A pilot study to determine the efficacy of continuous ambulatory wearable technology and a cascading alert system in reducing 30d readmission in high risk medical and surgical patients.

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Contents

RESEARCH PLAN

1.1 Summary

We propose to test our central hypothesis that readmission and post-discharge utilization in high risk medical and surgical patients can be reduced by using a vendor platform (PinpointIQ from the company physIQ) that involves wearable sensors (Vital Patch) that collect real-time, continuous ambulatory vital signs, a mobile device that collects patient reported outcomes and machine learning algorithms in the cloud that identify patients at risk of physiologic perturbation. Data from this vendor platform will be tied to operational workflows at NorthShore that involve a monitoring nurse who then conveys information to the clinical team as necessary in a cascading alert system.

1.2 Background and Significance

Hospital readmissions are common and costly and are increasingly being used as a metric for quality care. With the passing of the Affordable Care Act (ACA) hospital readmissions were targeted with the Hospital Readmission Reduction Program (HRRP) in which hospitals are penalized for higher than expected readmission rates.[1] Significant effort has been devoted to understanding how to reduce readmissions and utilization. To date there has been limited work looking at how wearable sensors that monitor physiologic data continuously and remotely can identify physiologic perturbation allowing care providers ample time to intervene and prevent decompensation and readmission.

Monitoring of vital signs for hospitalized patients to detect decompensation is checked manually and intermittently (spot check) for the majority of patients. When patients are discharged, vital signs are frequently not monitored in the 30-day readmission window. This lack of monitoring in the post discharge period may prevent identification of patients at risk of decompensation and readmission. When spot vitals are monitored at home, reductions in readmission rates for certain populations have been seen.[2-4]

New technology in wearables coupled with machine learning algorithms is able to detect vital signs remotely and continuously and correlate the output with signals that may indicate risk of physiologic perturbation.[5-17] Various studies have looked at how continuous monitoring of vitals can identify patients in the hospital quicker and more effectively than nurse driven spot checks of vital signs.[18-28] There is a lack of data on using these devices upon discharge to evaluate for decompensation and prospectively trying to reduce readmissions. Similarly, there is a lack of data in tying these devices to a cascading and escalating alert system to identify patients at risk of decompensation. There is qualitative data on looking at how wearables are perceived by providers and patients in the hospital[29-30] but there is a lack of data on perception of this technology for remote monitoring.

Postoperative ileostomy patients are frequently readmitted because of physiologic perturbation[31-35] and has readmission rates between 15-30% at NorthShore. Ileostomy patients are readmitted because of dehydration.[33-35] There has been early work establishing the predictive potential of multivariate physiological telemetry (pinpointIQ) from a wearable sensor providing accurate early detection of impending rehospitalization for postoperative ileostomy with a predictive accuracy comparable to implanted devices. [39] This population may benefit from remote continuous monitoring of vital signs tied to a cascading alert system to identify patients at risk of impending decompensation. There is limited literature looking at how continuous monitoring, ambulatory wearable devices can improve outcomes in high risk patients.

We propose conducting a mixed-methods study that will use a wearable device to collect ambulatory physiological data analyzed by a machine-learning algorithm to identify readmission risk. The alerts will be tied to a cascading escalation pathway that involves monitoring nurse, mid-level providers, specialists, and surgeons. We describe the quantitative and qualitative aspects of the study in detail below.

QUANTITATIVE

2.1 Quantitative Research Aims – Ileostomy Cohort

Aim 1: Determine if wearable technology deployed for 30 days in a high-risk patient population can augment 30-day readmission risk prediction and improve care processes via an escalating feedback protocol.

Aim 2: Understand and finalize thresholds and criteria for alert system at the levels of Vital Patch, physIQ's pinpointIQ, monitoring RNs for ileostomy patients

Aim 3: Finalize process maps and workflows for nurse navigators and clinical care teams that optimize identifying high risk patients while minimizing provider burden

Aim 4: Calculate the return on investment of the remote monitoring solution

Aim 5: Perform a deep analysis of the full process to understand effectiveness, feasibility, efficiency and bottlenecks

2.2 Experimental Plan and Methods

The goal of the study is to reduce readmission rates for high risk medical and surgical patients. The goal of the study is to understand how physIQ's platform Pinpoint IQ with a cascading set of alerts including the wearable device alerts, patient reported metrics, CAPE navigator or monitoring nurse alerts can be developed and improved upon to reduce the incidence of 30 day readmission. We will be enrolling 10 colorectal (post ileostomy formation) patients who will be using a standardized set of cascading alerts that have been fine tuned with the goal of reducing decompensation and 30-day readmissions.

Ileostomy

For the colorectal patients, we will attempt to enroll every patient that has a colectomy followed by ileostomy formation. These will be patients of Drs. Joseph Muldoon, Monika Krezalek, and James Spitz and will be at Evanston, Glenbrook, and Highland Park hospitals. The colorectal surgeons will notify the study team when a patient has undergone surgery and the research coordinator will perform recruitment. Patients will be approached by the study coordinator who will perform informed consent. If the patient is agreeable the patient will receive a kit from physIQ prior to discharge. A Vital patch will be placed on the patient prior to discharge and the patch will be connected via blue tooth to the physIQ mobile device and pinpointIQ application. The study coordinator will teach the patient how to apply and remove the patch and what to do if there are issues with the patch. The study coordinator will also teach the patient how to use the mobile device and the physIQ application. This will also occur immediately prior to discharge.

On discharge colorectal patients will be asked questions every morning and every afternoon from the pinpoint IQ application. The pintpoint IQ platform will query patients about their ostomy output every

morning. We would also ask if the patient has any infectious symptoms such as fever, discharge or redness around the incision site or stoma and if the patient has any dehydration symptoms such as decreased urine output, dark urine, or obstruction and other alarming symptoms that the team would like to know about. In the afternoon, the symptom questions will be asked again. The monitoring nurse will evaluate the pinpoint IQ in the morning after the patient has filled out the questionnaire and in the afternoon after the patient has filled out the symptom question again. They will evaluate the responses to the questions and the physiologic alerting system built by physIQ. There will again be an algorithm built within physIQ's system that provides an alert to the monitoring nurse if the criteria from Table 4 are met.

(Output volume - Morning question once a day)

Question 1: What is your ostomy output volume in the last 24 hours?

(Yellow and Red Zone symptom questions twice a day – 8am and 3pm)

Question 2: Do you have the following symptoms?

- Eating and drinking make you nauseous or vomit
- You notice dark urine or less urine
- You can't eat or drink anything for 12 hours
- You have a fever over 101.5F

Question 3: Please select if you are experiencing following symptoms:

Your surgical wound is:

- Red
- Leaking liquid, blood, or pus
- Opening up or getting worse

Question 4: Please select if you are experiencing following symptoms:

Your belly is:

- Swelling up and feels very firm
- Hurting and the pain medication don't help

Question 5: Please select if you are experiencing following symptoms:

Your ostomy is:

- Leaking, or your appliances do not stay on, or you are changing your pouch more than twice a day
- Putting out more stool than usual
- Not putting out stool or gas (bag filled with air) for 6 hours

Questions 6: If you choose any of the above symptom(s), are the symptoms getting better, worse, or the same?

- Better
- Worse
- Same
- Non Applicable

Question 7: If you experience the following symptoms, please call your nurse or doctor immediately, or go to the emergency room right away:

- You have trouble breathing
- You are having chest pains
- You have no urine output in 12 hours
- You are passing out

physIQ Alert System – Ileostomy
Patients:

Any positive symptom (dehydration,infection, or obstruction)
≥1200 ml ostomy output over one day
A high risk alert
A predefined number of standard alerts in a day

Table 4: PhysIQ alerts system for CAPE navigator or monitoring nurse for Ileostomy

For ileostomy the thresholds for the high-risk alerts and the number of standard alerts may be changed from patient to patient based on how each case progresses and the density and frequency of alerts. Determining the optimal thresholds for these two types of alerts will be a key aim of this study The goal is again maximizing signal while minimizing noise.

If any of these conditions listed in Table 4 are met the monitoring nurse will call the patient and go through a predefined note with the following data elements and questions.

Infection Symptom

a) Fever
b) Dysuria
c) Redness at ostomy site
d) Drainage or swelling at ostomy site
e) Other (Free Text)

Obstruction Symptom

a) Nausea
b) Vomiting
c) Bloating
d) Decreased or no ostomy output
e) No gas through ostomy

Dehydration Symptom

a) Lightheadedness
b) Dry mouth
c) Low or dark urine output
d) Dizziness
e) Increased ostomy output

Symptom Change (Obstruction, Dehydration, Infection) [This can show up if any symptom is picked]

1. New
2. Worsening
3. Stable
4. Improving
5. Resolved

Ostomy output

a) 500-1200cc
b) >1200cc
c) <500cc

Is patient NPO? Yes/No

Is patient on antibiotics? Yes/No

Patient is on stool thickening regimen?

a) None
b) Metamucil powder 1 tsp bid
c) Immodium 2mg bid w/ meals (20 mins before meals)
d) Immodium 2mg qid w/ meals (20 mins before meals)
e) Immodium 4mg qid w/ meals (20 mins before meals)
f) Stool thickening managed by clinical team

Alerts:

a) MCI alert
b) Afib with RVR alert
c) Tachypnea alert (First, frequent, increasing density, other alerts also present, no other concerning pulmonary comorbidities)

d) Tachycardia alert (First, frequent, increasing density, other alerts also present, no other concerning Comorbidities or ostomy output uptrending or near 1200cc threshold)
e) Other physiologic alert

FOLLOWUP PLAN

1. Case Communication to Clinical RN
2. Case Communication to Ostomy RN
3. Call Clinical RN
4. Call Ostomy RN
5. Consider Call Clinical RN
6. Evaluate trend of ostomy output
7. Stool thickening initiation Metamucil powder 1 tsp bid
8. Stool thickening escalation Immodium 2mg bid w/ meals (20 mins before meals)
9. Stool thickening escalation Immodium 2mg qid w/ meals (20 mins before meals)
10. Stool thickening escalation Immodium 4mg qid w/ meals (20 mins before meals)
11. Stool thickening escalation management by clinical team
12. IV fluids administration
13. Consider IV fluids administration
14. Consider Lab tests BMP, Mag, Phos
15. Consider Lab test CBC
16. Advance Diet as Tolerated (Clear liquids for 6 hours and then advance as tolerated to low residue diet)
17. Continue NPO status
18. Possible urgent clinic evaluation
19. Assess for home visit

LOGIC:

a) MCI, Afib w/ RVR, Tachycardia, Tachypnea (1, 3, 6)
b) Other physiologic alert (5)
c) Ostomy output >1200cc and patient on no stool thickening regimen (1, 5, 7, 13)
d) Ostomy output >1200cc and patient on metamucil stool thickening regimen (1, 5, 13, 8)
e) Ostomy output >1200cc and patient on immodium 2mg bid stool thickening regimen (1, 5, 13, 9)
f) Ostomy output >1200cc and patient on immodium 2mg qid stool thickening regimen (1, 5, 13, 10)
g) Ostomy output >1200cc and patient on immodium 4mg qid stool thickening regimen (1, 3, 13, 11)
h) Ostomy output <500cc (1, 3)
i) Has ANY Obstruction symptom, NEW, or WORSENING Obstructive Symptom, Patient not NPO (1, 3, 14)
j) Has ANY Obstruction symptom, RESOLVED Obstructive Symptom, Patient not NPO (1)
k) Has ANY Obstruction symptom, NEW or WORSENING Obstructive Symptoms, Patient NPO (1, 3, 14, 17)
l) Has ANY Obstruction symptom, STABLE or IMPROVING Obstructive Symptoms, Patient NPO (17)
m) Has ANY Obstruction symptom, RESOLVED Obstructive Symptoms, Patient NPO and Ostomy output 500-1200 (1, 3, 16)
n) Has ANY Obstruction symptom, RESOLVED Obstructive Symptoms, Patient NPO and Ostomy output >1200, patient not on stool thickening regimen (1, 3, 16)

o) Has the following Infectious symptoms (Redness at ostomy site, Drainage or swelling at ostomy site), NEW OR WORSENING Infectious Symptoms, Patient not on antibiotics (2, 4, 15)
p) Has the following Infectious symptoms (Redness at ostomy site, Drainage or swelling at ostomy site), RESOLVED Infectious Symptoms, Patient not on antibiotics (2)
q) Has the following Infectious symptoms (Redness at ostomy site, Drainage or swelling at ostomy site), NEW OR WORSENING Infectious Symptoms, Patient on antibiotics (2, 4, 15, 18)
r) Has the following Infectious symptoms (Redness at ostomy site, Drainage or swelling at ostomy site), RESOLVED Infectious Symptoms, Patient on antibiotics (2)
s) Has the following Infectious symptoms (Fever, Dysuria or Other), NEW,WORSENING, IMPROVING, OR STABLE Infectious Symptoms, Patient not on antibiotics (1,3, 15)
t) Has the following Infectious symptoms (Fever, Dysuria or Other), RESOLVED Infectious Symptoms, Patient not on antibiotics (1)
u) Has the following Infectious symptoms (Fever, Dysuria or Other), NEW OR WORSENING Infectious Symptoms, Patient on antibiotics (1,3, 15, 18)
v) Has the following Infectious symptoms (Fever, Dysuria or Other), RESOLVED Infectious Symptoms, Patient on antibiotics (1)
w) Has ANY Dehydration symptom, NEW, or WORSENING Dehydration Symptom, Patient not NPO (1, 3, 12, 14)
x) Has ANY Dehydration symptom, STABLE OR IMPROVING Dehydration Symptom, Patient not NPO (1, 5, 13)
y) Has ANY Dehydration symptom, RESOLVED Dehydration Symptom, Patient not NPO (1)

Table 5: CAPE Navigator or monitoring nurse alerts system for clinical team for Ileostomy

Table 5 will be configured into a note template within EPIC that allows for data elements to be captured and have all the logics built in to automatically highlight the recommended options for the monitoring nurse. The EHR smart note will be tested out by the research team to ensure the logic is correct.

If patients have any high risk alerts (MCI, Afib with RVR, Tachycardia, Tachypnea), the monitoring nurse will route a note and call clinical RN and evaluate the trend of ostomy output. All other physiological alerts will result in consideration call to clinical RN.

If patient ostomy output >1200cc and patient not on stool thickening regimen yet, the monitoring nurse will send note and call clinical RN, consider IV fluids administration and start stool thickening regimen escalation. Monitoring RNs will call cinical RNs for guidance on IV fluid administration guidance. The stool regimen escalation can occur daily while the output is ≥1200ml in 24 hours. There is no monitoring nurse de-escalation protocol, and this will be performed by the clinical team. If a patient is non-adherent to Metamucil and/or Imodium and output is ≥1200ml in 24 hours, medications will be maintained without escalation and patient will be counseled on the importance of adherence to medications. If the output continues to be greater than ≥1200ml in 24 hours and there are no further options for escalation, the monitoring nurse will call the clinical care team for further guidance.

If ostomy output is <500cc, monitoring nurse will route note and call clinical RN. If patient has any new or worsening obstruction symptom but **not NPO** yet, monitoring nurse will route note and call clinical RN, and consider lab tests (BMP, Mag, Phos). If the obstructive symptoms resolve while patient is NPO, home healrh RNs will route not to clinical RN.
If patient has new or worsening obstruction symptoms but **is NPO already,** monitoring nurse will note and call clinical RN, consider lab tests (BMP, Mag, Phos), and continue NPO status. If patient obstruction

symptom is stable or improving under the NPO status, monitoring nurse will keep patient NPO. If patient has resolved obstructive symptoms, still NPO and ostomy output is >1200 cc or between 500-1200 cc, monitoring nurse will note and call clinical RN, and instruct patients to advance diet as tolerated.

Any new or worsening redness at ostomy site, drainage or swelling at ostomy site, but **patient not on antibiotics**, monitoring nurse will note and call the ostomy RN for guidance in management, and consider CBC labs. If the above symptoms resolve without antibiotics, home healrh RN will call ostomy RN to update.

If patient has new or worsening redness at ostomy stite, drainage or swelling at ostomy site, and is already on antibiotics, home healrh RNs will note and call ostomy RN, consider CBC labs and urgent clinic evaluation. If above symptoms resolve with antibiotics, home healrh RN will call ostomy RN.

Any new, worsening, improved or stable fever, dysuria or other infectious symptoms, but patient **not on antibiotics,** the monitoring nurse will note and call clinical RNs, and consider CBC labs. If the above symptoms resolve without antibiotics, the monitoring nurse will route note to clinical RN.

If patient has any new, worsening, improved or stable fever, dysuria or other infectious symptoms, **but is already on antibiotics,** the monitoring nurse will note and call clinical RNs, and consider CBC labs and urgent clinic visits. If the above symptoms resolve with antibiotics, the monitoring nurse will route note to clinical RN.

If patient has new or worsening dehydration symptoms, but not NPO, monitoring nurse will note and call clinical RN, consider IV fluids administration, and consider labs (BMP, Mag, Phos). If the dehydration symptoms are stable or improving while patient is not NPO, the home healrh nurses will route note to clinical RN, consider call clinical RN, and consider IV fluids administration under guidance of clinical team. When dehydration symptoms resolve, the home healrh RNs will route note to clinical RN.

We will be evaluating the high risk alerts and other physiological alerts to find the optimal alert types, thresholds and alerting frequency to maximize signal and minimize noise.

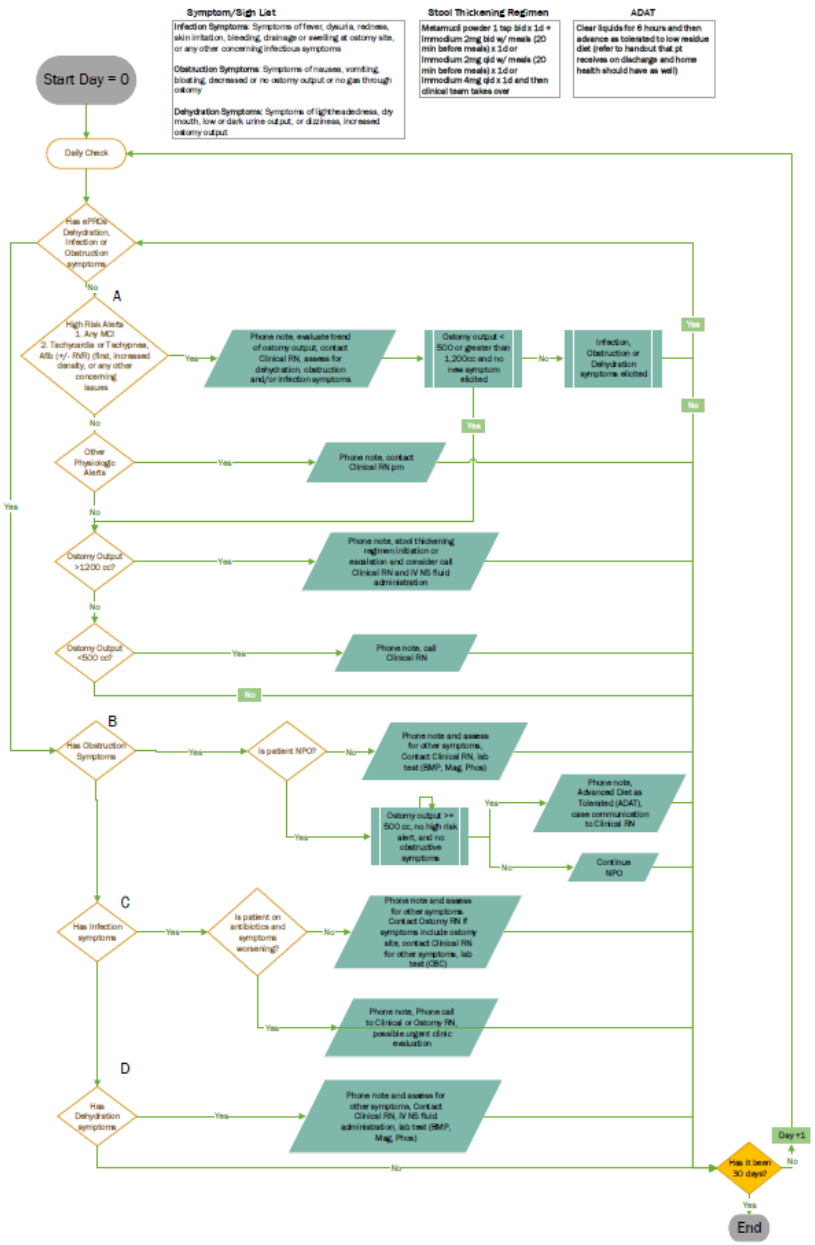


Figure 2: Process map for Ileostomy Patients

If care is escalated to the clinical care team which includes ostomy RNs, clinical RNs, and Physicians, the care team will pursue various interventions including counseling, altering medication therapy such as antibiotic therapy, procedures such as debridement or drainage, urgent visits to the colorectal surgery clinic ideally within 72 hours, and if no other available options readmission. These workflows will be left

to the discretion of the clinical care team given the nuance in taking care of these high-risk patients and the existing relationship and prior history with these providers. There are some standardized workflows that will be followed by the care team that are of note. Infusions of IV fluids will occur if the patient has ≥1200 ml of ileostomy output and dehydration symptoms. If these symptoms are identified, the goal will be to have monitoring nurse perform infusion at the patient's home. Also, all messaging from the monitoring nurses will be forwarded to the colorectal/ileostomy pool per protocol and logic in Table 5 to create the most rapid response back to the patient if required.

The final specs of the study will include:

1. Optimal inclusion/exclusion criteria.
2. Specific thresholds for high risk alerts for each use case
3. Specific thresholds for standard alerts (likely use physIQ standard thresholds)
4. Finalized physIQ alerts to CAPE navigators and monitoring nurse
5. Finalized CAPE navigator and monitoring nurse alerts to clinical care team
6. Finalized EPIC note
7. Finalized process maps
8. Finalized workflows by clinical care team
9. Discussion with physIQ to optimize the pinpointIQ portal to best support the CAPE navigators and monitoring nurse

The recruitment goals for this study is 10 ileostomy patients each for 30d of monitoring to evaluate if the remote monitoring technology from physIQ and cascading alert system and process can reduce 30-day readmissions. We will also perform economic calculations to determine if there is return on investment for this workflow tied to remote monitoring. Finally, we would like to do an in-depth analysis of the process to understand effectiveness, feasibility, efficiency, and bottlenecks. Some of the questions we would like to understand include: 1) What component of the cascading alert system provides the highest effectiveness of identifying patients at risk? 2) Can we reduce the number of monitored days and still effectively reduce 30 days of readmission? 3) Are there specific subgroups of patients who may benefit from the remote monitoring solution, or alternatively, are there subgroups who do not benefit from the remote monitoring solution? 4) Can we take our process maps and perform process simulation with data from the study and process mining to optimize our process and identify chokepoints with our current flow.

QUALITATIVE

3.1 Qualitative Research Aims

Receive provider and patient feedback on the application of wearable technology to post-discharge care to conduct a theory-driven evaluation of feasibility, usability, and effectiveness. We will address motivational and self-care issues at baseline, continuing and post-study from both providers and patients' viewpoints. 1) ascertain perceptions of telemonitoring and remote patient management of high-risk patients, of organization and effectiveness of care by providers using interviews and surveys; and 2) evaluate patient acceptance, perceptions of and satisfaction with wearable patches, with prompted requests for patient status information, and with escalation pathways for nurse navigators and physicians using interviews and survey tools.

3.2 Experimental Plan and Methods

We will assess remote monitoring combined with non-invasive wearable technology's potential by applying the Affective Adaptation of the Technology Acceptance Model (A/TAM).[52] We describe the approach to providers and patients in detail below. We stress that these will be linked to care delivery processes and the measures described above in the quantitative section to realize the full potential of a mixed-methods approach.

I. Ascertain providers' perceptions of telemonitoring and remote patient management of high-risk patients, organization, and effectiveness of care using interviews and surveys.

Provider induction (prior to patient enrolment): Provider induction will include an in-depth review of the wearable device, remote management, and escalation pathway, followed by an interview informed by A/TAM to establish each provider's comfort level (i) with wearable technology and any experience of such a device (e.g., habitual use of wrist-worn activity monitoring), and (ii) with wearable technology as a means of monitoring a post-discharge patient's status, including (iii) anticipated challenges in technology-mediated interaction with patients; and finally (iv) identification of any knowledge gaps that may need to be filled through the induction process.

Provider progress monitoring (throughout the trial period): Providers' progress and experience of the program will be assessed through: (a) a survey including open-ended questions with each provider following the completion of the study, to evaluate the extent to which anticipated issues and challenges may be realized. (b) a partly randomized, recurring opportunity to respond to one question once at the point of interaction with the patient; based on a matrix of questions, patients and providers, a single multiple choice question appears as part of a best practice alert to ensure that it is seamlessly integrated; nevertheless, collectively, all questions, all providers and all patients will receive adequate coverage.

Provider satisfaction (after the trial): At the conclusion of the study, providers: (a) will be debriefed through a comprehensive semi-structured interview to assess (i) their subjective perception of the effectiveness of wearable-mediated, post-discharge care; and (ii) actual challenges encountered in the course of the program (e.g., frequency of interaction, patients' comprehension of instructions, perception of patients' adherence, including any socio-emotional issues that may be impinging); (b) will participate in a post-trial half-day event to network with patients and the research team towards an open-ended

evaluation of the joint experience and to elicit opinions and contributions towards a follow-up randomized clinical trial proposal, and (c) will be invited to contribute to one or more joint evaluative publications.

A timeline illustrating provider related study activities can be found in Figure 4**.**

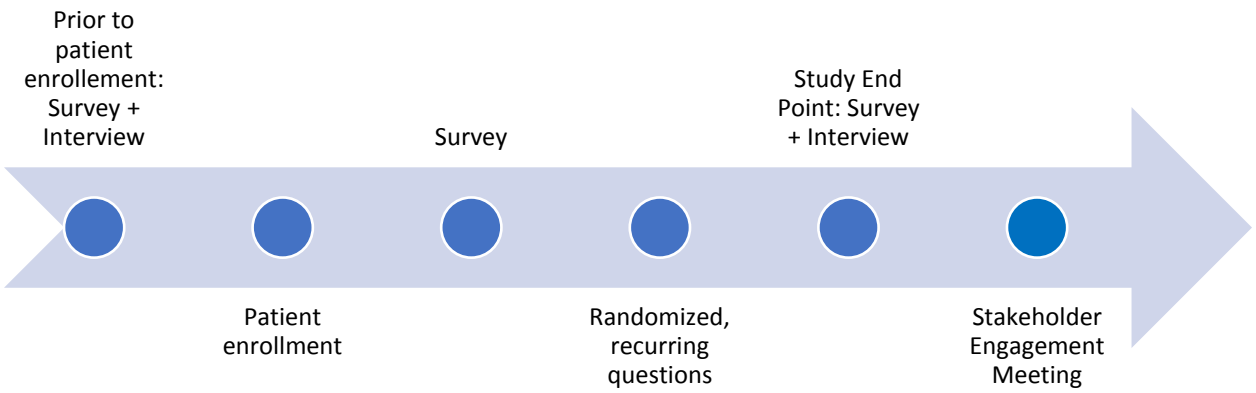


Figure 4 Provider Interview Timeline

II. **To evaluate patients' acceptance, perceptions of and satisfaction with wearable patches, with prompted requests for patient status information, and with escalation pathways for nurse navigators, midlevel providers and specialists.**

Patient enrollment (prior to discharge): Following a detailed presentation of the device and study, and informed consent, researchers will administer a questionnaire to establish the participant's comfort and experience level with a wearable device and to ascertain that the participant has understood the limitations of the devices (e.g. that they provide continual but not constant, "real-time" monitoring) prior to hospital discharge. This will be followed by an in-person semi-structured interviewThe interview is informed by A/TAM to establish the patient's readiness to use a wearable device as a means of monitoring their post-discharge status, including to establish any anticipated challenges in technology-mediated interaction with the care team; and finally, to identify any knowledge gaps that may need to be filled through the induction process. Paradata will be collected at the interview to assist with analysis.

Patient progress (throughout the period of device use): Monitoring of the patient's experience and satisfaction with the device and the study process will be combined with weekly monitoring questions focusing on the following aspects: **(a)** experience with physical use and tolerance of the device; assess any difficulty in keeping it in place, any skin reaction, possible somatization of health concerns; **(b)** experience of self-monitoring and communication with care team through the device **(c)** degree of reassurance or anxiety about the patient's recovery process; finally, **(e)** paradata from device and interaction metrics, including possible sentiment analysis of interaction text.

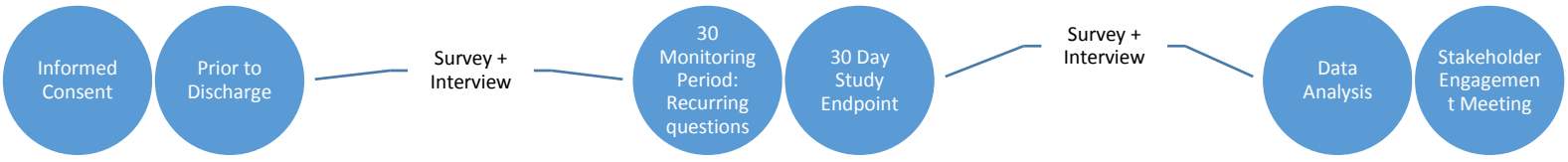
Conclusion (Study endpoint): (a) Surveys will be administered at study endpoint to assess each patient's strength of feeling in each response by recording not only the response itself but also the "paradata"—the researcher's assessment of the patient's affect in providing the response. On this basis, **(b)** in

conjunction with process measures captured through surveys, the first patient group participants will complete a post-study interview with the researcher. Using a mixed methods philosophy, the interview will seek links between performance measures and the experience of participants. **(c)** The interview will link to the quantitative results in terms of outcome and process measures, as well as to the patient status reports throughout the 30-day period to propose hypotheses for further study, e.g. on subjective tolerability of the wearable device or faith in a remote monitoring system and care process measures, such as unscheduled visits. **(d)** Patients will be invited to a post-trial half day event to network with their providers and the research team towards an open-ended evaluation of the joint experience and to elicit opinions and contributions towards a follow-up randomized clinical trial proposal; and **(e)** will be invited to contribute to a publication on the patient experience and to review scientific publications by the research team.

For the ileostomy cohort, we will use think-aloud methods to compliment the semi-structured interviews during the study end-point interview. Patients will think-aloud and convey their thoughts and experience to interviewer while using the patch, phone, and physIQ app. The other topics during study end-point will continue with the semi-structured formats.

A timeline illustrating patient related study activities can be found in Figure 5.

Figure 5 Patient Interview Timeline



3.3 Content and focus of interviews

3.3.1 Patient

Interview questions are developed based on A/TAM to elicit information. An example of the potential survey and interview questions the research team will use during the interview can be found in the appendices as **Appendix 1**.

Table 8. Patient A/TAM Structure

	Positive Affect	**Negative Affect**	**Perceived Usefulness**	**Perceived Ease of Use**	**Attitude Toward Using**	**Behavioral Intention to Use**	**Actual System Use**
Wearable Device	Past positive experience with using wearable devices	Past negative experience with using wearable devices (Technology anxiety)	Perceived usefulness of the wearable technology improving life quality/ med adherence/ health management / health outcomes… Perceived benefits/barriers associated with wearable device	Perceived ubiquity of the wearable technology Easiness of wearing/changing the patch Easiness of using the mobile phone Easiness of answering the survey via mobile platform	Positive attitude towards using the wearable device/mobile phone/technology Negative attitude towards using the wearable device/mobile phone/technology	Compliant with device usage Non-compliant with device usage	Readmission
Telemonitoring	Past positive experience with remote monitoring	Past negative experience with remote monitoring	Perceived usefulness of the telemonitoring process improving life quality/ med adherence/ health management / health outcomes..	Perceived easiness of communicating with care team Perceived easiness of following care team instructions	Positive attitude towards telemonitoring Negative attitude towards telemonitoring	Compliant with clinical instructions Non-compliant with clinical instructions	Readmission

			Perceived benefits/barriers associated with telemonitoring process				
Sociocultural factors	Positive disease management experience Language (English) Social support (Family/friend/PCP) Marital status (Married, good support system) Non-smoker Good control over diet Income status (Stable) Traditional/Religion values Good mental health status	Negative disease management experience Language (Non-English) Social support (Family/friend/PCP) Marital status (Single, Widowed, no support) Smoking Hx Poor control over diet Income status (Unstable) Traditional/Religion values Depression		Perceived control over the external factors	Self-motivation to tech usage adherence	Positive/Negative attitude towards technology and device acceptance	Self-care

Demographic Form – Sociodemographic information will cover gender, ethnicity, race, household income, education level and marital status.

The Self-Care Self-Efficacy Scale – The Self-Care Self-Efficacy Scale is authored by Dr. Barbara Riegel. Confidence is not part of self-care per se, but a factor that greatly influences self-care. For this reason, Dr. Riegel include a confidence (or self-efficacy) scale as part of the self-care scales. The Self-Care Confidence scale can be used alone.

Stoma Quality of Life Scale – The QOL instrument is a 21-item questionnaire that mesures work/social function, secuality/body image, and stoma function.

Device User Experience – These questions ask about patient's experience on using the vital patch and physIQ platform.

Telemonitoring Experience – These questions ask about patient's experience the telemonitoring process.

3.3.2 Provider

The survey and interview questions for the provider cohort are developed based on A/TAM to elicit information. An example of the potential survey and interview questions the research team will use during the interview can be found in the appendices as **Appendix 2**.

Table 8. Provider A/TAM structure

	Positive Affect	**Negative Affect**	**Perceived Usefulness**	**Perceived Ease of Use**	**Attitude Toward Using**	**Behavioral Intention to Use**	**Actual System Use**
Wearable Device	Past positive experience with using wearable devices with patients	Past negative experience with using wearable devices (Technology anxiety)	Perceived usefulness of monitoring patient vitals	Easiness of using the physIQ portal to review vitals Easiness of using smart note template in EPIC	Positive attitude towards promoting the device for patient usage Negative attitude towards promoting the device for patient usage	Intend to promote usage among patients	Engagement in device monitoring
Telemonitoring	Past positive experience with remote	Past negative experience with remote	Perceived usefulness of monitoring patient	Easiness of communication betwee	Positive attitude towards telemonitoring	Intend to practice telemonitoring as a method	Engagement in patient remote monitoring process

	patient monitoring	patient monitoring	disease progress	n providers Easiness of communication between patients Easiness of managing patient medication Easiness of providing clinical instructions	Negative attitude towards telemonitoring	for patient management	
Sociocultural factors	Individual's tendency to innovate in daily life Individual's level of technology usage in personal life Organizational level factors	Individual's tendency to innovate in daily life Individual's level of technology usage in personal life Organizational level factors	Will the usage of technology enable providers to reduce effort/enable patients to better disease manage	Organization support (education on device/tech usage)	Positive/Negative attitude towards participating in the program	Intention to participate in the program	Activeness in the program

Demographic Form – Demographic form will cover position title and the target patient population they are caring for.

Device User Experience – These questions ask about providers' experience on using the physIQ platform. We developed this questionnaire based on the systematic usability scale (SUS).

Telemonitoring User Experience – These questions ask about providers' experience in the telemonitoring process.

3.4 Interview methods

Semi-structured individual interviews will be used to maximize depth of detail and minimize bias introduced with cross-contamination from other interviewees.[53] Researchers trained in semi-structured interview techniques will conduct the interviews. They will use a nondirective interview style, with open-ended questions, and allow the participant to adopt their own pace and style of response, along with freedom of subject matter, so that they may change and emphasize alternate points to those already brought up by the interviewer. We will use probes and follow-up questions when indicated, and new constructs and ideas will be allowed to emerge. The interviewer may take notes during interviews, but de-identified transcriptions will be the primary source for analysis.

3.5 Codebook Development

The research team will develop study codebook based on the A/TAM theory:

1. Codes will be generated from the A/TAM theory.
2. Researchers will review and revise the code in context of the data.
3. Researchers will determine the reliability of coders and the code

3.6 Analyses

We will complete a systematic analysis of interview transcripts to identify specific themes guided by the A/TAM to inform future implementations of the wearable device and cascading alert system. After the initial few interviews have been completed, two researchers, working independently, will use a codebook of constructs adapted from the A/TAM to identify significant phrases that exemplify each construct. They will then independently review each other's work and come together to discuss differences of opinion and achieve consensus. The principal investigator will meet with the coders to review the codes, adding or consolidating as warranted. The researchers will then continue to perform interviews, adding codes to the codebook as needed, and meeting as a team periodically to review the codes and achieve consensus. We will use Atlas TI qualitative data analysis software to manage data and assist in analysis. Finally, we will create an overview description of the important themes, and their relationship to A/TAM constructs.

STUDY PROCEDURES

4.1 Recruitment Procedure

4.1.1 Patients

The participants will be recruited from Northshore University HealthSystem's Evanston Hospital, Glenbrook and Highland Park hospitals by the study team. The recruitment process will follow protocol standards to ensure consistency in the recruitment process. The participants will be informed that their participation is completely voluntary and that they can drop out at any time. The participants will also be required to sign consent forms to participate.

4.1.2 Providers

Clinical team staff will be asked to participate in surveys and semi-structured interviews.

4.2 Inclusion and Exclusion Criteria

4.2.1 Patients

Ileostomy Cohort

Inclusion Criteria:

- Patient underwent a new ileostomy formation at index hospitalization
- Patient is an inpatient at Evanston, Glenbrook, Highland Park hospitals
- Patient of Drs. Joe Muldoon, Monika Krezalek and James Spitz
- At least 18 years of age
- Fluent in English
- Patient is discharging with home health services
- Patient agrees to protocol-required procedures

Exclusion Criteria:

- Patient has cognitive or physical limitations that, in the opinion of the investigator, limit the patient's ability to maintain patch/wrist device, phone
- Patient has allergy to hydrocolloid adhesives
- Patient has present skin damage preventing them from wearing a study device
- Patient discharges to a skilled nursing facility, or other subacute facilities
- Pregnancy

4.2.2 Providers

All members of the clinical care team staff will be asked to participate in the implementation of the project. We will include clinical team involved in the caring for ileostomy patients. We will recruit a total of 10 providers to participate in the semi-structured interviews.

4.3 Informed Consent Procedure

4.3.1 Patients

The research coordinator is responsible for explaining the study to potential and willing participants. The consent process begins once the participant is interested in being enrolled in the study. At this time, the research coordinator will conduct a thorough review of the consent details, including study procedure, risks, confidentiality, etc. with the potential participants. Participants will be given adequate time to think about their decision to participate without under coercion on the part of the researchers. Whether a patient wishes or not, to be enrolled, that patient's medical care will not be affected. No consent will be completed if the participants have unanswered questions, and potential participants may talk over the details with the consent with whomever they wish, prior to giving consent.

Participants will need to be consented in a face-to-face meeting with the research coordinator and if they wish to obtain a copy of the consent, they are free to do so. If there is a change in the consent during ongoing study activities, the participant may be asked to re-consent, if changes will have a direct effect on the participant.

The research coordinator is responsible for explaining the study to potential and willing participants or to their Legally Authorized Representative (LAR). The consent process begins once the participant is interested in being enrolled in the study. At this time, the research coordinator will conduct a thorough review of the consent details, including study procedure, risks, confidentiality, etc. with the potential participants or if applicable, with their LAR. Participants will be given adequate time to think about their decision to participate without coercion on the part of the researchers. Whether a patient wish to be enrolled, that patient's medical care will not be affected. No consent will be completed if the participants have unanswered questions, and potential participants may talk over the details with the consent with whomever they wish prior to giving consent.

Participants or when applicable, their LAR will need to consent in a face-to-face meeting with the research coordinator. If there is a change in the consent during ongoing study activities, the participant may be asked to re-consent if changes will directly affect the participant.

If the participant cannot provide informed consent but are interested in the study, their LAR can sign the form on their behalf. The research coordinator will answer all study-related questions and communicate all study details before signing the consent form. In addition, the research coordinator will file all legal documents confirming LAR's relation to the participant in the study binder.

During patient recruitment, if any of theapproached eligible patients expresses interest in the study but is unwilling to participate in interviews, the research coordinator will present the no-interview consent form to patients as an alternative option. Once the no-interview group is full, patients will only be presented the consent form with interviews.

As part of the informed consent process:

1. The participant agrees to wear a total of 5 VCI VitalPatch for 7 days each adding up to 35 total days of monitoring. The research coordinator will place the VitalPatch on patients when they are still hospitalized. Our goal is to collect 30 days of post-discharge data.
2. The participant agrees to replace the VitalPatch every 7 days and to answer survey questions either daily (in the morning) or twice a day for the duration of the study in a timely fashion
3. The participant agrees to follow directions on the pinpointIQ application
4. The participant agrees to allow access to basic demographics, medical conditions, wearable and pinpointIQ platform data, other vital signs, medical care received during the hospitalization and subsequent 30 days, labs, medications, other procedures and surgeries, outcomes such as readmissions, surgical complications and mortality and clinical and nursing notes.
5. Importantly, the research coordinator will emphasize that the physiological data are not being monitored continuously with the patient. Patients should still follow the instructions given by their care team on what symptoms should be reported immediately, and how to report them.
6. Research coordinator documents informed consent process completion and files informed consent form
7. VitalPatch is placed on participant and patch is paired with phone.
8. Research coordinator teaches participant about VitalPatch, phone requirements, phone application and presents written information on wearing the devices and what is expected for the next 30 days
9. For enrolled participants who are discharged over the weekend or discharged before research staff placed devices on them, research coordinators will mail the study kit and schedule a phone call to guide and educate patients on placing the patch and operating the study phone. The questionnaires or interviews may be completed over the phone if participants did not complete them before discharge.
10. Participant agrees to complete required self-reported questionnaires and interviews if applicable.
11. Participant agrees to mail back the phone and any unused supplemental patches in a pre-paid mailer

Once the patient agrees to the study, the patient will sign the consent form the next day. We will give every patient at least 24 hours to decide whether or not they are willing to participate in the study. The

research coordinator will follow up with potential participants after 24 hours. We will scan the signed consent form into EPIC and link the patient's chart to the study.

However, starting on 4/19/2021, the research team noticed that someileostomy patients were admitted over the weekend but discharged the following Monday. For sampling purposes, we will include these patients in the study. For patients who require a phone consent, research coordinators will follow the below process:

1. Research coordinators will approach the eligible patients the day of discharge, introduce the study, and go over the consent form with patients
2. Research coordinators will provide the patient with two copies of the consent form and a pre-paid mailing envelope
3. Research coordinators will schedule a follow-up phone call with the patient for the next day
4. Research coordinators will call patients the next day and answer any remaining questions the patients and caregivers might have about the study

Suppose the patient is agreeable to participate in the study. In that case, the research coordinator will either (a) ask the patient for their email address and send a copy of the consent form to the patient's email address via part 11 compliant DocuSign. The research coordinator will review the consent form with the patient over the phone and have the patient sign via DocuSign. Research coordinators and the patient will both receive a signed copy of the consent form. Research coordinators will schedule to overnight the study kit to the patient. (b) If the patient does not have an email address, the research coordinators will ask the patient to sign the consent form they received at discharge, and mail back the consent form using the prepaid mailing envelope provided by the research team. Upon receiving the signed consent form, coordinators will overnight the study kit to the patient.

5. Once the patient receives the study kit, the coordinators will call the patient to guide them to put on the patches and pair the phone.
6. Coordinators will also complete required questionnaires and interviews over the phone with the patient

4.3.1 Providers

The research coordinator will be responsible for the consent of the clinical team staff for enrollment in this study. The consent process begins once the participant is interested in being interviewed for the study. At this time, the researcher will conduct a thorough review of the consent details, including study procedure, risks, confidentiality, etc., with the potential participant. It is assumed that working providers in the field will be mentally capable of participating in the study; therefore, no screening measures will be undergone to obtain eligibility. Researchers and investigators will be available to answer any questions the professionals have prior to consenting. The consent must be done in a face to face meeting or via video conferencing by the researcher and the clinician. If consent is done through video conference, a signed consent form will still be collected by the research coordinator.

4.4 Semi-Structured Interview Process

4.4.1 Patients

After obtaining informed consent, the research coordinator will set up a time to complete the questionnaire and a 30-minute semi-structured interview with the patient before discharge. Patients will be asked at the time of consent if they are willing to provide an email address for reminders and updates. After 30 days of remote monitoring, the research coordinator will contact patients via phone to complete the survey.

At the study endpoint, the research team will make three phone attempts to reach the patient on different days and times. If unable to reach the patient, the patient will then be contacted by their provider to remind them of completing the survey and interview if applicable.

Before the interview starts, the researcher will remind the participant not to use their name during the interview as it will be recorded. These interviews will be transcribed and then de-identified by study staff. They will also be reminded that recording is required for participation.

4.4.2 Providers

Upon signing the consent forms, the research coordinator will complete a self-administered survey and interview with the clinical team staff. After completion of the study, the research coordinator will send out a questionnaire link to the clinical staff to complete within five business days. The research coordinator may set up an appointment with the clinical team to complete the questionnaire via phone if the survey is not sent back, or if the survey contains skipped or missing questions. At the study endpoint, the research coordinator will set up appointments with the clinical staff for a 30-minute interview.

Before the interview starts, the researcher will remind the provider not to use their name during the interview as it will be recorded. These interviews will be transcribed and then de-identified by study staff. They will also be reminded that recording is required for participation.

4.5 Record keeping and transcripts

The interview recordings will be sent to a transcription service company with whom the research team has a strong working relationship. The transcription service company have a secure server for uploads of recordings and delete them after transcription is complete. If any patient's name is recorded on the transcripts, we will have the transcription service replace the name with an abbreviation instead. Transcripts will be scrubbed of PHI during transcription and will be given a study ID number. Quality control to make sure all PHI has been removed from each transcript will be conducted by the Research Coordinator prior to analysis. The final transcripts will be analyzed by the study team. The list that links the transcripts to the research participants will also be stored on the secure collaboration portal. The recordings will be deleted once they have been transcribed and analyzed. The key for the study ID numbers will be destroyed once the analysis is complete.

4.6 Provisions to Protect the Privacy Interests of Participants

All study information will be stored on NorthShore University HealthSystem password-protected, encrypted computers and servers that are password protected. All of these will be stored in locked rooms and will not be accessible to those outside the study team

Patients will be given a unique study record number that is not their medical record number. This unique record number will be given to physIQ for entering into their portal. No identifying information will be provided to physIQ. The key that identifies the unique study record number to the patient MRN will only be kept by the study team and by the NorthShore teams that operationalize the study (CAPE navigators, monitoring nurse and the clinical care team).

In order to protect participant privacy, the research coordinator's phone number and office address will be registered on the physIQ pinpointIQ portal for each participant. PhysIQ's technical support team will contact the research coordinator with the subject ID to inform the research team of noncompliance use of device. The research coordinator will call participant to review device usage instruction and provide technical assistance as needed.

No PHI will be provided to physIQ and other study team members outside of NorthShore. The study team will collect patient name, MRN, date of birth, phone number for the purpose of conducting the study. All patient information will be aggregated during study analysis and no identifiers will be provided in the analysis.

Upon study completion all study data will be destroyed, and verification will be provided to data governance.

During informed consent and enrollment, the study coordinator will make sure that patients are alone or in a room with family members that the patient agrees to participate in decision making around the study. The door will be closed, and any study-related information will be paused when other staff or visitors enter the room. We will allocate 1 hour for consent, and if required, we can extend the amount of time to make sure that the patient has all their questions answered and privacy maintained.

4.7 Compensation and Economic Burden to Patients and Providers

There is no economic burden to patients who choose to participate in this study for the devices and remote monitoring. Participants will be responsible for all routine care if incurred, including home health, counseling by nurses and care providers, office visits, diagnostic tests and procedures, ER visits, and hospitalizations. If a participant is at risk of hospital readmission or has worsening conditions that require medical attention during the study period, in that case, participants will be responsible for all standard of care payments incurred during their escalation process.

Patients enrolled in the Ileostomy cohorts who complete all interviews with the study team will be provided a gift card as compensation for their time and participation.

There is no economic burden to care team members who choose to participate in the interview other than time spent answering questions to evaluate the process and wearable solution. We will provide a gift card to the providers as compensation for their time and participation.

DATA MANAGEMENT

5.1 Data Security

Survey data will be recorded and managed using REDCap. REDCap will contain only a subject ID, assigned by the research coordinator. The PI, research coordinator and data scientist will maintain the only linking document between study ID and patient name. It will be password protected and stored on Northshore University HealthSystem's secure internal server. During the study period, the operational team will also receive access to the linking information to identify which patients are in the pinpointIQ portal. Other study team members will not have access to the key.

PhysIQ's solution, including wearable devices, mobile device and cloud platform on Microsoft Azure was evaluated and approved by data security (HIT) as part of a prioritized active project. No PHI will be uploaded to the physIQ platform. The vital and alert data will be transferred back to NorthShore for storage using an sFTP. PhysIQ's telemonitoring platform will be used for the study procedure. PhysIQ will not receive any protected health information.

PhysIQ operates in line with both HIPAA and GDPR. Neither HIPAA nor GDPR support an external authority that can formally attest to compliance, but physIQ does operate and measure its internal security and privacy program against both frameworks and is operating in line with each.

There are three (3) core components of the physIQ product; 1) a 3rd party disposable patch worn by the patient, 2) a physIQ supplied mobile phone running as a data hub, and 3) a web browser-based clinical portal for viewing analytics and raw data. The data flow within these basic components is secure at all time. No sensitive and/or protected data resides in the physIQ offices nor on the corporate network.

The sensor patch collects physiological data (not considered PHI) and through a 128-bit encrypted Bluetooth offload, transmits that data to an Android-based, dedicated lockdown (kiosk) mobile phone, which is validated and approved to interface and collect patient data. The device is provided by physIQ; this is not a bring-your-own-device (BYOD) system. In kiosk mode this device runs only the physIQ mobile application with no ability to make calls, SMS text, nor internet browsing. All Bluetooth offloaded physiological data is stored in Android's encrypted memory. Furthermore, all data is deidentified; there is no PHI on the mobile device. The phone is assigned a "node ID" in the cloud platform which functions as the alias and link to the specific phone. Uploads are made to the cloud with the node ID credentials. The mobile phone then uploads the data through cellular connection to physIQ's Google Cloud Services (GCS) cloud platform.

The physIQ cloud architecture includes service relationships with certified partners. The production (VPC) stack is in GCS, with the back-up snapshot in Amazon Web Services (AWS). The physIQ platform is an isolated GCS network inside which servers communicate with limited pinholes to the outside world. Port 443 is the "front door" and uses TLS encryption for all traffic. All data exchange is sanctioned and handled by the API. physIQ's product is entirely API-enabled. Mobile phone (node) uploads of data and Clinical Portal browser sessions are both API calls. There are also two (2) VPN "back doors" for occasional maintenance of the VPC and for the read-only requests from AWS for back-ups.

Other cloud security measures include; role-based-access-controls (RBAC) for all URL routes in the API and inside the product, all data-at-rest in GCS and AWS is encrypted by default schema, all patients in the

system are known by GUIDs and identity data is stored separately from medical data, and all servers (VMs) are instances of a security-hardened image

Carnegie Mellon University (CMU) is a collaborating site and will have access to de-identified and date shifted patient and healthcare provider information. No HIPAA identifiers will be included in the data shared with CMU. Collaborators at CMU will be involved in developing and evaluating the 30-day readmission prediction model. Deidentified and date shifted data will be transferred to CMU over a Secure Sockets Layer (SSL) using a HIPAA compliant File Transfer Protocol (FTP). Data will be stored at NorthShore and at CMU on password-protected, encrypted computers. All research team members and graduate and doctoral students working with the data will complete Human Subjects Research certification. After completion of this project, all data at both NorthShore and CMU will be destroyed.

5.2 Protection of Participant Privacy

Patient Privacy – During this study, non-invasive wearable devices will be provided to patients to collect continuous physiologic data. PhysIQ's solution, including wearable patches, mobile device and Microsoft Azure cloud platform comply with the administrative safeguards and implementation specifications described in 45CFR§164.308, with respect to HIPAA. No PHI will be uploaded to the physIQ platform.

The physiological data upload via digital cellular network is secured with TLS cryptographic protocol between the mobile phones and the server. The physIQ platform is securely hosted in the Google cloud. The physIQ cloud stores the raw physiological telemetry data captured by the study device, and also stores analytical results generated by running that raw data through the physIQ Analytics Modules. All the telemetry and analytical results are stored separately from any personally identifiable information (PII) that an institution might choose to enter in the system. There is no requirement to enter PII to use the platform, as all data can be tracked solely by random ID as well. PHI will not be transmitted to physIQ for this process and the only data that will be transmitted is a random study ID generated at NorthShore. NorthShore will maintain the key to the identifier. The data can only be obtained or viewed via secure authenticated login.

The physiologic, alert, and patient reported status data will be transferred back to NorthShore for storage using a sFTP. Data from wearable devices and physIQ platfrom and EHR data from NorthShore will be linked, deidentified using standard NorthShore protocol prior to transfer to CMU via secure FTP. There is an existing Data Use Agreement in place between NorthShore and Carnegie Mellon University (CMU) which will be renewed for this project. Only the PI at NorthShore and Co-PI at CMU will have access to the sFTP site. Only named study personnel will have access to data. PhysIQ will not have access to any PHI. Northshore and CMU will delete all data after study termination.

DEVICE INFORMATION

COMPANY ADDRESS: physIQ, Inc.
200 West Jackson Blvd., Suite 550
Chicago, IL 60606

6.1 DEVICE DESCRIPTION:

The pinpointIQ Solution is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. The pinpointIQ Solution consists of clinical-grade wearable sensors such as the VitalPatch™ Sensor (a 510k-cleared disposable patch with integrated biosensors and a wireless transceiver) and the physIQ Platform (a mobile application for secure data transmission, cloud-based information-technology [IT] infrastructure, physiology analytics modules, and clinician user interface). The patch is worn on the torso for up to 5 days and measures and records physiological variables that can include, but are not limited to, electrocardiography (ECG), vital signs and activity. Data are transmitted wirelessly from the VitalPatch™ Sensor to the physIQ cloud for storage and analysis and presentation within the clinician user interface.

INVESTIGATIONAL DEVICE:

Device Description

PinpointIQ is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. PinpointIQ consists of:

- VitalPatch™ Sensor (chest-worn disposable biosensor patch)
- Mobile application ("app") for secure data transmission
- Cloud-based IT infrastructure
- Physiology Analytics modules, comprising:
    - Personalized Physiology Analytics
    - Vital Sign Feature Analytics
    - Heart rhythm analytics
    - Actigraphy analytics
    - Clinician-defined rules
- Browser-based clinician user interface

Biosensors

Vital Connect VitalPatch

VitalPatch™ (Vital Connect Inc) is an FDA 510(k)-cleared, wearable adhesive Band-Aid-like multi-sensor device which will be used to stream and collect continuous vital sign data from patients. The device is a disposable adhesive patch with an integral one-time-use battery and integrated electronics. The battery life of each disposable adhesive patch lasts about 7 days.

The VitalPatch™ is generally applied to the skin of the patient's left upper chest (worn diagonally on the chest above the heart or laterally on the rib cage just below the heart). Further VitalPatch™ description

and instructions for that application are shown in an attached document. VitalPatches™ can be worn continuously, including in the shower. VitalPatches™ should be replaced when adhesion or the battery fails. In addition, physIQ recommends considering the use of UNI-SOLVE wipes to assist in the removal of the VitalPatch™.

6.2 Data Transport via physIQ Android Mobile App and physIQ Platform

The physIQ Android mobile app is loaded onto an Android-based phone or tablet mobile device. The mobile device offloads vital sign data from the VitalPatch™ (via low energy Bluetooth) and uploads it using digital cellular or WiFi network to the cloud-based server. In addition to transmitting physiological data, the app also may present questionnaires to the patient that are answered directly within the app.

Upload via digital cellular network is secured with TLS cryptographic protocol between the mobile phones and the server. The physIQ platform is securely hosted in the Google cloud. The physIQ cloud stores the raw physiological telemetry data captured by the study device, and also stores analytical results generated by running that raw data through the physIQ Analytics Modules. All the telemetry and analytical results are stored separately from any personally identifiable information (PII) that an institution might choose to enter in the system. There is no requirement to enter PII in order to use the platform, as all data can be tracked solely by random ID as well. PHI will not be transmitted to physIQ for this process and the only data that will be transmitted is a random ID generated at NorthShore. NorthShore will maintain the key to the identifier. The data can only be obtained or viewed via secure authenticated login.

6.3 Analytics

The study will utilize physIQ's multivariate analytical methods that learn the behavior of an individual patient's vital signs at a baseline, and then detect changes in the behavior of the vital signs compared to the baseline. Changes in vital signs relationships may be indicative of current or future important clinical events. These changes are indicated through the Multivariate Change Index ("MCI"), which is a scalar index between 0 and 1, where values close to 0 indicate no significant change from baseline and values close to 1 indicated greater changes from baseline.

Additional "feature" analytics include atrial fibrillation detection, arrhythmia (ectopic beat) burden, Cheyne-Stokes respiration, sleep quantification, and walking detection. Clinician-defined rules include applying thresholds to time series vital signs, sleep fragmentation, tachycardia, bradycardia, A-Fib with RVR, elevated respiration rate, and long-duration horizontal posture.

6.4 Regulatory Status

This study is considered a non-significant risk (NSR) Investigational Device Exemption (IDE) study according to 21 CFR §812.2(b) to evaluate the clinical utility of PhysIQ vital patch solution. All FDA-cleared devices in pinpointIQ will be used according to their intended use. The components of this system and clearance status are described below:

1. VitalPatch wearable biosensor: FDA 510k-cleared Class II-regulated medical device – Vital Signs Biosensor (K190916)
2. PhysIQ Cloud-based IT platform (physIQ mobile app, IT platform, Clinician User Interface): FDA Class I-regulated medical device – Medical device data system

3. PhysIQ Personalized Physiology Analytics: FDA 510k-cleared Class II-regulated medical device – Multivariate Change Index (K142512)
4. PhysIQ feature analytics: FDA 510K cleared Class II-regulated medical device – heart rate, heart rate variability, respiration rate and atrial fibrillation detection (K183322)
5. PhysIQ actigraphy analytics: FDA Class-I-regulated medical device – walking, steps, posture, sleep, body tilt, gross activity, activity stratification.

- **Potential Risks and Benefits**

When used in accordance with the clinical protocol, risks associated with pinpointIQ are considered low. To ensure proper use of the solution, subjects, patients and providers will be trained in accordance with the manufacturer's instructions for use. In addition, clearly defined study eligibility criteria have been established to ensure that only appropriate patients are enrolled in the study.

The potential risks of VitalPatch may include the following: adverse skin reactions, skin irritations, mild soreness, redness (see attached IFU).

- **Device Packaging, Labeling and Use**

The VitalPatch™ and mobile phone will be shipped as a kit to NorthShore in the care of the PI/research coordinator. Device components will be labeled "For Prescribed Use in a Clinical Trial" and packaged by physIQ according to applicable regulations. Upon completion of data collection, the subject will mail back all study equipment in a pre-paid mailer that was provided in the kit. PhysIQ and NorthShore research team will maintain device accountability records for each study site and for each subject enrolled, pursuant to 21 CFR§812.110 and Good Clinical Practices (GCP).

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APPENDIX 1 – PATIENT QUESTIONNAIRE & INTERVIEW

8.1 Demographic Survey (Ileostomy Cohort – Pre)

- What is your gender?
    1. Female
    2. Male
    3. Other (specify) :_____
- Do you consider yourself to be of Hispanic, Latino/a, or Spanish origin?
    1. Yes
    2. No
- Which racial group or groups do you consider yourself to be in?
        1. American Indian or Alaska Native
        2. Asian
        3. Black or African American
        4. Native Hawaiian or Other Pacific Islander
        5. White
        6. Other
- What is the highest degree or education level you have completed?
    1. Some high school
    2. High School
    3. Some college/Associate's degree
    4. Bachelor's degree
    5. Master's degree or higher
    6. Prefer not to say
- What is your marital status?
    1. Single
    2. Married
    3. Separated
    4. Divorced
    5. Widowed
- How many people live in your household with you?
- What was your total household income before taxes during the past 12 months?
    1. Less than $25,000.
    2. $25,000 to $34,999.
    3. $35,000 to $49,999.
    4. $50,000 to $74,999.
    5. $75,000 to $99,999.
    6. $100,000 to $149,999.
    7. $150,000 or more

8.2 Self-Care Self-Efficacy Scale (Ileostomy Cohort – Post only)

In general, how confident are you that you can:

	(Circle **one** number for each statement)				
1. Keep yourself stable and free of symptoms?	1	2	3	4	5
2. Follow the treatment plan you have been given?	1	2	3	4	5
3. Persist in following the treatment plan even when difficult?	1	2	3	4	5
4. Monitor your condition routinely?	1	2	3	4	5
5. Persist in routinely monitoring your condition even when difficult?	1	2	3	4	5
6. Recognize changes in your health if they occur?	1	2	3	4	5
7. Evaluate the importance of your symptoms?	1	2	3	4	5
8. Do something to relieve your symptoms?	1	2	3	4	5
9. Persist in finding a remedy for your symptoms even when difficult?	1	2	3	4	5
10. Evaluate how well a remedy works?	1	2	3	4	5

8.2.1.1.1.

Device related questions:

In general, how confident are you that you can:

1. Continuously wear the device for 30 days?
2. Follow the research study protocol for 30 days?

Enrichd Social Support Instrument (Ileostomy cohort – Pre)

Appendix 1 • ENRICHD SOCIAL SUPPORT INSTRUMENT (ESSI)

Please read the following questions and circle the response that most closely describes your current situation.

1. Is there someone available to you whom you can count on to listen to you when you need to talk?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

2. Is there someone available to give you good advice about a problem?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

3. Is there someone available to you who shows you love and affection?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

4. Is there someone available to help you with daily chores?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

5. Can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

6. Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?

None of the time	A little of the time	Some of the time	Most of the time	All the time
1	2	3	4	5

7. Are you currently married or living with a partner?

Yes No

402 / Journal of Cardiopulmonary Rehabilitation 2003;23:398-403

8.3 Monitoring Process Random Question Bank

Week 1

I had difficulty learning to use the devices.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

I felt safe being monitored through the system.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Week 2

I experienced problems with the patch.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

I felt reassured seeing my data on the phone.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Week 3

I experienced problems with the phone application.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

I felt more self-conscious of my symptoms as a result of the monitoring.

- Not at all
- A little bit
- Somewhat

- Quite a bit
- Very much

Week 4

Using the system requires a lot of technical support.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Using the devices helped me overall.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Week 5

I am excited to be using a device to monitor my health.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

I think using devices to monitor my health is an advance in modern medicine.

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

8.4 User Experience Survey (Ileostomy Cohort – Post)

(5 point likert scale, 1=strongly disagree, 3=neither disagree/agree and 5=strongly agree)

Definition of application: The mobile phone application downloaded on the smart phone. It is used by participant's to respond to survey questions.

Device

1. I could use the patch anytime and anywhere throughout my daily life.
2. The patch is easy to replace.
3. The application is easy to use.

4. The patch makes me feel more secure.
5. Using the application makes me feel more secure.
6. I have doubts using the patch in the future.
7. I have doubts using this application in the future.

Home Health

8. The home health nurses are responsive to my questions and concerns.
9. My home health nurses are interested in my health.
10. The instructions given by my home health nurses are easy to follow.
11. I am satisfied with the amount of communication I receive from the home health nurses.
12. I am satisfied with the quality of my interactions with my home health nurses.

Clinical Care Team

13. The care team is responsive to my questions and concerns.
14. My care team is interested in my health.
15. The instructions given by my care team are easy to follow.
16. I am satisfied with the amount of communication I receive from the care team.
17. I am satisfied with the quality of my interactions with my care team.

Program

18. I am satisfied with the remote monitoring program.
19. The remote monitoring program allows me to stay better connected to my care team.
20. The remote monitoring program helped me eat healthier.
21. The remote monitoring program helped me take my medications on time.
22. Participating in this program makes me feel more secure in detecting problems with my health in general.
23. Participating in this program helped me stay out of hospital.
24. I would recommend this program to other patients.

8.5 Stoma Quality of Life (Ileostomy Cohort – Post)

Part 1

1. Rate your **overall** satisfaction with *your life in general* **right now** on a scale of 0 to 100, with 0 being totally unsatisfied and 100 being totally satisfied.
2. Rate your **overall** satisfaction with *your life in general* **during the last month** on a scale of 0 to 100, with 0 being totally unsatisfied and 100 being totally satisfied.

Part 2

Never (1)
Seldom (2)
Occasionally (3)
Frequently (4)
Always (5)

For each of the following questions, please choose a number from the choices above that corresponds to your answer.

3. I am able to participate in hobbies that I enjoy. _____
4. I am able to go out with friends. _____
5. My stoma interferes with my ability to work or attend school. _____
6. I worry about traveling because of my stoma. _____
7. I enjoy sexual activity. _____
8. I feel attractive. _____
9. My sexual partner is bothered by my stoma. _____
10. It bothers me if others are aware I have a stoma. _____
11. I worry about lack of privacy when I need to empty my pouch. _____
12. I feel comfortable in my clothing. _____
13. I am satisfied with the foods I eat. _____
14. I have financial concerns regarding my ostomy supplies. _____
15. I have problems with odor. _____
16. I am able to share my feelings and concerns about my ostomy with a family member or friend. _____
17. I am embarrassed by gas (noises or rapid filling of bag). _____
18. I worry my ostomy appliance will leak. _____

19. I am bothered by skin irritation around the stoma. _____
20. Social situations make me feel anxious. _____
21. I perform the same household and family duties. _____

APPENDIX 2

Suggested Scoring of the SQOLS

Part 1

Overall satisfaction with life is scored from 0 to 100. Question 1 reflects current satisfaction and may be more useful when changes over short periods of time are important. Question 2 reflects satisfaction during the previous month.

Part 2

Work/Social Function Scale = 25 × (12 + Que3 + Que4 − Que5 − Que6 − Que20 + Que21)/6
Sexuality/Body Image = 25 × (1 + Que7 + Que8 − Que9 + Que12 + Que16)/5
Stoma Function = 25 × (24 − Que10 − Que11 + Que13 − Que15 − Que17 − Que18)/6
Financial Concerns = 25 × (5 − Que14)
Skin Irritation = 25 × (5 − Que19)

If any two questions are missing for a subscale, the entire subscale should be set to missing. If one is missing, the scale score can be prorated.

8.6 Semi-Structured Interviews

Definitions

Wearable Device: Electronic devices that a person can wear, like Fitbits and smartwatches (applewatch, Samsung watch), and are designed to collect someone's personal health and exercise data, like how many steps you walked, or how fast your heart is beating.

Telemonitoring: Clinical providers using information technology, such as phone calls, video calls, chat functions, to monitor patients at a distance.

8.6.1 Ileostomy Pre-discharge Interview

Example of questions	**Example of probing questions**
What is your previous experience with using wearable devices?	• If no experience, probe why • Did you find it useful? How was it useful? • What were some of the challenges with it?
What is your previous experience with telemonitoring?	• If no experience, probe why • How did you feel about the telemonitoring? • What were some of the challenges with telemonitoring?
Can you describe your experiences living with XXX prior to the surgery?	
How do you manage your health conditions at home?	• Is there anything you do related to diet or medications? • Tell me about some of the challenges with … • Are your family/friends involved with managing your health? How do you feel about …
What happened leading up to this ileostomy procedure?	• What physical symptoms of your illness did you experience? • Who participated in the decision to go through with this procedure? • What did they say? • How do you feel about being in the hospital?

We know that managing your health condition could be very expensive. Can you give us some examples of what those expense are? Has that been a problem for you?	• Can you give us some examples of how you have dealt with those expenses?
Can you describe your initial reaction to the stoma?	
In what way, if any, do you think participating in this study might be beneficial to you?	
How do you feel about the upcoming discharge?	Negative feelings – Why? Positive feelings – Is being enrolled in the study part of the reason (of the positive feelings)? Why?
Is there anything you would like to add? Or is there anything else you would like to discuss?	

8.6.2 Ileostomy Study Endpoint Interview

Example of questions	**Example of probing questions**
Device	
Tell me about your experience using the device.	How was the patch/phone/physIQ app? Tell me more about that.

Home Health	*Home health nurses are the nurses from Home Health that visits you at your house.*
Tell me about your experience working with the monitoring nurse.	Were there any challenges? Please tell me more about that.
Do you think the monitoring nurse have good awareness of your needs?	Why or why not?
In what ways, if any, did working closely with the monitoring nurse impact your health?	Why or Why not?
Care Team	*Clinical Care Team are the physicians, physician assistants, nurse practitioners and nurses who took care of you during hospitalization.*
Did your surgery team contact you, or did you contact your csurgery team during the 30 day remote monitoring period?	*Yes → Complete Care team question session* *No → Skip entire Care team session*
Tell me about your experience working with the clinical care team (for the past 30 days)	Were there any challenges? Please tell me more about that.
In what ways, if any, did working closely with the clinical team impact your health?	Why or Why not?
Stoma	
Can you describe how daily life is now with the stoma?	How does the change impact your social life? How does the change impact your work? (if applicable)

How would you compare your experience now with life prior to the colorectal surgery?	
Program	*By program, we mean the whole experience wearing the devices, interacting with home health, and clinical care team.*
What was it like to be part of this program?	
How practical do you think the program is?	Were the instructions easy to follow? Were the daily requirements easy to complete? Why or why not?
What do you think about the discharge care you received for the past month?	
Do you feel like this study prevented a hospital readmission? (Skip if patient is readmitted)	Why or why not?
Please walk me through how you (or your caregiver) managed your ostomy while enrolled in the program?	Tell me more about that.
Has being in this program led to any changes in how you feel about your ostomy?	What kind of changes? Tell me more about that. Do you feel stressed about having an ostomy? Did the study help you reduce stress for the past month? Why or why not? Do you feel down or depressed about having an ostomy? Did the study help you reduce depressing feelings for the past month? Why or why not?

Has the study made you feel more secure in the past month?	Why or why not?
Has the study empowered you to own and mange your care?	Why or why not? Or How/In what ways did it…
Were your family or friends assisting you with the devices?	How does your family/friends feel about the program? Do they feel like the program is practical? Why or why not? Does it help ease burden of care? Why or why not? Do you think you could have done the study without their assistance?
Please walk me through your feelings towards using the devices in the past month. (Ex. Enthusiastic in the beginning → felt bored later or worried at the beginning → felt comfortable later)	
I want to ask you a question for you to help us. How do you think we could make this program better?	
Is there anything you would like to add?	

APPENDIX 2 – PROVIDER SURVEY AND INTERVIEW

9.1 Study Start point (Demographic Survey + Interview)

Demographic Survey:

1. Please tell me your position title: _____

Interview at Study Start Point

Example of questions	**Example of probing questions**
What experience do you have with telemonitoring?	Yes → Tell me more about that No → No probe Vague response → Probe to see if they have telemonitoring experience (Experience during COVID-19 pandemic)
When you first heard about the program, what did you think about it?	What do you think about the workflow/protocol? What do you think about the monitoring platform?
In what ways, if any, do you think the program could be beneficial to your patients?	Why or why not?
What expectations, if any, do you have about this program as this relates to your work?	

What supports do you think you will need, if any, withimplementing remote monitoring?	What do you think it will take for us to continue offering this as standard of care?
For clinical team: How do you feel about implementing patient remote monitoring with Home Health? *For home health:* How do you feel about implementing patient remote monitoring with the regular care team?	Why or why not?
What concerns do you have about this program, if any?	Yes → Tell me more about that No → No probe Vague response → Probe
Is there anything you think we should have asked you and didn't?	
For colorectal providers:	
What are you experiences with taking care of colorectal patients?	What about new ileostomy patients? Can you walk me through taking care of a typical ileostomy patient after discharge? What were some challenges with patient care? How do you think this study would help with patient care?
Sometimes patients have difficulty with treatment plan adherence and as a result they adapt based on their life situations.	What do you think about this? Is this frequent in ileostomy patients? What tactics do you use to assist with adherence? How effective do you think they are?

What are you thoughts on the study helping with patient communication?	Do you expect the communication to be more targeted and efficient?
What are your thoughts on the study helping patients (and or patient family) transition to this new life?	

9.2 End Point (Survey + phone follow up if survey incomplete)

Experience Survey

(5 point likert scale, 1=strongly disagree, 3=neither disagree/agree and 5=strongly agree)

1. I received adequate support to participate in the program.
2. The platform was easy to use.
3. The workload was manageable.
4. The protocol made sense to me.
5. The escalation process was easy to follow.
6. I had problems communicating with some patients.
7. *For home health*: I had problems communicating with the clinical team.
   For clinical team: I had problems communicating with the home health team.
8. The program improved patient care effectiveness.
9. The program improved patient care timeliness.
10. *For home health:* I experienced moments of uncertainty.
    For clinical team: I experienced occasions of doubts concerning the severity of the patient's condition.
11. I felt like this program is an improvement to usual care.
12. What are some challenges you experienced so far? _____

9.3 Study Endpoint (User experience survey + Interview)

Remote Monitoring Platform User Experience

(5 point likert scale, 1=strongly disagree, 3=neither disagree/agree and 5=strongly agree)

1. I think that I would like to use the platform frequently.
2. I found the platform unnecessarily complex.
3. I thought the platform were easy to use.
4. I think that I would need the support of a technical person to be able to use the platform.
5. I found the various functions in the platform were well integrated.

6. I thought there was too much inconsistency in the platform.
7. I would imagine that most people would learn to use the platform very quickly.
8. I found the platform very cumbersome to use.
9. I felt very confident using the platform
10. I needed to learn a lot of things before I could get going with the platform.

Interview Guide at Study Endpoint

Questions: Do providers feel that the wearable-mediated post-discharge care was effective in preventing readmission in patients with postoperative ileostomy formation.

Questions for providers	**Probing questions**
Platform: 1. How would you describe your experience in the program?	- Could you describe that more in detail? - Was that helpful/unhelpful?
2 What features or capabilities are important to you in a monitoring platform?	- Why is _____ important for you? - What does it help with? - What if that feature did not exist?
Program:	
2. How would you describe your experience with the program?	- Please tell me more about _____.
3. What are your impressions of what patients think about the program?	- Why do you think that? - How did patients respond to the program?
4. In your opinion, what is the impact of this program on patients' ability to manage their condition at home?	- Medication management - Monitoring symptoms - Reach out to providers - Engaging family members - Diet management
5. How was your experience communicating with enrolled patients in this program?	- Tell me more about that - How did the program change how you communicate with your patients?
6. How did the program change how you communicate with your patients?	- Method of communication - Frequency

	- How do you feel about the changes? - How did it impact how you did your job?
7. How did participating in this program affect your work load?	
Monitoring nurse only: a. What was your experience with escalating patient cases to the care team? b. What changes, if any, would you suggest for the escalation pathway? Note to interviewer: provide visual aid to interviewer	- Timeliness of provider responses - Ability to get ahold of the pt - Methods to get ahold of pt / provider
Clinicians only: c. What is your experience with handling the escalation to your team?	- How was your experience working with the monitoring nurses? Please tell me more about: - Timeliness of escalation - Communication between providers involved
8. How do you feel about this remote monitoring program compared to usual patient care?	- How did it differ? - How was it the same?
9. How did you feel about patient adherence to this program?	- Monitoring symptoms - Taking medications as prescribed - Following new changes to their care plan (e.g. P.T, medication changes, ect.)
10. What supports do you think patients need to continue with remote monitoring work?	- Who do you think should provide _____ support? / whose role is it to provide that support? - What type training do patients need?
11. What is your opinion on the effectiveness of this program preventing hospital admissions?	- Please tell me more about _____.

12. What resources or support would you require to continue with remote monitoring work?	- Staff support - Hospital support - Clinician education
13. What changes would you make to this program?	- Could you go into more detail about that? - How would that change help?