TOPICAL USE OF VANCOMYCIN IN REDUCING STERNAL WOUND INFECTION IN CARDIAC SURGERY

Protocol

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Sponsored By University of Alberta

Protocol #: SWI-01-14

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STUDY SUMMARY

Title	Topical Use of vancomycin in Reducing Sternal Wound Infection in Cardiac Surgery
Objective	To determine if using topical vancomycin as a prophylactic treatment during open heart surgery will reduce the incidence of sternal wound infection (SWI).
Methodology	Prospective, double-blind, randomized (1:1) controlled trial.
Rx Arms	During open heart surgery, patients will have a 4x8 inch piece of sterile gauze covering each side of the divided sternum. The gauze will be soaked in the following solutions: Group 1: 5 g vancomycin dissolved in 50 mL sterile water for injection Group 2: 50 mL sterile water for injection
Number of Subjects	A total of 1,552 patients will be randomized to either vancomycin or no vancomycin. This will provide an 80% power to detect a 50% reduction in infection rates (7% versus 3.5%).
1° Endpoints	The incidence of SWI (including superficial incisional, deep incisional, and organ/space surgical site infections) at 3 months postoperative.
2° Endpoints	• Incidence of SWI at 1 year postoperative • Duration of index hospitalization and subsequent readmissions due to SWI • Use of prophylactic antibiotics • Cost analysis • Adverse events
Duration	Accrual is expected to take 3 years. All patients will be followed for one year postoperatively.
Inclusion Criteria	• Able to sign Informed Consent and Release of Medical Information Form • Age ≥ 18 years • Undergoing cardiac surgery with complete sternotomy (including re-operations)
Exclusion Criteria	• Evidence of active infection (any culture positive or blood positive infection) • Undergoing organ transplantation • Patients with known hypersensitivity to vancomycin • Pregnant or nursing women • Mental impairment or other conditions that may not allow participant to understand the nature, significance, and scope of study

DATA COLLECTION SUMMARY

ASSESSMENT	BASELINE	PROCEDURE	PRE-DISCHARGE	EVENT DRIVEN
Informed Consent	X			
Eligibility and Enrollment	X			
Baseline Characteristics	X			
Index Surgery		X		
Index Hospital Discharge			X	
Postoperative Laboratory Results			X	X
APPROACH Data	X	X	X	X
ProvServ Data			X	X

ABBREVIATIONS & ACRONYMS

SWI	Sternal wound infection
DM	Diabetes mellitus
OR	Operating room
EPICORE	Epidemiology Coordinating and Research
DIN	Drug Identification Number
APPROACH	Alberta provincial project for outcome assessment in coronary heart disease
RedCap	Research electronic data capture
CR	Creatinine
GFR	Glomerular filtration rate
QMCR	Quality management in clinical research
HREB	Health research ethics board
HGB	Hemoglobin
HCT	Hematocrit
PLT	Platelet count
WBC	White blood cell count
NEUT	Neutrophil count
LYMPH	Lymphocyte count
MONO	Monocyte count
EOS	Eosinophil count
BASO	Basophil count
Na	Sodium
K	Potassium

BACKGROUND

Sternal wound infection (SWI) is an uncommon yet serious risk associated with open heart surgery. Both superficial and deep SWI are associated with significant comorbidities, longer hospital stay and costs. Deep SWI affects 1-3% of patients postoperatively with a mortality rate of 20-30% for patients who develop mediastinitis [1-3]. A number of risk factors – such as diabetes (DM), obesity, and complex cardiovascular operations requiring longer surgical time – have been associated with the development of SWI [1]. Given that these risk factors are on the rise in today's cardiovascular surgical practices, alternative strategies should be considered to reduce and/or avoid the complication of SWI. Topical use of antibiotics has been shown to be effective in reducing at least Deep SWI both in small randomized studies and Meta analyses [3-4]. The most common bacterial culprits in SWI are staphylococcus species that are mostly sensitive to Vancomycin. However, systemic use of these antibiotics is associated with drug side effects such as nephrotoxicity and therefore their use is limited in patients with renal failure or insufficiency, which make up a significant number of patients undergoing open heart surgery. Studies have shown that the use of topical Vancomycin could be both safe and effective in reducing deep SWI even in patients with renal failure and insufficiency [5, 6]. Vancomycin is currently being used topically in a number of American centres (such as Cleveland Clinic and Boston Medical Center [5]). However, the topical use of vancomycin is considered off-label use of this drug in Canada and is not generally being used. The current overall rate of superficial and deep SWI in our institute is around 7%, the proposed study will attempt to assess and reduce the rate of SWI in patient undergoing open heart surgery.

OBJECTIVES

The primary objective of this clinical trial is to determine if using topical vancomycin as a prophylactic treatment during open heart surgery will reduce the incidence of SWI.

TRIAL DESIGN

This is a double-blind, randomized clinical trial. The study will be conducted at the University of Alberta Hospital and 1,552 patients will be randomized. All patients will be followed for one year postoperatively.

TREATMENT ASSIGNMENT

During open heart surgery, patients will have one piece of sterile gauze covering each side of the divided sternum. The investigators intend to use Derma Sciences Inc. Dupaque X-Ray Detectable 4 x 8 inch sponges for the purpose of this study. The gauze will be soaked in one of the following solutions (depending on the randomized treatment assignment) until the solution is absorbed (approximately 1-2 minutes):

Group 1: 5 g vancomycin dissolved in 50 mL sterile water for injection
Group 2: 50 mL sterile water for injection

The soaked gauzes will be applied and remain on the divided sternum once hemostasis has been achieved. The gauzes will be removed in the operating room (OR) at the end of the surgical procedure(s), just prior to chest closure.

RANDOMIZATION

Patients will be randomized in a 1:1 fashion. By this arrangement, 50% of the patients will receive topical vancomycin (Group 1) and 50% will not receive topical vancomycin (Group 2) during open heart surgery.

MASKING

This is a double-blind, sham procedure controlled trial. In order to maintain blinding of the investigators, the study coordinators, and the patients, Epidemiology Coordinating and Research (EPICORE) Centre will create a confidential randomization key. This key will be provided to the site's Research Pharmacy Office in order to guide the preparation of masked syringes containing either 5 g vancomycin dissolved in 50 mL sterile water (Group 1) or 50 mL sterile water (Group 2). The syringes will be prepared in small batches and labeled with expiration dates based on the chemical stability (96 hours) of vancomycin in sterile water for injection at a concentration of 100 mg/mL [7]. The study syringes will be stored in a refrigerator in the OR and therefore readily available for use.

INTERVENTIONAL AGENT

The interventional agent to be used in this clinical trial is ^{Pr}vancomycin hydrochloride for injection, USP (Pharmaceutical Partners of Canada Inc, Richmond Hill, ON). The product's Drug Identification Number (DIN) is 02139383.

ADVERSE REACTIONS

There have been rare reports of renal failure in patients treated intravenously with vancomycin, particularly when given large doses [7]. Most of these cases involved patients who had pre-existing kidney dysfunction or patients who received concomitant aminoglycosides.

The development of reversible neutropenia has been reported; usually beginning at least a week after the onset of treatment with vancomycin or after a total dose of more than 25 g has been administered [7].

Approximately two dozen patients have reported hearing loss associated with the use of vancomycin [7]. In most of these cases, patients also had kidney dysfunction, pre-existing hearing loss, or concomitant treatment with an ototoxic drug.

DOSE RATIONALE

Topical use of 5 g of vancomycin, in paste form, has been shown to reduce the rate of deep SWI without any significant adverse effect on the patient undergoing open heart surgery [5]. However there is no double blinded randomized controlled study to confirm the effectiveness of topical vancomycin in reducing SWI. The current randomized controlled trial will use 5 g of solubilized vancomycin, in 50 mL of sterile water for injection, for a topical application on sternal wound to evaluate the rate of total sternal wound (superficial and deep) infection.

Note: The investigators intend to use Sterile Water for Injection USP (Baxter Corporation, Mississauga, ON) based on availability (DIN: 02014882).

ELIGIBILITY CRITERIA

INCLUSION CRITERIA

- Able to sign Informed Consent and Release of Medical Information Form
- Age ≥ 18 years
- Undergoing cardiac surgery with complete sternotomy (including re-operations)

EXCLUSION CRITERIA

- Evidence of active infection (any culture positive or blood positive infection)
- Undergoing organ transplantation
- Patients with known hypersensitivity to vancomycin
- Pregnant or nursing women
- Mental impairment or other conditions that may not allow participant to understand the nature, significance, and scope of study

DATA COLLECTION

The majority of data collected in this trial will be obtained from pre-existing hospital databases. The Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) database will be the source of information such as the patients' medical history, index procedure, and in-hospital postoperative complications. The Cardiac Surgery Data Collection Form (APPENDIX I) contains a complete list of data elements that will be obtained from the APPROACH database.

Alberta Health Services' ProvServ database maintains record of all patients who are treated at the clinical site for SWI, within one year of surgery. This database will provide follow-up information regarding the incidence of SWI in both study groups. A complete list of data elements that will be obtained from the ProvServ database can be found on the Surgical Site Infection Surveillance Form (APPENDIX II).

All data collected using the Case Report Forms (APPENDIX III) will be entered into the Research Electronic Data Capture (REDCap) system created by EPICORE Centre.

CONSENT

Prior to protocol-defined data collection, the study personnel will meet with the potential study participant to thoroughly discuss the nature of the clinical trial. All risks and benefits of the study will be explained; and all questions will be answered to the satisfaction of the participant prior to signing the informed consent form.

ELIGIBILITY AND ENROLLMENT

The inclusion and exclusion criteria will be document by the study personnel prior to randomization. All consented patients will be given a unique 5-digit identification code which will be used throughout the course of the study.

BASELINE CHARACTERISTICS FORM

This form captures the necessary patient identifiers that will be used to match and pull data from the hospital's databases. Information pertaining to the patient's baseline functionality, immune system functionality, and laboratory results will also be collected. The study personnel will obtain laboratory results from routine preoperative blood work, specifically selecting the assessment that was performed closed to the patient's index surgery.

INDEX SURGERY FORM

The identification number of the used masked syringes will be recorded, as well as any adverse reactions to the study product observed within 24 hours.

INDEX HOSPITAL DISCHARGE FORM

This form captures whether the patient is discharged on antibiotic medications.

POSTOP LABORATORY RESULTS FORM

The study personnel will review the standard of care postoperative laboratory results listed on this form and record the last value obtained for each parameter, prior to index hospital discharge. If the creatinine (CR), or Glomerular filtration rate (GFR) is abnormal at this time, the patient's laboratory results will be monitored post-hospital discharge. The study personnel will record all protocol-defined laboratory results until the patient has reached their baseline value (± 10%) or normal range; or until they have reached one year postoperative (whichever comes first).

ENDPOINTS

PRIMARY ENDPOINTS

Incidence of SWI

The primary endpoint of this trial is the incidence of SWI at 3 months postoperative. This includes superficial incisional, deep incisional, and organ/space surgical site infections as defined in Appendix II. The data will be obtained from the ProvServ database.

SECONDARY ENDPOINTS

Incidence of SWI

The incidence of SWI at 1 year postoperative will also be determined.

Duration of index hospitalization and subsequent re-admissions due to SWI

The length of hospital stay from index surgery to hospital discharge will be recorded for all patients. The duration of subsequent re-admissions due to SWI will also be documented.

Use of prophylactic antibiotics

The use of prophylactic antibiotics at index hospital discharge will be recorded for all patients. The ProvServ database will also provide information regarding the use of prophylactic antibiotics for those patients returning to hospital with signs of infection.

Cost analysis for SWI treatment
The study personnel will obtain hospital costing data for the various assessments and procedures involved in the treatment of SWI. This will allow comparisons to be made regarding the cost effectiveness of using topical vancomycin as a prophylactic treatment.

Adverse events
The study personnel will document and compare the occurrence of adverse events in each treatment group (see the Adverse Events section for further details).

ADVERSE EVENTS

RENAL INSUFFICIENCY/FAILURE
Defined as significant increases in creatinine or decreases in glomerular filtration rate between baseline and pre-discharge laboratory results.

NEUTROPENIA
Abnormally low postoperative neutrophil count.

HEARING LOSS
New onset hearing loss or worsening of a pre-existing condition.

ALLERGIC REACTIONS TO VANCOMYCIN
Abnormal redness or sensitivity of skin at the site of vancomycin application. Hypotension following the administration of vancomycin.

GENERAL
Further postoperative complications/adverse events will be obtained from the APPROACH database. Please refer to APPENDIX I for a complete list.

DATA MANAGEMENT
All study data actively collected by the study personnel (APPENDIX III) will be entered in the secure web-based REDCap system. Study personnel requiring access will have their own login and password. Data obtained from the hospital databases (APPENDICES II-III) will be collected and stored according to the security measures currently implemented by the custodians of the databases.

On-site monitoring will be provided by the University of Alberta's Quality Management in Clinical Research (QMCR), as per established guidelines.

STATISTICAL ANALYSIS PLAN
The statistical plan and analysis for this study is being provided by EPICORE Centre.

ANALYSIS OF PRIMARY END POINT:

The primary analysis will compare the proportions of patients having sternal wound infection between the two treatment groups using chi-squared test. Analyses will be performed according to the intention-to-treat principle. Descriptive statistics including frequency distributions, percentages, means and standard deviations will be presented for the baseline variables. The median and the IQR (Inter Quartile Range) will be used to represent variables with skewed distributions. The baseline variables will be compared between the treatment groups using chi-squared test, t-test or Wilcoxon Mann-Whitney test, as appropriate. If necessary, a multi-variable analysis will be performed using logistic regression to control potential confounding effect in the analysis stage. All the statistical tests will be two-sided. A p-value of <0.05 will be considered statistically significant.

ANALYSIS OF SECONDARY END POINTS:

Secondary end points will be evaluated at the end of the study. Duration of index hospitalization between the treatment groups will be compared using survival analysis. The log rank test will be used. The total and the mean number of readmissions between the two groups will be compared by t-test or Wilcoxon Mann-Whitney test, as appropriate. A chi-squared test will be used to compare the use of prophylactic antibiotics. Cost analysis will be performed by comparing means or medians between the groups using t-test or Wilcoxon Mann-Whitney test, as appropriate. If necessary, multi-variable linear or logistic regression will be performed for the secondary end points, as appropriate. All the statistical tests will be two-sided. A p-value of <0.05 will be considered statistically significant.

ANALYSIS OF ADVERSE EVENTS:

Adverse events will be reported by frequency tables, percentages, means, standard deviations, medians or IQRs as appropriate at the interim and the final analysis. Proportions of adverse events between the groups will be compared by chi-squared test. Means or medians will be compared by t-test or Wilcoxon Mann-Whitney test, as appropriate. Count data will be compared by Poisson regression.

INTERIM ANALYSIS:

One interim analysis will be performed in a half way of the trial (after 776 patients will be followed). Interim analysis will be performed on the primary end point and the adverse events using a two-sided significance test with O'Brien-Fleming type spending function and a type I error rate of 5%.

TRIAL CONDUCT

This study will be conducted in compliance with the protocol approved by the University of Alberta Health Research Ethics Board (HREB), and according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval of the HREB except where it may be necessary to eliminate an immediate hazard to a research subject. In such case, the deviation will be reported to the HREB as soon as possible.

REFERENCES

[1] Borger MA, Rao V, Weisel RD, et al. Deep sternal wound infection: risk factors and outcomes. Ann Thorac Surg 1998;65:1050-6.

[2] Mauermann WJ, Sampathkurmar P, Thompson RL. Sternal wound infections. Best Pract Res Clin Anaesthesiol 2008;22:423-36.

[3] Friberg O, Svedjeholm R, Söderquist B, Granfeldt H, Vikerfors T, Källman J. Local gentamicin reduces sternal wound infections after cardiac surgery: a randomized controlled trial. Ann Thorac Surg 2005;79:153-61.

[4] Mavros MN, Mitsikostas PK, Alexiou VG, Peppas G, Falagas ME. Gentamicin collagen sponges for the prevention of sternal wound infection: A meta-analysis of randomized controlled trials. J Thorac Cardiovasc Surg 2012;144:1235-40.

[5] Lazar HL, Barlam T, Cabral H. The effect of topical vancomycin applied to sternotomy incisions on postoperative serum vancomycin levels. J Card Surg 2011;26:461-5.

[6] Vander Salm TJ, Okike ON, Pasque MK, Pezzella AT, Lew R, Traina V, Mathieu R. Reduction of Sternal Infection by Application of Topical Vancomycin. Thorac Cardiovasc Surg 1989;98:618-22.

[7] Pharmaceutical Partners of Canada Inc., Product Monograph, ^{Pr}VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP. Control # 144773, March 7, 2011.

APPENDIX I: CARDIAC SURGERY DATA COLLECTION FORM

Alberta Health Services — Capital Health

MAZANKOWSKI ALBERTA HEART INSTITUTE

Cardiac Surgery Data Collection Form

Case Number 2014 - _____ Patient Medical Record _____

Last Name: _____ First Name: _____ MI_____

Ht:_____cm Wt:_____kg OR Start date/time _____ End Time_____

Surgeon:_____ Resident:_____ Anesthetist:_____

CCS: _____ NYHA: _____ Surgery Type:_____

Diseased Vessels: _____ Left Main: Yes__No___ Most Resp Diagnosis_____

Operative Procedure: _____

☐**CABG**
☐**Valve Replace** ☐A ☐M ☐T ☐P
☐**Valve Repair** ☐A ☐M ☐T ☐P
☐**Aortic Aneurysm** ☐Asc+Root ☐Abd-supra
☐**Aortic Dissection** ☐Acute

Other Cardiac ☐LVA ☐Congenital ☐TMLR ☐Tumor ☐Septal Myectomy ☐ASD ☐VSD ☐DOR ☐Trauma ☐Transplant ☐Pacemaker ☐Maze ☐Bental ☐Other _____ ☐AICD ☐Atrial Ablation ☐Aortic Repair
☐Asc w/o root ☐Arch ☐Desc ☐Thoracic
☐Abd-infra ☐AAA Endo ☐AAA open ☐TAA _____
☐Chronic ☐Type A ☐Type B

☐**Other Non-Cardiac** ☐Carotid Endarterectomy ☐Vascular ☐Thoracic ☐Other_____
☐Fem-fem Bypass ☐Axillo-fem Bypass ☐Aorto-bifem Bypass ☐Fem-tibial Bypass
☐**Lung Transplant** **Type** L R B

Incidence: ☐1st Op ☐Reop 1st, 2nd, 3rd, 4th, _____ Reason for Reop:_____
If Reop is it Same Adm? _____ Unique Record Yes/No Old Record # _____-_____
Angina (72 Hr) _____
Tracking Adm d/t_____ OR in_____ OR out_____ To Unit_____

Prior Procedure Most Recent Procedure_____Date_____

☐**CABG**
☐**Valve Replace** ☐A ☐M ☐T ☐P
☐**Valve Repair** ☐A ☐M ☐T ☐P
☐**Aortic Aneurysm** ☐Asc+Root ☐Abd-supra
☐**Aortic Dissection** ☐Acute
☐**Other Non-Cardiac** ☐Carotid Endarterectomy
☐Fem-fem Bypass ☐Axillo-fem Bypass
☐**Lung Transplant Type** L R B

Other Cardiac ☐LVA ☐Congenital ☐TMLR ☐Tumor ☐Septal Myectomy ☐ASD ☐VSD ☐DOR ☐Trauma ☐Transplant ☐Pacemaker ☐Maze ☐Bental ☐Other _____ ☐AICD ☐Atrial Ablation ☐Aortic Repair
☐Asc w/o root ☐Arch ☐Desc ☐Thoracic
☐Abd-infra ☐AAA Endo ☐AAA open ☐TAA _____
☐Chronic ☐Type A ☐Type B
☐Vascular ☐Thoracic ☐Other_____
☐Percutaneous ☐ASD ☐Valvuloplasty ☐Other

Indication/Cardiac Status (if ACS get CK/TP etc)_____

Selection Factors

LVEF_____% Calc / Est by_____
LVEDP _____mm Angio
Mean PAP_____

☐Arrhythmia
☐VTach/Fib
☐AFib/Flutter
☐CHB
☐Acute ☐ RBBB
☐Chronic ☐ LBBB
☐ Perm Pacemaker

Outcome Determinants

☐Hypertension
☐Hyperlipidemia
mmol/L Chol_____TG_____
HDL_____LDL_____
☐Renal Failure
Last Creat preop _____
☐Dialysis
☐Family History of CAD
☐Diabetes Mellitus Type I II
HbA1C _____

☐Prior Infarction D/T_____
☐Prior PCI
☐Prior CABG
☐Congestive Heart Failure
☐PAD / PVD
☐Cerebrovascular Disease -Type_____
☐Infective Endocard
Active or Treated
☐Smoking Status
Unk Never Current Former
☐Pulmonary FEV1_____
☐ GI Disease

Meds

☐Beta Blockers ☐Nitrates IV ☐ACE Inhibitors ☐ARB Inhibitors
☐Digitalis ☐Diuretics ☐ASA (Aspirin) ☐ADP Inhib – Clopidogrel / Ticlopidine
☐Coumadin ☐Oral Hypoglycemic ☐Insulin ☐Amiodarone
☐Inotropes ☐Anticoagulants – Heparin (Unfrac/IV) / Heparin (Low molec.) / Thrombin Inhibitors
☐Steroids ☐Gly IIb IIIa Inhib – Abciximab (ReoPro) / Eptifibatied (Integrilin) / Tirofiban (Aggrastat)
☐Immunosuppresives ☐Lipid Lowering – statin / non-statin

Bypass Data:

Endarterectomy Performed: Yes/No
Arterioplasty: Yes/No
# of Dist Anast with Venous:_____
# of Dist Anast with Arterial:_____ # of Proximal Grafts:_____
# of IMA Grafts:_____ # of IMA Distal:_____ Harvest site:_____
Intraop Graft Revision:Yes/No T-Graft or Y-Graft: Yes/No
Prior PCI Vessels:_____
Diseased Vessels: LM___ LAD___ D1___ D2___ D3___ RI___
CX___ OM1___ OM2___ OM3___ RCA___ AM___ PDA___ CB___
Vessels Grafted: LM___ LAD___ D1___ D2___ D3___ RI___
CX___ OM1___ OM2___ OM3___ RCA___ AM___ PDA___ CB___

Valve Data:	Dx	Stenosis	Insuff	Etiology	Gradient Cath/Echo
Aortic	__	_____	_____	_____	_____/_____mmhg
Mitral	__	_____	_____	_____	_____/_____mmhg
Tricuspid	__	_____	_____	_____	_____/_____mmhg
Pulmonary	__	_____	_____	_____	_____/_____mmhg

Valve Surgery:

Aortic Procedure:
No
Replacement
Repair/Reconstruction
Root Reconstruction w/ Valve Conduit
Replacement + Aortic Graft Conduit
Root Reconstruction w/ Valve Sparing
Resuspension Aortic Valve w/ Replacement Ascending Aorta
Resuspension Aortic Valve w/o Replacement Ascending Aorta
Resection Sub-Aortic Stenosis

Mitral Procedure:
No
Annuloplasty Only
Replacement
Reconstruction w/ Annuloplasty
Reconstruction w/o Annuloplasty
↓ (if Replacement)
Mitral Repair Attempt: Yes No

Tricuspid Procedure:
No
Annuloplasty Only
Replacement
Reconstruction w/ Annuloplasty
Reconstruction w/o Annuloplasty
Valvectomy

Pulmonic Procedure
No
Replacement
Reconstruction

Aortic Annular Enlargement: Yes No

↓ Key M = Mechanical B = Bioprosthesis H = Homograft A = Autograft (Ross) R = Ring/Annuloplasty BA = Band/Annuloplasty

Aortic Prosthesis -	Implant Type:	None M B H A R BA	Implant: _____	Size: _____(mm)
	Explant Type:	None M B H A R BA	Explant: _____	Size: _____(mm)
Mitral Prosthesis -	Implant Type:	None M B H A R BA	Implant: _____	Size: _____(mm)
	Explant Type:	None M B H A R BA	Explant: _____	Size: _____(mm)
Tricuspid Prosthesis -	Implant Type:	None M B H A R BA	Implant: _____	Size: _____(mm)
	Explant Type:	None M B H A R BA	Explant: _____	Size: _____(mm)
Pulmonic Prosthesis -	Implant Type:	None M B H A R BA	Implant: _____	Size: _____(mm)
	Explant Type:	None M B H A R BA	Explant: _____	Size: _____(mm)

CPB Data

OH# 14 -_____ Perfusionist: _____ XClamp_____min Pump_____min

On Pump Case Yes/No If No XClamp, give reason _____

Cardioplegia Yes/No Conversion from off pump to on pump Yes/No

Low Core Temp _____ Pre-op HgB _____ Pre-pump HgB_____

Prophylactic OR Antibiotics
- Ordered or Given Prior to Surgery Yes/No
- Ordered or Given within 1 hour of incision Yes/No (within 2 hrs if Vanco or Fluoroquinolone)
- Discontinued within 48 hours postop (post surgical end time) Yes/No

Intraop Medications ☐ Aprotinin/Trasylol ☐ Tranexamic Acid:

Cannulation Method Arterial: ☐Femoral ☐Arch ☐Asc Aorta ☐Other _____
Venous: ☐Femoral ☐Jugular ☐Atrial (2 stage) ☐Caval ☐Bicaval

IABP Yes/No Timing_____Reason_____
VAD Yes/No Timing_____Type_____

Intraop TEE Yes/No Return to CPB Yes/No if Yes: Once More than Once
Inotropes Leaving OR Yes/No Antiarrhythmics Leaving OR Yes/No

Blood Products (# of units)

	Intra-op	Post-op
RBC	_____	_____
FFP	_____	_____
Cryo	_____	_____
Platelets	_____	_____

Postop Studies within 30 Days Yes/No
ECHO Yes/No Cath Yes/No PCI Yes/No Other _____

First Extubation Date: _____ Time:_____
Reintubation During Hosp Adm: Yes/No

Reintubation	Date:_____	Time: _____
Extubation	Date:_____	Time: _____
Reintubation	Date:_____	Time: _____
Extubation	Date:_____	Time: _____
Reintubation	Date:_____	Time: _____
Extubation	Date:_____	Time: _____

Postop Complications: Yes/No If Yes: <30 Days >30Days

Pulmonary: Yes/No
☐ Prolonged Vent ☐ Pulm Embolism ☐ Pneumonia ☐ ARDS
☐ Chest Tube ☐ Pulm Edema ☐ Pleural Effusion ☐ Pneumothorax

Reoperation: Yes/No
☐ Bleeding ☐ Graft Occlusion ☐ Other Non-Cardiac ☐ Valve Dysfunction
☐ Other Cardiac Reop Date _____ Type _____ Surg _____
Reop Date _____ Type _____ Surg _____

Neurologic: Yes/No
☐ Postop Stroke for > 72 hrs ☐ Transient Neurologic Deficit
☐ Continuous Coma >=24 hrs ☐ Paralysis ☐ Other _____

Infection: Yes/No
☐ Sternum Super/Deep ☐ Thoracotomy ☐ Arm ☐ Leg ☐ Septicemia

Renal: Yes/No Postop Creatinine Level _____ (Peak)
If Yes is Dialysis Required? Type: Prisma or Hemo or Both

Vascular: Yes/No
☐ Illiac/Femoral Dissection ☐ Acute Limb Ischemia

Cardiac: Yes/No
☐ Peri-op MI ☐ Heart Block ☐ Cardiac Arrest ☐ Atrial Fib ☐ VT/VFib
☐ Low CO ☐ Bradycardia ☐ Tamponade ☐ Anticoag Comp
☐ Other _____

Gastrointestinal: Yes/No ☐ GI Bleed ☐ Ileus
☐ Ischemia ☐ GI Surgery ☐ Other _____

CV ICU Readmission: Yes/No
Readmission Reason _____ If "Other" _____

Discharge Status: Home Other Facility Extended/Transitional Care/Rehab
Nursing Home Deceased To OR for Re-op Unknown

Discharge Date/Time: _____

Referral: Cardiac Rehabilitation: Yes/No Anticoagulation Clinic: Yes/No

Cause of Death: Primary COD: _____
Cardiac Infection Neurologic Pulmonary Renal
Vascular Valvular Other Unknown

Readmission within 30 Days: Yes/No
Primary Reason _____
Secondary Reason _____
Procedure Done _____

Discharge Meds:

☐ Beta Blockers
☐ ACE Inhibitors
☐ ADP Inhibitors
☐ ARB Inhibitors
☐ Lipid Lowering - Statin / Non-Statin
☐ ASA (Aspirin)
☐ Antiarrhythmics - Amiodarone / Other
☐ Coumadin

Transplant Meds Given:
☐ Solu-medrol
☐ ATGAM / RATGAM
☐ Zenapax / Daclizumab
☐ Basiliximab
☐ Tacrolimus / FK506
☐ Cyclosporine
☐ MMF / CellCept
☐ Prednisone

APPENDIX II: SURGICAL SITE INFECTION SURVEILLANCE FORM

Alberta Health Services

Name _____
AB PHN/ULI _____
Hospital ID#_____

Surgical Site Infection Surveillance Form
Revised: May 2014 for UAH & Stollery

DEMOGRAPHIC DATA

Name:
Last name First Name Middle Name

Date of Birth: (yyyy/mmm/dd)_____/_____/_____ | **Gender:** ☐ **M** ☐ **F** ☐ **Unk** | **AB PHN/ULI:**

Hospital ID # ☐ Unk | CHEC # (if applicable)

SURGICAL INFORMATION

Procedure Type:
☐ **Provincial**-Total Hip Replacement (TH)
☐ **Provincial**-Total Knee Replacement (TK)
☐ Other: (**see reverse**)

Bilateral Procedure: ☐ Y ☐ N
☐ Right
☐ Left

Donor Site:

Procedure Date: (yyyy/mmm/dd) _____/_____/_____

Incision Start Time:
Incision Closure Time & Date:

Classification: ☐ Clean ☐ Clean-Contaminated ☐ Contaminated ☐ Dirty-Infected

ASA Score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Procedure Zone: | **Procedure Facility:**

Name of Surgeon:

Antibiotic Prophylaxis ☐ Acceptable ☐ Unacceptable
☐ Unable to collect
☐ None Given
☐ Cefazolin (ancef) ☐ 1g ☐ 2g
☐ Ciprofloxacin ☐ 400 mg
☐ Clindamycin ☐ 600mg ☐ 900mg
☐ Flagyl ☐ 500 mg
☐ Gentamicin ☐ 7 mg/kg
☐ Vancomycin ☐ 1g ☐ 1.5g
☐ Other (specify):
Antibiotic Date & Time:

Antibiotic Prophylaxis Re-dose ☐ Acceptable ☐ Unacceptable
☐ Unable to collect
☐ None Given
☐ Cefazolin (ancef) ☐ 1g ☐ 2g
☐ Ciprofloxacin ☐ 400 mg
☐ Clindamycin ☐ 600mg ☐ 900mg
☐ Flagyl ☐ 500 mg
☐ Gentamicin ☐ 7 mg/kg
☐ Vancomycin ☐ 1g ☐ 1.5g
☐ Other (specify):
Antibiotic Date & Time:

INFECTION INFORMATION

Surgical Site Infection Type:
☐ Superficial Incisional (up to 30 days only)
☐ Deep Incisional
☐ Organ-Space
Infection Onset Date:

_____/_____/_____
yyyy/ mmm / dd

Culture Result: ☐ Positive ☐ Negative ☐ None taken

Culture Date:(yyyy/mmm/dd) _____/_____/_____

Culture Type (see reverse): _____
Organism isolated (if applicable):
☐ Coagulase negative *Staphylococcus* spp ☐ *Enterococcus* spp (specify):
☐ *Staphylococcus aureus*
☐ Gram negative organism (specify): ☐ Other:

Clinical signs and symptoms of infection (check all that apply):
☐ **Aseptically-obtained** culture taken (fluid or tissue)
☐ **Purulent** drainage
☐ Pain and/or tenderness
☐ Localized swelling, redness and/or heat
☐ Diagnosis of **superficial** SSI by surgeon, attending physician or other designee
☐ Dehiscence
☐ Fever (>38°C)
☐ Incision deliberately opened by surgeon
☐ Abscess or other evidence of infection (on direct exam, during reoperation, by histopathologic or radiologic examination)

Additional Infection Comments:

CURRENT LOCATION INFORMATION

Re-admission Date:
(if applicable) (yyyy/mmm/dd) _____/_____/_____

Current Encounter Facility:

Case Identification (check all that apply):
☐ Microbiology Report
☐ Emergency Room Visit
☐ Readmission to Hospital
☐ IV Antibiotic Therapy Clinic
☐ Revision or other Surgical Procedure
☐ At Orthopaedic Surgeon Office
☐ Observation of patient/incision/chart review
☐ Other (specify):

Current Encounter Zone:

Re-operation date (if applicable):
_____/_____/_____
yyyy/ mmm / dd

ICP Name:

QUICK GUIDE FOR CDC/NHSN SURVEILLANCE DEFINTIONS (Feb. 2014)

1. **Superficial incisional surgical site infection**:

Infection occurs within 30 days after the operative procedure AND
Involves only skin and subcutaneous tissue of the incision AND
Patient has at least 1 of the following:

a. Purulent drainage from the superficial incision.
b. Organisms isolated from an **aseptically obtained culture of fluid or tissue** from the superficial incision.
c. Superficial incision that is **deliberately opened by a surgeon**, attending physician or other designee ***and*** is **culture positive or not cultured *and*** patient has **at least one of the following signs or symptoms**: pain or tenderness; localized swelling; redness; or heat. A culture negative finding does not meet this criterion.
d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee

2. **Deep incisional surgical site infection:**

Infection occurs within 1 year if implant is in place and the infection appears to be related to the operative procedure AND
Involves deep soft tissues (eg, fascia and muscle layers) of the incision AND
Patient has at least 1 of the following:

a. Purulent drainage from the deep incision.
b. A deep incision that spontaneously **dehisces** or is **deliberately opened by a** surgeon, attending physician or other designee ***and*** is **culture-positive or not cultured *and*** the patient has at least 1 of the following signs or symptoms: fever (>38^{0}c); localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

3. **Organ/space surgical site infection:**

Infection occurs within 1 year if implant is in place and the infection appears to be related to the operative procedure AND
Infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure AND
Patient has at least 1 of the following:

a. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
b. Organisms isolated from an **aseptically obtained culture** of fluid or tissue in the organ/space.
C. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination ***and*** meets at least one criterion for a specific organ/space infection site listed in NHSN **Table 4 here**
http://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf

Table 4. ***Specific Sites of an Organ/Space SSI.*** Criteria for these sites can be found in the NHSN Help system (must be logged in to NHSN) or the Surveillance Definitions for Specific Types of Infections chapter.

Code	Site	Code	Site
BONE	Osteomyelitis	LUNG	Other infections of the respiratory tract
BRST	Breast abscess or mastitis	MED	Mediastinitis
CARD	Myocarditis or pericarditis	MEN	Meningitis or ventriculitis
DISC	Disc space	ORAL	Oral cavity (mouth, tongue, or gums)
EAR	Ear, mastoid	OREP	Other infections of the male or female reproductive tract
EMET	Endometritis	OUTI	Other infections of the urinary tract
ENDO	Endocarditis	PJI	Periprosthetic Joint Infection
EYE	Eye, other than conjunctivitis	SA	Spinal abscess without meningitis
GIT	GI tract	SINU	Sinusitis
HEP	Hepatitis	UR	Upper respiratory tract
IAB	Intraabdominal, not specified	VASC	Arterial or venous infection
IC	Intracranial, brain abscess or dura	VCUF	Vaginal cuff
JNT	Joint or bursa		

Culture Types:
Fluid - aspirate
Deep wound
Tissue
Superficial wound swab
Other

Other Procedure Types:

Misc. Surgery:
- Appendix Surgery
- Biliary Liver Pancreas
- Breast Surgery
- Colon Surgery
- Exploratory Abd Surgery
- Gallbladder Surgery
- Gastric Surgery
- Herniorrhaphy
- Kidney Surgery
- Neck Surgery
- Prostate Surgery
- Rectal Surgery
- Small Bowel Surgery
- Spleen Surgery
- Thoracic

OB-GYN:
- Abdominal Hysterectomy
- Caesarean Section
- Ovarian Surgery
- Vaginal Hysterectomy

Cardiac:
- CABG - Chest Only
- CABG – Chest and Donor
- Cardiac Surgery
- Pacemaker Surgery

Neurosurgery:
- Craniotomy
- Ventricular Shunt
- Laminectomy-Discectomy
- Spinal Fusion
- Spinal Re-fusion

Vascular:
- AAA Repair
- Atriovent Shunt Dialysis
- Carotid Endarterectomy
- Vascular Bypass

Transplant:
- Heart Transplant
- Kidney Transplant
- Liver Transplant

Local – Ortho:
- Limb Amputation
- Open Reduction Fracture
- Other Ortho Surgery
- Revision – Hip
- Revision - Knee

APPENDIX III: CASE REPORT FORMS

SWI-01: ELIGIBILITY AND ENROLLMENT **PATIENT ID: __ - __ __ __ __**

INCLUSION CRITERIA: ALL RESPONSES MUST BE YES FOR ELIGIBILITY			
1.	Able to sign Informed Consent and Release of Medical Information Form	☐ Yes	☐ No
2.	Age ≥ 18 years	☐ Yes	☐ No
3.	Undergoing cardiac surgery with complete sternotomy (including re-operations)	☐ Yes	☐ No

EXCLUSION CRITERIA: ALL RESPONSES MUST BE NO FOR ELIGIBILITY			
1.	Evidence of active infection (any culture positive or blood positive infection)	☐ Yes	☐ No
2.	Undergoing organ transplantation	☐ Yes	☐ No
3.	Known hypersensitivity to vancomycin	☐ Yes	☐ No
4.	Pregnant or nursing women	☐ Yes	☐ No
5.	Mental impairment or other conditions that may not allow participant to understand the nature, significance, and scope of study	☐ Yes	☐ No

Signature: _____ Investigator/Coordinator Date: _____ DD/MMM/YYYY

SWI-02: BASELINE CHARACTERISTICS **PATIENT ID: __ - __ __ __ __**

1.	Last Name: _____	First Name: _____
2.	Date of birth (DD/MMM/YYYY):	__ __/__ __ __/__ __ __ __
3.	PHN/ULI #:	☐☐☐☐☐☐☐☐☐☐
4.	Hospital ID#:	☐☐☐☐☐☐☐☐

5. Walking
   - ☐ No problems
   - ☐ Assisted
   - ☐ Prosthesis
   - ☐ Comments: _____

6. Immune deficiency ☐ Yes ☐ No
   Specify: _____

LABORATORY PARAMETERS		
Hematology Assessment Date (DD/MMM/YYYY):		
1.	Hemoglobin (HGB)	☐☐☐ g/L
2.	Hematocrit (HCT)	☐.☐☐ L/L
3.	Platelet Count (PLT)	☐☐☐ 10^9/L
4.	White Blood Cell Count (WBC)	☐.☐ 10^9/L
5.	Neutrophil Count (NEUT)	☐.☐ 10^9/L
6.	Lymphocyte Count (LYMPH)	☐.☐ 10^9/L
7.	Monocyte Count (MONO)	☐.☐ 10^9/L
8.	Eosinophil Count (EOS)	☐.☐ 10^9/L
9.	Basophil Count (BASO)	☐.☐ 10^9/L
Blood Chemistry Assessment Date (DD/MMM/YYYY):		
10.	Sodium (Na)	☐☐☐ mmol/L
11.	Potassium (K)	☐.☐ mmol/L
12.	Urea	☐.☐ mmol/L
13.	Creatinine (CR)	☐☐ umol/L
14.	Glomerular filtration rate (GFR)	☐☐ mL/min/1.73m^2

Signature: _____ Investigator/Coordinator Date: _____ DD/MMM/YYYY

SWI-03: INDEX SURGERY **PATIENT ID: __ - __ __ __ __**

STUDY PRODUCT SYRINGE IDENTIFICATION NUMBER: _____

1.	Surgery date (DD/MMM/YYYY):	__ __/ __ __ __/ __ __ __ __
2.	Was the chest closed in the OR?	☐ Yes ☐ No

ADVERSE REACTIONS TO STUDY PRODUCT		
1.	Was there evidence of an allergic reaction along the sternal wound within 24 hours of gauze application?	☐ Yes ☐ No
	DESCRIBE: _____	

Signature: _____ Date: _____ DD/MMM/YYYY

SWI-04: INDEX HOSPITAL DISCHARGE **PATIENT ID: __ - __ __ __ __**

DISCHARGE ANTIBIOTIC MEDICATIONS		☐ Yes ☐ No
☐	Cefazolin (ancef)	_____ g
☐	Ciprofloxacin	_____ mg
☐	Clindamycin	_____ mg
☐	Flagyl	_____ mg
☐	Gentamicin	_____ mg/kg
☐	Vancomycin	_____ g
☐	Other (specify): _____	

Signature: _____ Date: _____
DD/MMM/YYYY

SWI-05: POSTOP LABORATORY RESULTS (1:2) **PATIENT ID: __ - __ __ __ __**

ASSESSMENT DATE AND TIME	LABORATORY TEST						
	CR (umol/L)	GFR (mL/min/1.73m^2)	Urea (mmol/L)	Na (mmol/L)	K (mmol/L)	HGB (g/L)	HCT (L/L)

Signature: _____ Date: _____

Investigator/Coordinator DD/MMM/YYYY

SWI-05: POSTOP LABORATORY RESULTS (2:2) **PATIENT ID: __ - __ __ __ __**

ASSESSMENT DATE AND TIME	LABORATORY TEST						
	PLT (10^9/L)	WBC (10^9/L)	NEUT (10^9/L)	LYMPH (10^9/L)	MONO (10^9/L)	EOS (10^9/L)	BASO (10^9/L)

Signature: _____ Date: _____

Investigator/Coordinator DD/MMM/YYYY