AHRQ Grant Final Progress Report

Title of Project:

Optimizing Acute Post-Operative Dental Pain Management Using New Health Information Technology

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Structured Abstract

Purpose: The purpose of the project was to evaluate the use of an existing mHealth application (FollowApp.Care) to collect patient reported outcomes (PRO) after painful dental procedures, and to determine the impact on the patient pain experience.

Scope: The project was implemented at one academic dental institution and one large dental group practice with 54 offices covering three states. The research focused on management of pain experience after specific painful dental procedures of adult patients ≥18 years old.

Methods: The study employed a cluster-randomized experimental study design with: (1) an intervention arm where patients were prompted to complete two PROMIS[1, 2] pain intensity questions through text notifications on their smartphone on Days 1, 3, 5 and 7; and (2) a control arm where patients received usual care. All patients were asked three questions on pain interference/pain management from the APS-POQ-R[3-5] questionnaire one week after their dental procedure. Intervention arm patients also received three questions assessing their experience with FollowApp.Care. Provider interviews and surveys were conducted to evaluate usability and provider acceptance of FollowApp.Care**.**

Results: There did not appear to be a significant effect on average pain intensity, pain interference, or satisfaction with pain management for patients using FollowApp.Care. There was also no significant change in opioid prescribing in the intervention arm, although it was found that three dentists prescribed nearly 50% of all opioids. Provider and patient acceptance of the mHealth application was high.

Key Words: PROs, HIT, dentistry, mHealth, dental pain

Purpose

The goal of this study was to test the hypothesis that increased collection and utilization of Patient Reported Outcome (PRO) data will help improve dental care delivery quality, patient-dentist communication, patient engagement, and patient satisfaction, as well as reduce unnecessary opioid prescription by enabling dental providers to explore modifying prescribing behaviors.

The study implemented an innovative mHealth solution to monitor patients' pain during the critical acute postoperative phase after a dental procedure in order to address the following hypotheses:

Hypotheses 1: For the usability outcome, the hypothesis is that a user-centered and iterative process will allow for the development of acceptable user experience of the mHealth platform as measured by the System Usability Scale (SUS) questionnaire.

Hypothesis 2: For the pain intensity outcome, the hypothesis is that there will be a significant difference in the pain intensity as measured by the mHealth questionnaire between intervention and control groups.

Hypothesis 3: For the pain interference outcome, the hypothesis is that there is a significant difference in pain interference among intervention and control groups.

Hypothesis 4: For the use of analgesic medication outcome, the hypothesis is that there is a significant difference in opioid prescribing between intervention and control groups.

Hypothesis 5: For the patient satisfaction outcome, the hypothesis is that there is a significant difference in patient satisfaction among those in the intervention group versus those in the control group.

Hypotheses 6: For the provider acceptance outcome, the hypothesis is that intention to use mHealth technology is closely associated with perceived usefulness and ease of use among dental providers as measured by the UTAUT.

Scope

Background

Pain has been deemed the fifth vital sign[6] and many describe it as an adverse event.[7-9] Managing acute post-operative pain remains sub-optimal for most US adults undergoing outpatient surgery,[10-13] often associated with poor health outcomes.[14] The Joint Commission's standards on pain management call to "assess and manage patients' pain and minimize the risks associated with treatment."[15-17] Patient self-report is a critical part of comprehensive pain assessment,[18, 19] given pain's subjective and multi-dimensional nature.[7] Patient-reported outcomes (PROs) allow clinicians to directly assess patient's symptoms, symptom burden, functional status, health behaviors, health-related quality of life, and care experiences,[20, 21] and deliver value-based care.[22]

Due to the duration of action of most commonly-used local anesthetic agents, dental patients are unable to predict their pain following dental procedures until many hours later, when they have already returned home, and dental offices are closed. This has led to an over-reliance on pre-emptively prescribed opioids by dental providers because they have no means to actively track their patients' pain after hours. Dentists' limited ability to actively assess patients' pain

levels post-operatively (Day 1-7) has led to pre-emptive opioid prescriptions (Rxs) despite addiction and inferior post-op pain relief compared to non-opioids,[23-32] to safeguard against worst case scenarios and/or patient dissatisfaction from misconceptions about opioids.[28, 33, 34]

Emerging health information technologies (IT), such as mobile health applications and secure messaging, can effectively collect PRO data[35-39] to inform clinical care and promote patient engagement in medicine,[40, 41] however have remained largely unexplored in dentistry. Innovative mobile applications and connected health technologies that allow real-time tracking of patients' symptoms, functional status, and quality of life, provide healthcare professionals with data that were previously unavailable, and have fostered patient engagement, shared decision-making, and adherence to treatment plans.[42-47]

This project explored an innovative solution to optimize the quality of dental pain monitoring and management by implementing mobile phone technology to monitor patients' pain during the critical acute postoperative phase. Active tracking of these symptoms using mobile phones, would allow for the prompt identification of patients with sub-optimal pain experiences and offer providers an opportunity to intervene in the moment (e.g., modify analgesic prescriptions), thereby enhancing the overall care experience.

Health IT System Evaluated

The project focused on the FollowApp.Care Health IT system:
FollowApp.Care text messaging platform is a stand-alone product. FollowApp.Care is a communications platform that collects patient-generated health data prior to or after a procedure in order inform treatment, care decisions, drive quality and generate actionable performance reports.

Context

This study implemented an existing and tested mHealth system (FollowApp.Care) into real-world dental office settings to facilitate the timely and efficient capture of PRO data (post-op pain experience) in order to inform the clinical management of acute post-op dental pain, with as goal to improving patient health outcomes, experience of care, and provider performance.

Dentists had access to one of two user interfaces (UIs); 1) notifications could be viewed and answered via email or mobile phone text message when alerted of a patient's response and 2) providers could access a website with dashboard access and other functionalities that allow them to interact with their patients. In contrast, the patient's single UI consisted of a survey accessed via a link embedded within a text message received on the participant's mobile phone. Both patient and provider interactions were initiated by a patient-triggered alert or a patient-derived question. Once alerted, dentists had the option to resolve the alert by contacting the patient through the messaging application or "acknowledge" the receipt of the alert but perform no action. Providers always had the option to phone/contact the patient outside of the application, and patients had the option to contact the provider's office outside of using the app.

The strength of this study lies in the ubiquity of mobile phones, which makes it a convenient platform to collect PRO data. The secure-messaging feature of the FollowApp.Care system is deployable on any text message-enabled smart phone, and the high engagement rates among dental patients is a testament to its 'fit' for this study. For patients, PROs must be easy (simple user-interface, convenient timing), fast (short questionnaire length and frequency) and relevant (inform clinical care). For providers, PROs should make care easier (reduce administrative burden), faster/better (improve quality of visit) and relevant (solve discipline-specific problems).

The targeted outcome (i.e., effective post-op pain management) is of great concern to most dental providers as they struggle to reduce their opioid Rx footprint in the midst of the opioid epidemic.

Settings

The study was conducted at two dental institutions: 1) Willamette Dental Group (WDG) an accountable care organization (ACO) and 2) University of California San Francisco (UCSF) Dental Center. WDG consists of 54 dental offices located in the states of Oregon, Washington, and Idaho that serve areas with wide-ranging demographic and socioeconomic characteristics. Offices range from 1 to 10 dentists with a staff range of 4 to 37. Each office has a practice manager who reports to a director of operations.

The UCSF Dental Center is the clinical care arm of the University of California, San Francisco, School of Dentistry. It comprises of the pre-doctoral teaching clinics, resident and faculty group practices. The pre-doctoral teaching clinics have students (3rd and 4th year dental students) practicing under the supervision of full-time and part-time faculty members. The resident clinics comprise general dentistry and specialty residency programs, and the faculty group practice allows clinical faculty to provide patient care using a private practice model. Patients are drawn from all over the San Francisco Bay Area, offering a demographically and socioeconomically diverse population.

Table 1: Characteristics of Participating Institutions

	#Residents	#Dentists/ Clinical Faculty	#Hygienists	#Clinical Staff	# Total Patients (2016)	# Total Patient Visits (2016)
WDG	N/A	163	133	814	242,904	589,100
UCSF	68	217	8	83	35, 317	104, 261

Participants

There were 16 dental providers who participated in the usability and pilot phases (9 in usability, 11 in pilots testing). Five (5) dental providers participated in both the usability and pilot phases. The main RCT study included 42 Dental Providers (1 dental provider participated in both the pilot testing and the main study): General dentists and endodontists, periodontists, and oral surgeons. Eligible providers were dental providers with a minimum of two clinic sessions per week (one day) and at least 6 months of practice experience.

There were 6 patients who participated in the usability phase and 34 patients who participated in the pilot phase. The main RCT study included an additional 1,525 Patients: patients of the providers who were enrolled in the study. Eligible patients were English speaking adults (≥18yrs), who had undergone specific, likely to be postoperative painful dental procedures (endodontic, periodontal, oral surgery and implant procedures).

Patients and dental providers needed to have access to a working smartphone with internet capabilities.

Methods

Study Design/Intervention

The multicenter, phase 2 clinical trial employed a cluster-randomized experimental study design with: (1) an intervention arm where patients were prompted to complete two PROMIS[1, 2] pain intensity questions through text notifications on their smartphone on post operative Days 1, 3, 5

and 7; and (2) a control arm where patients received usual care. All patients were asked three questions on pain interference/pain management from the APS-POQ-R[3-5] questionnaire one week after their dental procedure. Intervention arm patients also received three questions assessing their experience with FollowApp.Care. Provider interviews and surveys (UTAUT[48]) were conducted to evaluate provider acceptance of FollowApp.Care**.** Each of the participating providers were randomized to receive either the FollowApp.Care intervention plus standard care or standard care only and each patient assumed the randomization status of their respective provider.

The study protocol was reviewed and approved by the Institutional Review Board of UCSF upon which WDG relied (IRB# 18-25477). The study has been registered with ClinicalTrials.gov under number NCT03881891.

Table 2: Timeline for clinical sites

Sites	2018		2019				2020				2021				2022	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Customize mHealth platform																
WDG																
UCSF																

Legend
Pilot Studies
RCT implementation
Provider assessment

This project consisted of three stages: customize the design features of FollowApp.Care and assess its capacity to accurately capture patient-reported outcomes through a user-centered and iterative process; implementation of pilot and full study; and assessment of provider acceptance of and performance with the platform. Duration of the full study was longer than originally expected due to the initial restrictions around the COVID-19 pandemic. See Table 2 for the implementation timeline.

Measures and data collection

Means of Data Collection: We used the mobile health (mHealth) platform (FollowApp.Care®) to collect PRO data (pain experience) from patients after dental procedures. EHR data for post-procedure prescribing data was extracted using the patient enrollment data. EHR data was then merged with the mHealth survey response data for each patient.

Data Analysis: Descriptive statistics were calculated for all items on the mHealth Questionnaires. Means and standard deviations were estimated for continuous variables and frequencies with corresponding percent contributions were calculated for categorical variables. In order to test whether there was a difference in pain intensity, interference, or satisfaction with pain management among the study arms at 7 days, a hierarchical model was performed that adjusted for within clinic correlations and repeated measures over patient responses.

Usability: Usability was established in 3 phases: I) Lab-based rapid cognitive walkthroughs;[49] II) 1-hour semi-structured interviews for usability testing consisting of simulated scenarios of a 7-day post-operative dental experience where participants interacted with the mHealth platform while following a think-aloud protocol;[50] and III) in-situ pilot testing. The representative users were provided “real life” use cases to complete, using FollowApp.Care while the project team observed. Quantitative usability data was collected by assessing fidelity and administering the System Usability Scale (SUS) questionnaire,[51] using the Qualtrics XM experience software. A purposive sample of patients and providers was used for all testing.

Fidelity: Table 3 outlines the fidelity metrics for both patients and providers.

Table 3: Fidelity measures

Fidelity measures (Patients)	Fidelity measures (Dentists)
Provided verbal consent and received the Information Sheet	Signed consent forms before training
FollowApp.Care Profile was created	Completed 1-hr training
Received text notifications on Day 0	Verified FollowApp.Care Profile
Patient Response Time	Unique Identifiers provided
# of Patients who have phone service provided by T-Mobile	Completed SUS Survey
Response rate Day 1	Number of Log-Ins
Response rate Day 3	# of Successful Log-Ins
Response rate Day 5	# of Unsuccessful Log-ins
Response rate Day 7	# of Alerts triggered
	# of Alerts Resolved
	# of Alerts Resolved by chat
	# of Alerts Resolved by phone
	# of Alerts resolved by Acknowledgement
	# of Alerts Unresolved
	Average Response Time to Alerts

Pain Intensity: Pain Intensity is an assessment of how much the patient experiences pain after undergoing one of the eligible procedures and the data was collected using the mHealth questionnaire using two items from the validated PROMIS Shortform 3A Version 1 questionnaire.[52] The response categories range from “No pain” to “Very severe” and was measured on a 0 to 10 rating scale. The outcome was treated as continuous.

Pain Interference: Pain interference is an item captured by the mHealth questionnaire using three items adapted from the validated Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) form.[3] Response categories range from “No interference” to “High interference” on a 0 to 10 rating scale. Each item queries how pain interfered with; 1) doing activities out of bed such as walking, sitting, standing; 2) falling asleep; and 3) Staying asleep.

Patient Satisfaction: Patient satisfaction details the extent to which patients were satisfied with the overall pain management. It is an item captured by the mHealth questionnaire, using two items adapted from the validated APS-POQ-R form and measured on a 0 to 10 rating scale.[3] Each outcome was treated as a continuously measured variable.

Use of Analgesic medications: We assessed the number of participating patients prescribed opioids using data from the patient record and the frequency of pain medication from self-reports using two separate questions on the mHealth questionnaire. Through secondary analysis of the electronic health record (EHR), medication-prescribing patterns were collected by deploying query scripts to identify the patients who received Rxs postoperatively, including type, dosage, frequency, and duration.

Post-operative complications: Bleeding and swelling were the two postoperative complications collected using two separate questions on the mHealth questionnaire.

Technology Acceptance: To ensure that practitioners were not unduly burdened by the technology and that it fit seamlessly into their workflow, the unified theory of acceptance and use of technology (UTAUT) questionnaire was administered. There are 4 key constructs measured, performance expectancy (PE), Effort expectancy (EE), and the Social Influence (SI). A descriptive analysis was performed to describe the constructs of the UTAUT questionnaire. Additionally, we assessed its impact on their clinical workload, satisfaction with pain management, and prescribing behaviors through focus group discussions.

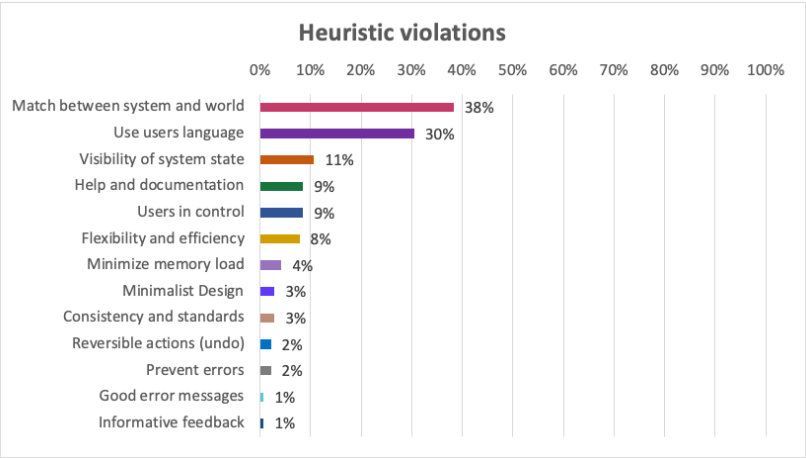
Results:
One or more hypotheses are associated with the three research questions.

Research question 1: Can acceptable patient and provider user interfaces (UI) for the mHealth platform be developed, using a user-centered and iterative process?

Hypotheses 1: A user-centered and iterative process will allow for the development of acceptable patient and provider user interfaces (UI) of the mHealth platform as measured by the SUS questionnaire.

Usability: Phase I of the usability testing consisted of the rapid cognitive walkthrough of the prototype A; 23 issues with the potential to have a negative impact on users' experience were identified. The majority were categorized as system issues (n=17, 74%), followed by content issues (n=4, 17%). Two issues (9%) related to the workflow and implementation of the app within the clinical context. Overall, 13 issues belonged within the dentists' user interface (UI) (57%) and 10 belonged within the patients' UI (43%). Table 7 shows examples of each category and their level of impact on usability. Among all issues identified in Phase I, 17 (74%) were classified as having a high impact on usability, 4 (17%) were classified as medium impact on usability, and 2 (9%) were classified to have low impact on usability. We did not identify any issues that were out of the scope of the project. 21 (91%) of the issues needed to be addressed in a short term, and 2 (9%) in a medium term.

Figure 4: Issues found during the usability testing lab sessions



In Phase II of the usability testing, 15 semi-structured interviews were conducted, ranging between 35 and 160 minutes with an average duration of approximately 60 minutes. The first and second rounds of analytical conceptualization and re-classification of issues to achieve a consensus yielded 141 usability issues; Table 5 describes the frequency and percentage of each type of issue classified by the level of impact on usability. Among all issues, 42% were classified as system issues of the mHealth platform interface (n=59), 35% were related to the content (n=50), and 23% were associated to the workflow process of the use of the mHealth platform in the participants' environment (n=32). Of the 141 issues, 43% were encountered by the patients (n=61) and 57% by the dentists (n=80). If an issue appeared more than once, it was only documented one time; non-duplicated issues summed to 141 issues. Figure 4 shows the distribution of heuristic violations; 54 issues referred to a lack of match between the mHealth platform and the world (38%) and in 43 cases the system did not follow the users' language (30%). Other usability issues included a lack of visibility of system state (n=15,11%), help and documentation challenges (n=12, 9%), users not feeling in control (n=12, 9%), lack of flexibility and efficiency (n=11, 8%), problems with minimizing the user's memory load (n=11, 4%). Other issues were associated to challenges in violations to the principles of minimalist design (n=4, 3%), consistency and standards (n=4, 3%), reversible actions (n=3,

2%), prevent errors (n=3, 2%), good error messages (n=1, 1%) and informative feedback (n=1, 1%).

Table 5: Quantitative results of the Rapid Cognitive Walkthrough and Usability Lab Testing

			PHASE I: Cognitive walkthrough System = 17 issues (74%) Content = 4 issues (17%) Workflow = 2 issues (9%) **Subtotal = 23** (100%) Total=23/164=14%		**PHASE II: Usability lab testing** System = 59 issues (42%) Content = 50 issues (35%) Workflow = 32 issues (23%) **Subtotal =** 141 (100%) Total=141/164=86%	
		Type of User Interface (UI) / **Level of impact on usability**	**Patients' UI** System = 8(61%) Content = 4(31%) Workflow = 1(8%) **Total** = 13 (100%) 13/23 = 57%	**Dentists' UI** System = 9(90%) Content =0 Workflow =1(10%) **Total** = 10 (100%) 10/23 = 43%	**Patients' UI** System = 14(23%) Content = 22(36%) Workflow = 25(41%) **Total** = 61 (100%) 61/141 = 43%	**Dentists' UI** System = 45(56%) Content = 28(35%) Workflow = 7(9%) **Total** = 80(100%) 80/141 = 57%
TYPE of USABILITY ISSUE System + Content + Workflow = 164 (100%)	**SYSTEM** **By impact level:** High= 49(64%) Medium=12(16%) Low = 3 (4%) Out = 12 (16%) **By phase:** Phase I = 22% (17/76) Phase II = 78% (59/54) **By UI - Phase I vs II:** **DDS:** 17% vs 83% (9/54 vs 45/54); I+II=54 (100%) **PT:** 36% vs 64% (8/22 vs 14/22); I+II = 22 (100%) --- **Total = 76 (100%)** **76/164=46%**	High impact	**6 (75%)**	**6 (75%)**	**5 (36%)**	**32 (71%)**
		Medium impact	**1 (13%)**	**2 (22%)**	**1 (7%)**	**8 (18%)**
		Low impact	**1 (13%)**	**1 (11%)**	**1 (7%)**	**0**
		Out of scope	**0**	**0**	**7 (50%)**	**5 (11%)**
	CONTENT **By impact level:** High=26 (48%) Medium=7 (15%) Low=2(4%) Out=19(35%) **By phase:** Phase I = 7% (4/54) Phase II = 93% (50/54) **By UI – Phase I vs II:** **DDS:** 0% vs 100% (0/28 vs 28/28); I+II=28 (100%) **PT:** 15% vs 85% (4/26 vs 22/26); I+II = 26 (100%) --- **Total= 54(100%)** **54/164=33%**	High impact	**3 (75%)**	**0**	**3 (14%)**	**20 (71%)**
		Medium impact	**1 (25%)**	**0**	**2 (9%)**	**4 (14%)**
		Low impact	**0**	**0**	**1 (5%)**	**1 (4%)**
		Out of scope	**0**	**0**	**16 (73%)**	**3 (11%)**
	WORKFLOW **By impact level:** High=18(53%) Medium=1(3%) Low=0 Out=15(44%) **By phase:** Phase I=6% (2/34) Phase II=94% (32/34) **By UI – Phase I vs II:** **DDS:** 12% vs 88% (1/8 vs 7/8); I+II=8 (100%) **PT:** 4% vs 96% (1/26 vs 25/26); I+II = 26 (100%) --- **Total=34(100%)** **34/164=21%**	High impact	**1 (100%)**	**1 (100%)**	**11 (44%)**	**5 (71%)**
		Medium impact	**0**	**0**	**0**	**1 (14%)**
		Low impact	**0**	**0**	**0**	**0**
		Out of scope	**0**	**0**	**14 (56%)**	**1 (14%)**

After identifying all usability issues, the dentists', and patients' user interfaces (UI) were modified into Prototype B. The dentists' major UI modifications included an improved design where the dashboard's features were more user-centered and task-oriented. The changes to

the patients' UI were minor, such as improvements in screen visibility by adjusting contrast between text font and background.

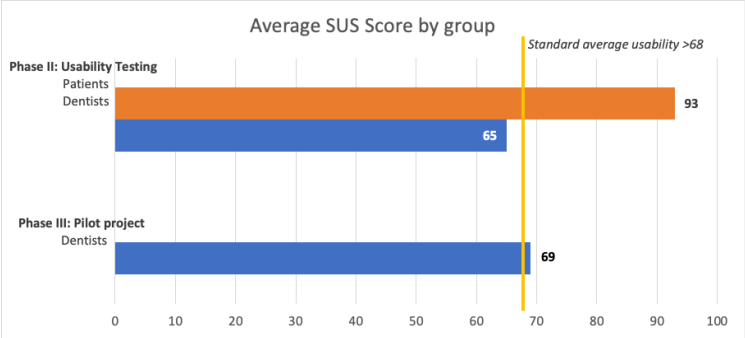
For Phase III of the usability testing, which consisted of three pilot tests, fidelity metrics were summarized. Table 6 outlines the fidelity metrics for both patients and providers. The usability errors identified during the pilot testing of prototype B included 1) undelivered messages due to cellphone carrier and service-related issues, 2) errors in patients' cellphone number data entry, 3) problems in the training of providers, and 4) mHealth platform registration issues

Table 6: Pilot-testing results**:** Fidelity measures outcomes

	Description	Results
Fidelity measures (Patients)	Provided verbal consent and received the Information Sheet	100% of patients completed it (35/35)
	FollowApp.Care Profile was created	100% of patients had a FollowApp.Care profile (35/35)
	Received SMS/Email notifications on Day 0	100% of patients received it (35/35)
	Average Patient Response Time	6 hrs and 12 minutes (SD: 17 hrs. and 55 minutes)
	Number of Patients who have phone service provided by T-Mobile	9% of patients had T-mobile service (3/35)
	Response rate Day 1	54% of patients responded (19/35)
	Response rate Day 3	57% of patients responded (20/35)
	Response rate Day 5	54% of patients responded (19/35)
	Response rate Day 7	57% of patients responded (20/35)
Fidelity measures (Dentists)	Signed consent forms before training	100% of dentists completed it (11/11)
	Completed 1-hr training	100% of dentists completed it (11/11)
	Verified FollowApp.Care Profile	100% of dentists verified their profile (11/11)
	Unique Identifiers provided	100% of dentists had a unique identifier (11/11)
	Number of Log-Ins	Total number of Log-ins: 74
	Number of Successful Log-Ins	71.6% of Log-ins successful (53/74)
	Number of Unsuccessful Log-ins	29.4% of Log-ins unsuccessful (21/74)
	Number of Alerts triggered	60% of messages triggered an alert (9/15)
	Number of Alerts Resolved by chat	44% of alerts were resolved by chat (4/9)
	Number of Alerts Resolved by phone	11% of alerts were resolved by phone (1/9)
	Number of Alerts resolved by Acknowledgement	22% of alerts were resolved by acknowledgement (2/9)
	Number of Alerts Unresolved	No alerts were left unresolved (0/9)
	Average Response Time to Alerts	9 hrs. 58 minutes (SD:6 hrs. 55 minutes)

Figure 5: Average SUS score by group

All participants in Phase II completed the System Usability Scale (SUS) survey. The SUS score among patients during usability testing indicating excellent usability. Providers completed a second SUS survey after pilot testing and marked the mHealth platform as average usability. (Figure 5)



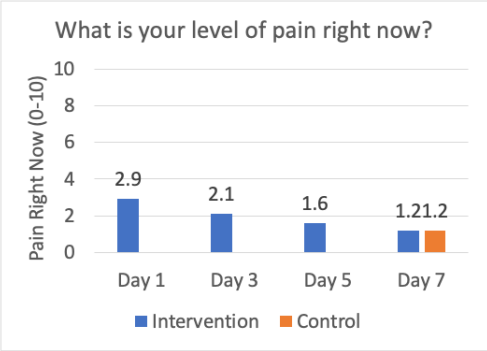
***Patients did not answer the SUS in Phase III as it was not changed from Phase II.**

We conclude that the user-centered and iterative process allowed for the identification of important user interface issues that were addressable, resulting in a practical and feasible mHealth product.

Research question 2: Does the implementation of an mHealth system lead to improved patient oral health outcomes?

Hypothesis 2: There will be a significant difference in the pain intensity as measured by the mHealth questionnaire between intervention and control groups.

Figure 6



There were two key pain questions. 1) "What is your pain level right now?" and 2) "How intense was your pain at its worst following your procedure?". Figure 6 shows the results of patient reported pain over the 7-day period. The mean pain ranged from 2.9 (SD=2.4) on Day 1 post procedure to 1.2 (SD=1.8) on day 7 post procedure. Patients in the intervention group reported an average pain intensity of 4.8 (SD = 2.6) after their procedure while those in the control group reported an average pain level of 4.7 (SD = 2.8). The mixed effects regression model showed no substantial effect of using the mHealth platform on the outcome of measured pain intensity post dental procedure adjusting for provider, gender, and procedure group (β = = -0.03, p-value = 0.9).

Hypothesis 3: There will be a significant difference in pain interference among intervention and control groups.

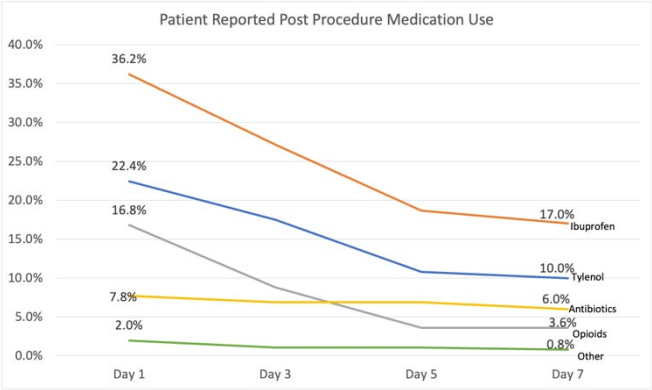
Patients were asked a three-part question detailing how pain interfered with their daily functioning. Table 7 shows that respondents in the intervention group reported slightly higher levels of interference in activities, falling asleep, and staying asleep than the control group. All interference measures were below 2 units on the Likert score. There did not appear to be a substantial effect of using the mHealth platform on the outcome of measured pain interference post dental procedure. In the adjusted, mixed effects model controlling for provider, gender, and procedure group, the effect of the mHealth platform on "Activity" was β = 0.34(95% CI: -0.2, 0.9,

p-value = 0.25, on "falling asleep" β = 0.48(95% CI: -0.16, 1.12), p-value = 0.17, and staying asleep β = 0.37(95% CI: -0.35, 1.09), p-value = 0.33.

Table 7: Pain interference

Status	Total	Activity	Fall Asleep	Stay Asleep
Control	674	0.8 (SD = 1.4)	1.6 (SD = 2.0)	1.4 (SD = 1.8)
Intervention	851	1.0 (SD = 2.2)	1.9 (SD = 2.7)	1.7 (SD = 2.7)

Hypothesis 4: There will be a significant difference in opioid prescribing between intervention and control groups.



In response to the question, "How often have you taken pain medications related to your dental procedure in the last 24 hours?" (0 to 10 times) respondents reported an average of 2 to 3 times over the 7 days. Figure 7 displays the most frequently used patient reported medications.

Figure 7: Patient reported medications

Descriptive statistics were used to determine the distribution of opioids prescribed to the responding patients by the providers. 26.4% of patient in the intervention group were prescribed an opioid while on 16.8% of those in control group were prescribed an opioid. Further, nearly 50% of the prescribed opioids were given by 3 providers. There did not appear to be a limiting effect of using the mHealth platform on the odds of opioids prescribed post dental procedure (OR = 1.17, 95% CI: 0.61, 1.64, p-value = 0.40) after adjusting for gender, procedure group, and provider. (Table 8)

Table 8: Opioid use from patient reports and EHR

	Intervention		Control		Total	
	Mean	SD	Mean	SD	Mean	SD
Avg. No. of CDT Codes per Visit	3.34	2.9	3.64	2.6	3.48	2.77
Avg. No. of Rx per Visit	2.1	1.4	1.7	2.9	1.9	1.3
Opioid Patient Report						
Yes	156	18.3%	44	6.5%	200	13.1%
No	851		674		1525	
Opioid EHR	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Yes	225	26.4%	113	16.8%	338	22.2%
No	851		674		1525	

Hypothesis 5: There will be a significant difference in patient satisfaction among those in the intervention group versus those in the control group.

Most respondents did not report bleeding or swelling but among those who did, bleeding and swelling lessened over time. See Table 9a and 9b.

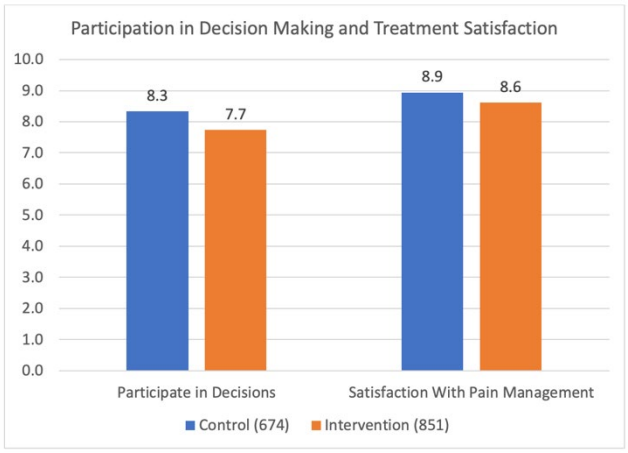
Table 9a: Bleeding as a complication

Day	No Bleeding	Worst	About the same	Better	Unanswered	Completion Rate
1	274	0	21	187	369	56.6%
3	377	3	11	62	398	53.2%
5	--	--	--	--	--	--
7	--	--	--	--	--	--
7 (Control)	234	0	--	28	412	38.9%

Table 9b: Swelling as a complication

Day	No Swelling	Worst	About the same	Better	Unanswered	Completion Rate
1	169	27	99	186	370	56.5%
3	222	14	73	145	397	53.4%
5	221	7	59	113	451	47.0%
7	226	7	41	82	316	53.0%
7 (Control)	146	2	20	94	412	38.9%

Figure 8



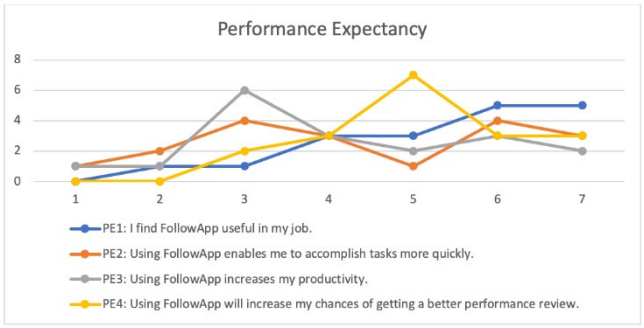
Patients were asked 2 questions to address their satisfaction/dissatisfaction with treatment. In response to the question, "Were you allowed to participate in decisions about your pain treatment as much as you wanted to? (0 to 10)", respondents in the intervention group reported an average of 7.7 (SD = 3.5) out of 10 in participation in decision making while those in the control group reported an average of 8.3 (SD = 3.0). When asked, "Select the one number that best shows how satisfied you are with the results of your pain treatment", respondents in the intervention group reported average of 8.6 (SD = 2.2) out of 10, while those in the control group reported 8.9 (SD = 2.0). See Figure 8. There did not appear to be a substantial effect of using the mHealth platform on the outcome of patient satisfaction on pain management post dental procedure. In the adjusted, mixed effects model controlling for provider, gender, and procedure group, the effect of the mHealth platform on "participation in decisions" was β = -0.36(95% CI: -1.13, 0.4), p-value = 0.37 and on "satisfaction with pain management" β = -0.01(95% CI: -0.53, 0.53), p-value = 0.98.

Research question 3: Is the intention to use the FollowApp.Care platform in practice associated with its perceived usefulness and ease of use among dental providers?

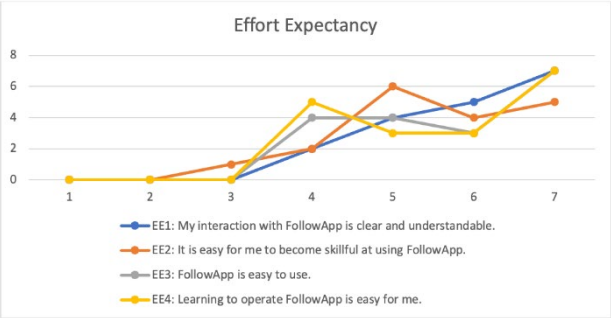
Hypotheses 6: The intention to use mHealth technology is closely associated with perceived usefulness and ease of use among dental providers.

The validated UTAUT questionnaire was administered to 18 intervention providers. The four key constructs are associated with a behavioral intention to use the FollowApp.Care application; high scores on each of the constructs are associated with a higher behavioral intention to use the FollowApp.Care platform.

Performance expectancy - "the degree to which an individual believes that using the system will help him or her to attain gains in job performance".[48] The responses to the four items that form the performance expectancy construct showed that most providers found FollowApp.Care useful, enabling them to perform tasks more quickly, increasing productivity, and increasing the chances of a positive performance review. Median scores for each item were greater than or equal to 4 on the 7-point Likert scale.



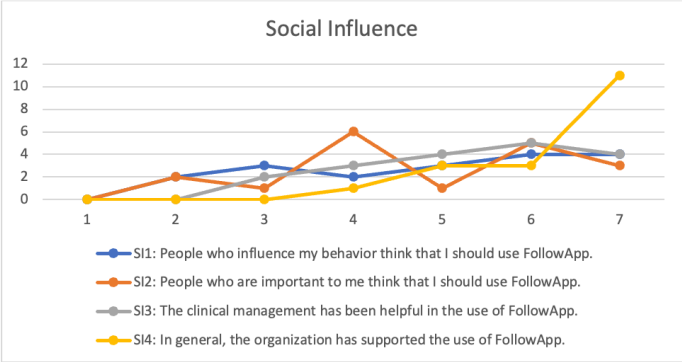
Questionnaire Item	Median	Mean	SD
PE1: I find FollowApp useful in my job.	6.0	5.4	1.5
PE2: Using FollowApp enables me to accomplish tasks more quickly.	4.0	4.4	1.9
PE3: Using FollowApp increases my productivity.	4.0	4.2	1.7
PE4: Using FollowApp will increase my chances of getting a better performance review.	5.0	5.1	1.2



Effort expectancy - "the degree of ease associated with the use of the system".[48] The responses to the four items that form the effort expectancy construct showed that most providers found that FollowApp.Care is clear and understandable, believing that they can become skillful, and that the platform is easy to use and operate. Median scores for each item were greater than or equal to 5 on the 7-point Likert scale.

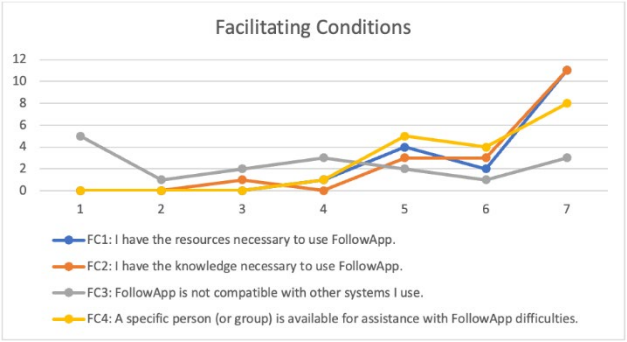
Questionnaire Item	Median	Mean	SD
EE1: My interaction with FollowApp is clear and understandable.	6.0	5.9	1.1
EE2: It is easy for me to become skillful at using FollowApp.	5.5	5.5	1.2
EE3: FollowApp is easy to use.	6.0	5.7	1.2
EE4: Learning to operate FollowApp is easy for me.	6.0	5.6	1.3

Social influence - "the degree to which an individual perceives that it is important others believe that they should use the new system".[48] The responses to the four items that form the social influence construct showed that most providers found that those who influence their behavior, people who are important to them, and their clinical management as well as the organization in general thought that they should use the platform. Median scores for each item were greater than or equal to 5 on the 7-point Likert scale.



Questionnaire Item	Median	Mean	SD
SI1: People who influence my behavior think that I should use FollowApp.	5.0	4.9	1.7
SI2: People who are important to me think that I should use FollowApp.	4.5	4.8	1.6
SI3: The clinical management has been helpful in the use of FollowApp.	5.5	5.3	1.3
SI4: In general, the organization has supported the use of FollowApp.	7.0	6.3	1.0

Facilitating or enabling conditions - "the degree to which an individual believes that an organizational and technical infrastructure exists to support use of the system".[48] The responses to the four items that form the facilitating conditions construct show that most providers found that they have the necessary resources and knowledge to use FollowApp.Care, that it is generally compatible with other systems that they use, and that there is assistance for its operation. Median scores for each item were greater than or equal to 4 on the 7-point Likert scale.



Questionnaire Item	Median	Mean	SD
FC1: I have the resources necessary to use FollowApp.	7.0	6.3	1.0
FC2: I have the knowledge necessary to use FollowApp.	7.0	6.3	1.1
FC3: FollowApp is not compatible with other systems I use.	4.0	3.6	2.3
FC4: A specific person (or group) is available for assistance with FollowApp difficulties.	5.5	6.1	1.0

In total, 25 providers were interviewed. Almost all providers had no expectations when joining the study.

The majority of the providers received no patient messages or alerts via FollowApp.Care and as a result had no interaction with patients on the platform. In the few instances of an alert, due to high pain, the patients would in general add a comment, which made it easy for the provider to respond using the platform, making the workflow easy and fast.

The positive feedback received included themes like improving patient provider relationship and helping track pain levels and reduce opioid prescribing. The providers found the platform to be a useful tool to respond to patient queries in a timely manner and reassure patients that they care for them postoperatively, thereby improving patient dentist relationships. Providers liked how the platform helped them reduce unnecessary post operative appointments and not get interrupted by a patient's call during a procedure, as patients would text their questions on FollowApp.Care. Some providers mentioned how FollowApp.Care would help them reduce unnecessary pain medication prescribing and especially opioid prescribing. The majority of providers found the mHealth patient survey helpful, straightforward, and short, with relevant questions.

The negative feedback received from the providers included themes like extra burden on the clinic workflow/workforce and lack of patient acceptance. Providers felt that there was a lack of patient acceptance due to frequent surveys, privacy concerns and age. Many providers stated that older patients were more reluctant to join this study owing to privacy concerns, preference to call over texting, limited technological literacy, and lack of personal touch when using the platform. Providers stated that the platform did not interface well on their mobile device, was not seamless and had a tedious login process which slowed down the clinic workflow. FollowApp.Care was mentioned as an extra step for the WDG providers, however providers mentioned that their patients were happy to have this tool to connect and text their questions to their dentists post operatively.

When asked about adding any features to the platform, providers stated that they would like to have an option for the patients to add pictures which would help providers view intra-oral issues and reduce post operative appointments. They would like the interface to be a more desktop friendly or mobile friendly applications. They also mentioned about adding features around requesting prescription refills.

Overall, providers were pleased with the platform and would like to continue using it.

Limitations

The majority of patients had low pains scores. We were not able to enroll periodontal providers and as such were not able to include an important group of painful procedures (flap surgery).

Discussion

In most of the WDG clinics, the front desk staff was involved in monitoring the FollowApp.Care for alerts and informing the provider about the alerts which greatly helped resolve workflow issues.

This study was a first attempt to measure patient reported outcomes (PROs) in the dental setting. The overall results, as measured by pain intensity, pain interference and patient satisfaction with pain management after painful dental procedures did not appear to show a substantial impact using a text messaging platform. This is not surprising as the average pain level was low.

This study targeted various types of dental procedures of which only the oral surgical procedures triggered the need for opioid medication. In fact, of the 327 patients receiving opioids, 92.6% underwent an extraction. The remaining 7.3% received a root canal treatment, of which more than half a pulpal debridement (initial treatment of a “hot tooth”). As such, a more targeted intervention, focusing on just oral surgical and periodontal patients needing surgery (e.g., flaps) might have produced more patients with higher pain scores.

Additionally, the majority of the data were generated through the Willamette Dental Group (WDG) practices, and WDG, as an accountable care organization (ACO) type dental group, already had a superb process in place of post-operative patient care management that included 24-hour dentists on-call, who are available by phone after hours for all questions and emergencies between 5PM and 8 AM. As such patient already felt adequately involved with post operative care decisions.

The dental provider focus-groups indicated a clear benefit of improved patient-dentist relationship and communication, especially among their patient population comfortable using technology. As such we conclude that using PROs in the form of mHealth technology does pose benefits, mostly for surgical patients and especially for dental patients who do not have access to immediate after-hours care from their dental clinic.

We noted that some patients using the text messaging platform received more opioid medications than patients not using the platform. This was driven in half of the cases by three providers. Here the use of ongoing monitoring of data analysis will allow for specific training and targeted improvement. As such, the mHealth technology has proven a helpful tool.

The multi-phase iterative usability evaluation highlighted the importance of formally assessing usability of the mHealth platform and we discovered challenges in the use of the patient and dentist user interfaces, the understanding of the pain-related content questionnaires (based on the PROMIS [2] and APS-POQ-R[4] questionnaires), and disruptions in the workflow of clinical practice. The study confirmed the benefits of using different methods for determining usability so that investigators and developers can rapidly capture critical issues a user may find while interacting with the mHealth platform. Patients and dentists faced different types of issues, and multiple iterations of the mHealth platform prototype testing allowed for prompt identification of issues at various stages of the project.

Provider acceptance was initially just at a C grade level when normalizing the SUS questionnaire score. SUS measures not only perceived ease of use, but also provides a global measure of system satisfaction and sub-scales of usability and learnability.[53] The UTAUT questionnaire administered after the study showed that our users were able to accept the new

technologies and had a greater than average ability to deal with it. The focus group interviews further confirmed this. We concluded that FollowApp.Care platform was well accepted by the dental provider users. We already knew that patients really liked the user interface of the platform and provider interviews further confirmed that patients liked using the platform. This is important as this is the first such approach, as far as we know, to collect PROs in the dental setting.

Conclusion

This multicenter, phase 2 clinical trial recruited dentists and dental patients exploring a mHealth platform to measure patient reported outcomes (PROs) for pain management after certain dental procedures. The study showed that multi-phase iterative usability evaluation allowed for prompt identification of issues, leading to good acceptance of the mHealth technology by dental providers and patients. As average pain levels were low, using the text messaging platform did not have a significant impact on the oral health of the patients as measured by pain intensity, pain interference and patient satisfaction with pain management after painful dental procedures. Patients and providers indicated increased improvements in patient-provider communication, patient-provider relationship, post-operative complication management, and ability to manage pain medication prescribing.

List of Publications and Products

1. Ibarra Noriega, A.M., Yansane, A., Mullins, J., Simmons, K., Holmes, D., White, J., Kalenderian, K.*; Walji, M.F.* Evaluating and Improving the Usability of a mHealth Platform to Assess Post-Operative Dental Pain. J Am Med Inform Assoc. *Submitted.*
2. Herzog CM, White J, Yansane AI, Walji MF, Kalenderian E, Holmes D. Neighboring Tooth Pain. JDR Clin Trans Res. *In preparation*.
3. Yansane, A.I., Tokede, O., Mehta, U., Ibarra, A., Mullins J., Skourtes N., Brandon R., White J., Holmes D., Walji M.F.*, Kalenderian E*. Optimizing Acute Post-Operative Dental Pain Management Using New Health Information Technology. *In preparation*

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