



RESEARCH SCHOLAR PROGRAM – 2018

SUPERVISOR & PROJECT INFORMATION FORM

Please complete and return, via email only (crems.programs@utoronto.ca) by **November 3rd 2017** (*forms received after this date will not be posted*).

Supervisor Information

Name: Stephen E. Fremes

Email: stephen.fremes@sunnybrook.ca

Degree: MD MSc

SGS Appointment (IMS, IHPME, LMP etc.): IMS

Academic Rank: Professor of Surgery
bypass grafting, clinical trials, clinical outcomes

Field of Research: Transcatheter valves, coronary artery

Research Institution Affiliation (if applicable): Sunnybrook Research Institute

Allocation of student contact time (number of hours per week YOU are available to the student for any concerns or to review progress):

1-2 hours (the student can also meet with my full-time PhD student, a surgeon-scientist trainee at any time).

Project Information

Title: The optimal management of aortic valve disease in the era transcatheter valve technology.

Description (max 500 words):

Background: Traditionally, surgical aortic valve replacement (SAVR) was the gold standard for the management of symptomatic aortic stenosis (AS). However, transcatheter aortic valve replacement (TAVR), a minimally invasive approach whereby blood vessels in the groin are accessed to replace the damaged valve, has emerged as the treatment of choice in high-risk patients. In addition, TAVR may be used to replace a previously failed surgical valve, although the efficacy remains uncertain. Here, we examine how surgical management of AS has evolved since the introduction of TAVR and seek to optimize the management of AS, particularly in middle aged patients (50-70 years), where evidence to support guidelines remain sparse.

Specific Objectives: **(1)** To determine the proportion of biological SAVR and mechanical SAVR performed before and after the introduction of TAVR in various age groups in the North American context. **(2)** To determine the safety and efficacy of TAVR versus redo SAVR in patients with a failed previous artificial valve. **(3)** To develop a decision analytic model incorporating both cost and effectiveness to determine the optimal treatment of AS.

Hypotheses: **(1)** Since the introduction of TAVR in North America, the proportion of biological SAVR has increased along with the number of middle aged patients receiving biological SAVR. **(2)** There is no difference in efficacy and safety between TAVR and redo SAVR. **(3)** A cost-effectiveness analytic model can be developed to help inform the optimal treatment of AS.

Methods: This proposed research will require the separate use of two databases from two different entities: The Society of Thoracic Surgeons (STS) National Database (ND) (housed at Duke University) and the Institute for Clinical and Evaluative Sciences (ICES, Toronto, ON). Over 95% of hospitals performing cardiac surgery report to the STS-ND; thus, it is a clinically rich administrative database that is poised to address **Objective #1**. We have received STS approval to use the STS-ND. We will employ a segmented time regression model to determine the effects of TAVR introduction of SAVR trends, controlling for prior baseline level of changes. **Objective #2** will be addressed through linkage of databases housed at ICES, specifically the Cardiac Care Network Registry (for all cardiac interventions and patient risk factors), the Canadian Institute of Health Information Discharge Abstract Database (for all hospital admission and complications) and the Registered Persons' Database (death registry). We will use propensity scored matching techniques to elucidate the safety and efficacy of TAVR and redo SAVR. **Objective #3** will be informed by the findings in Objectives #1 and #2 and the available literature. A cost-utility analysis that incorporates both costs and effectiveness from the perspective of the Canadian healthcare system will be conducted using a Markov model to simulate repeated events over the lifetime of the patient. A clinician friendly bedside tool will be developed to consolidate our findings in meaningful way to help clinicians determine the optimal treatment for individuals based on patient factors and preferences.

Implications: Findings from this study will have a potential impact on the management of valvular heart disease in Canada that may require a fundamental restructuring of care delivery. This in turn will increase the equitable and timely access to life-saving treatment.

If human subjects are involved, have Ethics been obtained?

YES

NO

Application Submitted

N/A

Do you expect this work will be published within the 20 months?

YES

NO

Uncertain

Student's roles and responsibilities:

The student will directly report to Dr. Derrick Tam, PhD student and Surgeon Scientist Trainee in cardiac surgery (Health Services Research at IHPME) and our research coordinator and MSc Student at IHPME, Dr. Reena Karkhanis for day to day instructions. I will meet with the student on an as-needed basis and at least monthly to review their progress.

The specific role of the student in this project includes:

- Performing systematic literature reviews according to best practices.
- Performing basic meta-analyses using Review Manager.
- Statistical analyses using Excel, SPSS or SAS.
- Development of macro skills and visual basic skills on Excel to create clinician friendly tools for Knowledge translation activities.
- Large database management using Excel. The use of logic functions on Excel.
- Review of patients for entry into clinical trials.