IMPROVING SURGICAL CARE AND OUTCOMES IN OLDER CANCER PATIENTS THROUGH IMPLEMENTATION OF AN EFFICIENT PRE-SURGICAL TOOLKIT (OPTI-SURG)

Patient Eligibility Criteria: (See Section 3.1)

- Patients must have known or suspected cancer diagnosis and have one of the following cancer-directed operations planned: Gastrectomy; Colectomy; Proctectomy; Esophagectomy; Pancreatectomy; Hepatectomy; Total cystectomy; Total Nephrectomy; Lung lobectomy/pneumonectomy
- Age ≥ 70 years
- Patients with known metastatic disease with a plan for curative intent resection are eligible.
- Patients with double primaries undergoing planned curative operation for both are eligible.
- Patients undergoing emergent surgery are not eligible.
- Patients with second primary, or metachronous malignancy are not eligible.
- Patients with known metastatic disease who are undergoing palliative resection are not eligible.
- Patients with psychiatric illness or other mental impairment that would preclude their ability to give informed consent or to participate in the prehabilitation program are not eligible.
- Patients must be able to speak and complete questionnaires in English.

Institutional Randomization:

- ARM 1: Usual Care
- ARM 2: OPTI-Surg Group 1 with Coach
- ARM 3: OPTI-Surg Group 2 with Coach

Patient Schema:

- Group 1: Usual Care
- Group 2: OPTI-Surg
- Group 3: OPTI-Surg plus Coach

Sample size is about 15 consented patients per each of 30 surgical practices (450 consented patients)
Consented patients will complete the CHAMPS and EQ-5D questionnaires at baseline and 8 weeks post-surgery.

NOTE: Practice-level data will be collected for all eligible patients (including those not registered to the trial) over the entire study duration. Surgical complications will be assessed for all eligible patients at 8 and 12 weeks after surgery.

See Sections 7.1 and 4.3.1 for institutional participation requirements.
2.0 Objectives

2.1 Primary objective

To compare 8-week postoperative function among elderly patients between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.2 Secondary objectives

2.2.1 To compare postoperative morbidity between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.2.2 To compare the penetration of the OPTI-Surg toolkit between sites randomized to implement the OPTI-Surg toolkit with a coach versus sites randomized to implement the OPTI-Surg toolkit without a coach.

2.3 Exploratory objectives

2.3.1 To compare postoperative mortality, hospital length of stay, discharge to a facility, and hospital readmission between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.3.2 To assess subsequent initiation and follow through of appropriate referral for the indicated optimization intervention and assess practice-level structural factors associated with uptake of the OPTI-Surg package.

2.3.3 To document and assess barriers and facilitators to implementation and dissemination through mixed-methods research.

3.0 Patient Selection

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.1 Eligibility Criteria

3.1.1 Eligible patients must have known or suspected cancer diagnosis and have one of the following cancer-directed operations planned:

- Gastrectomy
- Colectomy
- Proctectomy
- Esophagectomy
- Pancreatectomy
- Hepatectomy
- Total cystectomy
- Total Nephrectomy
- Lung lobectomy/pneumonectomy

3.1.2 Age ≥ 70 years
3.1.3 Patients with known metastatic disease with a plan for curative intent resection are eligible (e.g. curative liver resection for metastatic colorectal cancer).

3.1.4 Patients with double primaries undergoing planned curative operation for both are eligible (e.g. synchronous colon cancers undergoing colectomy to treat both).

3.1.5 Patients undergoing emergent surgery are not eligible.

3.1.6 Patients with second primary, or metachronous malignancy are not eligible.

3.1.7 Patients with known metastatic disease who are undergoing palliative resection are not eligible.

3.1.8 Patients with psychiatric illness or other mental impairment that would preclude their ability to give informed consent or to participate in the prehabilitation program are not eligible.

3.1.9 Patients must be able to speak and complete questionnaires in English.