Improving medical protocols through formalisation: a case study

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Medical practice protocols or guidelines contain more or less precise recommendations to assist practitioners and patient decisions about appropriate health care for specific circumstances. In order to reach their potential benefits, protocols must fulfill strong quality requirements. Medical bodies worldwide have made efforts in this direction, but mostly using informal methods such as peer review of protocols. In this paper we present a different approach, namely the quality improvement of medical protocols through formalisation.

Currently, protocols are described using a combination of different formats, e.g. text, flow diagrams and tables. The underlying idea of our work is that making these descriptions more precise, with the help of a more formal language, will expose parts where the protocols are ambiguous, incomplete or even inconsistent. By pointing out these anomalous parts, we expect to obtain useful indications for the improvement of the protocols. This idea is widely acknowledged in fields like software engineering, where formal methods are used as a tool for early detection of specification and design errors, but has been largely unexplored for medical protocols.

The research question that we try to answer in this paper is: **can formalisation contribute to improve the quality of medical protocols?** To answer this question, we have carried out a case study on protocol formalisation. For this purpose, a choice had to be made on the specific protocol representation language as well as on the medical protocols to be used. Several languages exist for representing medical protocols. For our case study we need a sufficiently formal and detailed enough language since only precise descriptions will allow us to uncover anomalies in the protocols. We have chosen Asbru, firstly because it is more precise in the description of various medical aspects, and secondly because Asbru protocols are more declarative, and thus they are more amenable to formal analysis. Concerning the protocols, we have tried to select two examples covering different features. The first one is a protocol for the management of diabetes mellitus type 2, which comes from the set of protocols developed by the Dutch Association of General Practitioners. The second example is a pediatrics protocol for the management of jaundice in healthy newborns, developed by the American Academy of Pediatrics.

During the Asbru formalisation of the protocols, numerous anomalies became apparent. In a general sense, we have used the term anomaly to refer to any issue preventing a satisfactory interpretation of the original protocol. The fact that these anomalies were de-
ected during formalisation is already a surprising result, since the two selected protocols can be considered of the highest quality produced by the medical profession. Below we give some examples of the different types of anomalies we found. For presentation purposes, we describe them under general categories such as ambiguity and incompleteness.

As example of ambiguity, we can cite different terms (e.g. “jaundiced” and “clinically jaundiced”) that appear throughout the jaundice protocol with no clarification about whether they are used indistinctively or not. Incompleteness can be related either to insufficient information or to completely missing pieces of information. Missing information is by far the most common anomaly in the studied protocols. An example is the use in the jaundice protocol of the abstract notion “rapidly rising TSB\(^1\) levels” without an indication of when the TSB rise can be considered rapid. Inconsistency refers to elements that may result in different (and even conflicting) decisions given the same patient data. The jaundice protocol presents several inconsistencies. In general they involve differences between alternative formulations of the same recommendations. An example is a sentence stating that continued observation may be an alternative to repeated TSB measurement and phototherapy. This is not reflected elsewhere in the protocol, specially not in the table specifying the appropriate therapy based on the TSB value. Finally, redundancy occurs when some part of a protocol can be removed without any (noticeable) effect in the resulting prescriptions. The only redundancy we have detected is in the diabetes protocol, and involves a repeated question about weight in the annual control.

To give a better idea of the extent of uncovered anomalies, some concrete numbers follow. In the case of jaundice protocol we found 1 ambiguity, 10 incompleteness anomalies, 6 inconsistencies and no redundancy. Regarding the diabetes protocol, we identified 4 ambiguities, 38 incompleteneeses and 2 redundancies, but no inconsistency. Here, it is important to note that these high numbers are due to the high complexity of the protocol and thus should not be interpreted as an indicator of a lower quality.

As we have shown in our study, a significant number of anomalies can be detected, even in high quality protocols, through Asbru formalisation. These anomalies are protocol parts in which potential problems might arise, and therefore indicate points where improvements are possible. Although it can be argued that the anomalies we found could have been detected by alternative means, the fact is that formalisation has proved to be useful for this purpose. We think that formalisation does provide a good foundation for detection of anomalies, since the use of precise notions enforces a critical examination of the protocol. Solving the anomalies detected through formalisation not only can contribute to the enhancement of protocol quality but also would allow for a wider range of applications, including the use of protocols as a basis for the development of computerised tools.

The main drawback of our approach is the high cost of formalisation. It can be argued that this cost is too high with respect to the number and seriousness of the problems we have detected. In our view, it is a price that must be paid if we want to ensure the reliability of medical practice protocols. Besides, the costs of formalisation should be also weighed up against several other benefits.

\(^1\)Total serum bilirubin.