# TIME-SERIES STUDY OF THE IMPACT OF ADE SCORECARDS ON ADVERSE DRUG EVENTS: PRELIMINARY RESULTS

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### **Kurzfassung**

ADE Scorecards sind ein neuer Ansatz, um "Team Awareness" in Bezug auf Adverse Drug Events (ADE) zu erhöhen. ADE Scorecards präsentieren all automatisch entdeckten ADE-Fälle und zeigen mögliche Ursachen und Details der involvierten Patienten an. In einer Zeitreihenanalyse auf drei Studien in einem französischen Krankenhaus wurden die Auswirkungen der ADE Scorecards auf ADE-Raten evaluiert. Vorläufige Ergebnisse konnten keine signifikanten Veränderungen der ADE-Raten zeigen. Strategien sind offenbar notwendig, um ADE Scorecards besser in die klinische Routine einzubinden und um ihre Präzision zu erhöhen.

#### Abstract

ADE Scorecards are a new approach to raise the team awareness regarding ADEs. They present automatically detected ADE cases, together with possible causes and details of the affected patients. ADE Scorecards were introduced on three wards of a French General Hospital. A timeseries analysis of ADE data was conducted. Preliminary results could not show a significant change of ADE rates. Strategies need to be designed to integrate ADE Scorecards better into clinical routine, and to increase precision of ADE detection.

Keywords – Patient safety, medication therapy management, medical order entry systems, evaluation studies

## 1. Introduction

Adverse Drug Events (ADE) occur frequently during patient care [1]. Many of them are related to medication errors and are thus considered preventable [2]. The quality of the medication process depends, among others, on good communication and cooperation between different professionals such as physicians, pharmacists, and nurses [3,4]. Medication safety can thus considered a team task, based on a common "team situation awareness" [5].

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Within the European Union project "Patient Safety through Intelligent Procedures in Medication" (PSIP) [6,7], a novel approach called "ADE Scorecards" [8] was developed to prevent ADEs. It aims at making the team aware of ADE risks and their underlying causes [9]. We expected that ADE Scorecards may improve team awareness on medication safety issues and may at the end even reduce ADE rates. This paper reports on the preliminary findings of an impact evaluation of ADE Scorecards. The study took place in Denain General Hospital, a 416-bed hospital in Northern France.

# 2. Background: ADE Scorecards

The ADE Scorecards present detailed information about ADE cases and their suspected causes for a given hospital department. The motivation of using ADE Scorecards is to make the team aware of ADE cases and to learn how to avoid such ADEs in the future. The ADE data presented in the ADE Scorecards are generated based on rules that were developed within the PISP project (for details on the ADE data generation, see [10,11]).

Overall, at the time of the study, ADE Scorecards contained 236 validated rules to detect automatically 27 classes of ADEs and their causes (e.g. hyperkalaemia, VKA overdose, renal failure, and anaemia). The positive predictive value of the hyperkalaemia rules within the ADE Scorecards was found to be 53,5% [10]. This was found sufficient for further clinical evaluation.

The ADE Scorecards give clinical users a web-based, password-restricted access to ADE data concerning their own department. This includes an overview on ADE classes that occurred in a department and number of related cases per month (see *Figure 1*). From this page, users can select an ADE class of interest, to get information on the characteristics of the patients for whom the given ADE class occurred, the causes that may have contributed to the given ADE class and information on available evidence (e.g. references) (see *Figure 2*). It was also possible to assess details of the inpatient stays that were affected by an ADE (such as demographic information, diagnoses, procedures, medications, lab values, and important free-text documents).

# 3. Methods

The evaluation question was: Does introducing the ADE Scorecards have an effect on ADE rates in a given department? The study was designed as an interrupted time series design with control group. The outcome measure was monthly ADE rates as detected by the ADE Scorecards. Three medical departments that were involved in the PSIP project (cardiology/gastroenterology, internal medicine/infectious diseases and the acute geriatrics) were chosen as study wards. Here, ADE Scorecards were implemented and physicians and nurses were invited to participate; pharmacists were also invited. One other ward (respiratory department) was chosen as control wards without implementation of ADE Scorecards.

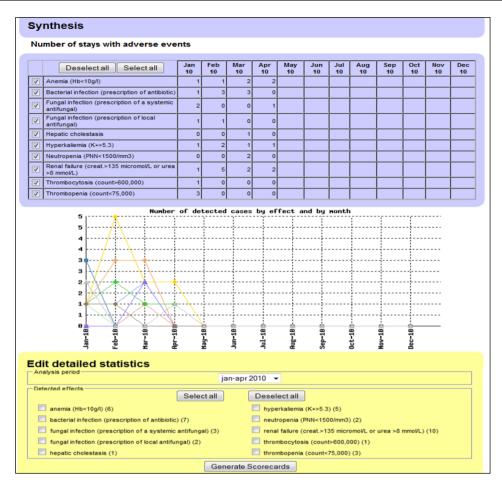


Figure 1: Overview of detected ADE in a given department. On the top, the number of detected ADE per month is displayed. On the bottom, the user can generate detailed statistics for selected ADE classes.

The study started in July 2010, presenting ADE data available back to 2007. The ADE information was then updated every two months. Physicians, pharmacists and nurses were encouraged to use the ADE Scorecards by regularly joint meetings, organized by the study organizers approx. every 4 months. To answer the study question, we exported the ADE data from January 2007 till March 2012 from the ADE Scorecards and analysed them. To determine changes of time, ADE numbers and ADE ratios of 15 months pre-intervention and 15 months post-intervention were compared using a segmented regression analysis using SPSS® version 17. To test the time series for serial autocorrelation, the Durbin-Watson statistics was used. Statistical significance was defined as p<0.05 for all tests. In addition, log files were analysed regarding usage.

#### 4. Results

Overall, ADE Scorecards detected 3,586 ADE cases in 20,983 patient stays in all observed departments (study and control) between January 2007 and end of March 2012. The ADE Scorecards were used 441 times between July 2010 and March 2011 by four physicians, eight nurses and two pharmacists. The pharmacists were the group that used the ADE Scorecards most often.

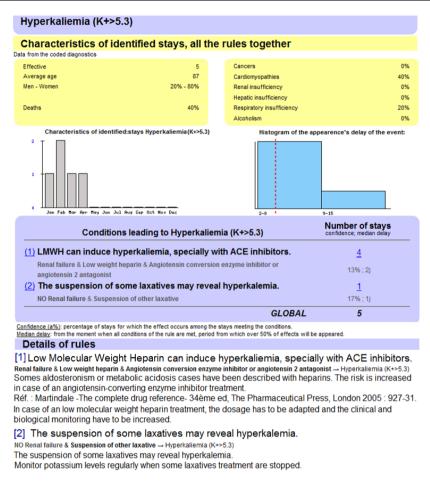


Figure 2: Detailed information on detected hyperkalemia cases and their possible causes.

Results of segmented regression analysis comparing study departments versus control departments for the top-four accessed ADE classes (hyperkalaemia, Vitamin-K antagonist overdose, renal failure, anaemia) showed no significant changes in ADE rates after introduction of the ADE Scorecards. *Figure 3* shows ADE data of hyperkalaemia as an example.

#### 5. Discussion

All participating physicians, nurses and pharmacists were using the ADE Scorecards from time to time, but not very often. Reasons could be that using ADE Scorecards was not integrated in the routine clinical workflow. Also, the ADE Scorecards did only present data of patients that had stayed in the hospital some months before, and did not contain more recent patient cases, due to time-delay in extracting and presenting data. This may have reduced the feeling of usefulness.

As a randomized controlled trial was not possible due to organizational reasons, we conducted a quasi-experimental study [12]. We strengthened this weaker study design by involving a control group. In this controlled time-series analysis, no significant effect of the ADE Scorecard implementation on the ADE rates of the top-four accessed ADE classes was found. The potential impact of the ADE Scorecards may have been reduced by the fact that not all physicians and nurses participated in the study, and that the participating users did not access the ADE Scorecards quite often.

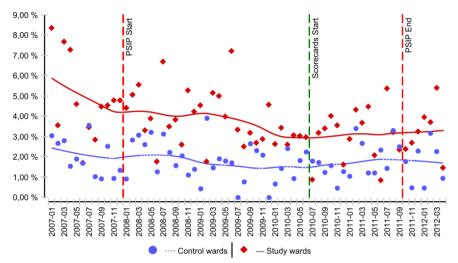


Figure 3: Percentage of patients where ADE Scorecards detected hyperkalemia.

A limitation of this study is that we relied on ADE cases detected by the ADE Scorecards themselves. For this, the ADE Scorecards used a set of pre-defined rules. The sensitivity and specificity of these rules may still be limited (a sub-study with hyperkalaemia found a PPV of 53,5%, as reported above). No additional chart review was conducted to verify the identified ADE cases.

Nevertheless, to our knowledge, this study is the first to evaluate the impact of the presentation of department-specific ADE statistics, and our experiences may be worthwhile for comparable projects. We assume that ADE Scorecards will be used more often when their positive predictive value is improved, when usability issues are addressed, and when the ADE Scorecards are better integrated into on-going quality initiative to improve medication safety in a hospital.

In general, the ADE Scorecards seem to be transferable to other hospitals, as the same set of rules to detect ADE can be used. Types, numbers, and causes of ADE could then be compared between different hospitals, establishing a benchmark for ADE rates. In the meantime, the ADE Scorecards have also been successfully introduced in a specialized endocrinologic hospital in Sofia (Bulgaria) [13].

#### 6. Conclusion

ADE Scorecards did not yet have an impact on ADE rates in three pilot wards. Possible reasons are limited usage of the ADE Scorecards. Strategies seem needed to integrate ADE Scorecards better into clinical routine, and to increase precision of ADE detection. The Hospital in Denain is just starting a re-launch of an updated version of the ADE Scorecards. In this context, usability evaluations and user interviews are also under way, to identify approaches to improve usage and potential impact of ADE Scorecards.

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