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How to Represent the Decision Process in a Medication Plan: the Case of the Swiss Cohort of Inflammatory Bowel Diseases

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Abstract. Inflammatory bowel diseases (IBD) belong to healthcare problems impacting the quality of life and inducing important costs for the healthcare system. There is still no magical cure against this kind of diseases, but many promising therapies are under investigation. In order to study the efficiency and side effects of the existing drugs and to evaluate new ones, large numbers of patients are followed in long term cohort studies. The particular constraints associated to the follow up of patients with IBD require the implementation of adapted and efficient tools. On the one hand, clinicians must be able to perform daily changes to the patient treatment in order to adapt it for its best efficiency and react to side effects. On the other hand, the tool must provide long term view on the data to allow large scale analyses regarding the efficiency of the investigated treatment. There are few solutions allowing a clear visualization of the treatment plan of the patients in the long term that indicates clearly the changes and the adverse events. In this work, we propose a new integrated tool that offers a clear temporal view over the patients’ treatment.

Keywords. Cohort Studies, Medical Order Entry Systems, Inflammatory Bowel Diseases, Chronic Disease, Drug-Related Side Effects and Adverse Reactions, User-Computer Interface

1. Introduction

Inflammatory bowel disease, or IBD, is a family of systemic diseases involving inflammation of the gastrointestinal tract. IBD includes two (or three) diseases of unknown causation: ulcerative colitis, which affects only the large bowel; Crohn's disease, which can affect the entire gastrointestinal tract; and, indeterminate colitis, which consists of large bowel inflammation that shows elements of both Crohn's disease and ulcerative colitis.

The advent of biological drugs has had a significant impact on the management of inflammatory bowel diseases. For an important group of patients with Crohn’s disease and ulcerative colitis, treatment with biologics has led to an improved quality of life, fewer admissions in hospitals and fewer side effects from corticosteroids and/or immuno-modulators. Nonetheless, biologic agents are still being used with reluctance.

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The most frequently cited reasons for this are the high cost and uncertainty about long-term safety. The idea that biologic agents interfere with key molecules in the human physiology justifies these concerns, as unexpected toxicity problems have occurred and recognized to be related to biologic therapies. A few examples include: deterioration of heart failure; reactivation of mycobacterial infections with anti-tumour necrosis factor (TNF) agents; rare occurrences of lethal viral encephalitis with the anti-integrin antibody natalizumab and the dramatic cytokine release syndrome that was observed in healthy volunteers treated with a monoclonal antibody directed against CD28. Fortunately, stringent post-marketing surveillance programs and registries have allowed early recognition of most of these problems and appropriate measures and guidelines have been developed to prevent and treat them.

Due to the risks associated to the use of biological drugs, it is important to have a clear overview of the follow-up of patients, covering: administrated drugs; adverse events; length of the treatment and interruptions. The classical display of the treatment plan is provided as a sequence of prescriptions. While this sequential representation allows an easy identification of the drugs prescribed to the patient, it has two main drawbacks: a) It doesn’t allow a precise temporal localization of different adverse events and modifications that occur during the therapy (discrete timeline); and b) it makes it complicated to compare this timeline with additional layers of information that are important to understand the cases in their context.

Figure 1 Sequential presentation of the treatment plan

1.1. Challenges and constraints:

One tool for daily and retrospective uses: The tool must support clinicians in the creation and editing of the treatment plan necessary for the long term patients’ follow-up. Since clinicians must be able to prescribe new drugs with precision, the tool must enable differentiating the induction and maintenance period, to define clearly their duration and associated dosage. It must also enable the clinician to catch and comment any events occurring during the treatment.

The tool must also provide an overall view of the treatment plan and associated events. This overall view must enable a clear understanding of the complete process using an exploratory approach. Adverse events, treatment modifications and treatment stops, various phases, relations, must be clearly identified and explicit. The tool should also assist the researchers to answer numerous questions related to the treatment. For instance, they must be assisted to evaluate the treatment adherence by comparing the expected and the real treatment.

Following simultaneous prescriptions: Many patients receiving treatment with biologic agents also have concomitant therapies to which the biologics are added. It is
important to realize that not all toxicity problems occurring to these patients are related to biologic therapy, but can be caused by the concomitant therapies in inflammatory bowel disease (IBD), most often corticosteroids and/or immunomodulators.\(^6,8,9\)

2. Method

This preliminary work proposes an alternative representation of the treatment history of patients with IBD. Based on focus groups involving clinicians and epidemiologists, we have identified the main constraints related to the patient follow up and treatment analysis and produced a functional specification.

3. Results

Based on the functional specification, a working prototype has been developed using a HTML5/JavaScript framework. The software performs a connection to the cohort database and retrieves the treatment plan for the selected patients. An informal preliminary evaluation has been performed with clinicians. The implemented solution is composed of three views, one to enter a new treatment, one for the treatment modifications and reporting and finally an innovative temporal summative view over the complete treatment representing the decision process. The goal of the summative view was 1) to allow a precise reporting of the different event occurring during the treatment; and 2) visualizing this information in context with other indicators that can be useful for the understanding of the emergence of adverse events.

3.1. Starting a new treatment

In order to perform the long term follow up of the patients with IBD, clinicians must be able to start a new treatment, to define its length and the dosage to be used during the induction and maintenance stages (Figure 2).

![Figure 2 Interface for starting a new treatment](image)

3.2. Treatment follow up

It is important to be able to react to all the side effects that can occur during the patient treatment. The treatment follow up interface (Figure 3) allows for the suspension of a treatment, the notification of adverse events and the modification of dosages. This is a simple and efficient way to manage the current treatment. However we would like to insert these features directly in the treatment overall view presented below.
3.3. Representing the decision process

The view offers an insight over the medication plan for the whole duration of the patient treatment. Information is displayed over a temporal axis. Each information type is identified with a specific color scheme. The drug prescribed to the patient is usually administered in several stages, including the induction and the maintenance stages. These two stages are clearly represented with different colors, blue for induction and green for maintenance. The yellow box contains the decision process information, such as the treatment modifications including dosage or modification of stage. Finally, the red boxes are devoted to adverse events.

The interface can be easily manipulated using a mouse or tactile surfaces. For instance, on figure 4, we have an example of the zooming capabilities of our interface. Selecting an element or a temporal window will zoom that specific part of the treatment plan and display all details.

The display of several simultaneous treatments on a different tread on the screen, makes it possible to visualize the parallel evolution of these treatments (Figure 5). This parallel representation may help physicians to identify which events are related with a specific therapy.
4. Conclusion

Great hope exist for biological treatments for numerous diseases, among them IBD. The duration and specificities of these biological treatments require specific tools that allow reporting and visualizing long term medication plans. These tools must provide efficient interactions paradigm and adapted interfaces to facilitate the understanding of the treatment processes and represent the decision steps. The system must also ease the representation and overview of the adverse events, which can be very severe.

In this work, we propose a new tool to support biological treatments, allowing both the creation of treatment plans by clinicians and their analysis by researchers. This tool provides three different views allowing the start of a treatment, its follow-up, its modification as well as the reporting of adverse events. An intuitive interface offers a temporal overview of the entire treatment emphasizing all decisions modifying the treatment process. The first impression of the clinicians toward the tool is very positive, but a more formalized study, comparing the exploration process between the prior and the new interface, is ongoing to validate quantitatively and qualitatively the benefits of our representation.

References