

Steps to Eliminate Postoperative Problems

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PROTOCOL TITLE: Steps to Eliminate Postoperative Problems

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INTRODUCTION AND PURPOSE:

Radical cystectomy with urinary diversion is associated with substantial perioperative morbidity, including deep venous thrombosis, prolonged ileus, and postoperative functional decline. Post-operative morbidity after cystectomy prolongs the length of stay, increases the risk of readmission, and adds substantially to health care costs. Protocols that emphasize early and frequent ambulation after surgery decrease post-operative morbidity, but poor patient adherence diminishes the effectiveness of these protocols, which are currently implemented only during the hospital stay. Financial incentives overcome present bias and offer a novel and practical approach to increasing ambulation during the post-operative period in the hospital and after discharge. In this application, we propose a pilot randomized, controlled trial to estimate the effect size of financial incentives on increasing post-operative ambulation in the hospital and post-discharge after radical cystectomy. Secondary outcomes include step count, composite morbidity, and functional decline. This proposal will provide the preliminary data needed to design future, larger trials that will test the effect of financial incentives to increase ambulation on post-operative complications, readmissions, and functional decline

OBJECTIVES:

In this study, we seek to determine whether financial incentives can be used as novel and practical approach to increase post-operative ambulation and thereby decrease post-operative morbidity. The primary outcome variable will be the percentage of the first 30 post-operative days on which study participants meet patient-specific ambulation goals. Secondary outcomes include 1) the number of steps taken per day, 2) composite morbidity outcome of complications, unplanned readmissions, or Emergency Department (ED) visits, and 3) functional decline as measured by the Stanford Health Assessment Questionnaire.

BACKGROUND:

Radical cystectomy (RC) with urinary diversion is the standard therapy for patients with invasive bladder cancer and is associated with substantial post-operative morbidity. Approximately 30% of patients experience a major complication and 20% are readmitted within 30 days of RC.^{1,2} In addition to increasing patient morbidity, a complication after RC adds \$10,756 to the cost of inpatient care after surgery.³ Protocols that emphasize early and frequent postoperative ambulation reduce the risk of common causes of surgical morbidity and mortality, including deep venous thrombosis, prolonged ileus, and postoperative functional decline.⁴⁻¹⁰ However, pain, lethargy from opioids, and poor patient motivation decrease adherence to early ambulation protocols. Additionally, poor reliability of ambulation data and documentation during the inpatient stay and lack of ambulation data after discharge has resulted in uncertainty regarding the frequency and intensity of physical activity needed to prevent morbidity after major surgery. Applying the principles of behavioral economics to increase post-operative ambulation offers a novel approach to improving outcomes for surgical patients. Through regular positive reinforcement, financial incentives¹¹⁻¹⁹ could increase ambulation and decrease post-operative morbidity by offsetting the focus on immediate barriers to ambulation and tendency to discount the possibility of future morbidity.^{11,20} Financial incentives have improved medication adherence, weight loss, and glycemic control, but have not yet been applied to surgical diseases.^{17,18,21-28} This approach may be particularly relevant to decreasing post-operative morbidity because financial incentives may be exploited for their benefits in the critically important immediate post-operative period with less importance placed on establishing durable changes in health behaviors that persist after the incentive is withdrawn.

CHARACTERISTICS OF THE STUDY POPULATION:

1. Target Population and Accrual:

The target population is adults undergoing radical cystectomy (RC) at the Hospital of the University of Pennsylvania (HUP). 75-100 patients undergo RC at HUP each year. We anticipate recruiting and retaining 50% of eligible patients (n=46) over a one-year enrollment period. Each patient will be followed for 30 days post-operatively with the option for patients to continue submitting data for up to 90 days after their procedure. We anticipate initiating recruitment in July of 2016.

2. Key Inclusion Criteria:

1. Patient is at least 21 years old. – This excludes pediatric patients who would certainly not be representative of the general cystectomy population.
2. Patient is planned to undergo radical cystectomy at the Hospital of the University of Pennsylvania. – This is the population to which we have access for recruiting purposes.
3. Patient is ambulatory with baseline ECOG performance status less than or equal to 2. – This excludes patients for whom step counts would not be relevant or a good measure of daily activity.

3. Key Exclusion Criteria:

1. Patient is non-ambulatory or use of Fitbit to monitor activity is otherwise impossible or impractical. – See inclusion criterion #3 above.
2. Patient has a preoperative ECOG performance status of 3 or greater. – See inclusion criterion #3 above.
3. Patient knows *a priori* that he or she will be unwilling or unable to use a mobile device and online tool to upload activity data.
4. Patient is incapable of consenting for him or herself prior to surgery – Because participation in this trial involves ongoing effort on the part of the subject, we exclude patients who are incapable of consenting for themselves at baseline.
5. Patient is unable to collect step count data for at least 3 days preoperatively – Because step count goals are determined based on preoperative status, we exclude patients for whom we have insufficient preoperative step count data.

4. Subject Recruitment and Screening:

Potential participants will be identified from digital review of the HUP operating room schedule based on current procedural terminology (CPT) codes 51590, 51595, 51596, 51597 or others that may be used to encode radical cystectomy. OR schedules will be reviewed for the coming two months by the research coordinator in conjunction with clinical staff. All patients scheduled for cystectomy will have their charts reviewed for eligibility. After being scheduled for cystectomy, patients are usually seen at a separate pre-admission testing (PAT) appointment and/or an appointment for stoma marking. Scheduled patients will be approached at the conclusion of one of these visits for recruitment by the study coordinator. For the small number of patients who have neither of these visits preoperatively, the study coordinator will initiate contact over the phone, consent will be obtained, the device will be mailed to the participant's home, Way to Health staff or the study coordinator will assist the patient in set up of the device, the consent documents will be signed in the preoperative holding area.

5. Early Withdrawal of Subjects:

Participants may choose to withdraw by simply ceasing to submit ambulation data. Participants will agree that all data submitted to the Way to Health (WTH) will be retained and may be used as part of the study. However participants may stop submitting new data at any time. If a participant fails to submit data for 24 hours while hospitalized, he or she will be approached in the hospital by the research coordinator who can help resolve technical problems, answer questions, and obtain ongoing consent or register the participant's withdrawal. If a patient fails to submit data for 24 hours between the time when they begin submitting data preoperatively and the end of the 30 day post-operative period, the research coordinator will contact the patient by phone and carry out the same process of troubleshooting or registering withdrawal.

The main scenarios that might prompt early withdrawal are: 1) the patient voluntarily withdraws because he or she finds data tracking and submission too cumbersome or 2) the patient becomes incapable of submitting further data. There are no safety concerns that would necessitate study withdrawal. In the first scenario, the patient can simply cease reporting/recording data as above and sacrifice any further financial awards that might have been earned. If the second scenario occurs in the hospital, research staff will continue to submit data on the patient's behalf unless he or she expresses an objection. If the second scenario occurs after discharge, the participant or research staff may arrange for assistance from friends/family in submitting data. If such assistance is not possible or not desired by the participant, the participant will be withdrawn from the study.

6. Vulnerable Populations:

Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study

7. Populations vulnerable to undue influence or coercion:

This study is unlikely to involve populations considered to be vulnerable to undue influence, including children, prisoners, pregnant women, mentally disabled persons, or employees or students of Penn. It may involve economically or educationally disadvantaged persons inasmuch as these populations are part of the usual patient population seen in our clinic. Since recruitment and education will be performed in one-on-one sessions, education regarding the study and its goals can be tailored to the appropriate learning level and style. Financial incentives are nominal and not expected to unduly influence economically disadvantaged participants.

STUDY DESIGN:

In this application, we propose a randomized controlled trial to test the hypothesis that small financial incentives can be used to increase post-operative ambulation. The randomized controlled trial design is necessary to demonstrate a causal relationship between the intervention (provision of financial incentives) and the outcome (increased ambulation). This design will also provide preliminary data (e.g. effect sizes, feasibility) needed to design larger trials that will determine whether increases in ambulation produced by financial incentives can be translated into decreases in clinically relevant outcomes such as post-operative complications, readmissions, and functional decline in patients undergoing major abdominal surgery.

All participants will receive education about the importance of early ambulation and knowledge of their daily step goals. Goals will be based on data collected during a lead in period during which patients' daily activity levels will be tracked to measure baseline step counts. Specifically, goals will be defined as 10%, 25%, 40%, and 55% of baseline during post-operative days 1-7, 8-14, 15-21, and 22-30 respectively. These are based on the limited experience in the literature with post-operative step-counting as well as our clinical experience with this population at HUP.⁴²⁻⁴⁵ A Fitbit Zip, a commercially available activity tracking device with the ability to record and wirelessly upload step counts, will be provided to each participant to measure the outcome of daily step counts for a lead in period of 1-2 weeks before surgery and 30 days after surgery with the option for patients to continue to submit data independently for up to 90 days after surgery. Data will be collected using the Way To Health platform, a digital platform specifically designed to facilitate randomized controlled trials testing interventions increase health-promoting behavior.

Participants will be randomized using simple balanced randomization into one of two arms: "control" or "financial incentives". Participants randomized to the financial incentives arm will receive daily payments of \$1.50 (with 100% probability)²⁶ for each day in the first 30 days after surgery that they achieve their daily step goals. Individuals will be informed if they fail to achieve adequate steps and would have otherwise been eligible for payments in order to leverage regret aversion. We chose to frame the financial incentive as a "gain" rather than a "loss"³⁰ because striving to achieve a positive reward may provide the necessary support to positively motivate patients who just had major, painful surgery.³⁴ Through a lottery, each participant who achieves 75% of the daily goals will also be eligible for a 1/5 chance of receiving \$100 at the end of the study period. We combine small definite payments with larger lottery-based payments to provide ongoing feedback coupled with the possibility of winning a higher magnitude reward. Automated notification about payments will be delivered through the participant's preferred mode of communication (e.g., phone call, email). Patients will track their earnings and step count over time through WTH.

Investigators, statisticians, and clinical staff will be blinded to participant group assignments. The research coordinator, however, will be unblinded by necessity. Participants similarly must be unblinded to their incentive structure, however they will not be told the incentive structure of the other group, nor whether their group is designated the treatment or control group.

Implementation of this project will occur in four phases.

- Phase 1: Preparation. (Study Approval – July 2016). During this phase, a research coordinator will be hired, equipment will be purchased, and all systems will be tested to ensure basic functionality prior to recruitment of the first participant.
- Phase 2: Recruitment. (July 2016 – June 2017). This phase describes the up to 10 month recruitment period during which patients will be screened and enrolled on a rolling basis into the trial.
- Phase 3: Data acquisition. (Enrollment – 30 days post-operative). This phase, which will overlap with phase 2 and start at a different time for each participant, describes the period for each participant in which they are enrolled and actively encouraged to submit data via the Way to Health platform and via interviews by the research coordinator. This phase bounds the total time commitment for any single study participant.
- Phase 4: Optional additional data submission and final survey (31 days post-operative to 90 days post-operative). This phase describes a period where patients will be allowed to continue to access the Way to Health platform and submit data should they choose to do so. No financial rewards or active encouragement will take place during this time. A final survey will be administered at the conclusion of this 90 day period to capture mid-term outcomes and complications.
- Phase 5: Analysis and Publication (Enrollment completion – December 2017). Final analysis of all acquired data is projected to be complete and ready for submission for publication by the end of 2017.

METHODS:

1. Study Instruments:

- Beginning shortly before the planned surgery and continuing for 30 days after date of surgery, all participants will use Fitbit Zips to measure daily step counts. Patients will have the option of submitting up to 90 days of post-operative data. Post-operative ambulation has been repeatedly demonstrated to be beneficial to recovery by a number of different metrics, and the Zip device has been shown to be an accurate measure of step counts.^{4-10,31}
- The Stanford Health Assessment Questionnaire (SHAQ) is a broadly used and validated questionnaire which, in its shortened form, assesses subjects' ability to perform 20 different actions and the need for assistance with these actions. It also captures patients' global assessments of pain and well-being.³⁷ This will be administered preoperatively, 30 days post-operatively, and 90 days post-operatively to measure post-operative functional decline.
- The International Physical Activity Questionnaire (IPAQ) Short Seven Day form quantifies patient reported levels of physical activity over the seven days prior to the interview. It is similarly broadly used and has been previously validated against accelerometer data.³⁸ This will be administered preoperatively, 30 days post-operatively, and 90 days post-operatively to measure post-operative decline in physical activity and to discover differences in baseline physical activity that are not captured by preoperative step-count data.
- The Multidimensional Scale of Perceived Social Support (MPPSS) is a validated tool for assessing patient's self-assessed degree of support from others.³⁹ Prior research has suggested social support as an important factor in exercise behavior, which is consistent with our clinical observations.⁴⁰ This will be administered pre-operatively and at 30 and 90 days post-operatively to help account for confounding by this important and otherwise unmeasured variable.
- Barriers to ambulation in the hospital: Previous work has attempted to identify modifiable factors that prevent inpatient ambulation.⁴¹ Based on the factors identified in this study, we will ask participants to respond to a simple questionnaire consisting of a five-point Likert scale from "was a major barrier that prevented me from walking" to "was not a barrier that prevented me from walking". The prompts will be as follows: "Physical discomfort (e.g. pain, weakness, shortness of breath)", "Cumbersome medical devices (e.g. IVs, catheters, monitors)", "Fear of falling", "Lack of assistance from people", "Social discomfort/embarrassment", and "Lack of desire/motivation".

2. Group Modifications:

No modifications necessary.

3. Method for Assigning Subjects to Groups:

Subjects will be assigned to groups using simple balanced randomization. Upon enrollment in Way To Health, patients will be automatically randomized into "financial incentives" and "control" arms by an off-site computerized randomization system which is part of the WTH platform.

4. Administration of Surveys and/or Process:

Step count data will be recorded and uploaded independently by participants after initial instruction by the research coordinator. Before and after hospitalization, the research coordinator will ensure that patients are successfully uploading data and will be available to address issues that arise.

Questionnaires will be administered via the Way To Health platform. At the specified time points in the study (initial enrollment, immediately prior to discharge from the hospital, 30 days post-operative, and 90 days post-operative) the patient will be prompted to log in to the platform and fill out the questionnaire. Responses will be automatically recorded to the secure database.

Patients will also be contacted by phone at 30 days and 90 days by the research coordinator to screen for complications that would not be present in the University of Pennsylvania Health System (UPHS) electronic medical record (EMR).

5. Data Management:

Data will be collected principally through the Way to Health platform, which is a web-based platform designed by the University of Pennsylvania Center for Health Incentives and Behavioral Economics specifically for the purpose of testing behavioral interventions such as ours in an academic research setting. This platform has already been used in a number of similar IRB-approved randomized trials at the University of Pennsylvania.

All data not stored on WTH will be stored on hospital or university-owned computers or on encrypted storage drives. Data access will be granted only as needed to a small number of researchers who have completed the appropriate training as mandated by the University of Pennsylvania.

Upon completion of the study, data collection sites will be taken down and data stores disconnected from live web servers. Data will be stored on research computers for a period of 5 years, after it will be stored entirely on encrypted archival drives if no follow-up projects have been initiated.

6. Subject Follow-up:

Participants enrolled in the data-collection phase of the study will be required to upload step count data daily to the Way to Health Website. Upload rates will be monitored and participants who fail to upload data for 24 hours will be contacted via their preferred contact phone number listed in the electronic medical record. The research coordinator will attempt to reach the participant daily for 3 days by phone, email, and the MyPennMedicine secure messaging service. If there is no response, the participant will be considered to have declined further participation. A final attempt will be made to contact the participant for the study conclusion interview. Regardless of participation status at the study conclusion, a check for all earned funds will be mailed to the study participant at the conclusion of the 30 day trial period. If participants stop uploading data daily but it can be confirmed that they are continuing to use the Zip device, arrangements may be made to upload the data for the study period in batch within 10 days of the conclusion of the study and allocate financial rewards according to the data collected.

STUDY PROCEDURES:

1. Detailed Description:

Participants will be enrolled on a rolling basis as they are identified. The following describes the sequence of steps for each participant

1. A potential participant is scheduled for radical cystectomy by the clinical staff. The surgical case is entered into the University of Pennsylvania Health System's electronic medical record by a Division of Urology surgery scheduler.
2. The research coordinator, with the assistance of clinical staff, reviews the surgery schedule on a weekly basis to detect patients who have been scheduled for radical cystectomy. Clinical staff are asked to alert the research coordinator if a patient is scheduled for cystectomy with a short lead time prior to the procedure. When a new case is scheduled, the coordinator reviews the patient's chart for eligibility.
3. If the patient is deemed eligible and has an upcoming PAT or stoma-marking appointment, the patient is met by the research coordinator after the appointment. Consent is obtained, preoperative questionnaires are administered (see schedule below), the patient is given the Fitbit device, the patient is registered with WTH, randomization occurs, and the patient is instructed on how to upload data. Data collection begins immediately and preoperative step counts are uploaded to the WTH website. Patients with ECOG performance status greater than or equal to 3 will be screened for by review of the medical record and by asking patients to select which of the first four statements in the performance status best describe them.
 - a. In the event that eligible patients are identified with no PAT or stoma-marking visit prior to surgery, the patient will be contacted by phone. Preliminary verbal consent will be obtained, questionnaires will be administered, the patient will be registered with WTH and randomized and the Fitbit device will be mailed to the patient's home. Consent is finalized in the preoperative holding area.
4. The research coordinator will monitor the data being uploaded to WTH and follow up as needed with the patient to ensure that he or she is able to begin tracking and uploading step counts.
5. Demographic information for the participant is abstracted from the medical record and recorded along with questionnaire and randomization arm in the study database.
6. On the morning of the first post-operative day, the research coordinator explains the financial reward scheme specific to the patient's randomization arm.
7. The initial \$25 compensation for participation will be written and sent upon submission of the patient's preoperative step data.
8. In the morning of each day of the hospitalization, the research coordinator assists the patient in uploading the previous day's step-count data to the Way to Health website. The website provides feedback and allocates financial rewards into a virtual wallet. During this time, the research coordinator will also assess for safety and burden on the patient as well as assisting the patient in making any preparations to transition data collection to the home setting.
9. On the day of discharge, the patient will be prompted to respond to a brief questionnaire addressing perceived barriers to ambulation in the hospital.

10. After discharge, participants resume independently for uploading their daily step count data. The website continues to provide feedback with each upload and may be accessed *ad lib* should participants want to check their progress and rewards more frequently. Data collection continues through the 30th post-operative day.
11. On the 31st post-operative day, the WTH platform prompts the participant to fill out questionnaires according to the schedule below. On the business day following the 31st post-operative day, the research coordinator will also contact the patient to inquire about any hospitalizations, stays at skilled nursing facilities or rehab facilities, emergency room visits, or unplanned doctor visits occurred since discharge and relevant medical records will be obtained if these are not already available through the UPHS EMR. Contact information is updated as needed, and financial awards are mailed in the form of a bank check to the participant's preferred mailing address. The research coordinator will follow up with patients to ensure the questionnaires are completed.
12. Participants are allowed to continue collecting and uploading data through WTH for 90 days post-operatively, although no further financial incentives or monitoring by the research coordinator will be provided.
13. On the 91st post-operative day, the patient is prompted to fill out questionnaires according to the schedule below. This will include a brief section addressing continued personal use of the Fitbit or another personal activity tracking device. On the business day following the 90th post-operative day, the research coordinator contacts the participant by phone to screen for uncaptured complications.

The schedule for questionnaires will be as follows:

- Initial contact (PAT visit, stoma-marking visit, or phone): SHAQ20, IPAQ, MPPSS
- Day of discharge: barriers to ambulation in the hospital
- 30 day post-operative phone call: SHAQ20, IPAQ, MPPSS, screen for uncaptured complications
- 90 day post-operative phone call: SHAQ20, IPAQ, MPPSS, screen for uncaptured complications

2. Data Collection:

This study does not involve the analysis of existing data, blood, or tissue specimens. It will involve review of the patient's University of Pennsylvania Health System electronic medical record at several points in the study. After the patient is scheduled for cystectomy, the record will undergo screening for eligibility. No data will be abstracted from the record at this point. After enrollment the chart will be reviewed again for demographic information and past medical history which will be abstracted into the research database. It may also be reviewed as necessary during the course of the study to ensure ongoing safety of participants. Finally, the record will be reviewed at the conclusion of the study to assess for complications. In the case of missing or contradictory data, the electronic medical record may be referenced to ensure the quality of collected data after the end of the study, but these reviews shall not substantially expand the scope of the data collected beyond demographic information, vitals, and past medical history present at time of study initiation.

3. Genetic Testing:

Not applicable

4. Use of Deception:

Not applicable.

5. Statistical Analysis:

We will use generalized estimating equations with participant random effects and fixed effects for time to determine the association between financial incentives and 1) achieving step goals, 2) mean number of steps taken, 3) complications, ED visits and hospital readmissions, and 4) functional decline.

As a pilot study, the proposed research will provide preliminary data (*e.g.* effect sizes, feasibility) needed to design larger trials that will determine the effectiveness of financial incentives to increase ambulation on decreasing post-operative complications, readmissions, and functional decline. This study was therefore not powered to detect a statistically significant difference between the groups.

RISK/BENEFIT ASSESSMENT:

1. Risks:

The primary risk is that the interventions taken in this trial result in behavioral changes that are actually deleterious to patient recovery. In theory, increased ambulation may lead to increased falls, increased pain, herniation or other wound

complications, etc. None of these outcomes would be consistent with current literature and are therefore considered highly unlikely.⁴⁻¹⁰ It is also possible that patients respond paradoxically to financial incentives or biometric monitoring and perform fewer of the desired behaviors. Finally, the psychological impact of our behavioral tools is incompletely understood: while subjects in other studies usually report finding financial incentives to be positively motivating and even empowering, failure to achieve objectives may lead to feelings of guilt or shame. Overall the risk of participation is considered low.

2. Benefits:

The primary goal of the randomized portion of the study is to develop strategies to motivate patients to increase behaviors that are beneficial to their post-surgical recovery in the short term. The benefits of post-operative early ambulation are well documented and include decreased risk of serious complications such as venous thromboembolism (e.g. deep venous thrombosis, pulmonary embolism), pneumonia, and post-operative deconditioning. Participation in the study alone is likely to increase ambulation via a Hawthorne effect, and a subset of patients will further receive direct financial benefit for engaging in this beneficial behavior.

3. Subject Privacy:

Subject privacy will be maintained by limiting subject-researcher interaction to settings which are already deemed appropriate for clinical interactions, namely outpatient clinics, telephone conversations, the preoperative holding bay, and hospital rooms. The Way to Health website is also specifically designed to allow for confidential upload of information. Step counts, a novel piece of data about subjects which would not otherwise be recorded, will be exposed only to the patient, the research coordinator, and the Way to Health website unless the patient chooses to share that information with others.

4. Subject Confidentiality:

How will confidentiality of data be maintained? Check all that apply.

- Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
- Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- Whenever feasible, identifiers will be removed from study-related information.
- A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
- A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)
- Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
- Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

5. Protected Health Information

The following elements of PHI will be explicitly recorded:

- Name
- Street address
- All elements of dates (except year) for dates directly related to an individual and all ages over 89
- Telephone numbers
- Electronic mail address
- Medical record number
- Device identifiers/serial numbers

6. Compensation:

All participants who enroll, complete the initial education, and provide a single day of step count data will keep their assigned Fitbit Zip device and will receive \$25 in cash on the second post-operative day. All participants who complete the study and have recorded step count data for at least 27 days (90%) will receive another \$75. Finally, participants who are randomized to the financial incentives arm will have the opportunity to earn an additional \$145 for meeting daily step goals (\$1.50/day plus a 1 in 5 chance at \$100). The final \$75 for study completion in addition to the earned financial rewards will be mailed as a check within 10 days of completion of the 30 day post-operative study period.

7. Data and Safety Monitoring:

Patients participating in the study will initially be subject to the intensive monitoring of the post-operative acute care hospital setting. Safety issues caused by the study are very likely to be detected early in this environment. Dr. Guzzo is already highly involved in the care of these patients, and as the principal investigator responsible for clinical implementation, he will be immediately available to the staff who may report safety issues that arise during study implementation. Safety issues may also be detected by or reported to the research coordinator who will see the participants daily during their hospitalization. Given the relatively small sample sizes, no interim analyses are planned, however data will be assessed for quality on a continuous basis.

8. Investigator's Risk/Benefit Assessment:

The benefits of participation in this study dramatically outweigh the risks from both the perspective of the individual participant and from the perspective of the cystectomy patient population in general. Participants are likely to be motivated to engage in activities that will prevent major complications and speed recovery at the cost of minimal inconvenience, risk of breach of privacy, and possible psychological stress.

INFORMED CONSENT:

1. Consent Process:

Eligible patients will be approached following their PAT or stoma-marking visit. A medical interpreter will be used if such was deemed necessary during the patient's clinical visit. The research coordinator will identify him or herself as an employee of the University of Pennsylvania working with the Division of Urology on research to promote improved surgical outcomes in patients undergoing radical cystectomy. It will be emphasized that participation is entirely voluntary and that declining enrollment will not have any other effects on the patient's clinical care. The patient will be given the opportunity to ask questions and informed consent will be obtained. Consenting participants will respond to questionnaires, will be given the Fitbit, will be enrolled in WTH, and will be instructed on the use of the device.

For patients who do not have a PAT or stoma-marking visit, the research coordinator will attempt to reach the patient via his or her preferred telephone number in the medical record. A medical interpreter will be used if such was deemed necessary during the patient's clinical visit. The research coordinator will identify him or herself as an employee of the University of Pennsylvania working with the Division of Urology on research to promote improved surgical outcomes in patients undergoing radical cystectomy. He or she will identify the purpose of the call, to gauge interest in participation in a clinical trial investigating the effect of financial rewards on promoting behaviors that improve post-operative recovery. It will be emphasized that participation is entirely voluntary and that declining enrollment will not have any other effects on the patient's clinical care. If the patient expresses interest, a brief overview of the project will be provided in laymen's terms. The patient will then be given the opportunity to ask questions or schedule another time for further discussion. Questionnaires will be administered over the phone and the Fitbit will be mailed to the patient's house with instructions to begin data recording and uploading. Informed consent documents will be signed in the preoperative holding area on the day of surgery. This process of preliminary phone consent is necessary in order to obtain preoperative ambulation data. Data will be discarded from any patient who agrees to participate over the phone but ultimately declines participation prior to signing the formal consent documents.

At the time of initial contact, all participants and potential participants will be given a secure email address and phone number that can be used to contact the research coordinator with any questions that might arise before, during, or after the study period.

All adult subjects will be competent to consent. Assessment of competency is made by the clinical team at the time of consent for surgery. Only adults who sign their own consent form for radical cystectomy will be considered competent to consent for this study.

2. Waiver of Informed Consent:

Not applicable. No waiver is being sought.

RESOURCES NECESSARY FOR HUMAN RESEARCH PROTECTION:

Research staff will include the two Principal Investigators, Gregory Tasian and Thomas Guzzo, at least one resident physician, and at least one research coordinator. The last of these will be hired as 0.75 of a full time employee. All project members in this small team will be intimately involved in the design and implementation of protocols. The Co-PIs will be jointly responsible for overseeing project planning, strategy, and operations. Dr. Guzzo will be the clinical operations leader at UPHS and will be primarily responsible for resolving clinical questions about eligibility for study participation and developing effective communications with participants. Dr. Tasian will hold primary responsibility for coordination of the research activities with Way To Health, designing the structure of the financial incentives, and overseeing data analysis. Both co-PIs have completed fellowships including at least 1 year of dedicated research time and have earned advanced degrees in the design and implementation of clinical studies. Dedicated research space is available at the offices of the Division of Urology in the Perelman Center for Advanced Medicine, which will be sufficient to provide working space for dedicated research personnel and to provide storage space for the Zip devices, documentation, and a small amount of peripheral equipment that may need to be purchased.

The target population is adults undergoing radical cystectomy (RC) at the Hospital of the University of Pennsylvania (HUP). 75-100 patients undergo RC at HUP each year. We anticipate recruiting and retaining 50% of eligible patients (n=46) over a one year enrollment period. Each patient will be followed for 30 days post-operatively with the option for patients to continue submitting data for up to 90 days after their procedure. We anticipate initiating recruitment in July of 2016.

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