

Validation of a knowledge base for advanced CPOE systems based on test cases

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Abstract and Objectives

Medication errors and resulting Adverse Drug Events (ADEs) are an important issue of global healthcare, and CPOE systems are promoted to prevent them. Within the European PSIP project (<http://www.psip-project.eu>), contextualized decision support modules being part of CPOE systems and aiming at preventing ADEs are being developed. The objective of this paper is to describe the methodology used for their validation and to present first results.

Keywords:

Validation studies, Medical order entry systems, Medication error, Adverse drug event, Clinical decision support

Methods

Our validation comprises the following questions:

- How clinically correct are the alerts provided?
- How complete does the prototype cover the defined clinical setting?
- Is the priority of the alerts adequate for the given context?
- How understandable are the alerts to the clinicians?

We first conducted a literature search to identify available test cases. As we were not successful here, we then developed and validated test cases using an international iterative expert-based approach. The developed test cases were made available in a web-based repository (<http://ufo.umat.at:8080/psip>). The alerts given by the knowledge base after entering the test cases were documented and then compared to the expected outcome.

Results

At the moment of this first validation run, the knowledge base contained 135 rules. When entering the first 15 test cases, 125 alerts were generated by 45 different rules, most of them firing

several times. When eliminating double alerts, each test case generated between two and five alerts.

In 33 cases, the system generated correct alerts, but the expert felt that 24 of them should be displayed with another (mostly lower) priority. In 12 cases, alerts were judged to be false-positive – some of these alerts were not phrased in a clear way, leading to this judgment. In 7 cases, expected alerts did not come - this is mostly due to the still incomplete knowledge base that is used.

Conclusion

Alert overloading and unjustified alert overriding are a large problem and may prevent decision-support systems to positively affect patient safety. Prioritization and contextualization may help to address this problem. We presented an approach to validate the underlying knowledge base using test cases.

The development of the test cases showed that a clear phrasing of alerts is very important, that there are differences among experts of different countries in interpreting the correctness of an alert, and that the context of an alert is important when judging whether it is adequate.

Context information relevant for alert prioritization and alert filtering may comprise, among others, the clinical specialty of the user, the level of experience of the user, the ward, the hospital, the country, and the recent history of ADEs that occurred in a department. The PSIP project (<http://www.psip-project.eu/>) strives to further analyze and implement the most relevant context information.

In the next validation steps, the number of test cases will be increased, and the analysis of test cases outcome will be done by two experts, allowing calculation of inter-rater reliability. Results of the validation will be fed back to further development of the knowledge base (formative evaluation).