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Knowledge Editor and Execution Engine Development for Optimal Ventricular Assist Device Weaning

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***Abstract*—In this work, the weaning module of the SensorART specialist decision support system (SDSS) is presented. SensorART focuses on the treatment of patients suffering from end-stage heart failure (HF). The use of a ventricular assist device (VAD) is the main treatment for HF patients. However in certain cases, myocardial function recovers and VADs can be explanted after the patient is weaned. In that framework an efficient module is developed responsible for the selection of the most suitable candidates for VAD weaning. In this study we describe all technical specifications concerning its two main sub-modules of the weaning module, of the Clinical Knowledge Editor and the Knowledge Execution Engine.**

I. Introduction

Congestive heart failure (HF) is the fastest growing cardiovascular condition, with approximately 1 million new diagnoses worldwide annually [1]. Medical therapy and cardiac resynchronization therapy are effective in treating many of those patients. However, in some cases, patients develop decompensated HF, requiring hemodynamic support with a mechanical circulatory support device. Ventricular assist devices (VADs) have been shown to effectively support patients to successful cardiac transplantation or, in some patients, provide destination therapy [2-4]. A number of reports have demonstrated the potential use of left VAD (LVAD) as a therapy for promoting myocardial recovery and eventually allowing device explantation [5-7]. Left ventricular unloading was thought to be the key mechanism in achieving this goal.

Nowadays the incidence of VAD weaning remains relatively low compared with the volume of patients treated with VAD therapy. In addition, the underlying cellular, biochemical, and biomechanical mechanisms remain uncertain and thus, different sets of criteria have been proposed for attempting to wean patients from VAD support [7-9]. These differences may arise from different types of heart failure, different medical treatments during mechanical unloading, differences in devices used for ventricular support, and also differences in patient selection for VAD implantation. So far, only a few clinical decision support systems (DSS) have been reported in the literature for supporting optimal VAD weaning [7-9].

Santelices *et al* [7] in their work included patients who were supported by an LVAD or a biventricular assist device, and originally identified as bridge-to-transplant, but later considered for recovery. Knowledge derived from retrospective experience was elicited through a series of structured interviews and questionnaires of 11 members of the multidisciplinary Artificial Heart Program at university of Pittsburgh medical center, including surgery, clinical bioengineering, nursing, and psychiatry. The interviews were conducted individually and in small groups to derive a binary decision flowchart for selecting VAD weaning candidates. The flowchart was reviewed and revised in a second interview. The individual flowcharts were combined into a final version, consisting of a five-tier health status screening, followed by a three-tier evaluation of cardiac recovery.

In the work of Dandel *et al* [8], the authors analyzed data on cardiac morphology and function collected before VAD implantation, echocardiographic parameters recorded during ‘off-pump’ trials, duration of HF before implantation, and stability of recovery before and early after VAD removal. To assess the predictability of post-weaning outcome without heart transplantation or other VAD implantation and to identify risk factors for post-weaning HF recurrence, the authors used the data collected before and during VAD support. After successful weaning of patients from LVADs, the authors finalized and proposed the final weaning protocol.

Birks *et al* [9], proposed the following criteria with the LVAD at 6000 rpm for 15 minutes: Left Ventricular End-Diastolic Diameters (LVEDD) <60 mm, LV end-systolic diameter < 50 mm, and Left Ventricular Ejection Fraction (LVEF) >45%, LV end-diastolic pressure or pulmonary capillary wedge pressure (PCWP) <12 mm Hg, resting cardiac index >2.8 L•min^{-1}•m^{-2} and maximal oxygen consumption with exercise > 16 mL•kg^{-1}•min^{-1}. These criteria were considered the minimum for explantation, and if the above parameters were still improving, the combination therapy was continued until the maximum improvement had been achieved in each patient.

In the framework of the SensorART project [10], a platform responsible for the management of patients suffering from end-stage HF has being developed,

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incorporating different hardware and software components in a holistic approach, in order to improve the quality of the patients' treatment and the workflow of the specialists. Core component of the SensorART project is the specialist's DSS (SDSS), incorporating functionalities like selection of the most suitable candidates for VAD weaning, decision of the most appropriate treatment strategy for the medication process, detection of different pump states and identification of possible issues associated to the suction phenomenon, identification of the most proper pump speed settings, *etc*. From the above mentioned opportunities, identification and selection of candidates who might be weaned from LVAD, is being managed by the weaning module. The weaning module is an innovative platform for the creation, editing and application of new weaning expert crisp rules. The scope of this paper is to present the architecture and functional specifications of the weaning module and especially its two main sub-modules: the Clinical Knowledge Editor and the Knowledge Execution Engine. In addition, an application scenario is presented for detailed identification of the weaning process.

II. MATERIALS AND METHODS

The weaning module is a web-based application that enables specialists to create and modify expert rules for weaning. These are in the form of comprehensive and personalized IF-THEN rules. The weaning module combines expert knowledge with multivariate statistical analysis, in order to support the specialists on the weaning decision, i.e. the selection of patients with adequate cardiac recovery that may be removed from the VAD therapy. The module interacts initially with the patient's data repository component that is the main repository of the SDSS, the crisp engine and the fuzzy knowledge subsystem. More specifically, the module handles data such as patient information (e.g. demographics, medical history, medication), VAD parameters, sensor measurements, laboratory measurements, clinical evaluations as well as knowledge data (in the form of expert rules) coming from medical and VAD experts. These data are processed and analyzed in order to provide the situation of each patient (candidate for weaning or not).

A. Implementation Design

The module is a web-based component, providing advanced functionalities through a controlled environment. Its user interface features flexible data presentation controls and fully customizable charts, providing rich and dynamic layouts. The aim was to develop an intuitive application that the specialists can easily master in order to perform complex analyses. Its implementation conforms to the Research-Based Web Design & Usability Guidelines produced by the U.S. Government Department of Health and Human Services (HHS) [11]. The weaning module is based on well-acknowledged web technologies such as XHTML, CSS, PHP and JavaScript. It consists of client-side and server-side scripts that implement a set of pages, and enable authorized access to the different functionalities of the SDSS. Particular attention also is given to the inclusion of Ajax, thus supporting a highly interactive environment without interfering with the behavior of an existing page and avoiding full page reloads.

In Fig. 1, the data flow diagram of the overall process is presented. The SensorART administrator can use the Clinical Knowledge Editor to create a new weaning model. The model is then automatically stored in the SensorART database using web services. The models can be accessed remotely either from the administrator or other researchers by using an easy-to-use web interface. This platform allows the user to perform several actions using various technologies, including *PHP, Javascript, SQL, XSLT, XParser, XLink, XML DOM* etc. Then, from the knowledge execution engine section, he can initially choose a patient and a model that has been already stored in the SensorART database. Thereafter, the administrator can confirm or edit the structure of the model (except those already proposed in the literature), apply crisp or fuzzy rules and receive the result. The output of the weaning module is weaning or non-weaning.

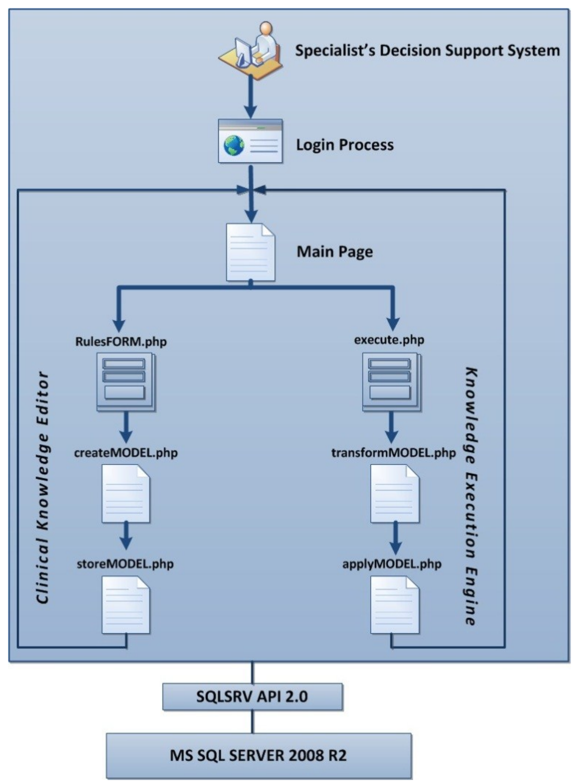

Figure 1. Data flow diagram of the weaning module.

B. Scenario

The administrator has two main options, to create a new crisp model (using the *Clinical Knowledge Editor* tab) or choose a model from the models repository applying a crisp knowledge-based weaning model (from the *Knowledge Execution Engine*).

- *Clinical Knowledge Editor*

Choosing the Clinical Knowledge Editor, the user is transferred to the main form of the weaning application and especially the model creator. The application main page is shown in Fig. 2.

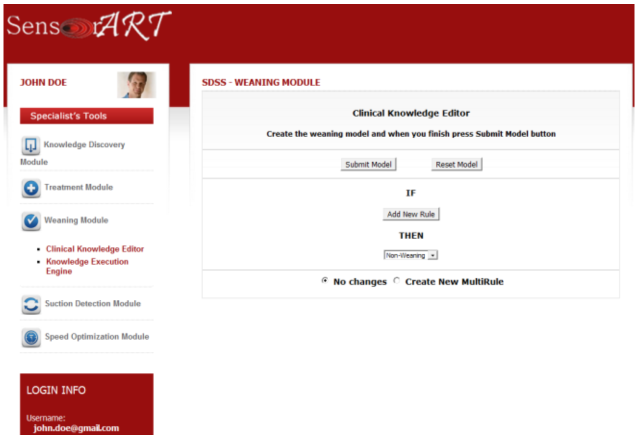

Figure 2. The Clinical Knowledge Editor main page.

The administrator can create/build rules and conditions forming the model structure. Also, he can choose from a specific set of parameters operational conditions and values obtained automatically from the SensorART database. Medical expert can choose from a list of 72 parameters concerning ECHO recordings, comorbidities etc. The creation of the model components is visible step by step to the administrator. The models are created using the disjunctive normal form (DNF) formulation, i.e. the model is a disjunction of rules (rules connected with the OR binary operator) and each rule is a disjunction of literals (literals connected with AND binary operator). Fig. 3 shows a case of rules creation. The first contains 4 rules with output *Weaning* while the second one has 2 rules with output *Non-Weaning*.

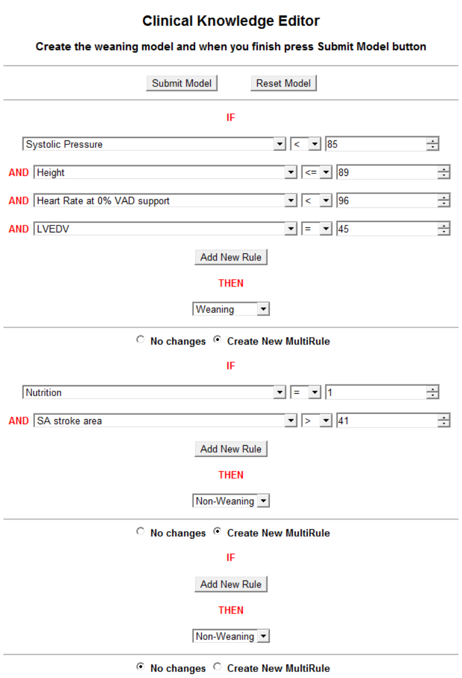

Figure 3. A snapshot of the rule editor.

Finally, the model is automatically stored in the database in XML markup representation, together with a unique model id number, the id of the administrator automatically retrieved from the platform (*User id*), the date created and the model name (given by the administrator).

- *Knowledge Execution Engine*

The main page of Knowledge Execution Engine sub-module is shown in Fig. 4. The administrator has to choose from two different lists. The first contains all patients that exist in the database. The second one contains all models, already stored in the database. The list of the patients and models is retrieved dynamically from the SensorART database.

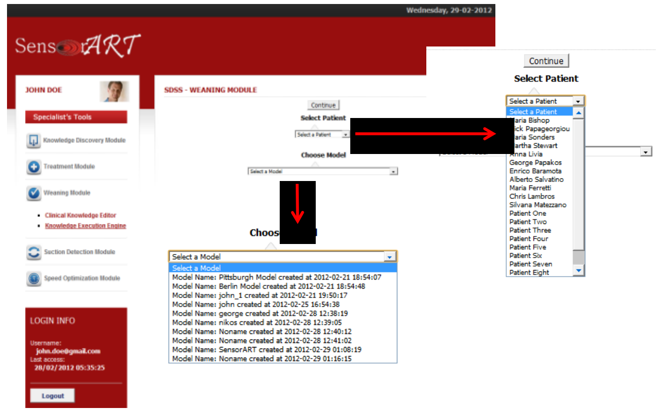

Figure 4. A snapshot of the Knowledge Execution Engine main page.

When a specific patient is chosen, personal information of the patient is presented. In the same way, the structure of the model is shown automatically. In the next step, the administrator has the opportunity to edit the structure of the model, except of the proposed models already described [7-9], that have been incorporated in the database as crisp models. In all remaining models, there are several options for editing, including change of a parameter/relational condition/ values of a rule, deleting a node, deleting a rule. Fig. 5 presents the rule editor in case of the model created in the previous section.

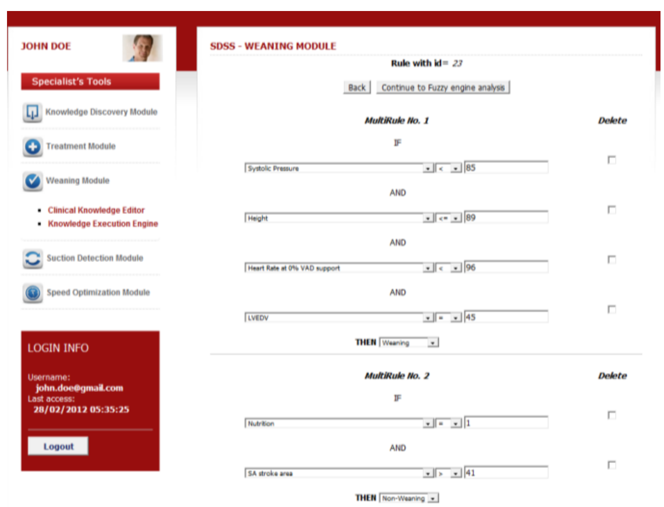

Figure 5. The model editor.

In the final step, the crisp or fuzzy engine (depending of the administrator's choice) is applied using the patient data and the model selection. The recordings of the patient and the model are retrieved automatically from the database, and the output (weaning/non-weaning) is reached.

C. *Weaning model structure*

The weaning models are created automatically from the platform based on the XML markup representation [12]. XML provides a grammar for parsing a particular file or stream format. This XML grammar covers basic syntax, the most interesting being that of element tags and attribute specifications. The structure of the model is based on a XML schema, initially designed from us. An XML schema specifies valid elements and attributes in an XML instance. Furthermore, a schema specifies the exact element hierarchy (for nested elements). In our case we created a schema to specify the value, the type, the order in which they can appear, the way to be nested inside each other as well as possible restrictions of the weaning models. The model schema document is in accordance with the rules of the XML Schema specification defined by the World Wide Web Consortium (W3C). The schema contains a set of *MultiRule* nodes, using the DNF formulation:

IF <CONDITION 1> AND <CONDITION 2> AND … <CONDITION N><parameter> THEN <> Non-Weaning or Weaning.

Each *CONDITION* is in the form of *<parameter><Relational_operator><value>*. In Fig. 6 the content model of the model schema is presented and in Fig. 7 the XML markup representation for a crisp model is shown.

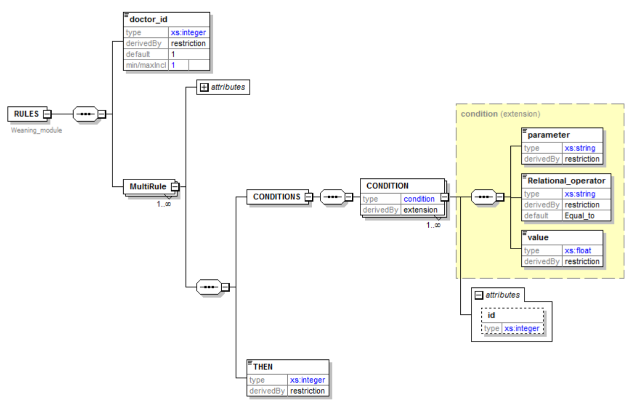

Figure 6. The XSD schema used in the weaning module.


```
<?xml version="1.0" encoding="UTF-8"?>
- <RULES>
    <doctor_id>23</doctor_id>
  - <MultiRule id="0">
    - <CONDITIONS>
      - <CONDITION id="0">
          <parameter>5 </parameter>
          <Relational_operator>4</Relational_operator>
          <value>85</value>
        </CONDITION>
      - <CONDITION id="1">
          <parameter>13 </parameter>
          <Relational_operator>6</Relational_operator>
          <value>89</value>
        </CONDITION>
      - <CONDITION id="2">
          <parameter>64 </parameter>
          <Relational_operator>4</Relational_operator>
          <value>96</value>
        </CONDITION>
      - <CONDITION id="3">
          <parameter>1 </parameter>
          <Relational_operator>1</Relational_operator>
          <value>45</value>
        </CONDITION>
      </CONDITIONS>
      <THEN>2</THEN>
    </MultiRule>
  - <MultiRule id="1">
    - <CONDITIONS>
      - <CONDITION id="4">
          <parameter>49 </parameter>
          <Relational_operator>1</Relational_operator>
          <value>1</value>
        </CONDITION>
      - <CONDITION id="5">
          <parameter>45 </parameter>
          <Relational_operator>3</Relational_operator>
          <value>41</value>
        </CONDITION>
      </CONDITIONS>
      <THEN>1</THEN>
    </MultiRule>
</RULES>
```


Figure 7. The XML markup representation of a crisp model.

III. Discussion and Conclusions

The SensorART weaning module is a web-based innovative tool that allows the experts to easily create and modify knowledge-based weaning models, based on a set of comprehensive and personalized crisp rules. The weaning module is based on a "mixture of experts" approach, in the context of including several weaning models presented in the literature and providing the necessary tools for the incorporation of new weaning models. Thus, given that all necessary information for a patient is available, the user of the SensorART platform (medical expert) can examine a patient's weaning possibility against several different "experts". This approach has been selected because it resembles the real life, where a patient in critical condition will seek the opinion of more than one expert. Knowledge-based crisp models are more comprehensive for the medical experts and thus they have been selected for the initial formulation of the medical expert's knowledge and expertise. However, fuzzy models have developed based on the initial crisp knowledge-based models, since they have flexible decision boundaries and thus they are able to cope with the complexity of the decision more accurately [13].

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