JMIR Perioperative Medicine

Technologies for pre- and post-operative education, preventative interventions, and clinical care for surgery and anaesthesiology patients, as well as informatics applications in anesthesia, surgery, critical care, and pain medicine

Volume 1 (2018), Issue 1 ISSN 2561-9128 Editor in Chief: Nidhi Rohatgi, MS, MD, SFHM

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Original Paper

Sex Similarities in Postoperative Recovery and Health Care Contacts Within 14 Days With mHealth Follow-Up: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: Previous studies have shown that women tend to have a poorer postanesthesia recovery than men. Our research group has developed a mobile phone app called Recovery Assessment by Phone Points (RAPP) that includes the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire to monitor and assess postoperative recovery.

Objective: The aim of this study was to investigate sex differences in postoperative recovery and the number of health care contacts within 14 postoperative days in a cohort of day-surgery patients using RAPP.

Methods: This study was a secondary analysis from a single-blind randomized controlled trial. Therefore, we did not calculate an a priori sample size regarding sex differences. We conducted the study at 4 day-surgery settings in Sweden from October 2015 to July 2016. Included were 494 patients (220 male and 274 female participants) undergoing day surgery. The patients self-assessed their postoperative recovery for 14 postoperative days using the RAPP.

Results: There were no significant sex differences in postoperative recovery or the number of health care contacts. Subgroup analysis showed that women younger than 45 years reported significantly higher global scores in the SwQoR questionnaire (hence a poorer recovery) on postoperative days 1 to 10 than did women who were 45 years of age or older (P=.001 to P=.008). Men younger than 45 years reported significantly higher global scores on postoperative days 2 to 6 than did men 45 years of age or older (P=.001 to P=.006). Sex differences in postoperative recovery were not significant between the age groups.

Conclusions: This study found sex similarities in postoperative recovery and the number of health care contacts. However, subgroup analysis showed that age might be an independent factor for poorer recovery in both women and men. This knowledge can be used when informing patients what to expect after discharge.

Trial Registration: ClinicalTrials.gov NCT02492191; https://clinicaltrials.gov/ct2/show/NCT02492191 (Archived by WebCite at http://www.webcitation.org/6y2UtMbvz)

(JMIR Perioper Med 2018;1(1):e2) doi:<u>10.2196/periop.9874</u>

KEYWORDS

sex; mHealth; telemedicine; mobile phone; cell phone; patient outcome assessment; postoperative complications; postoperative period

Introduction

Previous research has shown that women seem to have a poorer quality of postanesthesia recovery than men [1,2]. Even though

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women emerged faster from general anesthesia [1-3], women reported higher pain scores in the postanesthesia care unit (PACU) and in the first 3 days after surgery, and they also experienced more postoperative nausea and vomiting, as well as longer stays in the PACU, than did men [1]. Physical

differences might explain these observed differences [1]. Also worth noting is that there may be gender role expectations resulting in men being less willing than women to report pain [4]. However, a weakness is that previous studies reporting patients' recovery measured this only 2 to 3 times postoperatively [1,2,5-7]. As well, there is no consensus regarding on which day or days it is most important to follow up. Furthermore, patients experience several barriers to self-management during their recovery [8]. This may be one reason for unplanned health care contacts [9] and, according to one study, the most common reason was postoperative pain [10]. Another reason can be that follow-up after anesthesia and surgery is not performed routinely or as a telephone call on postoperative day 1 or 2 [11]. One way to follow up after surgery is to use mHealth solutions [12-14] to increase patients' satisfaction [12,14] and to facilitate postoperative follow-up [12,15].

Evidence is lacking with respect to daily potential sex differences in postoperative recovery and the number of health care contacts. Therefore, the aim of this study was to investigate, through use of an mHealth solution, whether there were any sex differences in postoperative recovery within 14 postoperative days in a cohort of day-surgery patients in Sweden.

Methods

Study Design and Participants

This was a secondary analysis of data from a prospective, single-blind, multicenter, randomized controlled trial performed at 4 different day-surgery settings in Sweden. We carried out this study in accordance with the study protocol [16] and obtained approval from the regional ethical review board in Uppsala, Sweden (2015/262) [17]. The trial was registered with ClinicalTrials.gov (NCT02492191).

Participants received written information about the study before the planned surgery. Oral information was provided by the research nurse, who also was responsible for participant inclusion on the same day as surgery, and for collecting oral and written consent from all participants. Inclusion criteria were undergoing day surgery, being able to understand the spoken and written Swedish language, having access to a mobile phone, and being 18 years of age or older. Exclusion criteria were having memory impairment, visual impairment, or alcohol or drug abuse, or undergoing a surgical abortion.

The secondary aim of the randomized controlled trial was to investigate postoperative recovery. This paper presents only the participants who were randomly allocated to the intervention group [16]. In the intervention group, an app called Recovery Assessment by Phone Points (RAPP), which includes the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire [13,14,18], was installed on the participant's own mobile phone. No personal data were registered in the app. Every participant got a unique study code, and only the research team had access to study codes. The participant was instructed in how to report postoperative recovery daily for 14 days, starting from postoperative day 1. An additional function in the app was the possibility for the participant to be contacted by a

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nurse. Every day the app presented the question "Do you want to be contacted by a nurse? [Answer yes or no]". If requested, a registered nurse, from the department where the surgery had been performed, called within 24 hours (on weekdays).

Outcomes

The primary end point for this study was postoperative recovery assessed by the SwQoR questionnaire. Reliability and validity tests have provided sufficient evidence that the SwQoR questionnaire is appropriate to use for day-surgery patients [13,14,18,19] and is clinically feasible for systematic follow-up over time during postoperative recovery [19]. The SwQoR questionnaire comprises 24 items measuring postoperative recovery to be reported on an 11-point response scale, ranging from 0, "none of the time," to 10, "all of the time" [19]. Guided by the main study, in this substudy, the SwQoR questionnaire had a possible global score ranging from 0, "excellent quality of postoperative recovery," to 240, "extremely poor quality of recovery," with cutoff values of less than 31 at day 7 and less than 21 at day 14 indicating good recovery [17].

On postoperative day 14, the participants answered a study-specific, paper-based questionnaire including yes/no questions (n=5) and the number of and reasons for all surgery-related health care contacts with primary care, an emergency department, Sweden's 24-hour helpline (1177), an outpatient hospital, and contact via RAPP. We chose a 14-day follow-up because most care contacts are reported to be made in the first 2 weeks after day surgery [20].

We also recorded the following data: sex, American Society of Anesthesiologists (ASA) classification, type of surgery, type of anesthesia, duration of surgery, and time spent in the PACU.

Statistical Analysis

We have presented the sample size calculation elsewhere; we did not calculate an a priori sample size regarding sex differences [16]. Descriptive statistics of baseline characteristics (age, sex, ASA classification, type of surgery, duration of stay at the PACU) were analyzed as the number, percentage, or mean (SD). We regarded missing answers in the returned questionnaires regarding health care contacts as no contact (scored 0). We tested continuous data for normality using the Shapiro-Wilk test. In this study, when analyzing the overall level of recovery, we used the global score. Guided by earlier studies [21-23], we used the mean (SD) of SwQoR scores. To compare differences between men and women, we used chi-squared, Student t test, and Mann-Whitney U test, as appropriate. We analyzed various subgroups to determine differences between types of surgery (general surgery, urology, and gynecology vs orthopedic and hand surgery) and age groups (<45 years vs \geq 45 years, guided by the mean age in this study's population). To determine differences between age groups, we used the mean value as the cutoff. To assess clinical significance, we analyzed the Cohen *d* effect size (small effect: 0.2-0.5; moderate effect: 0.5-0.8; large effect: >0.8) [24].

For statistical analyses, we used IBM SPSS Statistics version 24 for Windows (IBM Corporation). A P value <.01 was considered statistically significant in all analyses.

Results

Participants

We enrolled patients between October 2015 and July 2016 and assessed 1796 patients for eligibility. In all, we excluded 770 patients before randomization for various reasons, as described elsewhere [17]. We randomly assigned the remaining 1027 patients to either the RAPP intervention or the control group. The RAPP group consisted of 513 patients, of whom 19 did not

receive the intervention, leaving a total of 494 patients (n=220, 44.5% men and n=274, 55.5% women). Of these, 127 men and 215 women returned the questionnaire regarding health care contacts.

There were no significant differences between men and women in terms of age, ASA classification, duration of surgery, or time spent in the day-surgery unit. There were significant differences in type of anesthesia, type of airway management, and type of surgery between men and women (P<.001; Table 1).

Table 1. Demographic data, patient characteristics, and anesthetic and surgical factors.

Characteristics	Men (n=220)	Women (n=274)	P value
Age (years)	·		
Mean (SD)	44.13 (15.09)	45.49 (14.87)	.31 ^a
<45, n (%)	115 (49.8)	116 (50.2)	
≥45, n (%)	104 (39.7)	158 (60.3)	
American Society of Anesthesiologists classification, n $\left(\%\right)^{b}$.45 ^c
Ι	115 (47.5)	127 (52.5)	
Ш	61 (41.5)	86 (58.5)	
III	6 (54.5)	5 (45.5)	
Type of anesthesia, n (%)			.004 ^c
General anesthesia	176 (48.6)	186 (51.4)	
Regional or local anesthesia	35 (32.7)	72 (67.3)	
Type of airway management, n (%)			.001 ^c
Endotracheal tube	42 (54.5)	35 (45.5)	
Laryngeal mask	131 (49.1)	136 (50.9)	
Mask	1 (16.7)	5 (83.3)	
Spontaneous breathing	37 (31.1)	82 (68.9)	
Type of surgery, n (%) ^d			<.001 ^c
Orthopedic	75 (46.9)	85 (53.1)	
General	60 (47.6)	66 (52.4)	
Hand	50 (43.1)	66 (56.9)	
Ear, nose, or throat	28 (53.8)	24 (46.2)	
Gynecologic	N/A ^e	26 (100.0)	
Eye	3 (60.0)	2 (40.0)	
Urologic	3 (100.0)	N/A	
Dental	N/A	2 (100.0)	
Duration of surgery (minutes), mean (SD)	43.61 (30.20)	37.92 (28.90)	.16 ^f
Time spent in day-surgery unit before discharge (hours), mean (SD)	2.28 (1.66)	2.35 (1.82)	.67 ^a

^aIndependent *t* test.

^bMissing values for men: n=38; women: n=56. ^cChi-squared test.

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- ^dMissing values for men: n=1; women: n=3.

^eN/A: not applicable.

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^fMann-Whitney U test.

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Table 2. Response rate for the Swedish Web version of the Quality of Recovery questionnaire.

Postoperative day	Response rate, n (%)	
	Men (n=220)	Women (n=274)
1	186 (84.5)	243 (88.7)
2	173 (78.6)	232 (84.7)
3	169 (76.8)	224 (81.7)
4	154 (70.0)	226 (82.4)
5	151 (68.6)	212(77.3)
6	149 (67.7)	207 (75.5)
7	140 (63.6)	201 (73.3)
8	137 (62.2)	199 (72.6)
9	136 (61.8)	189 (68.9)
10	128 (58.1)	182 (66.4)
11	127 (57.7)	178 (64.9)
12	117 (53.1)	187 (68.2)
13	129 (58.6)	191 (79.7)
14	117 (53.1)	167 (60.9)

Comparisons by Sex and Age

There were no significant differences between men and women in their replies to items of the SwQoR questionnaire except on postoperative day 1, in which women scored higher than men in *dizziness* (*P*=.002, effect size 0.28), and on postoperative day 4, in which women scored higher on *more sleeping difficulties* (*P*=.003, effect size 0.30). On postoperative day 12, men scored higher than women on *reddened surgical wound* (*P*=.006, effect size 0.20).

The response rate decreased over time in both men and women (Table 2).

The SwQoR global score decreased over time. The mean score for men was 46 (SD 34) on postoperative day 1 and 17 (SD 21) on postoperative day 14. Corresponding numbers for women were 53 (SD 36) on postoperative day 1 and 22 (SD 28) on postoperative day 14. There were no significant differences in the global score between the sexes in postoperative recovery at any time point. Men had a global score below 30 at postoperative day 5, and women had a global score below 30 at postoperative day 8 (Figure 1).

When analyzing differences in items in the SwQoR questionnaire between the sexes in the 2 age groups, we found that women (<45 years) scored significantly higher (ie, poorer recovery) than men on the following items: *nausea or vomiting* on postoperative day 1 (P=.003, effect size 0.43) and postoperative days 3 and 4 (P=.001 and P=.003, effect size 0.43 and 0.53, respectively); *anxiety* on postoperative day 1 (P=.006, effect size 0.39); *dizziness* on postoperative day 1 (P=.002, effect size 0.43) and postoperative days 3 to 5 (P range .001 to .005, effect size range 0.39 to 0.54); *sleeping difficulties* on postoperative day 4 (P=.005, effect size 0.48) and postoperative day 8 (P=.008, effect size 0.36); and *headache* on postoperative day 9 (P=.002, effect size 0.61) and postoperative day 13

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(P=.008, effect size 0.39). Women 45 years and older of age scored higher on the items *having difficulty returning to work* or usual home activities on postoperative day 1 (P=.01, effect size 0.38) and *having difficulty taking care of my personal* hygiene on postoperative day 2 (P=.01, effect size 0.30).

Men scored significantly higher (ie, poorer recovery) on the items *having trouble breathing* (P=.001, effect size 0.45), *sore throat* (P=.01, effect size 0.34), and *fever* (P=.007, effect size 0.24) on postoperative day 10. Also, men scored higher than women on *reddened surgical wound* (P=.01, effect size 0.24) on postoperative day 12.

When analyzing the differences in SwQoR global score by age group (<45 years and \geq 45 years), we found that men and women had somewhat similar recovery profiles. Younger men (<45 years) reported significantly higher global scores (ie, poorer recovery) on postoperative days 2 to 6 (P range .001 to .006) than did men 45 years of age or older (Figure 2). Women younger than 45 years reported significantly higher global scores (ie, poorer recovery) on postoperative days 1 to 10 than did women 45 years of age or older (*P* range <.001 to .008; Figure 3). A higher proportion of older women (\geq 45 years) than younger women (<45 years) had undergone orthopedic and hand surgery (n=98, 64.9% vs n=53, 35.1%) and general gynecologic surgery (n=48, 52.2% vs n=44, 47.8%). For men, the proportions for surgery were somewhat the same: a higher proportion of older men (≥45 years) than younger men had undergone general or urologic surgery (n=42, 66.7% vs n=22, 33.3%). The proportions for orthopedic and hand surgery were 42.7% (n=53) for older men versus 57.3% (n=71) for younger men. Finally, higher proportions of younger women (n=19, 67.9%) and younger men (n=22, 71.0%) had ear, nose, and throat surgery, eye surgery, or dental surgery than did the older age groups (n=9, 32.1% of older women and n=9, 29.0% of older men).

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Figure 1. Global score (mean) for the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire for men and women (higher scores indicate poorer recovery).

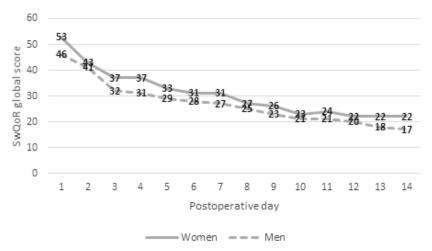


Figure 2. Differences in global score (mean) for the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire by age for men (higher scores indicate poorer recovery). Differences between postoperative days 2 to 6 were statistically significant (*P* range .001 to .006).

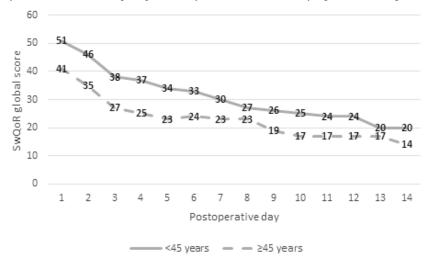


Figure 3. Differences in global score (mean) for the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire by age for women (higher scores indicate poorer recovery). Differences between postoperative days 2 to 10 were statistically significant (*P* range <.001 to .008).

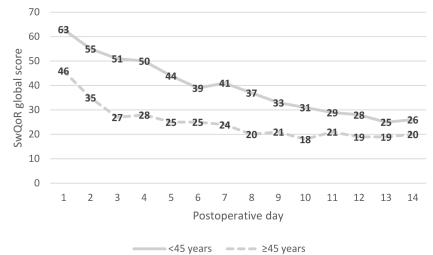




 Table 3. Comparison of unplanned health care contacts (n=342).

Type of contact	Men (n=127) ^a	Women (n=215) ^a	P value
Primary health care			
Number of persons, n (%)	4 (3.1)	12 (5.6)	.30 ^b
Number of contacts ^c	4	12	.30 ^d
Emergency department			
Number of persons, n (%)	4 (3.1)	8 (3.7)	.78 ^b
Number of contacts ^c	4	8	.78 ^d
Swedish 24-hour helpline (1177)			
Number of persons, n (%)	6 (4.7)	22 (10.2)	.07 ^b
Number of contacts ^c	7	26	.07 ^d
Outpatient hospital visits			
Number of persons, n (%)	7 (5.5)	16 (7.4)	.49 ^b
Number of contacts ^c	7	24	.46 ^d
Phone call to the day-surgery department, n	1	1	
Contact request via RAPP ^e app			
Number of persons, n (%)	17 (13.3)	37 (17.2)	.35 ^b
Number of contacts ^c	21	40	.36 ^d
Sum of unplanned contacts			
Number of persons, n (%)	25 (19.6)	67 (31.1)	.02 ^b
Number of contacts ^c	43	110	.03 ^d

^aMissing questionnaires for men: n=93; women: n=59.

^bChi-squared test.

^cUnless otherwise specified, 1 contact per person was made.

^dMann-Whitney U test.

^eRAPP: Recovery Assessment by Phone Points.

When comparing differences in SwQoR global scores by sex in the 2 age groups (<45 years and \geq 45 years), we found no significant differences between the sexes at any time during postoperative days 1 to 14.

There were no statistical differences between sexes in health care contacts (planned or unplanned). Both men and women had most of their health care contacts via RAPP (21/43, 48.8% of all contacts for men and 40/110, 36.4% of all contacts for women; Table 3).

Discussion

Principal Findings

This study evaluated patients' postoperative recovery during the first 14 postoperative days using RAPP, an mHealth solution. To our knowledge, this type of follow-up has never been performed previously. The focus of this study was sex differences, and the results showed no significant differences in postoperative recovery, either in the global score of SwQoR during the first 14 postoperative days or in health care contacts. In individual items, there were sex differences in only 3 of the

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24 items, *dizziness* and *sleeping difficulties* on postoperative day 1 and *reddened surgical wound* on postoperative day 12.

The absence of differences between men and women in this study is in line with an Icelandic study using the 40-item Quality of Recovery (QoR-40) questionnaire, investigating 427 men and women undergoing day surgery [5]. Their results and ours are, however, in contrast with other studies showing sex differences, reporting women to be prone to poor postoperative recovery [1-3,25]. The underlying mechanism for the absence of sex differences in our study is not clear, and there may be several possible explanations. To mention a few, there could be cultural differences, or our findings may be a result of awareness of possible sex difference and implementation of evidence-based medical guidelines in clinical practice, such as preventing postoperative symptoms such as nausea and pain.

It may be that using mHealth is more beneficial for women. If so, this is consistent with a study investigating a telehealth intervention, showing that women in the intervention group had lower incidences of depression, fatigue, sleeping difficulties, and pain after coronary artery bypass surgery [26]. The

possibility of reporting the postoperative recovery process on a daily basis has been shown to significantly decrease scores in SwQoR on individual items and to lower global scores compared with a control group [17]. On the last day of follow-up in our study, the response rate decreased; however, 60.9% of the women still reported their postoperative recovery. Another explanation may be that the intervention itself increased the feeling of self-efficacy; thus, it may have lessened any potential difference between men and women. Also, the patients could at any time press the button if they wished to be contacted by a nurse. This may have given a sense of security. However, Hyde [27] stated, in a review of gender differences and similarities, that gender differences in emotional experience are small, or in many cases, trivial, that there still exists a stereotype that portrays women as the emotional ones, and that there are large gender differences in emotions such as fear and anxiety. In our study, we also found similarities between the sexes in number of health care contacts, which is in line with an earlier study investigating predisposing factors for emergency department visits, which found no sex differences in such visits after surgery [28].

We assessed postoperative recovery in this study using the patients' own mobile phones. The benefit of using e-assessment with a mobile phone is familiarity with the technology, which makes it easy to use [14]. Previous research has shown that barriers to using mobile technology can depend on one's sex, among other factors, indicating that women have higher levels of anxiety and technophobia than men [29]. Therefore, the use of an app in relationship to the sexes and postoperative recovery needs to be investigated further.

Postoperative pain has been reported to be a common symptom during recovery at home [10]. SwQoR measures how often (from none of the time to all of the time) a symptom, feeling, or impaired ability occurs and not how severe a feeling or symptom is. It is not to be confused with a numeric rating scale measuring, for example postoperative pain. In this study both men and women patients reported pain from the surgical wound to be present most of the time, especially on the first postoperative days. One study investigating patients' symptom management techniques after orthopedic day surgery reported that patients managed postoperative pain using different strategies, including taking pain medications, using ice to relieve pain and induce numbness, and reducing food and drink so they wouldn't have to get up and move [8]. In respect of that result, it is likely that the sense of feeling relaxed and comfortable, as well as having a feeling of general well-being, and the difficulty in taking care of one's personal hygiene and in returning to work or usual home activities may be interrelated with the patients' postoperative pain in this study.

Our study showed that women 45 years and older reported significantly better postoperative recovery (hence, lower global scores on the SwQoR). The effect of the menstrual cycle phase on overall postoperative recovery have been investigated, showing that premenopausal women reported higher pain scores and had poorer recovery according to their scores [1]. This study also showed that men 45 years and older reported significantly lower global scores (ie, better recovery) on postoperative days 2 to 6. On the other hand, both younger women and younger

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men reported poorer recovery (ie, higher global scores on the SwQoR) in the first week after discharge. It may be argued that the cutoff used in this study was not appropriate. Different age cutoffs have been used when investigating younger and older patients—for example, less than 52 years [3] or less than 65 years [30]. This study's result is somewhat in line with a large-scale study including 17,638 day-surgery patients, which found that elderly patients (ie, >65 years) had a lower incidence of any postoperative event (eg, pain, nausea and vomiting, shivering, and agitation) measured in the PACU and in the ambulatory surgical unit (adjusted odds ratio 0.43). However, the elderly patients had mostly undergone ophthalmologic surgery, which causes minimal postoperative pain [30]. The role of age, sex, and postoperative recovery needs further investigation. It is possible that this study's results depended on the presence of generation gaps, attitudes, and gender role expectations. This Swedish sample may have had fewer gender role expectations.

A total of 158 (57.6%) of the women and 104 (47.2%) of the men were 45 years of age or older. As a result of these differences, we analyzed the type of surgery, in case the younger population was confounded by the distribution of type of surgery. The analysis showed significant differences between the groups. Hence, there is a possibility that surgery and type of anesthesia can also be confounders related to the nonsignificant findings between the sexes.

Study Limitations

The absence of significant differences between the sexes could have been due to the small sample size, and there might be a type II error. We calculated the sample size for the primary outcome, the cost effectiveness of RAPP [9,16]. However, the sample size in this study is almost the same as in other studies reporting sex differences [1,2]. Another limitation we acknowledge is that the patients did not report any baseline SwQoR scores. Patient-reported outcome after surgery and anesthesia is of great interest for health care professionals, as well as for the patient. The question is not why, but when and how patient-reported outcomes should be measured. There are also some concerns regarding how to compare results between different studies. Therefore, this study's result must be interpreted with caution, and the results between studies are difficult to compare. Different instruments have been used in different studies, such as QoR-40 [5,6,22], the Postdischarge Surgical Recovery Scale [31,32], and the Postoperative Quality Recovery Scale [33]. These instruments were developed to be used with inpatients [33], outpatients [32], or both inpatients and outpatients [21]. In addition, the wording of items differs: usually there is a mix of positively and negatively worded items in an instrument [34]. In the SwQoR questionnaire, all items are negatively worded [18], and this construction is consistent with visual analog scales, which are anchored by two extreme values [35]. The SwQoR global score is also anchored by two values, 0 (excellent recovery) and 240 (poor recovery). The QoR-40 [21] and the Postoperative Quality Recovery Scale [33] were developed to be analyzed in dimensions. SwQoR evaluates the patient's recovery on an item level, in the belief that the patient needs to be cared for according to which individual item indicating distress is disturbing. However, having said this, the

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possibility of analyzing global scores may offer an insight into the overall recovery process and be a surrogate measure for quality in the recovery process.

Conclusions

This study indicated to that there are similarities in postoperative recovery and health care contacts between men and women.

Acknowledgments

This study was founded by FORTE (the Swedish Research Council for Health Working Life and Health Care; grant No. 2013-4765) and the Swedish Research Council (Vetenskapsrådet; grant No. 2015-02273).

Authors' Contributions

UN and MJ designed the study. UN and KD coordinated the study. UN, MJ, KD analyzed the data. UN, MJ, and KD wrote and approved the final manuscript.

Conflicts of Interest

UN and the Örebro University Enterprise AB hold shares in RAPP-AB.

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Abbreviations

ASA: American Society of Anesthesiologists
PACU: postanesthesia care unit
QoR-40: 40-item Quality of Recovery
RAPP: Recovery Assessment by Phone Points
SwQoR: Swedish Web version of the Quality of Recovery

Edited by G Eysenbach; submitted 18.01.18; peer-reviewed by J Odom-Forren, J Jakobsson; comments to author 08.02.18; revised version received 23.02.18; accepted 15.03.18; published 26.03.18.

<u>Please cite as:</u> Jaensson M, Dahlberg K, Nilsson U Sex Similarities in Postoperative Recovery and Health Care Contacts Within 14 Days With mHealth Follow-Up: Secondary Analysis of a Randomized Controlled Trial JMIR Perioper Med 2018;1(1):e2 URL: <u>http://periop.jmir.org/2018/1/e2/</u> doi:<u>10.2196/periop.9874</u> PMID:<u>33401367</u>

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Original Paper

Accessible Communication Tools for Surgical Site Infection Monitoring and Prevention in Joint Reconstruction: Feasibility Study

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Abstract

Background: The National Surgical Quality Improvement Program logs surgical site infections (SSIs) as the most common cause of unplanned postoperative readmission for a variety of surgical interventions. Hospitals are making significant efforts preoperatively and postoperatively to reduce SSIs and improve care. Telemedicine, defined as using remote technology to implement health care, has the potential to improve outcomes across a wide range of parameters, including reducing SSIs.

Objective: The purpose of this study was to assess the feasibility and user satisfaction of two automated messaging systems, EpxDecolonization and EpxWound, to improve perioperative care in a quality improvement project for patients undergoing total joint replacement.

Methods: We designed two automated text messaging and calling systems named EpxDecolonization, which reminded patients of their preoperative decolonization protocol, and EpxWound, which monitored pain, wound, and fever status postoperatively. Daily patient responses were recorded and a post-usage survey was sent out to participants to assess satisfaction with the systems.

Results: Over the 40-week study period, 638 and 642 patients were enrolled in EpxDecolonization (a preoperative decolonization reminder) and EpxWound (a postoperative surgical site infection telemonitoring system), respectively. Patients could be enrolled in either or both EpxDecolonization and EpxWound, with the default option being dual enrollment. The proportion of sessions responded to was 85.2% for EpxDecolonization and 78.4% for EpxWound. Of the 1280 patients prescribed EpxWound and EpxDecolonization, 821 (64.14%) fully completed the postoperative system satisfaction survey. The median survey score (scale 1-9) was 9 for patient-rated overall care and 8 for whether the telemonitoring systems improved patient communication with providers. The majority of patients (69.0%, 566/821) indicated that the systems sent out an ideal number of messages (not too many, not too few).

Conclusions: EpxDecolonization and EpxWound demonstrated high response rates and improved patient-rated communication with providers. These preliminary data suggest that these systems are well tolerated and potentially beneficial to both patients and providers. The systems have the potential to improve both patient satisfaction scores and compliance with preoperative protocols and postoperative wound monitoring. Future efforts will focus on testing the sensitivity and specificity of alerts generated

by each system and on demonstrating the ability of these systems to improve clinical quality metrics with more authoritative data.

(JMIR Perioper Med 2018;1(1):e1) doi:10.2196/periop.7874

KEYWORDS

communication tool; decolonization; mobile health; surgical site infection; automated; messaging

Introduction

According to the National Surgical Quality Improvement Program of the American College of Surgeons, surgical site infections (SSIs) were the most common cause (1.1%) of unplanned surgical 30-day readmissions overall in 2012 for 346 US hospitals [1]. The cost of treating an SSI can be between US \$27,000 and US \$40,000 per infection per patient. In particular, SSIs for orthopedic patients result in longer hospital stays, higher readmission rates, and up to quadruple the health care costs due to prolonged antibiotics and additional hardware revisions [2,3]. It is estimated that by 2020 there will be at least 70,000 total hip and knee arthroplasty revision surgeries due to deep SSIs at a cost of US \$1.62 billion annually [4]. Readmission rates are now an important quality metric for hospitals and the Centers for Medicare and Medicaid Services are focusing on identifying the causes for readmission in an effort to improve quality of care and control costs. Given the importance of SSIs in postsurgery readmissions and their clinical impact on patients receiving implanted orthopedic hardware, we wanted to study how enhanced telemedicine techniques could prevent, detect, and treat SSIs earlier and at reduced system costs.

Telemedicine, the use of technology to deliver health care remotely [5], shows promise in improving prevention and detection of SSIs. Medication adherence and patient outcomes have been shown to improve with interventions that include reminders [6]. In a survey querying patients' experiences with postoperative self-management of wounds after surgery, patients reported concern about the efficacy of self-monitoring and whether health care providers would be accessible if wound issues developed [7]. Despite these initial concerns, the majority of patients expressed openness toward a mobile intervention. Although there are currently many digital platforms for telemedicine that include email or health portals, those both require reliable Internet access or "smart" mobile phones. A text message-based intervention seems particularly promising due to the wide and convenient availability of cell phones. Short message service (SMS) text messaging increases treatment compliance, including medication adherence [8]; however, there is no previous research on the use of SMS text message-based digital communication on reducing rates of SSIs.

Many strategies, including preoperative antibiotic prophylaxis protocols, exist for preventing SSIs for elective surgery patients [9]. Decolonization is an antibiotic prophylaxis protocol in which patients apply intranasal mupirocin ointment and use chlorhexidine gluconate wash prior to surgery, resulting in decolonization of *Staphylococcus aureus*. Studies on the use of intranasal mupirocin ointment for the decolonization of *S. aureus* show reductions in SSIs [10-14]. Immerman et al [15] found

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that a protocol consisting of a 5-day course of nasal mupirocin and one preoperative chlorhexidine gluconate shower scrub resulted in decolonization in 61% to 72% of patients. Unfortunately, patient compliance for these procedures remains as low as 31.1% [16]. Patient compliance remains low for a number of reasons: (1) forgetting to use the products each day, (2) not understanding the instructions, (3) mistaking the frequency of application, or (4) not retrieving the prescription from the pharmacy. An automated reminder system can address many of these issues. Patients can be prompted to ensure that they have received their prescription and decolonization materials; they can also be sent daily reminder messages on when to use the decolonization materials.

To improve communication, some health care providers use electronic portals or apps, each of which has its own advantages and disadvantages. One disadvantage with apps and website-based systems is that the increased time for profile creation and app installation becomes a consistent usability concern [17]. Automated phone calls and text messages bypass such activities and remove complex barriers to implementation. In one meta-analysis, Kashgary et al [18] found that mobile interventions were able to increase medication adherence by 22%. This improvement in medication adherence suggests the potential for mobile interventions to significantly improve outcomes, streamline preoperative documentation, and lower long-term costs.

The purpose of this study was to investigate the feasibility of an automated intervention by focusing on patient response rates and satisfaction of using such a system. A decolonization protocol was previously implemented at Barnes-Jewish Hospital in St Louis, MO, for the orthopedic joint reconstruction service. Automated text messaging systems, named EpxDecolonization for preoperative messages and EpxWound for postoperative monitoring of pain and wound infections, were then implemented. The infrastructure for the implemented systems was provided by Epharmix, a startup company in St Louis, which named all its interventions with the prefix "Epx."

We hypothesized that a telemedicine intervention in the form of automated text messages or phone call reminders would increase compliance with decolonization to prevent SSIs and effectively detect signs and symptoms of SSIs postoperatively to reduce unnecessary readmissions.

Methods

Procedure

This implementation was submitted to Washington University's Institutional Review Board for review and was approved to be pursued as a quality improvement (QI) project. Patients undergoing primary joint reconstructions (hip and knee

replacement) at an academic tertiary care facility (Barnes-Jewish Hospital) from November 29, 2015 to September 3, 2016 (data cutoff) were offered the option to enroll in the EpxDecolonization and EpxWound systems in addition to the standard perioperative care; some chose to be enrolled in only one system. Patients signed a consent form and provided a cellphone number or landline to be contacted at. To include as many patient populations as possible, such as older patients or those of lower socioeconomic status who may not be comfortable with texting or may not have access to smartphones, the systems were designed to enable usage with either text or voice calling capabilities. The only inclusion criterion was that the patient was undergoing an elective hip or knee replacement surgery. Patient responses were included in the analysis only if the entire session (EpxDecolonization or EpxWound) was completed by September 3, 2016.

Six days prior to their surgery, patients commenced with the EpxDecolonization system. EpxDecolonization sent texts or voice calls to ensure that patients received their decolonization supplies and, once procured, asked patients daily whether they had used their nasal ointment or chlorhexidine gluconate. When patients responded that they had not procured their decolonization materials, an alert was sent to the nurse in charge of their care. This information was recorded in the Epharmix system and could be checked by clinical staff, but the system did not generate an alert if a patient did not use their decolonization supplies to ensure that the number of alerts did not become a burden.

EpxWound sent texts or calls to patients to track pain and status of the wound. EpxWound was designed to identify SSIs between the patient's surgery and their 2-week follow-up appointment. Thus, patients received daily messages from postoperative day 5 to 19 (15 consecutive days of messages) to cover a slightly longer time frame in case the patient's 2-week follow-up appointment was delayed. Patients answered questions about their pain, wound status, and temperature. An alert was generated to the nurse in charge of their care in the event of increased redness, drainage, or odor, and if a fever was present.

The preoperative EpxDecolonization system and postoperative EpxWound system are depicted in Figure 1. Alerts were sent to nurses either via automated email or phone calls. Following a generated alert, patients were contacted by a nurse within 2 hours or, if after hours, the following morning. Nurses who were responding to an alert called the patient to inquire about any further suggestions of an SSI or to ensure that the patient procured their decolonization supplies. Patients were asked to present to the clinic or were prescribed an antimicrobial if an SSI was suspected. Daily response rates for each patient were recorded throughout the study.

Following use of the systems, an automated electronic survey using a 1 to 9 response scale was delivered to assess the care delivered by the provider (On a scale of 1 to 9, how would you rate your care by your provider?), the number of messages they received (On a scale of 1 to 9, how do you feel about the number of messages you received through our service? [1=too few, 5=perfect amount, 9=too many]), and whether the EpxDecolonization and EpxWound improved communication

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XSL•F() RenderX with their doctors (On a scale of 1 to 9, do you think this service improved communication with your doctor? [1=significantly worsened, 5=no change, 9=significantly improved]). Only fully completed survey responses were included in our analysis (fewer patients responded to the survey than used the Epharmix systems).

The primary outcome was the daily response rate for all patients enrolled in a given week. Secondary outcomes were whether patients reported that EpxDecolonization and EpxWound improved communication, how many alerts were generated during the study, and how patients felt about the message frequency and overall care provided.

The algorithm and questions for the Epharmix systems were developed by medical students with the assistance of the joint reconstruction team. Software engineers at Epharmix (St Louis, MO, USA) coded the algorithm and created an enrollment platform on a Health Insurance Portability and Accountability Act (HIPPA)-compliant server. The system was then reviewed by the HIPPA compliance officer at Washington University.

Participants

Participation was voluntary. Patient ages were not collected because we were not authorized to access patient health information. Enrollment was offered at a preoperative patient education joint replacement class. Attendance at the joint replacement class was required for all patients who had not received a joint replacement within the last 12 months.

Statistical Analysis

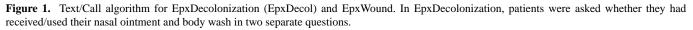
Daily response rates for EpxDecolonization and EpxWound included all responses from patients who consented via the text message authorization sequence or via phone using the voice system. The proportion of sessions responded to each day of the intervention during the months of November 2015 to September 2016 was calculated by using the following formula: number of patients who responded to a text message or phone call on a particular day of the intervention over the 40-week study period divided by the total number of patients who received a text message or phone call on that same day of the intervention over the 40-week study period. The percentage of patients who responded at least once during that day was recorded.

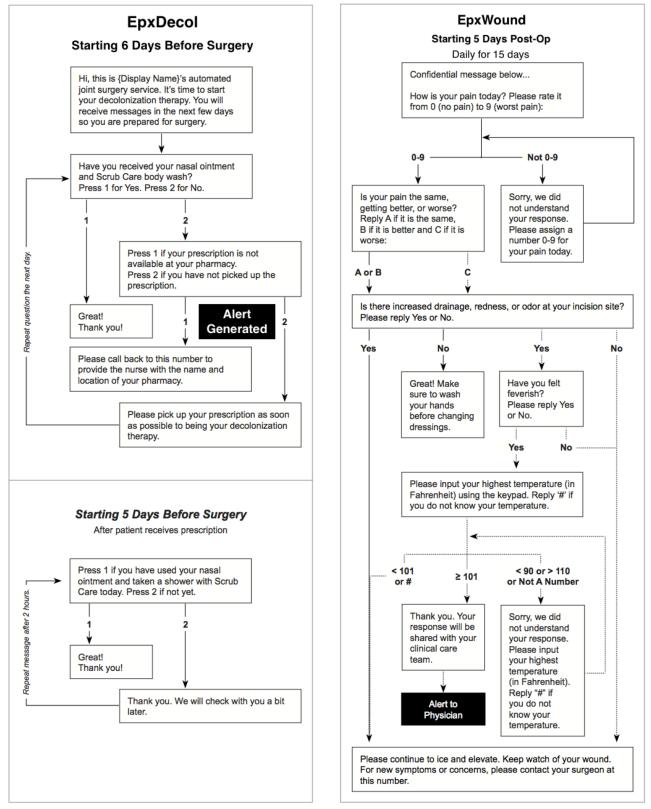
Using the automated survey results, median, mean, and standard deviation scores for how the participants rated the overall quality of care and whether the system improved communication were calculated using Microsoft Excel. Median, mean, and standard deviation scores for frequency of messages were also calculated using Excel.

Server

Epharmix maintains a mature stack on HIPAA-compliant servers at Washington University in St Louis. This stack allows maintenance personnel to focus on a single environment instead of having two separate environments, which can introduce more complexities. Updates and patches are more easily monitored and applied under this single environment.

Epharmix is hosted on servers provided by Armor, an industry-leading security-hosting provider that specializes in compliant hosting environments and offers advanced security services (eg, network perimeter defense, intrusion detection). For all the data Epharmix retains, the app stores them in secured, AES256-encrypted vaults that are managed by a role-based access control system. All connections to the Epharmix Web portal were encrypted via SSL/TLS so providers could access in a secure manner. Messages sent to patients were carefully designed; patient identifiers were removed from the content.





Results

Overview

At the end of the 40-week period, 638 and 642 patients were enrolled in EpxDecolonization and EpxWound, respectively. Approximately one-quarter of the patients chose the automated phone call intervention (27.6%, 176/638 for EpxDecolonization and 25.4%, 163/642 for EpxWound). The remaining three-quarters chose text messages (72.4%, 462/638 for EpxDecolonization and 74.6%, 479/642 for EpxWound). The proportion of total sessions responded to was 85.2% for EpxDecolonization and 78.4% for EpxWound. The surgical site infection rate for hip and knee replacement during our study period was 0.8%.

Daily Response Rates and Enrollment

For EpxDecolonization, the proportion of sessions responded to decreased from 86.5% (552/638) on the first day to 84.0% (526/626) on the second-to-last day (Figure 2). For EpxWound, the proportion of sessions responded to decreased from 81.2% (521/642) on the first day to 75.0% (466/621) on the second-to-last day (Figure 2). Due to limitations with the QI project implementation, we could not obtain the number of patients who declined enrollment in the study. However, nurses responsible for enrollment in the study estimated to us that more than 95% of patients enrolled. These nurses also indicated that the primary reason for not enrolling was that the patient did not believe that the system was necessary for their care. As shown in Figure 3, 71.3% (455/638) of EpxDecolonization patients and 52.0% (334/642) of EpxWound patients responded to 90% to 100% of messages.

Dropout Rate

The dropout rate, defined as the percentage of patients who requested to stop receiving text messages, was 2.0% (13/638) for EpxDecolonization and 3.7% (24/642) for EpxWound (Multimedia Appendix 1). The greatest number of dropouts occurred on day 4 for EpxDecolonization (6 patients dropped out) and on day 1 for EpxWound (6 patients dropped out).

Alerts

Figure 4 shows that the percentage of patients who triggered an alert in a given week never exceeded 8% for either system; the proportion of patients that generated an alert over the 40-week period was 1.1% (7/642) for EpxWound and 1.9% (12/638) for EpxDecolonization. Twelve alerts were generated for EpxDecolonization and seven for EpxWound. All 12 alerts from EpxDecolonization were triggered because the patient had procured their decolonization not supplies. The EpxDecolonization system was not designed to alert the medical team if the patient had not completed their decolonization procedure. The patient decolonization completion record was available for viewing in the Epharmix portal. For ExpWound, three alerts were generated for increased redness, odor, and drainage, and four for increased redness, odor, and drainage with fever. Nurses called each of these patients within 2 hours of the generated alert or, if after hours, the next business day. Once contacted by a nurse, the intervention continued for each patient that generated an alert.

Figure 2. The proportion of sessions responded to during each day of the intervention over the 40-week trial period for the EpxDecolonization (6 intervention days) and EpxWound (15 intervention days) programs.

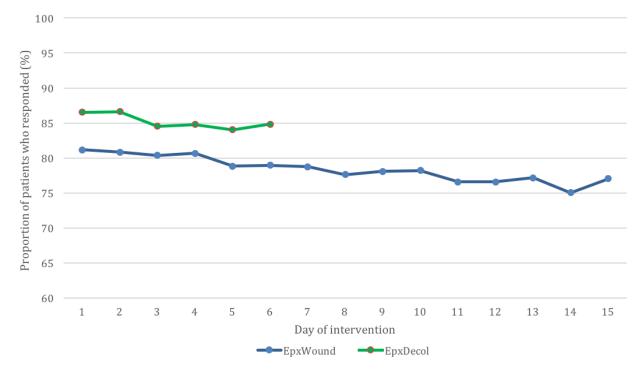


Figure 3. The distribution of percentage of sessions answered by patients enrolled in the EpxDecolonization (EpxDecol) and EpxWound interventions.

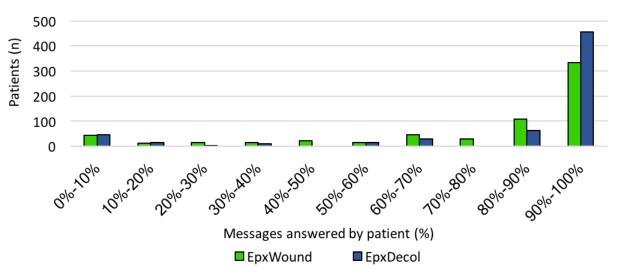
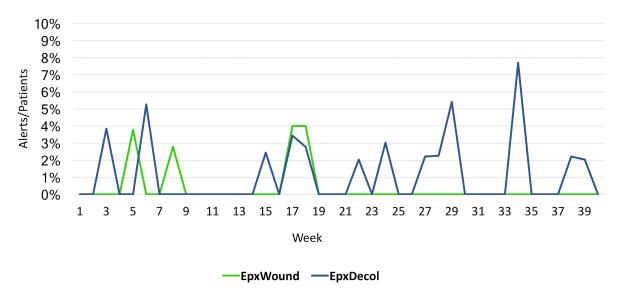


Figure 4. Percentage of patients that triggered an alert each week using EpxDecolonization (EpxDecol) and EpxWound over the 40-week trial period.



Survey Results

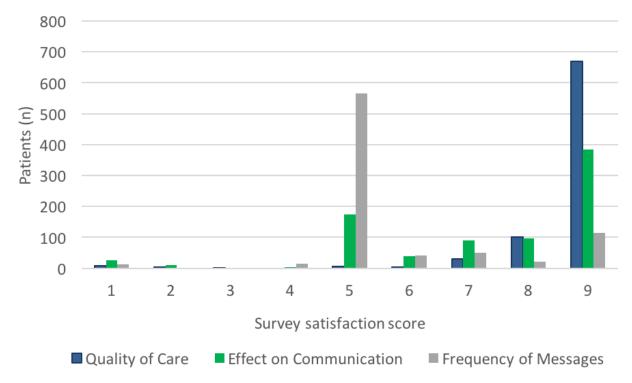
For the combined 1280 EpxWound and EpxDecolonization sessions, 821 (64.14%) postoperative satisfaction surveys were fully completed. One survey was sent for each session and because patients could be enrolled in one or both systems, patients were able to complete one or two surveys. When asked about the overall care provided during this study, patients reported a median score of 9 out of 9 (mean 8.6, SD 1.1), as shown in Figure 5. The overwhelming majority (97.0%, 796/821) of patients rated the overall quality of their care as 6 out of 9 or higher. Patients reported a median score of 8 out of

9 (mean 7.3, SD 2.1) when asked if Epharmix improved communication with the care team (Figure 5). The majority of patients (69.9%, 566/821) reported that the system improved their communication.

The median satisfaction score for the number of messages sent was 5 (best possible) and mean 5.7 (SD 1.6) (Figure 5). The majority of patients (68.9%, 566/821) felt that the systems sent out the perfect number of messages (rating of 5). However, a subset (26.9%, 221/821) of patients reported that too many messages were sent (rating of >5), and a smaller (4.2%, 34/821) subset indicated that not enough messages were sent (rating of <5).



Figure 5. Patient satisfaction with EpxDecolonization and EpxWound. Patients rated their care provided by their medical care team on a scale from 1 to 9 (1=terrible, 5=average, 9=excellent), whether EpxDecolonization and EpxWound improved communication with their doctor (1=significantly worsened, 5=no change, 9=significantly improved), and their satisfaction with the number of messages that they received (1=too few, 5=perfect amount, 9=too many).



Discussion

Principal Findings

Overall, we report high total response rates (85.2% and 78.4% for EpxDecolonization and EpxWound, respectively); high satisfaction scores (median values of 9, 8, and 5 [perfect score] for patient-rated care, improvement in communication, and number of messages received, respectively); and a low dropout rate (2.0%, 13/638 for EpxDecolonization and 3.7%, 24/642 for EpxWound) for both automated phone and SMS text messaging systems.

Historically, the perioperative surgical management of patients comprised of unsupported patients self-monitoring their own care status (based on discussions with providers). Patients were expected to recall and implement the prescribed perioperative protocol correctly and providers had to hope for compliance. On discharge, health care providers relied on patients for symptom monitoring and alerting their providers in a timely manner when issues arose in addition to the scheduled postoperative clinic visit. Our system has the potential to facilitate better patient self-monitoring and provides a new way for patients to communicate the results to their health care providers. These communications could include first signs of infection as well as a notification that the patient has not yet received decolonization materials.

Our study demonstrates that EpxDecolonization and EpxWound are effective at reaching patients and facilitating patient self-monitoring of SSI prevention and identification, as concluded from high response rates. Also, user survey data

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shows high satisfaction with each system. Specifically, patients reported that the Epharmix systems sent the appropriate number of messages and that the systems improved communication with their provider. These positive impressions likely contributed to the high response rates. Our promising findings with these systems suggest potential for use in broader applications.

Text message interventions offer advantages over more traditional interventions, such as nurses calling patients. Text messages can be sent in the morning and the patients can respond at their own convenience. When a nurse calls, the patient must be available to speak at that moment. The difficulty that nurses have getting in contact with patients via a phone call is a documented dilemma. Bebko et al [9] reported that despite three attempts, nurses could not reach over 28% (31/110) of patients after hospital discharge. Our interventions primarily used text messages; therefore, this increased time frame for patient response may have contributed to our high response rates.

Another potential domain of enhanced telemedicine approaches is improving patient satisfaction. Patient satisfaction is becoming increasingly important. Systems such as EpxDecolonization and EpxWound may play a critical role in improving patients' rating of overall care. This is partly captured by the 9 out of 9 median rating for the overall care provided. A potential component of that highly rated provided care could be explained by the patients' 8 out of 9 median rating that the Epharmix systems improved communication with the health care team.

In our results, we found that EpxDecolonization had a higher response rate than EpxWound. This difference could be

explained by the fact that EpxDecolonization was preoperative whereas EpxWound was postoperative and that EpxDecolonization had fewer questions than EpxWound. EpxWound and EpxDecolonization suggested that automated communication systems could elicit high patient response rates during the critical perioperative period. The high response rates also demonstrate ease of use because there are other forms of communication that could serve the same purpose of communication, but presumably put more burden on the respondent [18].

Although response rates were high, patient engagement decreased over the length of the study. A small percentage of patients dropped out (2.0%, 13/638 for EpxDecolonization and 3.7%, 24/642 for EpxWound) and response rates decreased (1.7% decrease for EpxDecolonization and 4.1% decrease for EpxWound). This usage fatigue is well demonstrated in other studies [19,20].

Despite the largely positive responses, approximately 20% of patients (Figure 5) did not feel the system affected their communication, and a very small subset indicated that the systems worsened their communication. After talking to the nurses, a potential explanation may be that these patients generated an alert but did not receive prompt follow-up by the nurse receiving the alert. This emphasizes the importance of medical staff implementing robust processes to ensure that patients obtain prompt follow-up after triggering the system. Due to the limitations of this study, no further investigation into the patient demographics or patient situations could be pursued. Another reason could be the patients were already diligent about medication compliance and wound monitoring, and felt that our system added little to no value to their experience. Future studies will aim to better understand the reasons why certain patients felt that the system made no difference or even worsened the communication with the health care team.

Patient survey data showed that patients were inclined to use our system. At the same time, because the system is automated, it improved communication (based on patient-rated results) without putting a significant burden on surgical group employees. Providers reported that the system was convenient because it required minimal work for them to enroll and was efficient at monitoring patients. Further, they were assured that their patients were being tracked perioperatively and knew that they would be alerted to patients who needed extra attention. In terms of cost measures and savings, surgical groups who pay staff to check in on patients by phone may be able to save in this area, especially because many surgeries are becoming reimbursed by bundled payments that will not reimburse for individual aspects of care delivery. A study conducted by Semple et al [21] that implemented an app to monitor surgical sites post-breast reconstruction or orthopedic surgery found similar high satisfaction rates among patients and providers.

Follow-up conversations with the nursing staff and surgeons indicated that the number of alerts was within manageable limits for the health care team. It is also notable that 1.1% of patients triggered an EpxWound alert, which is reflective of the observed SSI rate of the clinic (0.8%) in which the QI project was conducted. This adds additional validity to our observations.

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Even with this low alert rate, three of the seven total alerts for EpxWound were triggered by the same patient, highlighting the ability of Epharmix interventions to track in-need patients until all their complications are addressed. These data indicate that EpxDecolonization and EpxWound patient alerts are manageable for the nursing staff without creating an excessive work burden.

We also tried to determine whether either of our systems was sending automated messages too frequently or not frequently enough. Approximately 70% of patients reported that the number of messages was just right. Due to the scaling of previous questions, a number of patients commented at the end of the survey that they had mistakenly selected 9 for this question instead of 5. This issue may explain some of the patients who reported that there were sent too many messages, and this can be easily modified when designing future survey questions.

As bundled payments become more prevalent, providers will bear most of the cost of postoperative complications. Given the numerous Enhanced Recovery After Surgery initiatives across the United Stats aimed at decreasing postoperative complications while maximizing use of resources, automated communication systems such as EpxDecolonization and EpxWound are uniquely poised to facilitate these cost-reducing measures in a standardized and patient-centered way. Effort is currently being focused on integrating the EpxWound and EpxDecolonization systems into existing electronic medical record platforms. Additionally, the technology used to build EpxDecolonization and EpxWound is currently being expanded to other surgical specialties including but not limited to cardiothoracic, colorectal, neurosurgery, trauma, and urology to have a broader impact on improving overall surgical care.

Limitations

Limitations of the study related to the QI status of the project, the voluntary enrollment structure, and the lack of a concurrent control group. Because this was an early QI study to assess feasibility, we were unable to measure the clinical effectiveness of these automated systems that we hope to study in the future. EpxDecolonization encouraged patients to procure their prescriptions and solicited daily responses on whether their ointment and chlorhexidine gluconate was used. However, we were unable to investigate significant improvements in decolonization compliance because this QI project did not include a mechanism to objectively assess decolonization compliance beyond the patient-reported responses. We were also unable to determine the percentage of patients who procured their decolonization supplies after a generated alert from the EpxDecolonization system and nurse intervention. Also, due to the QI status of this project, we were not permitted to obtain and evaluate the number of patients that declined enrollment in our study and the number of patients who underwent a knee replacement versus a hip replacement surgery. We were also limited by the amount of follow-up and patient interviewing that we were able to conduct. For example, it would have been instructive to investigate the reasons for the small subset of patients who responded to 0% to 10% of messages, but it was not within the scope of the QI project. The voluntary enrollment structure of this study provides another limitation. It is possible that those who were willing to consent were more likely to

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respond to inquiries from the automated systems. Another limitation was that there was no concurrent control group without the Epharmix interventions. Future studies will incorporate this type of follow-up to provide maximal opportunity for improvement. The studies will also investigate the specificity and sensitivity of the systems' alerts, because any new tool for treatment should be assessed for reliability and validity [22]. With further data on specificity and sensitivity, we can assess the efficacy of EpxDecolonization improving decolonization compliance and EpxWound in detecting SSIs earlier.

Conclusions

In summary, we developed automated SMS text messaging and calling systems called EpxDecolonization and EpxWound in an effort to improve perioperative care in patients undergoing orthopedic joint reconstruction. Our project demonstrated that patients responded to 85.2% and 78.4% of all sessions sent by EpxDecolonization and EpxWound, respectively. The majority of patients felt that the Epharmix systems improved communication with their providers and sent out the appropriate number of messages. From discussions with providers, surgeons and nurses readily adopted the systems, and most patients were interested in using the system. The automated text or phone call systems, EpxDecolonization and EpxWound, were shown to be proactive tools that are not overly burdensome and have the potential to improve perioperative care within orthopedics and other surgical fields in a cost-effective manner. Although the QI status of this project limited our ability to correlate responses with patient outcomes, this will be addressed in future studies. These studies will also assess quality metrics as well as the sensitivity and specificity of the generated alerts EpxDecolonization and EpxWound.

Acknowledgments

We would like to thank Avik Som for his advice and critical comments, Tonya An for her ideas and feedback, Evan Huang for his data retrieval, Christine Stavridis for her design help, and everyone on the Epharmix surgery research team who have provided support and feedback. We appreciate Drs Barrack, Nunley, Nam, Adelani, McDonald, Cipriano, O'Keefe, and Wright for contributing patients, and all the nurses—Joanna Waller, Madelyn Curry, Alyssa Hesser, Desiree Trotter, Kelly Osterman, Mendi Lawson, Stephanie Hanneken, Kim Burgess, and Emily Peters—on the joint reconstruction team for helping with enrollment of patients. We would like to acknowledge the in-kind support the Epharmix Research Center development team gave to make this project possible.

Conflicts of Interest

None of the coauthors were compensated for any of their work on this project or have equity in Epharmix. The authors of this manuscript are research volunteers at Epharmix. Epharmix paid for the costs associated with the sending of messages to enrolled patients and the storage of the data.

Multimedia Appendix 1

Number of patients receiving text messages/phone calls during each day of the EpxDecol and EpxWound interventions. [PNG File, 61KB - periop v1i1e1 app1.png]

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Abbreviations

QI: quality improvement SMS: short message service SSI: surgical site infection



Edited by G Eysenbach; submitted 08.06.17; peer-reviewed by E Sezgin, J Schmier; comments to author 24.08.17; revised version received 17.11.17; accepted 06.12.17; published 17.01.18. <u>Please cite as:</u> Lu K, Chermside-Scabbo CJ, Marino NE, Concepcion A, Yugawa C, Aladegbami B, Paar T, St John TA, Ross W, Clohisy JC, Kirby JP Accessible Communication Tools for Surgical Site Infection Monitoring and Prevention in Joint Reconstruction: Feasibility Study JMIR Perioper Med 2018;1(1):e1 URL: http://periop.jmir.org/2018/1/e1/ doi:10.2196/periop.7874 PMID:<u>33401369</u>

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