]".

<b>Flowchart 4</b>	<b>S9</b>	Lead Impedance Alert	Latest CIED Data	The following attribute is used: - MDC_IDC_MSMT_LEADHVCHNL_STATUS : Possible values are "Check Lead" or "Null"
<b>Flowchart 4</b>	<b>S9</b>	Lead Impedance Trend	Latest CIED Data	The following attribute is used: - MDC_IDC_MSMT_LEADHVCHNL_STATUS : Possible values are "Check Lead" or "Null"
<b>Flowchart 4</b>	<b>S9</b>	Amplitude of Signal	Latest CIED Data	The following attribute is used: - MDC_IDC_SET_LEADCHNL_[CHAMBER]_PACING_AMPLITUDE
<b>Flowchart 5</b>	<b>D9</b>	Sinus Tachycardia	Latest CIED Data	EGM in the IHE IDCO Message.
<b>Flowchart 5</b>	<b>D10</b>	SVT	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_SVT or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_SVT or MDT-Epis_SVT or
<b>Flowchart 5</b>	<b>D11</b>	AF existence	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF
<b>Flowchart 6</b>	<b>D12</b>	Inappropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT
<b>Flowchart 7</b>	<b>D13</b>	Inappropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT
<b>Flowchart 8</b>	<b>D14</b>	Inappropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT

<b>Flowchart 9</b>	<b>D15</b>	CHADS2 Score: 1. History of Stroke 2. History of Congestive Heart Failure 3. History of Diabetes Mellitus 4. History of Hypertension 5. Age of Patient	IHE CM (EHR/PHR)	All of the data is retrieved from EHR/PHR by using the "Problem Entry" (except age of the patient). This information is provided by EHR/PHR in response to a IHE CM - PCC-9 (MEDCAT) query. The following SNOMED CT codes will be used to specify the information items: 1. History of Stroke: Cerebrovascular accident [230690007(SNOMEDCT)], Cerebrovascular accident [C0038454] 2. History of Congestive Heart Failure: Congestive heart failure [42343007(SNOMEDCT)], [C0018802] 3. History of Diabetes Mellitus: Diabetes mellitus [73211009(SNOMEDCT)], [C0011849] 4. History of Hypertension: (Hypertensive disease) or (hypertension) [266287006(SNOMEDCT)], Hypertensive disease [C0020538]
<b>Flowchart 10</b>	<b>S16</b>	The conditions of the patient that may result in absolute contraindication	IHE CM (EHR/PHR)	All of the data is retrieved from EHR/PHR by using the "Problem Entry". The following SNOMED CT codes will be used to specify the information items: 1. Major bleeding in the previous six months: Bleeding [131148009(SNOMEDCT)], Hemorrhage [C0019080] 2. Intracranial hemorrhage: Intracranial hemorrhage [1386000(SNOMEDCT)], Intracranial Hemorrhages [C0151699] 3. Intracranial aneurism: Intracranial aneurysm [128609009(SNOMEDCT)], Intracranial Aneurysm [C0007766] 4. Recent major trauma: Trauma [19130008(SNOMEDCT)] or Major injury [2734008(SNOMEDCT)], Major injury [C0332677] 5. Gastrointestinal bleeding: Gastrointestinal hemorrhage [74474003(SNOMEDCT)], Gastrointestinal Hemorrhage [C0017181] 6. surgery performed or planned within one month: "Procedure" entry will be used for this item 7. Severe hepatic impairment: Abnormal liver function [75183008(SNOMEDCT)] or Hepatic impairment[ A2017333/MedDRA/LT/ ], Hepatic impairment [C0948807] 8. Blood dyscrasia: Disorder of hematopoietic system [34093004(SNOMEDCT)], Hematological Disease [C0018939] 9. Severe uncontrolled hypertension: (Hypertensive disease) or (hypertension) [266287006(SNOMEDCT)], Uncontrolled hypertension

			<p>[C1868885]</p> <p>10. Pregnancy (1st and 3rd trimester) or lactation: Lactation [63158009(SNOMEDCT)] or Pregnancy [289908002(SNOMEDCT)] or Third trimester pregnancy [41587001(SNOMEDCT)], Pregnancy [C0032961], Pregnancy Trimester, Third [C0032981], Pregnancy Trimester, First [C0032979], Lactation [C0022925]</p> <p>11. Severe cognitive impairment (severe dementia or psychiatric disease): Impaired cognition [386806002(SNOMEDCT)] or Dementia [52448006(SNOMEDCT)] or Mental disorder [74732009(SNOMEDCT)], Impaired cognition [C0338656], Dementia [C0497327], Mental disorders [C0004936]</p> <p>12. Severe chronic alcoholism: Alcoholism [7200002(SNOMEDCT)] or Unspecified chronic alcoholism [191809008(SNOMEDCT)],Alcoholic Intoxication, Chronic [C0001973]</p> <p>13. Failure to comply: Will be decided by the Medical Professional</p> <p>14. Hypersensibility: Will be decided by the Medical Professional</p> <p>15. Patient rejection: Will be decided by the Medical Professional</p>
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<b>Flowchart 10</b>	<b>S17</b>	The conditions of the patient that may result in relative contraindication	IHE CM (EHR/PHR)	<p>All of the data is retrieved from EHR/PHR by using the "Problem Entry". The following SNOMED CT codes will be used to specify the information items:</p> <ol style="list-style-type: none"> <li>1.Hemorrhagic retinopathy (depending on its degree it can be an absolute contraindication): Hemorrhagic [255345002(SNOMEDCT)], Retinopathy [399625000(SNOMEDCT)] or Retinopathy hemorrhagic [10055332(MDR)], Retinopathy haemorrhagic [C0948059]</li> <li>2.Active gastroduodenal ulcer: Ulcer [429040005(SNOMEDCT)] or Unspecified peptic ulcer [196697002(SNOMEDCT)], Ulcer [C0041582]</li> <li>3.Chronic hepatic disease: Disease of liver [235856003(SNOMEDCT)], Liver diseases [C0023895]</li> <li>4. Active alcoholism: Alcoholism [7200002(SNOMEDCT)] or Unspecified chronic alcoholism [191809008(SNOMEDCT)]</li> <li>4. Moderate cognitive impairment: Impaired cognition [386806002(SNOMEDCT)] or Dementia [52448006(SNOMEDCT)] or Mental disorder [74732009(SNOMEDCT)], Impaired cognition [C0338656], Dementia [C0497327], Mental disorders [C0004936]</li> <li>5. Epilepsy: Epilepsy [84757009(SNOMEDCT)], Epilepsy [C0014544]</li> <li>6. Pericarditis with pericardial effusion: Pericarditis [3238004(SNOMEDCT)] or Pericardial effusion [373945007(SNOMEDCT)], Pericardial effusion [C0031039]</li> <li>7. Short life-expectancy</li> </ol>
<b>Flowchart 10</b>	<b>S18</b>	Lab results that may result in absolute contraindication	IHE CM (EHR/PHR)	<p>"Simple Observation" (<a href="http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.13">http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.13</a>) in response to IHE PCC 9 Query (LABCAT) query is used for these items. If the result will contain an image then the query will be DICAT. The following lab results will be retrieved from EHR/PHR (The SNOMED CT codes are also specified):</p> <ul style="list-style-type: none"> <li>• Hepatic impairment &amp; chronic hepatic disease: GOT (AST): Aspartate aminotransferase [26091008(SNOMEDCT)], UMLS [C0004002] GPT (ALT): Alanine aminotransferase [56935002(SNOMEDCT)] or Alanine aminotransferase measurement:LOINC 1741-8, [ C0201836 ] LDH: Lactate dehydrogenase [259319003(SNOMEDCT)] or Lactate</li> </ul>

				<p>dehydrogenase measurement:2527-0 LOINC, [ C0202113 ]          alk. Phosphatase: Phosphoric monoester hydrolase          [130132002(SNOMEDCT)] or Alkaline phosphatase measurement:15112-6          LOINC, [ C0201850]          Gamma-GT: gamma-Glutamyltransferase [60153001(SNOMEDCT)] or          Gamma glutamyl transferase measurement:2322-6 LOINC, [ C0202035 ]          • Blood dyscrasia: Disorder of hematopoietic system          [34093004(SNOMEDCT)]          Erythrocytenzahl (erythrocyte count): Erythrocyte          [41898006(SNOMEDCT)] or Red Blood Cell Count measurement:13530-1          LOINC, [C0014772]          hämoglobin (hemoglobin): Hemoglobin [38082009(SNOMEDCT)] or          Hemoglobin measurement:16931-8 LOINC, [C0518015]          Thrombocyten (platelets): Platelet [16378004(SNOMEDCT)] or Platelet          Count measurement:26515-7 LOINC, [ C0032181 ]          Leukocyten (leucocytes): Leukocyte [52501007(SNOMEDCT)] or White          Blood Cell Count procedure:804-5 LOINC, [ C0023508 ]          PT: Prothrombin time [396451008(SNOMEDCT)], Prothrombin time assay          [C0033707]  <b><u>TZ:</u></b>          PTT: Partial thromboplastin time, activated [42525009(SNOMEDCT)],          Activated Partial Thromboplastin Time measurement [C0030605]          fibrinogen: Fibrinogen measurement [250346004(SNOMEDCT)],          [C0016006]          BLEEDING TIME: will be checked</p>
<b>Flowchart 10</b>	<b>S19</b>	The list of drugs that the patient use and that may result in contraindication with Anticoagulation drugs	IHE CM (EHR/PHR)	"Medications" ( <a href="http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.7">http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.7</a> ) in response to IHE PCC 9 Query (MEDLIST) query is used for these items.
<b>Flowchart 11</b>	<b>D20</b>	AF normofrequent	Latest CIED Data	EGM in the IHE IDCO Message.

<b>Flowchart 11</b>	<b>D21</b>	AF bradycardia	Latest CIED Data	EGM in the IHE IDCO Message.
<b>Flowchart 11</b>	<b>D22</b>	AF tachycardia	Latest CIED Data	EGM in the IHE IDCO Message.
<b>Flowchart 12</b>	<b>D24</b>	AF persistent	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF - MDC_IDC_EPISODE_DURATION
<b>Flowchart 12</b>	<b>D25</b>	SR (Sinus rhythm)	Latest CIED Data	EGM in the IHE IDCO Message.
<b>Flowchart 12</b>	<b>D26</b>	One or more episode in that week	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF or - MDC_IDC_STAT_EPISODE_RECENT_COUNT_DTM_[STRTEND]
<b>Flowchart 12</b>	<b>D38</b>	Duration of AF	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF or - MDC_IDC_EPISODE_DURATION
<b>Flowchart 12</b>	<b>D39</b>	Lab results that may result in absolute contraindication	IHE CM (EHR/PHR)	PT: Prothrombin time [396451008(SNOMEDCT)], Prothrombin time assay [C0033707]
<b>Flowchart 13</b>	<b>D29</b>	Hypertension	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for these items. Hypertensive disease [C0020538], Hypertensive disorder [38341003(SNOMEDCT)]

<b>Flowchart 13</b>	<b>D30</b>	History of heart failure	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for these items. The SNOMED CT code to be used is "Congestive heart failure [42343007(SNOMEDCT)]. [C0018802]
<b>Flowchart 13</b>	<b>D31</b>	COPD	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for these items. COPD (chronic obstructive pulmonary disease) or Chronic Obstructive Airway Disease [C0024117], 155585005 (SNOMEDCT)
<b>Flowchart 14</b>	<b>D32</b>	Duration of AF	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF - MDC_IDC_EPISODE_DURATION
<b>Flowchart 15</b>	<b>D33</b>	1. Heart Disease	IHE CM (EHR/PHR)	All of the data is retrieved from EHR/PHR by using the "Problem Entry" (except age of the patient). This information is provided by EHR/PHR in response to a IHE CM - PCC-9 (MEDCAT) query. The following SNOMED CT codes will be used to specify the information items: 1. Heart disease: Heart disease [56265001(SNOMEDCT)], Heart Diseases [C0018799]

<p><b>Flowchart 15</b></p>	<p><b>D34</b></p>	<p>1. CHF 2. CAD 3. Hypertension with LVH</p>	<p>IHE CM (EHR/PHR)</p>	<p>The data is retrieved from EHR/PHR by using the "Problem Entry" (except age of the patient). This information is provided by EHR/PHR in response to a IHE CM - PCC-9 (MEDCAT) query. The following codes will be used to specify these information items:</p> <p>1. CHF: Congestive heart failure [C0018802], 42343007(SNOMEDCT) 2. CAD: Coronary Artery Disease [C1956346], 414024009(SNOMEDCT) 3. Hypertension with LVH: Hypertensive disease [C0020538], 38341003(SNOMEDCT); Left Ventricular Hypertrophy [C0149721], 164873001(SNOMEDCT)</p>
<p><b>Flowchart 15</b></p>	<p><b>D35</b></p>	<p>1. NYHA III/IV or unstable NYHA II 2. Stable NYHA I/II</p>	<p>IHE CM (EHR/PHR)</p>	<p>The data is retrieved from EHR/PHR by using the "Problem Entry" (except age of the patient). This information is provided by EHR/PHR in response to a IHE CM - PCC-9 (MEDCAT) query. The following codes will be used to specify this information item:</p> <p>1. NYHA Class I, F-3018B (NCDR) 2. NYHA Class II, F-3018C (NCDR) 3. NYHA Class III, F-3018D (NCDR) 4. NYHA Class IV, F-3018E (NCDR)</p>

<p><b>Flowchart 15</b></p>	<p><b>D36</b></p>	<p>1. Paroxymal AF</p>	<p>IHE CM (EHR/PHR)</p>	<p>The data is retrieved from EHR/PHR by using the "Problem Entry" (except age of the patient). This information is provided by EHR/PHR in response to a IHE CM - PCC-9 (MEDCAT) query. The following code will be used to specify this information item:</p> <p>- Paroxymal AF: Paroxysmal atrial fibrillation [C0235480], [282825002(SNOMEDCT)]</p>
<p><b>Flowchart 15</b></p>	<p><b>D36</b></p>	<p>AF persistent</p>	<p>Latest CIED Data</p>	<p>The following are used:</p> <ul style="list-style-type: none"> <li>- MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_ATAF or</li> <li>- MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_AT_AF or MDT-Epis_AT_AF</li> <li>- MDC_IDC_EPISODE_DURATION</li> </ul>

## APPENDIX V – VT CARE PLAN INFORMATION ITEMS AND THEIR DATA SOURCES

Flowchart No	Box identifier	Information Item	Source Type	Source Description
Flowchart 1	S1.1	EGM	Latest CIED Data	IDCO Message's OBX Segment with ED Datatype: It is assumed that the EGM is in the CIED data and it is in PDF format. Electrocardiogram [C0013798]
Flowchart 1	D1.1	Noise	Latest CIED Data	EGM in the IHE IDCO Message
Flowchart 1	D1.2	Real VT	Latest CIED Data	The following are used: - MDC_IDC_EPISODE_TYPE: The value will be Epis_VT or - MDC_IDC_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_VT or MDT-Epis_VT or
Flowchart 1	D1.3	Real SVT	Latest CIED Data	The following are used: - MDC_IDC_STAT_EPISODE_TYPE: The value will be Epis_SVT or - MDC_IDC_STAT_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_SVT or MDT-Epis_SVT
Flowchart 2	D2.1	Electrode Dysfunction	Latest CIED Data	The following attribute is used: MDC_IDC_LEAD_CONNECTION_STATUS
Flowchart 2	S2.1	Impedance	Latest CIED Data	The following attribute is used: - MDC_IDC_MSMT_LEADHVCHNL_STATUS : Possible values are "Check Lead" or "Null"
Flowchart 2	S2.1	Trends	Latest CIED Data	The following attribute is used: - MDC_IDC_MSMT_LEADHVCHNL_STATUS : Possible values are "Check Lead" or "Null"
Flowchart 2	S2.1	Amplitude	Latest CIED Data	The following attribute is used: - MDC_IDC_SET_LEADCHNL_[CHAMBER]_PACING_AMPLITUDE
Flowchart 2	D2.4	Extern Disturbances	Latest CIED Data	EGM in the IHE IDCO Message
Flowchart 2	D2.3	# of noise case in the past week	Care Management DB	The noise cases are kept in the Care Management DB component of iCARDEA. The "Problem entry" ( <a href="http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.5">http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.4.5</a> ) is used to store these noise events in the Care Management DB by EHR/PHR components through the use of IHE CM profile. The code will be "Noise

				[C0028263]".
<b>Flowchart 3</b>	<b>D3.1</b>	Real VT	Latest CIED Data	The following are used: - MDC_IDC_EPISODE_TYPE: The value will be Epis_VT or - MDC_IDC_EPISODE_VENDOR_TYPE: The value will be STJ-Epis_VT or MDT-Epis_VT or
<b>Flowchart 4</b>	<b>D4.1</b>	ATP	Latest CIED Data	The following are used: - MDC_IDC_STAT_TACHYTHERAPY_ATP_DELIVERED_RECENT
<b>Flowchart 4</b>	<b>D4.2</b>	Shock	Latest CIED Data	The following are used: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT
<b>Flowchart 4</b>	<b>D4.4</b>	EGM	Latest CIED Data	IDCO Message's OBX Segment with ED Datatype: It is assumed that the EGM is in the CIED data and it is in PDF format. Electrocardiogram [C0013798]
<b>Flowchart 5</b>	<b>D5.1</b>	ATP	Latest CIED Data	The following are used: - MDC_IDC_STAT_TACHYTHERAPY_ATP_DELIVERED_RECENT
<b>Flowchart 5</b>	<b>D5.2</b>	Shock	Latest CIED Data	The following are used: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_DELIVERED_RECENT
<b>Flowchart 5</b>	<b>D5.5</b>	EGM	Latest CIED Data	IDCO Message's OBX Segment with ED Datatype: It is assumed that the EGM is in the CIED data and it is in PDF format. Electrocardiogram [C0013798]
<b>Flowchart 6</b>	<b>D6.1</b>	Medication Compliance	IHE CM (EHR/PHR)	"Medication.text" in response to IHE PCC 9 Query (MEDLIST) query is used for this item. Medication Adherence [C1629505], 418633004(SNOMEDCT)
<b>Flowchart 6</b>	<b>D6.2</b>	Medication Change	IHE CM (EHR/PHR)	"Medication.text" in response to IHE PCC 9 Query (MEDLIST) query is used for this item. Change of medication [C0580105], 182838006(SNOMEDCT)

<b>Flowchart 6</b>	<b>D6.3</b>	Symptoms: 1. Vomit 2. Diarrhea 3. Chest Pain 4. Shortness of Breath 5. Weight Gain 6. Fever	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. 1. Vomiting [C0042963], 249497008(SNOMEDCT) 2. Diarrhea [C0011991], 62315008(SNOMEDCT) 3. Chest Pain [C0008031], 29857009(SNOMEDCT) 4. Shortness of breath:-:Point in time:^Patient:- [C2707305], 248552009(SNOMEDCT) 5. Weight Gain [C0043094], 8943002(SNOMEDCT) 6. Fever [C0015967], 386661006(SNOMEDCT)
<b>Flowchart 6</b>	<b>D6.4</b>	Lab Results	IHE CM (EHR/PHR)	"Simple Observations" in response to IHE PCC 9 Query (LABCAT) query is used for this item. (Previous 1 week)
<b>Flowchart 7</b>	<b>D13</b>	Inappropriate Discharge	Latest CIED Data	The following attributes are used in this case: - MDC_IDC_STAT_TACHYTHERAPY_SHOCKS_ABORTED_RECENT
<b>Flowchart 8</b>	<b>D8.1</b>	LV Dysfunction	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Ventricular Dysfunction, Left [C0242698], 10049694(MDR)
<b>Flowchart 8</b>	<b>D8.2</b>	Dilated cardiomyopathy	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Cardiomyopathy, Dilated [C0007193], 195021004(SNOMEDCT)
<b>Flowchart 8</b>	<b>D8.3</b>	Hypertrophic cardiomyopathy	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Hypertrophic Cardiomyopathy [C0007194]
<b>Flowchart 8</b>	<b>D8.4</b>	Arrhythmogenic right ventricular cardiomyopathy	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Arrhythmogenic Right Ventricular Cardiomyopathy [C0349788], 281170005(SNOMEDCT)
<b>Flowchart 8</b>	<b>D8.5</b>	Heart Failure	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Heart failure [C0018801], 195117009(SNOMEDCT)
<b>Flowchart 8</b>	<b>D8.6</b>	Long QT syndrome	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Long QT Syndrome [C0023976], 9651007(SNOMEDCT)
<b>Flowchart 8</b>	<b>D8.7</b>	Brugada Syndrome	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Brugada Syndrome (disorder) [C1142166], 418818005(SNOMEDCT)

<b>Flowchart 8</b>	<b>D8.8</b>	Valvular Heart Disease	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Heart valve disease [C0018824], 368009(SNOMEDCT)
<b>Flowchart 8</b>	<b>D8.9</b>	Congenital Heart Disease	IHE CM (EHR/PHR)	"Problem Entry" in response to IHE PCC 9 Query (MEDCAT) query is used for this item. Congenital heart disease [C0152021], 13213009(SNOMEDCT)

## **APPENDIX VI – TECHNICAL CARE PLAN INFORMATION ITEMS AND THEIR DATA SOURCES**

<b>D1.1</b>	Battery Voltage	MDC_IDC_MSMT_BATTERY_STATUS: EOL or ERI
<b>D1.2</b>	Capacitor Charge Time	MDC_IDC_MSMT_CAP_CHARGE_TIME