



Project presentation IST-2001-33049 – PROTOCOLCURE: Improving medical protocols by formal methods

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1. Project number and acronym

IST-2001-33049 – PROTOCURE.

2. Project title

Improving medical protocols by formal methods.

3. Key action/Action line

Future and Emerging Technologies arm of the IST Programme, FET Open scheme.

4. Project logo



5. Project abstract

During the last decade, the approach of evidence-based medicine has given rise to an increasing number of medical practice protocols. However, the work done on developing and distributing protocols outweighs the efforts on guaranteeing their quality. Indeed, anomalies like ambiguity and incompleteness are frequent in medical protocols. Recent efforts have tried to address the problem of protocol improvement, but they are not sufficient since they rely on informal processes and notations. As a result, many practical protocols are still ambiguous or incomplete. Even when ambiguity and incompleteness are intentional, so that organisational or personal practices can be deployed, it is important to make them explicit. A different approach, grounded on a formal representation of protocols, can answer these needs. The proposed solution relies on an appropriate protocol representation language that allows for a systematic verification by formal methods.

6. Problem statement and approach

During the last decade, the approach of evidence-based medicine has given rise to an increasing number of clinical practice guidelines and protocols. They provide clinicians with health-care recommendations based on valid and up-to-date empirical evidence. In this way, they facilitate the spreading of high standard practices that otherwise would have much less impact. Moreover, it has been proved that adherence to guidelines and protocols may reduce health-care costs up to a 25%.

A high number of medical guidelines have been published in the literature and Internet, making them more accessible. **However, the work done on developing and distributing guidelines far outweighs the efforts on guaranteeing their quality.** Indeed, anomalies like ambiguity and incompleteness are frequent in medical guidelines. Even more, they can be inconsistent because of the lack of familiarity of the designer with certain principles and notations. The most important consequence of these problems is that they preclude the effective application of guidelines.

Recent efforts have tried to address the problem of guideline quality improvement. The medical community has sought to organise and integrate guidelines into compendiums, to make them more accessible, usable and comprehensible. With the aim of ensuring a high degree of quality, the organisations promoting these initiatives have also set minimal standards for the inclusion of guidelines in the compendiums. These standards take into account, for instance, the relevance and validity of the sources employed for the development of the guidelines. **These approaches are not sufficient since they rely on informal processes and notations.** As a result, many practical guidelines are still ambiguous, incomplete or inconsistent. Even when ambiguity or incompleteness are intentionally included in guidelines by the designer, so that organisational or personal practices can be deployed at certain points, it is important to make them explicit as choices. A substantially different approach, grounded on a formal representation of guidelines, can answer these needs.

An appropriate representation language, with a clear and well-defined semantics, would allow for a systematic verification of guidelines by formal methods. Unlike the after-dissemination activities mentioned before, this approach would make quality improvement possible during the stage of guideline development.

Research from the fields of computer science and artificial intelligence can help in both the definition of an adequate guideline description language and the development of techniques for the formal analysis of guidelines. The language must give means to represent explicitly, and in a non-ambiguous way, all the relevant knowledge about guidelines. Based on the formal semantics of this language, the analysis techniques should allow for the determination of, for instance, completeness (no missing cases), consistency (no contradictions) and correctness (objectives are satisfied).

7. Objectives

The solution suggested to the problem of quality improvement of protocols consists in the utilisation of formal methods. It supposes the definition of an adequate protocol representation language, the development of techniques for the formal analysis of protocols described in that language and, more importantly, the evaluation of the feasibility of the approach based on the formalisation and verification of real-life medical protocols. For the first two aspects we will rely on earlier work by consortium partners, on the Asbru language for protocol description and on the KIV interactive verification system. The third aspect, namely **the evaluation of the feasibility of the use of formal methods for quality improvement of protocols, constitutes the main objective of this assessment project.**



8. Description of the work

The steps with which we will carry out this evaluation are the following:

1. Take two real-life reference protocols which cover a wide variety of protocol characteristics
2. Formalise these reference protocols
3. Check the formalisation in an exercise for the verification of interesting protocol properties
4. Determine how many errors (expected and unexpected) can be uncovered in this way

where step 4. will be our measure of success.

We will rely on earlier work by consortium partners, in particular, on the Asbru language for protocol representation and on the KIV interactive verifier system. This leads to the following tasks:

- Select reference protocols and model them in Asbru
- Define formal semantics for Asbru elements in KIV, and identify desirable/required properties to verify on these Asbru elements
- Translate Asbru model of reference protocols into KIV
- Verify some of the properties on the Asbru-in-KIV reference protocols
- Evaluate the verification results

9. Milestones and expected results

Different reports will be issued during the project, roughly after the completion of every one of the above tasks. The results of this assessment project will be in short:

- a consolidated formal language to model medical practice protocols
- two protocols, each both in Asbru and formalised in KIV
- a list of properties that medical protocols should verify
- verification proofs for these protocols using KIV
- perspectives of the potentials for this approach

10. List of participants

The consortium is made up of the following five institutions:

- Vrije Universiteit Amsterdam (VUA), Netherlands. Coordinator.
- Vienna University of Technology (UW), Austria.
- University of Augsburg (UAU), Germany.
- Dutch Institute for Healthcare Improvement (CBO), Netherlands.
- University of Aberdeen (UAB), United Kingdom.

11. Total cost and Community funding

The total cost of the Protocure project amounts to EU 112.725, and the Community contribution is EU 100.000.

12. Project start and duration

The Protocure project started on December 1st, 2001 and has a duration of 12 months.

13. Co-ordinator contact details

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