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Do false positive alerts in naïve clinical decision support system lead to false adoption by physicians? A randomized controlled trial

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ABSTRACT

Objectives: False positive alerts in patient-safety-related clinical decision support systems (CDSS) are defined as alerts which incorrectly prompt when no-risk patients are encountered. It is an unfavorable condition which may potentially mislead physicians. The aim is to investigate physician responses toward false positive (FP) and true positive (TP) alerts in CDSS for the prevention of contrast-induced nephropathy (CIN).

Methods: A two-arm cluster randomized controlled trial was conducted in university hospitals. Eligible physicians were randomized to receive alert intervention or no intervention (groups 1 and 2, respectively). The alert system was embedded with a deliberately non-specific risk detection tool in order to generate TP and FP alerts. The naïve alert system would alert the physician to cancel the order regardless of the patient being at-risk or not at-risk. CIN risk was stratified as at-risk and no-risk according to a patient's pre-existing renal function. Contrast imaging order-cancellation rate was measured as primary outcome.

Results: 3802 contrast-enhanced examination orders from 66 physicians were analyzed. Demographic data and risk distributions of patients were similar and well-balanced between two groups. In the intervention group, a total of 1892 alerts were generated (332 TP alerts and 1560 FP alerts). Order-cancellation rates were 5.1% versus 1.4% in groups 1 and 2 for at-risk patients (relative risk [RR] = 3.69) from TP alerts, and 1.0% versus 1.4% for no-risk patients (RR = 0.71) from FP alerts. Using generalized linear model with generalized estimating equation, the FP alerts had no order-cancellation effect when compared to the control arm (adjusted RR = 0.69; 95%CI, 0.36–1.32). The TP alerts had a larger order-cancellation effect

Abbreviations: TP, true positive; FP, false positive.

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than that of the control arm (adjusted RR = 2.95; 95%CI, 0.94–9.27), which revealed a marginal trend toward significance. However, the effect was not statistically significant (adjusted RR = 1.24; 95%CI, 0.71–2.18) if TP and FP alerts were mixed.

Conclusions: Physicians are not likely to adopt recommendations provided by false positive alerts in patient-safety-related CDSS. If reporting only the adoption rate of CDSS as a whole without differentiating between TP and FP alerts, the effects of TP and FP alerts will be mixed, and thus, will lead to an underestimation of system effectiveness.

1. Introduction

1.1. CDSS and research quality

Clinical decision support systems (CDSS) are computer-based information systems designed to assist physicians' medical decision-making. They are usually integrated with an existing computerized physician order entry (CPOE) system to optimize the safety and quality of clinical practices by providing physicians with alerts and recommendations at the point-of-care. Effective alert-based CDSS have shown to improve physicians' practice in reducing medical errors and improving adherence to clinical guidelines in various clinical settings [1–6]. However, other studies showed negative results with no improvement or limited effects of CDSS [7–16]. Therefore, it is important to further investigate how decision making of physicians changes with suggestions from CDSS that contradict their own original decisions.

Owingto inconsistent findings, rigorously designed studies are called for further exploration of CDSSs. In a review article concerning the research quality on CDSS, Jia et al. [17] reported that most studies were non-comparative studies. In addition, there were only 22 (3.57%) randomized controlled trials (RCT) published in the past two decades. As a result, more methodologically rigorous designs were suggested to improve the research quality on CDSS [17].

1.2. False positive alerts in CDSS

In some way, the role of an alert-based CDSS is similar to that of a laboratory test result which provides the physician with dichotomous information to make a decision (positive or negative results). For example, an alert system provides a "positive" result if the alert prompts the physician, whereas it provides "negative" results if no alert prompts the physician. Thus, for the evaluation of an alert-based CDSS, standard clinical test characteristics such as sensitivity and specificity of the CDSS should be analyzed. In fact, an alert-based CDSS can be evaluated as a risk detection tool or a test, which may generate true positive (TP) or false positive (FP) alerts to physicians. A TP alert is defined as the alert which prompts when a real at-risk patient is encountered. On the contrary, a FP alert is defined as the alert which prompts when the patient without risk is encountered. Unfortunately, a FP alert is an unfavorable condition which may potentially mislead the physician. In the literature, few studies have addressed physician responses to FP alerts [18].

When alert system performance or physician responses to alert systems are measured, most studies reported on physicians' adherence rate, or other commonly used terms such as acceptance rate, compliance rate, or adoption rate of the alert systems [3,7,15]. From another perspective, some studies reported on the override rates of the system. No matter whether adoption rate or override rate was measured, these measurements only regarded the responses to alerts as a whole, but did not further differentiate the responses to TP alerts from that of FP alerts. However, adoption to TP alerts is the favorable response for patient safety, whereas adoption to FP alerts is the unfavorable response. If reporting only the adoption rate to alerts as a whole without differentiation, the favorable and the unfavorable responses to the alert system will be mixed.

The unfavorable FP alerts may have two impacts on physicians. The first impact derives from overriding FP alerts. Physicians should override those FP alerts to justify their clinical decision. However, excessive FP alerts may lead to alert fatigue, which means if physicians were exposed to a large number of FP alerts, they may be desensitized to most alerts. Desensitization can lead to overriding vital alerts (TP alerts) [15,19,20], or even lead to adverse events on patient outcomes [21]. Alert fatigue phenomenon in CDSS has been mostly proposed in observational studies and before–after studies [15,19,20,22–26], but rarely in RCTs. On the other hand, the second impact of FP alerts derives from adopting these alerts. If physicians adopt FP alerts, they will change their original orders and use alternative orders for patients instead. It is assumed that alternative orders/treatments may lead to a deviation from routine practice for the patients, such as providing less effective medications or switching to more expensive treatments. However, limited studies have measured the adoption rates of FP alerts in real clinical settings. As such, the purpose of this research aims to address the issue in detail.

To address the concern of FP alert adoption by physicians, a randomized controlled trial (RCT) was conducted to measure the physician responses to FP and TP alerts in an outpatient setting. An alert-based CDSS was designed to prevent contrast-induced nephropathy as an experimental model to investigate physician responses toward FP alerts.

1.3. Background of contrast-induced nephropathy

Contrast medium is widely used in medical imaging such as computed tomography or intravenous urography. Contrast-induced nephropathy (CIN) is an iatrogenic complication of contrast-enhanced examinations, defined as the impairment of renal function after contrast administration. Therefore, physicians who order and refer patients for contrast-enhanced imaging should identify at-risk patients and prevent CIN. The most important independent risk factor for CIN is pre-existing