

Improvement of Surveillance of Hemophilia Treatment through ICTs

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Abstract— hemophilia, in addition of being a chronic disease, is also a rare disease, and as such, quite expensive for the National Health Service (NHS) due to the cost associated with the drugs used in treatments (Clotting Factor Concentrate - CFC). On the other hand, due to the specific characteristics of this type of disorder, it is necessary to ensure that data generated during the treatments are quickly communicated to the clinicians responsible for monitoring those patients. As such, an effective management of this disease, with maximum safety for patients, involves not only an efficient information management process, but also the coordination and management of all the associated resources. This article aims to present one specific component of a technological solution that can help in coordinate actions of patients, physicians and nurses, as well as improve the surveillance of hemophilia treatment, within a specific Comprehensive Hemophilia Diagnostic and Treatment Center (HTC).

I. INTRODUCTION

Hemophilia is a chronic disease that affects a small percentage of people worldwide, which allows classifying this pathology in the rare diseases category. The treatment of this disease is complex, very expensive and involves highly specialized skills in multidisciplinary teams, generally concentrated in specialized centers, known as Comprehensive Hemophilia Diagnostic and Treatment Centers (HTCs).

In the 1980s and 1990s, people with hemophilia (PWH) were faced with the tragic consequences of HIV and HCV infection through blood transmission. This circumstance led to a coordinated action from patients, clinical professionals (physician and nurses), government entities and pharmaceutical industry, in order to control all treatments

Manuscript received March 29, 2012. This work was made in collaboration with the Hematology Service of Coimbra Hospital Center (HS_CHC) and the Portuguese Association of Hemophilia (PAH), in Portugal.

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made by this type of PWH. This control can benefit from the integration of information and communications technologies (ICTs) as it is mentioned by the different authors [1-6].

This paper aims to present a component of a technological solution (*Hemo@care-Home*) that can help coordinate actions of patients, physicians and nurses, as well as improves the surveillance of hemophilia treatments within a specific HTC.

In order to present this solution and the potential advantages that it could provide for their main users, this paper was structured in four sections. In the present section we describe some particularities of this disorder in a clinical context. In the second section, a brief overview of home-treatment registry and the main particularities of this disorder justifying the importance of an integrating technological solution are presented. The third part is devoted to a brief description of the technological solution, in a functional perspective, to improve the surveillance for hemophilia treatment. Finally, conclusions are presented in the last section.

II. HEMOPHILIA, HOME TREATMENT REGISTRY AND ICTS

Hemophilia is a congenital bleeding disorder caused by low concentrations of a specific coagulation factor, requiring a specific treatment through infusions of Clotting Factor Concentrates (CFC), to compensate the missing clotting factor in the body. With treatment products, PWH can live healthy lives, whilst without treatment, hemophilia causes crippling pain, severe joint damage, disability and death [7].

The development of CFC contributed to life improvement of the PWH, making possible the treatment at home with a high level of independence. Most people with severe hemophilia who have the conditions for self-infusion are on therapy at home [8].

Concerning the home-therapy using CFC, there are significant benefits associated with it, decreasing the economic impact and improving the life quality for patients and their families [8]. With home-therapy, CFC can be administered as soon as a bleeding starts (on-demand), or in a prophylactic regime, minimizing the amount of CFC needed and avoiding long-term joint damage [8-10]. Reductions in hospitalizations and time lost from work or school associate with treatments at home, represent also a marked improvement in patients' quality of life [2].

Nevertheless, if on the one hand this kind of treatment

presents great benefits to patients, on the other hand, it contributes to difficulties in monitoring their treatments and progress, as well as to detect complications resulting from those treatments. In the countries, regions or Hospitals without appropriate systems to register hemophilia domiciliary treatment, the patients record the results from home treatments in paper diaries and send them to the HTC too late, using inappropriate supports. Therefore, the time between the treatments made by patients and the knowledge of the results by physician may be long, which is undesirable, since that data is crucial for clinical decision concerning future plans of treatments. In this pathology the timely information is more than a resource, as further clinical decisions about patients' treatment depend on it.

In this context, the web-based ICTs in supporting the home-treatment registry, claiming to be one of the most relevant applications of electronic recording to identify early episodes of bleeding in the home setting, which otherwise would not have become apparent until the patient's next clinic visit [11-14]. ICTs are also helpful in identifying inappropriate use of CFC during home-therapy. On the other hand, at a time when the cost of providing CFC has risen significantly, it is important to the hemophilia community to establish more effective mechanisms for recording home-therapy data in order to track the usage of this drug at any time.

Furthermore, the haemophilia is a chronic and rare disease, and its treatment involves highly specialized skills in multidisciplinary teams concentrated in HTCs, being considered an extremely costly disease for the National Health Service (NHS), due to the cost associated to the CFC. A patient with a moderate degree of haemophilia can lead to the government entities a cost of around € 30,000 per year, while one patient with a severe level could reach a value of € 125,000 per year. Using the principle of classification ABC or curve '80/20' to classify the costs of different diseases within the NHS, haemophilia would certainly be included in Class 'A', with a high concentration of costs associated with a small portion of the population. This fact, not only points to the need for efficient management of the disease, but also for effective management of the resources involved, having the ICTs an important role in that process of management, as well as in the improvement of surveillance of hemophilia treatment.

II. HEMO@CARE-HOME: COMPONENT OF HEMO@CARE TO MONITOR HEMOPHILIA TREATMENT

Hemo@care is a Web-based application to manage the clinical information in haemophilia care, used by clinical haematologists, nursing staff, and patients suffering from haemophilia, developed to a specific HTC located in Portugal [15]. It incorporates an extensive dataset, including medical information (eg. physical examination results, laboratory data, detailed information on the primary diagnosis, symptoms and manifestations, treatments,

potential complications.) and non-medical information (eg. demographic information, socio-psychological background), providing healthcare professionals with tools to manage all the essential information regarding patients' data.

Hemo@care-Home is an important component of this application (*Hemo@care*) devoted to support the management, tracking and monitoring of treatments administrated in PWH, Figure 1.

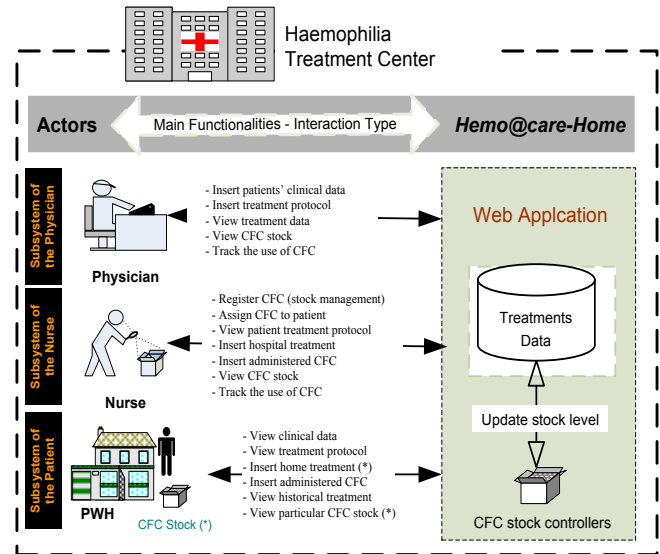


Fig 1 - Interactions in *Hemo@care-Home*.

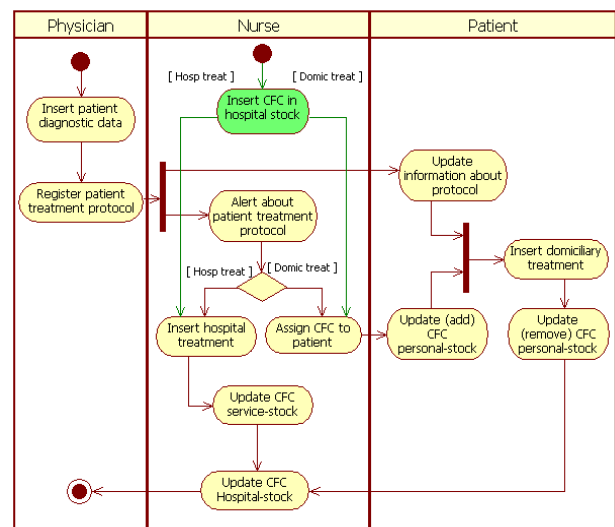


Fig. 2 – Flow-chart with the transversal process of CFC stocks and treatments components.

Hemo@care-Home has a set of features divided by three different subsystems (subsystem of the physician, subsystem of the nurse and subsystem of the patient) in order to track and monitor the treatment of patients and, consequently, improving their surveillance, Figure 1. This requires the compilation of a set of data, generated in different contexts by the Physician, Nurse and Patient actors, in a transversal process that connects the CFC stocks and treatments management components, Figure 2.

A. Subsystem of the Physician

The *Physician* is the actor who inserts patients' clinical data resulting from the diagnosis observed, and, consequently, inserts the treatment protocol. This protocol, beyond the characterization of the type of treatment (on-demand, prophylactic) also defines the treatment regime, as well as the amount of CFC administered each time. This treatment regime, according to the particular conditions of each patient relating to the autonomy for self-infusion, can be domiciliary or only in hospital. After introducing treatment protocol, the system automatically alerts the nurse responsible by the follow-up the patient's treatment, and, at same time, updates this information in the respective patient subsystem (see process in Figure 2).

Concerning the information that this actor can visualize in order to monitor the treatment and surveillance of the patient, the system presents different functionalities, namely:

- the option to view all detail related to treatment data (type of treatment; in case of on-demand treatment the symptoms observed, body region of the bleeding and time of bleeding; time of infusion, batch number of CFC administrated and amount of CFC in international units administrated);
- the option to check the CFC assigned to patients;
- the option to track the use of CFC (using the batch number of CFC is possible to know the brand name of the product and consequently to recover the information about all patients that used this type of drug in treatment, and the location of some products that weren't yet consumed).

B. Subsystem of the Nurse

The *Nurse* is the actor responsible for the management of stocks of CFC and for the registry of hospital treatments. This subsystem allows the nurse to make the management of stocks of CFC, registry the patient's hospital treatments, as well as monitor the entire treatment process.

The first step to the management of stocks of CFC begins with the nurse, by inserting in the system the batch number and the corresponding quantity of CFC, when the products arrive at the hospital. After this, the nurse can assign this CFC to patients in order to be used in domiciliary treatment, or register their use in a hospital treatment administrated to a specific patient (see process in figure 2 and the interface in Figure 3).

It is important to note that on the process of assigning CFC to patients, the batch number of those products will be removed from the service-stock, and will be registered in the patient's personal-stock. However, these batches are still considered in the hospital-stock, since this included the service-stock adding the sum of the total patient's personal-stock, (eq.1).

$$(eq.1) \quad [hospital-stock = service-stock + \sum personal-stock]$$



Fig. 3 - Display and Assign CFC to patients (Interfaces in Portuguese).

C. Subsystem of the Patient

In this particular disease, patients have a very important role in the information management, as they are directly involved in the registration of the data generated in the home treatments.

At home, patients insert the bleeding episode and the treatment data as a nurse. While the nurse registers the hospital treatment, the patient is responsible for the registration of the same type of data in case of home treatment. These data are automatically transmitted to the HTC, and the physician, in online overview, can analyze them. In order to be able to register a home treatment, patients must have the CFC product in their personal stock, and the information about treatment protocol that was introduced by physician. CFCs dispensed in the patients' virtual personal-stock were electronically assigned by the nurse; however they will be accounted in the hospital-stock until its consumption (eq.1). When a patient registers one treatment, he/she selects the batch number of their personal-stock and, automatically, those batches are marked as consumed by that patient. As a result of this consumption, the personal-stock and consequently the hospital-stock are updated (see process in Figure 2).

With these automatic mechanisms it is possible to track all the lifecycle of a specific CFC product, since it remains in the system, until it was consumed. Based on this mechanism, in the future, if necessary, it will be very easy to locate a specific CFC product or to track the usage of a particular batch, Figures 4 and 5.

Actually, one of the most important features of this system is the possibility to track the CFC batches, a feature resulting from the perfect integration between the stock management and the treatment register components, Figure 5. All the products of the same type, of the same

laboratory and created with the same substances, have the same characteristics and therefore are associated with the same batch number. In a potential abnormal situation, such as occurred in the 1980s and 1990s, it is possible to track a CFC batch number (Figure 4) and, automatically know all the patients that consumed this product as well as the location of the products not yet consumed (Figure 5).

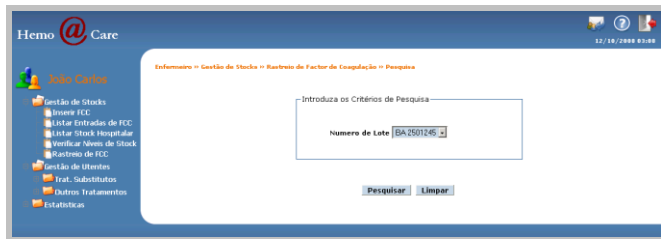


Fig. 4 - CFC Tracking: search by batch number (Interface in Portuguese).

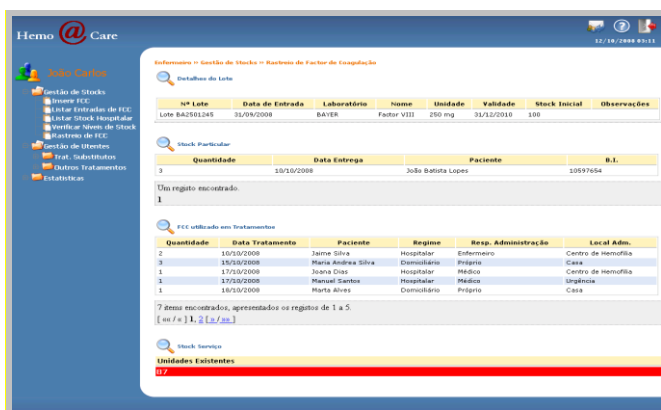


Fig 5 - CFC Tracking: search by batch number and visualization of results (Interface in Portuguese).

Another important feature of this system that strongly contributes to the quality of hemophilia treatment surveillance is the possibility given to physicians of monitoring the treatment process, as emergency situations are automatically alarmed using priority messages. The system can alert bleeding and treatment problems, as well as incorrect data insertion (treatment inserted) by the patient.

IV. CONCLUSION

Hemophilia is a congenital bleeding disorder caused by low concentrations of a specific coagulation factor, requiring a specific treatment through infusions of CFC. This type of rare and chronic disease requires strong coordinated actions from patients, clinical professionals (physician and nurses), government entities and pharmaceutical industry, in order to control all the treatments process made by this type of PWH. *Hemo@care-Home* is a component of a complete technological solution (*Hemo@care*), developed in a close collaboration with a specific HTC located in Portugal, and is devoted to help coordinate actions by patients, physicians and nurses, as well as improving the surveillance of the hemophilia treatments of that particular HCT. It allows the management of hemophilia treatments, integrating large sets of data generated by the three main actors: Physician, Nurse

and Patient. Thus, this system improves the process of information management associated with the clinical practice, since it allows clinicians too quickly and easily access a set of meaningful data. Additionally the system provides a set of alerts to abnormal situations, or to those that requires being reviewed by a clinician. For the patients, the system also brought additional benefits, as it allows recording and sending their treatments data, when previously they would have to be recorded on paper and delivered at the hospital. This helped to improve the quality of life for patients, putting them in constant contact with the hospital. Finally, there is the possibility to automatically manage the stocks of CFCs used in treatments, which relieves the nurses from those manual, time consuming and error prone tasks.

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