Real-time Decision Support for Postoperative Nausea and Vomiting (PONV) Prophylaxis

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Background

Nausea and vomiting after surgery (PONV) is a common side effect of the surgical procedure, general anesthesia and opioid use occurring in about one third of patients. In addition to being very unpleasant for patients, it is associated with longer recovery room stays and increased costs.[1] Specific prophylactic interventions may be applied during general anesthesia with the aim to prevent PONV in individual patients. These interventions mainly consist of administering one or more prophylactic drugs either at the start or the end of the procedure, and/or selecting a different type of anesthetic - i.e. total intravenous anesthesia rather than inhalational anesthesia. The efficacy of these interventions have been extensively studied in several clinical trials and meta-analyses.[2,3]

Current national guidelines as well as departmental guidelines recommend that patients receive prophylactic interventions for PONV according to their risk of PONV as predicted by a formal risk score.[1] A risk score predicts the PONV risk for each individual patient (Tables 1 and 2), based on specific characteristics of that patient and the scheduled procedure. However, in a busy operating room where the anesthesia provider performs multiple patient care tasks, closely following the recommendations to minimize the risk of PONV is often difficult.[4,5]

A clinical decision support system (CDSS) may help anesthesia providers to adhere to best practices for PONV prevention. Such a CDSS automatically calculates the risk of PONV for an individual patient and presents this predicted risk to the anesthesia provider on the computer screen that is being used by the anesthesia team for record keeping. In recent studies, such decision support systems have been demonstrated to improve adherence to PONV guidelines, especially when a recommendation on the number of interventions is added to the predicted risk.[6–8] Despite that improvement, there was still quite some room for improvement of the adherence to PONV guidelines in these studies.

Current literature on decisions support systems suggests that the design may have a great influence on what impact a CDSS has on medical decision making.[9] However, we are still only beginning to understand which CDSS design features will have the largest impact on the behavior of healthcare providers. The context of the clinical problem may be an important factor in what design for a decision support tool is the most appropriate.[5] The proposed study aims to improve the adherence to PONV guidelines by implementing multiple decision support elements with different design features.

Research question and hypotheses

Research question

Does the adherence to the recommendations of a clinical decision support system for postoperative nausea and vomiting depend on the proximity of the advice to specific decisions?

Hypotheses

The research question will be addressed in this study by testing the following hypotheses:

1. An automated recommendation on PONV prophylaxis that is based on a patient-specific PONV risk that is sent by email to individual anesthesia providers the day before the scheduled procedure increases the adherence to PONV guidelines.

2. An automated recommendation on PONV prophylaxis that is based on a patient-specific PONV risk that is presented at the start of anesthesia increases the adherence to PONV guidelines (and has an added value to the automated email recommendation).

Study Design and Participants

Study design

The time series consists of three phases. The first phase is the preintervention phase – i.e. before the decision support has been implemented. The second phase is the first intervention phase in which the email with recommendations is being sent (Figure 1). The third phase is the second intervention phase in which the real time decision support guidance (Figure 2) is being displayed along with the email intervention.

Study population

All adult patients (18 years and older) that are scheduled for an elective surgical procedure under general anesthesia within the study period will be considered eligible. We will exclude patients undergoing emergency surgery, and patients who will not go to the PACU to recover (i.e. patients that are transferred directly to the Intensive Care Unit or die intraoperatively). Procedures that only require a sedative level of anesthesia will be excluded from the analysis.

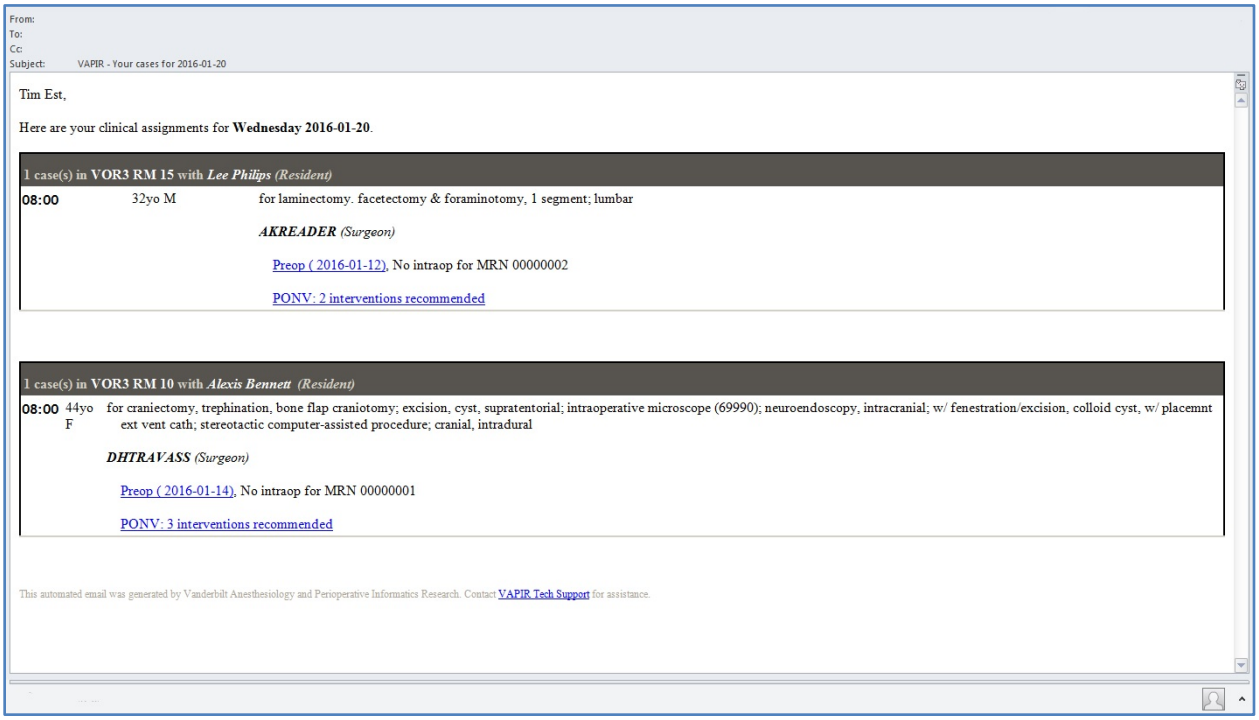

Figure 1. Screenshot example of email recommendations.

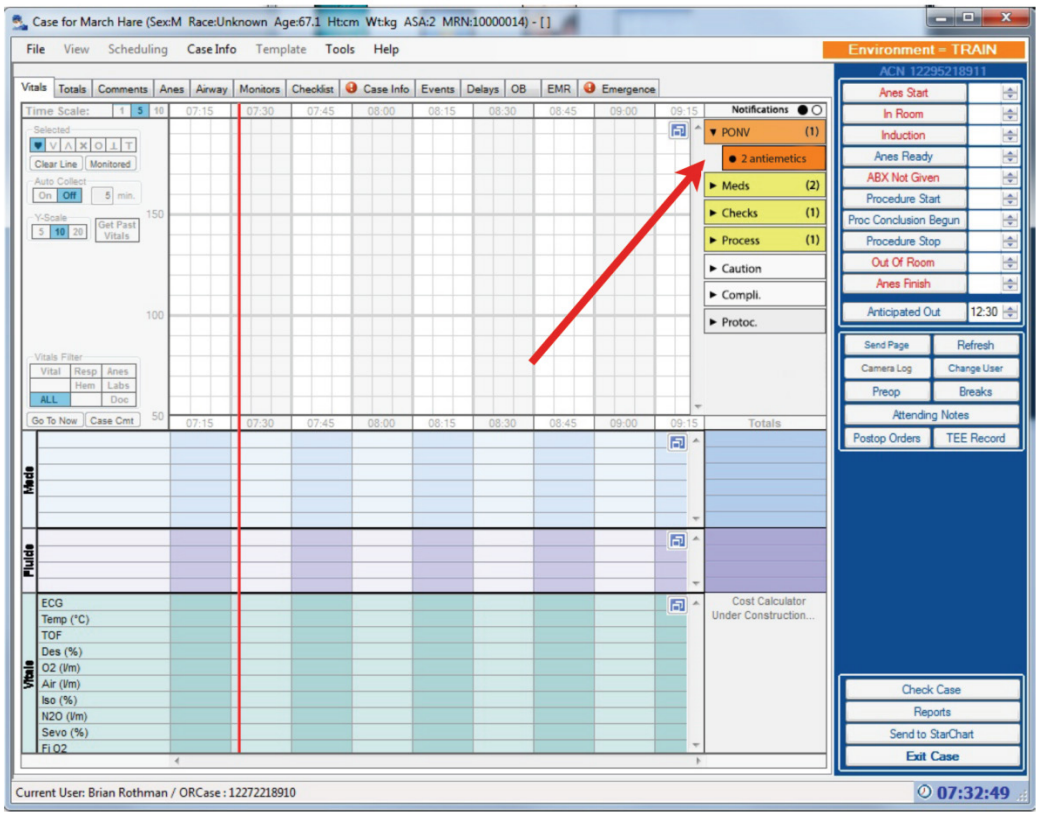

Figure 2. A screenshot mockup of the real-time decision support within our perioperative information management system.

Table 1 - Apfel's simplified risk score

Factor	Risk Score
Gender – Female	1
History of PONV/Motion sickness	1
Expected postoperative use of opioids	1
Non-smoker	1

Table 2 - Relation between predicted risks and recommendations

Number of PONV risk factors	Predicted PONV risk	Recommended number of interventions
0	0%	0
1	20%	1
2	40%	2
3	60%	3
4	80%	4

Outcome

Primary outcome

The adherence to PONV guidelines will be used as the primary outcome. This is defined as an exact match between the recommended and applied numbers of interventions. Either a lower or a higher number of interventions will be considered as noncompliant to the guidelines. For the primary analysis the overall change in adherence as well as the added values of the different decision support elements to that adherence will be quantified. Medications with antiemetic properties will be considered prophylactic administrations, if they occur before the documented anesthesia stop time. We will consider scopolamine, dexamethasone, ondansetron, haloperidol, droperidol as prophylactic medications.

Secondary outcomes

The occurrence of PONV within the patient's PACU admission. PONV will be defined as the administration of rescue antiemetics. The list of rescue antiemetics is similar to the list of prophylactic interventions, excluding the pre-anesthesia interventions, but complemented by the use of promethazine and compazine. Other secondary process outcome variables are: the absolute number of prophylactic interventions applied and time to discharge readiness at the PACU.

Data collection

We plan to use the Perioperative Data Warehouse (PDW), an IRB-approved data repository, as the data source to study the effects of the decision support on the application of prophylactic interventions for PONV and the occurrence of PONV within the PACU.

Data safety monitoring

The principal investigator (PI) will be responsible for data safety and monitoring within the VUMC. Quality control will include regular data verification and protocol compliance checks. Protocol adherence at the VUMC will be monitored by the PI throughout the study. Events determined by the PI to be unanticipated problems involving risks to subjects will be reported by the PI to the VUMC IRB within 10 working days of the Investigator's knowledge of the problem.

Statistical analysis plan

A two-sided alpha of 0.05 will be considered to be statistically significant. Continuous variables will be visually assessed for a normal distribution using histograms and QQ-plots. In descriptive statistics, parametric variables will be expressed as means with standard deviations, nonparametric variables will be expressed as medians with interquartile ranges, and discrete variables will be expressed as numbers with percentages. The primary analysis will be performed under the intention-to-treat principle. We will compare the incidence of the primary and secondary outcomes between the study groups utilizing analysis of variances to compare the means of multiple groups.

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