

THE  
**SMArTVIEW**  
CoVeRed

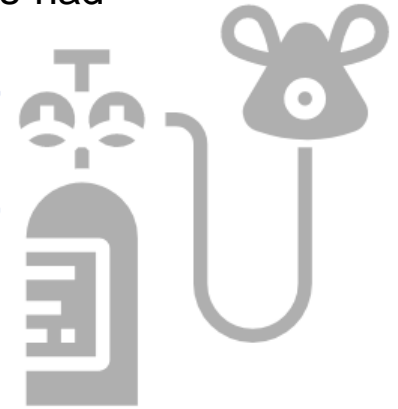


*TecHnology Enabled remote automated monitoring and  
Self-MAnagement: VIision for patient EmpoWerment  
following Cardiac and VasculaR surgery*

Co-Principal Investigators: Drs. Michael McGillion and PJ Devereaux

# Background

- Tens of thousands of cardiac and vascular surgeries occur each year in Canada and the United Kingdom
- Previous studies of continuous oximetry versus routine care vital signs:
  - Routine care detected 5% incidence of hypoxemia ( $SpO_2 < 90\%$ )
  - Continuous oximetry demonstrated 38% of these patients had  $\geq 1$  continuous episode of  $SpO_2 < 90\%$  lasting  $\geq 1$  hour
  - 10% of patients had  $\geq 1$  continuous episode of  $SpO_2 < 85\%$  lasting  $\geq 1$  hour
- Hypoxemia for  $> 5$  minutes in duration is associated with increased risk of myocardial ischemia



# Background

- Sub-optimal monitoring on surgical floors comes at risk to patients and can lead to:



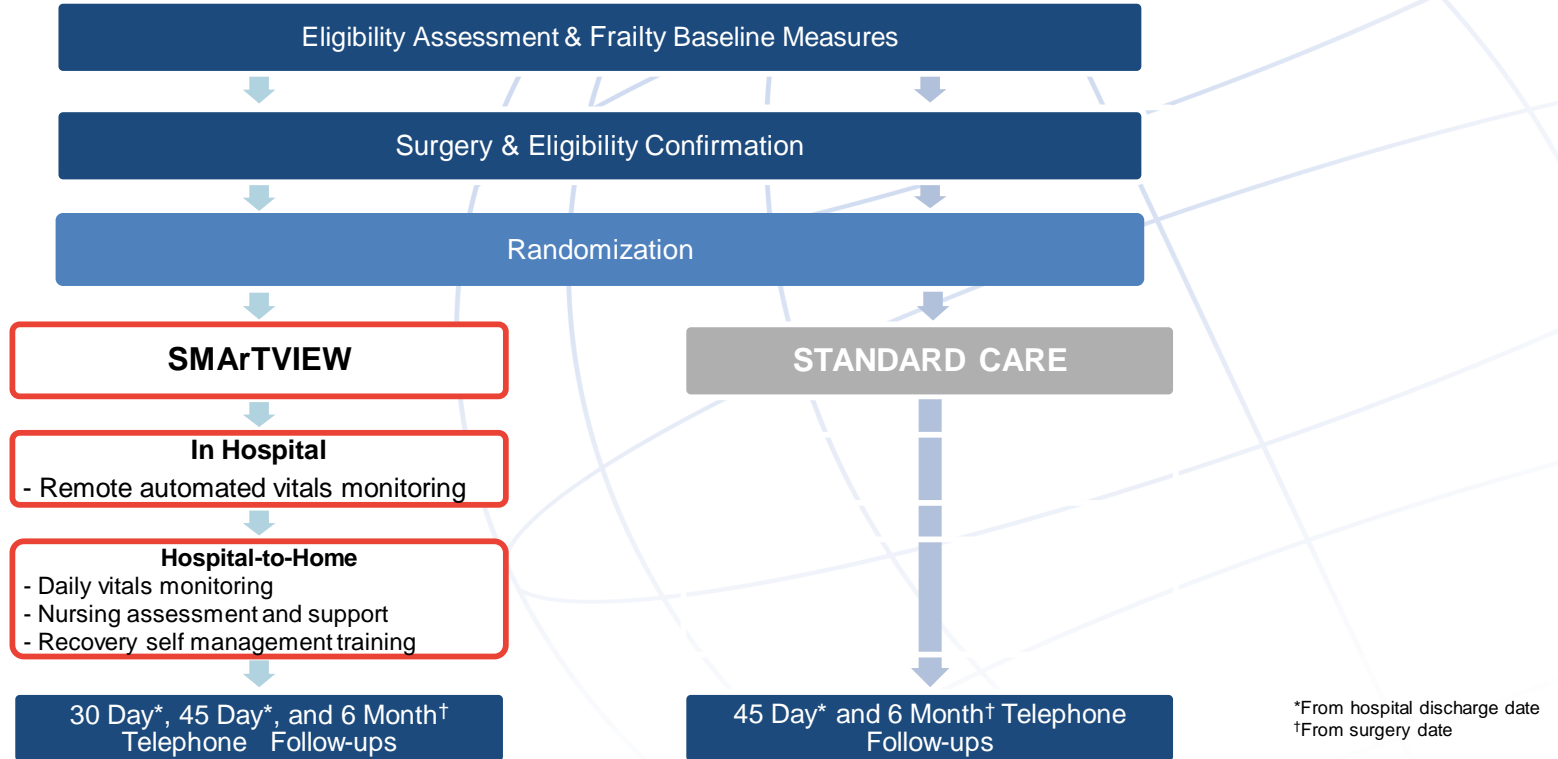
- undetected hemodynamic compromise
  - surgical site infection
  - chronic post-surgical pain
- Missed issues in hospital can lead to increased readmission rates

# Trial Design

- Parallel group international RCT
- Sample size: 800 patients
  - 2 hospitals in 2 countries



# Intervention



# Patient Population

## Inclusion Criteria

1. Age  $\geq$  60 years
2. Patient has undergone major cardiac or vascular surgery and has been admitted post-op to the surgical floor
3. Anticipated length of stay on the surgical floor is  $\geq$  48 hours
4. Patient randomized within 24 hours of arriving on surgical floor
5. Patient provides consent autonomously

## Exclusion Criteria

1. Patient is unable to communicate with research staff, complete surveys and questionnaires, or a telephone interview (i.e. language barriers, language, vision, or hearing impairment)
2. Patient has an intolerance/allergy to adhesive
3. Patient unable to complete 30 days of at-home follow up due to current or planned relocation to nursing home or rehab facility after discharge
4. Patient has a positive CAM result preceding randomization
5. Patients resides in a known area without cellular network coverage



# Outcomes

## Primary Outcome

- To determine the effect of the SMArTVIEW intervention compared to standard care on the 45-day risk of a composite of hospital readmission and emergency department/urgent care centre visits (not requiring hospital admission), in patients who undergo cardiac or major vascular surgery



# Outcomes

## Secondary Outcomes

- To determine the effect of the SMArTVIEW intervention compared to standard care on the 45-day and 6-month risk of the following outcomes post cardiovascular surgery:
  - 1) composite of death, nonfatal MI, nonfatal stroke, nonfatal cardiac arrest; and
  - 2) individual components of the primary outcome and the secondary outcome composite, and other postoperative complications (i.e., congestive heart failure, clinically important atrial fibrillation, DVT or PE, bleeding, infection/sepsis, respiratory failure, acute kidney injury with dialysis, clinically important hypotension, falls, delirium and reoperation)
  - 3) Patient medication error detection and correction
  - 4) Economic outcomes: health service utilization-related costs and patient level cost of recovery



# Follow-up

## Baseline

- Eligibility assessment
- Demographics, medical history, and current medications
- Baseline vitals and laboratory assessments
- Frailty assessment, Short Form-12, and digital literacy questionnaires

## Randomization

- Confusion Assessment
- Device application and education (Intervention arm only)

## Hospital Discharge

- Discharge location
- Post-operative clinical events
- Monitoring device compliance on surgical floor
- Brief Pain Inventory and analgesic chart audit

# Follow-up

30 Day  
Follow-up

- Daily vitals monitoring and video visits
- Daily health surveys and Brief Pain Inventory on Days 7 and 14
- Digital Literacy Questionnaire
- Hospital to home enrollment and compliance
- Medication audit

\*Hospital-to-Home – Intervention arm only

45 Day  
Follow-up

- Events since hospital discharge
- Brief Pain Inventory
- Short Form-12
- Patient Activation Outcome
- Ambulatory Home Care Record
- Schwartz Center Compassionate Care Scale

6 Month  
Follow-up

- Events since 45 Day Follow-up
- Brief Pain Inventory
- Short Form-12
- Patient Activation Outcome
- Ambulatory Home Care Record

