Project title: Patient-Centered Postoperative Wound Surveillance Using Current Technology

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A.   STRUCTURED ABSTRACT

Purpose: To design and test an Outpatient Wound Surveillance Program using smartphones for older adults having vascular surgery.

Scope: We develop a smartphone app for early detection of postoperative infection and other complications for use in the first 2 weeks after hospital discharge.

Methods: We first validated the use of images for wound evaluation by calculating agreement coefficients. We then developed an app and tested its usability with nine postoperative inpatients on the vascular surgical service. Following app redesign, we recruited 40 postoperative inpatients to use the app at home. On the day of discharge, participants underwent training. Following discharge, they were asked to complete the app and transmit data daily for 14 days. Primary endpoints of the trial were participant adherence to and satisfaction with the protocol. Secondary outcomes included infection detection and readmission.

Results: Digital images provide sufficient information to make first-line treatment decisions. In usability testing, 81.8% of images were sufficient for diagnosis. User satisfaction was high, with an average usability score of 83.3 out of 100. During the trial, training participants to use the app required an average of 16.9 minutes. There were a total of 8 infections in the patient cohort, 7 of which were detected using our app. There were no false positives. There was one false negative in a patient with infection detected at an early follow-up visit. Vascular surgery patients and caregivers are able to complete the protocol with high fidelity and satisfaction.

Key words: smartphone, surgical site infection, transitional care, telehealth

B.   PURPOSE

AIM 1: Determine whether health care providers/surgeons can differentiate between infected or complicated wounds and normally healing wounds using a Smartphone digital photograph. Using Smartphone technology, we photographed normal and infected/complicated post-operative wounds. Using a standardized evaluation adapted from the CDC, we measured agreement between gold standard in-person assessment of wounds versus photo-based assessment with regard to 1) presence of infection or complication, 2) infection or complication stage, and 3) recommended clinical care.

AIM 2: Design and evaluate the three major components of a patient centered Outpatient Wound Surveillance Program (OWSP): A) Application (App) Design for a Web-based Smartphone, B) Training Module Design for patients or caregivers to photograph and transmit Smartphone images of their postoperative wounds, and C) Create methodology for assimilation and review of data by a surgical service. With collaborators that include IT experts, a photographer, and an app design team, we designed a patient-centered web module the enables patients to transmit wound photos and symptom information to the vascular service. Images were uploaded to a secure server in the Department of Surgery, permitting side-by-side review of chronological images with linkage to the medical record. In collaboration with geriatricians and community/patient research advisors, we also designed a patient-centered protocol to teach patients or caregivers to take and transmit photos of their wound using Smartphones. We utilized print and picture based teaching materials, "teach-back" by the patients, and pre-discharge reinforcement with a test photo transmission.

AIM 3: We combined the three components and pilot tested the full patient centered outpatient wound surveillance program. With a targeted enrollment of 40 patients, outcomes included evaluation of the module's technological capability, including (1) barriers to participation, (2) patient attrition/adherence, (3) picture and information quality, (4) successful information transmission and review, and (5) the ability of health care professionals to identify early wound infection from photographs.

C.   SCOPE

Surgical site infection (SSI) is the most common nosocomial infection in surgical patients and accounts for 38% of post-operative complications.[1,2] SSI results in physical and emotional stress for a significant number of patients and their families and can lead to readmission, reoperation, limb loss, or death.[3,4] It also produces increased health care costs and is the leading cause of unplanned, potentially preventable hospital

readmissions for surgical patients.[1,3,5,6] In a recent review of the surgical literature on early readmissions, wound infections and surgical site complications were the most common readmitting diagnoses for patients recovering from surgery.[5] These infections and resulting treatment are costly and, more importantly, stressful and inconvenient for patients and their families.

Importantly, readmissions for SSI are potentially preventable. If diagnosed at an early stage, SSI can be treated in the outpatient setting with oral antibiotics and wound care, precluding the need for readmission, intravenous antibiotics, and reintervention. Extant research documents increased mortality for late versus early stage SSI.[1] Nevertheless, patients rarely recognize early stage wound infections and often present with an advanced infection that requires intensive treatment and rehospitalization.[8,9] Although interventions have been designed and employed to prevent SSI (versus early diagnosis which is the goal of this strategy), wound infections remain a frequent occurrence. The focus of these interventions has been on the surgical procedure itself employing appropriate antibiotics and periprocedural wound care.[1,10] Despite these efforts, wound infection remains a frequent occurrence. Importantly, the majority of wound infections (up to 84%) develop in the critical interval following hospital discharge but prior to routine follow-up.[1] The fact that SSI develops or progresses in the outpatient setting makes transitional care coordination an important focus in the management of SSI.

Transitional care coordination following surgical procedures has received little attention from researchers and hospital systems relative to transitional care following hospitalization for medically managed conditions.[11,12] Moreover, care processes surrounding surgical procedures differ from those involving medical inpatient stays in the following ways: (1) surgery is most often elective, permitting preoperative planning for transitional care and complication surveillance, and (2) the surgery itself introduces additional risk factors for complication, including the surgical incision.[11] Patient-centered interventions to improve transitional care for surgical patients are absent from the literature and routine practice but have the potential to stem the burden of SSI and readmissions in this complex patient population. Moreover, hospitals are increasingly incentivized to improve transitional care for surgical patients as the Center for Medicare and Medicaid Services (CMS) increasingly imposes financial penalties for unplanned readmissions after surgery.[13]

We employ the Coleman Model as our theoretical framework.[14,15] The Coleman Model, operationalized as the Care Transitions Intervention, is specifically designed to reduce discontinuity in care transitions and addresses the needs of elderly patients and patients with complex, chronic conditions.[16] Moreover, it focuses on patients and caregivers as the "common thread linking differing providers and settings," emphasizing patient education and empowerment as the essential components for managing care transitions.[14,15] Using a Transition Coach, such as a nurse care manager, the intervention focuses on (1) medication self-management, (2) use of a dynamic patient-centered record, (3) follow-up care, and (4) knowledge of red flags. We adapt this validated model for post-operative monitoring of SSI using smartphones.

We focus on vascular surgery because this population has the highest readmission rate among surgical specialties; almost a quarter of patients are readmitted within 30 days of a vascular surgery (24.3%).[17] Moreover, as the U.S. population ages, vascular surgery has the highest projected demand growth among medical specialties (31% by 2025) after adjusting for expanded coverage under the Patient Protection and Affordable Care Act.[18] The majority of readmissions in this population are for treatment of SSI.[4,5] Patients undergoing lower extremity revascularization procedures and amputations are particularly susceptible to infection and readmission.[4,19,20] These patients experience an overall high rate of post-operative complications owing to their high level of comorbidity. Patients with vascular disease who undergo intervention have poor circulation and are often older adults who are obese, smokers, or have diabetes. Each of these comorbidities uniquely predisposes vascular patients to develop SSI.[1] Consequently, the large volume of patients undergoing vascular procedures represents a fertile target for an intervention to reduce SSI and early readmission after surgery. Demonstrated efficacy in the highest-risk, elderly vascular population would justify generalization of this intervention to all other areas of surgery.

Evaluations of personal digital assistant (PDA) and touch-based technological interfaces for older adults have produced very encouraging results.[21] A study evaluating a touch-based user interface for elderly users found that the interface is natural and intuitive, reducing the cognitive load of using a new technology, and, importantly, that impaired motor functioning does not impede use.[22] Additional research has demonstrated the feasibility and validity of measuring cognitive functioning in older adults using a smartphone.[23] Studies of telemedicine applications in geriatric populations have shown that a majority of patients can use these interfaces without assistance (similar to younger adults with a small time delay), and telemedicine can improve patient satisfaction among older adults.[24-26] Moreover, a majority of older adults who do not have previous experience with mobile health applications are willing to try to the devices.

D. METHODS

Aim 1

Development of the checklist. The investigators drafted a preliminary version of the wound evaluation checklist using an iterative process modeled after that used for the World Health Organization Surgical Safety Checklist.[27] We used previously described wound infection diagnostic criteria defined by the Centers for Disease Control and Prevention and measures compiled by Cutting and colleagues.[28-30] The checklist is composed of two sections: wound characteristics and treatment recommendations. Expert feedback informed revisions, ensuring that the final checklist encompassed the full scope of wound assessment and treatment.

Subjects. Eligible patients were aged 18 years and older and had a vascular surgery procedure involving an incision of at least 3 cm between May 2014 and February 2015. The level of analysis was the wound, such that for the small number of patients with multiple wounds (e.g., leg bypass graft using arm vein), each wound was included separately. We recruited vascular surgery attending surgeons, surgical residents, physician assistants, nurse practitioners, and registered nurses to evaluate postoperative wounds. In-person and remote wound evaluation protocol. Using the finalized checklist, between one and four providers examined in-person 80 postoperative wounds. A nonclinical researcher concurrently captured digital images of patients' wounds without flash. After in-person evaluations, nine health care professionals used digital images to examine all 80 postoperative wounds (also using the finalized checklist). We presented each evaluator with an image or series of images for the wound on a computer screen. For each wound, each evaluator saw the same set of images as the other evaluators did. Each wound had a total of one to four total images, depending on the size of the wound (e.g., a single image for a carotid incision; three or four images for a lower extremity bypass). All evaluators evaluated the wound assuming the patient was discharged home in the last 1 to 2 weeks.

Image capture protocol. We captured the incision only with a white centimeter ruler in the frame for measurement and assessment of lighting. We held the camera 6 to 18 inches away from the incision; the overhead examination light was on, rendering all images comparable in terms of environmental lighting. Photographers were instructed to "fill the frame" with the wound; to angle the camera to be in line with the incision; and to take three images of large wounds, such as lower extremity bypass and thoracoabdominal incisions. The images were uploaded to a secure server using a hardline connection to avoid the problem of Health Insurance Portability and Accountability Act compliance in wirelessly transmitting the images.

Photographic quality assessment. A professional photographer judged image quality on a scale of 0 to 3 along the following dimensions: clarity/focus, lighting, scope, and color quality.[31-32] Based on the image quality, photographs were categorized into two categories, (1) high quality and (2) suboptimal. We used Spearman correlation to evaluate associations between the components of wound image quality.[33] All correlations were high and significant, varying from 0.35 for scope and clarity/focus to 0.89 for light and color. As a result, we summed the ratings for each image to create a composite image quality score ranging from 0 to 8; the distribution of scores was skewed left, indicating that photographs were largely of high quality. We thus designated an image as being of high quality vs suboptimal if it had a summary score of 7 or 8.

Statistical analysis. Considering in-person wound evaluation as the standard of care, our analysis plan proceeded in three phases. First, we established the standard of care for in-person wound characteristics; we examined the percentage of wounds with an abnormality according to in-person assessment and the associated inter-rater agreement. This analysis established a baseline for the frequency and variability in clinical assessment, serving as a reference point for image-based assessment. We then evaluated frequency and inter-rater agreement for image-based assessment of wound characteristics. This analysis determined whether agreement between image-based evaluations differs from in-person agreement. Second, we conducted a similar program of in-person evaluation followed by image-based wound treatment recommendations. Third, we explicitly analyzed agreement between in-person and image-based wound evaluations and treatment recommendations. Specifically, we computed sensitivity and specificity for each image-based wound characteristic and treatment recommendation, treating in-person assessment as the "gold

standard." We then calculated between-modality interrater agreement. This analysis determined whether detecting an abnormality or recommending treatment varies on the basis of the modality of assessment.

We quantified inter-rater agreement and reliability as follows. For each wound that had at least two raters, we formed all possible rating pairs and took the proportion of those pairs that agreed on each characteristic. The observed agreement is calculated as average proportion of agreement for all wounds. We measured inter-rater reliability for the checklist wound assessment and treatment plan using Gwet agreement coefficient (AC). Gwet AC is a statistical measure of inter-rater agreement for qualitative and categorical items when there are two or more raters; for the same two raters, the observed agreement in the more familiar Cohen k is equal to that in Gwet AC.[34] Extending to the setting with multiple different raters per wound, we chose Gwet AC over the more commonly used suite of k statistics to overcome the k paradox[35] wherein agreement appears low owing to overcorrection for chance agreement, and to address our data structure, which involved distinct, multiple raters for each arm (in-person and image-based evaluation). AC values are interpreted as follows: In addition, to compare image-based evaluation with in-person standard of care, we present the sensitivity and specificity of the image-based evaluation using the aforementioned in-person consensus as the gold standard. To assess agreement between the in-person and image-based evaluations, we reshaped the data such that for each wound, every response for a given question from an in-person rater was paired with every response from a remote rater for the same question. This was done for all survey items. Observed agreement and Gwet AC were calculated using this inperson vs remote paired data set. We used 1000 bootstrap samples with replacement to calculate 95% confidence interval of Gwet AC for in-person vs remote raters.

Aim 2

Subjects

Eligible participants included inpatients 18 years of age or older on the vascular or general surgery service of a large, academic tertiary care hospital. Subjects were recruited during one of two usability sessions in November and December 2015. Participants were eligible if they had a surgical incision longer than 3 cm and were close to their baseline functional status. Subjects with major cognitive or neurologic deficits prohibiting their independent use of the app were included only if they had a capable caregiver who consented to complete the app on their behalf. All subjects who met inclusion criteria were approached to participate. Participants were asked regarding their prior experience with smartphones, whether they owned their own smartphone, and whether they had used a smartphone to take a digital image. We aimed for a sample size of at least 5 participants, a number based on evidence from the usability literature indicating that 5 participants make a sufficient sample size to detect 80-85% of an interface's usability problems.[36,37] We continued to enroll purposively past our sample size goal to utilize the remaining time.

The App

WoundCheck is an iOS app that enables patients to capture digital images of surgical wounds and sends them to their providers from home, along with brief updates on postoperative recovery. This app was developed internally through the University of Wisconsin Department of Surgery with the assistance of software programmers in our Information Technology division. In designing the app, we consulted ISO 9241-12, an international standard for screen layout and the visual display of complex information, and established guidelines on user interface design to ensure that the user interface was easily navigated by our target population of older adults and novice users.[38,39] The app is accompanied by a training program to be delivered prior to discharge that draws on evidence-based tenets of adult learning and memory retention, in keeping with similar transitional care programs targeting older adults.[40-42] Among these tenets is the need for adult learners to feel actively engaged in the learning process, to frequently receive positive reinforcement, and to set the pace of learning. We allowed ample time for questions and for participants to interject comments. We also allowed participants to use the smartphone and the app directly after a short demonstration, engaging visual, auditory, and kinetic forms of learning. Adult learners also require repeated exposure to new material and to have it presented in a variety of formats. Each participant received a training booklet that reinforced the steps of the app for reference if questions arose after discharge.

The program is ultimately designed for use during the period between hospital discharge and the routine postoperative clinic visit. The app was designed to be linear with one pathway through the app to maintain simplicity and intuitiveness. There are 2 phases to the app: an image-taking phase where participants take digital images of their wound and have the ability to review or retake their images, and a brief survey with yes or no questions regarding their recovery. Screenshots of the app are provided in Figure 1, and survey questions are provided below.
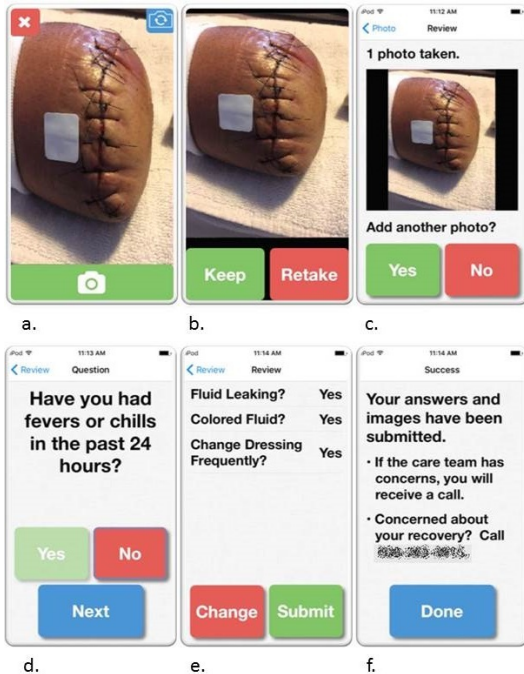

Figure 1

Screenshots of the final app. A. Modified camera screen. B. Image review screen where participants can choose whether to keep the image they have taken or try again. C. Review screen of all added images; up to 4 images may be added. D. A series of yes or no questions follow. E. Participants can review their survey responses and have the option to change them prior to submission. F. Submission confirmation screen.

Questions included in the survey portion of the WoundCheck app.

1. Have you have fevers or chills in the past 24 hours?

2. Have you changed how you take your medication in the last 24 hours?

   2a. (If responded yes to 2) Is this change related to your pain medication?

   2b. (If responded yes to 2a) Did you increase your pain medicine?

3. Has the area around your wound become red in the past 24 hours?

4. Has the area around your wound become swollen in the past 24 hours?

5. Is there a bad smell coming from your wound?

6. Is fluid leaking from your wound?

   6a. (If responded yes to 6) Is the fluid white, yellow, or green?

   6b. (If responded yes to 6) Do you change the dressing more than once because fluid soaks through?

To vet the content of the app and training and meet the burden of the ISO design standard, we conducted 2 focus groups to review the app with Community Advisors on Research Design and Strategies (CARDS). These are standing focus groups of community members from diverse racial, ethnic, socioeconomic, and educational

backgrounds who are recruited from food pantries, senior meals, parenting programs, and other similar programs. They are trained to give constructive feedback to researchers, health educators, and outreach professionals. The CARDS members, the majority of whom are novice smartphone users, evaluated prototype screens of the app and all app language in the first focus group. The image capture training protocol was evaluated in the second focus group.

Health Insurance Portability and Accountability Act Compliance

The app and transmission of patient data were developed to fully comply with the Health Insurance Portability and Accountability Act. A passcode is used to secure and encrypt the device. Each device is profiled, allowing us to remotely wipe the device, prevent the installation of additional apps, and limit other device features. No information is stored on the mobile phone itself; the app can only be used to submit information, not retrieve it. The app transmits data to the University of Wisconsin Department of Surgery research server using the Hypertext Transfer Protocol Secure (HTTPS). A unique nonmedical record number identifier is used for each participant. No identifying information is transmitted, and participants were instructed not to send pictures that included identifying marks or their face. If the participant is idle for more than 10 minutes during data collection, the app times out and the data is deleted. Only research personnel with responsibility to review images have access to the submitted images. The system automatically logs off users after 30 minutes of inactivity. Audit controls monitor access.

User Tasks

Following preliminary design, we formally tested the usability of the app with postoperative vascular and general surgery patients at a major academic medical center. The app was loaded onto a 5th generation iPod Touch running iOS8. We assessed patients' baseline familiarity with smartphones prior to testing. A researcher introduced the device to participants with an overview of its general functions and how to operate it, if needed. User tasks included waking up the device, launching the app, image capture, review and retake or acceptance of captured images, question response, and submission. Following the first round of usability testing, an interim assessment of the app was performed and adjustments were made based upon the findings of the first round. The updated version of the app was then used for the second round of testing.

Measures and Analysis

We consulted ISO 9241-11 in designing the format for formal usability testing of the app.[36] Effectiveness (ie, the ability to successfully complete each task independently and whether assistance was required) and efficiency (ie, the time needed to complete each task) were measured by direct observation and by mirroring of the device onto a research computer using the software AirServer (App Dynamic). The mirrored screen on the laptop was recorded using Morae (TechSmith) screen recording software. Training sessions were audio recorded for later review.

Following usability testing of the app, participants were asked to rate their performance and to provide feedback on the app itself. Participants also completed a system usability scale (SUS) to evaluate their satisfaction with the app.[42,43] Images generated during the testing sessions were independently reviewed by 3 physicians to assess whether they could be used for diagnostic and treatment purposes. If a reviewer deemed an image as not usable, they were asked to provide a reason.

Aim 3

Subjects

We recruited English-speaking inpatients 18 years of age or older on the vascular surgery service at a large, academic tertiary care hospital between June 8, 2016 and November 15, 2016. Eligible patients had a surgical incision longer than 3 cm and no identifying marks (e.g., tattoos) in the area of the incision. Patients with major cognitive or neurologic deficits that prohibited their independent participation were eligible if they had a caregiver to serve as their proxy. In order to complete enrollment and protocol training, patients needed to be in the hospital for at least two days after giving consent. This excluded most patients who underwent carotid surgery, as these patients typically leave the day after surgery at our institution. Subjects who met inclusion criteria were consecutively approached to participate. We recorded stated reasons for declining participation.

Patients who consented to participate provided information regarding their prior smartphone familiarity, including whether they owned a smartphone and whether they had ever used a smartphone to take a picture.

The University of Wisconsin Health Sciences Institutional Review Board approved the study protocol. The full protocol has been published previously[44].

Intervention

WoundCheck is a HIPAA-compliant, internally-developed, and user-tested iOS application (app) that enables patients to transmit daily surgical wound images and symptom information from their home or post-acute care facility to a clinician involved with the inpatient vascular surgery service, either a nurse practitioner or a physician member of the research team[45]. There are two phases of the app: an image-taking phase in which participants take up to four digital images of their surgical wound, and a brief survey of yes/no questions regarding recovery, with particular attention paid to the surgical wound. Survey questions were developed based on prior work from our group validating smartphone digital images for postoperative wound monitoring and were designed to capture information not as easily appreciated from images, such as drainage and odor [46]. Submission of data happens automatically upon app completion.

During the post-operative inpatient stay, participants underwent tailored training to learn to use the WoundCheck app. Novice smartphone users received additional dedicated training to become comfortable navigating the iPhone. We measured in minutes the amount of time required to complete training. Following training, participants or their caregiver completed the System Usability Scale, a validated scale to measure the ease of use for technology platforms, to evaluate their comfort with the app. At the completion of training, participants received an iPhone 5S, as well as an accompanying visual reference guide for participants who needed additional reminders about how to use the phone and app. Each device cost $0.99 with an associated data plan of $41.56/month. Reference guides cost $9 per participant, bringing the total material cost per participant to $51.55.

On the day of discharge, participants underwent a reminder training session, during which they completed the app to provide baseline information. Following discharge, they were asked to complete the app and transmit data daily for 14 days. Research personnel called participants at the following time points: if they missed a day of submission; if their images were insufficient for review; at 6 days following discharge to provide technical support, answer any questions, and ensure continued consent; and at the completion of the protocol to obtain final feedback and complete an exit survey.

Each afternoon, a clinician on the inpatient vascular surgery service (a nurse practitioner or a physician member of the research team) reviewed submitted images and survey responses and filled out a validated checklist documenting the appearance of the surgical wound, using an internally developed review interface [46]. Nurse practitioners were chosen for this role because they were familiar with participants during their inpatient stay prior to discharge and were determined to be best able to provide continuity of care. If the nurse practitioner detected concerning findings on image review or in survey responses, they called the participant to obtain further information and make recommendations for additional care as indicated, which could include returning to the clinic or hospital. If nurse practitioners were unable to review submissions due to time constraints, a physician member of the research team reviewed submissions the following morning.

Measures

The primary endpoints of this pilot trial were participant adherence to and satisfaction with the protocol and the burden of the protocol on clinician workflow. Measures of participant adherence included the percent of participants who submitted data daily without requiring a reminder phone call, and the number of days missed among participants who missed at least one day of submission. Participant satisfaction was measured via semi-structured interviews at study completion with all participants. The burden to clinician workflow was measured by the amount of time required to review images. Additionally, semi-structured interviews with each NP evaluated provider buy-in and satisfaction.

Secondary outcomes included surgical site infection (SSI) detection and hospital readmission. SSI detected by the protocol, the post-discharge day of detection, and the clinical response were recorded. SSI not detected by the protocol were also tracked. Patient self-report during the exit survey as well as chart review from our institution provided information regarding hospital readmission. A surgeon member of the research team

performed manual abstraction of data from the medical record to collect wound complications and hospital readmissions. Participants were followed for the 30 days after hospital discharge from their index admission.

The study was registered at clinicaltrials.gov on April 1, 2016 (NCT02735525).

Limitations

We were unable to achieve integration into our PACS system despite multiple efforts with information technology and legal personnel at UW Health. As a result, we programmed a provider interface and housed the images on a secure server within the Department of Surgery. Although the results of the pilot trial were very promising, this limitation significantly hinders the likelihood of dissemination. Moreover, we had very little racial diversity in the enrolled trial participants. Although the racial composition of the sample reflects the demographics of our patient population, we cannot discern whether our app is effective for black and other dark-skinned patients.

E. RESULTS

Aim 1: We finalized the wound evaluation with multiple focus groups of surgical providers, biostatisticians, and health services researchers. We obtained multiple, in-person evaluations for 80 wounds, 40% of which were normal. Results are published in the Journal of Vascular Surgery: Venous and Lymphatic Disorders Volume 4, Issue 3, p 320-8. Results and Discussion are excerpted below and summarize our findings.
Results: The majority of in-person ratings were provided by vascular midlevel providers (n = 82), followed by surgery residents (n = 68), attending vascular surgeons (n = 21), and registered nurses (n = 9). For remote evaluations, the majority were performed by vascular midlevel providers (n = 240). Eighty in-person wounds were evaluated, with a median of two to three raters per wound. For remote evaluations, nine providers rated every wound. The majority of wounds were found in the lower extremity (n = 23), followed by groin incisions (n = 20), thoracic/abdominal wounds (n = 18), carotid neck incisions (n = 10), upper extremity wounds (n = 5), major amputation stumps (n = 3), and one toe amputation.

The Figure 2 shows agreement (AC) among in-person raters relative to image-based and between-modality agreement, permitting comparison across evaluation modalities. For redness, image-based and between-modality agreement was slightly lower than standard of care agreement but within the 95% confidence interval. Agreement for the presence of a drain, dehiscence, and necrosis was universally high with tighter confidence intervals; this was true regardless of the modality of evaluation. Overall, agreement for treatment was universally high regardless of evaluation modality.
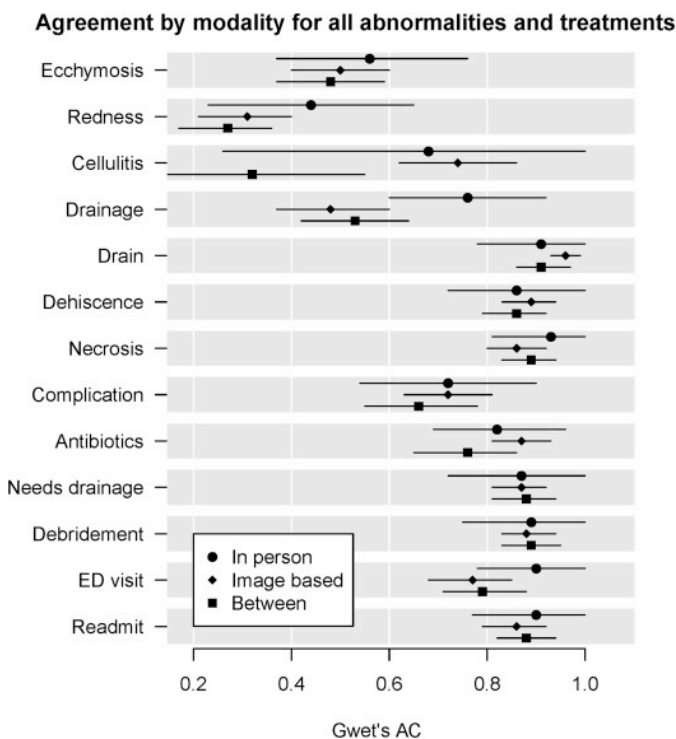

Agreement by modality for all abnormalities and treatments

Fig. 2
The shape represents the value for Gwet agreement coefficient (*AC*); the *error bar* represents the bootstrapped 95% confidence interval for the AC. *ED,* Emergency department.

Figure options

Conclusion Digital images provide sufficient information to make meaningful, first-line treatment decisions. We also anticipate that tracking a wound over time will increase the detection of abnormalities that a single static image did not provide. Supplementary survey questions to accompany the image will provide important information that cannot be ascertained from an image, such as fever, pain, and wound drainage, which was the characteristic that remote raters had the most difficulty accurately detecting.

Aim 2: Aim 2 is complete, and findings of formal usability testing of our app are accepted for publication in JMIR: mHealth and uHealth. Working with Department of Surgery educational psychologist, Sarah Sullivan, we have developed training materials informed by

distributed practice and adult motivation theories and evidence. All materials have received IRB approval and legal/cybersecurity documentation of HIPAA compliance. Training materials and flashcards to accompany the training are produced. We have remedied an identified gap in the scope of our project by contracting with Marshfield Bioinformatics Research to undertake formal, rigorous usability testing of the app in the inpatient setting. Unable to achieve PACScan integration, we developed a provider review interface for the app that has the image review functionality described (side-by-side comparison, zoom capability, etc.). Eligible participants included inpatients 18 years of age or older on the vascular or general surgery service of a large, academic tertiary care hospital. Subjects were recruited during one of two usability sessions in November and December 2015. Participants were eligible if they had a surgical incision longer than 3 cm and were close to their baseline functional status.

Results: Of the 14 patients who were approached to participate, 5 declined due to time constraints or disinterest. Nine participants completed usability testing, 3 of whom had caregiver assistance or proxy participation. Five participants owned their own smartphone, and 7 had used a smartphone to take a digital image at least once prior to this study, leaving 2 who had no prior experience with smartphones. Two participants had 2 wounds, bringing the total number of wounds to 11. We followed the International Organization for Standardization (ISO) 9241-11 guidelines, focusing on effectiveness, efficiency, and user satisfaction. An accompanying training module was developed by applying tenets of adult learning. Sessions were audio-recorded, and the smartphone screen was mirrored onto a study computer. Digital image quality was evaluated by a physician panel to determine usefulness for clinical decision making. The mean length of time spent was 4.7 (2.1-12.8) minutes on the training session and 5.0 (1.4-16.6) minutes on app completion. 55.5% (5/9) of patients were able to complete the app independently with the most difficulty experienced in taking digital images of surgical wounds. Novice patients who were older, obese, or had groin wounds had the most difficulty. 81.8% of images were sufficient for diagnostic purposes. User satisfaction was high, with an average usability score of 83.3 out of 100.

Conclusion: Surgical patients can learn to use a smartphone app for postoperative wound monitoring with high user satisfaction. We identified design features and training approaches that facilitate ease of use. This protocol illustrates an important, often overlooked, aspect of mHealth development to improve surgical care.

Aim 3: The protocol paper is published in JMIR Research Protocols. Final results from the trial are under review at the Journal of the American College of Surgeons.

Results: *Patient Characteristics*

Between June 6 and November 15, 2016, 141 patients were screened, 69 of whom were approached for participation. Nine of these were unable to complete the protocol independently and had no caregiver to assist. Of 60 eligible patients, 47 patients (78%) were enrolled. Stated reasons for declining to participate included feeling overwhelmed with postoperative care, being uninterested in learning new technology, and hesitation about participating in research.

Of the 40 participants who were fully enrolled and completed the 14-day protocol, the majority were male and white (Table 1), which is consistent with the vascular surgery patient population at our institution. Twenty-two (55%) participants traveled more than 50 miles to receive care at our institution, and participants were not scheduled for routine follow-up until an average of two weeks following hospital discharge. The majority of participants had a caregiver to assist them (Table 1). In 32.5% of cases, neither the patient nor their caregiver, if they had one, had prior experience with smartphone technology.

Training and Protocol Completion

Training participants to use the device and complete the WoundCheck app required an average of 16.9 minutes (Table 2). Participants found the app very user friendly, with an average System Usability Scale score of 87.2 (scored out of 100; scores above 68 are considered above average by industry standards). Forty-five percent of participants (18/40) submitted data every day for the full two weeks (Table 2). Those that did not missed an average of 1.4 days, giving an overall daily submission rate of 90.2% (505/560 days, given 40

participants submitting data for 14 days). Of the 55 missed days, 6 (10.9%) were on the first day, 9 (16.4%) were on the last day, and 17 (30.9%) were over a weekend.

Clinical Service Line Integration

On average, nurse practitioners reviewed submitted data 580.5 minutes (9.7 hours) after submission (Table 2). Of the 160 days that participants submitted data, 139 (86.9%) were reviewed per protocol by a nurse practitioner; a physician member of the research team reviewed submissions on the remaining days. 91.9% of submissions (464/505) were reviewed within 24 hours. When interviewed, the nurse practitioners were positive about the protocol, saying that "the patients who participated…seemed enthusiastic about it," "the pictures were helpful," and "I really think there's a lot of merit to these pictures." However, they struggled to find time in their day that was required to do submission review, in addition to the clinical work they were already doing for the inpatient service.

Participant Satisfaction

Participants were universally positive in their exit interviews (Box 1). Six participants wished there had been a free text or comment section to add more detail to their survey responses beyond yes/no, or to ask a question about the appearance of the wound. Four participants had difficulty submitting data due to poor cell service. One participant suggested adding a mechanism to notify patients that their submissions had been reviewed by a provider, and a record of past submissions so they could be sure their data had been transmitted successfully.

Clinical Outcomes

There were a total of 8 SSIs in the patient cohort, 7 of which were detected using images and survey responses from our app. There were no false positives. There was one false negative in a patient whose infection was detected at an early follow-up visit on post-discharge day 5; the corresponding image from that day did not demonstrate and obvious infection. Of the 7 patients diagnosed by our protocol, 6 had their infections successfully managed as outpatients. In 4 cases, patients were brought back to clinic and were successfully treated far in advance of their regularly scheduled follow-up. Two of the 6 were readmitted, but for reasons unrelated to their SSI. One patient fell on his amputation stump several days after we detected and treated his SSI, and he returned to the operating room for a traumatic wound dehiscence, not for his SSI. Another patient had been readmitted on post-discharge day 2 to an outside facility due to respiratory failure, and he and his continued to submit images. He developed peri-incisional erythema around his groin incision on post-discharge day 15, and our vascular surgeons spoke with the inpatient team at the other facility to coordinate appropriate wound care and an antibiotic regimen. The final patient had early detection of their SSI, but their case is perhaps an illustration than not all readmissions for SSI are preventable. This patient's SSI was detected by the protocol, and he was sent to the emergency room, where he received appropriate antibiotic therapy. However, the SSI did not completely resolve with this regimen, and he required operative management and IV antibiotics in an inpatient setting.

Conclusion: Vascular surgery patients and their caregivers are willing to participate in a mobile health program aimed at remote monitoring of postoperative recovery, and they are able to complete the program with a high level of fidelity and satisfaction. Such a program is easily integrated into existing service lines and does not add a significant additional burden. Preliminary results indicate the ability to detect and intervene on wound complications at earlier stages and prevent hospital readmission.

Table 1. Demographic characteristics of study participants, their method of participation, and their previous experience with smartphones.

Characteristic	
Male, n (%)	30 (75.0)
Age (years), median (range)	63 (35-89)
White, n (%)	39 (97.5)
Number of incisions, median (range)	1 (1-7)
Incision site, n (%)	
Groin	19 (47.5)
Abdomen	16 (40.0)
Lower extremity	10 (25.0)
Amputation stump	6 (15.0)
Number of days until scheduled follow up, median (range)	14 (5-52)
Distance from home to hospital (miles), median (range)	61.4 (7.2-1661)
Method of participation	
Caregiver, n (%)	30 (75)
Independent, n (%)	10 (25)
Smartphone familiarity	
Participant/Caregiver Pairs, n (%)	
Neither has experience	11 (37)
Only caregiver has experience	4 (13)
Both have experience	14 (47)
Only patient has experience	1 (3)
Independent Participants, n (%)	
Prior experience	8 (80)
No experience	2 (20)

Table 2. Training success, participant adherence to the protocol, and provider compliance with reviewing daily submissions in a timely manner.

Training Success	
Training time (min), mean (range)	16.9 (4-30)
SUS Score, mean (range)	87.2 (37.5-100)
Participant Compliance	
Total submissions, n (%)	
Days submitted	505 (90.2)
Days missed	55 (9.8)
Completed patients (n=40)	
Submitted for all 14 days, n (%)	18 (45.0)
Average number of days sent, n (range)	12.6 (5-14)
Average number of days missed, n (range)	1.4 (0-9)
Provider Compliance	
Time for NP/MD to complete checklist (min), mean (range)	1.7 (1-9)
Time from patient submission to NP/MD review	
Minutes, (range)	580.5 (3-5386)
Days missed, n (%)	21 (13.1)
Submissions reviewed within 24 hours, n (%)	464 (91.9)

SUS = System Usability Scale; NP = nurse practitioner

Box 1. Representative participant quotes from the exit survey

- "It was pretty easy…you could see if something was wrong better than my judgment"
- "[It] helped me pay more attention to [the wound]…every time you take down the dressing you had to look at it…if you guys saw something in the pictures that I didn't see…it kept me from having to run down [there]"
- "I found it very helpful in my case where I had to come back because it didn't look good…it was very reassuring knowing you guys were right along with me taking a look at it" (said by a participant who had a wound infection detected by the protocol)
- "I'm really glad you developed this for the patients, especially when they live so far away because that way we don't know if we're being overly concerned or not, and for us to drive 2.5 hours, that's a long way just to say 'that's nothing, you're fine'"
- "It made me feel safer, more secure; if he had waited even a couple of days it would have been a lot worse because it just happened in two days…you were right on top of it…a wife doesn't know…you don't know, and I just thank you so much" (said by the wife of a participant who developed a wound infection detected by the protocol)
- "The study was so beneficial…just knowing it was going to be monitored…if I wasn't sure if there was a problem, I didn't even have to worry about it because I knew they were monitoring it"

F.   LIST OF PUBLICATIONS AND PRODUCTS

Gunter RL, Fernandes-Taylor, S, Rahman, S, Awoyinka, L, Bennett, KM, Weber, SM, Greenberg, CC, Kent, KC. Feasibility of an Image-Based Mobile Health Protocol for Postoperative Wound Monitoring. Under review at *Journal of the American College of Surgeons.*

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Gunter RL, Fernandes-Taylor S, Rahman S, et al. Feasibility of an image-based mobile health protocol for postoperative wound monitoring. 2017 Academic Surgical Congress. Las Vegas, NV.

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