Contrast RISK: Reducing Injury Sustained by Kidneys

Enhancing Clinical Decision Support for Prevention of Contrast-Induced Acute Kidney Injury in Cardiac Catheterization

Contrast RISK Project Protocol: University of Alberta - Mazankowski Alberta Heart Institute

MAZANKOWSKI ALBERTA HEART INSTITUTE

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1.0 Project Overview

Contrast-induced acute kidney injury (CI-AKI) is a common and expensive complication of cardiovascular procedures, including angiograms and percutaneous coronary intervention. There are accurate ways to identify patients at high risk for developing CI-AKI, and to prevent this complication. These include minimizing the volume of contrast used, and optimizing the use of intravenous fluids. These interventions may be neglected if care teams do not recognize high-risk patients. Preventable cases of CI-AKI contribute to longer hospital stays, hospital readmissions, and even the need for dialysis in some cases - all of which contribute to unnecessarily high costs of health care in Alberta.

Quality improvement initiatives in cardiac catheterization facilities in the United States have been shown to prevent 1 in every 5 cases of CI-AKI. The purpose of this project is to implement key features of these initiatives in all 3 cardiac catheterization facilities in Alberta and to evaluate whether it leads to improved and sustained use of CI-AKI prevention strategies (i.e. reduced volumes of contrast dye, and optimized intravenous fluid), reduced rates of CI-AKI, and more efficient use of health resources (shorter time in hospital, and lower costs of care). This project will ultimately determine whether implementation of this strategy results in cost saving to the health care system in Alberta. If these tools prevent 1 in every 5 cases of CI-AKI in Alberta, as reported elsewhere, this could lead to a savings of $1.4 million dollars in yearly health care costs for the province.

1.1 Project Partners

Steering Committee: Dr. Michelle Graham (Co-PI, UAH Site Lead), Dr. Bryan Har (FMC Site Lead), Dr. Matthew James (Co-PI, APPROACH Research Lead), Dr. Ben Tyrell (RAH Site Lead)
Funding Agency: Alberta Innovates – Health Solutions: Partnership for Research & Innovation in the health system (PRIHS)
AHS Strategic Clinical Network Partners*:* AHS Cardiovascular and Stroke Strategic Clinical Network, AHS Kidney Health Strategic Clinical Network
Partner Sites and Leads: Foothills Medical Centre - Libin Cardiovascular Institute of Alberta (Dr. David Goodhart, Tanya Federico), Royal Alexandra Hospital - CK Hui Heart Centre (Dr. Neil Brass, Michael Powell), University of Alberta - Mazankoswski Alberta Heart Institute (Dr. Robert Welsh, Cheryl Louglin)
Collaborating Teams: Alberta Provincial Project for Outcomes Assessment in Coronary Heart Disease (APPROACH), AHS Analytics (Allan Ryan), AHS Research Facilitation (Peter Faris)

2.0 Background and Rationale

Cardiac catheterization is performed throughout the world to identify and treat heart disease. In 2015 more than 14,000 Albertans underwent a diagnostic or therapeutic cardiac catheterization procedure; part of an approach that has been proven to reduce the risk of death, avoid future cardiovascular events and improve the quality of life of people with heart disease[1-3]. Unfortunately, exposure to the radiocontrast dye required for these procedures can lead to contrast-induced acute kidney injury (CI-AKI); a common and costly complication[4-7].

Almost 1 in 10 patients undergoing cardiac catheterization in Alberta develop CI-AKI as a procedural complication. In 2015 an estimated 1,344 patients (9.6%) were affected by CI-AKI in Alberta. In contrast, the best-performing (benchmark) hospitals in the United States have achieved substantial reductions in CI-AKI incidence approaching 4%[8,9]. Patients who are older and have comorbidities such as diabetes, pre-existing kidney disease, and heart failure are at particularly high-risk of CI-AKI[10,11]. These patients are also at highest risk of poor outcomes from heart disease and stand to gain the greatest benefits from cardiac catheterization[12-14]. Therefore, rather than restricting the use of these procedures, it is critical to focus efforts on safety for high-risk patients, to improve outcomes[2,3].

CI-AKI is an important problem because it has been consistently associated with several adverse patient and health system outcomes[12-17]. In Alberta, patients with CI-AKI currently experience a 2.5-10 day increase in the average length of time in hospital, a 50% increase in the risk of a hospital readmission, and a small but clinically significant 3% risk of kidney failure requiring dialysis[15,17]. These complications have substantial financial implications for our health system[18,19]. Depending on its severity, AKI is independently associated with an additional $2,800 to $17,000 per hospital stay in Alberta[18]. Patients with CI-AKI also experience increased health care costs after discharge from hospital, with incremental increases in costs ranging from $3,700 to $22,000 per patient due to readmissions, need for additional care, and dialysis up to 3 months after hospitalization. Every additional patient that requires chronic dialysis incurs up to $80,000 per year for its provision[20].

CI-AKI is preventable, thus many of these consequences can be avoided**.** Recent evidence demonstrates that 1 in every 5 cases of CI-AKI can be avoided when cardiac catheterization units implement appropriate preventive practices[8,9]. Reducing the relative risk of CI-AKI by even 20% would immediately reduce annual direct health care costs in Alberta by $1.8 million dollars[18,19]. Failure to improve current practices results in a missed opportunity to reduce the risk of CI-AKI and its associated adverse health consequences and costs. Conversely, implementing CI-AKI prevention strategies for all patients receiving cardiac catheterization would be inefficient, as it would lead to unnecessary prevention strategies (and attendant costs) to low-risk patients. Instead, the objective of this quality improvement initiative is to implement a precision approach that identifies high-risk patients and ensures they receive evidence-based CI-AKI prevention strategies and follow-up, to improve the appropriateness and efficiency of care. The purpose of this study is to evaluate the impact of this quality improvement initiative on processes and outcomes.

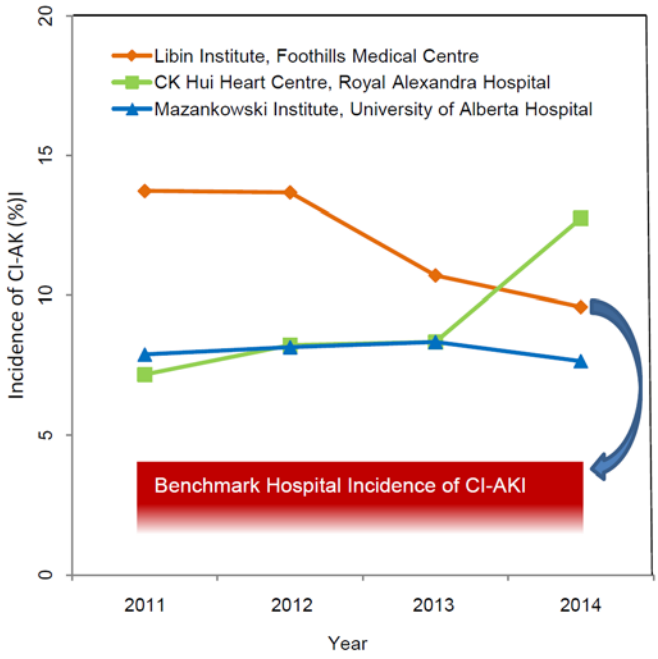


Figure 1 – Incidence of CI-AKI in Alberta by Hospital and Year. *The red bar indicates the CI-AKI incidence after cardiac catheterization achieved in the best performing (benchmark) hospitals in the United States (4%), and the blue arrow indicates the potential for reduction in CI-AKI incidence in Alberta.*

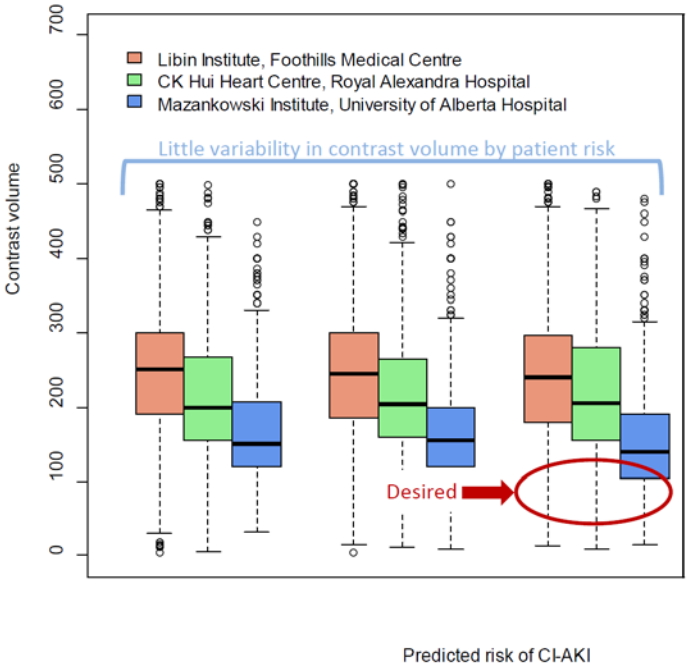


Figure 2 - Amount of Contrast used by Hospital and Patient CI-AKI Risk Status in Alberta, 2011-2014. *There is little variability in the amount of contrast used according to a patient's CI-AKI risk, but large variability within each centre. The desired amount of contrast for high-risk patients is indicated by the red arrow and circle.*

3.0 Supporting Evidence and Knowledge Translation

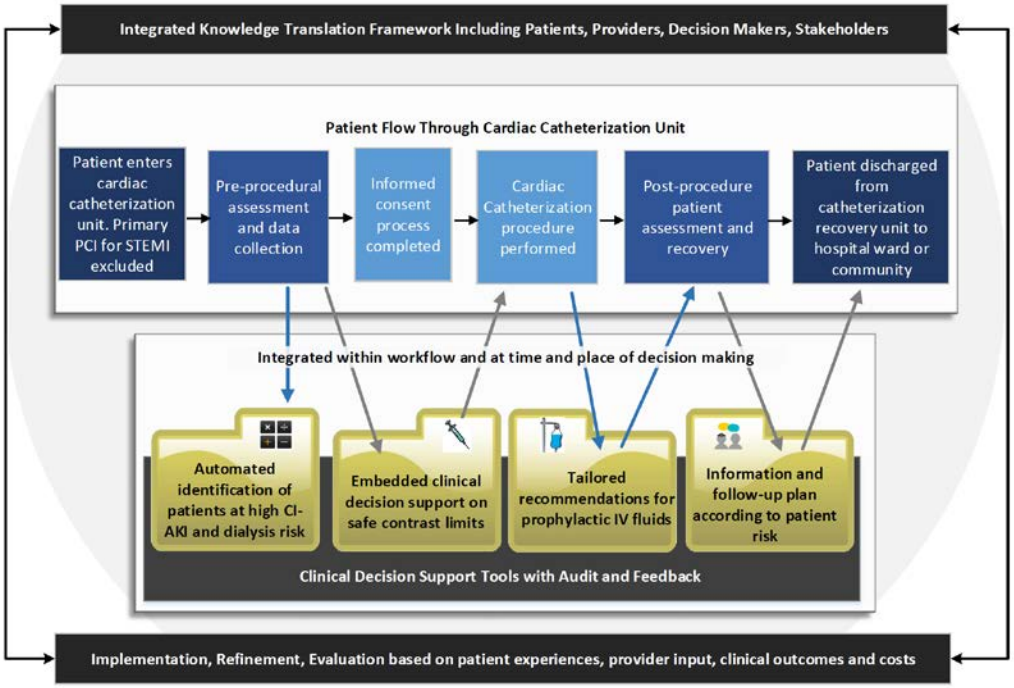
Evidence-based guidelines for CI-AKI prevention uniformly recommend; 1) pre-procedural assessment of risk, 2) minimization of the dose of radiocontrast media, 3) use of hydration strategies incorporating intravenous (IV) fluids for prevention of CI-AKI in high-risk patients, and 4) follow-up of kidney function in high-risk patients[23-25]. Yet, incomplete uptake of prevention approaches for CI-AKI is well documented[26-28]. The purpose of this quality improvement initiative is to systematically and consistently implement these 4 key evidence-based strategies to reduce the risk of CI-AKI and mitigate its severe consequences on patient outcomes and costs of care:

1) Automated identification of patients at high risk of CI-AKI integrated within the current clinical workflow. There is robust evidence that patients at risk of CI-AKI can be accurately identified[29-32]. In fact, risk scores based on commonly measured clinical variables can accurately predict the risk of CI-AKI including the most severe forms of CI-AKI requiring dialysis, with excellent validity demonstrated across many settings[31,32]. Furthermore, several studies have illustrated how formulas for determining a patient-specific safety limit for radiocontrast dye volume can be used to plan procedures that can be completed with significantly reduced rates of CI-AKI[33-38]. All the information needed to predict an individual patient's risk of CI-AKI and calculate safe dye limits is collected in the process of preparing patients for cardiac catheterization in Alberta. This project will allow this information to be applied in real-time to identify high-risk patients and plan safer cardiac catheterization procedures and care.

2) Embedded clinical decision support to facilitate safe radiocontrast dye volumes for each patient. Reducing the volume of radiocontrast dye administered during procedures is a cornerstone of prevention. Tactics that have been proven to effectively reduce dye volume include using smaller syringes and catheters, biplane / rotational angiography, avoidance of left ventriculography, and staging of procedures (performing diagnostic and therapeutic procedure on different days)[39-43]. The tools to do this are currently available in Alberta, but uptake is variables and left to the discretion of each care provider. This initiative will help ensure these these tactics are directed most appropriately towards high-risk patients.

3) Tailored recommendations to individualize prophylactic IV fluid recommendations for each patient. Adequate hydration is another important element of CI-AKI prevention, with efficacy proven in several large randomized trials[21,22,44]. A tailored approach to IV fluid administration based on a patient's left ventricular end-diastolic pressure (LVEDP; a measure of the heart's capacity to safely accommodate more fluid), has been shown to safely increase the volume of IV fluids administrated and achieve a 20% further reduction in CI-AKI incidence, while requiring patients to spend a shorter amount of time in hospital, as compared with conventional fluid administration[45]. Tailoring IV fluid recommendations provides an opportunity to further optimize prevention of CI-AKI in high-risk patients while avoiding inefficient resource use and costs of administering further IV fluids to low-risk patients.

4) Appropriate information provided to patients and care teams according to risk. Patients at high risk of CI-AKI require clear instructions for maintaining adequate hydration, and follow-up laboratory checks of kidney function and electrolytes. For those with progressive loss of kidney function, timely referral and management for chronic kidney disease may be required,[46-51]. This initiative supports standardized follow-up procedures in Alberta for patients at high risk of CI-AKI, including orders for subsequent IV fluids and laboratory tests for inpatients, and clear instructions to patients about hydration, and timing for follow-up laboratory tests after discharge following day procedures.



4.0 Procedures

4.1 Project Resources and Education

CI-AKI risk prediction models and decision support tools for calculation of safe contrast limits and LVEDP based IV fluid calculations have been integrated within the APPROACH clinical information system to support this initiative. We have mapped and appropriately modify workflow in cardiac catheterization and recovery units to support integration of data collection, risk stratification, and decision support output. Project leads for each site have developed agreed upon processes for CI-AKI avoidance in high-risk patients (incorporating staging of procedures, avoiding LV grams, selection of smaller catheters, more careful/less injections of contrast dye). Nursing and support staff in cardiac catheterization units will receive training to support these elements and the IV fluid protocols and critical pathways for patient follow-up through in-services to prepare for implementation. Cardiologists who perform diagnostic and interventional cardiac catheterization procedures will receive academic detailing on the initiative by each site lead, including information on safe contrast limits and procedures to reduce contrast volumes in high-risk patients and selection of LVEDP based fluid protocols.

4.2 Clinical Implementation

This initiative is being implemented in a province-wide initiative involving all cardiac catheterization units in Alberta (Foothills Medical Centre, Royal Alexandra Hospital, and University of Alberta Mazankowski Alberta Heart Institute). The deployment of the intervention will be carried out in a staged manner, following a stepped-wedge design[56] that sequentially adds random groups of cardiologists to the intervention, through an academic detailing session to a new group of 2-5 cardiologist every 45 days, and including each of the 35 eligible physicians who perform diagnostic and therapeutic cardiac procedures. Once education and training have been provided to a physician they will subsequently begin receiving safe contrast limit calculations and LVEDP based fluid recommendations, to facilitate uptake. Throughout the project processes of care and clinical events will be tracked using APPROACH and AHS laboratory data to evaluate the degree to which the initiative achieves the expected improvement in the use of appropriate CI-AKI prevention strategies (i.e. exceeding contrast dye safety limits and adhering to LVEDP based IV fluid recommendations), and reduction in CI-AKI incidence. These data will be used to implement a continuous audit and feedback system in this phase of the project, to report performance and outcomes according to patient risk status for each physician, measure adherence to the protocol, and provide feedback reports to physicians and unit managers to improve consistency of care.

4.3 Project Evaluation Plan

The effectiveness of this quality improvement initiative will be evaluated based on uptake of CI-AKI risk stratification, use of prevention measures, CI-AKI incidence, and downstream clinical events and health outcomes, including use of health resources (post-procedural bed days per patient managed, healthcare contacts for CI-AKI complications, and costs. Although this initiative is expected to improve the appropriateness of care and efficiency of resource use, for such savings to be meaningful it is also important to demonstrate that implementing CI-AKI prevention approaches does not lead to unintended clinical consequences. Thus the non-inferiority of implementing the quality improvement initiative will also be evaluated based on generic and cardiovascular-specific quality of life using the EQ-5D[57] and Seattle Angina Questionnaire

(SAQ)[58,59] quality of life tools (collected by APPROACH), as well as on adverse cardiac outcomes of mortality, and readmission for myocardial infarction[60], heart failure[61], or new revascularization procedure[52]. This will also allow a full cost-effectiveness analysis of the quality improvement initiative. Survey of health care providers will be also be distributed to physicians and health care staff before and after implementation of the initiative, to characterize benefits and challenges of the initiative. All surveys are administered through the web and will be filled out by participants using SurveyMonkey.

5.0 Protocol and Procedures: University of Alberta - Mazankowski Alberta Heart Institute

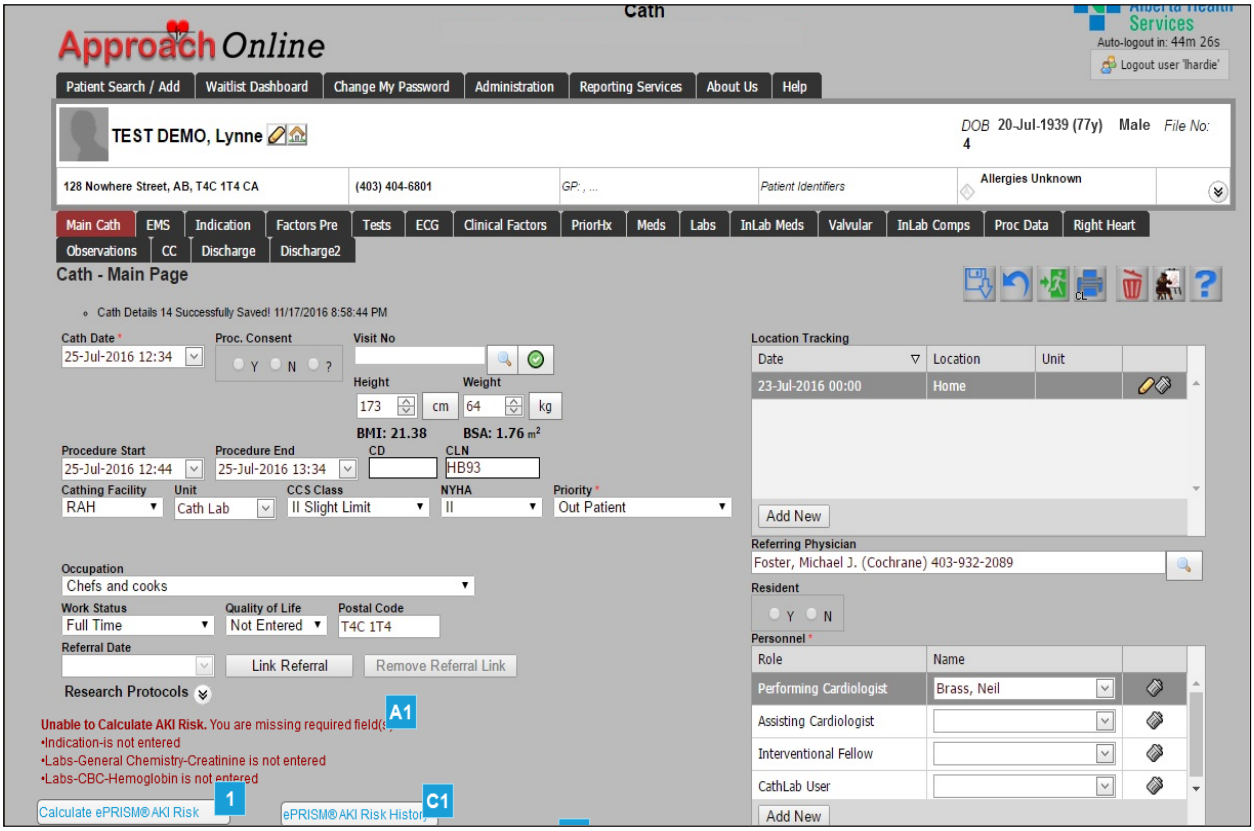
1. Patient is admitted to the recovery/ holding area. The **Diagnostic Imaging (DI)** staff obtain available clinical information and laboratory data (hemoglobin and creatinine) from the admission data collected in recovery on the nursing assessment sheet. **DI technicians** enter these data into APPROACH (see critical variables in item #10).

2. **Nurse** checks GFR and Creatinine; if abnormal pre-hydration IV fluid protocol is initiated.

3. Patient history, APPROACH questionnaire, APPROACH consent and procedure consent are completed by the patient (data is entered into APPROACH by the **Holding/Recovery room RN or DI tech**)

4. Patient arrives in the cardiac catheterization lab.

5. The **X-Ray Tech** creates a CATH / PCI event in APPROACH.



6. The **X-Ray Tech** updates required fields from the requisitions and confirms that the patient is eligible for inclusion in the Contrast RISK QI initiative (**Recovery room RN** can also inform on the nursing notes) Once ready to determine AKI Risk the user selects the ***Calculate ePRISM® AKI Risk*** button [1].

7. The System determines that all the non-editable data elements on the AKI Risk Pop up window can be populated so System opens the ***AKI Risk Popup Window*** and pre-populates each data element.

8. The **X-Ray Tech** reviews and updates any editable data element on the ***AKI Risk Popup Window*** if necessary.

   Ten Clinical factors (Y/N)

   - Age
   - Sex at birth
   - Race-Black or African American
   - Indication
   - Cardiac Arrest
   - Cardiogenic Shock
   - IABP
   - History of Heart Failure
   - Heart Failure within 2 weeks
   - Diabetes
   - History of Cerebrovascular Disease

   Two Laboratory variables (Value)

   - Most Recent Creatinine
   - Most Recent Hemoglobin

ePRISM® Data input variables for Acute Kidney Injury / Dialysis Predictive Models:

- **AKI Pre-Procedure no contrast** - The patient's risk of AKI
- **AKI Target Risk** - The desired risk contrast level to reduce the risk of AKI
- **Dialysis Pre-Procedure no contrast** - The patient's risk of Dialysis

Age in years: 77

Sex at birth: 1-Male

Race-Black or African American: Y N Missing

Indications:

CAD Presentation: 3-Stable Angina

Factors Pre:

Cardiac Arrest: Y N

You have changed this value from what is currently in the database.
This field will be updated in the database when you select Save and Calculate

Cardiogenic Shock: Y N

IAB: Y N

Clinical Factors:

History of Heart Failure: Y N

Heart Failure within 2 weeks: Y N

Diabetes: Y N

History of Cerebrovascular Disease: Y N

Labs:

Most Recent Serum Creatinine (µmol/L): 115 24-Jul--2016 15:34 Creatinine (mg/dL): 1.3

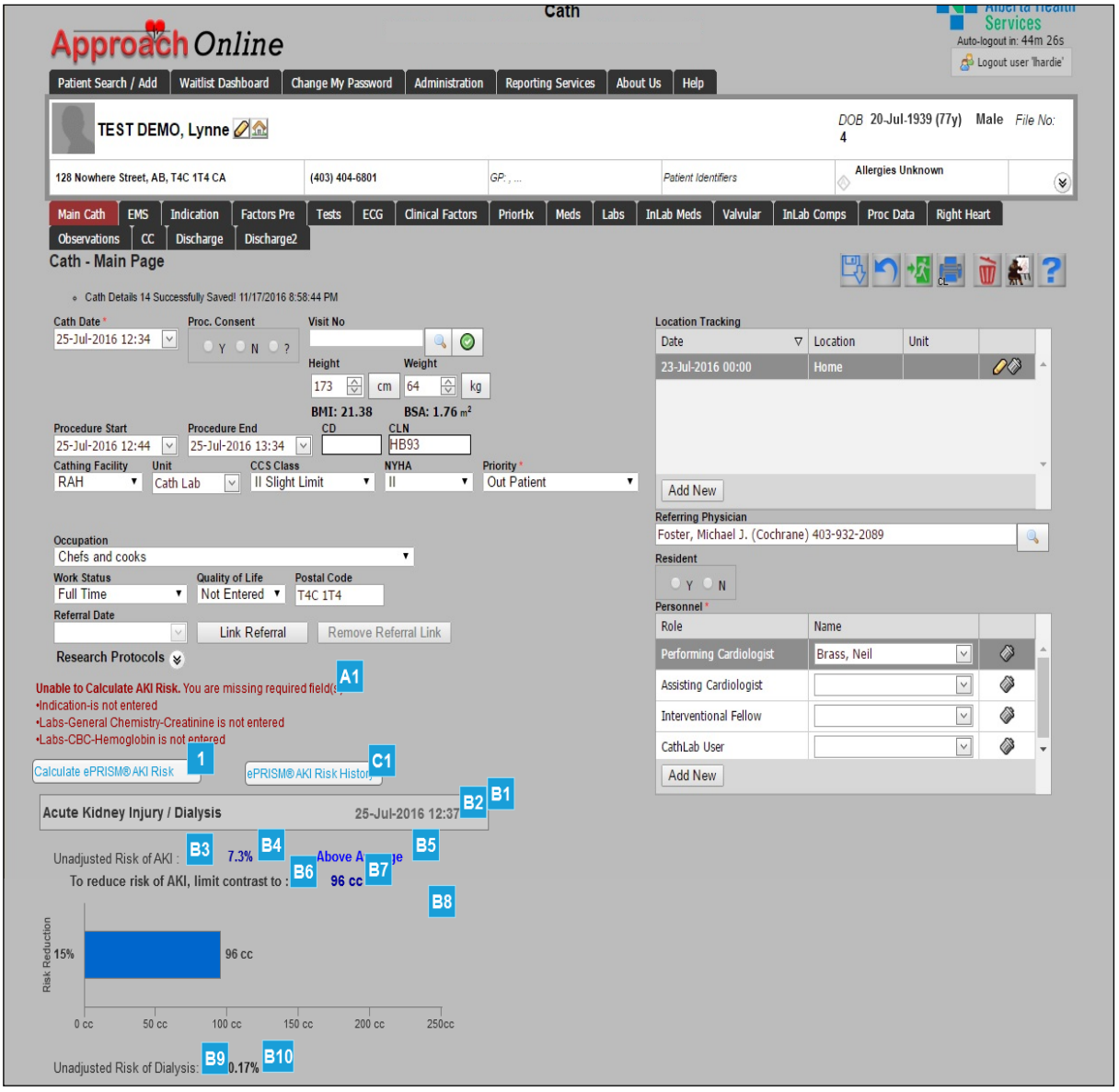
Most Recent Hemoglobin (g/L): 220 24-Jul-2016 15:33 Hemoglobin (g/dL): 22

Save and Calculate Risk | Cancel

9. The **X-Ray Tech** clicks ***Save and Calculate Risk*** button to execute the calculations for Risk of AKI, Risk of Dialysis, and Safe contrast limit.

10. Upon clicking the Save and Calculate Risk button, APPROACH minimizes the 'AKI Risk Popup' window, and in a matter of seconds you will see the results for Risk of AKI, Risk of Dialysis, and Safe Contrast Limit in one of the outputs shown below. Note that the Safe contrast limit will only be displayed in APPROACH if the AKI risk calculator identifies that the patient is ***Above Average or High Risk***. The safe contrast limits are shown graphically Blue for ***Above Average*** Risk patients and in Red for ***High Risk*** patients.

11. The **X-Ray Tech** reviews the pre-procedural contrast limit recommendations when provided by APPROACH on the main page for ***Above Average and High Risk*** patients and communicates the safe contrast volume limit to the Cath room circulating nurse and staff during time out and to the **MD** prior to the start of the procedure.



12. The **MD** scrubs in for the case with the knowledge of safe contrast dose for an ***Above Average or High Risk*** patient.

13. During the procedure, the **RN** monitors Philips and informs the **MD** at the time the safe contrast limit is reached. The **MD** may decide to end the case or continue the

case while exceeding the safe contrast volume at their discretion.

14. Upon completion of the procedure, the **X-Ray Tech** enters the actual contrast volume used, along with any strategies used to minimize contrast volume, LVEDP and weight into APPROACH.

Contrast Minimization Strategies

- Avoid LV or aortogram
- Rotational or biplane angiography
- Stage PCI

15. If the LVEDP was not obtained then the reason is entered instead.

Reason unable to obtain LVEDP:

- Mechanical aortic valve
- Aortic Stenosis
- Not technically possible
- Insufficient time to obtain

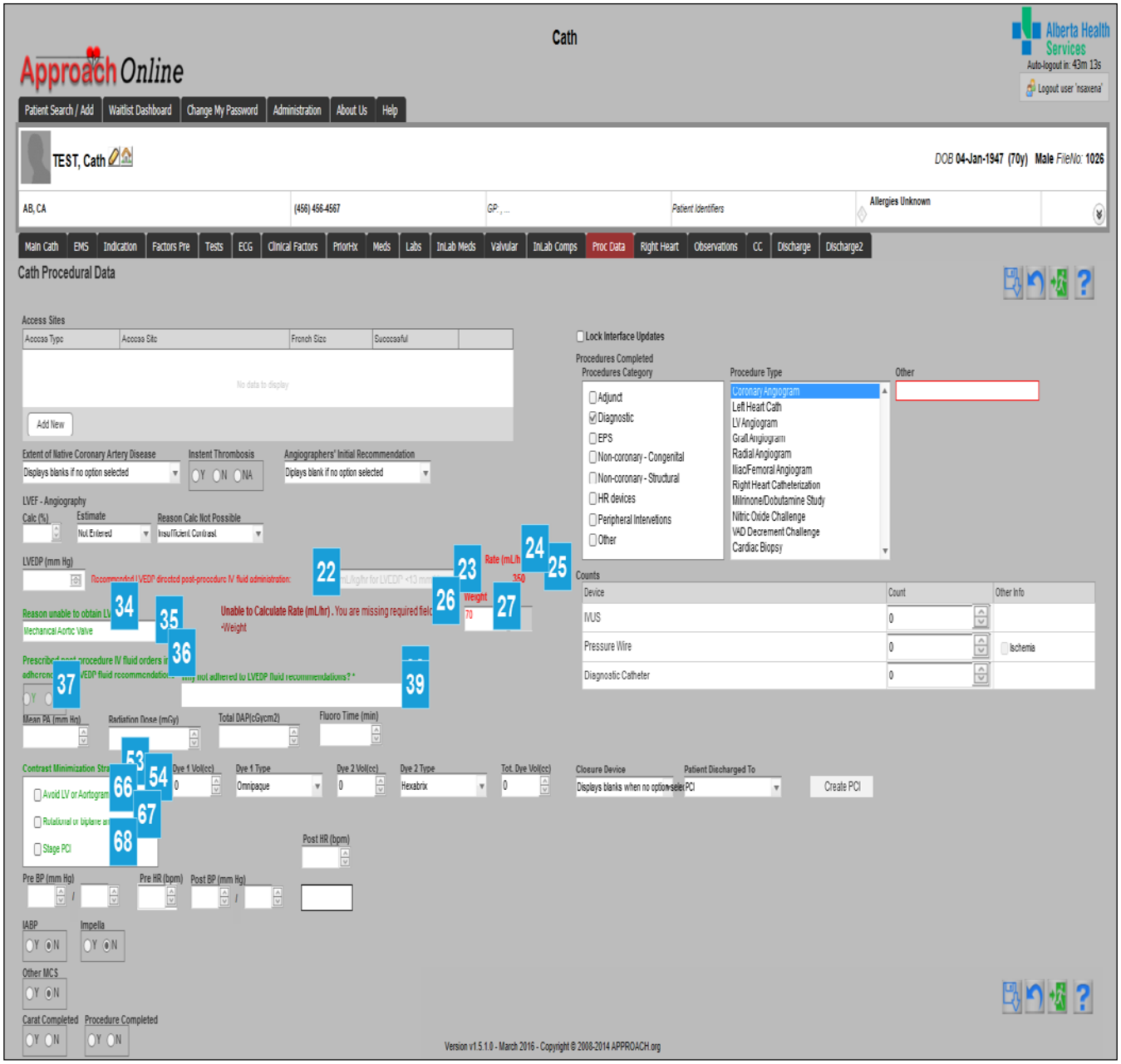
16. The recommended post-procedure IV fluid order (based on LVEDP and weight) is obtained from APPROACH by the **X-Ray Tech**, who then communicates the recommended 0.9% (Normal Saline) IV rate to the **MD**. The **MD** then confirms whether or not they will follow the recommendation. If not, the reason for not following the recommendation is entered into APPROACH.

Prescribed Post-procedure IV fluid orders in adherence with LVEDP-guided fluid recommendation?

● Yes
● No, (why not adhere to LVEDP fluid recommendations? Enter valid reason -50 characters limit)

17. The post-procedure IV fluid order is entered into the post procedure orders by the **physician**. IV fluid orders are then implemented by the Recovery Room or Accepting Unit based on LVEDP. 0.9% NaCl be administered post procedure based on the LVEDP that has been entered into APPROACH :

Selection	LVEDP	IV Rate
□	<13 mm Hg	5 mL/kg/h for 4 h
□	13-18 mmHg	3 mL/kg/h for 4 h
□	>18 mmHg	1.5 mL/kg/h for 4 h



18. If an **Above Average or High Risk** patient is discharged home from the unit (Day procedures), the **Recovery Room RN** completes 4 hours of post-procedure IV fluids before discharge. The **RN** provides the patient with the one page patient information sheet on oral hydration instructions and laboratory requisition for follow up creatinine and electrolytes (to be done 48-72 hours post-procedure) at the time of discharge teaching.

    The **RN** completes the letter to the primary care physician for above average and high risk patients explaining the required follow-up of post-procedure serum creatinine levels and providing guidance for the follow-up of patients with abnormal kidney function tests according to the Alberta online chronic kidney disease (CKD) clinical pathway (www.diagnoseckd.ca). The letter is sent directly to the primary

care physician or provided to the patient to take to their primary care physician with their next appointment.

19. If an Above Average or High Risk patient is being transferred to another unit (inpatient), the **RN** communicates the recommended 0.9% NaCl infusion rate for the next 4 hours plus instructions for the receiving unit to ensure serum creatinine and electrolytes are checked between 48-72 hours after the procedure. A copy of the patient and physician information sheets is provided with the patient chart upon transfer to another unit.

Alberta Health Services

Contrast RISK Reducing Injury Sustained by Kidneys

Patient Information After X-Ray Contrast Administration

Date: _____

Dear Patient:

Today you received an x-ray contrast media (dye) during your heart procedure.

You are at risk for a drop in your kidney function due to this dye.

For this reason, you have been given a laboratory requisition to have a blood test in 2-3 days from today to check your kidney function. The results of this test will be sent to your doctor (usually your family doctor).

You can take the following steps to minimize the effects of the dye on your kidneys:

1. Drink plenty of clear fluids (6-8 glasses of water per day) on the day of and 2 days following your procedure, unless otherwise directed by your doctor who did your procedure.

2. Please take the laboratory requisition to a laboratory of your choice in 2 to 3 days from today to have blood work drawn to check your kidney function

3. Follow-up with your family doctor to review your blood work to determine whether there has been any changes to your kidney function.

4. If you have any concerns or are feeling unwell in any way, please contact your family doctor.

Sincerely

Mazankowski Alberta Heart Institute

780-407-1112

Contrast Reducing Injury Sustained by Kidneys

Alberta Health Services

Patient Identifier

Physician Name:_____
Physician Phone: _____ Fax: _____

Your patient received cardiac catheterization on _____ (date) and was identified as being at risk of contrast-induced acute kidney injury.

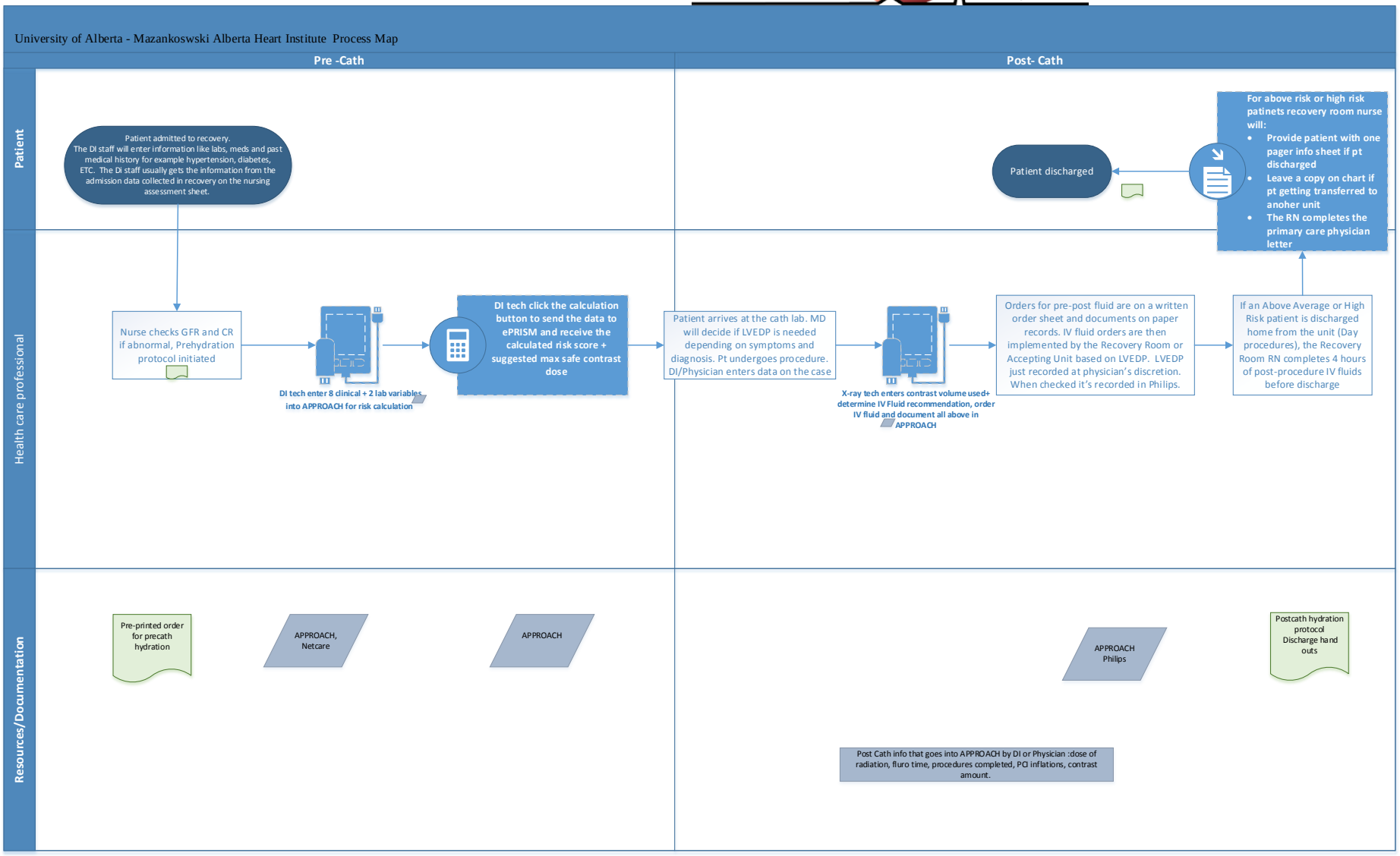
Your patient has been given a requisition for a serum creatinine level to be checked 2 to 3 days after the procedure and these results will be sent to you. It has been recommended to your patient that they see you within a week after their procedure, including follow-up of their kidney function.

Information and the management and referral of patients identified with kidney disease can be found on the Alberta online chronic kidney disease clinical pathway at:
www.diagnoseckd.ca

Sincerely

Mazankowski Alberta Heart Institute

780-407-1112


University of Alberta - Mazankoswski Alberta Heart Institute Process Map
Pre -Cath
Post- Cath
Patient
Health care professional
Resources/Documentation
Patient admitted to recovery. The DI staff will enter information like labs, meds and past medical history for example hypertension, diabetes, ETC. The Di staff usually gets the information from the admission data collected in recovery on the nursing assessment sheet.
Patient discharged
For above risk or high risk patinets recovery room nurse will:
Provide patient with one pager info sheet if pt discharged
Leave a copy on chart if pt getting transferred to anoher unit
The RN completes the primary care physician letter
Nurse checks GFR and CR if abnormal, Prehydration protocol initiated
DI tech enter 8 clinical + 2 lab variables into APPROACH for risk calculation
DI tech click the calculation button to send the data to ePRISM and receive the calculated risk score + suggested max safe contrast dose
Patient arrives at the cath lab. MD will decide if LVEDP is needed depending on symptoms and diagnosis. Pt undergoes procedure. DI/Physician enters data on the case
X-ray tech enters contrast volume used+ determine IV Fluid recommendation, order IV fluid and document all above in APPROACH
Orders for pre-post fluid are on a written order sheet and documents on paper records. IV fluid orders are then implemented by the Recovery Room or Accepting Unit based on LVEDP. LVEDP just recorded at physician's discretion. When checked it's recorded in Philips.
If an Above Average or High Risk patient is discharged home from the unit (Day procedures), the Recovery Room RN completes 4 hours of post-procedure IV fluids before discharge
Pre-printed order for precath hydration
APPROACH, Netcare
APPROACH
APPROACH Philips
Postcath hydration protocol Discharge hand outs
Post Cath info that goes into APPROACH by DI or Physician :dose of radiation, fluro time, procedures completed, PCI inflations, contrast amount.

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