Preparing older adults for major abdominal surgery with preoperative comprehensive geriatric assessments: a three-phase research protocol using systems engineering and implementation science

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Table of Contents

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Abstract

Background: Older Americans are a growing segment of the population with an increasing need for surgical services, and they suffer a disproportionate burden of postoperative complications compared to their younger counterparts. Preoperative comprehensive geriatric assessment (pCGA) is recommended to reduce risk and improve surgical care delivery for this vulnerable population. The pCGA optimizes multiple chronic conditions and factors commonly overlooked in routine preoperative planning, including physical function, polypharmacy, nutrition, cognition, mental health, and social/environmental support; pCGA has been shown to decrease postoperative morbidity, mortality and length of stay in a variety of surgical specialties. Although national guidelines recommend the use of pCGA, a paucity of strategic guidance for implementation limits its uptake to a few academic centers. By applying human factors engineering methods, this study will provide the necessary evidence to optimize the implementation of the pCGA in a variety of healthcare settings.

Objective: The purpose of this paper is to describe the study protocol to design an adaptable, user-centered implementation package for the pCGA for use among older adults before major abdominal surgery.

Methods: This protocol uses systems-based engineering methods to develop, tailor and pilot test a user-centered implementation package for the pCGA – one that can be adapted to community-based hospitals in preparation for a multi-site implementation trial. The protocol is based upon the National Institutes of Health Stage Model and aligns with the goal to develop behavioral interventions with an eye to real-world implementation. In phase 1, we will use observation and interviews to map the pCGA process and identify system-based barriers and facilitators to its use among older adults undergoing major abdominal surgery. In phase 2, we will employ user-centered design methods, engaging healthcare providers, patients and caregivers to co-design an implementation package for the pCGA. The implementation package will be applicable to a diverse population of older patients undergoing major abdominal surgery at (2a) a large academic hospital and (2b) an affiliate community site. In phase 3, we will pilot test and refine the pCGA implementation package in preparation for a future randomized controlled implementation-effectiveness trial. We anticipated this study will take approximately 60 months in total, beginning in April 2023 and ending in March 2028.

Results: This study protocol will generate (1) a detailed process map of the pCGA, (2) an adaptable, user-centered implementation package for the pCGA ready for feasibility testing in a pilot trial, and (3) preliminary pilot data on implementation and effectiveness of the implementation package. We anticipate that these data will serve as the basis for future

multi-site hybrid implementation-effectiveness clinical trials of the pCGA in older adults undergoing major abdominal surgery.

Conclusions: The expected results of this study will improve perioperative care processes for older adults before major abdominal surgery. Clinical Trial: NCT06184919 (Phase 1 & 2 – Observational phases) and NCT06184724 (Phase 3 – Pilot trial)

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ABSTRACT

Background: Older Americans are a growing segment of the population with an increasing need for surgical services, and they suffer a disproportionate burden of postoperative complications compared to their younger counterparts. Preoperative comprehensive geriatric assessment (pCGA) is recommended to reduce risk and improve surgical care delivery for this vulnerable population. The pCGA optimizes multiple chronic conditions and factors commonly overlooked in routine preoperative planning, including physical function, polypharmacy, nutrition, cognition, mental health, and social/environmental support. The pCGA has been shown to decrease postoperative morbidity, mortality and length of stay in a variety of surgical specialties. Although national guidelines recommend the use of pCGA, a paucity of strategic guidance for implementation limits its uptake to a few academic centers. By applying implementation science and human factors engineering methods, this study will provide the necessary evidence to optimize the implementation of the pCGA in a variety of healthcare settings.

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Conclusions: The expected results of this study will improve perioperative care processes for older adults before major abdominal surgery.

Trial Registration: NCT06184919 (Phase 1 & 2 – Observational phases) and NCT06184724 (Phase 3 – Pilot trial).

Keywords: systems engineering, participatory design, user centered design, implementation science, surgery, aging research, randomized control trial

Abbreviations: Preoperative comprehensive geriatric assessment (pCGA), System

Engineering Initiative for Patient Safety (SEIPS),

INTRODUCTION

Each year, approximately 4.5 million older adults undergo major surgery.[1] On average, 25% of these older adults develop postoperative complications, costing the healthcare system approximately $8K-13K per complication[2] and an average of $20K-30K for the postoperative hospitalization.[3-6] Unfortunately, the risk of complications doubles with preoperative functional decline, frailty or cognitive impairment,[7-14] risk factors which are rarely measured. Preoperative comprehensive geriatric assessment (pCGA) is a multicomponent intervention evaluating and optimizing multiple chronic conditions and factors commonly overlooked in routine preoperative planning, including physical function, polypharmacy, nutrition, cognition, mental health, and social/environmental support.[15] Major abdominal surgery carries unique risks, disrupting the core muscles with often-delayed functional recovery,[16-21] cognitive decline,[17, 20, 22-24] and disproportionately high morbidity and mortality.[7, 25-28] When implemented properly, pCGA improves outcomes for patients having abdominal surgery, reducing postoperative complications by 40% and length of stay by 2 days.[29, 30]

Experts and best practice guidelines recommend pCGA for all older patients undergoing major surgery.[15, 31-33] In prior work with the American College of Surgeons, an expert consensus conference of over 50 stakeholder organizations generated national standards for surgical care of older adults through the Geriatric Surgery Verification program.[34, 35] These standards include conducting the pCGA for older surgical patients. Defining the standards is a critical first step, however, this work is incomplete without generalizable implementation strategies applicable to real-world settings. A lack of evidence on how to best implement the pCGA in a variety of health systems has limited patient access to this intervention.[36] The few implementation studies that exist demonstrate challenges due to contextual factors (e.g., misaligned incentives) and low fidelity to the intervention.[36, 37] As a result, few programs use the pCGA for older surgical patients and reach is limited to patients receiving care at large academic centers with significant resources. Thus, there is a critical need for novel, evidence-based strategies to promote successful implementation of this intervention into a variety of healthcare settings. To address this gap, this study seeks to answer the research question: what implementation strategies will improve provider use (adoption) and patient access (reach) to the pCGA, while preserving effectiveness (fidelity) in academic and community settings?

The overall objective of this study is to use implementation science and systems engineering methods to tailor and pilot test a user-centered implementation package for the pCGA – one that can be adapted to community-based hospitals for future multi-site implementation-effectiveness trials. We therefore aim to (1) Map the pCGA process and identify system-based barriers and facilitators to its use among older adults undergoing major abdominal surgery, (2) Co-design an implementation package for the pCGA applicable to a diverse population of older patients undergoing major abdominal surgery at (2a) a large academic hospital and (2b) an affiliate community site, and (3) Test and refine the pCGA implementation package in preparation for a future randomized controlled implementation-effectiveness trial. We hypothesize that systems engineering methods of process mapping and co-design can successfully be applied to the pCGA (Aims 1&2) and that a rigorous user-centered implementation package for the pCGA will improve surgical care processes (reach and adoption, primary implementation outcomes) and patient outcomes (length of stay, primary effectiveness outcome) for older adults undergoing major abdominal surgery.

METHODS

Design and Conceptual Framework

This study will apply implementation science and human-factors engineering principles to optimize the delivery of an existing, effective intervention, the pCGA, and generate an adaptable implementation package for future work. Through process mapping, supplemented with interviews and observation, we will identify opportunities for system redesign that will improve pCGA delivery (phase 1) and employ participatory design with patients, caregivers and healthcare providers to develop a user-centered implementation package (phase 2) that is adaptable to academic and community settings. We then will pilot test the implementation package (phase 3) using the RE-AIM framework[38] to measure reach, effectiveness, adoption, implementation and maintenance, generating preliminary data in preparation for a larger randomized implementation-effectiveness trial. This work aligns with the National Institutes of Health Stage Model[39] to intervention development, considering implementation early in development (IA) and recognizing that the development and evaluation of complex interventions may not be linear.

The pCGA listed below **(Table 1)** is based on a model by McDonald et al. which has demonstrated decreased length of stay, readmission rates and discharge to non-home destination for patients having abdominal surgery.[29] In order to improve outcomes, the pCGA must be implemented with fidelity to key elements[15]. Treatment fidelity, particularly for complex behavioral interventions, is conceptualized as consistency in the content of the intervention, the quality of intervention delivery by healthcare professionals, and the receipt and adherence by patients.[40] The content of the pCGA requires a multi-domain assessment,[41, 42] however, equally important is the presence and quality of a follow-up plan to optimize identified deficits, and patient adherence to that plan. The pCGA often generates recommended tasks for the patient (exercises, nutritional shakes), provider (medication changes) or identifies additional preoperative workup to be performed (imaging or physiologic testing). Many studies on pCGA fall short by using it primarily as a risk stratification tool without a plan or sufficient time to address modifiable factors.[43-45] In a well-done study using quasi-experimental design McDonald et al. demonstrate decreased length of stay, readmission rates and discharge to non-home destination for patients having abdominal surgery.[29] Studies from the United Kingdom similarly demonstrate that pCGA, performed in multidisciplinary settings with a plan to address deficits, reduces postoperative length of stay and complications.[30, 46] These studies have led to national and international guidelines that recommend pCGA for older adults before major surgery.[15, 31-33]

Table 1. Preoperative Comprehensive Geriatric Assessment

Domain	Assessment	Staff Performing	Example Output
Polypharmacy	(1) medication reconciliation, (2) identification of high-risk Beer's criteria medications, (3) anticholinergic cognitive burden score	Pharmacist	Medication changes made directly or referred to PCP
Medical comorbidities	History and physical, including cardiac risk assessment with revised cardiac risk index	Geriatrician	Additional testing ordered; specialist referral placed
Physical function	(1) Mobility testing (e.g., Timed Up and Go Test) (2) Lawton Independent Activities of Daily Living, Activities of Daily Living, Home support and resources	(1) Medical Assistant (2) Social Worker	Home exercises prescribed or preoperative physical therapy referral ("prehabilitation")
Cognition	Delirium risk assessment (e.g., Montreal Cognitive Assessment)	Social Worker	Memory clinic referral

Mood	Depression screen (e.g., Patient Health Questionnaire-9)	Medical Assistant	Medication or specialist referral
Nutrition	Nutritional status (e.g., Mini-Nutritional Assessment Short-Form), Body mass index	Medical Assistant	Nutritional supplementation
Goals of care	Discussion and documentation of acceptable outcomes and code status. Assist patient with documenting healthcare power of attorney.	Geriatrician	DNR status established and communicated to surgeon

Systems-based engineering methods improve healthcare delivery and outcomes by tailoring the fit of the intervention to the local context. A seminal report from the Institute of Medicine and National Academy of Engineering outlines the unique methods and tools by which systems-engineering can transform the quality and delivery of healthcare.[47] We will employ a human-factors engineering model, the System Engineering Initiative for Patient Safety (SEIPS) model.[48] It builds on Donabedian's structure-process-outcome model[49] by providing a detailed and expanded structure of interacting components (i.e. the work system), inclusive of people (or teams); tasks; tools and technology; organizational factors (e.g., policies, teamwork); physical environment (clinic location); and external environment that influence healthcare processes and outcomes. SEIPS has been extensively and successfully applied to healthcare delivery[50-58], including work to improve care transitions for older adults.[59-64] We will use SEIPS 2.0[65] which expanded the original model[48] to acknowledge that patients and families perform work within the healthcare process and that their internal environment (i.e. patient home) plays a role within the system **(Figure 1)**.

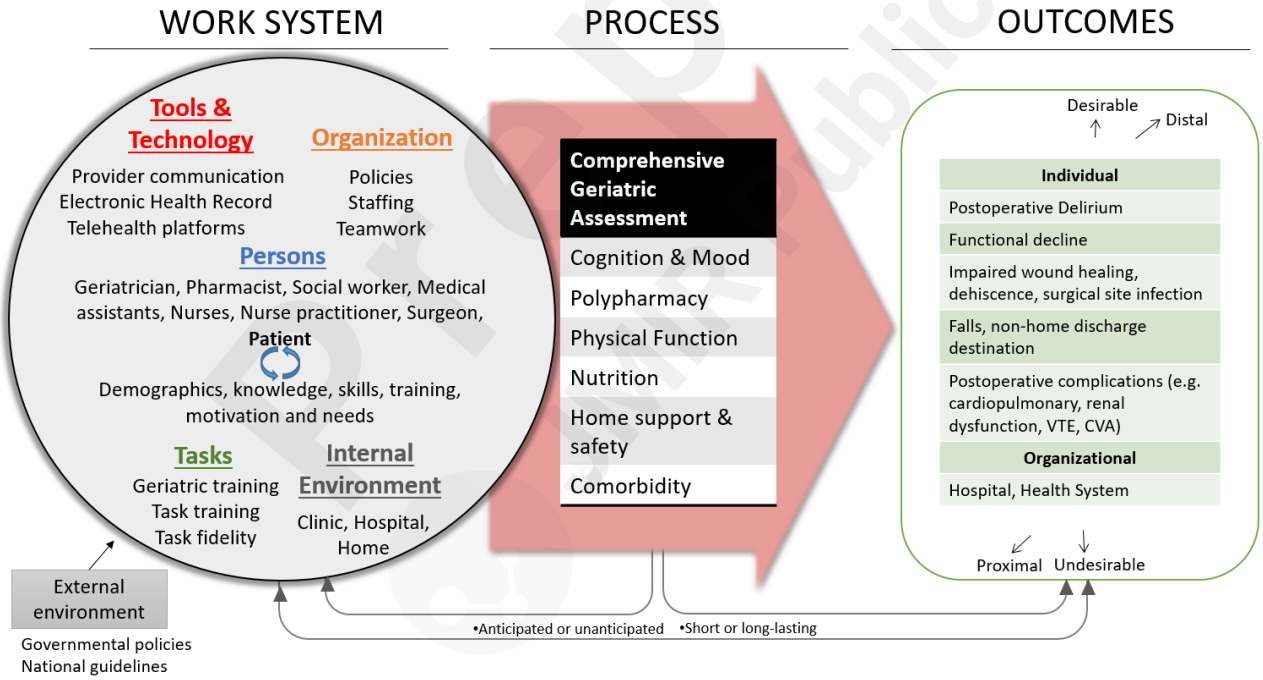


Figure 1. Preliminary SEIPS 2.0 model depicting the pCGA process.
SEIPS = System Engineering Initiative for Patient Safety; pCGA = preoperative Comprehensive Geriatric Assessment

Ethical Review & Approval

The study will occur in three separate phases. Each phase will be reviewed separately by the University of Wisconsin-Madison institutional review board. Phase 1 of the study was approved by the institutional review board on 1/19/2023 (2022-1516). All participants provide informed consent for both observations and interviews. To protect privacy and

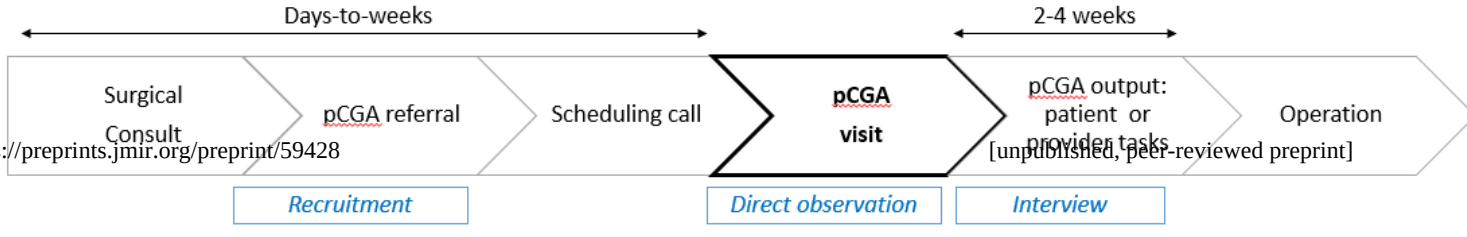
confidentiality, all data are de-identified. Compensation is provided in gift cards. Participants receive $20 for participating in observation and $20 for a 45 minute qualitative interview. Healthcare staff will receive $45 for a 90 minute focus group. Surgeons will receive $50 for a 45 minute interview. Phase 2 of the study was approved by the institutional review board 3/1/2024 (2024-0044). All participants provide informed consent. To protect privacy and confidentiality, all data are de-identified. Compensation is provided in gift cards. Patient and caregiver participants will receive $50 per 90 minute session. Healthcare professionals will receive $100 per 90 minute session. Phase 3 will be submitted, reviewed and approved by the institutional review board prior to initiating study activities. All participants will provide informed consent. To protect privacy and confidentiality, all data will be de-identified. Compensation is provided in gift cards. Participants will receive $5 per survey completed. The study was registered with ClinicalTrials.gov as NCT06184919 (Phase 1 & 2 – Observational phases) and NCT06184724 (Phase 3 – Pilot trial).

Phase 1. Process Mapping

Study Design: We will perform process mapping[66, 67] via direct clinical observation of the pCGA visit, qualitative interviews with patients and a focus group with staff, using SEIPS as a framework.[60, 67, 68] Process mapping is a fundamental systems engineering approach, based upon the recognition that work, as it is performed in real world settings, is not always consistent with its expected or prescribed form. We expect Phase 1 will catalog components of the SEIPS-based work system (traditional process map) and we will supplement the map by identifying barriers and facilitators to each step.

Participants: (1) Patients/Caregivers: Eligible participants are any patient age 85 or older, or any patient age 65 or older with multiple comorbid conditions (>2), diagnosed or suspected cognitive impairment, diagnosed or suspected functional impairment, or poor nutrition (documented weight loss of 10% within a year). Inclusion criterion are older adults for whom the surgeon is recommending an operative intervention and who intend to undergo the elective major abdominal surgery. Exclusion criterion will be non-English speakers because we do not have the resources for translation or the absence of a caregiver for those without decisional capacity. Based upon prior literature,[68] we will enroll N=20 older adults and their caregivers, if present, for observation and interviews. We will use purposeful sampling to recruit at least two patients each for groups traditionally under-represented in medical research by race, ethnicity, socioeconomic background and rural/urban backgrounds.[69] Research staff will screen patients for eligibility. Clinic staff will approach participants to assess interest and research staff will obtain informed consent. Patients and caregivers will receive gift card incentives for participation. (2) Healthcare professionals and staff: All healthcare professionals working in the preoperative geriatric clinic (n=10) who are responsible for performing the tasks of the pCGA will be approached and consented for direct observation and focus groups to provide feedback on the pCGA process map. Additional staff (n=5) engaged in the clinic (administrative leads, schedulers, tech support) will be invited to participate. We will invite referring surgeons (n=10) for one-on-one interviews, with the plan to recruit additional participants as informed by thematic saturation during ongoing analysis. We will purposefully select surgeons to represent a range of surgical specialties, men and women. Recruitment will occur by email for healthcare professionals. We will obtain informed consent and all healthcare professionals will receive gift card incentives for participation.

Predicted pCGA Process Map: The Preoperative Comprehensive Geriatric Assessment



Clinic is conducted after the initial surgical consultation and prior to surgical operation. A predicted map of the existing process is outlined in **Figure 2**. The patient consults with a surgeon who recommends operative intervention and places a referral for the pCGA clinic. The pCGA is conducted in two locations and provides virtual options for patients travelling from a distance. The pCGA results includes recommendations for patient-level tasks (exercises, nutritional shakes), provider tasks (medication changes) or additional preoperative evaluation.

Figure 2. Predicted process map of patient journey through pCGA. Each point along the process will be evaluated according to SEIPS identifying key work tasks and associated barriers. *Research activities noted in blue italics.*

Data Collection: Direct observation: We will embed a trained research assistant in the clinic and use direct observation guided by a fidelity checklist to document the events of the pCGA and take notes on the process. We will follow the patient from initial check-in through the completion of the visit, providing a detailed and direct account of the patient's journey. [66] Observers will use a standardized template to document the persons, tasks, tools/technologies, environment and organizational factors according to the SEIPS model. Observer notes will be supplemented with an audio recording of the patient-physician interaction. Interviews: We will interview patients and caregivers 2 weeks after the pCGA visit. Research staff trained in qualitative methods will conduct interviews using a semi-structured interview guide to elicit feedback on the predicted process map **(Figure 2).** Probes will assess barriers, facilitators, motivation, and adherence to patient work tasks, and reflections on the process of scheduling, attending and participating in the pCGA. We will conduct interviews through a virtual platform. The interviewer will ask the patient to visually show on screen the home environment and ask probing questions to gain a more in-depth understanding of how tasks are performed. We expect each interview to take 45 minutes. We will interview surgeons using semi-structured guides to elicit feedback on the process map and any barriers or facilitators according to the SEIPS model. The interview will provide an understanding of perceived barriers and facilitators to adoption of the pCGA and explore how the surgeons' separate workflow fits into the proposed process map. Surgeon interviews will take 45 minutes. Focus Groups: Qualitative research staff will engage pCGA healthcare professionals and staff (n=10) in a focus group after completing direct observations. Focus groups naturally foster within-group interactions, allowing us to gain additional insight on the accuracy of the map from multiple perspectives. A semi-structured guide based on the SEIPS model will elicit feedback on the process map, clarifying its accuracy as a representation of the tasks and procedures performed, and identifying system-level barriers and facilitators at each step. The focus group will be audio recorded and will take 90 minutes.

Data Analysis: Qualitative analysis: Interview and focus group audio recordings will be transcribed and analyzed using a deductive strategy[70, 71] and the SEIPS framework to develop the coding taxonomy, with a focus on identifying barriers and facilitators within each SEIPS category for each step. Our analysis will utilize triangulation comparing observed data points from the pCGA visit to patient interviews. The transcripts will be coded by each of the three individually followed by a joint discussion to explore dissent and achieve consensus. We will use qualitative analysis software NVIVO (14) to catalogue coded data. Process mapping: The qualitative analysis as described above and direct observations will be used to adapt the SEIPS-based process map.[68] We will supplement the map with a table, cataloging individual tasks in rows, numbered in reference to the map, with columns listing the persons, environment, tools, technology, barriers and facilitators to

completion of each task.

Phase 2. Participatory Design

Study Design: In phase 2, we will apply user-centered participatory design methods to adapt the process map (phase 1) into an implementation package, consisting of a set of implementation strategies, to address barriers and enhance facilitators at each step. Participatory design[72] is a systems engineering method where researchers and participants work together in designing the workflow of an intervention. Co-design sessions will be conducted in parallel at a large quaternary academic center (2a) and an affiliated community hospital (2b). There will be two groups (design teams) of patients/caregivers and healthcare professionals per location, for a total of four groups.

Participants: Each design team will consist of N=7 participants. Because participatory design aims for solution convergence, odd numbers purposefully facilitate tie-breaking within groups. The small number of stakeholders in each group (i.e., rather than 14 in one group) allows all stakeholders to provide their input and facilitates critical evaluation. 1) Patients and caregivers. Older adults are eligible after having completed pCGA followed by major abdominal surgery and subsequent recovery. We will approach patients and caregivers at each location (University and Community hospital) with the goal to enroll n=7 for participation. Patients and their caregivers will be approached at the follow up surgical visit which is conducted at 14 days postoperatively. Of note, older adults with Alzheimer's Disease or related dementias will be included, if they provide assent and are accompanied by a caregiver who also consents and participates alongside them. We will use purposeful sampling to recruit at least one patient or caregiver from under-represented groups by race, ethnicity, socioeconomic and rural/urban backgrounds.[69] We intend to over-sample to ensure that perspectives from vulnerable patients are heard. All patient and caregiver participants will receive gift card incentives for participation. 2) Healthcare professionals. Eligible health care professionals will include surgeons performing major abdominal surgery whose patients may benefit from pCGA and healthcare professionals who conduct or could potentially conduct elements of the pCGA. For the academic center (2a), this will include the same set of healthcare professional participants as involved in Phase 1. These include geriatricians, primary care providers, advanced practice providers, social workers, medical assistants, pharmacists, and physical therapists. We will also invite participation of additional ancillary staff, such as administrative leads, schedulers and tech support. All healthcare professionals will receive gift card incentives for participation.

***Data Collection*:** We will conduct 5 co-design videoconference sessions with each group over 6 months, with 2-3 weeks between each session **(Table 2)**. In session one, we will present the process map generated in Phase 1 and a prototype of the current implementation package for the pCGA. Researchers will facilitate the discussion, maintaining respectful debate among design team members as they identify process changes that will promote implementation of the pCGA. The facilitator will focus on solution convergence from session to session. Each design team will participate in sessions independently, however, we will summarize output from each session and provide this content to the alternate design team for comment. Each session will last 90 minutes. Sessions will be conducted virtually to promote participation and retention, and audio recorded for qualitative analysis. Co-design will be conducted separately for the academic center and the community hospital.

Table 2. Outline of participatory co-design sessions.

Session	Content for pCGA implementation redesign

1	Methods introduction, process map review, initial implementation package design
2	Refinement of inputs (e.g. referrals)
3	Refinement of pCGA system workflows (e.g. phone calls)
4	Refinement of pCGA output & feedback mechanisms
5	Finalizing implementation package, roll-out planning

Between session activities: Input from alternate design team is synthesized for presentation to next team, analysis performed of prior session content.

***Data Analysis*:** Qualitative data analysis of design sessions will occur using the Rapid Identification of Themes from Audio-recordings method[73] to facilitate rapid iterative refinement of the implementation package between sessions. Following each session, the research team will analyze audio recordings directly without transcription, identifying key themes, an initial codebook, and preliminary analysis of codes. We will synthesize these findings with outputs from the design session such as sketches, case scenarios, ratings, research team observation notes, and stakeholder notes. This allows early identification of key themes after each session which can then be provided back to stakeholders in the subsequent session. Data analysis will focus on identifying implementation strategies to mitigate perceived barriers or strengthen known facilitators (**Table 3**). We will investigate novel solutions as well as known implementation strategies, such as the 73 discrete strategies delineated in the Expert Recommendations for Implementing Change.[74, 75]

Table 3. Examples of potential implementation strategies to improve reach and adoption while maintaining fidelity

SEIPS Category	Possible Strategy
People	Dedicated referral coordinator (or RN) within surgical clinics
Organization	Clear parameters for referral, script for telephone triage
Tools	Telehealth for remote patients, educational handouts, order sets
Tasks	Automate recommendations to primary care or referring provider
Environment	Travel vouchers for patients with limited transport

Phase 3. Pilot trial of the pCGA implementation package.

Study Design: We will conduct a pre-post pilot study of the implementation package over 10 months, conducted at the clinic-level within two busy academic center surgical subspecialty clinics performing major abdominal surgery (selecting one that does not routinely refer for pCGA in addition to one that does routinely refer). We will collect baseline pre-pilot data via retrospective chart abstraction of the year prior to intervention. After an implementation roll out period of 2 months, post-intervention data will be collected over 10 months. Specifically we will assess outcomes according to the RE-AIM framework[38] (reach, effectiveness, adoption, implementation and maintenance) using chart abstraction for patient-level data and simple self-reported surveys for healthcare professionals. We hypothesize that a user-designed implementation package will improve the reach and adoption of the pCGA compared to the historic baseline.

Participants: 1) Patients: Older adults presenting to surgical clinics will be screened for eligibility criteria by study staff. Eligible participants are patients age 85 or older, or 65 or older with multiple comorbid conditions (>2), diagnosed or suspected cognitive impairment, diagnosed or suspected functional impairment, or poor nutrition (documented weight loss of 10% within a year). Inclusion criteria are eligible older adults planning to undergo elective major abdominal surgery. Exclusion criterion will be non-English-speakers because we lack resources for translation or caregivers for those without decisional capacity. 2) Healthcare professionals: Consistent with implementation research, healthcare professionals using the

pCGA implementation package are considered study participants.[76] Because we are recruiting pilot participation from healthcare professionals who participated in co-design, they will be familiar with the intervention. Surgeons referring from the two clinics (n=12) and healthcare professionals engaged in the pCGA clinic (n=10) will be asked to participate in the pilot. Healthcare professionals will receive gift card incentives for survey completion.

Recruitment and Enrollment: Clinic staff will approach potential participants to determine interest and a study team member will then share study details and obtain consent. At baseline n=40 patients per year are seen for pCGA. We expect to enroll n=20 patients over the pilot period. All patient data for the pilot will be obtained via chart abstraction. The study will be subject to ethical review board approval.

Intervention: The pCGA implementation package (generated via Phase 2) will include a set of implementation strategies[74, 75] and an explicit step-wise plan defining the people, tasks, tools or technology, relevant organizational factors and physical or virtual environment[65] for the pCGA. The implementation package will target systems-level processes to promote pCGA administration prior to surgery, for example automating referrals in the electronic medical record, improved patient education materials, or increased telehealth opportunities.

Data Collection & Variables: We will obtain quantitative data from two sources: (1) chart abstraction for patients and (2) self-reported survey instruments for healthcare professionals. (1) Chart Abstraction: Trained research assistants will prospectively abstract and enter data into a de-identified database on a secure server using a data dictionary. We will conduct random audits for inter-rater reliability according to best practices for retrospective chart review.[77] *Patient-level characteristics* will include: demographics (age, sex, height, weight, zip code, race, Hispanic ethnicity), comorbidities (diabetes, chronic corticosteroid use, cancer diagnosis, congestive heart failure, chronic obstructive pulmonary disease, bleeding disorders or anticoagulant use, renal insufficiency and dialysis). *Clinical data from the pCGA* will include: polypharmacy (Anticholinergic burden score[78], Beer's criteria medications[79]), physical function (Timed Up and Go Test[80], Lawton Independent Activities of Daily Living[81], Activities of Daily Living[82]), cognition (Montreal Cognitive Assessment[83]), mood (Patient Health Questionnaire-9[84]), nutrition (Mini-Nutritional Assessment Short-Form[85], Body mass index), multiple chronic conditions (Charlson comorbidity index[86, 87], Revised cardiac risk index[88]), documentation of code status, completion of healthcare power of attorney forms, and recommendations for additional tests or referrals (e.g. physical therapy). *Clinical data from the surgical hospitalization* will include date of surgery, procedure performed, postoperative complications (pneumonia, myocardial infarction, surgical site infection, sepsis, urinary tract infection, venous thromboembolism, renal failure, readmission, unplanned reoperation), postoperative delirium, date of discharge, discharge destination, readmission within 30 days and death. We will abstract postoperative delirium using a validated method.[89-91]

Table 4. RE-AIM Domains and Associated Outcome Measures

Domain	Definition	Measurement
Reach	The percentage and characteristics of older patients who receive pCGA prior to abdominal surgery.	(A) Referred / potentially eligible patients (B) Comparison of referred / eligible patients by age, sex, race, ethnicity, BMI, zip code *Target Reach: >50% referral of eligible pCGA patients per clinic*
Effectiveness	The improvement in clinical	Primary: postoperative length of stay,

	outcomes from pCGA receipt.	Secondary: 30-day morbidity and mortality (see text)
Adoption	Surgeon Intent, decision & action to refer eligible patients for pCGA.	Percentage of surgeons referring / total surgeons in the pilot clinic *Target Adoption: >75% of surgeons achieving >50% referrals*
Implementation: Fidelity	Multifaceted outcome which includes (1) treatment "dose" or amount of intervention delivered, (2) quality or content of intervention delivered by health-care professionals, (3) treatment receipt and enactment by patients (NIH Best Practices)[40]	(1&2) Percentage of completed pCGA components, as abstracted from the medical record at pCGA visit. (3) Completion of pCGA recommendations as abstracted from the medical record at time of surgery. *Target fidelity: >90% pCGA components completed*
Implementation: Feasibility	Perceived ease of use of pCGA implementation package	Feasibility of Intervention Measure (4-item survey)[92]
Implementation: Acceptability	Satisfaction with the pCGA implementation package	Acceptability of Implementation Measure (4-item survey)[92]
Implementation: Appropriateness	Fit & relevance of pCGA implementation package	Intervention Appropriateness Measure (4-item survey)[92]
Maintenance	The extent to which pCGA use is sustained over the pilot period.	Trends in reach, adoption & implementation outcomes will be evaluated at 6 mos and 12 mos.

We will assess feasibility, acceptability & appropriateness of pCGA implementation package according to healthcare professionals (e.g., surgeons, geriatricians, advanced practice providers, nurses, medical assistants, technicians, staff).

Outcomes: The primary outcomes of this pilot trial will be reach and adoption. We will apply the RE-AIM framework[38] to measure reach, effectiveness, adoption, implementation and maintenance **(Table 4)**. Reach refers to the percentage and characteristics of older adults receiving the pCGA intervention while adoption accounts for those health systems and healthcare professionals who refer to or deliver the pCGA.[38, 93] Of note, implementation in the RE-AIM framework refers to fidelity, or the extent to which an intervention is delivered as intended. We will expand the implementation domain to include measures of fidelity as defined by NIH Best Practices[40] and feasibility, acceptability, and appropriateness according to Proctor's taxonomy of implementation outcomes.[94] The *primary effectiveness outcome* will be postoperative length of stay, an easily measured, continuous outcome variable commonly used in the surgical literature on pCGA.[29] We will collect *exploratory measures* to inform the selection of effectiveness outcomes for a future implementation-effectiveness trial. These exploratory outcome measures will include: (1) a composite of death or postoperative complication events, and data points relevant to pCGA, including (2) a cognitive outcome (postoperative delirium), (3) functional outcome (discharge destination to home, rehabilitation or skilled nursing), (4) nutritional outcome (discharge diet, albumin level and weight at discharge), and (5) polypharmacy (Beers criteria discharge medications[79], Anticholinergic burden score[78] and number of opioid pain pills prescribed at discharge). (2) Self-report surveys: We will administer surveys to healthcare professionals (surgeons and pCGA staff) to assess feasibility, acceptability and appropriateness of the implementation package at 6 and 12 months into the pilot. We will contact healthcare professionals for survey completion via email with an option for

electronic completion; due to busy clinical demands, a research assistant will make paper copies of the survey available for completion during clinic time. We will utilize a previously-validated survey instrument to measure implementation outcomes, specifically the acceptability, appropriateness and feasibility of the intervention.[92] The survey is administered by self-report and consists of 4-items for each domain, 12-items total. Time required is estimated at 15 minutes or less, approximately 5 minutes per domain. Published psychometric assessment of the instrument demonstrated high validity (Crohnbach's alpha 0.85-0.91) and high reliability (test-retest 0.73-0.88). The items are scored on a 5 point scale. For each 4-item domain, the score can be created by averaging the responses. While cut-off scores have not been established, higher scores indicate greater acceptability, appropriateness, or feasibility.

Data analysis: The aim of the pilot is to maximize reach and adoption while maintaining implementation fidelity before a full-scale implementation-effectiveness hybrid trial. Therefore, sample size will limit our ability to evaluate differences in effectiveness outcomes such as mortality or morbidity, however, more proximal effectiveness estimates will be explored in abstracting short-term clinical outcomes, (e.g., medication changes at discharge). We will use exploratory measures to establish some preliminary point estimates for event rates and confidence intervals within our sample for the purpose of planning a future study. As such, there is no role for formal power calculations in this pilot study. Recruitment data will inform calculation of reach, adoption and maintenance outcomes. We will explore all RE-AIM outcomes for differences across underrepresented groups[69] (rural vs urban as determined by zip code, racial majority vs minority, men vs women vs other gender identity, Hispanic ethnicity vs non-Hispanic). All data will be entered into STATA for analysis. Data will be evaluated for accuracy and missingness. Descriptive univariate and bivariate analyses will be conducted, including $\chi 2$ tests for categorical data, t-tests and Mann-Whitney-U tests for continuous data as appropriate with a cut-off at $P < .05$ for statistical significance.

RESULTS

We anticipate this study will take approximately 60 months to complete, from study start-up procedures to completion of the pilot trial. The three phases will take place between June 2023 and June 2028. We expect the following results:

Phase 1: The results of this phase will include a detailed process map and the corresponding barriers/facilitators as a starting point for system redesign to improve implementation of the pCGA, specifically expanding reach while maintaining fidelity.

Phase 2*:* The results of participatory co-design sessions at the academic center are expected to converge upon an adaptable implementation package of the pCGA, ready for stage 1B feasibility and pilot testing. Stakeholder design sessions at the community hospital will serve as a template for user-centered implementation of the pCGA at a future date. The results of co-design at the community hospital will provide a starting point for understanding potential generalizability of the implementation package and the extent to which adaptation may be needed to begin implementation at new sites.

Phase 3: The pilot trial will test the pCGA implementation package using a pre-post design in two surgical clinics enrolling n=20 pre- and n=40 patients in the post-implementation period. Using the RE-AIM framework[38] we will measure reach, effectiveness, adoption, implementation and maintenance. We aim to improve reach and maintain fidelity. Exploratory analyses will assess differences across historically underrepresented groups[69] (rural vs urban, racial majority vs minority, men vs women).

We hypothesize that reach will increase while maintaining fidelity in the post-implementation phase of the pilot.

Findings from each phase of the study will be disseminated following best practices throughout the conduct of this research. We will publish peer-reviewed manuscripts and present findings at professional conferences for each phase of the study. The study is registered at ClinicalTrials.gov in accordance with National Institutes of Heath (NIH) policies and regulations (NCT06184919, Phase 1 & 2 – Observational phases, and NCT06184724, Phase 3 – Pilot trial). Results will be posted to ClinicalTrials.gov within 12 months of study completion.

DISCUSSION

Anticipated Principal Findings: This study protocol will apply both implementation science and human-factors engineering methods to generate the following main findings for each phase of the study: (1) detailed process map for the pCGA, (2) a co-designed implementation package to improve the use of pCGA among older patients having major abdominal surgery and (3) preliminary data to support a future implementation-effectiveness trial. In addition to the aforementioned expected output, the study will allow us to explore our hypothesis that systems engineering methods of process mapping and co-design can successfully be applied to the pCGA in surgical care (Aims 1&2) and that a rigorous user-centered implementation package for the pCGA will improve surgical care processes (reach and adoption, primary implementation outcomes) and patient outcomes (length of stay, primary effectiveness outcome) for older adults undergoing major abdominal surgery.

Comparison to Prior Work: The findings will be interpreted in the context of prior literature. There are few studies to address implementation challenges for the pCGA. Implementation science can provide insight into the heterogeneity of the literature on the pCGA. Poor implementation of the pCGA contributes to variable effectiveness among older adults undergoing abdominal surgery. Two RCTs have been conducted including abdominal surgery patients; however, both were underpowered with significant variability in the fidelity to and implementation of the pCGA.[95, 96] Hempenius et al. randomized a heterogeneous group of 260 surgical oncology patients undergoing minor, intermediate and major operations (e.g., abdominal surgery) to usual care or an in-hospital “geriatric liaison” service conducting pCGA tests within 24 hours of the operation. They found a 34% relative reduction in postoperative delirium, but it was not significant due to an underpowered sample size and a lower-than-expected rate of delirium.[95] The effect of the intervention was likely reduced because the “liaison” model leaves inadequate time to reduce risks and minor procedures carry very low complication rates with lower postoperative delirium rates. Ommundsen et al. randomized a population of frail patients with colorectal cancer to receive outpatient pCGA versus usual care, finding no significant difference in the primary outcome of severe surgical complications.[96] This study was limited by the lack of a multidisciplinary team supporting the intervention, inadequate preoperative time to implement pCGA recommendations, unclear patient adherence to recommendations, and inability to reach the necessary sample size. This resulted in an underpowered study and a weak intervention with poor fidelity.

Strengths: By applying an implementation focus, this study will define system-level strategies to maintain fidelity while improving implementation, thereby elevating the quality of evidence in examining the effectiveness of the pCGA. We expect the current study will

facilitate a paradigm shift toward rigorous implementation-effectiveness[97] work to enhance perioperative care for older surgical patients. Our line of research is innovative because it aims to refine the implementation of an existing intervention, engaging an affiliate community hospital in user-centered design, in order to expand the reach of pCGA to patients in a variety of settings. Our methods are also innovative, applying human-factors engineering methods and the SEIPS model to a new field, the use of pCGA among older patients having major abdominal surgery.

Limitations: We anticipate there will be limitations and potential challenges in conducting this study. Recruitment and retention will be addressed by incentivizing participation (gift cards) and recruiting at least 10% more participants than required. Because user-centered design sessions will require continuity, we will conduct team-building exercises to promote investment in the process and provide sufficiently generous incentives to retain participants. Smaller design teams are often more effective, and we will accept n=2 dropouts per group. Patient and caregiver access to technology may limit participation in video-based assessments in Phases 1 and 2; however, we believe this challenge can be overcome as these methods have successfully been applied over the course of the Coronavirus-19 pandemic. Alternative strategies such as in-person attendance of interviews and design sessions also risk potential limitations or exclusion of those with poor access to transportation. We recognize that the process map within the academic medical center may not be generalizable to the community site. It is possible the implementation package cannot be successfully adapted to that setting. In this case, user-centered design will allow us to explore pCGA components that will be most valuable to the healthcare professionals and patients at the community hospital. This may require a shift toward intervention adaption, evaluating a pared-down, community-specific pCGA intervention. The implementation package and pilot test in Phase 3 will focus on system-level changes, however, we anticipate identifying individual-level barriers and facilitators to implementation (PCP follow-through or patient barriers to performing exercises). The role of individual behavior in fidelity of the intervention cannot be ignored and may serve as an area for future research. We plan to track these findings, however, interventions to alter individual behavior is beyond the scope of this system-level investigation.

Future Directions: This study will produce preliminary data on which to build a future implementation-effectiveness trial. Upon successful adaptation of the implementation package, we anticipate performing a step-wedge randomized controlled trial to implement the pCGA in multiple sites. The anticipated Type II hybrid trial will equally weigh implementation and effectiveness outcomes. It will track both short-term (30-day) and longer-term (90, 120-day) outcomes including morbidity and mortality, and, as noted in the exploratory measures, will include outcomes across pCGA domains (cognition, function, nutrition, polypharmacy, mood, quality of life). If proven, the adaptable pCGA implementation package will provide an actionable strategy for hospitals seeking to improve surgical care for older adults. With an effective intervention and a well-tested implementation strategy, future work will focus on scalability and dissemination. By engaging an affiliate community hospital in user-centered design, this research will develop implementation strategies by which to expand the reach of pCGA. We will explore for the differential receipt and experience of pCGA across diverse populations, consistent with the NIH commitment[98] to diversity, equity and inclusion, including the study of health equity. Throughout the study, we will engage and elicit the voices of patients and caregivers traditionally underrepresented in medical research[69] according to race, ethnicity, socioeconomic status and rural/urban backgrounds. In addition to hybrid implementation-

effectiveness trials, future directions will focus on adaptation to new populations, dissemination strategies and scalability of the intervention.

Dissemination Plans: We anticipate that surgeons and hospitals participating in state-wide quality improvement collaboratives, such as the Surgical Collaborative of Wisconsin, may be interested in interventions to improve surgical care for older adults. Larger national initiatives, such as the American College of Surgeons' Geriatric Surgery Verification Program,[99] require the performance of a pCGA. If proven, the pCGA implementation package may serve as a valuable resource and provide an actionable strategy for hospitals in these or similar programs. Our ability to provide an effective intervention with a well-tested implementation strategy will open the possibility of regional or national dissemination.

CONCLUSION

Completion of the study will produce a comprehensive and rigorously evaluated pCGA implementation package and feasibility data to support a multi-site hybrid implementation-effectiveness clinical trial. This study will advance the field, improving the quality of implementation data on pCGA, providing replicable implementation strategies for pCGA, and adding human factors methods to perioperative science. It will further our overall goal to improve surgical care for older adults through transdisciplinary research that promotes implementation and dissemination of effective, evidence-based, patient-oriented interventions.

Data Sharing Statement

The data generated and/or analyzed during this study will be available after study completion from the corresponding author in a de-identified form on reasonable request.

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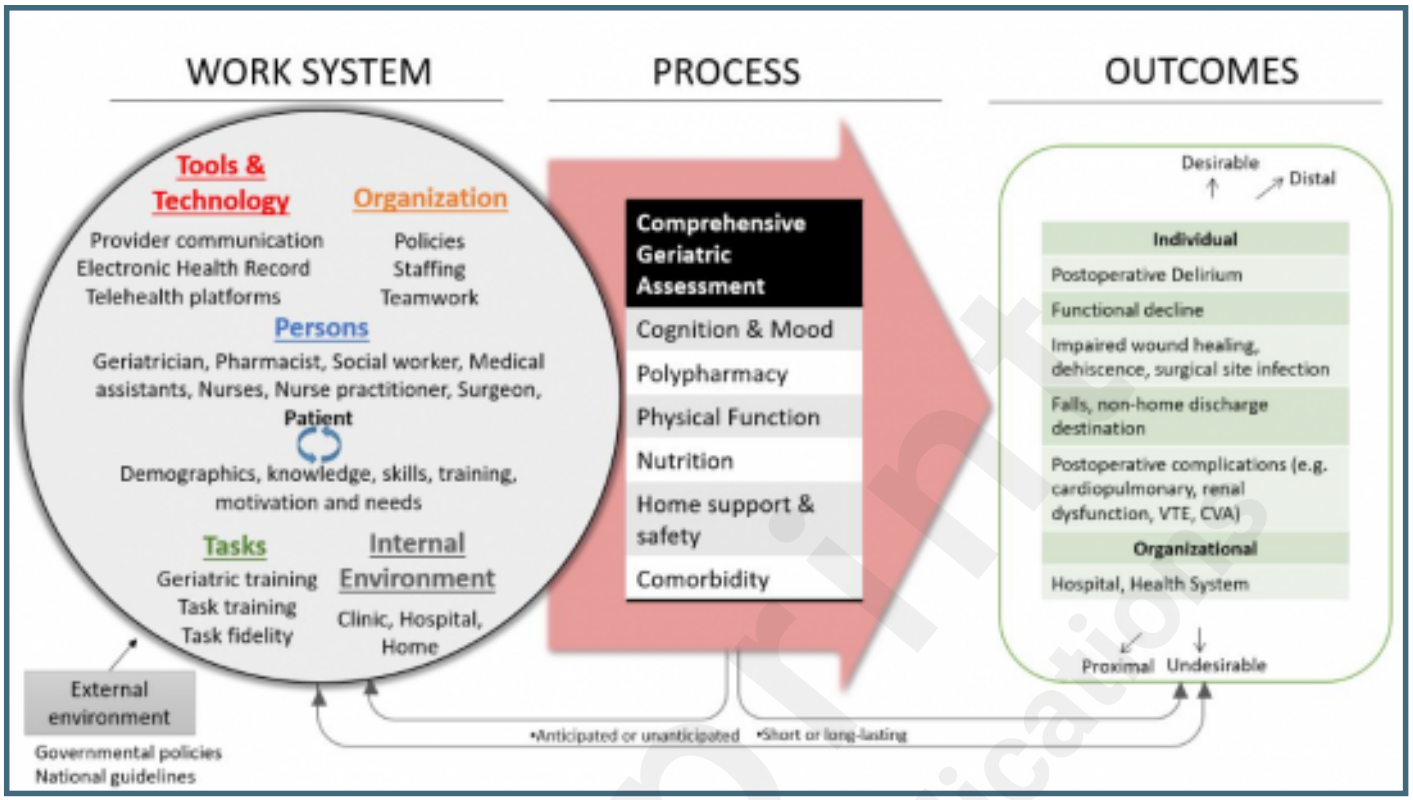
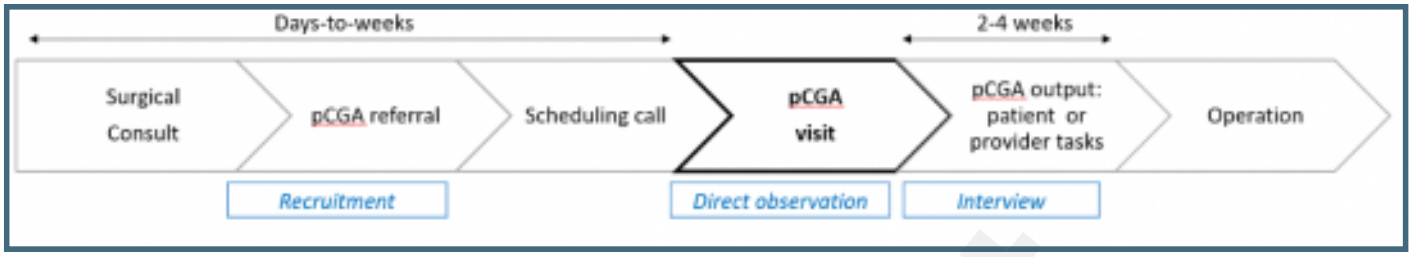
Supplementary Files

Figures

Preliminary SEIPS 2.0 model depicting the pCGA process.



Predicted process map of patient journey through pCGA. Each point along the process will be evaluated according to SEIPS identigying key work tasks and associated barriers. Research activities noted in blue italics.



Multimedia Appendixes

Summary Statement Expert Review.
URL: http://asset.jmir.pub/assets/dc4618b3aefdb7f2a5b3b2da532cd291.pdf