Text Messaging for Assessment of Postoperative Nausea and Vomiting after Discharge Compared to a Nurse-led Phone Call a Feasibility Study

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**Number of words in Abstract (312), in Introduction (740), and in Discussion (1889)**

# Abstract

**Background:**

**Methods:**

**Results:**

**Discussion:**

# Introduction

Postoperative nausea and vomiting (PONV) is perceived by patients as one of the most important outcomes after anesthesia1. PONV has significant economic impact as a leading cause of unplanned admissions after same day surgery2 and can lead to serious clinical consequences3. Risk factors for PONV are established and incidence can reach 80% in high risk patients4. Cost effective prophylaxis is detailed in up to date, evidence based, widely accepted guidelines2. However, most PONV outcomes research focuses on immediate postop, intra-hospital PONV, while PONV may plague patients beyond discharge and may compromise their postoperative pain control. Opioids can trigger or aggravate PONV and force patients to choose between nausea from taking opioids or pain (if they forego opioid pain killers to avoid the nausea). Vomiting can compromise bioavailability of perioperative medication, for example antibiotics or reduce compliance with prescribed medications.

Little research exists on the prevalence of PONV beyond discharge, also because assessment is costly and patients may often be often difficult to reach, leading to excessive attrition and unknown bias in outcomes estimates as data are not missing completely at random. No clinical trials examined the feasibility, attrition, accuracy or precision of smartphone based assessment of anesthesia related outcomes after patient discharge, especially compared versus assessment by a nurse-led phone call. Telemedicine for perioperative care and research may offer significant benefits, but also risks, including disparities in which patients can be reached effectively, because the required technology can be difficult to use for the elderly and may not be accessible to all patients5.

## Objective

To test the feasibility of smartphone-based assessment of postoperative nausea and vomiting in a rural setting, to gauge attrition and loss to follow up, and to estimate the precision and accuracy of patient responses compared to assessment by nurse led phone interview.

## Hypothesis

We hypothesize that text based assessment of PONV outcomes after patient discharge is feasible, with comparable attrition, accuracy and precision as follow up by a nurse led phone call.

# Methods

## Population

We will select research subjects randomly among the population eligible for PONV assessment by text messaging. Among the population selected for text messaging, we will randomly select the subpopulation for assessment by a nurse led phone call. For randomization we will use a computer generated randomization list, which will be concealed from all investigators until the call is made in the subset allocated for a nurse led phone call.

### Inclusion Criteria

All adult (>18 years old) patients who undergo anesthesia for *elective* surgery in the study period at Penn State Milton S. Hershey Medical Center, will be eligible for inclusion.

### Exclusion Criteria

Pregnant patients are automatically excluded, as female patients routinely receive a pregnancy test on the day of the procedure and a positive test precludes elective surgery.

## Outcomes

### Primary Outcome

The primary outcome is PONV as reported by the patient on a simplified validated PONV impact score6. We measure the concordance between nurse led and text messaging based patient reported outcomes.

### Secondary Outcome

We will record patient feedback on the text based messaging in response to open questions. We will explore predictors of PONV as reported by patients and predictors for discordance between assessment by nurses versus by text messaging.

## Data Collection

The analysis is based on the data extracted from electronic medical record of observations recorded during routine medical care. Additionally, we will contact patients via text message to solicit their experience of PONV after surgery as the validated simplified PONV impact score6, as two responses on a Likert Scale. Patients provide their response via text message as two single digit numbers.

The unit of analysis is the anesthesia record. We will not retain patient identifiers and hence patients undergoing anesthesia on several occasions in the study period will be counted as separate anesthetics and analyzed independently.

## Approach

### Data Source

The source of the data is the electronic medical record (EMR) and the anesthesia information management system (AIMS) containing the information collected and documented during routine medical care perioperatively.

### Data retrieval

A medical data specialist employed by the anesthesia department for EMR based quality improvement, who is not involved in our study or analysis, will identify all patients who underwent anesthesia using the billing system, Cerner and other medical record databases. She will extract the patient and procedure specific risk factors for PONV from the EMR and the AIMS, detailed below. She will remove HIPPA identifiers prior to handling the de-identified data file to the investigators. She will also extract the perioperative pharmacological and non-pharmacological interventions relevant to the prevention of PONV from the AIMS and the EMR.

### Waiver of informed consent

We request a waiver of informed consent as the research involves no more than minimal risk to the subjects and the waiver or alteration will not adversely affect the rights and welfare of the subjects, because the research results will not affect the care of the subjects. Given the number of subjects and the possibility that subjects may no longer be living or lost to follow-up, this research would not be practical without waiver. No information which would be pertinent to the on-going care of individual subjects is expected to result from this study. The only risk to the patients would be loss of confidentiality/privacy, but the data will be de-identified before the investigators have access.

### Justification of chart review

Retrieval of study data necessitates access to patient charts through their MRNs. The computer-generated text messaging will require access to the patients (or patient' next of kin) cell phone number. The call will be triggered though RedCap and the response will also be recorded through RedCap, removing all patients' identifiers after the completion of the call. The nurse led phone call will require access to the patient's phone number and clinical file. Neither will be retained or recorded after the contact has been established, except the responses, which will be documented in Redcap. Once this information is obtained, it will be de-identified including the removal of the telephone number and all code numbers linking to patient medical record number.

### Data collected

The data extracted from the EMR and AIMS will include

#### demographics for the patient

* age in years (or in decades if older than 89 years for compliance with HIPPA),
* gender,
* history of PONV or history of motion sickness if available,
* smoking history,
* race

#### anesthesia specific information

* dose and time of any antiemetic medications administered (Dexamethason, Ondansetron, Aprepitant, Metoclopramide, Pheneragan, Droperidol, Propofol),
* time and dose of any antiemetics (listed above) given preoperative if any,
* time and maximum concentration of any volatile anesthetic recorded on the AIMS,
* time and dose of long acting opioid administered intra-operatively,
* anesthesia technique (General versus regional versus monitored anesthesia care)

*case specific information*

* start and end time (but not date) of the procedure, to time the administration of medication with regards to the anesthetic provided,
* billing codes specifying the surgical procedure and anesthetic,

*anesthesia provider specific demographics*

* provider identifier or name for the first supervising and supervised provider on the case, respectively with
* provider roles (attending, resident, CRNA),
* presence of multiple providers without provider identifiers.

## Statistical analysis

### Primary Analysis

We will investigate agreement between the automated PONV assessment and the nurse-led PONV assessment, (both measured on the same validated simplified PONV impact score6), estimating Cohen's weighted kappa statistic with its 95% confidence intervals7. We will also attempt a Bland-Altman analysis, considering the (discrete) numerical simplified PONV impact score6 as continuous8.

### Exploratory analysis

#### Regression analysis

##### Exploring PONV risk

For the exploratory analysis of risk factors for the PONV outcomes as measured by the simplified PONV impact score6, we will fit multivariate ordinal regression models.

##### Exploring predictors for failure to respond and data missing at random

We will compare the charactersitcs of patients who faile to respond to text messaging with those who do, conducting chi-sqaure test for categorical variables (gender, smoking status...) and t-tests or Wilcoxon rank sum tests for continuous variables, contingent on their distributions. For an exploratory analysis of predictors for failure to respond to text messaging, we will also fit binrary logistic regression models. We will suspect that data are not missing at random, if our binary logistic regression yields highly significant results.

##### Exploring if risk factors and treatment interact to affect PONV outcome

To explore the interaction between risk factors and treatment in their effect on PONV outcome, measured by the simplified PONV impact score6, we will again us ordinal logistic regression with interaction terms.

### Software used

We used the statistical software *R*, the public domain statistical software package9.

# Results

## Description of the data set

# Discussion

## Summary of the findings

## Significance

Text messaging could provide a cost effective, yet efficient and reliable tool to assess PONV outcomes, especially in rural settings, both for health services and outcomes research and for quality improvement. Text messaging may help to identify patients at need for interventions for severe PONV and such may reduce emergency room visits for PONV, besides increasing patient satisfaction.

## Generalizability

## Critique of the modeling approach

#### Confounding, missing data and model misspecification

# Conclusion:

# Figures

## Figure 1

Figure 1

Figure 1

### Figure 1 Caption

# References

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