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Improving the quality of the performance and delivery of continuous renal replacement therapy (CRRT) to critically ill patients across a healthcare system – QUALITY CRRT

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Abstract (235 words)

Introduction: Continuous Renal Replacement Therapy (CRRT) is a continuous form of dialysis used to support critically ill patients with acute kidney injury. The ideal delivery of CRRT requires ongoing monitoring and reporting to adjust practice and deliver optimal therapy. However, this practice occurs variably.

Methods: QUALITY CRRT is a multi-center, prospective, stepped-wedged, interrupted time-series evaluation of the effectiveness, safety and cost of implementing a multi-faceted CRRT quality assurance and improvement program across an entire healthcare system. This study will focus on the standardization of CRRT programs with similar structure, process and outcome metrics by the reporting of CRRT Key Performance Indicators (KPIs). The primary outcome will be the quarterly performance of CRRT KPIs. Secondary outcomes will include patient-centered outcomes and economic outcomes. Analysis will compare pre- and post-implementation groups as well as for the performance of KPIs using an interrupted time-series methodology. The health economic evaluation will include a within-study analysis and a longer-term model-based analysis.

Discussion: The effective delivery of CRRT to critically ill patients ideally requires a standardized approach of best practice assessment and ongoing audit and feedback of standardized performance measures. QUALITY CRRT will test the application of this strategy stakeholder engagement and stepped-wedged implementation across an entire healthcare system.

Ethics and Dissemination: This study has received ethics approval. We will plan to publish the results in a peer-reviewed journal.

Trial Registration: clinicaltrials.gov, NCT04221932, first posted 9 January 2020.

Strengths and Limitations

- **Quality CRRT involves the implementation of CRRT KPIs across an entire healthcare system**
- **Study includes pilot program followed by broader stepped-wedged roll out of CRRT KPIs across all ICUs performing CRRT**
- **Included CRRT KPIs informed from current evidence-base as well as stakeholder surveys**
- **Study limited to CRRT and does not include IRRT**

Introduction

Continuous renal replacement therapy (CRRT) is a continuous method of blood purification that provides slow uninterrupted clearance of uremic toxins and enables acid-base, electrolyte and volume homeostasis while preserving hemodynamic stability.[1, 2]

CRRT is the most common initial form of dialysis in ICU settings

The recent epidemiological study, AKI-EPI, revealed that CRRT was the most common form of initial acute RRT for patients with severe AKI.[3] These patients have greater illness severity, are more likely to die and have significantly increased healthcare utilization when compared to their non-CRRT critically ill counterparts.[2] As our population ages, becomes more medically complex, and presents with greater severity of illness, the utilization of CRRT is likely to increase and become an increasingly vital component of life-sustaining therapy.[3]

CRRT is expensive but there are substantial opportunities to improve costs

CRRT is a costly and labour intensive resource.[4] In the setting of increasingly constrained healthcare resources, intervention is needed which may identify and eliminate inefficiencies, improve performance, and decrease waste while improving provider satisfaction and achieving better patient outcomes.[5, 6] Currently, performance indicators for CRRT are not routinely measured, and as such, we are not in a position to understand or identify the inefficiencies or gaps in the quality of care of CRRT delivered to our sickest patients.[6]

Current CRRT practices are not standardized

In our healthcare system, CRRT is delivered as per individual unit protocols and practice patterns and is not consistently monitored (i.e., initiation strategies, anticoagulation techniques, dose delivered, ultrafiltration, etc). Discrepancies from best practices and lack of standardization

of CRRT delivery can result in unplanned CRRT interruptions, decreased treatment time, inadequate dose delivery, and impaired clearance of toxic metabolites which can lead to worsened patient outcomes.[7, 8]

Such suboptimal practice variation may relate to the lack of well-developed key performance indicators (KPIs) for CRRT delivery and performance, and the associated audit and feedback function such KPIs can facilitate. KPIs are measures that can be used to monitor the performance of healthcare delivery.[9] They are necessary and can improve reliability of care, standardize complex interventions, and provide a platform to measure and monitor performance and the impact of practice changes.[10, 11]

Recently, previous phases of work have identified and prioritized KPIs for CRRT care.[12, 13] Implementing these CRRT KPIs may change practice to provide effective, validated and standardized CRRT.[12, 13] Though several previous programs of work have looked to implement these CRRT KPIs into clinical practice, but no program has rigorously tested the implementation of this structure and monitoring across an entire healthcare system.[14-16]

Objectives and Research Questions:

Primary Objective

The primary objective is to improve the quality of care delivered to critically ill patients receiving CRRT in Alberta, as measured by CRRT KPI performance.

Secondary Objectives

These will include patient centered outcomes (i.e., ICU mortality and length of stay, duration of

CRRT therapy, 90-day renal recovery) and cost of health services, including unit specific CRRT costs.

Research Hypotheses:

1. Can we improve the performance of CRRT programs through the implementation of evidence-based clinical practice guidelines and provision of targeted multi-faceted CRRT audit, feedback and education sessions?
2. Will the implementation of standardized CRRT programs our healthcare system's ICUs result in decreased healthcare systems costs?
3. What is the impact of a multi-faceted quality assurance and improvement program on the efficacy and safety of care in critically ill patients requiring CRRT across our healthcare system?

Methods

Trial Design

The QUALITY CRRT trial is a pragmatic, multi-center, population-level, stepped-wedged, interrupted time series evaluation of the implementation of an evidence-based CRRT quality assurance and improvement program to standardize the delivery of CRRT in the 15 adult general and cardiac ICUs and 3 pediatric ICUs in our healthcare system that provide CRRT (Table 1). It conforms with the SPIRIT Checklist for study protocols (see Appendix 1).

Trial Oversight

QUALITY CRRT will be led by a small but specialized Steering Committee whose members bring extensive experience with CRRT programs and clinical leadership, implementation science and healthcare systems research. This pan-provincial team will be based at the University of Alberta Hospital and will include representation from the Critical Care Strategic Network of Alberta Health Services (the provincial body which provides provincial liaison, networking and coordination of adult and pediatric critical care in Alberta.[17] The Steering Committee will be responsible for program management, development and implementation of minimum standards for CRRT programs, KPI reporting, targeted education and overall trial management.

Patient and Public Involvement

While this study currently does not directly include patients in its design, the Critical Care Strategic Clinical Network includes patient representatives on its core committee and is represented on the study team. The study objectives and research hypotheses have been developed along with these members. Finally, the results of this study will be disseminated to patients and families leveraging the strengths of the Critical Care Strategic Clinical Network through online resources, publications and public engagement events (i.e., Café Scientifiques).

Population and Eligibility

This study will be conducted at all ICUs in Alberta capable of providing CRRT. All subjects in this study will be critically ill patients (i.e., pediatric and adult) receiving CRRT as part of their care. There will be no exclusion criteria. The inclusion criteria are purposely broad in scope to capture a systems level sample of critically ill patients where new monitoring and policy may be implemented, and outcomes measured on a population-based level.

All new ICU admissions receiving CRRT in the 15 adult and 3 pediatric ICUs in Alberta who provide this therapy will be included in this project. In 2019, there were 12,132 adult and 1,592 pediatric admissions per year with 5.6% and 1.4% of these patients (i.e., 680 adult and 22 pediatric patients) receiving CRRT. As this study will be conducted over a 4-year period, thus data on approximately 3,000 adult and pediatric (i.e., 2900 adult and 100 pediatric) patients will be included in this project.

Interventions, duration and frequency of follow-up

The project consists of a 24-month baseline phase to measure current CRRT practice and a 24-month intervention phase to implement a standardized CRRT program targeting ICUs-based CRRT KPIs and monitor performance and compliance of participating sites. Data from the 24-month intervention phase will be used to model long-term health economic outcomes.

Baseline Phase

Baseline data collection: baseline clinical and resource utilization data will be collected on all patients having received receiving CRRT between November 1, 2017 and October 31, 2019.

Stakeholder survey: A healthcare system-wide survey of care providers and stakeholders at participating ICUs will be conducted to identify and establish agreement on the most appropriate KPIs to measure at their ICU during the intervention phase. The survey will be administered through Survey Monkey (www.surveymonkey.com).

Intervention Phase

KPI benchmark reporting: The primary study intervention will be the implementation of audit and feedback on CRRT KPI benchmarks identified by the individual ICU teams in the baseline survey. We will implement a minimal bundle of potential CRRT KPIs with evidence to measure

will include CRRT program structure, filter life, downtime, delivered dose, ultrafiltration achieved, alarms, adverse events, ICU mortality and renal recovery (Table 2).[6, 12, 13] Reports will be implemented and reviewed with ICU stakeholders ad hoc and at quarterly intervals.

Prior to implementation of the reports, each ICU will receive multi-faceted education strategies tailored to their site and informed by local CRRT leaders, champions and stakeholders (Table 3). Education strategies will include, 1) inter-professional grand rounds, seminars and webinars supported by a web-based information repository, 2) identification of site champions to provide onsite advocacy and education. The intervention will be multidisciplinary, targeting CRRT prescribers, nurses, unit operational leaders and educators. After the intervention is implemented quarterly audit and feedback reports and quarterly tele/videoconference and/or in-person visits will be conducted to support the ICUs. The content of this feedback and methods will be individualized to individual ICU needs and preferences.

While the initial education strategy will contain similar themes across all sites, each site will be encouraged to facilitate and participate with our working group in their own audit and educational activities to address unit specific shortcomings in their CRRT KPI performance. A central website repository of troubleshooting tools that will be hosted by the Critical Care Strategic Network of Alberta Health Services will be available for sites who are not achieving KPI benchmarks.

The CRRT KPI reporting program will be implemented in a stepped fashion with a pilot occurring at the GSICU at the UAH over a 3-month period to ensure feasibility, proper reporting and compliance. This will lead to optimization of the tools prior to more generalized use. The pilot will be followed by a stepped-wedge roll out at centers across Alberta over the

subsequent 12 months.

Intervention data collection: At the end of the intervention phase, clinical and resource utilization data will be collected on all patients receiving CRRT during the 24-month intervention period (Table 4).

Outcomes

Primary Outcome

The primary endpoint measures are quarterly changes in the performance of the CRRT process KPIs**:**

- Average filter lifespan, measured in hours
- Downtime, as percentage of prescribed time
- Delivered dose, as a percentage of prescribed dose
- Ultrafiltration achieved, as a percentage of prescribed ultrafiltration
- Alarms as recorded per machine, per day

Secondary Outcomes

Patient centered

- Mortality - ICU, hospital, 90-day post discharge
- Length of stay - ICU and hospital
- Duration of CRRT treatment in hours
- Renal recovery 90-days post ICU discharge

Health economic

- Supply costs - dialysis filters, fluids, dialysis catheters

- Medication costs – anticoagulation, renal specific replacement medications (e.g. erythropoietin analogues, calcium binders, etc.)
- Health care worker costs – physician billing, nursing (hrs)
- ICU and hospital stay costs (length of stay)
- Progression to end stage renal disease - projected chronic dialysis costs
- Quality of life adjusted years (QALYs)
- Health-related Quality of Life (HRQoL)
- Total health care costs

Data Management

Data elements will include patient centered variables: (i.e., demographics, type of admission [medical, surgical, trauma]), clinical characteristics (i.e., comorbid diseases, primary diagnosis), illness severity (i.e., APACHE II, Sequential Organ Failure Assessment [SOFA], Clinical Frailty Score [CFS]), treatment intensity (i.e., duration of renal replacement therapy, mechanical ventilation, vasoactive therapy), ICU and hospital lengths of stay, and outcomes (i.e., renal recovery, mortality, HRQoL); and CRRT associated cost data: (i.e., filter use, prescription/dose, machine alarms/down time, coagulation, adverse events, re-hospitalizations, progression of renal disease). A schedule of data variables to be captured is summarized in Appendix 2.

Data sources will include TRACER and Enterprise data repository, AHS Data Integration, Management and Reporting (DIMR) administrative databases, the Nephrology Information System (NIS), the Patient based Renal Information System (PARIS) and Baxter Healthcare Inc.[18]

All study documents will be kept in a locked filling cabinet in a locked office, and computer files will be encrypted and stored on a secure network for 5 years following completion of the study.

Co-Enrollment

QUALITY CRRT is a pragmatic, real world, quality improvement and assurance program. Due to the healthcare systems scope of the program, there are no patient-level interventions. Accordingly, there will be no limitations to co-enrollment or specific patient or clinician practices.

Statistical Analyses

Analysis will be conducted between the pre- and post-implementation groups. Analyses of the primary and secondary outcomes will involve summary measures obtained by aggregating the endpoints. Analyses will be performed using SAS Enterprise Guide 7.1 (Cary, North Carolina, USA). Baseline comparisons will be performed using chi-squared test for equal proportions with results to be reported as frequencies with percentages. Continuous normally distributed variables will be compared using t-tests and reported as means with standard deviation, while non-parametrically distributed will be compared using Wilcoxon rank sum tests and reported as medians and interquartile ranges (IQRs). In case of small sample size, Fisher's exact test will be used.

Interrupted time series (ITS) analyses using autoregressive integrated moving average (ARIMA) models will be employed for important risk factors to account for temporal trends and to determine whether there were changes in the clinic outcomes at the intervention period (compared with the baseline period) and associated with implementation of the evidence-based

acute RRT pathway.

Cost-effectiveness or net-benefit (investment-return) analysis using a decision tree will be adopted to compare return (or benefit, B) and investment (or cost, C) of the evidence-based RRT pathway. Reduction of healthcare systems costs including inpatient services (length of stay of primary admission, number of readmissions, and readmission LOS), outpatient services (emergency room visits, and clinic visits), physician services (specialist visits, and general practitioner visits), and ongoing new end-stage renal disease will be estimated based on generalized linear models. Cost-effectiveness will be analyzed by estimating incremental cost and effectiveness based on quality-adjusted life years (QALYs) gained. QALYs will be calculated based on health-related quality of life as measured by the 5Q-5D-5L and SF-36 in adults and the PedsQL in children.

Performance of CRRT KPIs

Our primary outcome will be the iterative performance of selected CRRT KPIs. Based on prior work, KPIs might include filter life (measured in hours), delivered dose (measured in mL/kg/hr), downtime (measured in percentage of time), ultrafiltration realized (measured in percentage of prescribed) and access alarms (measured in total number per day). We will aim to both compare the performance of these KPIs to historical controls, as well as prospectively through an interrupted time-series analysis. The interrupted time-series analysis will allow us to follow variable changes over time, allow for assessment of gradual change, and is consistent with traditional quality improvement initiatives.

Patient-Centered Outcomes Analysis

The patient-centered outcome analysis will include ICU, hospital and 90-day mortalities, ICU and hospital lengths of stay, duration of CRRT treatment, and renal recovery measured at 90-

days months. While this study is not designed to evaluate the effect that the implementation of the reporting of CRRT KPIs will have on mortality, lengths of treatment and stay or renal recovery, these are important patient-centered outcomes that will need to be considered as balancing measures for CRRT KPI reporting and implementation of our multi-faceted knowledge translation intervention.

Health Economic Evaluation

The economic evaluation will comprise two parts: 1) a within-study analysis, and 2) a longer-term, model-based analysis.

The within-study analysis will focus on costs and outcomes collected during the study period. It will include total quarterly unit-specific CRRT-associated costs following the implementation of the CRRT KPI reporting program. This endpoint will be determined from our provincial CIS and Alberta Blue Cross databases. Specifically, we will evaluate and compare the 1) costs of supplying CRRT filters, 2) costs of CRRT fluids, 3) cost of CRRT anticoagulation and, 4) costs and utilization of dialysis catheters. Costs will be calculated in part using CRRT process measures captured by our CRRT KPIs (i.e., filter life and number of filters used, anticoagulation modality, dose delivered, and effluent used, etc.). CRRT-associated costs were selected as an important secondary outcome as these will be most immediately affected with the implementation of the CRRT KPI quality assurance program across unit.

We will also determine healthcare systems costs to include total ICU and hospital stay associated costs, ongoing new end-stage renal disease (i.e., chronic RRT) costs, total healthcare costs, and outcomes [mortality, quality-adjusted life years (QALY)]. Modelling analysis will provide cost estimates from both a healthcare system and societal perspective (capturing costs to the health service, social care providers and patients). Results will be reported as the

incremental net benefit and incremental cost-effectiveness ratios. Uncertainty will be captured in the analyses through probabilistic sensitivity analysis and reported using cost-effectiveness acceptability curves, showing the likelihood the intervention will be cost-effective over a range of values of willingness-to-pay for specific outcomes.

Planned Subgroup Analyses

Pre-specified subgroup analysis will include ICU patients to 1) adult vs. pediatric, 2) female vs. male, 3) academic vs. community ICUs, 4) cardiovascular ICUs vs. medical/surgical ICUs, 5) high volume vs. low volume centers (i.e., as per quartiles) 6) patients requiring acute RRT vs. those on chronic dialysis. Adult, pediatric, female and male patients are fundamentally different patient populations and deserve specific study.

Cardiovascular ICU patients differ from general medical/surgical patients as often these patients are immediately post-operative, have a specific timing of insult (i.e., cardiac surgery) and hence have different pathophysiology related to their critical illness. It is important to delineate academic vs. community ICUs as, for mechanically ventilated patients (i.e., another form of critical life-sustaining therapy) with acute respiratory distress syndrome (ARDS), mortality rates differ significantly.[19] Finally, higher ARDS hospital case volume has also been associated with lowers ARDS hospital mortality and it will be important to determine if this association is present in CRRT.[20] We will perform the above analyses for health economic evaluations, patient and process of case measures to include our pre-specified primary and secondary outcomes for each subgroup. Each analysis will be accompanied by a test for interaction between treatment and subgroup to ascertain whether effects differ significantly between subgroups.

Ethics Approval and Consent to Participate

This project is an evaluation of impact of a multi-faceted CRRT quality assurance and improvement program on patient outcomes and health care resource utilization in Alberta ICUs delivering CRRT. All diagnostic and management strategies are within standard of care and all data with relevance to the project are already routinely captured as part of standard patient care by means of machine specific data cards or clinical charting. No added trial-specific investigations or clinical documentation is required.

This evaluation was reviewed by the University of Alberta Health Research Ethics Board (HREB) (Pro00075274 January 22, 2020) and a waiver of consent was granted based on the premise this project represents health services implementation and evaluation compatible with a quality assurance and improvement initiative (see Appendix 3).

Any protocol modifications will be submitted to the appropriate relevant parties.

Dissemination

The findings of QUALITY CRRT will directly inform and guide policy on establishing evidence-based best-practices guidelines for delivering CRRT in Alberta ICUs. In addition, establishing evidence-based benchmarks across the entire health care system will enable systematic evaluation of CRRT performance. These outcomes will help create a framework for the standardization of CRRT programs across Alberta and other jurisdictions providing CRRT. (Table 2).

Alberta's comprehensive ICU clinical information and analytics infrastructure (Connect Care, eClinical TRACER) will be leveraged to implement a CRRT Quality Dashboard, accessible to all Alberta ICU practitioners. The dashboard will contain statistics on KPI benchmarks to provide real-time feedback on individual ICUs performance in delivering CRRT.

A central website containing a summary of CRRT guidelines and best practices and a repository of troubleshooting tools on attaining KPI benchmarks will be developed and made available to all Alberta CRRT practitioners.

We are proposing to publish the study results. Further, this work will be presented at local, provincial and national critical care and nephrology meetings. Finally, QUALITY CRRT will serve as the basis for a broader program of work, DIALYZING WISELY, which will aim to transform the fashion in which acute dialysis is conducted in Alberta.

Discussion

The importance of the quality and management for critically ill patients with acute kidney injury requiring CRRT has been previously recognized.[5, 6] Previous studies have focused on single unit or individual hospital-level quality improvement and assurance interventions (Table 5).[14-16] Griffin et al., first conducted such a quality improvement study at the University of Colorado Hospital where they assessed the magnitude in variability in CRRT dosing. They followed specific implementation that included optimizing their electronic medical record to calculate CRRT dosing in real-time to then comment on dosing and provide guidance and education in order to better adhere to national guidelines. This led to the doubling of the rate of appropriate CRRT dosing, and reduction in variability.[14] Mottes et al., at the University of Cincinnati Children's Hospital, created a 'CRRT Dashboard' which tracked important KPIs such as 'filter life,' 'mean prescription dose,' and 'fluid balance,' and found that this platform provided a significant means for measuring adherence to robust standards on the delivery of CRRT, specifically in the process of care.[15] Finally, most recently a group from the University of Kentucky Medical Centre reported the development, implementation, and subsequent outcomes

associated with a quality assurance system to support the provision of CRRT in the ICU.[16] This was the largest program to date, numbering 1185 adult patients on CRRT over a 34-month period. Using the monitoring of evidence-based KPIs and targeted education, they doubled the appropriate use of citrate-based anticoagulation, improved the appropriateness of CRRT-dosing, increased filter life while decreasing machine alarms and maintaining similar CRRT duration and patient mortality while reducing CRRT-costs. While these programs demonstrate that the implementation of evidence-derived KPI-based CRRT quality assurance programs are effective in improving the efficiency and quality of CRRT, none of these programs have sought to do this on an entire healthcare systems level. QUALITY CRRT will build on the experience of these programs in order to scale such a quality improvement and assurance initiative across a provincial health system of ICUs which provide CRRT.

Strengths & Limitations

While QUALITY CRRT focuses on standardizing CRRT programs across an entire provincial healthcare system by ensuring a robust framework is in place and the monitoring of CRRT performance and delivery occurs, this is limited to only continuous RRT. Intermittent RRT can also occur in the acute setting for critically ill patients in the ICU. Accordingly, the experience and infrastructure realized in QUALITY CRRT will pave the work for additional critical care nephrology programs aimed at improving all forms acute RRT (i.e., continuous and intermittent) in the ICU.

Contributorship Statement

SMB and OGR were responsible for the conception, design and planning of this study. XW and VL were responsible for data analysis and interpretation of the data. All authors were part of reporting and drafting of this manuscript.

Competing Interests

Drs. SBM and OGR have received honoraria from Baxter Healthcare Inc.

The study sponsors had no role in protocol development, trial management or data analysis and reporting.

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Table 1. Alberta ICUs Delivered CRRT

Site	City	ICU Type	Hospital Type	Beds
University of Alberta Hospital General Systems ICU	Edmonton	Mixed	Academic	32
Mazankowski Alberta Heart Institute Cardiovascular ICU	Edmonton	Cardiac surgery	Academic	24
Mazankowski Alberta Heart Institute Cardiac ICU	Edmonton	Cardiac	Academic	8
Royal Alexandra Hospital ICU	Edmonton	Mixed	Academic	25
Grey Nuns Hospital ICU	Edmonton	Mixed	Community	8
Misericordia Hospital	Edmonton	Mixed	Community	10
Sturgeon Hospital ICU	Edmonton	Mixed	Community	5
Stollery Children's Hospital Pediatric ICU	Edmonton	Mixed	Academic	16
Stollery Children's Hospital Pediatric Cardiac ICU	Edmonton	Cardiac	Academic	16
Foothills Medical Centre ICU	Calgary	Mixed	Academic	28
Foothills Medical Centre Cardiovascular ICU	Calgary	Cardiac surgery	Academic	16
Foothills Medical Centre Cardiac ICU	Calgary	Cardiac	Academic	18
Peter Lougheed Centre ICU	Calgary	Mixed	Academic	18
Rockyview General Hospital ICU	Calgary	Mixed	Community	10
South Health Campus ICU	Calgary	Mixed	Community	10
Chinook Regional Hospital ICU	Lethbridge	Mixed	Regional	7
Red Deer Regional Hospital ICU	Red Deer	Mixed	Regional	12
Alberta Children's Hospital Pediatric ICU	Calgary	Mixed	Academic	15

Table 2. Standardized Elements of CRRT Programs

Program Element	Operational Definition	Benchmark
CRRT Leadership	Presence of both CRRT physician and clinical nurse educator	100%
CRRT Education	Number of CRRT providers with training/ total number of CRRT providers	100%
Filter Life	Number of filters lasting 72 hours/ Total number of filters used	> 50% of filters
Delivered Dose	Actual delivered dose in ml/Kg/h / Prescribed dose in ml/Kg/h	> 85% of dose and between 25-30 ml/Kg/h
Downtime	Time CRRT not running per day/ Each day of CRRT prescription	< 15%
Ultrafiltration	Actual ultrafiltration achieve in ml/Kg/h/ Prescribed ultrafiltration in ml/Kg/h	>85% of prescription
Access Alarms	Number of alarms recorded per machine per day of therapy	< 5 alarms
Adverse Events	Number of adverse events as per RLS per quarter	0 events
ICU Mortality	Patient survival to ICU discharge	> 50%
Renal Recovery	Number of patients still requiring RRT at 90-days	< 10%

*CRRT Program Elements are shaded from white to light grey to dark grey as per the Donabedian framework of *structure, process* and *outcome*. Specific CRRT KPIs are in bold. Benchmarks have been taken from our internal and external validation of the KPIs. Our primary outcome will measure the performance of specific CRRT process KPIs.

Table 3. Components of the multi-faceted intervention and knowledge implementation strategy

Strategy	Description
Education	• Site grand rounds and inter-professional seminars • Monthly video/teleconferencing sessions • Site specific educational sessions by inter-professional content experts and local champions • Provide a summary of current guidelines and best practice • Development of website for repository of evidence supporting implementation including banked webinar of project • In-person or virtual visits with ICU leadership, champions and investigator teams
Coaching	• Provide ongoing resources for interpretation of KPI reports • Common troubleshooting advice cards • Provide clinical decision support resources
Audit and Feedback	• Baseline and monthly reports of process of care indicators of implementation of the intervention • Comparative performance relative to peer ICUs across province • Quarterly video/teleconferencing sessions to discuss provincial KPI reports
Reminders	• Promotional items (posters; bulletins) • Weekly electronic communication to local site champions to ensure ongoing review of KPI reports and access to additional resources

Table 4. Project Timeline

	2020				2021				2022				2023		
Activity by Quarter	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**
	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep
Approvals															
Ethics approval/renewal - HREB	■				■				■				■		
Ethics approval/renewal - CHREB		■				■				■				■	
CTA/Administrative approvals	■														
DDA – Edmonton/Calgary/Regional		■													
Baseline phase															
Recruit Executive/Steering committee			■	■											
Conduct survey			■												
Extract baseline data - UAH			■												
Extract baseline data – all sites				■											
Develop education strategies			■	■	■	■	■								
Intervention phase															
Initiate pilot GSICU							■								
Initiate other sites								■	■						
Implement education strategies							■	■	■	■	■	■	■	■	
CRRT KPI reporting							■	■	■	■	■	■	■	■	
Protocol Manuscript						■	■	■							
Extract intervention phase data														■	
Study Manuscript															■

Table 5. Previous CRRT QI Initiatives

Study	Setting	Sample Size	KPI(s) studied	Intervention	Outcomes
Griffin et al. 2019	• Single center • Adult • Medical/ Surgical • Nephrology prescription	• 837 CRRT treatment sessions	• Delivered dose	• Stakeholder engagement • Modification to EMR • Training of ICU nurses • Standardization of protocol • Improved documentation • Modification of order sets • Result dissemination	• Increased in treamtents achieving dose (66.3% vs. 33.3 %, p<0.001) • Decline in under-dose treatments (11.7% vs. 20.7%, p< 0.001) • Decline in over-dosed treatments (22% vs. 46%, p<0.001)
Mottes et al. 2019	• Single center • Pediatric • Newborn, cardiac, pediatric • Nephrology prescription	• 184 patients • 2090 patient days	• Filter life • Unplanned filter changes • Prescribed effluent dose • Delivered vs. prescribed effluent dose • Fluid balance	• Development of CRRT quality dashboard • Provided targeted provider based CRRT education	• Mean filter life increase from 50 to 56 hours • Unplanned filter change 33% to 15% • Mean delivered dose increased from 2400ml/hr/1.73m^2 to 2845ml/hr/1.73m^2 • Delivered time increased from 81.1% to 92.7% • Increase in achievement of daily desired fluid balance from 69.2% to 83.3%
Ruiz et al. 2020	• Single center • Adult • Medical/Surgical • Nephrology prescription	• 1185 patients • 7420 patient-days	• CRRT modality • Anticoagulation • Delivered dose • Delivered/Prescribed dose • Filter life • CRRT access alarms	• Assembly of multidisciplinary team • Standardization of CRRT protocol • Improvement of CRRT charting • Report of CRRT QI metrics • Education to clinicians and ICU nurses	• Increase in CVVHDF use (92.4% to 100%, p<0.001) • Increase in RCA use (23.1% to 39.5%, p<0.001) • Improved filter life (26 to 31.2h, p=0.02) • Decrease in access alarms (2.95 to 1.68/d, p=0.02)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 19

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	7
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5,6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	6

		be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7,8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6,8,9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10,11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8,25
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7,8

Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7,8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.	10,11

		Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13,14,15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	n/a

		and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	n/a
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the	7,16

		public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Appendix 2. List of data variables

Data Variable	Data source	Description
ICU location	TRACER/Enterprise	admission ICU
Age	TRACER/Enterprise	years
Sex	TRACER/Enterprise	M/F
BMI	TRACER/Enterprise	n/a
Date of Hospital Admission	TRACER/Enterprise	dd/mm/yyyy
Date of ICU Admission	TRACER/Enterprise	dd/mm/yyyy
Admission class	TRACER/Enterprise	med/surg/neuro/trauma
ICU discharge location	TRACER/Enterprise	unit/hospital
ICU Admission Diagnosis CV Respiratory Gastrointestinal Genitourinary/Renal Endocrinological/Metabolic Neurological Trauma Burn Sepsis Surgery	TRACER/Enterprise	yes/no
Co-morbidities AIDS Chronic Dialysis Chronic Heart Failure Respiratory Insufficiency Cirrhosis Diabetes Mellitus Hepatic Failure Immune Suppression Leukemia Lymphoma Metastatic Cancer Coronary Artery Disease	TRACER/Enterprise	yes/no
Clinical Frailty Scale	TRACER/Enterprise	number
APACHE II Score	TRACER/Enterprise	number
SOFA score	TRACER/Enterprise	number
Invasive/non-invasive ventilation	TRACER/Enterprise	hrs/min
Vasopressors (include type)	TRACER/Enterprise	hrs/min
CRRT Duration	TRACER/Enterprise	hrs/min
Cumulative daily fluid balance prior to RRT	TRACER/Enterprise	mls
Creatinine, urea, pH, bicarbonate, potassium on day of RRT initiation	TRACER/Enterprise	result

Renal Recovery at ICU Discharge	TRACER/Enterprise	y/n - IHD
Renal Recovery at Hospital Discharge	NIS/PARIS/DIMR	y/n – IHD/PD
Renal Recovery at 90 days	NIS/PARIS/DIMR	y/n - IHD/PD
ICU Mortality	TRACER/Enterprise	A/D
Hospital Mortality	TRACER/Enterprise	A/D
90-day Mortality	DIMR	A/D
ICU length of Stay	TRACER/Enterprise	days
Hospital Length of Stay	TRACER/Enterprise	days
Number of admissions to site	TRACER/Enterprise	aggregate
Patient days	TRACER/Enterprise	aggregate
Ventilator days	TRACER/Enterprise	aggregate
Dialysis days	TRACER/Enterprise	Days CRRT/IHD/SLED
CRRT data	Baxter	aggregate
Filter life		aggregate
Reasons for retiring filters		aggregate
Treatment time lost		aggregate
Prescription/dose		aggregate
Machine alarms		aggregate
Machine down times		aggregate
Type of coagulation		aggregate
Blood flow rates		aggregate
Filtration fraction		aggregate
Adverse events		aggregate
Economic data	DIMR	aggregate
Cost of filters, fluids, anticoagulation		aggregate
medications, dialysis catheters		aggregate
Patient life-years gained		aggregate
Quality of life adjusted years		aggregate
(QUALY)		aggregate
Re-hospitalizations		aggregate
Recurrence/chronic RRT		aggregate
Health care provider related costs		aggregate

Health Research Ethics Board

308 Campus Tower
University of Alberta, Edmonton, AB T6G 1K8
p. 780.492.9724 (Biomedical Panel)
p. 780.492.0302 (Health Panel)
p. 780.492.0459

Approval Form

Date: January 22, 2020

Study ID: Pro00075274

Principal Investigator: Oleksa Rewa

Study Title: Improving the quality of the performance and delivery of CRRT to critically ill patients in Alberta

Approval Expiry Date: Thursday, January 21, 2021

Sponsor/Funding Agency: Baxter Healthcare Inc

Sponsor/Funding Agency: University Hospital Foundation UHF

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0044818	Development of a CRRT Quality Dashboard (QUALITY CRRT)		Baxter Healthcare
View	RES0040497	QUALITY ICU	ZAAIH	UHF - Kaye Fund

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including the following, has been reviewed and approved on behalf of the committee;

- Quality CRRT Survey (1/22/2020)
- Items to Be Included in Medical Record Review (1/22/2020)
- Quality CRRT Protocol (11/26/2020)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. It has been determined that a portion of the research described in the ethics application is retrospective review for which consent for access to personally identifiable health information would not be reasonable, feasible or practical. Consent therefore is not required for access to personally identifiable health information described in the ethics application. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

Any proposed changes to the study must be submitted to the REB for approval prior to implementation. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (Thursday, January 21, 2021), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approvals should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, PhD.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

BMJ Open

Improving the quality of the performance and delivery of continuous renal replacement therapy (CRRT) to critically ill patients across a healthcare system – QUALITY CRRT: A Study Protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-054583.R1
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Date Submitted by the Author:	29-Nov-2021
Complete List of Authors:	Opgenorth, Dawn; University of Alberta Faculty of Medicine & Dentistry, Department of Critical Care Medicine Reil, Ellen; Alberta Health Services Lau, Vincent; University of Alberta Faculty of Medicine & Dentistry, Department of Critical Care Medicine Fraser, Nancy; Alberta Health Services, Critical Care Strategica Clinical Network Zuege, Danny; Alberta Health Services, Critical Care Strategic Clinical Network; University of Calgary, Department of Critical Care Medicine Wang, Xiaoming; Alberta Health Services Bagshaw, Sean; University of Alberta Faculty of Medicine & Dentistry, Department of Critical Care Medicine; Alberta Health Services, Critical Care Strategic Clinical Network Rewa, Oleksa; University of Alberta Faculty of Medicine & Dentistry, Department of Critical Care Medicine; Alberta Health Services, Critical Care Strategic Clinical Network
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Intensive care, Renal medicine
Keywords:	INTENSIVE & CRITICAL CARE, Dialysis < NEPHROLOGY, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Improving the quality of the performance and delivery of continuous renal replacement therapy (CRRT) to critically ill patients across a healthcare system – QUALITY CRRT: A Study Protocol

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Word Count 3569 **Figures 0** **Tables 5** **Appendices 3**

Keywords: Critical Care Medicine; Intensive Care; Continuous Renal Replacement Therapy; Dialysis; Quality; Key Performance Indicators

Trial Registration: clinicaltrials.gov, NCT04221932, first posted 9 January 2020

Protocol Version: 1.0, June 15 2020

Abstract (232 words)

Introduction: Continuous Renal Replacement Therapy (CRRT) is a continuous form of dialysis used to support critically ill patients with acute kidney injury. The ideal delivery of CRRT requires ongoing monitoring and reporting to adjust practice and deliver optimal therapy. However, this practice occurs variably.

Methods: QUALITY CRRT is a multi-center, prospective, stepped-wedged, interrupted time-series evaluation of the effectiveness, safety and cost of implementing a multi-faceted CRRT quality assurance and improvement program across an entire healthcare system. This study will focus on the standardization of CRRT programs with similar structure, process and outcome metrics by the reporting of CRRT Key Performance Indicators (KPIs). The primary outcome will be the quarterly performance of CRRT KPIs. Secondary outcomes will include patient-centered outcomes and economic outcomes. Analysis will compare pre- and post-implementation groups as well as for the performance of KPIs using an interrupted time-series methodology. The health economic evaluation will include a within-study analysis and a longer-term model-based analysis.

Discussion: The effective delivery of CRRT to critically ill patients ideally requires a standardized approach of best practice assessment and ongoing audit and feedback of standardized performance measures. QUALITY CRRT will test the application of this strategy stakeholder engagement and stepped-wedged implementation across an entire healthcare system.

Ethics and Dissemination: This study has received ethics approval. We will plan to publish the results in a peer-reviewed journal.

Trial Registration: clinicaltrials.gov, NCT04221932, first posted 9 January 2020.

Strengths and Limitations

- **Quality CRRT involves the implementation of CRRT KPIs across an entire healthcare system**
- **Study includes pilot program followed by broader stepped-wedged roll out of CRRT KPIs across all ICUs performing CRRT**
- **Included CRRT KPIs informed from current evidence-base as well as stakeholder surveys**
- **Study limited to CRRT and does not include IRRT**

Introduction

Continuous renal replacement therapy (CRRT) is a continuous method of blood purification that provides slow uninterrupted clearance of uremic toxins and enables acid-base, electrolyte and volume homeostasis while preserving hemodynamic stability.[1, 2]

CRRT is the most common initial form of dialysis in ICU settings

The recent epidemiological study, AKI-EPI, revealed that CRRT was the most common form of initial acute RRT for patients with severe AKI.[3] These patients have greater illness severity, are more likely to die and have significantly increased healthcare utilization when compared to their non-CRRT critically ill counterparts.[2] As our population ages, becomes more medically complex, and presents with greater severity of illness, the utilization of CRRT is likely to increase and become an increasingly vital component of life-sustaining therapy.[3]

CRRT is expensive but there are substantial opportunities to improve costs

CRRT is a costly and labour intensive resource.[4] In the setting of increasingly constrained healthcare resources, intervention is needed which may identify and eliminate inefficiencies, improve performance, and decrease waste while improving provider satisfaction and achieving better patient outcomes.[5, 6] Currently, performance indicators for CRRT are not routinely measured, and as such, we are not in a position to understand or identify the inefficiencies or gaps in the quality of care of CRRT delivered to our sickest patients.[6]

Current CRRT practices are not standardized

In our healthcare system, CRRT is delivered as per individual unit protocols and practice patterns and is not consistently monitored (i.e., initiation strategies, anticoagulation techniques, dose delivered, ultrafiltration, etc). Discrepancies from best practices and lack of standardization

of CRRT delivery can result in unplanned CRRT interruptions, decreased treatment time, inadequate dose delivery, and impaired clearance of toxic metabolites which can lead to worsened patient outcomes.[7, 8]

Such suboptimal practice variation may relate to the lack of well-developed key performance indicators (KPIs) for CRRT delivery and performance, and the associated audit and feedback function such KPIs can facilitate. KPIs are measures that can be used to monitor the performance of healthcare delivery.[9] They are necessary and can improve reliability of care, standardize complex interventions, and provide a platform to measure and monitor performance and the impact of practice changes.[10, 11]

Recently, previous phases of work have identified and prioritized KPIs for CRRT care.[12, 13] Implementing these CRRT KPIs may change practice to provide effective, validated and standardized CRRT.[12, 13] Though several previous programs of work have looked to implement these CRRT KPIs into clinical practice, but no program has rigorously tested the implementation of this structure and monitoring across an entire healthcare system.[14-16]

Objectives and Research Questions:

Primary Objective

The primary objective is to improve the quality of care delivered to critically ill patients receiving CRRT in Alberta, as measured by CRRT KPI development, monitoring and performance.

Secondary Objectives

These will include patient centered outcomes (i.e., ICU mortality and length of stay, duration of CRRT therapy, 90-day renal recovery) and cost of health services, including unit specific CRRT costs.

Research Hypotheses:

1. Can we improve the performance of CRRT programs through the implementation of evidence-based clinical practice guidelines and provision of targeted multi-faceted CRRT audit, feedback and education sessions?
2. Will the implementation of standardized CRRT programs our healthcare system's ICUs result in decreased healthcare systems costs?
3. What is the impact of a multi-faceted quality assurance and improvement program on the efficacy and safety of care in critically ill patients requiring CRRT across our healthcare system?

Methods

Trial Design

The QUALITY CRRT trial is a pragmatic, multi-center, population-level, stepped-wedged, interrupted time series evaluation of the implementation of an evidence-based CRRT quality assurance and improvement program to standardize the delivery of CRRT in the 15 adult general and cardiac ICUs and 3 pediatric ICUs in our healthcare system that provide CRRT (Table 1). It conforms with the SPIRIT Checklist for study protocols (see Appendix 1).

Trial Oversight

QUALITY CRRT will be led by a small but specialized Steering Committee whose members bring extensive experience with CRRT programs and clinical leadership, implementation science and healthcare systems research. This pan-provincial team will be based at the University of Alberta Hospital and will include representation from the Critical Care Strategic Network of Alberta Health Services (the provincial body which provides provincial liaison, networking and coordination of adult and pediatric critical care in Alberta.[17] The Steering Committee will be responsible for program management, development and implementation of minimum standards for CRRT programs, KPI reporting, targeted education and overall trial management.

Patient and Public Involvement

While this study currently does not directly include patients in its design, the Critical Care Strategic Clinical Network includes patient representatives on its core committee and is represented on the study team. The study objectives and research hypotheses have been developed along with these members. Finally, the results of this study will be disseminated to patients and families leveraging the strengths of the Critical Care Strategic Clinical Network. This will be conducted through online resources, publications, and public engagement events (i.e., Café Scientifiques).

Population and Eligibility

This study will be conducted at all ICUs in Alberta capable of providing CRRT. All subjects in this study will be critically ill patients (i.e., pediatric and adult) receiving CRRT as part of their care. There will be no exclusion criteria. The inclusion criteria are purposely broad in scope to capture a systems level sample of critically ill patients. This will be done so that these new KPI

monitoring processes may be developed and implemented as policy, and outcomes measured on a population level.

All new ICU admissions receiving CRRT in the 15 adult and 3 pediatric ICUs in Alberta who provide this therapy will be included in this project. In 2019, there were 12,132 adult and 1,592 pediatric admissions per year with 5.6% and 1.4% of these patients (i.e., 680 adult and 22 pediatric patients) receiving CRRT. As this study will be conducted over a 4-year period, thus data on approximately 3,000 adult and pediatric (i.e., 2900 adult and 100 pediatric) patients will be included in this project.

Interventions, duration and frequency of follow-up

The project consists of a 24-month baseline phase to measure current CRRT practice and a 24-month intervention phase to implement a standardized CRRT program targeting ICUs-based CRRT KPIs and monitor performance and compliance of participating sites. Data from the 24-month intervention phase will be used to model long-term health economic outcomes.

Baseline Phase

Baseline data collection: baseline clinical and resource utilization data will be collected on all patients having received receiving CRRT between November 1, 2017 and October 31, 2019.

Stakeholder survey: A healthcare system-wide survey of care providers and stakeholders at participating ICUs will be conducted to identify and establish agreement on the most appropriate KPIs to measure at their ICU during the intervention phase. The survey will be administered through Survey Monkey (www.surveymonkey.com).

Intervention Phase

KPI benchmark reporting: The primary study intervention will be the implementation of audit

and feedback on CRRT KPI benchmarks identified by the individual ICU teams in the baseline survey. We will implement a minimal bundle of potential CRRT KPIs with evidence to measure will include CRRT program structure, filter life, downtime, delivered dose, ultrafiltration achieved, alarms, adverse events, ICU mortality and renal recovery (Table 2).[6, 12, 13] Reports will be implemented and reviewed with ICU stakeholders ad hoc and at quarterly intervals.

Prior to implementation of the reports, each ICU will receive multi-faceted education strategies tailored to their site and informed by local CRRT leaders, champions and stakeholders (Table 3). Education strategies will include, 1) inter-professional grand rounds, seminars and webinars supported by a web-based information repository, 2) identification of site champions to provide onsite advocacy and education. The intervention will be multidisciplinary, targeting CRRT prescribers, nurses, unit operational leaders and educators. After the intervention is implemented quarterly audit and feedback reports and quarterly tele/videoconference and/or in-person visits will be conducted to support the ICUs. The content of this feedback and methods will be individualized to individual ICU needs and preferences.

While the initial education strategy will contain similar themes across all sites, each site will be encouraged to facilitate and participate with our working group in their own audit and educational activities to address unit specific shortcomings in their CRRT KPI performance. A central website repository of troubleshooting tools that will be hosted by the Critical Care Strategic Network of Alberta Health Services will be available for sites who are not achieving KPI benchmarks.

The CRRT KPI reporting program will be implemented in a stepped fashion with a pilot occurring at the GSICU at the UAH over a 3-month period to ensure feasibility, proper

reporting and compliance. This will lead to optimization of the tools prior to more generalized use. The pilot will be followed by a stepped-wedge roll out at centers across Alberta over the subsequent 12 months.

Intervention data collection: At the end of the intervention phase, clinical and resource utilization data will be collected on all patients receiving CRRT during the 24-month intervention period (Table 4).

Outcomes

Primary Outcome

The primary endpoint measures are quarterly changes in the performance of the CRRT process KPIs**:**

- Average filter lifespan, measured in hours
- Downtime, as percentage of prescribed time
- Delivered dose, as a percentage of prescribed dose
- Ultrafiltration achieved, as a percentage of prescribed ultrafiltration
- Alarms as recorded per machine, per day

Secondary Outcomes

Patient centered

- Mortality - ICU, hospital, 90-day post discharge
- Length of stay - ICU and hospital
- Duration of CRRT treatment in hours
- Renal recovery 90-days post ICU discharge

Health economic

- Supply costs - dialysis filters, fluids, dialysis catheters
- Medication costs – anticoagulation, renal specific replacement medications (e.g. erythropoietin analogues, calcium binders, etc.)
- Health care worker costs – physician billing, nursing (hrs)
- ICU and hospital stay costs (length of stay)
- Progression to end stage renal disease - projected chronic dialysis costs
- Quality of life adjusted years (QALYs)
- Health-related Quality of Life (HRQoL)
- Total health care costs

Data Management

Data elements will include patient centered variables: (i.e., demographics, type of admission [medical, surgical, trauma]), clinical characteristics (i.e., comorbid diseases, primary diagnosis), illness severity (i.e., APACHE II, Sequential Organ Failure Assessment [SOFA], Clinical Frailty Score [CFS]), treatment intensity (i.e., duration of renal replacement therapy, mechanical ventilation, vasoactive therapy), ICU and hospital lengths of stay, and outcomes (i.e., renal recovery, mortality, HRQoL); and CRRT associated cost data: (i.e., filter use, prescription/dose, machine alarms/down time, coagulation, adverse events, re-hospitalizations, progression of renal disease). A schedule of data variables to be captured is summarized in Appendix 2.

Data sources will include TRACER and Enterprise data repository, AHS Data Integration, Management and Reporting (DIMR) administrative databases, the Nephrology Information System (NIS), the Patient based Renal Information System (PARIS) and Baxter Healthcare Inc.[18]

All study documents will be kept in a locked filling cabinet in a locked office, and computer files will be encrypted and stored on a secure network for 5 years following completion of the study.

Co-Enrollment

QUALITY CRRT is a pragmatic, real world, quality improvement and assurance program. Due to the healthcare systems scope of the program, there are no patient-level interventions. Accordingly, there will be no limitations to co-enrollment or specific patient or clinician practices.

Statistical Analyses

Analysis will be conducted between the pre- and post-implementation groups. Analyses of the primary and secondary outcomes will involve summary measures obtained by aggregating the endpoints. Analyses will be performed using SAS Enterprise Guide 7.1 (Cary, North Carolina, USA). Baseline comparisons will be performed using chi-squared test for equal proportions with results to be reported as frequencies with percentages. Continuous normally distributed variables will be compared using t-tests and reported as means with standard deviation, while non-parametrically distributed will be compared using Wilcoxon rank sum tests and reported as medians and interquartile ranges (IQRs). In case of small sample size, Fisher's exact test will be used.

Interrupted time series (ITS) analyses using autoregressive integrated moving average (ARIMA) models will be employed for important risk factors to account for temporal trends and to determine whether there were changes in the clinic outcomes at the intervention period (compared with the baseline period) and associated with implementation of the evidence-based

acute RRT pathway.

Cost-effectiveness or net-benefit (investment-return) analysis using a decision tree will be adopted to compare return (or benefit, B) and investment (or cost, C) of the evidence-based RRT pathway. Reduction of healthcare systems costs including inpatient services (length of stay of primary admission, number of readmissions, and readmission LOS), outpatient services (emergency room visits, and clinic visits), physician services (specialist visits, and general practitioner visits), and ongoing new end-stage renal disease will be estimated based on generalized linear models. Cost-effectiveness will be analyzed by estimating incremental cost and effectiveness based on quality-adjusted life years (QALYs) gained. QALYs will be calculated based on health-related quality of life as measured by the EQ-5D-5L in adults and the PedsQL in children. Patients will be sent letters with study team contact information in order for them to contact our team in order to complete these questionnaires.

Performance of CRRT KPIs

Our primary outcome will be the iterative performance of selected CRRT KPIs. Based on prior work, KPIs might include filter life (measured in hours), delivered dose (measured in mL/kg/hr), downtime (measured in percentage of time), ultrafiltration realized (measured in percentage of prescribed) and access alarms (measured in total number per day). We will aim to both compare the performance of these KPIs to historical controls, as well as prospectively through an interrupted time-series analysis. The interrupted time-series analysis will allow us to follow variable changes over time, allow for assessment of gradual change, and is consistent with traditional quality improvement initiatives.

Patient-Centered Outcomes Analysis

The patient-centered outcome analysis will include ICU, hospital and 90-day mortalities, ICU

and hospital lengths of stay, duration of CRRT treatment, and renal recovery measured at 90-days months. While this study is not designed to evaluate the effect that the implementation of the reporting of CRRT KPIs will have on mortality, lengths of treatment and stay or renal recovery, these are important patient-centered outcomes that will need to be considered as balancing measures for CRRT KPI reporting and implementation of our multi-faceted knowledge translation intervention.

Health Economic Evaluation

The economic evaluation will comprise two parts: 1) a within-study analysis, and 2) a longer-term, model-based analysis.

The within-study analysis will focus on costs and outcomes collected during the study period. It will include total quarterly unit-specific CRRT-associated costs following the implementation of the CRRT KPI reporting program. This endpoint will be determined from our provincial CIS and Alberta Blue Cross databases. Specifically, we will evaluate and compare the 1) costs of supplying CRRT filters, 2) costs of CRRT fluids, 3) cost of CRRT anticoagulation and, 4) costs and utilization of dialysis catheters. Costs will be calculated in part using CRRT process measures captured by our CRRT KPIs (i.e., filter life and number of filters used, anticoagulation modality, dose delivered, and effluent used, etc.). CRRT-associated costs were selected as an important secondary outcome as these will be most immediately affected with the implementation of the CRRT KPI quality assurance program across unit.

We will also determine healthcare systems costs to include total ICU and hospital stay associated costs, ongoing new end-stage renal disease (i.e., chronic RRT) costs, total healthcare costs, and outcomes [mortality, quality-adjusted life years (QALY)]. Modelling analysis will provide cost estimates from both a healthcare system and societal perspective (capturing costs

to the health service, social care providers and patients). Results will be reported as the incremental net benefit and incremental cost-effectiveness ratios. Uncertainty will be captured in the analyses through probabilistic sensitivity analysis and reported using cost-effectiveness acceptability curves, showing the likelihood the intervention will be cost-effective over a range of values of willingness-to-pay for specific outcomes.

Planned Subgroup Analyses

Pre-specified subgroup analysis will include ICU patients to 1) adult vs. pediatric, 2) female vs. male, 3) academic vs. community ICUs, 4) cardiovascular ICUs vs. medical/surgical ICUs, 5) high volume vs. low volume centers (i.e., as per quartiles) 6) patients requiring acute RRT vs. those on chronic dialysis. Adult, pediatric, female and male patients are fundamentally different patient populations and deserve specific study.

Cardiovascular ICU patients differ from general medical/surgical patients as often these patients are immediately post-operative, have a specific timing of insult (i.e., cardiac surgery) and hence have different pathophysiology related to their critical illness. It is important to delineate academic vs. community ICUs as, for mechanically ventilated patients (i.e., another form of critical life-sustaining therapy) with acute respiratory distress syndrome (ARDS), mortality rates differ significantly.[19] Finally, higher ARDS hospital case volume has also been associated with lowers ARDS hospital mortality and it will be important to determine if this association is present in CRRT.[20] We will perform the above analyses for health economic evaluations, patient and process of case measures to include our pre-specified primary and secondary outcomes for each subgroup. Each analysis will be accompanied by a test for interaction between treatment and subgroup to ascertain whether effects differ significantly between subgroups.

Ethics Approval and Consent to Participate

This project is an evaluation of impact of a multi-faceted CRRT quality assurance and improvement program on patient outcomes and health care resource utilization in Alberta ICUs delivering CRRT. All diagnostic and management strategies are within standard of care and all data with relevance to the project are already routinely captured as part of standard patient care by means of machine specific data cards or clinical charting. No added trial-specific investigations or clinical documentation is required.

This evaluation was reviewed by the University of Alberta Health Research Ethics Board (HREB) (Pro00075274 January 22, 2020) and a waiver of consent was granted based on the premise this project represents health services implementation and evaluation compatible with a quality assurance and improvement initiative (see Appendix 3).

Any protocol modifications will be submitted to the appropriate relevant parties.

Dissemination

The findings of QUALITY CRRT will directly inform and guide policy on establishing evidence-based best-practices guidelines for delivering CRRT in Alberta ICUs. In addition, establishing evidence-based benchmarks across the entire health care system will enable systematic evaluation of CRRT performance. These outcomes will help create a framework for the standardization of CRRT programs across Alberta and other jurisdictions providing CRRT. (Table 2).

Alberta's comprehensive ICU clinical information and analytics infrastructure (Connect Care, eClinical TRACER) will be leveraged to implement a CRRT Quality Dashboard, accessible to

all Alberta ICU practitioners. The dashboard will contain statistics on KPI benchmarks to provide real-time feedback on individual ICUs performance in delivering CRRT.

A central website containing a summary of CRRT guidelines and best practices and a repository of troubleshooting tools on attaining KPI benchmarks will be developed and made available to all Alberta CRRT practitioners.

We are proposing to publish the study results. Further, this work will be presented at local, provincial and national critical care and nephrology meetings. Finally, QUALITY CRRT will serve as the basis for a broader program of work, DIALYZING WISELY, which will aim to transform the fashion in which acute dialysis is conducted in Alberta.

Discussion

The importance of the quality and management for critically ill patients with acute kidney injury requiring CRRT has been previously recognized.[5, 6] Previous studies have focused on single unit or individual hospital-level quality improvement and assurance interventions (Table 5).[14-16] Griffin et al., first conducted such a quality improvement study at the University of Colorado Hospital where they assessed the magnitude in variability in CRRT dosing. They followed specific implementation that included optimizing their electronic medical record to calculate CRRT dosing in real-time to then comment on dosing and provide guidance and education in order to better adhere to national guidelines. This led to the doubling of the rate of appropriate CRRT dosing, and reduction in variability.[14] Mottes et al., at the University of Cincinnati Children's Hospital, created a 'CRRT Dashboard' which tracked important KPIs such as 'filter life,' 'mean prescription dose,' and 'fluid balance,' and found that this platform provided a

significant means for measuring adherence to robust standards on the delivery of CRRT, specifically in the process of care.[15] Finally, most recently a group from the University of Kentucky Medical Centre reported the development, implementation, and subsequent outcomes associated with a quality assurance system to support the provision of CRRT in the ICU.[16] This was the largest program to date, numbering 1185 adult patients on CRRT over a 34-month period. Using the monitoring of evidence-based KPIs and targeted education, they doubled the appropriate use of citrate-based anticoagulation, improved the appropriateness of CRRT-dosing, increased filter life while decreasing machine alarms and maintaining similar CRRT duration and patient mortality while reducing CRRT-costs. While these programs demonstrate that the implementation of evidence-derived KPI-based CRRT quality assurance programs are effective in improving the efficiency and quality of CRRT, none of these programs have sought to do this on an entire healthcare systems level. QUALITY CRRT will build on the experience of these programs in order to scale such a quality improvement and assurance initiative across a provincial health system of ICUs which provide CRRT.

Strengths & Limitations

While QUALITY CRRT focuses on standardizing CRRT programs across an entire provincial healthcare system by ensuring a robust framework is in place and the monitoring of CRRT performance and delivery occurs, this is limited to only continuous RRT. Intermittent RRT can also occur in the acute setting for critically ill patients in the ICU. Accordingly, the experience and infrastructure realized in QUALITY CRRT will pave the work for additional critical care nephrology programs aimed at improving all forms acute RRT (i.e., continuous and intermittent) in the ICU.

Contributorship Statement

SMB and OGR were responsible for the conception, design and planning of this study. ER assisted in the development of CRRT KPIs. VL and XW have assisted in creating the analysis plan and will work with interpretation the data. DO, NF and DZ assisted with manuscript preparation. All authors approved the final drafting of this manuscript.

Competing Interests

Drs. SBM and OGR have received honoraria from Baxter Healthcare Inc.

The study sponsors had no role in protocol development, trial management or data analysis and reporting.

Funding

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Table 1. Alberta ICUs Delivered CRRT

Site	City	ICU Type	Hospital Type	Beds
University of Alberta Hospital General Systems ICU	Edmonton	Mixed	Academic	32
Mazankowski Alberta Heart Institute Cardiovascular ICU	Edmonton	Cardiac surgery	Academic	24
Mazankowski Alberta Heart Institute Cardiac ICU	Edmonton	Cardiac	Academic	8
Royal Alexandra Hospital ICU	Edmonton	Mixed	Academic	25
Grey Nuns Hospital ICU	Edmonton	Mixed	Community	8
Misericordia Hospital	Edmonton	Mixed	Community	10
Sturgeon Hospital ICU	Edmonton	Mixed	Community	5
Stollery Children's Hospital Pediatric ICU	Edmonton	Mixed	Academic	16
Stollery Children's Hospital Pediatric Cardiac ICU	Edmonton	Cardiac	Academic	16
Foothills Medical Centre ICU	Calgary	Mixed	Academic	28
Foothills Medical Centre Cardiovascular ICU	Calgary	Cardiac surgery	Academic	16
Foothills Medical Centre Cardiac ICU	Calgary	Cardiac	Academic	18
Peter Lougheed Centre ICU	Calgary	Mixed	Academic	18
Rockyview General Hospital ICU	Calgary	Mixed	Community	10
South Health Campus ICU	Calgary	Mixed	Community	10
Chinook Regional Hospital ICU	Lethbridge	Mixed	Regional	7
Red Deer Regional Hospital ICU	Red Deer	Mixed	Regional	12
Alberta Children's Hospital Pediatric ICU	Calgary	Mixed	Academic	15

Table 2. Standardized Elements of CRRT Programs

Program Element	Operational Definition	Benchmark
CRRT Leadership	Presence of both CRRT physician and clinical nurse educator	100%
CRRT Education	Number of CRRT providers with training/ total number of CRRT providers	100%
Filter Life	Number of filters lasting 72 hours/ Total number of filters used	> 50% of filters
Delivered Dose	Actual delivered dose in ml/Kg/h / Prescribed dose in ml/Kg/h	> 85% of dose and between 25-30 ml/Kg/h
Downtime	Time CRRT not running per day/ Each day of CRRT prescription	< 15%
Ultrafiltration	Actual ultrafiltration achieve in ml/Kg/h/ Prescribed ultrafiltration in ml/Kg/h	>85% of prescription
Access Alarms	Number of alarms recorded per machine per day of therapy	< 5 alarms
Adverse Events	Number of adverse events as per RLS per quarter	0 events
ICU Mortality	Patient survival to ICU discharge	> 50%
Renal Recovery	Number of patients still requiring RRT at 90-days	< 10%

*CRRT Program Elements are shaded from white to light grey to dark grey as per the Donabedian framework of *structure, process* and *outcome*. Specific CRRT KPIs are in bold. Benchmarks have been taken from our internal and external validation of the KPIs. Our primary outcome will measure the performance of specific CRRT process KPIs.

Table 3. Components of the multi-faceted intervention and knowledge implementation strategy

Strategy	Description
Education	• Site grand rounds and inter-professional seminars • Monthly video/teleconferencing sessions • Site specific educational sessions by inter-professional content experts and local champions • Provide a summary of current guidelines and best practice • Development of website for repository of evidence supporting implementation including banked webinar of project • In-person or virtual visits with ICU leadership, champions and investigator teams
Coaching	• Provide ongoing resources for interpretation of KPI reports • Common troubleshooting advice cards • Provide clinical decision support resources
Audit and Feedback	• Baseline and monthly reports of process of care indicators of implementation of the intervention • Comparative performance relative to peer ICUs across province • Quarterly video/teleconferencing sessions to discuss provincial KPI reports
Reminders	• Promotional items (posters; bulletins) • Weekly electronic communication to local site champions to ensure ongoing review of KPI reports and access to additional resources

Table 4. Project Timeline

	2020				2021				2022				2023		
Activity by Quarter	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**
	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep
Approvals															
Ethics approval/renewal - HREB	■				■				■				■		
Ethics approval/renewal - CHREB		■				■				■				■	
CTA/Administrative approvals	■														
DDA – Edmonton/Calgary/Regional		■													
Baseline phase															
Recruit Executive/Steering committee			■	■											
Conduct survey			■												
Extract baseline data - UAH			■												
Extract baseline data – all sites				■											
Develop education strategies			■	■	■	■	■								
Intervention phase															
Initiate pilot GSICU							■								
Initiate other sites								■	■						
Implement education strategies							■	■	■	■	■	■	■	■	
CRRT KPI reporting							■	■	■	■	■	■	■	■	
Protocol Manuscript						■	■	■							
Extract intervention phase data														■	
Study Manuscript															■

Table 5. Previous CRRT QI Initiatives

Study	Setting	Sample Size	KPI(s) studied	Intervention	Outcomes
Griffin et al. 2019	• Single center • Adult • Medical/ Surgical • Nephrology prescription	• 837 CRRT treatment sessions	• Delivered dose	• Stakeholder engagement • Modification to EMR • Training of ICU nurses • Standardization of protocol • Improved documentation • Modification of order sets • Result dissemination	• Increased in treamtents achieving dose (66.3% vs. 33.3 %, p<0.001) • Decline in under-dose treatments (11.7% vs. 20.7%, p< 0.001) • Decline in over-dosed treatments (22% vs. 46%, p<0.001)
Mottes et al. 2019	• Single center • Pediatric • Newborn, cardiac, pediatric • Nephrology prescription	• 184 patients • 2090 patient days	• Filter life • Unplanned filter changes • Prescribed effluent dose • Delivered vs. prescribed effluent dose • Fluid balance	• Development of CRRT quality dashboard • Provided targeted provider based CRRT education	• Mean filter life increase from 50 to 56 hours • Unplanned filter change 33% to 15% • Mean delivered dose increased from 2400ml/hr/1.73m^2 to 2845ml/hr/1.73m^2 • Delivered time increased from 81.1% to 92.7% • Increase in achievement of daily desired fluid balance from 69.2% to 83.3%
Ruiz et al. 2020	• Single center • Adult • Medical/Surgical • Nephrology prescription	• 1185 patients • 7420 patient-days	• CRRT modality • Anticoagulation • Delivered dose • Delivered/Prescribed dose • Filter life • CRRT access alarms	• Assembly of multidisciplinary team • Standardization of CRRT protocol • Improvement of CRRT charting • Report of CRRT QI metrics • Education to clinicians and ICU nurses	• Increase in CVVHDF use (92.4% to 100%, p<0.001) • Increase in RCA use (23.1% to 39.5%, p<0.001) • Improved filter life (26 to 31.2h, p=0.02) • Decrease in access alarms (2.95 to 1.68/d, p=0.02)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	1
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 19

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	7
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5,6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	6

		be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7,8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6,8,9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10,11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8,25
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7,8

Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7,8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.	10,11

		Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13,14,15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	n/a

		and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	n/a
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	11
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the	7,16

		public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Appendix 2. List of data variables

Data Variable	Data source	Description
ICU location	TRACER/Enterprise	admission ICU
Age	TRACER/Enterprise	years
Sex	TRACER/Enterprise	M/F
BMI	TRACER/Enterprise	n/a
Date of Hospital Admission	TRACER/Enterprise	dd/mm/yyyy
Date of ICU Admission	TRACER/Enterprise	dd/mm/yyyy
Admission class	TRACER/Enterprise	med/surg/neuro/trauma
ICU discharge location	TRACER/Enterprise	unit/hospital
ICU Admission Diagnosis CV Respiratory Gastrointestinal Genitourinary/Renal Endocrinological/Metabolic Neurological Trauma Burn Sepsis Surgery	TRACER/Enterprise	yes/no
Co-morbidities AIDS Chronic Dialysis Chronic Heart Failure Respiratory Insufficiency Cirrhosis Diabetes Mellitus Hepatic Failure Immune Suppression Leukemia Lymphoma Metastatic Cancer Coronary Artery Disease	TRACER/Enterprise	yes/no
Clinical Frailty Scale	TRACER/Enterprise	number
APACHE II Score	TRACER/Enterprise	number
SOFA score	TRACER/Enterprise	number
Invasive/non-invasive ventilation	TRACER/Enterprise	hrs/min
Vasopressors (include type)	TRACER/Enterprise	hrs/min
CRRT Duration	TRACER/Enterprise	hrs/min
Cumulative daily fluid balance prior to RRT	TRACER/Enterprise	mls
Creatinine, urea, pH, bicarbonate, potassium on day of RRT initiation	TRACER/Enterprise	result

Renal Recovery at ICU Discharge	TRACER/Enterprise	y/n - IHD
Renal Recovery at Hospital Discharge	NIS/PARIS/DIMR	y/n – IHD/PD
Renal Recovery at 90 days	NIS/PARIS/DIMR	y/n - IHD/PD
ICU Mortality	TRACER/Enterprise	A/D
Hospital Mortality	TRACER/Enterprise	A/D
90-day Mortality	DIMR	A/D
ICU length of Stay	TRACER/Enterprise	days
Hospital Length of Stay	TRACER/Enterprise	days
Number of admissions to site	TRACER/Enterprise	aggregate
Patient days	TRACER/Enterprise	aggregate
Ventilator days	TRACER/Enterprise	aggregate
Dialysis days	TRACER/Enterprise	Days CRRT/IHD/SLED
CRRT data	Baxter	aggregate
Filter life		aggregate
Reasons for retiring filters		aggregate
Treatment time lost		aggregate
Prescription/dose		aggregate
Machine alarms		aggregate
Machine down times		aggregate
Type of coagulation		aggregate
Blood flow rates		aggregate
Filtration fraction		aggregate
Adverse events		aggregate
Economic data	DIMR	aggregate
Cost of filters, fluids, anticoagulation		aggregate
medications, dialysis catheters		aggregate
Patient life-years gained		aggregate
Quality of life adjusted years		aggregate
(QUALY)		aggregate
Re-hospitalizations		aggregate
Recurrence/chronic RRT		aggregate
Health care provider related costs		aggregate

Health Research Ethics Board

308 Campus Tower
University of Alberta, Edmonton, AB T6G 1K8
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p. 780.492.0302 (Health Panel)
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Approval Form

Date: January 22, 2020

Study ID: Pro00075274

Principal Investigator: Oleksa Rewa

Study Title: Improving the quality of the performance and delivery of CRRT to critically ill patients in Alberta

Approval Expiry Date: Thursday, January 21, 2021

Sponsor/Funding Agency: Baxter Healthcare Inc

Sponsor/Funding Agency: University Hospital Foundation UHF

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0044818	Development of a CRRT Quality Dashboard (QUALITY CRRT)		Baxter Healthcare
View	RES0040497	QUALITY ICU	ZAAIH	UHF - Kaye Fund

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including the following, has been reviewed and approved on behalf of the committee;

- Quality CRRT Survey (1/22/2020)
- Items to Be Included in Medical Record Review (1/22/2020)
- Quality CRRT Protocol (11/26/2020)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. It has been determined that a portion of the research described in the ethics application is retrospective review for which consent for access to personally identifiable health information would not be reasonable, feasible or practical. Consent therefore is not required for access to personally identifiable health information described in the ethics application. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

Any proposed changes to the study must be submitted to the REB for approval prior to implementation. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (Thursday, January 21, 2021), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approvals should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, PhD.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).