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Results of Telehealth Electronic Monitoring for Post Discharge Complications and Surgical Site Infections Following Arterial Revascularization with Groin Incision

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Abstract:

INTRODUCTION: Post-surgical discharge complications result in increased hospital readmissions, cost, and patient dissatisfaction. Telehealth technology to monitor patients, especially those in geographically isolated areas, may reduce post-operative complications, improve health and financial outcomes.

OBJECTIVE: The primary objective was to compare outcomes between patients that received **T**ele**h**ealth **e**lectronic **m**onitoring (THEM) to those with routine discharge instructions and no monitoring, **S**tandard **O**f Care (SOC).

METHODS: This was a prospective randomized study of vascular surgery patients with infra-inguinal incisions. THEM patients received a tablet and home monitoring devices that transmitted information to care managers. Monitoring tools included image capture, weight scales, blood pressure cuffs, thermometers and oxygen saturation monitors. Care managers used the TeleMed 2020 Enform™ platform to review alerts, real-time patient data, and dialogue with the care team.

RESULTS: Eighty patients were screened and thirty enrolled, of which 16 (53.3%) were randomized to the THEM and 14 (46.7%) control groups. Average age and BMI for THEM and control patients were similar (62.5 $\pm$ 7.2 vs 65.7 $\pm$ 7.3, p=0.234; and 27.7 $\pm$ 4.3 vs 29.1 7.1, p=0.487), respectively. There was a similar number of male participants in each group (THEM 62.5% versus SOC 42.9%, p=0.464). There were no significant differences in wound or 30-day readmissions (THEM 6.3% vs SOC 7.1%, p=1.000). Interestingly, 30-day infection rates indicated care managers identified marginally more superficial wound problems in the THEM group (31.3% vs 7.1%, p=0.175). Both groups reported an increase in SF8 physical summary scores, but was more pronounced in THEM patients (p=0.076). THEM patients reported a

significantly greater improvement in quality of life on three of the SF8 quality subscales (Physical function, Role-Physical and Role-Emotional; THEM Δ 7.5 vs Control Δ 1.1; THEM Δ 8.7 vs Control Δ 1.1; and THEM Δ 6.3 Control Δ -0.5; all $p<0.05$). THEM patients reported trends for higher satisfaction in terms of general satisfaction, technical quality and accessibility for PSQ18 survey questions (4.2 vs 3.7,$p=0.072$; 4.5 vs 4.1, $p=0.081$; and 4.2 vs 3.8, $p=0.063$), respectively.

Conclusion: THEM was technically feasible and provided some benefit to patients in geographically disparate areas. THEM was associated with increased patient satisfaction. Additional findings suggested THEM patients embraced telehealth technology and took advantage of increased access to health care professionals. Telehealth successfully merged remotely generated information with care manager interaction. Presently, a larger study, preferably multicenter, is warranted and under consideration.

Key Words

Tele-health, Tele-medicine, Vascular, Surgery, Infection, Wound

Introduction:

Modern telehealth utilization has evolved from using the telephone in the 1870's to reduce unnecessary office visits to using tablets or other devices to transmit voice, survey questions, email or text messages, images, and videos with or without conferencing.[1-3] Telehealth continues to progress and has grown into a larger domain in patient care that combines both telecommunications and information technologies. This digital approach has the potential to provide continuous remote medical care access to different aspects of patient care from different geographical locations for extended periods of time. The scope of telehealth communication may range from simple activities such as telephone consultation to more sophisticated technology as tele- or robotic surgery.[2] Feasibility of these approaches has been previously evaluated.[3-6] In one study, it was determined that there were no diagnostic errors made using remote telemedicine compared to in-person clinic follow-up. [7] Ironically, vascular interventionists, although currently practicing in highly technologically-laden environments, have limited use of modern telehealth approaches. Most large care centers and specialty physicians are located in metropolitan areas requiring patients to travel significant distances for simple office visits. Further, for a myriad of reasons, areas of the country remain relatively geographically isolated. Telehealth Electronic Monitoring (THEM) has emerged as a valid option to access and monitor patients within different levels of their healthcare. Telehealth is a vector that allows the transfer of information from the patient to the provider or vice versa. Indeed, THEM technology can decrease the burden placed on medical resources, increase the efficacy of health care and increase the time efficiency for both patients and physicians. Yet, a more comprehensive approach that includes patient satisfaction surveys and bio-sensors is needed to better define the utilization and role of telehealth for surgical and other vascular

interventions. The current prospective randomized controlled study was designed to evaluate clinical outcomes, utilization, feasibility, patient satisfaction and quality of life for patients using THEM after cut-down infra-inguinal incision (i.e., dissection of a vein or artery for insertion of a cannula or needle) for any vascular procedure.

Methods:

The specific details of the current study design have previously been reported. [8] Briefly, it was a **p**rospective, **r**andomized, **o**pen-label, single-center with **b**linded **e**ndpoints (PROBE) designed study.[9] The primary objective of the current project was to compare outcomes for patients who received post discharge health care monitoring (which includes using **T**ele**h**ealth **e**lectronic **m**onitoring; THEM) to patients who receive **s**tandard **o**f **c**are (SOC), which included routine discharge instructions with no telehealth monitoring. The primary outcomes included 30-day readmissions and deep surgical site infections. Secondary outcomes included pre and post-surgery quality of life measures (SF-8), patient satisfaction, superficial surgical site infection, in-home visits from visiting nurse service (VNS), and an occurrence of any 30-day stroke, myocardial infarction or death. The study had three main hypotheses: 1) A smaller percentage of THEM patients would require a 30-day unplanned readmission compared to patients who received standard of care (SOC). 2) A smaller percentage of THEM patients would develop deep SSIs (i.e., infections involving fascia and/or muscular layers requiring wound interventions such as opening, debridement, etc.) compared to SOC. 3) THEM patients would report greater post discharge satisfaction and higher quality of life measures than SOC patients.

Patients in the intervention group (THEM) received a tablet computer with the Enform® App and set of medical devices for home monitoring. Medical devices included weight scales, blood pressure cuffs, thermometer and oxygen saturation monitors. Each participant randomized to the THEM arm was provided a take-home kit. The kit contained (Samsung Galaxy Tab E 8" inch tablets with Supcase/Finitie rigid cases, Prooral professional digital thermometer, A&D UC-352 BLE weight scales, TaiDoc TD-3250-C blood pressure monitor, ChoiceMMed MD300C318T2 oxygen saturation device). (Figure 1) Data from these Bluetooth enabled devices along with routine wellness assessment question responses were securely transmitted and reviewed by care managers using the web enabled Enform® clinician portal. Clinical care managers were both registered nurses with over 30 years of experience. Each had experience in ambulatory cardiovascular nursing, and remotely monitored the patients using this tool daily. Clinical care managers engaged with patients by phone or used the integrated Enform® messaging based on alerts and/or data generated by the telehealth monitoring system. Participants were instructed to monitor the tablets daily, perform their measurements (i.e., blood pressure, heart rate, oxygen saturation, weight and temperature) and answer daily plus weekly quiz questions. (Table 1) The care manager logged into the TeleMed2020 website and monitored values daily, however, the care manager only initiated contact with participants by phone or internal messaging if there was a concern generated by any of the system alerts. Patients, however, were able to contact their care manager at any time.

Based on data collected, the care manager requested the patient take a picture of the surgical site for assessment and comparison with previously collected images. All images as well as other information such as, system alerts or aberrant results, when persistent, were shared with the medical director to proactively manage the patients in between in-person visits. The care

management team established the following thresholds for bio-sensor system alerts: high systolic (>150 mmHG), low systolic (<90 mmHG), high diastolic (>90 mmHG), low systolic (<50 mmHG), high pulse (>100 BPM), low pulse (<60 BPM), low oxygen saturation (<90%), weight +/- 10 lbs of baseline, and temperature > 101^0 (Fahrenheit). In addition, quiz alerts were generated when any of the following responses were provided for the accompanying quiz questions: “How is your pain today?”, a score of 8 or more; “To me, the surgical incision site appears”, to be getting worse; “Discharge or leakage of fluid form any part of the surgical site”, is yellow or green or is present but looks different from choices above; “Swelling or redness around the surgical incision is”, worse than yesterday; “In general, how would you rate your mental or emotional health?”, Poor. Participants that did not have in-home Wi-Fi were provided tablets with cellular connectivity to the internet. Care managers had access to the website and were required to log into the website daily, but had the ability to log in at any time. Monitoring equipment, tablets and website were all HIPAA- compliant. Tablets and kits were returned at the first follow-up visit. Tablets and monitoring equipment were physically cleaned and data-wiped before being distributed to the next participant. Four Wi-Fi and four cell coverage tablets were available for distribution.

Patients in the SOC group received the normal standard of care for vascular surgery patients, which is to apply a sterile dressing immediately after complete closure, and the surgery site assessed 24 hours after the procedure. If there were no local complications, hematomas or dehiscence, patients were discharged with the following instructions. Keep your incision dry for 24 hours. If covered, keep it covered for 24 hours. You may shower after 72 hours, pat incision dry with soft towel, do not sit in a tub or soak wound for 1 week (swimming, hot tub included).

Report any of the following: Fever greater than 101.0F, redness, swelling or pus-like drainage, pain that is not relieved by your prescribed medication, a change in the appearance of your wound noticed by your or your family member, no heavy lifting (more than 10 pounds in each hand) for one week, no excessive stair climbing, recline the seat in the vehicle for your trip home today, and take all medications as directed. In addition, notify your physician if you have a question about your medication, if you need your instructions clarified or you have other concerns about your health. If your diabetes or blood pressure is not controlled, notify your care team and/or family physician. Remember, no smoking or use of tobacco products. See your physician in the office for suture/staple removal if applicable as directed.

Sample:

The population for the current study was patients with any planned vascular procedures with cut-down access to the infra-inguinal area and treated by one of the board certified vascular surgeons in the Vascular Center of Excellence (VCOE). Sample size estimates were based on infection rates from previous research.[10, 11] An overall sample size of 200 subjects would have 80% power to detect a reduction in the 30-day infection/readmission rate from ~12 in the SOC group to ~2% in the THEM group using a 2-sided α of 0.05. We expected a 10% drop-out rate and planned to enroll 110 patients in each group (N=220 overall). Full enrollment, depending upon the number of patients that agree to participate, would have taken 2 years or longer. Based on available funding, the study enrollment was stopped after one year. Planned patient exclusions included the following: (1) did not plan to do follow-up visit at the VCOE; (2) inability to sign or understand the consent form; and (3) did not have home internet service with Wi-Fi and/or

resided outside of the provided cell coverage area (tablets with the Enform® App offered to patients without Wi-Fi access).

Statistical Analysis:

All analyses were based on intention-to-treat (ITT) analyses. Descriptive statistics are expressed in terms of frequencies, percentages, or means ± standard deviation (SD). Categorical variables were tested by chi-square or Fisher exact tests and continuous variables were tested by student t-test or paired t-test for pre/post measures, or repeated measures analysis of variance (ANOVA) where deemed appropriate. All probability values were 2 sided and 'p' values <0.05 was considered significant. Statistical analyses will be performed using SPSS version 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp).

Informed consent was obtained by the research coordinator. Eligible patients were randomly assigned to either the treatment group (THEM) or the control group (SOC). The study protocol was approved by our governing Institutional Review Board (IRB) and conducted in accordance with the Health Insurance Portability and Accountability Act (HIPAA) requirements and the prevailing ethical principles governing research. In addition, the study was registered on https://www.clinicaltrials.gov/;NCT02767011.[12] The randomization was performed centrally using an SPSS computer algorithm. Treating physicians were blinded to the randomization, although one of whom served as medical director of the care management team and was consulted by the care managers during post-surgical treatment decisions. Participants from either group were scheduled for in-home visits from "visiting nurse service (VNS) based on physician preference and comorbid conditions.

RESULTS:

Eighty vascular surgery patients were screened for possible inclusion into the current study. After the screening process, 50 patients did not meet inclusion criteria, refused to participate or were excluded from the study results. (Table 2) Ultimately, thirty patients were enrolled, of which 16 (53.3%) were randomized to the THEM and 14 (46.7%) to the SOC groups. The average age and BMI for THEM and SOC patients were similar (62.5 $\pm$ 7.2 versus 65.7 $\pm$ 7.3, p=0.234; and 27.7 $\pm$ 4.3 versus 29.1 $\pm$ 7.1, p=0.487). The average driving distance from the vascular center clinic for the THEM patients was similar to those in the SOC group (60.2 $\pm$ 42.1 miles versus 48.6 $\pm$ 28.5 miles; p=0.393). THEM patients had significantly more hypercholesterolemia 93.8 versus 50.0%, p=0.012. (Table 3)

There were no significant differences in wound or in 30-day readmissions (6.3% versus 7.1%, p=1.000; and 25.0% versus 14.3%, p=0.657). Interestingly, 30-day infection rates indicated care managers identified marginally more superficial wound problems in the THEM group (31.3% versus 7.1%, p=0.175). There was no difference in the number of patients that received home nursing visits (n=3 each group, p=1.000) or in the average number of visits (THEM 1.3 $\pm$ 2.9 vs SOC 1.4 $\pm$ 2.9, p=0.967). Both groups reported an increase in SF8 physical summary scores, but the increase was more pronounced in THEM (pre-post delta = 9.0 versus 4.5) patients (p=0.076). There was no significant difference between the two groups for SF8 mental health summary score. THEM patients reported a significantly greater improvement in quality of life on three of the SF8 quality subscales. The difference for THEM patients on the physical-function subscale

(pre-post delta) was 7.5 versus 1.1 for the SOC group (p=0.002). The difference for THEM patients on the role-physical subscale (pre-post delta) was 8.7 versus 1.1 for the SOC group (p<0.001). The pre-post delta difference for THEM patients on the role-emotional subscale was 6.3 versus -0.5 for the SOC group (p=0.030). THEM patients reported trends for higher satisfaction in terms of general satisfaction, technical quality and accessibility for PSQ18 survey questions (4.2 versus 3.7, p=0.072; 4.5 versus 4.1, p=0.081; and 4.2 versus 3.8, p=0.063), respectively. (Table 4)

Ancillary findings:

Sensor data was collected by the bio-sensors, uploaded to the tablets via Bluetooth and then synced with the care management website. The sensor data revealed 207 blood pressure and pulse rate measurements. The average systolic blood pressure was (mean,+SD) 132.4 $\pm$ 18.6 mmHG. The average diastolic blood pressure was 79.6 $\pm$ 13.9 mmHG. The average pulse rate was 78.3 $\pm$ 15.8 BPM. There were 33 (15.9%) high systolic alerts (>150 mmHG), 37 (17.9%) high diastolic alerts (>90 mmHG), 19 (9.2%) high pulse alerts (>100 BPM) and 24 (11.6%) low pulse alerts (<60 BPM). The average oxygen saturation rate was 94.8% $\pm$ 3.8% with 21 (9.7%) low (<90%) alerts. The average weight was 167.2 + 36.2 lbs. There were some system alerts generated by large variations in daily weight $\pm$10 lbs. However, it was discovered that the large variations or discrepancies in weights were explained by non-standard methods for obtaining weight, such as different mode of dress or at a different time of day. Daily temperature monitoring resulted in no alerts.

In addition, and not counting some inadvertent shutter pushes, THEM patients took 141 photographs (mean 8.8 ± SD; range 0-27 9.7) to be shared with the care management team. Four patients in the THEM arm had superficial wound infections that were treated without the need for an emergency room visit or an unscheduled office visit. Anecdotally, these patients told the care managers that they were very satisfied to take photographs and have them reviewed by a physician. Subsequently, the physician called in prescriptions for antibiotics to the patients' local pharmacies. Interestingly, patients that took photographs indicating no infection were also anecdotally pleased to receive reassurance from a physician. One patient in THEM with a deep wound infection was a redo-surgery for a graft wound infection, and in retrospect, current wound infection should have been part of our exclusion criteria. Another patient in THEM had a chronic non-healing wound. However, he had a closed bypass graft. Ultimately, three patients in THEM were sent to the hospital for emergency room visits, but their visits can be explained by clinical conditions that were not associated with the cut down procedure or infection. One was admitted with the deep wound infection (i.e., mentioned above), one with pulmonary embolism and the other had a non-wound related problem (urinary retention) and suspected deep vein thrombosis which was ruled out by non-invasive duplex ultrasound testing.

THEM patients had phone and electronic access to a care manager 7 days a week. The majority of THEM patients also rated the Enform™ technology easy to use (27/33 = 82%). Often care managers scheduled follow-up appointments, answered post-discharge questions, procured prescriptions and consequently provided direct access to the care management team. THEM patients became involved in monitoring their own bio-markers. This is evidenced by their responses to the daily and weekly quiz questions. Tables 5a & 5b) As you can see the quiz

question, “During the past week, would you say that information you provided to your Care Manager(s) via Enform™ enriched the conversation or quality of care provided?” most respondents (27/33 = 82%) selected “Definitely yes.” In addition, there were several anecdotal comments made to the care managers that also support this belief. For example, one patient reported to a care manager, “I knew you were going to call because my blood pressure was high this morning.”

Discussion:

Many researchers have evaluated utilization of THEM in several evolving aspects of vascular surgery. Chisci et al evaluated a THEM consultation model for planning and treatment of complex thoracoabdominal aortic disease (TAAD) and concluded that THEM may allow inexperienced surgeon to acquire and share knowledge from experienced surgeons at larger institutions.[13] Another important aspect of using THEM in postoperative wound care is the potential to facilitate transition of care and to decrease readmission for surgical site infections. [14] We found no significant differences in wound or 30-day readmissions (6.3% versus 7.1%, p=1.000; and 25.0% versus 14.3%, p=0.657). However, the central reason for not detecting any significant difference between groups was likely due to our low enrollment numbers, which will be discussed below.

Despite our lack of a primary statistically significant finding, we found several instances where our results suggested the benefit of using THEM and increased quality of life and patient satisfaction. THEM patients had a more pronounced change in pre/post SF-8 physical summary

scores (p=0.076). In addition, THEM patients had more pronounced effects for three of the subscales as well (i.e., physical function, physical role and mental health; all interactions <0.05). Besides quality of life measures, there was some evidence for THEM patients being more satisfied with their health care. We found marginal trends for THEM patients to have more general satisfaction, rate technical quality and accessibility higher (p values ranged from 0.063 – 0.081). As compared to others, [1-3, 6, 15] the current study went beyond a feasibility type of study and provided real world evidence that suggests patients will adopt and accept remote monitoring. THEM patients rated remote monitoring and medical device technology as easy to use and believed that their efforts enriched the quality of care that they received.

There are many potential uses for telehealth communications including reaching out to communities in underserved areas, achieving better quality of patient care, avoiding hospitalization, producing cost savings, improving surgeons' experience, providing an opportunity for international consultation to underdeveloped countries and expansion of medical knowledge and techniques among health professionals. [1] In our study, THEM patients lived an average of 60.2 miles from the vascular care center with some 31.3% more than 77 miles requiring a two to three hour drive. The patients that received call-in prescriptions were very satisfied and grateful for the continuity of care and were glad that they did not have to make a trip back to the vascular center.

In the current study, care managers used system alerts and wound pictures to determine whether a consultation with the medical director was necessary. Even though it was of secondary interest, we found patients to be appreciative of the direct connection to the care management team and

345 took advantage of this opportunity by having the care managers to schedule follow-up
346 appointments, answer post-discharge questions and help procure prescription medications.
347 Although somewhat underutilized [7], THEM can be used as a useful tool to minimize the costs
348 and challenges for postoperative vascular patients. Endean et al [3] reported the efficacy and
349 accuracy of THEM, and concluded that the evaluation of vascular patients is accurate and as
350 effective as on-site evaluations for a variety of vascular problems. Yet, important adjuncts
351 enhance the success of the evaluation are physician experience with the technology and the
352 presence of a knowledgeable on-site assistant. This technology can be easily adapted to other
353 clinical situations.
354
355 Another important aspect of THEM is the potential to improve quality of care in both outpatient
356 and inpatient wound care along with decreased medical cost and hospital resources by allowing
357 home care nurses to electronically transmit images of patients' wounds to treating surgeons. In
358 our study, nurse care mangers were able to have uninterrupted access to the condition of the
359 patient's wounds and maintained uninterrupted access to a supervising physician 24/7. Likewise,
360 THEM patients had phone and electronic access to a care manager 7 days a week. THEM
361 patients rated the technology as easy to use and believed these efforts impacted their health care.
362 Often care managers served as the direct connection to the health care system by scheduling
363 follow-up appointments, answering post-discharge questions and helping to procure prescriptions
364
365 In another vascular surgery study[2], the authors concluded that wound evaluation on the basis of
366 viewing digital images is comparable with standard wound examination and renders similar
367 diagnoses and treatment in the majority of cases. In our study, THEM patients took 141

368 photographs all of which were shared with the care management physician. Four of these photos
369 contained elements of superficial wound infections, all of which were treated by calling in a
370 prescription to a local pharmacy without the need for an emergency room visit or an unscheduled
371 office visit. Interestingly, patients were pleased to have their photographs reviewed by a
372 physician, whether antibiotic or reassurance of no infection was provided. Although not
373 measured, the photographic images seemed to be high quality and easily used by the care team to
374 make assessments about the patients' wound conditions. However, it is possible that THEM
375 technology provided an extra level of scrutiny which, led to increased or unnecessary diagnosis,
376 treatment or prescription medication. With this in mind, we believe that sharing information
377 among the care team members served to decrease the possibility of over utilization.
378
379 Although we found no significant differences for wound or any readmissions, or any of the office
380 or home nursing visits, it was noteworthy that three THEM patients were sent to the emergency
381 room. One was admitted with deep wound infection (i.e., the one that was a redo graft
382 infection), one for suspected PE and one with urinary retention where suspected DVT was ruled
383 out. Thus, we suspect an added benefit of THEM technology is to provide better and continuous
384 health care, perhaps avoiding a more complicated septic course or death.
385
386 Insurance companies are beginning to reimburse patients and providers for telehealth services,
387 which should help to drive health care costs down.[16, 17] On the other hand, THEM technology
388 carries potential concerns such as availability of internet service, cost of devices or internet
389 service, ease of usability as some patients are typically not as device-savvy (e.g., as the newer
390 generation), privacy of information according to HIPAA, concerns on scams from internet and a

general right to privacy. Therefore, at a minimum, we recommend these issues to be considered thoroughly by the hospital's legal and information technology teams in order to provide the best options for patients.

Limitations:

A major limitation of the findings for the current research study was sample size. There were several reasons for the lower than planned enrollment number. First, funding was only available for one year and thus limited the amount of time for open enrollment. Next, it took some time to develop a good method for identifying potential participants and providing them with the opportunity to learn about the study. Efforts were made to make contact with the patients during their pre-admission testing visit to introduce the general idea of participating in the study, but this was not always possible and in some cases contact was not before the procedure. Lastly, and perhaps equally important was the number of patients who refused to participate. Although our percentage of refusals was somewhat expected (22/80=27.5%), additional efforts in pre-study design could have potentially increased our yield. Nine of the 22 patients who refused did so because of apprehension to the technology. Perhaps a 10-15 minute video describing the study could have reduced some of the apprehension about the technological aspects of the study.

Conclusion:

THEM was technically feasible and provided some benefit to patients in geographically disparate areas. THEM was associated with increased patient satisfaction. Additional findings suggested

414 THEM patients embraced telehealth technology and took advantage of increased access to health
415 care professionals. Telehealth successfully merged remotely generated information with care
416 manager interaction. Presently, a larger study, preferably multicenter, is warranted.
417

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Figure legends

Figure 1: Take home kit for participants in the **T**ele**H**ealth **E**lectronic **M**onitoring (THEM) group

512
513 **Table 1 Tablet Quiz Questions**
514

Daily

How is your pain today?

0	1	2	3	4	5	6	7	8	9	10
No Pain					Moderate Pain					Worst Possible Pain

To me, the surgical incision site appears

to be healing nicely | to be getting worse | I am not really sure

Discharge or leakage of fluid form any part of the surgical site

is not present | is Clear or Blood Stained | is Yellow or Green | is present but looks different from choices above

Swelling or Redness around the surgical incision is

not present | less today than yesterday | about the same as yesterday | worse than yesterday

In general, how would you rate your mental or emotional health?

Excellent | Good | Fair | Poor

Weekly

During the past week, how often did your Care Manager(s) treat you with courtesy and respect?

Never | Sometimes | Usually | Always

During the past week, how often did you Care Manager(s) explain things in a way you could understand?

Never | Sometimes | Usually | Always

During the past week, how often did information you sent from Enform™, your tablet, result in a call from your case manager(s)?

Never | 1 to 2 times | 3 to 5 times | 6 or more times

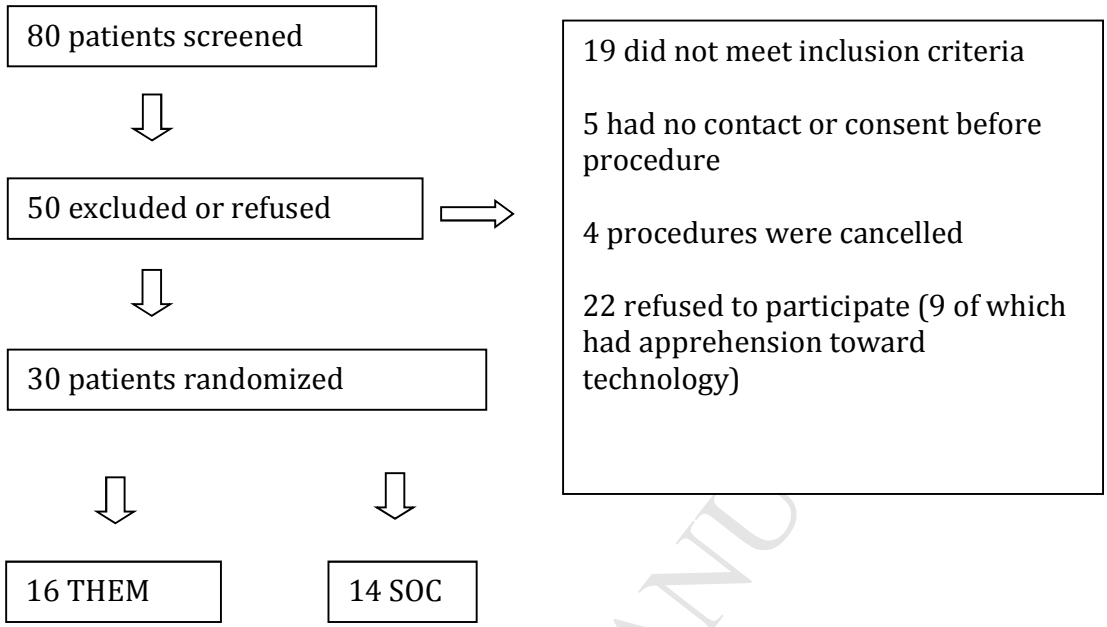
During the past week, what number would you use to rate the ease-of-use of Enform™?

1 HARD TO USE | 2 | 3 | 4 | 5 EASY TO USE

During the past week, would you say that information you provided to your Care Manage(s) via Enform™ enriched the conversation or quality of care provided?

Definitely no | Probably no | Probably Yes | Definitely yes

Table 2 Participant screening and randomization flow chart



THEM = **T**ele**H**ealth **E**lectronic **M**onitoring
SOC = **S**tandard **O**f **C**are

Table 3 Participant demographics

Outcome	THEM n= 16		SOC n= 14		
	n/mean	%/SD	n/mean	%/SD	p
Age (years)	62.5	7.2	65.7	7.3	0.234
BMI (body mass index)	27.7	4.3	29.1	7.1	0.487
Length of stay (days)	3.8	3.8	4.0	2.6	0.250
Distance from hospital (miles)	60.2	42.1	48.6	28.5	0.393
Long distance > 77 miles	5	31.3	3	21.4	0.689
Male gender	10	62.5	6	42.9	0.464
Diabetes	4	25.0	8	57.1	0.135
Myocardial infarction	8	50.0	11	78.6	0.142
Cerebrovascular accident	3	18.8	3	21.4	1.000
Hypertension	15	93.8	11	78.6	0.315
Hypercholesterolemia	15	93.8	7	50.0	**0.012**
Tobacco use	8	50.0	7	50.0	1.000
Infra-Inguinal Bypass	16	100.0	12	85.7	0.209

*p<0.05

THEM = **T**ele**H**ealth **E**lectronic **M**onitoring

SOC = **S**tandard **O**f **C**are

Table 4 Outcomes by study group

Outcome	THEM n= 16			SOC n= 14			
	n	%		n	%		p
Wound readmission	1	6.3		1	7.1		1.000
Any readmission	4	25.0		2	14.3		0.657
Wound site healed	14	87.5		11	78.6		0.642
30-day infection (any)	5	31.3		1	7.1		0.175
Office visit	2	12.5		1	7.1		1.000
Visiting nurse visit (any)	3	18.8		3	21.4		1.000
Visiting nurse visits (mean +SD)	1.3	2.9		1.4	2.9		0.967
SF-8	Pre	Post	Delta	Pre	Post	Delta	
Physical summary score	27.8	36.8	9.0	30.1	34.6	4.5	0.076
Mental health summary score	43.7	47.6	3.9	45.1	44.4	-0.7	0.110
Physical function subscale	28.7	36.2	7.5	35.07	36.2	1.1	0.002*
Physical role subscale	28.9	37.6	8.7	32.3	33.4	1.1	0.001*
Mental health subscale	40.5	46.8	6.3	44.6	44.1	-0.5	0.030*
PSQ-18							
General satisfaction		4.2			3.7		0.072
Technical quality		4.5			4.1		0.081
Accessibility		4.2			3.8		0.063

*p<0.05
THEM = **T**ele**H**ealth **E**lectronic **M**onitoring
SOC = **S**tandard **O**f **C**are
SF-8 = Optum™ SF-8™ Health Survey
PSQ-18 = Patient Satisfaction Questionnaire Short Form (PSQ-18)

573 **Table 5a Summary of daily survey quiz questions**
574

Response	How is your pain today?	To me, the surgical incision site appears	Discharge or leakage of fluid form any part of the surgical site	Swelling or Redness around the surgical incision is	In general, how would you rate your mental or emotional health?	Total
			Daily			
0 No Pain	7					7
1	16					16
2	24					24
3	14					14
4	22					22
5 Moderate Pain	34					34
6	14					14
7	13					13
8	25					25
9	5					5
10 Worst Possible Pain	13					13
to be healing nicely		145				145
to be getting worse		9				9
I am not really sure		33				33
is not present			112			112
is Clear or Blood Stained			66			66
is Yellow or Green			6			6
is present but looks different from choices above			3			3
not present				53		53
less today than yesterday				42		42
about the same as yesterday				87		87
Excellent					18	18
Good					130	130
Fair					34	34
Poor					4	4
	187	187	187	182	186	929

575
576

577 **Table 5b Summary of weekly survey quiz questions**
578

Response	During the past week, how often did your Care Manager(s) treat you with courtesy and respect?	During the past week, how often did you Care Manager(s) explain things in a way you could understand?	During the past week, how often did information you sent from Enform™, your tablet, result in a call from your case manager(s).	During the past week, what number would you use to rate the ease-of-use of Enform™?	During the past week, would you say that information you provided to your Care Manage(s) via Enform™ enriched the conversation or quality of care provided?	Total
	Weekly					
Sometimes	2					2
Usually						
Always	31					31
Never						
Sometimes		1				1
Usually		3				3
Always		29				29
Never			9			9
1 to 2 times			14			14
3 to 5 times			8			8
6 or more times			2			2
1 HARD TO USE						
2				1		1
3				2		2
4				3		3
5 EASY TO USE				27		27
Definitely no						
Probably no					1	1
Probably Yes					5	5
Definitely yes					27	27
Total	33	33	33	33	33	165

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Take Home Kit
TeleMed
2020
SAMSUNG
Mary Jones
Today's Activities
Probe
Covers
A&D Medical
Bluetooth