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Advancing Community Care and Access to Follow-up After Acute Kidney Injury Hospitalization: Design of the AFTER AKI Randomized Controlled Trial

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Abstract

Background: Acute kidney injury (AKI) is a common complication among hospitalized patients with long-term implications including chronic kidney disease (CKD). Although models are available to predict the risk of advanced CKD after AKI, there is limited evidence regarding follow-up for patients with AKI after hospital discharge, resulting in variable follow-up care. A risk-stratified follow-up approach may improve appropriateness and efficiency of management for CKD among patients at risk of declining kidney function following AKI.

Objective: The objective was to compare and evaluate the use of a risk-stratified approach to follow-up care vs usual care for patients with AKI after hospital discharge.

Design: This study was a pragmatic randomized controlled trial.

Setting: This study was conducted in 2 large urban hospitals in Alberta, Canada.

Patients: Hospitalized patients with AKI (KDIGO stage 2 or 3) not previously under the care of a nephrologist, expected to survive greater than 90 days being discharged home.

Measurements: We will evaluate whether guideline-recommended CKD care processes are initiated within 90 days, including statin use, angiotensin-converting enzyme inhibitor (ACEi)/angiotensin II receptor blocker (ARB) use in those with proteinuria or diabetes, and nephrologist follow-up if sustained eGFR <30 mL/min/1.73 m^2. We will also assess the feasibility of recruitment and the proportion of patients completing the recommended blood and urine tests at 90 days.

Methods: Patients with AKI will be enrolled and randomized near the time of hospital discharge. In the intervention group, low risk patients will receive information regarding AKI, medium risk patients will additionally receive follow-up guidance sent to their primary care physician, and high-risk patients will additionally receive follow-up with a nephrologist. Participants in the intervention and usual care group will receive a requisition for urine testing and bloodwork at 90 days following hospital discharge. Telephone follow-up will be conducted for all study participants at 90 days and 1 year after hospital discharge. Bivariate tests of association will be conducted to evaluate group differences at the follow-up time points.

Limitations: We expect there may be challenges with recruitment due to the significant co-existence of comorbidity in this population.

Conclusions: If the trial shows a positive effect on these processes for kidney care, it will inform larger-scale trial to determine whether this intervention reduces the incidence of long-term clinical adverse events, including CKD progression, cardiovascular events, and mortality following hospitalization with AKI.

Abrege

Contexte: L'insuffisance rénale aiguë (IRA) est une complication fréquente chez les patients hospitalisés qui peut avoir des conséquences à long terme, notamment l'insuffisance rénale chronique (IRC). Bien que des modèles de prédiction du risque d'IRC avancée après un épisode d'IRA soient disponibles, peu de données existent sur le suivi des patients atteints d'IRA après leur sortie de l'hôpital, ce qui se traduit par une variabilité dans les soins de suivi. Une approche de suivi stratifiée selon le risque d'IRC peut améliorer la qualité et l'efficacité de la prise en charge de l'IRC chez les patients dont la fonction rénale risque de se détériorer après un épisode d'IRA.

Objectifs: Évaluer l'utilisation d'une approche de suivi post-hospitalisation stratifiée selon le risque d'IRC chez les patients atteints d'IRA et la comparer aux soins habituels.

Conception: Essai contrôlé randomisé pragmatique.
Cadre: Deux grands hôpitaux urbains en Alberta (Canada).
Sujets: Patients hospitalisés avec une IRA (stade KDIGO 2 ou 3) qui n'étaient pas suivis auparavant par un néphrologue et dont on prévoyait la survie au-delà de 90 jours après leur sortie de l'hôpital.
Mesures: Nous évaluerons si, dans les 90 jours suivant le congé, les soins d'IRC habituels recommandés par les lignes directrices seront amorcés, c'est-à-dire l'utilisation de statines, l'utilisation d'IECA/ARA chez les patients souffrant de protéinurie ou de diabète, et le suivi avec un néphrologue pour les patients avec un DFGe inférieur à 30 ml/min/1,73 m^2 de façon soutenue. Nous évaluerons également la faisabilité du recrutement et la proportion de patients qui auront effectué les analyses sanguines et urinaires recommandées à 90 jours.
Méthodologie: Les patients atteints d'IRA seront recrutés et randomisés au moment de leur sortie de l'hôpital. Dans le groupe d'intervention, les patients présentant un faible risque d'évolution recevront de l'information sur l'IRA, les patients présentant un risque moyennement élevé recevront en plus des conseils de suivi envoyés à leur médecin de premier recours, et les patients présentant un risque élevé feront également l'objet d'un suivi avec un néphrologue. Les participants des groupes intervention et soins habituels recevront une requête pour des analyses de sang et d'urine 90 jours après la sortie de l'hôpital. Un suivi téléphonique sera effectué auprès de tous les participants à l'étude 90 jours et un an après la sortie de l'hôpital. Des tests d'association bivariés seront effectués pour évaluer les différences entre les groupes aux points temporels de suivi.
Limites: Nous nous attendons à ce que le recrutement soit difficile, considérant l'importance des comorbidités dans cette population.
Conclusion: Si l'essai montre un effet positif sur ces processus de soins rénaux, il informera un essai à plus grande échelle visant à déterminer si cette intervention réduit l'incidence des événements cliniques indésirables à long terme, notamment la progression de l'IRC, les événements cardiovasculaires et la mortalité après une hospitalisation avec épisode d'IRA.

Keywords
clinical research, AKI (acute kidney injury), clinical decision support systems

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Background

Acute kidney injury (AKI) commonly occurs in hospital, affecting nearly 200 000 patients each year in Canada alone.[1,2] Although previously considered a self-limiting syndrome, the long-term consequences of AKI are now well established, including progression to chronic kidney disease (CKD), cardiovascular events, and death.[3-7] Current international clinical practice guidelines recommend follow-up of patients who develop AKI 3 months following hospital discharge;[8] however, there is little information regarding which patients should receive follow-up, what care provider should conduct follow-up visits, and the type of care that should be provided. Data from a population-based cohort in Ontario, Canada, suggested a 24% lower incidence of death for patients with severe AKI who received nephrology follow-up in the 90 days following hospital discharge, compared with those who did not, although differences in care were not characterized.[9]

Despite current recommendations, less than 30% of patients who develop AKI requiring dialysis are seen by a nephrologist in the year following hospital discharge.[10-12] Appropriate follow-up for patients who develop CKD following AKI may optimize use of evidence-based therapies aimed at reducing kidney disease progression and cardiovascular consequences, such as use of statins and angiotensin-converting enzyme inhibitors (ACEi), or angiotensin II receptor blockers (ARBs).[13,14] However, only a subset of patients who experience AKI will progress to CKD,[7,15] suggesting it is neither feasible nor cost-effective for all patients with AKI to be followed up by a nephrologist. A risk-based approach to follow-up care may be a more efficient and appropriate approach to long-term management after hospital discharge.

We published a risk prediction tool with good performance for predicting the risk of developing advanced CKD for patients who experienced AKI in hospital.[16] This model included 6 variables measured before hospital discharge (age, sex, baseline and discharge serum creatinine, AKI stage, and

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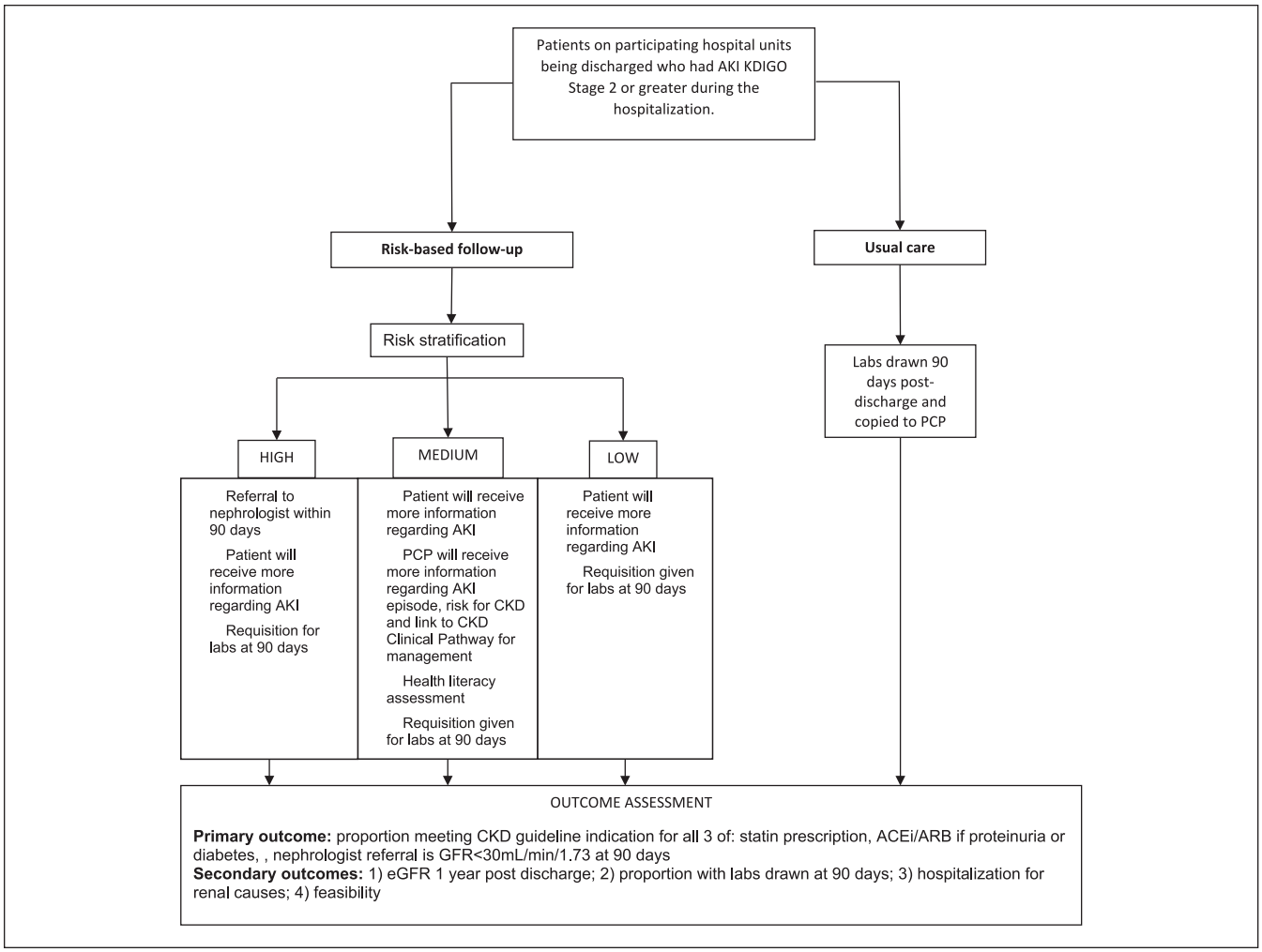

Figure 1. Diagram of study participant flow.

albuminuria) as predictors of progression to advanced CKD among patients with AKI.[16] This model has been internally and externally validated in cohorts from Alberta and Ontario, Canada, but requires testing to evaluate the impact of its use in clinical practice. In this report, we describe the design of a randomized controlled trial (RCT) evaluating the effect of a risk-stratified follow-up care strategy based on this risk prediction model to guide subsequent management of among survivors of a hospitalization with AKI.

Objectives

The trial aims to evaluate the systematic identification, risk stratification, and management of AKI survivors at hospital discharge, determine the feasibility and effectiveness of risk-based follow-up to improve adherence to current CKD guidelines for laboratory monitoring, and use of evidence-based medications (including statins and ACEi/ARBs) and nephrology specialist referral in the post-discharge period.

If the trial shows a positive effect on these processes for kidney care, it will inform larger-scale trial to determine whether this intervention reduces the incidence of long-term clinical adverse events, including CKD progression, cardiovascular events, and mortality following hospitalization with AKI.

Methods

Trial Design

The AFTER AKI is a pragmatic, RCT testing the feasibility and effectiveness of risk-based post-discharge care after hospitalization with AKI. This parallel-group RCT will compare a risk-based follow-up intervention to usual care among AKI survivors. The study has been approved by Health Research Ethics Boards at the University of Calgary and the University of Alberta. Figure 1 presents the study process from participant recruitment to outcome evaluation.

Study Population and Setting

Study participants will be recruited from medical and surgical hospital units in Calgary and Edmonton, Alberta. Patients who are 18 years of age or older will be eligible to participate if they have AKI defined by at least a doubling of serum creatinine during hospitalization (including need for dialysis), have a primary care physician (PCP), and no nephrologist follow-up arranged for after hospital discharge.

Patients will be excluded from the study if they meet any of the following criteria:

1. Baseline estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m^2 (based on the CKD-EPI equation)[17] or requiring chronic dialysis on admission.
2. Renal transplant recipients (as these patients should be followed by a nephrologist).
3. Poor prognosis (not expected to survive >6 months).
4. Residence at a nursing home facility.

Eligible patients will be identified using the following methods:

1. Clinical staff and discharge coordinators on the participating hospital units will have access to an electronic portal through the Tableau Software platform. This portal lists patients on the hospital unit with a doubling in serum creatinine results. The Alberta Strategy for Patient-Oriented Research Unit (AbSPORu) has developed the Tableau portal using a provincial data repository comprising blood test results for patients across Alberta. The electronic portal will be updated daily with a list of potentially eligible AKI patients.
2. The medicine teaching units have a morning patient care meeting where patients are discussed. The research coordinator will liaise with a member of the care teams every morning to determine whether any patients may meet eligibility criteria.
3. Nephrology consultation service attending staff and resident physicians in the participating hospitals will be informed of the study and asked to identify and seek permission from eligible patients with AKI if they are not planning to see them in follow-up after hospital discharge.

Patients identified through the electronic portal or by clinical staff will be asked by a member of the care team for permission to be approached by the research coordinator. The research coordinator will then screen the patients to determine eligibility and those who agree to participate will be asked to provide informed consent. Data collection will be paperless and entered at the study sites into an online RedCAP database (https://redcap.med.ualberta.ca). A screening log will be maintained to identify reasons for non-enrollment for eligible patients. The RedCAP system will be utilized to randomize patients to the intervention or usual care group. For participants in the intervention arm, the RedCAP system will calculate the risk for progression to advanced CKD.

Randomization

Participants who meet the eligibility criteria and give consent will be randomized to risk-based follow-up or usual care. The intervention assignments will be allocated equally between groups (1:1) using randomly generated permuted blocks of 8 and 12, stratified by center. The randomization schedule will be prepared and administered electronically to ensure allocation concealment. The randomization schedule will be generated by the study statistician and imported into RedCAP. The master randomization list will be secured in a locked cabinet.

Blinding

Due to the nature of the intervention, it is not possible to blind participants or study coordinators in this trial as the allocation to the intervention will be apparent to the study coordinator, who will trigger the information resources for patients and primary care providers as well as referrals based on the risk assignment. It is possible that general awareness of the trial by participants as well as care providers on the inpatient wards may prompt better post-discharge follow-up in the control arm and therefore reduce the effectiveness of the intervention. We will assess the impact of this potential source of bias by determining the frequency of the primary outcomes in AKI survivors for the 6 months preceding the introduction of the trial.

Intervention Groups

Risk-guided intervention. Participants will be risk-stratified for developing CKD stage G4 within 1 year into 3 groups, in light of their differences in risk profile: low ($<$ 1% risk of CKD), medium (1%-10% risk of CKD), and high ($>$10% risk of CKD) using the risk prediction model developed by our team.[16] Specific follow-up will be guided by risk status (Table 1).

Usual care. Participants will be discharged as per usual hospital unit discharge protocols. A requisition for follow-up labs (serum creatinine, serum electrolytes, urine albumin/creatinine ratio [ACR]) to be drawn at 90 days post discharge will be given to each participant. Appointments/referrals will be left at the discretion of the care team.

Trial participants in all risk strata will review and receive an educational pamphlet about AKI (Supplementary Material 1). Primary care providers of patients in the medium risk strata will receive additional discharge information on their

Table 1. Risk-stratified Follow-up Intervention for Patients Following Discharge After Hospitalization With AKI.

Risk	Intervention
HIGH >10% risk of CKD	• Referral to nephrologist to be seen within 90 days • Patient will receive information regarding AKI • Requisition for labs (serum creatinine, serum electrolytes, urine albumin/creatinine ratio [ACR]) at 90 days
MEDIUM 1-10% risk of CKD	• Patient will receive information regarding AKI • Primary Care Provider (PCPs) will receive information regarding AKI episode, risk for CKD, and link to the online Alberta Provincial CKD Clinical Pathway for management* • Requisition given for labs at (serum creatinine, serum electrolytes, urine albumin/creatinine ratio [ACR]) 90 days
LOW <1% risk of CKD	• Patient will receive information regarding AKI • Requisition given for labs (serum creatinine, serum electrolytes, urine albumin/creatinine ratio [ACR]) at 90 days

*The CKD Clinical Pathway is a web-based resource (www.CKDpathway.ca) for primary care providers (PCPs) developed to aid in the diagnosis, medical management, and referral of adults with CKD. It has been available to PCPs in Alberta since 2014.

patient's AKI episode, guidance for follow-up care after AKI, and a link Alberta's online CKD clinical pathway for management, accompanying the patients' usual discharge summary (Supplementary Material 2). Participants who are stratified as high risk will receive follow-up with a nephrologist. Nephrology clinic visits will focus on assessment of further risk of kidney injury, volume status, blood pressure (BP), and use of evidence-based therapies according to the recommendations of the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of CKD (Supplementary Material 3).[18] At least 1 visit within 90 days of discharge will be required; however, the timing and frequency of visits will be left to the discretion of the nephrologist.

Outcome Measures

Primary outcome. The primary process–based outcome of this trial is the proportion of patients with CKD, meeting all 3 of the following quality of care indicators: (1) statin use, (2) ACEi/ARB use in those with proteinuria (ACR >30 mg/mmol) or diabetes, and (3) nephrologist visit if sustained eGFR <30 mL/min/1.73 m^2 at 90 days after hospital discharge.

Secondary outcomes. In addition to each component outcome from the primary composite outcome, the following secondary outcomes will be assessed:

1. Proportion of patients having kidney lab work (eGFR and urine ACR) completed and seen by PCP or nephrologist within 90 days of hospital discharge.
2. Proportion of patients having eGFR tested at 1 year.
3. Safety outcomes: hyperkalemia with any serum potassium result >6 mmol/L, any eGFR result <15 mL/min/1.73 m^2; hospitalization for AKI or renal-specific ambulatory care sensitive conditions (congestive heart failure, volume overload, hypertensive emergency).
4. The BRIEF Health Literacy Assessment questionnaire for participants with 2 additional questions about AKI knowledge (Supplementary Material 4) at the time of enrollment.[19]
5. Feasibility regarding recruitment rates (proportion of eligible patients recruited to the study).

We will use the comprehensive provincial health data from Alberta Health Services, accessed through the Alberta Strategy for Patient-Oriented Research Support Unit (AbSPORU), Canada, to efficiently capture several outcomes of the trial. Data will be obtained from 4 sources: the Alberta Health Services (AHS) province-wide laboratory database, the Alberta Hospital Discharge Abstract Database, the Alberta Health (AH) Physicians' Claims Database, and the Pharmacy Information Network (PIN) database. These data sources will be linked via each subject's unique provincial health number (PHN). Outpatient PCP/nephrologist assessment within 90 days of hospital discharge will be determined using physician claims data. The laboratory database will be used to determine eGFR and urine ACR at 90 days and eGFR at 1 year post discharge. Data from the Pharmacy Information Network, which captures prescriptions dispensed for all Albertans from community pharmacies, will be used to identify prescriptions for ACEi/ARBs and/or statins within 90 days of discharge.

The following Anatomical Therapeutic Chemical (ATC) codes will be used for identification of the medication prescriptions of interest:

- Angiotensin-Converting Enzyme Inhibitor (ACE): ATC Code = C09A, C09B.
- Angiotensin Receptor Blocker (ARB): ATC CODE = C09C, C09D.
- Statin: ATC CODE = C10AA, C10BA, C10BX.

The research coordinator will contact all participants in the trial at 90 days and 1 year. A series of 6 questions will be asked of each patient—the results will be documented in the patient's study chart (Supplementary Material 5).

Sample Size

Based on prior provincial Alberta Health data from the Alberta Kidney Disease Network,[20] 32% of eligible participants for this trial currently meet the composite primary outcome criteria for all 3 quality indicators for kidney care following AKI in Alberta. The trial is designed to detect a 20% increase in the absolute percent of patients achieving these measures, which would achieve comparable rates for this outcome observed in other groups of patients with CKD in Alberta. To detect this difference with 90% power, and a 2-sided type one error rate of 0.05, we will require 83 patients per treatment group. Based on our preparatory work, we believe this sample size (n = 166 patients, 3-4 eligible patients discharged from the participating Edmonton and Calgary hospital wards per week) is a feasible target. All outcomes will be assessed using administrative data. Annual outmigration from the province of Alberta is less than 1%; therefore, we expect $<1\%$ loss to follow-up.

Statistical Analysis

The primary and secondary outcome analysis will follow an intention-to-treat (ITT) approach. In subgroup analyses, we will stratify outcomes based on the predicted risk of CKD as defined above. Descriptive statistics and bivariate tests of associations (chi-squared tests for dichotomous variables and *t*-tests for continuous variables) will be used as appropriate to evaluate between-group differences at the various time points of follow-up. In exploratory analyses, associations between key variables and study outcomes will be analyzed using univariable and multivariable mixed model multilevel analyses. No interim analyses are planned due to the short duration of the trial.

As we will be evaluating feasibility of recruitment, we will also determine the proportion of eligible patients that are enrolled in the study. If the proportion is low with respect to the number of eligible patients, we will discuss recruitment strategies with the study steering committee and modify accordingly before proceeding to a larger, scale-up study.

Trial Management and Patient Safety

The steering committee will include the principal investigator and all co-investigators. They will meet by teleconference quarterly prior to the start of the trial and throughout the duration of the trial period to review trial progress and address operational issues. We do not intend to use a data safety and monitoring board due to the very low perceived risk of treatment. The usual care arm exposes patients to no incremental risk. Health care providers are free to monitor, prescribe and refer for nephrology consultation, as they deem appropriate. To ensure that poor kidney function requiring urgent nephrology intervention isn't inadvertently missed, all participants receiving usual care will receive a blood work requisition for assessment of kidney function at 90 days (serum creatinine, electrolytes, urine for ACR). A copy of these results will be forwarded to the PCP. The intervention arm involves informing the patients of their AKI event and providing lab requisitions to assess kidney function post discharge (low risk), as well as risk-based follow-up either with their PCP (moderate risk) or a referral to a nephrologist (high risk). This should not result in any risk to the participants.

The Kidney Health Research Group (KHRG) housed at the University of Alberta will be the coordinating center for the trial, and along with data collection, will be responsible for the data management (including randomization and quality assurance) and data analysis. The KHRG consists of a research manager, statisticians, economists, study coordinators, database developers, and research and administrative assistants.

Discussion

Transitional care interventions have potential to improve care for patients, particularly in AKI where there is no specific recommended intervention, but instead they are recommended management strategies for patients at-risk of progressing to CKD. A risk-stratified follow-up approach has the potential to improve the appropriateness and efficiency of follow-up care after AKI by avoiding the use of specialized resources for patients who do not show signs of kidney disease progression, while ensuring that all patients are monitored in some capacity following discharge.

We will undertake this trial to evaluate the effectiveness and feasibility of deploying a novel strategy for risk-stratified follow-up care for AKI survivors following hospital discharge. This will evaluate the clinical impact and usability of a published tool for estimating the risk of progression to advanced CKD following AKI. Due to the pragmatic nature of this trial, challenges are expected with participant recruitment, risk-stratified care delivery, and outcome ascertainment. Considering this, we have planned mitigation strategies that are embedded into the trial design. To enhance recruitment from multiple sites across Alberta, we will implement a multipronged approach to identify potentially eligible patients including the Tableau electronic system, liaison with unit discharge coordinators and nursing staff, and referral from nephrology consultation services. To ensure that the appropriate care strategy is delivered to each risk strata in the intervention group, we are using the RedCAP electronic platform to assign participants to the treatment arm and compute the risk level based on the prediction model. The platform also produces the specific documentation to be provided to

the participants and auto-sends information to their PCPs, as indicated by their risk strata. Finally, we will maximize completeness in outcome ascertainment through direct telephone follow-up of patients to capture key process indicators and clinical events during follow-up, and by use of the comprehensive Alberta health administrative data holdings. The Alberta health data can capture each of the process of care outcomes including community medication prescriptions, lab measurements, and physician visits by primary care provider/specialist.

The proposed study utilizes innovative technologies for recruitment, implementation, and outcome ascertainment. Findings on the feasibility of these approaches will inform the larger studies and scale-up of interventions for follow-up care, and use of such technologies in future trials.

Dissemination

The findings from the study will be published in a peer-reviewed journal. We will also share the results widely at international and local conferences and communicate with frontline health care providers and patients in Alberta through the Alberta Health Services Kidney Health Strategic Clinical Network, and nationally through the Canadian Society of Nephrology. In addition, we expect to increase research capacity through training and mentorship. Through this project, we will develop multidisciplinary research capacity that provides research trainees with opportunities to benefit from interdisciplinary collaboration and co-mentorship.

Results from this trial have the potential to inform the design of health systems to improve the care of thousands of Canadians who develop AKI each year. If the trial is positive, results will guide the design of follow-up care strategies after hospitalization of AKI. If the trial demonstrates no effectiveness, it will avoid unnecessary investment in large-scale implementation of AKI follow-up programs and allow for investigation of alternate follow-up care strategies.

Author Contributions

MB contributed to process development and initial drafting the manuscript. EA, CB, NA, TP, and NR contributed to process development and revision of the manuscript. KM is involved in the study steering committee and contributed to revision of the manuscript. MTJ and NP developed the risk prediction model, conceived the study question, designed the clinical trial, obtained funding, and contributed to critical revision of the manuscript.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Supplemental Material

Supplemental material for this article is available online.

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