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Title	**Identification and Treatment of Hypoxemic Respiratory Failure (HRF) and ARDS with Protection, Paralysis, and Proning: TheraPPP Study**
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Protocol and SAP revision history

Protocol		**SAP**	
Version & Date	Summary of Change	Version	Action
1.0 04/27/2020	First version	N/A	SAP not finalized
2.0 12/09/2020	Access to data in new Clinical Information System	N/A	SAP not finalized
2.1 02/23/2022	Updated with the completion of the SAP by the Scientific Steering Group: • Follow-up period increased from 2 to 4 months	1.0	SAP finalized Feb 22, 2022
2.2 06/13/2022	Incentive added for Focus Group participants	1.0	SAP reviewed, **no change**
2.3 09/02/2022	Increased total number of Focus Groups	1.0	SAP reviewed, **no change**
2.4 10/28/2022	Incentive added for survey participation	1.0	SAP reviewed, **no change**
2.5 02/14/2023	Editorial updates, added summary of amendments table	1.0	SAP reviewed, **no change**

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Alberta Health Services
Critical Care Strategic Clinical Network™

Venting Wisely
HRF & ARDS Pathway

1 Study Summary

Title	Identification and Treatment of Hypoxemic Respiratory Failure (HRF) and ARDS with Protection, Paralysis, and Proning: TheraPPP Study
Short Title	TheraPPP Study
Protocol Number	REB20-0646
Methodology	Effectiveness-implementation hybrid study design (type 1). Clinical effectiveness and implementation of an HRF and ARDS standardized care pathway will be assessed. Implementation will occur via a pragmatic registry-based stepped wedge cluster randomization of Intensive Care Units (ICUs).
Study Duration	There will be a 10-month baseline data collection period at the beginning of the study. The total study duration will be 29 months.
Study Center(s)	Patients admitted to any one of 17 adult Intensive Care Units (ICUs) in Alberta will receive the intervention.
Objectives	The overall objective is to improve the quality of care for patients with HRF. The specific objectives are to evaluate: (1) **Clinical Effectiveness** of the pathway using a pragmatic registry-based cluster randomized stepped-wedge implementation study involving 17 ICUs. (2) **Implementation** of the pathway by conducting a process evaluation which will assess **fidelity** of the delivered interventions and clinician perceptions about the **acceptability** of the pathway. (3) A **cost-effectiveness** analysis of the pathway.
Number of Subjects	Effectiveness: We estimate a total of 18816 mechanically ventilated patients will be included with 11424 patients pre-implementation and 7392 patients post implementation. Within these patients we estimate a total of 2688 sustained ARDS patients with 1632 patients pre-implementation and 1056 patients post-implementation. Acceptability: We estimate up to a total of 1000 surveys from clinicians and 100 participants in focus groups.
Study Population	All patients admitted to ICU who are mechanically ventilated.
Intervention	A comprehensive evidence-based, stakeholder-informed pathway for the diagnosis and management of HRF (*Venting Wisely*). Although the pathway is comprehensive with 46 elements, it focuses on **5 key steps** that promote diagnosis and equitable delivery of life saving intervention: Step 1. All mechanically ventilated patients will have a height measured and documented Step 2. Screening for HRF Step 3. Initiate Lung Protective Ventilation (LPV) Step 4. Paralysis Step 5. Prone Positioning
Duration of Intervention	The intervention will be implemented into one cluster every two months. Two Intensive Care Units will comprise each cluster. The first month of each step will be a transition period from usual care, during which data will not be analyzed. Once implemented, the cluster will continue to receive it for the remainder of the study.
Reference therapy	Usual management

Analytic Plan	Clinical Effectiveness : For the primary outcome, we will compare the mean 28-day ventilator free days pre-implementation and post-implementation using mixed effects linear regression models to account for clustering of patients within site and adjusted for age, sex, severity of illness, severity of hypoxemia, type of ICU and size of ICU. We will include time (days) in models to account for secular trends over time. Differences in secondary outcomes will be similarly analyzed using mixed effects linear and logistic regression models, as appropriate. Implementation (fidelity): Quantitative assessment of fidelity will be tracked using a composite fidelity score that reflects adherence to the five key steps of the pathway. Differences in fidelity outcomes pre-implementation and post-implementation will be analyzed similarly to the effectiveness clinical outcomes using mixed effects regression models. Implementation (acceptability): Survey data will be presented as aggregated frequencies with proportions. Data will be stratified by participant profession, years of experience, and type of institution. Differences will be compared using Fisher's exact test or Chi-squared test for categorical variables, or the Wilcoxon rank-sum test or Kruskal Wallis test for Likert scale data, as appropriate. Focus groups will be audio taped, transcribed verbatim, de-identified, imported into NVivo10 for data management and independently coded by two investigators, drawing on qualitative thematic analysis to identify themes and sub-themes. Cost-Effectiveness (economic analysis): The trial-based analysis will be based on cost per ventilator free day saved and will be captured within the implementation-based analysis for all patients. Hospitalisation costs from the index admission will be estimated using micro-costing data and physician visits will be estimated using physician claims and billing codes. Uncertainty will be assessed using non-parametric bootstrap estimates to derive 95% confidence interval and mean cost differences between the treatment arms. The decision analytic model will use the observed effectiveness and discharge disposition from the trial to model the expected trajectory over the lifetime of the patient. A probabilistic analysis will be done with the mean expected QALYs and costs calculated for each treatment. The incremental cost per QALY will be calculated with the 95% confidence eclipse.

2 Table of Contents

3 List of Abbreviations

DCCM	Department of Critical Care Medicine
HRF	Hypoxemic Respiratory Failure
ARDS	Acute Respiratory Distress Syndrome
ICU	Intensive Care Unit
CHREB	Conjoint Health Research Ethics Board
ECLS	Extracorporeal Life Support
PEEP	Positive End Expiratory Pressure
PF ratio	PaO2/FiO2 or the arterial oxygen partial pressure to fractional inspired oxygen
HREB	Health Research Ethics Board
LOS	Length of Stay
EMR	Electronic Medical Record
CIS	Clinical Information System
HIA	Health Information Act
QALY	Quality Adjusted Life Year

4 Introduction and Background

4.1 Introduction

The Department of Critical Care Medicine in Calgary in partnership with the Department of Critical Care Medicine in Edmonton as well as the Alberta Critical Care Strategic Clinical Network is planning to implement a screening and management pathway for patients with and at risk of Hypoxemic Respiratory Failure (HRF) and acute respiratory distress syndrome (ARDS) across all 17 ICUs in Alberta. The intervention (*Venting Wisely* pathway) will be implemented in all adult ICUs within Alberta and the therapies within the pathway (including proning) are routinely used within adult Alberta ICUs and define *what should be* standard of care. A pilot study to assess feasibility and acceptability of the *Venting Wisely* pathway in one Intensive Care Unit (ICU) was completed in September 2020.

We are applying for CHREB approval to:

(1) Collect patient data to assess effectiveness and cost-effectiveness of the pathway as well as fidelity to the delivered interventions.
(2) Conduct a survey and focus groups post implementation to assess acceptability of the pathway for clinicians.

4.2 Background

4.2.1 The problem

Hypoxemic respiratory failure (HRF) and its most severe subtype, the acute respiratory distress syndrome (ARDS), are common and associated with considerable attributable morbidity and mortality among patients admitted to the Intensive Care Unit (ICU). (1-4) Acute HRF, defined as an arterial to inspired oxygen (PF) ratio ≤300, is common in critical care and occurs in approximately 15% of ICU admissions.(1, 2) For HRF patients who meet criteria for ARDS (bilateral infiltrates due to non-cardiogenic pulmonary edema, acute onset, and a known risk factor) approximately 40% will not survive to hospital discharge.(1, 2) Those who survive, suffer significant long-term functional disability.(5, 6) In addition to its burden on patients and families, HRF is associated with significant health care resource utilization.(5, 7)

Life-saving therapies for HRF and ARDS exist but are not consistently provided.(1, 2) Three interventions in particular have been shown to save lives: Lung Protective Ventilation (LPV), neuromuscular blockade (paralysis), and prone positioning.(8-12) Guidelines endorsing the use of these therapies exist; however, implementation is extremely inconsistent owing to challenges with diagnosis (particularly for ARDS), and ineffective knowledge translation.(1, 11, 13-20) Female patients with HRF are less likely than their male counterparts to receive life-saving, evidence-based therapies.(2, 21) In addition to inconsistent use of life-saving therapies, there is frequent use of unproven, invasive, and resource intensive therapy (e.g. extracorporeal membrane oxygenation; inhaled pulmonary vasodilators) rather than proven and less resource intensive therapies such as prone positioning.(1, 2, 22)

4.2.2 The potential solution: a comprehensive, multidisciplinary, evidence-informed care pathway

To bridge the knowledge-to-action gap, and equitably and rationally deliver life sustaining therapies for HRF patients, The Department of Critical Care Medicine in Calgary in partnership with the Department of Critical Care Medicine in Edmonton as well as the Alberta Critical Care Strategic Clinical Network is implementing an evidence-based, stakeholder-informed care pathway. The pathway (see Attachment 1) will standardize the diagnosis and management of patients with HRF with the goal of reducing practice variation and improving adherence to evidence-informed therapy. As noted above, pilot implementation of the pathway was conducted in one ICU. Full implementation of the pathway across Alberta is projected to begin in April 2021.

4.2.3 Foundational Work

1 - Building Essential Infrastructure. From 2010-2012, we conducted a registry-based (eCritical) HRF screening program (4 ICUs, Calgary) that successfully identified patients with HRF and ARDS. An updated registry based "*HRF screening module*" has been incorporated into the *Venting Wisely* pathway as well as our electronic medical record (both eCritical and Connect Care).

2 - Retrospective Review. Utilising eCritical registry data, we retrospectively reviewed the incidence, care practices and outcomes of HRF patients (Calgary) (2) and found significant practice variability. See previous CHREB approval Ethics ID number REB17-0941.

3 - Systematic Review. We conducted a systematic review to examine the effect of standardized pathways on survival in patients with HRF.(23) We demonstrated that the pooled relative risk of mortality was reduced by 23% in patients treated with standardized care in comparison to usual management (**RR 0.77**, 95% CI 0.65-0.91, 12 studies with 5031 patients). However, these studies had significant limitations due to high risk of methodological bias, none evaluating an evidence informed pathway, and none tracking implementation fidelity. Our proposed study will address many of the limitations identified in these studies.

4 - Pathway Developed. We brought together a multidisciplinary group of 31 clinicians (physicians (MD), respiratory therapists (RT), and nurses (RN) to develop a pathway of care for the diagnosis and treatment of HRF and ARDS using a modified Delphi consensus process (24) and recent evidence-based guidelines on HRF.(13, 14, 25) This evidence-informed applied 5-step pathway (Figure 1) aims to improve diagnosis and reduce evidence-care gaps by emphasizing the appropriate use of lifesaving therapies (lung protective ventilation, paralysis and prone positioning), while de-emphasizing less efficacious treatments. See previous CHREB approval Ethics ID number REB17-1053.

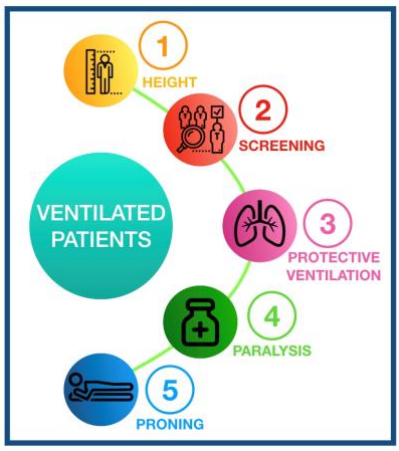

Figure 1 – *Venting Wisely* Pathway

5 - Pathway Validated. We surveyed ICU clinicians across Alberta to assess face validity of the pathway.(24) Over 700 ICU clinicians (including physicians, RTs, and nurses, from tertiary, community, and rural ICUs) responded. Consensus (>80% agreement) was achieved on 43 of 45 pathway elements. See previous CHREB approval Ethics ID number REB17-1053 MOD2.

6 - Barrier and Facilitators Assessment. We surveyed clinicians (RN/RT/MD) working in diverse ICUs (tertiary, community, and rural) to identify barriers and facilitators to pathway implementation. We mapped these barriers to the *Behaviour Change Wheel (COM-B)* and *Theoretical Domains Framework*.(26, 27) Our implementation strategy will specifically target these barriers. See previous CHREB approval Ethics ID number REB17-1053 MOD2.

7 - Pilot Study. We have conducted a single center before-after pilot study to assess feasibility and acceptability of the pathway (ClinicalTrials.gov NCT04070053).(28) See previous CHREB approval Ethics ID number REB19-0939.

5 Objectives and Hypothesis

The overall objective of this study is to improve the quality of care for patients with HRF by implementing a rigorously developed, evidence-based, stakeholder-informed, multidisciplinary standardized care pathway called *Venting Wisely* that standardizes the diagnosis and delivery of life-saving therapies for critically ill patients with HRF.

The specific objectives are to evaluate:

(1) **Clinical Effectiveness** of the pathway using a pragmatic registry-based cluster randomized stepped-wedge implementation study involving 17 ICUs.

(2) **Implementation** of the pathway by conducting a process evaluation which will assess **fidelity** of the delivered interventions and clinician perceptions about the **acceptability** of the pathway.

(3) A **cost-effectiveness** analysis of the pathway.

We *hypothesize* that the pathway will increase adherence to life-saving therapies, improve patient outcomes, and save costs within the health care system.

6 Study Methods

6.1 Study design

The study is designed as an effectiveness-implementation hybrid study design (type 1).(29) This study design evaluates both clinical e*ffectiveness* and *implementation* of the pathway, but is primarily powered to the primary clinical effectiveness outcome. Implementation will occur via a pragmatic registry-based stepped wedge cluster randomized implementation study.

6.2 Setting

The study will be conducted at 17 adult ICUs in Alberta, Canada. These 17 ICUs comprise a mix of tertiary, community and rural ICUs as listed in Attachment 2. One ICU (Calgary) served as the setting for a pilot study (completed September 2020). The remaining 16 ICUs will participate in the full study.

6.3 Randomization

The unit of randomization will be a cluster. Two ICUs will comprise each cluster. Each ICU will be randomly assigned to one of the 8 clusters using a computer-generated random number sequence to initiate the intervention at different times according to the stepped wedge allocation schedule (See Figure 2). Sites will be randomized using computer generated random number sequence by a blinded investigator. Details of the randomization method are held securely in the statistics master file. Two sites will be selected at any time. ICU sites will be excluded in a randomization step if critical unreadiness events are identified which would include, extreme Covid-19 demands, transition to a new Clinical Information System, and Provincial ICU accreditation. Sites will be randomized and notified four to eight weeks prior to the initiation schedule to prevent contamination.

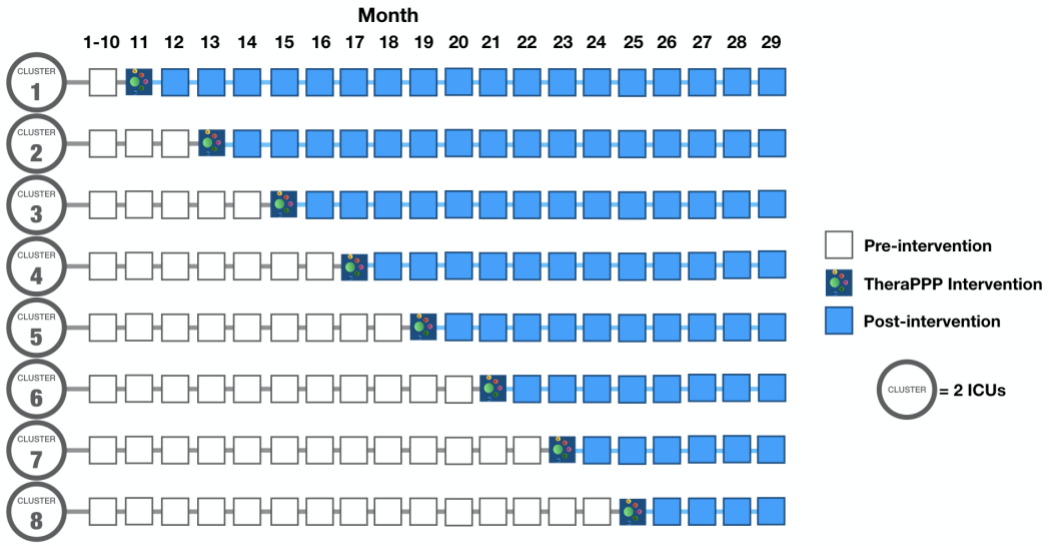

Figure 2 – TheraPPP Study

6.4 Duration of Intervention

The intervention will be implemented into one cluster (two ICUs) every two months. The first month of each step will be a transition period from usual care, during which data will not be analyzed. Once implemented, the cluster will continue to receive it for the remainder of the study.

6.5 Study Duration

There will be a 10-month baseline data collection period at the beginning of the study. There will be a four month follow up period after implementation of the final cluster. The total study duration will be 29 months (Figure 2).

6.6 Discontinuation

On completion of the study, the pathway will remain in place as standard of care. Patients already on the pathway will continue with pathway management and their data will be collected as part of the study until hospital discharge.

6.7 Patient Population

6.7.1 Inclusion Criteria

All patients admitted to the adult ICU will be screened for eligibility for the pathway. All mechanically ventilated patients admitted to the ICU will be included in the study and receive the pathway intervention. Physician approval will not be required. Patients admitted to ICU but cared for in non-traditional ICU settings due to Covid surges (Coronary Care Units, Post-operative care units) will be included even if manual data extraction is required.

6.7.2 Exclusion Criteria

There are no exclusion criteria for entry into in the pathway; however, however not all steps will be applicable to all patients.

6.8 Intervention

The intervention is a comprehensive evidence-based, stakeholder-informed pathway for the diagnosis and management of HRF called *Venting Wisely*. Although the *Venting Wisely* pathway is comprehensive with 46 elements, it focuses on 5 key steps that promote diagnosis and equitable delivery of life saving interventions (Figure 3). See Attachment 1 and 3 for the full *Venting Wisely* pathway.

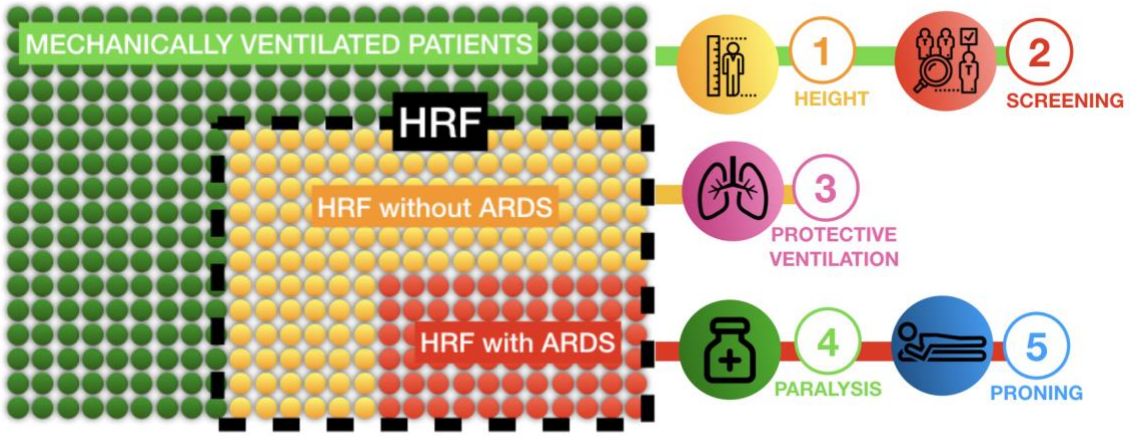

Figure 3 – *Venting Wisely* Pathway

Step 1. All mechanically ventilated patients will have a height measured and documented
The prescribed tidal volumes on the ventilator are dependent upon an estimation of lung size using the predicted body weight.(9) The predicted body weight is calculated using the height and sex of the patient.(9) Measurement and documentation of height will be conducted by Registered Respiratory Therapists (RTs) and will be able to independently execute step 1 (without physician approval).

Step 2. Screening for HRF
All patients admitted to the intervention ICUs will be screened for the presence of HRF through analysis of an arterial blood gas obtained during steady state (performed as a standard of care between midnight and 0800 and after a period of at least 30 minutes with no changes in ventilator settings or patient position). If the arterial to inspired oxygen ratio (PaO2:FiO2 or PF ratio) is ≤300, the patient is deemed to have met HRF criteria. Patients with HRF will continue to step 3 in the pathway. Those patients who do not meet HRF criteria will repeat step 2 and be rescreened for HRF at 0800 daily until they either meet criteria for HRF or they improve and are liberated from mechanical ventilation. HRF screening will be conducted by RTs. In the event an arterial blood gas is not obtainable (e.g. no arterial line), a non-invasive approach using pulse oximetry and the SpO2:FiO2 ratio will be used as previously described.(30-32) RTs will be able to independently execute step 2.

Step 3. Initiate Lung Protective Ventilation (LPV)
For patients with HRF, RTs will initiate LPV using pressure- and volume-limited ventilation in a controlled mode of ventilation (e.g. volume or pressure control). LPV includes limiting initial tidal volumes to 6-8 mL/kg predicted body weight and limiting the plateau pressure to ≤30 cm H_2O. To prevent inappropriately high tidal volumes in patients where the predicted body weight method is likely to overestimate lung size, such as in women or patients with short stature, driving pressure will be limited to ≤18 cm H_2O.(33) RTs will document mechanical ventilation goals daily during bedside rounds. Adjunctive measures in step 3 include consideration of a negative fluid balance goal to minimize lung edema, the use of recruitment maneuvers to improve atelectasis and reduce dead space ventilation, and intensification of sedation to minimize spontaneous or dyssynchronous ventilation (see Attachment 3 for details). RTs will be able to independently execute the core parts of step 3, not adjunctive therapy.

Step 4. Paralysis
For patients that develop worsening HRF or do not meet LPV goals, therapy will be escalated, beginning with the addition of neuromuscular blockade (pharmacological paralysis). For patients with a PF ratio ≤ 150, pharmacological paralysis will be suggested and for patients with a PF ratio ≤ 100, pharmacological paralysis will be strongly recommended. Paralysis will continue for periods of 24 hours or until criteria are no longer met. Patients whose HRF is due to a diagnosis not consistent with ARDS (commonly cardiogenic pulmonary edema, unilateral pneumonia, or pulmonary embolism) will be excluded from this step. Physician approval will be required prior to initiating paralysis.

Step 5. Prone Positioning
Patients with a worsening PF ratio despite steps 1-4 will be considered for prone positioning. This will be suggested for patients with a PF ratio ≤ 150 and on an FiO2 ≥ 0.60 (as applied in the RCT that demonstrated its lifesaving ability(34) and strongly recommended for patients with a PF ratio ≤ 100 and on an FiO2 ≥ 0.60. Prone positioning of the patient will be performed as per local unit policy and subject to standard exclusion criteria (e.g. diagnosis not consistent with ARDS such as cardiogenic pulmonary edema, unilateral pneumonia, and pulmonary embolism). Prone positioning will be maintained for 16-hours and repeated daily until criteria for its initiation are no longer present. Physician approval will be required prior to initiating prone positioning.

Rescue Therapies
Patients that do not respond to steps 1-5, will be considered for rescue therapies (e.g. referral for extracorporeal life support).

6.9 Implementation of the Intervention

Implementation will include eight key strategies including education, decision-support, reminders, audit and feedback, training, champions, implementation support, and empowerment (Attachment 4 for detailed strategy). Selected implementation strategies were informed by our assessment of contextual barriers and facilitators, which were mapped to the *Capability Opportunity Motivation – Behaviour (COM-B)* components and *Theoretical Domains Framework* of the *Behaviour Change Wheel*. The most common barriers identified include lack of skill or knowledge, lack of perceived benefit, and lack of opportunity to implement. The implementation strategies chosen specifically target these barriers and been previously reviewed and utilised by our team members in the Critical Care setting (e.g., lack of knowledge barrier targeted by education rounds).(35-39) Furthermore, feasibility of the implementation strategy was demonstrated by our pilot study. Implementation will be delivered by a multidisciplinary group of *pathway champions* (nurses, RTs and physicians).

Education: The principal investigator, implementation team, and pathway champions will conduct up to weekly inservice/interactive rounds for clinicians (Attachment 5) during the implementation period at each site.

Clinical decision-support tools: A clinical pathway guideline document has been developed to provide granular operational details for each pathway step. Clinical support tools have also been built into the eCritical/Connect Care user interface where RTs document elements of the pathway, to provide decision support (Attachment 6).

Reminders: RTs and nurses will be empowered to discuss pathway management suggestions during daily bedside rounds. RT supervisors and educators will audit adherence to the pathway and offer feedback to the respiratory care team. Direct reminders will include printed posters, digital pathways (smart phone compatible PDF), and laminated pocket cards.

Audit and feedback: Data will be abstracted from eCritical, synthesized and provided to clinician leadership (run chart) on a monthly basis with fidelity tracked to follow improvement (See Fidelity 6.12.2).

Training: Training via inservices, simulation, guidelines, and coaching will be provided for challenging pathway interventions; for example, prone positioning. Repetition with certification will be encouraged.

Champions: Respected pathway champions will provide education, training, support, and audit and feedback. ICUs who have successfully implemented the pathway, support and share lessons and expertise with onboarding ICUs.

Implementation support: Champions and implementation teams will collaboratively problem solve barriers to performing pathway interventions such as limited human and physical resources. Champions at successfully implemented sites will share ways in which other sites have dealt with similar challenges. If an intervention is critical to the pathway, the implementation team will attempt to make it available or develops workarounds.

Empowerment: Education will be made available to all disciplines to empower "out of scope" conversations. Prompts will be available to cue all members of the team toward evidence informed care. Champions will reinforce the ability to expand roles. Clinical decision support will empower RTs and RNs to suggest treatment options. Concerns regarding expansion of roles may be alleviated as audit and feedback demonstrates improvement in adherence to the evidence-informed care,

6.10 Tailoring of the intervention and implementation

Team leads at each site have been identified. Assessment of individual ICU characteristics (patient volumes/mix, staffing) and readiness has been conducted to tailor the intervention for implementation based on local contextual factors (i.e. timing of screening based on RT availability at night in community ICUs). Learnings from the pilot study continue to be incorporated into the implementation strategy. Further tailoring of the intervention will be conducted during the 1-month implementation transition phase for each ICU.

6.11 Control group

ICUs in the control group will continue with usual management. Implementation strategies including education, decision-support, reminders, audit and feedback, training, champions, implementation support, and empowerment will be restricted to intervention ICUs to prevent contamination.

6.12 Outcomes

6.12.1 Effectiveness Outcomes

Primary clinical effectiveness outcome:
28-day ventilator free days. This is a composite outcome of survival and days spent not ventilated over the first 28 days.
Secondary clinical effectiveness outcomes:
1) *28-day hospital survival* (censored at hospital discharge)*, hospital survival* (censored at 90 days), and *ICU survival*
2) Ventilator duration is the number of ventilated days
3) *Driving Pressure* (Plateau pressure – Positive End Expiratory Pressure (PEEP))
4) *Mechanical power* (0.098*respiratory rate•*(tidal volume/1000)*(Peak Pressure – (0.5 • Driving Pressure) 5) *Length of Stay (LOS). ICU LOS* and *hospital LOS* (censored at 90 days). We consider LOS both a clinical and economic outcome.
6) *Utilization of veno-venous Extracorporeal Membrane Oxygenation (VV-ECMO*)

All of the above measures are captured electronically in eCritical. See Attachment 7 for further details of data sources and data linkage.

6.12.2 Implementation Outcomes

A process evaluation of the *Venting Wisely* pathway implementation will be conducted using multi-methods to 1) quantitatively evaluate **fidelity** of the intervention, 2) qualitatively assess **acceptability** and 3) use these results to iteratively refine the pathway and implementation strategy. The process evaluation will provide vital information on why the implementation may or may not have worked as anticipated (type III error), identify opportunities for iteratively improving pathway fidelity, as well as insights for future sustainability and scalability to other ICUs nationally and internationally.

Primary implementation outcome:
Composite fidelity score. The primary implementation outcome is a composite score (out of 5) that is calculated daily and assesses adherence to the 5 key steps.

Secondary implementation outcomes (fidelity):
Secondary fidelity outcomes are *individual process of care indicators* that reflect the five key steps of the pathway*:*
1) Proportion of patients ventilated with a *height ever documented* (*step 1*)
2) Proportion of eligible patient days with PF ≤ 300 who receive a *tidal volume* ≤ 8mL/kg predicted body weight (*step2/3*)
3) Proportion of eligible patient days who have a *plateau pressure* measured (*step 3*)
4) Proportion of eligible patient days who receive *neuromuscular blockade* (*step 4*)
5) Proportion of eligible patient days receiving *prone ventilation* (*step 5*).
Fidelity process of care indicators will also be used to improve pathway adherence through audit and feedback reports, (see 6.9).

Secondary implementation outcomes (acceptability):
Secondary acceptability outcomes are based on the *seven component constructs of the Theoretical Framework of Acceptability (TFA)* listed below. These are measured on a five-point Likert scale, with a median of four or above indicating agreement.

1) The *Composite acceptability score* is the proportion of the seven TFA constructs on the acceptability survey graded with a median score of four or above from a 5-point Likert scale, indicating agreement
2) Intervention coherence (the extent to which the clinician (physician, RT, or RN) understands the intervention)
3) Opportunity costs (benefits or costs to the participant for using the pathway)
4) Perceived effectiveness of the pathway (the extent to which the intervention is perceived as likely to achieve its purpose)
5) Self-efficacy (clinician's confidence that they can use the pathway)
6) Affective attitude (how a clinician feels about the intervention)
7) Burden (the perceived amount of effort that is required to participate in the intervention)
8) Ethicality (the extent to which the intervention aligns with a clinician's value system).

6.12.3 Economic Outcomes

Full details of the statistical analysis plan for the economic analysis will be provided in a separate protocol.

Primary economic outcome:
Cost per ventilator free day saved from the perspective of the health care system over the index hospitalization period.

Secondary economic outcomes:
1) *Total cost* for the ICU admission
2) *Total cost* for the index hospitalization
3) *ICU* and *hospital length of stay*
4) *Cost per quality adjusted life year (QALY)* from the health care system perspective over the patient's lifetime.

See Attachment 8 for details on effectiveness and implementation outcomes.

7 Data

7.1 Data Access

7.1.1 Effectiveness

Demographic, clinical, and outcome data to evaluate effectiveness will be collected via TRACER which prospectively captures data for all patients admitted to Alberta ICUs using an integrated bedside electronic medical record (MetaVision™, EPIC Connect Care).(40) Data is stored in a repository (TRACER) which can be merged with provincial administrative databases maintained by Alberta Health Services. The provincial administrative databases include information on all hospitalizations, laboratory data, and orders. Within eCritical, an updated *HRF screening module* will facilitate decision support and data collection for patients who have HRF (Attachment 6). Additionally, Sunrise Clinical Manager (SCM) and Connect Care will be accessed to review discharge summaries, admission history and labwork. Impax will be used to review chest imaging, Xcelera to review echocardiograms, and TRACER to review respiratory and mechanical ventilation parameters.

Manual data extraction with direct access to paper charts will be required to audit data and ensure its integrity, as well as acquire missing data for patients cared for in non-traditional ICU settings (Coronary Care Unit, Post-operative care unit) due to Covid surges.

Cost-effectiveness data will be acquired from detailed AHS corporate financial databases will be used to calculate precise micro-costing estimates for inpatients. All of the above databases have been validated and used to support extensive prior research initiatives in Alberta.(39-41)

7.1.2 Implementation

Fidelity: Fidelity process of care indicators will be collected via eCritical TRACER and EPIC Connect Care as described above (7.1.1).

Acceptability**:** The target population includes clinicians (physicians, RTs, registered nurses, nurse practitioners) who participated in the intervention. Clinicians will be recruited using email addresses associated with eCritical login identification and patient care manager staff lists (as per previous studies by our team).(42, 43) Demographic data collected (in both survey and focus groups) will include age, gender, years of ICU experience, professional designation, and institution to ensure perceptions do not differ by provider characteristics.

On Surveys, participants will be asked for their perspectives on the acceptability of the pathway and its implementation. It will also assess their knowledge of HRF management and recollection of implementation strategies. Respondents will use multiple choice responses for best practice questions. Elements of the pathway and implementation strategy will be rated using a 5-point Likert scale as previously described by our group.(42, 43) Participants for the acceptability survey will be identified using patient care manager staff lists for employees working during the one month implementation and one year post implementation period. Data will be collected via Qualtrics, an online survey tool available to University of Calgary faculty and staff. To thank survey respondents and encourage participation, a $200 gift card may be offered to the unit managers of Intensive Care Units after clinicians complete at least 30 acceptability surveys per unit. See Attachment 9 for the acceptability survey.

Focus groups will be conducted as previously described by members of our team.(44) Purposive sampling will be conducted to ensure homologous representation from clinicians across institutions and with diversity in level of experience and primary discipline. Focus groups will be moderated by a trained qualitative research assistant, who will follow a semi-structured focus group guide designed to explore participants' perceptions of the pathway and the process of implementation (see draft interview guide, Attachment 10). Each focus group will include an introduction to the purpose, an icebreaker exercise, a series of questions which proceed from general to specific, and a summary to highlight and verify key points. Domains of inquiry will reflect the seven component constructs of the theoretical framework of acceptability(45) and include: 1) intervention coherence (the extent to which the

clinician (physician, respiratory therapist, registered nurse or nurse practitioner) understands the intervention, 2) opportunity costs (benefits or costs to the participant for using the pathway, 3) perceived effectiveness of the pathway (the extent to which the intervention is perceived as likely to achieve its purpose), 4) self-efficacy (participant's confidence that they can use the pathway), 5) affective attitude (clinician's confidence that they can use the pathway), 6) Burden (the perceived amount of effort that is required to participate in the intervention), and 7) Ethicality (the extent to which the intervention aligns with a clinician's value system). The focus group guide will be pilot-tested on a small group of specialty-specific stakeholders to refine wording and flow of questions. As we will use an iterative approach to data analysis, questions may be added or subtracted as the study progresses. A $50 gift card may be offered to all focus group participants to thank them for their time and mitigate recruitment challenges. See Attachment 10 for the focus group interview guide.

7.2 Data Transfer, Encryption, and Storage

7.2.1 Clinical Effectiveness Data

Data handling, record keeping, and confidentiality. Data collected from the Electronic Medical Record (eCritical MetaVision, EPIC Connect Care) will be accessed by only one member of the team. Direct access to paper charts will be required to audit the integrity of registry acquired data and manually collect data for a small proportion of patients cared for in non-traditional ICU settings during Covid surges. Patient charts will not leave the hospital where they are made available to the study team. Manually collected data will be entered into REDCap, a secure web application for building and managing online databases. No patient names will be entered into any database associated with patient data. Only one encrypted excel spreadsheet with patient record numbers and corresponding anonymized numbers will be kept on a password-protected Alberta Health Services Server in a locked office of the principal investigator/Senior Biostatistician (Andrea Soo). In a completely separate encrypted excel spreadsheet, the anonymized patient numbers will have corresponding patient data such as vitals, blood work, or imaging. All data abstracted will remain saved on the AHS protected and secure internal computer drive, encrypted and password protected. This data will be compiled as averages or total sums of all patients in the study if published. No individual patient data or lab values that could lead to identification will ever be disclosed.

Data available in the registries and databases will be abstracted by employees of eCritical/TRACER Alberta and DIMR. eCritical will assign a unique de-identified number in the initial database extract, in addition to identifying numbers (MRN/PHN). For paper charts, the Senior Biostatistician Andrea Soo will assign a random de-identified number. Identifying information will be stored within the data files until the data extracted from different repositories (eCritical) is linked through DIMR. The data files returned to the research team will be de-identified except for the MRN. The purpose of obtaining the MRN from the AHS analyst is to link 10% of patient charts (eCritical MetaVision, EPIC Connect Care) with eCritical TRACER data. This will allow us to manually audit these patient charts (eCritical MetaVision, EPIC Connect Care) to ensure the data variables that are electronically pulled from eCritical TRACER are the same data that we are looking at manually in eCritical MetaVison and EPIC Connect Care. Only one member of our team, Andrea Soo, Senior Biostatistician, will have access to eCritical TRACER MRNs. Subsequent to the linking of patient charts with eCritical TRACER data, the identifying information (MRN) will be removed from our database.

The databases will be stored on a secure AHS server in a password protected file a single secure password-protected AHS computer in a locked office (held by the study biostatistician). Data will only be presented in aggregate.

Meetings between the principal investigator and all other investigators have been held. Confidentiality and ethics have been discussed at these meetings. We will continue to hold regular meetings for this research project, where the importance of confidentiality for this study will be emphasized.

Records Retention: All identifiable data will be destroyed 5 years after publication. Patient charts will remain in the possession of Alberta Health Services.

Regulatory Binder: The authors will keep a regulatory binder with all information pertinent to this study.

7.2.2 Implementation Data

Data handling, record keeping, and confidentiality:
Fidelity: Fidelity process of care indicators collected via eCritical TRACER will be handled and retained as detailed above for effectiveness data (See 7.2.1).

Acceptability: Surveys will be administered via Qualtrics, an online survey tool, made available through the University of Calgary institutional license. Survey data collected through Qualtrics online survey tool is stored on servers located in Canada. Qualtrics uses advanced technology for internet security including but not limited to authentication, password, single-user sign on, and data encryption.

Focus groups will be conducted via the videoconferencing platform (Zoom) through a University of Calgary institutional account. The focus groups will be audio recorded using the Zoom recording feature as well as via a physical, handheld recorder (as backup). We are audio recording the focus groups to produce a written transcript for data analysis. All focus group audio recordings will be transcribed verbatim by a member of the research team or professional transcription service (REV.com) and be de-identified (remove identifying information and use pseudonyms when needed). The de-identified datasets (audio-recordings and transcriptions from focus groups) will be saved on the AHS password protected and secure computer server. The files will be encrypted and password protected also. No individual clinician data that could lead to identification will ever be disclosed.

No results or records of surveys or focus groups will be identifiable to the stakeholders involved in the study. Only one encrypted excel spreadsheet with participant and corresponding anonymized numbers will be kept on a password-protected computer in a locked office of the principal investigator. All data abstracted and synthesized will remain saved on the AHS protected and secure internal computer drive, encrypted and password protected. This data will be compiled as averages or total sums of all participants in the study if being published.

Records Retention: All identifiable data will be destroyed 5 years after publication.

8 Analytic plan

8.1 Clinical Effectiveness

8.1.1 Primary clinical analysis and sample size determination

Based on historical ICU admission rates in Alberta from 2018-2019, we estimate a total of 18816 mechanically ventilated patients will be included in this study with 11424 patients pre-implementation and 7392 patients post implementation. Based on this, a baseline mean VFDs of 21 (SD 10), a 90% power and a two-sided α=0.05 we estimate an ability to detect a difference of 0.9 VFDs (see Statistical Analysis Plan). To estimate the ARDS population within this cohort, we applied a population-based incidence of ARDS that was derived within Calgary using standardized screening for ARDS. Using this historical population-based incidence, we anticipate an average of 12 ARDS patients per 2-month period per site (based on our observed ARDS incidence of 0.42 per bed per month in Calgary).(2) Based on the stepped wedge design (8 clusters, with initiation of a new cluster every 2 months, a 10-month pre-period and a 4-month post period) we estimate that this will generate a sample size of 2688 sustained ARDS patients within the study cohort with 1632 ARDS patients pre-implementation and 1056 ARDS patients post-implementation. For the primary outcome of 28-day ventilator free days, we currently observe a mean 28-day ventilator free days (per patient) of 11 days (standard deviation of 10 days). This number of patients will provide the ability to detect a difference of 2.4 days (11 to 13.4) in the mean 28-day ventilator free days (with a 90% power and a two-sided α=0.05, ICC = 0.01). The power calculation was performed using the Stata function "steppedwedge". (46, 47) An expanded rationale and modelling for the sample size is provided within the Statistical Analysis Plan.

Clinical outcomes will be analyzed at the patient-level and will account for the clustering of patients within ICUs. For the primary analysis, we will compare the mean 28-day ventilator free days pre-implementation and post-implementation using mixed effects linear regression models to account for clustering of patients within site. Differences in secondary outcomes pre and post-implementation will be analyzed using mixed effects linear and logistic regression models accounting for clustering of patients within site, as appropriate. Models will be adjusted for age, sex, severity of illness (sequential organ failure assessment score on admission) and severity of hypoxemia (mild, moderate, or severe on diagnosis of HRF as defined using Berlin criteria), as well as type and size of ICU.(48) We will include time (days) in the models to account for secular trends over time, since failure to include such time effects can bias estimates of effect sizes. Data from the 1-month implementation transition phase within each step will not be included in the analysis of primary and secondary outcomes.

Additional details of the analysis plan, including detailed outcome definitions, pre-planned subgroup and sensitivity analyses can be found in the Statistical Analysis Plan.

8.2 Implementation

8.2.1 Primary clinical analysis and sample size determination:

Fidelity: Differences in fidelity outcomes pre-implementation and post-implementation will be analyzed similarly to the effectiveness clinical outcomes using mixed effects regression models.

Based on the sample of 2688 sustained ARDS patients (calculated for the primary clinical outcome) and a baseline mean Composite Fidelity Score (CFS) of 56% (standard deviation of 29%), this study will be powered to detect a minimum difference of 7.1% (56% to 63.1%) in the mean CFS score (with 90% power and a two-sided α=0.05, ICC=0.02) in patients with sustained ARDS.

Acceptability Surveys: Invitations will be sent to clinicians (nurse practitioners, nurses, physicians, and RTs) two to six months post implementation in each cluster. Based on our pilot study/previous work,(24) we anticipate a

conservative response rate of 50% (625 surveys completed of 1250 distributed) which will provide 95% binomial confidence intervals of ±3.9%.

Survey data will be presented as aggregated frequencies with proportions. Data will be stratified by participant profession, years of experience, and type of institution. Differences will be compared using Fisher's exact test or Chi-squared test for categorical variables, or the Wilcoxon rank-sum test or Kruskal Wallis test for Likert scale data, as appropriate. All analyses will be conducted using statistical software (R, Vienna Austria) and statistical significance set at $\alpha = 0.05$.

Acceptability Focus Groups: There are no *a priori* sample size considerations. We plan to conduct up to 17 ICU site specific focus groups, with up to eight clinicians from one profession per group, (approximately 100 participants), although additional groups may be required to achieve theoretical saturation of themes.(49) Focus groups will be conducted approximately two to six months post implementation on sites when their Composite Fidelity Score is above 70% or 10% above baseline.

Focus groups will be audio taped, transcribed verbatim, de-identified, imported into NVivo10 for data management and independently coded by two investigators with qualitative research experience, drawing on qualitative thematic analysis to identify themes and sub-themes.(50) The researchers will begin by reading the transcripts to gain familiarity with the content, followed by line-by-line coding and constant comparison analysis. They will meet after reviewing every 2 – 3 transcripts to review codes and identify emerging themes; discrepancies will be resolved through discussion. All focus group participants will be provided with a copy of the study report to review and comment upon as a form of member-checking.

Qualitative work will be reported using Standards of Reporting of Quality Research guidelines.(51)

8.2.2 Cost-Effectiveness Analysis

Trial-based analysis: cost per ventilator free day saved. Economic data will be captured within the implementation-based analysis for all patients. We will include both one time and ongoing costs of the intervention (creation of materials, ongoing educational activities, website maintenance for education). Hospitalisation costs from the index admission will be estimated using micro-costing data, providing a detailed cost per patient including all resources consumed during the hospital stay (overhead, drugs, nursing time, and physician fees). Physician visits will be estimated using physician claims and billing codes. These data are accessible from provincial administrative databases. Uncertainty will be assessed using non-parametric bootstrap estimates to derive 95% confidence interval and mean cost differences between the treatment arms. 1000 bias-corrected bootstrap replications (including sampling with replacement from the original data) will be conducted to estimate the distribution of a sampling statistic to derive 95% confidence intervals. Decision analytic model: Using the observed effectiveness and discharge disposition from the trial, we will model the expected trajectory over the lifetime of the patient. Long-term costs, utilities and survival estimates will be informed by previous work of this team, along with robust published Canadian data for ARDS patients (utilities).(2, 6, 52) Following best practices,(53) a probabilistic analysis will be done with the mean expected QALYs and costs calculated for each treatment. The incremental cost per QALY will be calculated with the 95% confidence eclipse. Full details of the statistical analysis plan for the economic analysis will be provided in a separate protocol.

9 Ethical Considerations

This study will be conducted according to Canadian and International Standards of Good Clinical Practice for all studies. Applicable government regulations and University of Calgary research policies and procedures will also be followed. This protocol and any amendments will be submitted to the University of Calgary CHREB for formal approval to conduct the study (Attachment 11).

The intervention (*Venting Wisely* pathway) will be implemented in all adult ICUs within Alberta and the therapies within the pathway (including proning) are routinely used within adult Alberta ICUs and define *what should be* standard of care. All data required in this study is collected as part of standard clinical documentation and will not require any additional measurements, and the interventions do not pose any additional risk. As a result, we propose to perform the study with a waiver of consent from our local research ethics board. This approach was used successfully in our pilot study (Calgary REB-19-0939).

9.1 Waiver of consent to access feasibility outcome data

To evaluate this initiative we are requesting a waiver of consent for research access to personal health information based on criteria outlined in the *Health Information Act*, Section 50 and detailed below.

(1) Obtaining consent for access to the personal health information is not feasible. We are not part of the direct line of care and do not have the resources to get consent from all mechanically ventilated patients in the ICU.
(2) We believe the research is of sufficient importance to justify a waiver of consent. The HRF and ARDS pathway is an important strategy to provide equitable and rational care to a high mortality patient group. It is important to know if they pathway improves patient and health systems as it may become the standard of care in Alberta ICUs.
(3) Adequate safeguards are in place to protect the privacy of personal information collected in the research as outlined in section 4.2.1.1.

9.2 Implied and explicit consent for survey and focus groups

The acceptability survey will be prefaced with an implied consent form explaining that participation is voluntary and implies consent. See Attachment 12 for the acceptability survey implied consent form. Participation in the focus group will be considered explicit oral consent; however, each participant will receive a copy of the consent form for their review prior to participation in the interview. See Attachment 13 for the focus group consent form.

10 Finance

We have received funding from the Canadian Institutes of Health Research (CIHR) and the Health Innovation Implementation and Spread (HIIS 2) grant from Alberta Health and Alberta Health Services.

11 Reporting guidelines and Publication Plan

The Identification and Treatment of Hypoxemic Respiratory Failure and ARDS with Protection, Paralysis, and Proning (TheraPPP Study) is registered on clinicaltrials.gov (NCT04744298) and will be published in a peer-reviewed journal. Study methods will be conducted and reported in accordance with standards for reporting stepped wedge cluster randomised trials (CONSORT, SW-CRT extension),(54) and standards for reporting implementation studies(StaRI) (55) and their replication (TIDieR).(56) Qualitative work will be reported using Standards of Reporting of Quality Research guidelines (SRQR) and Consolidated criteria for Reporting Qualitative research (COREQ). (51, 57) The protocol is also reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidance and checklist 2013(58).

12 Supplements

Attachment 1	Pathway diagram
Attachment 2	Setting (hospital sites)
Attachment 3	Comprehensive HRF and ARDS standardized management (*Venting Wisely*) pathway
Attachment 4	Detailed Implementation Strategy
Attachment 5	Education example
Attachment 6	HRF Screening Module
Attachment 7	Data sources and linkage
Attachment 8	Outcomes
Attachment 9	Acceptability survey
Attachment 10	Interview Guide
Attachment 11	Ethics modifications
Attachment 12	Acceptability survey implied consent form
Attachment 13	Focus group consent form

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Venting Wisely
HRF & ARDS Pathway

All Patients

Measure

All Mechanically Ventilated Patients
- Measure Height & Document in Electronic Medical record
- Obtain Predicted Body Weight (PBW)

RRT

Interventions with this symbol require an order or diagnosis by the MRHP (or designate) MD

Screen

Patients ventilated at midnight (00:00h) with PF ratio ≤300 (any ABG)
- Perform ABG at clinical steady state 00:00-08:00h on PEEP ≥5
- Report results of screen, positive or negative, on daily rounds

RRT

Interventions may be proposed by any member of the multidisciplinary team

PF ratio >300
rescreen Q 24H

PF ratio ≤300
meets criteria for HRF

Ensure recent CXR has been completed RRT

Presence of bilateral infiltrates & absence of heart failure meets criteria for ARDS MD

Escalation of treatment should be based on:
- Increasing FiO_2 requirements
- Decreasing PF ratio
- Worsening respiratory acidosis
- Violation of Lung Protective Ventilation

HRF & ARDS Patients

Manage

Lung Protective Ventilation RRT MD

Control Mode of Mechanical Ventilation
- Tidal Volume 6-8 ml/kg PBW
- Plateau pressure ≤30 cm H_2O
- Driving pressure ≤18 cm H_2O

Oxygenation and ventilation goals:
- Define on admission
- Review on daily rounds
- Document in Electronic Medical Record

Fluid Balance RN MD
Neutral or negative

Monitor

Plateau Pressure & Driving Pressure RRT
1st within 1H of meeting criteria for HRF, then Q12H (consider Q4H)

Optimal PEEP Study RRT
PF ratio ≤200 1st within 4H of meeting threshold, then Q24H

Basic Interventions

Sedatives RN MD
To meet lung protective goals or target a Richmond Agitation-Sedation Score (RASS) of ≤-3

ARDS Patients

Advanced Interventions

Neuromuscular Blockade RN MD
PF ratio ≤150 (Consider)
PF ratio ≤100 (Strongly recommended)

Proning MD RN RRT
PF ratio ≤150 & FiO_2 ≥0.6 (Consider)
PF ratio ≤100 & FiO_2 ≥0.6 (Strongly recommended)

Extracorporeal Life Support (ECLS) MD
Consider referral ONLY if PF ratio ≤100 despite above interventions & NO contraindications

Adjunctive Therapies

Recruitment Maneuvers RRT MD
Routinely assess for appropriateness; if used, perform Q4H

Esophageal Balloon RRT MD
Consider in obese or stiff chest

Inhaled Vasodilators RRT MD
Routine use is not recommended; available in exceptional circumstances

Attachment 1. Pathway Diagram
20-0646 v 1.0 Feb 14, 2023

Alberta Health Services Critical Care Strategic Clinical Network™ | University of Alberta | University of Calgary

Jan 27, 2022

Venting Wisely
HRF & ARDS Pathway

ALL PATIENTS

Within 1 hour of intubation/admission to ICU all mechanically ventilated patients should have documented in electronic medical record:

1. Height
2. Predicted Body Weight (PBW)

SCREENING

1. All patients who are mechanically ventilated at midnight (00:00 hrs) AND have a PF ratio less than or equal to 300 on ANY arterial blood gas (ABG) should be identified for screening for HRF/ARDS by the RRT
2. Screening for HRF consists of:
    a. ABG performed at clinical steady state between 00:00 and 08:00 to demonstrate PF ratio less than or equal to 300 (on a minimum PEEP of 5)
3. Screening for ARDS consists of the following 3 criteria:
    a. Meeting criteria for HRF (see step 2 above) plus:
    b. Bilateral infiltrates: Screening chest x-ray should be performed and interpreted by intensivist/delegate to determine the presence of bilateral infiltrates
    c. Absence of heart failure: Intensivist/delegate appropriately rules out heart failure as the primary cause of HRF
4. Results of the HRF/ARDS screen (positive or negative) should be reported on daily multidisciplinary rounds by the RRT
5. Patients should be screened every 24 hours to determine eligibility in the pathway and/or identify applicability of any new interventions

GOALS AND EARLY MANAGEMENT

1. Controlled mode of ventilation should be used for all patients with new onset HRF/ARDS
2. On controlled ventilation the following initial "lung protective" goals should be targeted:
    a. Tidal volume 6-8mL/kg PBW
    b. Plateau pressure less than or equal to 30 cm H_2O
    c. Driving pressure less than or equal to 18 cm H_2O (Pplat-PEEP)
3. Oxygenation and ventilation goals should be defined on patient admission and reviewed on daily multidisciplinary rounds. These should be documented by the RRT and intensivist/delegate in the electronic medical record
4. Target neutral or negative fluid balance in the absence of contraindications
5. Escalation of treatment should be based on:
    a. Increasing FiO_2 requirements,
    b. Decreasing PF ratio,
    c. Worsening respiratory acidosis, and/or
    d. Violation of lung protective ventilation (e.g. oxygenating or treating respiratory acidosis by using higher tidal volumes, higher plateau pressures, higher driving pressures than accepted)

MONITORING AND BASIC INTERVENTIONS

Monitoring Plateau and Driving Pressures

1. Measure a plateau and driving pressure on all patients with a controlled mode of ventilation (independent of PF ratio, FiO_2 requirements, or lung compliance)
    a. Initial plateau pressures should be measured within 1H of meeting criteria for HRF
    b. Should be repeated at least Q12H (consider Q4H)
    c. RRT to determine appropriateness and perform

Sedatives

1. Consider using sedatives to a target RASS of less than or equal to -3 or to reduce ventilator dyssynchrony
2. Sedatives may be proposed by any member of multidisciplinary team; however, needs Most Responsible Health Practitioner (MRHP) approval prior to initiation. RN to administer and meet sedation goals

Recruitment Maneuvers

1. Recruitment maneuvers should be routinely **assessed** for appropriateness
    a. If used, should be performed Q4H
    b. Recruitment maneuvers may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. RRT to perform

Optimal PEEP Study

1. A PEEP study should be completed for patients with a PF ratio less than or equal to 200
    a. First PEEP study should be completed within 4H of meeting PF ratio threshold
    b. Should be repeated Q24H
    c. A PEEP study may be proposed by any member of the multidisciplinary team. RRT to perform

Esophageal balloon

1. Consider an esophageal balloon to guide/determine both end inspiratory (trans-pulmonary plateau) and end expiratory (trans-pulmonary PEEP) pressures (especially if a patient is obese or is suspected to have a stiff chest wall)
    a. Esophageal balloons may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. RRT to perform

ADVANCED INTERVENTIONS

Neuromuscular Blockade

1. Neuromuscular blockade:
    a. **Consider** for patients with a PF ratio less than or equal to 150
    b. **Strongly recommend** for patients with a PF ratio less than or equal to 100
    c. Goals for neuromuscular blockade (e.g. $EtCO_2$, train of four, or ventilator dyssynchrony) should be determined by MRHP and documented in the appropriate electronic health record
    d. Neuromuscular blockade may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. RN to administer and meet goals

Proning

1. Proning:
    a. **Consider** for patients with a PF ratio less than or equal to 150 AND FiO_2 requirement greater than or equal to 0.60
    b. **Strongly recommend** for PF ratio less than or equal to 100 AND FiO_2 requirement greater than or equal to 0.60, in the absence of contraindications
    c. Proning may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. Multidisciplinary team to enact

Extracorporeal Life Support (ECLS)

1. Should be considered as a potential treatment modality for HRF/ARDS only if a patient has a PF ratio less than or equal to 100 despite above therapies and in the absence of contraindications
2. Referral for ECLS may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation of referral

Inhaled Vasodilators

1. Routine use of inhaled vasodilators is not recommended; however, they are available on a case by case basis in exceptional circumstances

Interventions are additive as PF ratio decreases

Attachment 2. Setting – hospital sites

Calgary:

(1) Foothills Medical Centre General Systems Intensive Care Unit (pilot site)

(2) Foothills Medical Centre Cardiovascular Intensive Care Unit

(3) Rockyview Hospital ICU General Systems Intensive Care Unit

(4) Peter Lougheed Hospital General Systems Intensive Care Unit

(5) South Health Campus General Systems Intensive Care Unit

Edmonton:

(6) University of Alberta Hospitals (UAH) General Systems Intensive Care Unit

(7) University of Alberta Hospitals (UAH) Neuro-Intensive Care Unit

(8) Mazankowski Alberta Heart Institute Cardiovascular Intensive Care Unit

(9) Grey Nuns Community Hospital Intensive Care Unit

(10) Misericordia Community Hospital Intensive Care Unit

(11) Royal Alexandra Hospital Intensive Care Unit

Lethbridge:

(12) Chinook Regional Hospital Intensive Care Unit

Medicine Hat:

(13) Medicine Hat Regional Hospital Intensive Care Unit

Red Deer:

(14) Red Deer Regional Hospital Centre Intensive Care Unit

St. Albert:

(15) Sturgeon Community Hospital Intensive Care Unit

Grande Prairie:

(16) Queen Elizabeth II Hospital Intensive Care Unit

Fort McMurray:

(17) Northern Lights Regional Health Centre Intensive Care Unit

Venting Wisely
HRF & ARDS Pathway

Attachment 3. Venting Wisely comprehensive pathway

ALL PATIENTS

Within 1 hour of intubation/admission to ICU all mechanically ventilated patients should have documented in electronic medical record:

1. Height
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SCREENING

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   c. Driving pressure less than or equal to 18 cm H_2O (Pplat-PEEP)
3. Oxygenation and ventilation goals should be defined on patient admission and reviewed on daily multidisciplinary rounds. These should be documented by the RRT and intensivist/delegate in the electronic medical record.
4. Target neutral or negative fluid balance in the absence of contraindications (e.g. unstable hemodynamics, rising creatinine, hypovolemia)
5. Escalation of treatment should be based on:
   a. Increasing FiO2 requirements,
   b. decreasing PF ratio,
   c. worsening respiratory acidosis, and/or
   d. violation of lung protective ventilation (e.g. oxygenating or treating respiratory acidosis by using higher tidal volumes, higher plateau pressures, higher driving pressures than accepted)

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MONITORING AND BASIC INTERVENTIONS

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    c. A PEEP study may be proposed by any member of the multidisciplinary team. RRT to perform

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    a. Esophageal balloons may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. RRT to perform if available

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ADVANCED INTERVENTIONS

Neuromuscular blockade

1. Neuromuscular blockade:
   a. **Consider** for patients with a PF ratio less than or equal to 150
   b. **Strongly recommend** for patients with a PF ratio less than or equal to 100
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Proning

1. Proning:
   a. **Consider** for patients with a PF ratio less than or equal to 150 AND FiO2 requirement greater than or equal to 0.60
   b. **Strongly recommend** for PF ratio less than or equal to 100 AND FiO2 requirement greater than or equal to 0.60, in the absence of contraindications
   c. Proning may be proposed by any member of the multidisciplinary team; however, needs MRHP approval prior to initiation. Multidisciplinary team to enact.

Extracorporeal Life Support (ECLS)

1. Should be considered as a potential treatment modality for HRF/ARDS only if a patient has a PF ratio less than or equal to 100 despite above therapies and in the absence of contraindications
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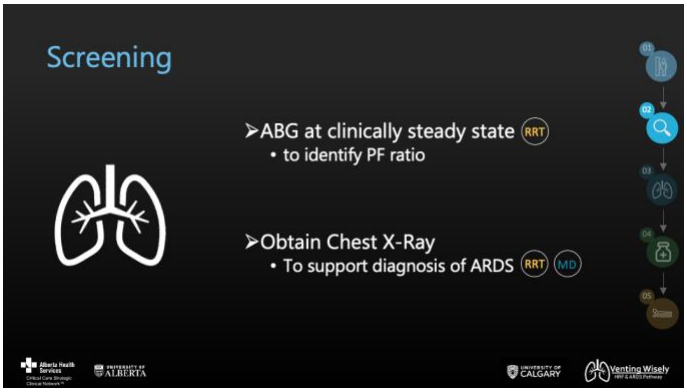
Attachment 4. Detailed Implementation Strategy

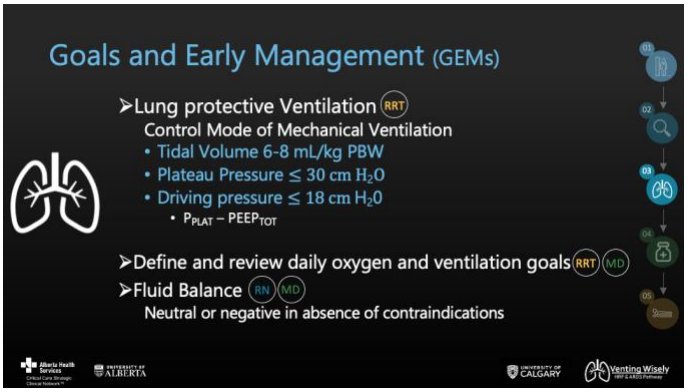
Menu of Implementation Activities

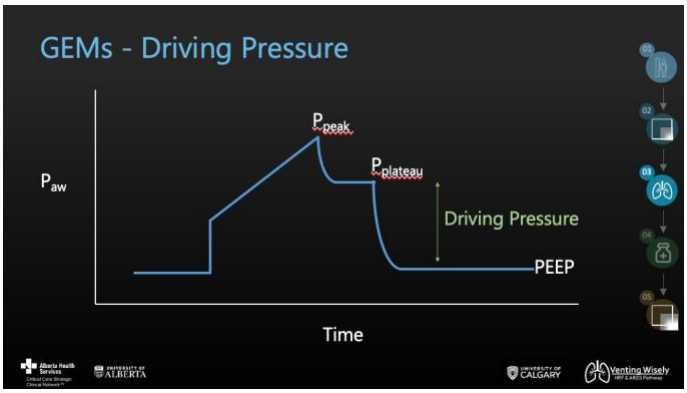
Implementation Strategy	Description	Details
(1) Education		
Distribution of Educational material	Web based educational materials	Learning modules (linked to on through eCritical) Pathway document with detailed explanation in each section
Educational rounds	Didactic seminars with individual clinician groups	Grand rounds Weekly in service seminars for each type of clinician
Educational outreach training visits	Trained person(s) in ICU to provide skill specific training with the intent of changing practice	Champion/Clinician teams with expertise in pathway elements will provide hands on inservice/training on specific pathway elements (ie prone positioning).
(**2) Clinical Decision Support**	Resources to help inform clinicians about how to follow pathway	Pathway document with detailed explanation criteria for each step and clinician roles and responsibilities eCritical built in decision support based on pathway. PF ratio will autopopulate suggested management in RT documentation section. This will allow RT to suggest and remind about appropriate therapies at rounds.
(3) Audit and Feedback	AUDIT: Collect what is going on FEEDBACK: Use this data to target messages back to people	Audit and feedback on (1) Height documented within 24 hours (2) Tidal Volume ≤8mL/kg if PF≤300 (3) Plateau Pressure measured if PF≤300 (4) Neuromuscular blockade appropriately if PF≤150 (5) Proning appropriately if PF≤150 and FiO2 ≥0.6 Data will be collected through eCritical and run charts automatically created. Local pathway champions will provide feedback to clinicians
(4) Reminders	Charts, checklist, daily goals, alarm	Reminders through local pathway champions eCritical Flags Pocket Cards, posters, digital pathway (smart phone compatible)
(5) Pathway Champions	RT, MD, RN Champions Study team Local site leads	Champions will be local supports, perform teaching, and provide audit and feedback to remainder of group
(6) Implementation support	Support is available to overcome site barriers	Implementation team and other sites provide support and trouble shoot to overcome barriers

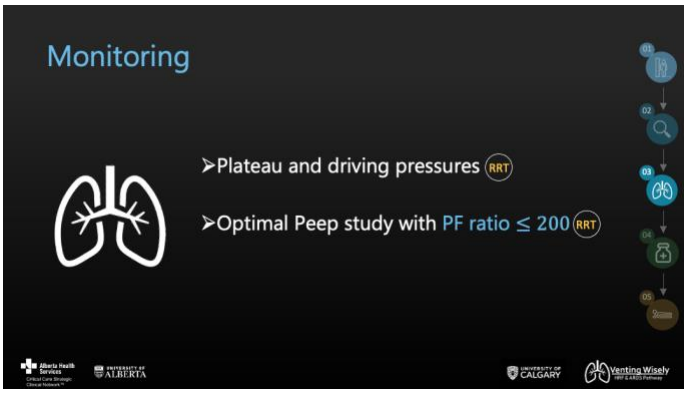
(7) Empowerment	Empowered to support care toward	Provide practice guidelines for all pathway elements for sites to refine to their context. Policies, checklists, and reminders are accessible to staff on unit
(8) Training	Training and simulations	Training provided for challenging pathway interventions

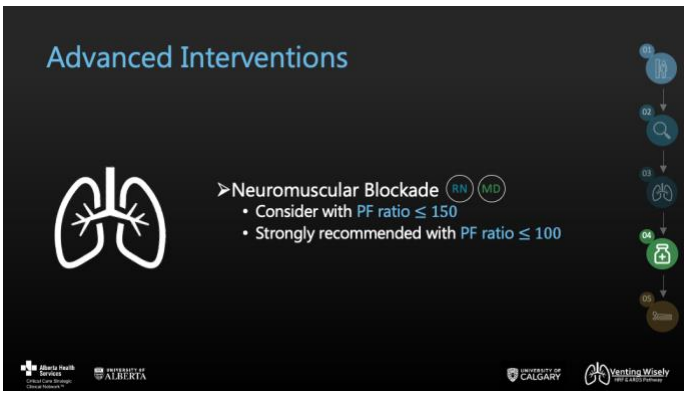
Attachment 5. Sample slides from educational in-services



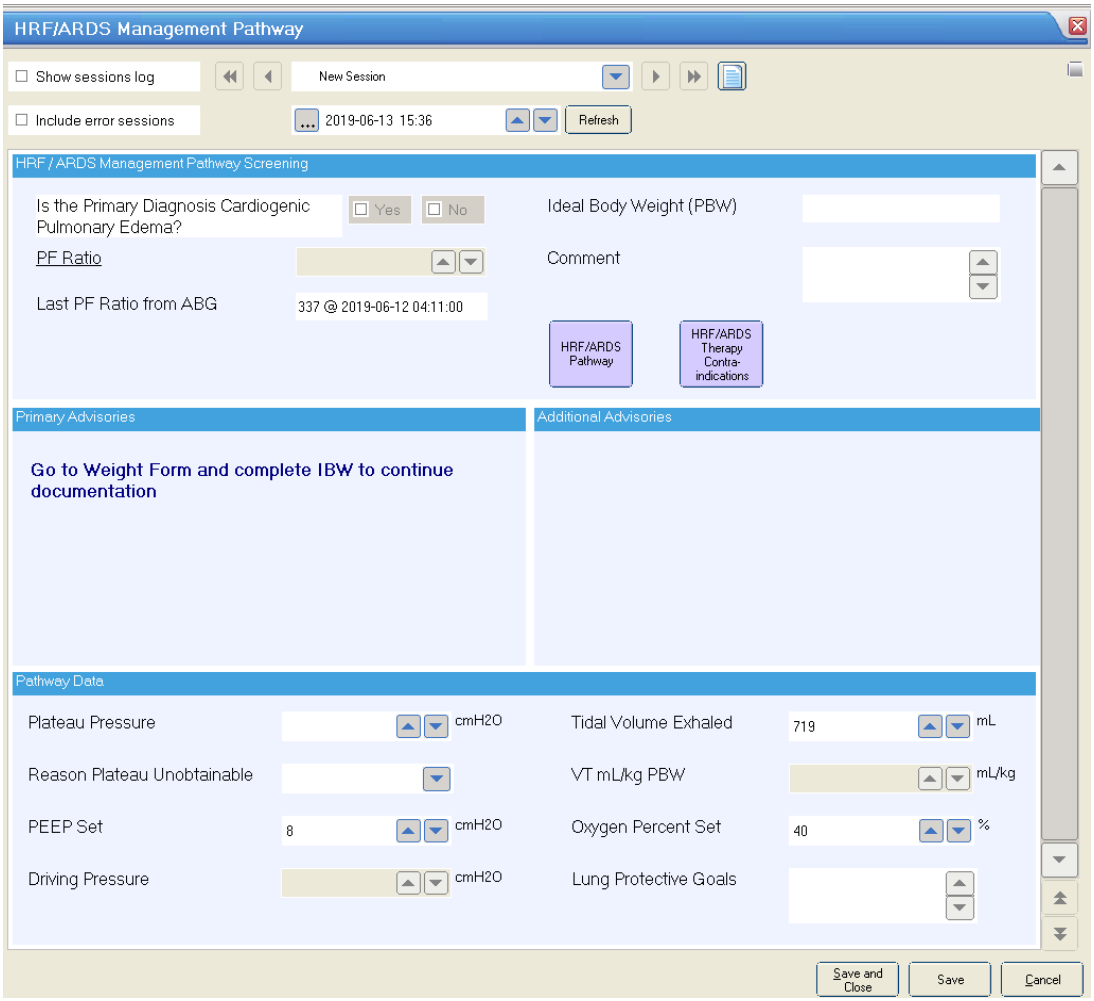


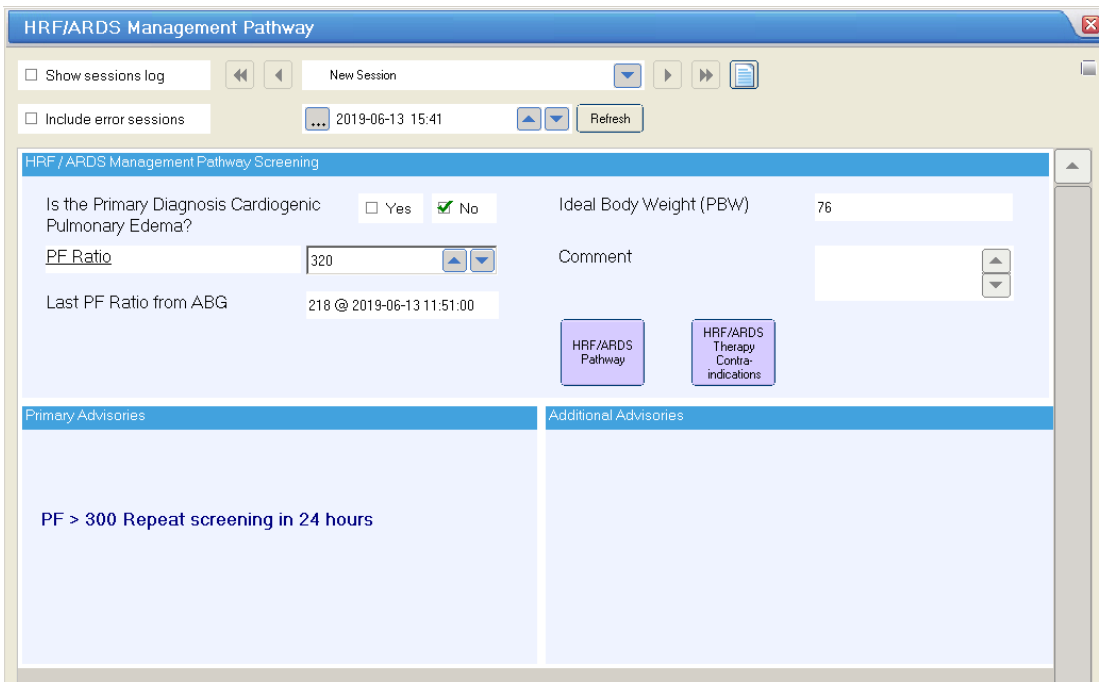


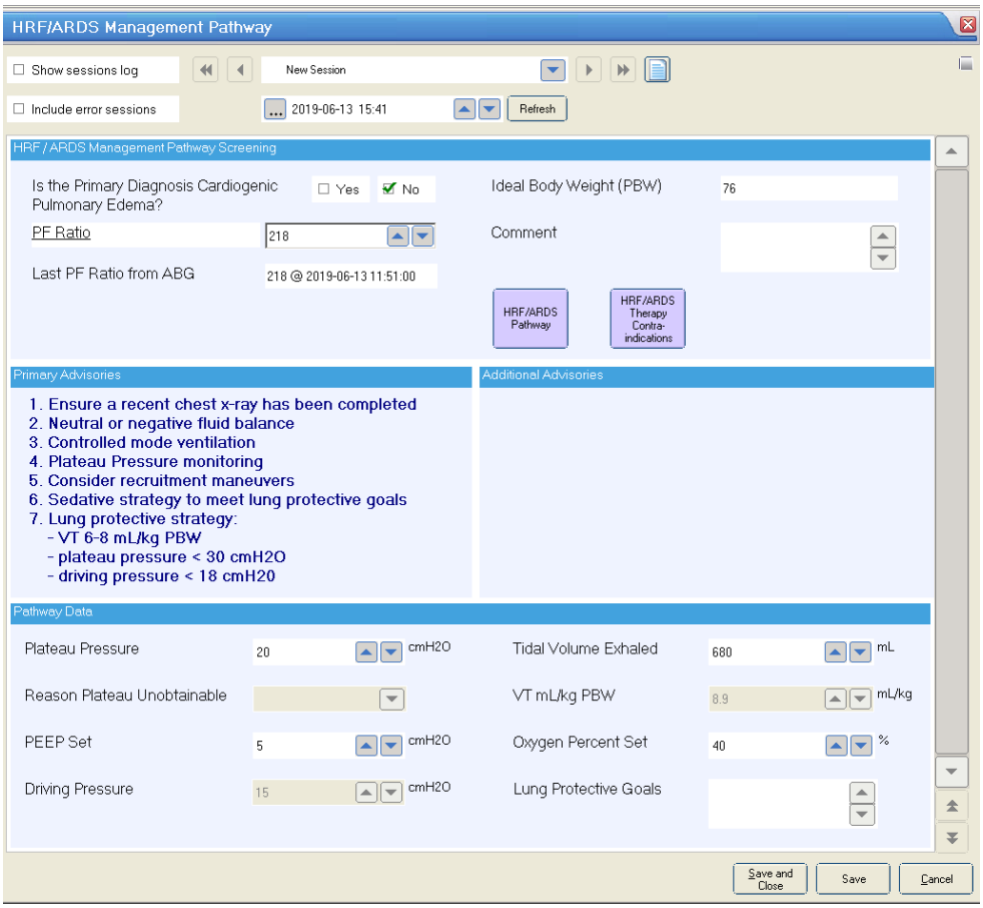


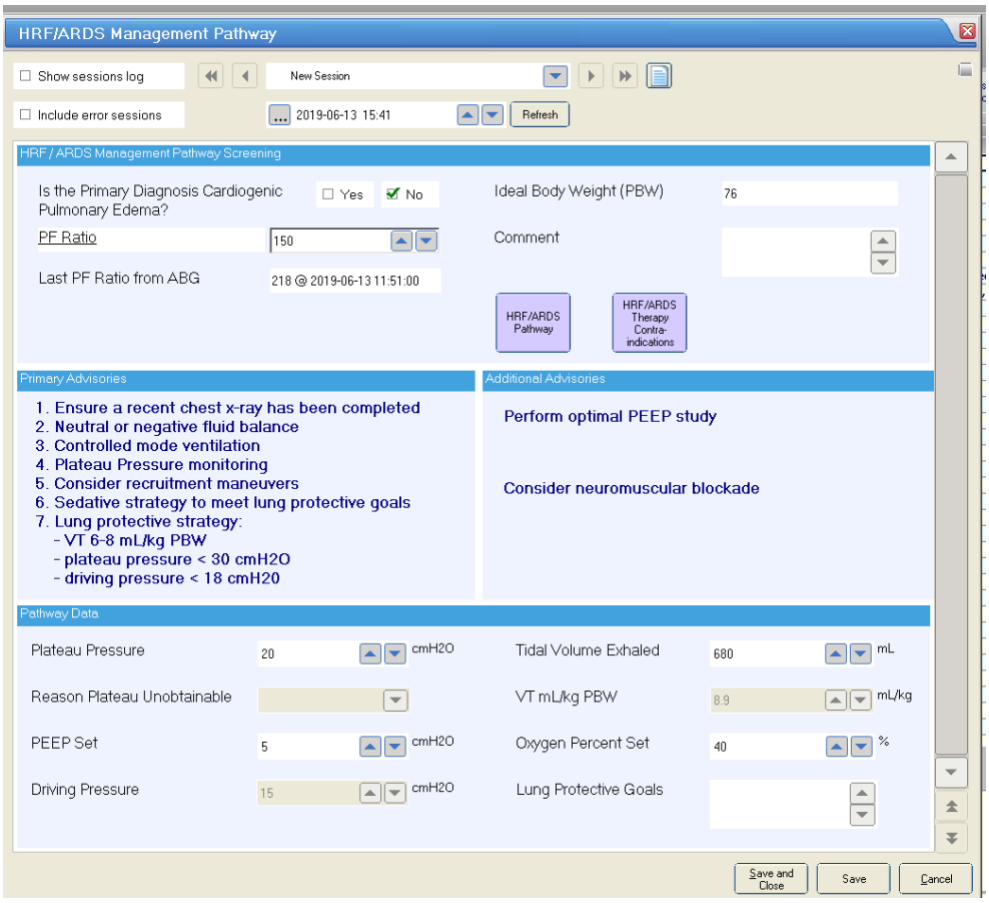


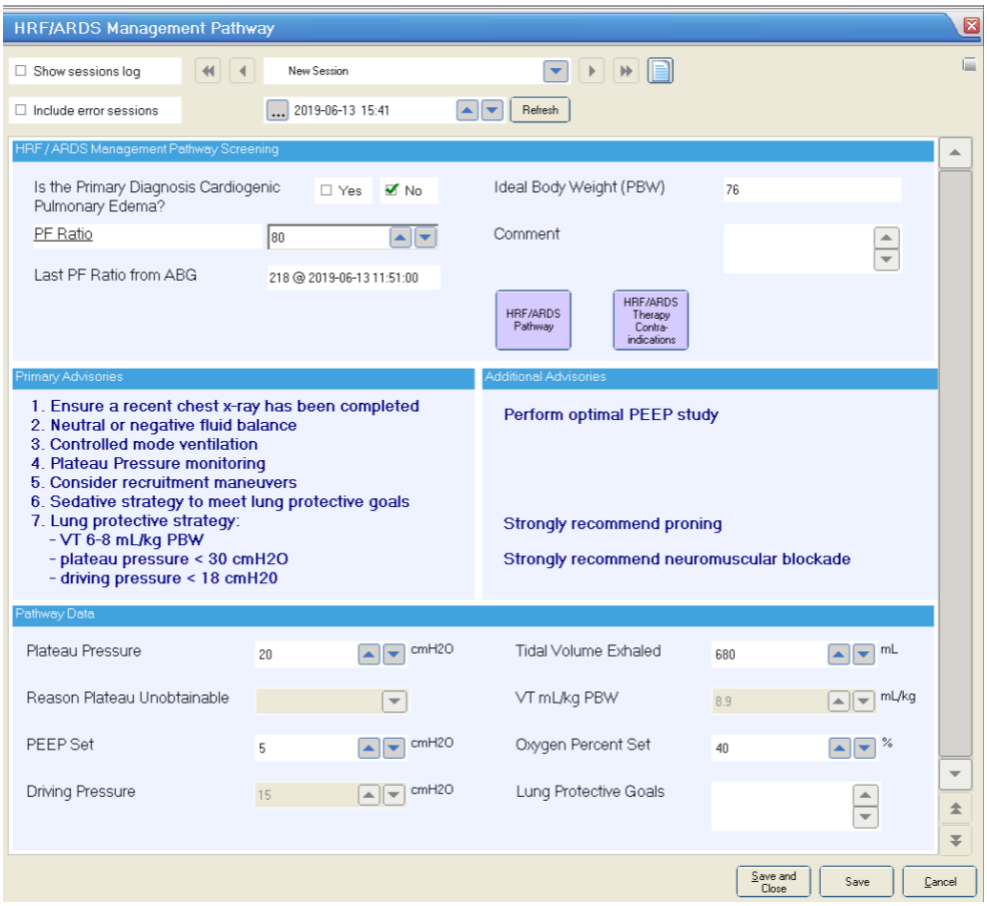
Attachment 6. HRF Screening and Data Entry Module






HRF/ARDS Management Pathway
Show sessions log
New Session
Include error sessions
2019-06-13 15:41
Refresh
HRF / ARDS Management Pathway Screening
Is the Primary Diagnosis Cardiogenic Pulmonary Edema?
Yes
No
Ideal Body Weight (PBW)
76
PF Ratio
218
Comment
Last PF Ratio from ABG
218 @ 2019-06-13 11:51:00
HRF/ARDS Pathway
HRF/ARDS Therapy Contra-indications
Primary Advisories
1. Ensure a recent chest x-ray has been completed
2. Neutral or negative fluid balance
3. Controlled mode ventilation
4. Plateau Pressure monitoring
5. Consider recruitment maneuvers
6. Sedative strategy to meet lung protective goals
7. Lung protective strategy:
- VT 6-8 mL/kg PBW
- plateau pressure < 30 cmH2O
- driving pressure < 18 cmH20
Additional Advisories
Pathway Data
Plateau Pressure
20
cmH2O
Tidal Volume Exhaled
680
mL
Reason Plateau Unobtainable
VT mL/kg PBW
8.9
mL/kg
PEEP Set
5
cmH2O
Oxygen Percent Set
40
%
Driving Pressure
15
cmH2O
Lung Protective Goals
Save and Close
Save
Cancel


HRF/ARDS Management Pathway
Show sessions log
New Session
Include error sessions
2019-06-13 15:41
Refresh
HRF / ARDS Management Pathway Screening
Is the Primary Diagnosis Cardiogenic Pulmonary Edema?
Yes
No
Ideal Body Weight (PBW)
76
PF Ratio
150
Comment
Last PF Ratio from ABG
218 @ 2019-06-13 11:51:00
HRF/ARDS Pathway
HRF/ARDS Therapy Contra-indications
Primary Advisories
1. Ensure a recent chest x-ray has been completed
2. Neutral or negative fluid balance
3. Controlled mode ventilation
4. Plateau Pressure monitoring
5. Consider recruitment maneuvers
6. Sedative strategy to meet lung protective goals
7. Lung protective strategy:
- VT 6-8 mL/kg PBW
- plateau pressure < 30 cmH2O
- driving pressure < 18 cmH20
Additional Advisories
Perform optimal PEEP study
Consider neuromuscular blockade
Pathway Data
Plateau Pressure
20
cmH2O
Tidal Volume Exhaled
680
mL
Reason Plateau Unobtainable
VT mL/kg PBW
8.9
mL/kg
PEEP Set
5
cmH2O
Oxygen Percent Set
40
%
Driving Pressure
15
cmH2O
Lung Protective Goals
Save and Close
Save
Cancel


HRF/ARDS Management Pathway
Show sessions log
New Session
Include error sessions
2019-06-13 15:41
Refresh
HRF / ARDS Management Pathway Screening
Is the Primary Diagnosis Cardiogenic Pulmonary Edema?
Yes
No
Ideal Body Weight (PBW)
76
PF Ratio
80
Comment
Last PF Ratio from ABG
218 @ 2019-06-13 11:51:00
HRF/ARDS Pathway
HRF/ARDS Therapy Contra-indications
Primary Advisories
1. Ensure a recent chest x-ray has been completed
2. Neutral or negative fluid balance
3. Controlled mode ventilation
4. Plateau Pressure monitoring
5. Consider recruitment maneuvers
6. Sedative strategy to meet lung protective goals
7. Lung protective strategy:
- VT 6-8 mL/kg PBW
- plateau pressure < 30 cmH2O
- driving pressure < 18 cmH20
Additional Advisories
Perform optimal PEEP study
Strongly recommend proning
Strongly recommend neuromuscular blockade
Pathway Data
Plateau Pressure
20
cmH2O
Tidal Volume Exhaled
680
mL
Reason Plateau Unobtainable
VT mL/kg PBW
8.9
mL/kg
PEEP Set
5
cmH2O
Oxygen Percent Set
40
%
Driving Pressure
15
cmH2O
Lung Protective Goals
Save and Close
Save
Cancel

Attachment 7. Data sources and Linkage

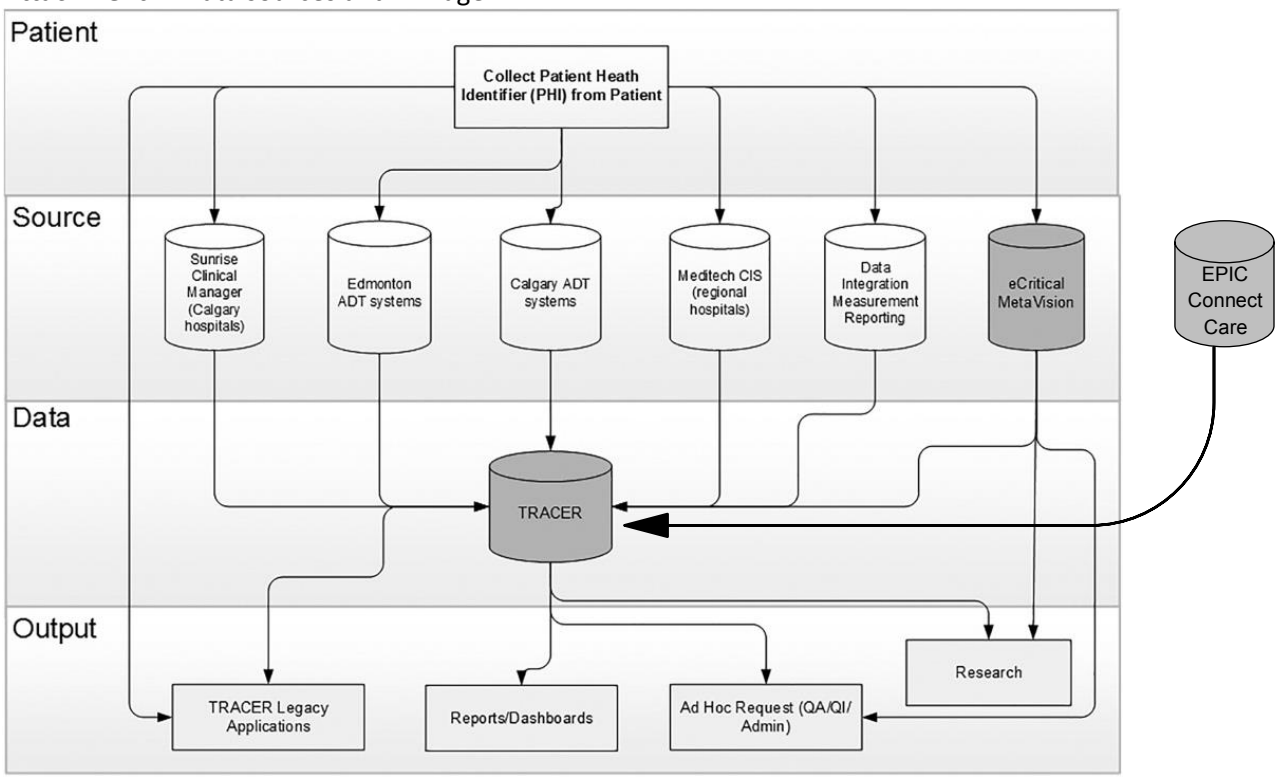


Fig. 1. eCritical system information data flow. Abbreviations: ADT - Admission, Discharge, Transfer; CIS - Clinical Information System; PHI - Patient Health Identifier.

Data source descriptions:
Sunrise Clinical Manager is an enterprise clinical information and electronic order entry system implemented in Calgary hospitals.

Edmonton and Calgary ADT systems are the Admission, Discharge and Transfer systems supporting Edmonton and Calgary hospitals.

Meditech is an enterprise ADT system and CIS implemented in a number of hospitals in Alberta.

Data, Integration, Measurement Reporting is a service of AHS providing analytic products through data integration across multiple provincial information systems.

eCritical MetaVision is the bedside critical care clinical information system that supports standardized clinical documentation, electronic data capture from medical devices and clinical decision supports in the electronic patient record.

eCritical TRACER is the data warehouse for the critical care clinical information system, supporting clinical analytics and reporting functions.

EPIC Connect Care is a clinical information system that is currently being implemented across Alberta Health Services in 9 waves.

Adapted from : Brundin-Mather R, Soo A, Zuege DJ, Niven DJ, Fiest K, Doig CJ, Zygun D, Boyd JM, Parsons Leigh J, Bagshaw SM, Stelfox HT (2018) Secondary EMR data for quality improvement and research: A comparison of manual and electronic data collection from an integrated critical care electronic medical record system. J Crit Care 47:295-301.

Attachment 8. Primary and secondary effectiveness, fidelity, and acceptability outcomes

Effectiveness Outcomes	Patient or subgroup	Timepoints at which the outcomes are measured	Primary or Secondary Outcome	Reporting of results (unit of measurement)
Clinical effectiveness outcomes				
28-day ventilator-free days (VFDs) (a composite of survival & days spent not ventilated over the first 28 days)	All patients/subgroups	Per admission 28-days Censored at hospital discharge	Primary	Meam (SD) and Median with interquartile range
ICU survival	All patients/select subgroups	Per admission	Secondary	Frequency with proportion of patients
ICU Length of Stay	All patients/select subgroups	Per admission	Secondary	Median with interquartile range
28-day hospital survival	All patients/select subgroups	28-days The first day of mechanical ventilation is day 0 Censored at hospital discharge	Secondary	Frequency with proportion of patients
Ventilator duration	All patients/select subgroups	Per admission	Secondary	Median with interquartile range
Hospital survival	All patients/select subgroups	Per admission censored at 90 days after mechanical ventilation	Secondary	Frequency with proportion of patients
Hospital Length of stay	All patients/select subgroups	Per admission censored at 90 days after mechanical ventilation	Secondary	Median with interquartile range
Driving Pressure (Plateau pressure – PEEP)	Patients ventilated with PF ratio ≤ 300 on controlled mode	Throughout the ICU stay	Secondary	Median with interquartile range
Mechanical Power (Mechanical power is calculated using the formula Power = 0.098*respiratory rate•*(tidal volume/1000)*(Peak Pressure – (0.5 • Driving Pressure)	Patients ventilated with PF ratio ≤ 300 on controlled mode	Throughout the ICU stay	Secondary	Median with interquartile range
Utilization of veno-venous Extracorporeal Membrane Oxygenation (VV-ECMO).	All patients/select subgroups	Per admission	Secondary	Frequency with proportion of patients

Implementation Outcomes - Fidelity	Patient or subgroup	Timepoints at which the outcomes are measured	Primary or Secondary Outcome	Reporting of results (unit of measurement)
Fidelity Indicators				
Composite fidelity score The Composite Fidelity Score awards point for fidelity indicators . It can be interpreted as the average proportion of time pathway elements are appropriately performed, it: ▪ Includes all mechanically ventilated patients ▪ Is based on patients being eligible for up to four possible interventions per day and height ever documented during the ICU stay (specific indicators indicated by asterisk* below) ▪ A day is only included if patient is eligible for that day ▪ Height measurement only contributes 1 point to the score if it is ever measured during the ICU stay	Patient subgroups for individual fidelity indicators are indicated by asterisk* in rows below	Per admission (height) & daily (tidal volume, plateau pressure, neuromuscular blockade and proning)	Primary	For each patient, the composite fidelity score is calculated as: The number of times pathway elements were appropriately performed out of the number of times the patient was eligible for pathway elements throughout their ICU stay. The composite fidelity score is reported as Median (IQR) % and Mean (SD) %
*Height ever documented	Mechanically Ventilated patients	Per admission	Secondary	Frequency with proportion of patients
Height documented within 1 hour of admission to ICU	Mechanically Ventilated patients	Per admission	Secondary	Frequency with proportion of patients
Height documented within 2 hours of admission to ICU	Mechanically Ventilated patients	Per admission	Secondary	Frequency with proportion of patients
Time in minutes to height measurement from ICU admission (among patients with height ever documented)	Mechanically Ventilated patients with a height measured	Per admission	Secondary	Median with interquartile range
*****Tidal volume ≤ 8ml/kg PBW: Previously noted as *Days of safe ventilation* ±If height is not documented, tidal volume indicator is determined based on using an average height of: - 162cm for females [IBW 54.2kg, TV <=434ml] - 176cm for males [IBW 71.5kg, TV <=572ml] Tidal volume set will be used for volume-controlled mode and tidal volume inhaled will be used for pressure-controlled mode. If inhaled or set tidal volume is not available, exhaled tidal volume is used. Indicator is based on the median daily tidal volume being ≤ 8 ml/kg PBW	Patients ventilated: - ABG done that day between 0000-0800 - PF ratio ≤ 300 on that day - On controlled mode	Daily	Secondary	Median (IQR) and mean (SD) proportion of eligible days Outcome is assessed daily, but then summarized as a proportion for each patient, and then the median or mean is taken
*****Plateau pressure measured	*Patients ventilated - ABG done that day - PF ratio ≤ 300 on that day - On controlled mode	Daily	Secondary	Median (IQR) and mean (SD) proportion of eligible days Outcome is assessed daily, but then summarized as a proportion for each patient, and then the median or mean is taken

*****Receive neuromuscular blockade (NMB) in the consider group	*Patients ventilated - ABG done that day - PF ratio ≤ 150 on that day - On controlled mode	Daily	Secondary	Median (IQR) and mean (SD) proportion of eligible days Outcome is assessed daily, but then summarized as a proportion for each patient, and then the median or mean is taken
*****Patient proned for those in the consider group	*Patients ventilated - ABG done that day - PF ratio ≤ 150 and FiO2 ≥ 0.60 on that day - On controlled mode - Not receiving ECLS that day	Daily	Secondary	Median (IQR) and mean (SD) proportion of eligible days Outcome is assessed daily, but then summarized as a proportion for each patient, and then the median or mean is taken
Implementation Outcomes - Acceptability	**Patient or subgroup**	**Timepoints at which the outcomes are measured**	**Primary or Secondary Outcome**	**Reporting of results (unit of measurement)**
Pathway acceptability (Survey)				
C**omposite Acceptability Score:** Summary of pathway acceptability measured using the 7 Theoretical Framework of Acceptability (TFA) component constructs (listed below†)	Survey clinicians and pathway educators / champions	Two to six months after implementation at each site	Secondary	Proportion of TFA component with median score 4 or 5 o a 5-point Likert scale, indicating agreement
†Affective attitude (How an individual feels about the intervention)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Burden (The perceived amount of effort that is required to participate in the intervention)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Ethicality (The extent to which the intervention has a good fit with an individual's value)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Intervention coherence (The extent to which the participant understands the invention and how it works)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Opportunity costs (The extent to which benefits, profits, or values must be given up to engage in the intervention	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Perceived effectiveness (The extent to which the intervention is perceived as likely to achieve its purpose)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)
†Self-efficacy (The participant's confidence that they can perform the behavior(s) required to participate in the intervention)	Survey clinicians and pathway educators / champions	"	Secondary	Median (IQR)

Effectiveness Outcomes - economic	Patient or subgroup	Timepoints at which the outcomes are measured	Primary or Secondary Outcome	Reporting of results (unit of measurement)
Economic effectiveness outcomes				
Cost per ventilator free day	All patients/subgroups	Daily	Primary	Median (IQR)
Total cost for the ICU admission	All patients/subgroups	Per admission	Secondary	Median (IQR)
Total cost for the index hospitalization	All patients/subgroups	Per admission	Secondary	Median (IQR)
ICU LOS (also noted as secondary clinical effectiveness outcome)	All patients/subgroups	Per admission	Secondary	Median (IQR)
Hospital LOS also noted as secondary clinical effectiveness outcome)	All patients/subgroups	Per admission	Secondary	Median (IQR)
Cost per quality adjusted life year (QALY) from the health care system perspective over the patient's lifetime.	All patients/subgroups	Per admission	Secondary	Median (IQR)

ABG=arterial blood gas. ECLS=extracorporeal life support. IBW=ideal body weight. ICU=intensive care unit. IQR=intraquartile range. LOS=length of stay. NMB=neuromuscular blockade. PEEP=positive end expiratory unit. PF ratio=PaO2/FiO2. TV=tidal volume. VFDs=ventilator free days.

Attachment 9. Acceptability survey

Please take a few minutes to complete the following survey about your experience with the *Venting Wisely* Pathway.

Demographics (Q 1-5)

Please share a little information about yourself.

The following questions will help us tailor the Venting Wisely Pathway implementation and sustainment.

Space will be provided at the end of the survey for additional notes/comments.

1. What is your gender identity?
Man
Woman
Non-binary
Transgender
Two-Spirit
Prefer not to answer
Prefer to self-identify
REQUIREMENT: Request Response

2. What is your age?

3. What is your primary role in the Intensive Care Unit?
**Intensivist
**Critical Care Fellow
** Resident
**Other Physician
Registered Nurse
Registered Respiratory therapist
Other clinician (Please specify, e.g. Physiotherapist, Occupational Therapist, Manager)

3a. What is your base specialty?
*BRANCHING LOGIC if ** above are checked*

4. The hospital / ICU I **primarily** work at is:
Chinook Regional Hospital Lethbridge
CVICU Calgary (at FMC)
CVICU (Mazankowski Heart Institute)
Foothills Medical Centre – ICU
Grey Nuns Hospital
Medicine Hat Regional Hospital
Misericordia Community Hospital
Northern Lights Regional Health Centre
Peter Lougheed Centre
QE II – Grande Prairie Regional Hospital

Red Deer Regional Hospital
Rockyview General Hospital
Royal Alexandra Hospital
South Health Campus
Sturgeon Community Hospital
University of Alberta Hospital – General Systems ICU
University of Alberta Hospital – Neuroscience ICU

5. How many years of experience do you have working in an Intensive Care Unit?
(Numerical response only)

Knowledge Assessment (Q 6-17)

The following **12** questions aid us in determining which aspects of education may require additional attention.

Space will be provided at the end of the survey for additional notes/comments.

6. It is essential for heights to be measured and documented on all mechanically ventilated patients.
True
False

7. What information do you need to determine predicted body weight? (**choose all that apply)**

- ○ Weight
- ○ Sex
- ○ Age
- ○ Height

8. In the Venting Wisely pathway, the arterial blood gas screening for hypoxemic respiratory failure (HRF) must be done: **(choose all that apply).**

- ○ While the patient is at steady state
- ○ Between 0000-0800
- ○ Any time during the day or night
- ○ When the patient is unstable

9. On an arterial blood gas that is obtained on a patient in a clinical steady state, what is the PF ratio threshold to be considered for the steps beyond height measurement in the Venting Wisely pathway?

- ○ Less than or equal to 100
- ○ Less than or equal to 200
- ○ Less than or equal to 300
- ○ Less than or equal to 400

10. Lung protective ventilation includes all of the following:
(Choose all that apply)

- ○ Calculating a predicted body weight
- ○ Limiting tidal volumes
- ○ Limiting plateau pressure

11. For patients with hypoxemic respiratory failure (HRF), when limiting **tidal volume** , what initial goal (mL/kg predicted body weight) should be targeted?

- ○ 4-6
- ○ 6-8
- ○ 8-10
- ○ 10-12

12. For patients with hypoxemic respiratory failure (HRF), when limiting **plateau pressure**, an upper limit of how many cmH2O should be targeted?

- ○ Less than or equal to 25
- ○ Less than or equal to 30
- ○ Less than or equal to 35
- ○ Less than or equal to 40

13. To prevent inappropriately high tidal volumes in patients where the predicted body weight method is likely to overestimate lung size, such as in women or patients with short stature, **driving pressure** should be limited to:

- ○ Less than or equal to 18
- ○ Less than or equal to 20
- ○ Less than or equal to 22

14. In the Venting Wisely pathway if a patient develops worsening hypoxemic respiratory failure (HRF) or does not meet lung protective ventilation goals, therapy will be escalated, beginning with neuromuscular blockade (paralysis). At what PF ratio should paralytics be considered?

- ○ Less than or equal to 100
- ○ Less than or equal to 150
- ○ Less than or equal to 200
- ○ Less than or equal to 300

15. In the Venting Wisely Pathway, neuromuscular blockade (paralytics) **(choose all that apply)**

- ○ May be PROPOSED by any member of the multidisciplinary team
- ○ Need Most Responsible Health Practitioner APPROVAL prior to initiation
- ○ Goals [eg. End-tidal CO2, Train of Four, ventilator dyssynchrony] should be determined by the Most Responsible Health Practitioner and documented in the Electronic Health Record

16. In the Venting Wisely pathway, a patient with a worsening PF ratio despite receiving lung protective ventilation and paralytics should be considered for prone positioning when they have:

- ○ PF ratio less than or equal to 150
- ○ PF ratio less than or equal to 150 and FiO2 requirement greater than or equal to 0.6
- ○ PF ratio less than or equal to 200 and FiO2 requirement greater than or equal to 0.6

17. According to the landmark PROSEVA trial, the minimal duration of prone positioning should be?

- ○ Greater than or equal to 4 hours out of a 24 hour period
- ○ Greater than or equal to 8 hours out of a 24 hour period
- ○ Greater than or equal to 16 hours out of a 24 hour period
- ○ Greater than or equal to 24 hours out of a 24 hour period

<u>Acceptability Assessment</u> (Q 18-24)

The following **7** questions focus on your perceptions about the pathway. For each question, please choose the response that fits best for you.

Space will be provided at the end of the survey for additional notes/comments.

18. How do you feel about the Venting Wisely pathway?

[Affective Attitude. How a clinician feels about the intervention]

I feel extremely negative about the Venting Wisely pathway
I feel negative about the Venting Wisely pathway
I feel neither negative nor positive about the Venting Wisely pathway
I feel positive about the Venting Wisely pathway
I feel extremely positive about the Venting Wisely pathway

19. How much time and effort are required to use the Venting Wisely pathway?

[Burden. Clinician's perceived amount of effort required to participate in the pathway]

The Venting Wisely pathway takes a significant amount of extra time and effort compared to your prior standard of care
The Venting Wisely pathway takes some extra time and effort compared to your prior standard of care
The Venting Wisely pathway neither decreases nor increases the time or effort compared to your prior standard of care
The Venting Wisely pathway takes reduced time and effort compared to your prior standard of care
The Venting Wisely pathway takes a significantly reduced amount of time and effort compared to your prior standard of care

20. Is the Venting Wisely pathway is in the patient and providers best interest?

[*Ethicality: The extent to which the intervention has good fit with an individual's value system]*

I strongly believe that the Venting Wisely pathway is not in the patient and providers best interest
I believe that the Venting Wisely pathway is not in the patients and providers best interest
The Venting Wisely pathway is neither against nor for the patient and providers best interest
I believe that the Venting Wisely pathway is in the patient and providers best interest
I strongly believe that the Venting Wisely pathway is in the patient and providers best interest

21. What is your level of understanding of the Venting Wisely pathway elements and how the pathway works?

[Intervention coherence]: the extent to which the clinician understands the intervention]

I have an extremely limited understanding of the Venting Wisely pathway
I have a limited understanding of the Venting Wisely pathway
I have neither a limited nor comprehensive understanding of the Venting Wisely pathway
I have a comprehensive understanding of the Venting Wisely pathway
I have an extremely comprehensive understanding of the Venting Wisely pathway

22. What was it like to balance the Venting Wisely pathway with all of the other daily tasks for your patients?

[Opportunity costs: benefits or costs to the clinician for using the pathway]

The Venting Wisely pathway made it significantly more difficult to balance all of the other daily tasks for my patients
The Venting Wisely pathway made it more difficult to balance all of the other daily tasks for my patients
The Venting Wisely pathway made no difference in balancing all of the other daily tasks for my patients

The Venting Wisely pathway made it easier to balance all of the other daily tasks for my patients
The Venting Wisely pathway made it significantly easier to balance all of the other daily tasks for my patients

23. How likely is the Venting Wisely pathway to impact the use of evidence-based care?

[*Perceived effectiveness. the extent to which the intervention is perceived by clinicians as likely to achieve its purpose]*

The Venting Wisely pathway is extremely unlikely to impact the use of evidence-based care
The Venting Wisely pathway is unlikely to impact the use of evidence-based care
The Venting Wisely pathway is neither unlikely nor likely to impact the use of evidence-based care
The Venting Wisely pathway is likely to impact the use of evidence-based care and patient
The Venting Wisely pathway is extremely likely to impact the use of evidence-based care

24. What is your confidence level that you can perform all of the elements of the Venting Wisely pathway associated with your discipline?

[self-efficacy: clinician's confidence that they can use the pathway]

I strongly lack confidence that I can perform all of the elements of the Venting Wisely pathway associated with my discipline
I somewhat lack confidence that I can perform all of the elements of the Venting Wisely pathway associated with my discipline
I neither lack nor have confidence that I can perform all of the elements of the Venting Wisely pathway associated with my discipline
I am somewhat confident that I can perform all of the elements of the Venting Wisely pathway associated with my discipline
I am extremely confident that I can perform all of the elements of the Venting Wisely pathway associated with my discipline

Enablers (Q 25-34)

The following **9** questions focus on the tools we used to bring *Venting Wisely* into your Intensive Care Unit.

During implementation of the *Venting Wisely*, several strategies were used to help promote its use. We are interested in **which strategies you recognize as having used to encourage pathway uptake and how helpful you felt they were.**

For each strategy listed below, please select those that you **RECALL** having seen, received, or participated in,
If you RECALL the strategy, you will be asked to **RATE how helpful you felt they were** in encouraging uptake of the Venting Wisely pathway.

Q25. I RECALL the Venting Wisely **Grand Rounds** presentation by Dr. Ken Parhar

Yes
No
REQUIREMENT: Request Response

Q25a. Please RATE how helpful Grand Rounds was in encouraging uptake of the Venting Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 25 is checked: yes.
REQUIREMENT: Request Response

Q26. I RECALL participating in virtual and / or in-person Venting Wisely **education sessions**. Yes
No
REQUIREMENT: Request Response

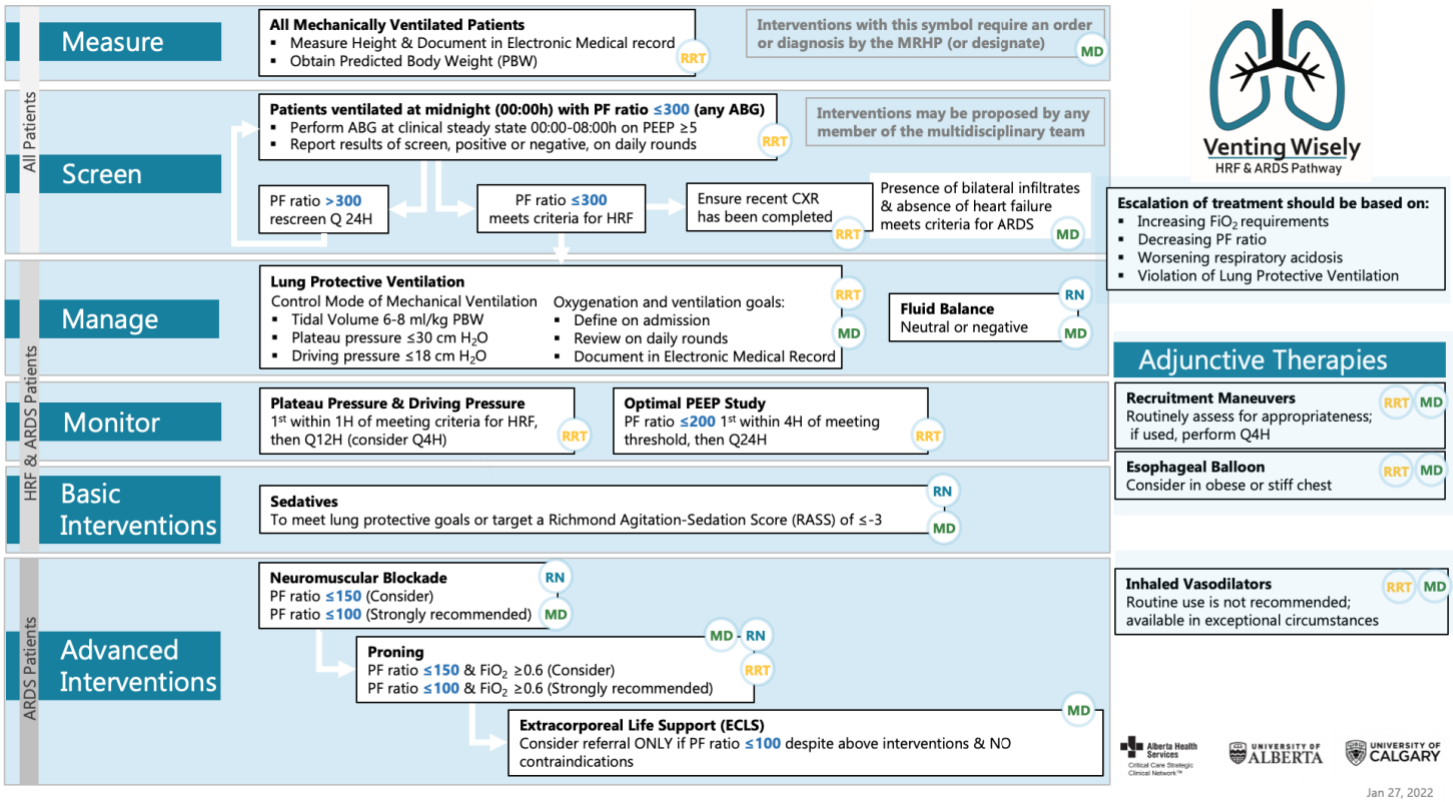
Q26a. The education session I participated in was facilitated by:
(choose all that apply):
An educator on my unit
A Venting Wisely Practice Lead
Other (please specify)
BRANCHING LOGIC if 25 is checked: yes.
REQUIREMENT: Request Response

_____
26b. Please RATE how helpful the **education session** was in encouraging uptake of the Venting Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 26 is checked: yes.
REQUIREMENT: Request Response

27. I RECALL watching the Venting Wisely **instructional videos**.
Yes
No
REQUIREMENT: Request Response

27a. Please RATE how helpful the Venting Wisely **instructional videos** were in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 27 is checked: yes.
REQUIREMENT: Request Response

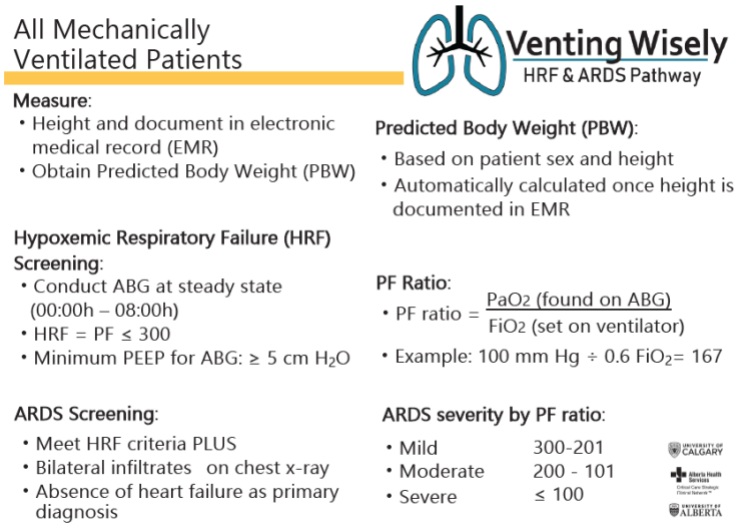
28. I RECALL the Venting Wisely **pathway diagram.**
(see below)



Yes
No
REQUIREMENT: Request Response

28a. Please RATE how helpful the Venting Wisely **pathway diagram** was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 28 is checked: yes.
REQUIREMENT: Request Response

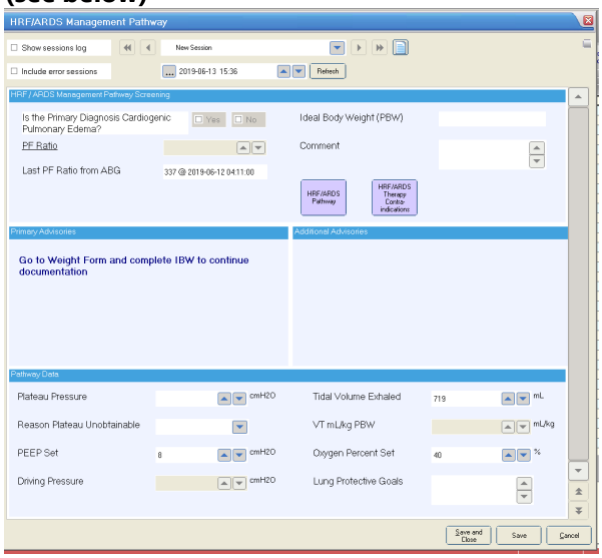
29. I RECALL the Venting Wisely pocket cards.
(see below)

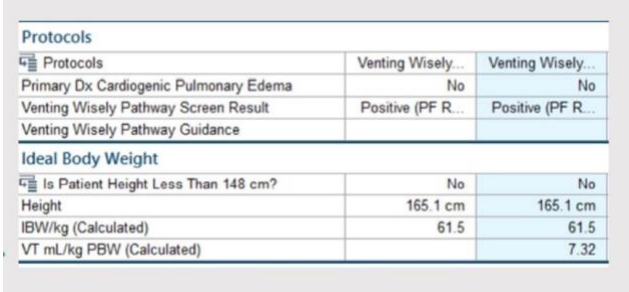


Yes
No
REQUIREMENT: Request Response

29a. Please RATE how helpful the Venting Wisely **pocket card** was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 29 is checked: yes.
REQUIREMENT: Request Response

30. I RECALL the Venting Wisely **electronic form** for Registered Respiratory Therapists in MetaVision or Connect Care. **(see below)**



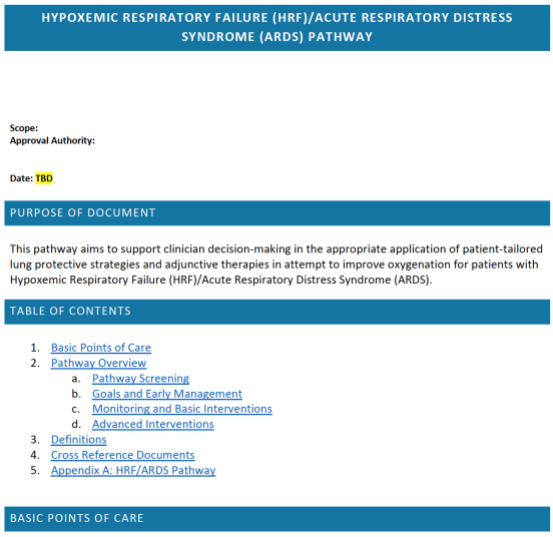


Protocols		
Protocols	Venting Wisely...	Venting Wisely...
Primary Dx Cardiogenic Pulmonary Edema	No	No
Venting Wisely Pathway Screen Result	Positive (PF R...	Positive (PF R...
Venting Wisely Pathway Guidance		
Ideal Body Weight		
Is Patient Height Less Than 148 cm?	No	No
Height	165.1 cm	165.1 cm
IBW/kg (Calculated)	61.5	61.5
VT mL/kg PBW (Calculated)		7.32

Yes
No
REQUIREMENT: Request Response

30a. Please RATE how helpful the Venting Wisely **electronic form** for Registered Respiratory Therapists was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 30 is checked: yes.
REQUIREMENT: Request Response

31 I RECALL the Venting Wisely practice guideline
(see below)



HYPOXEMIC RESPIRATORY FAILURE (HRF)/ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS) PATHWAY

Scope:
Approval Authority:

Date: TBD

PURPOSE OF DOCUMENT

This pathway aims to support clinician decision-making in the appropriate application of patient-tailored lung protective strategies and adjunctive therapies in attempt to improve oxygenation for patients with Hypoxemic Respiratory Failure (HRF)/Acute Respiratory Distress Syndrome (ARDS).

TABLE OF CONTENTS

1. Basic Points of Care
2. Pathway Overview
   a. Pathway Screening
   b. Goals and Early Management
   c. Monitoring and Basic Interventions
   d. Advanced Interventions
3. Definitions
4. Cross Reference Documents
5. Appendix A: HRF/ARDS Pathway

BASIC POINTS OF CARE

Yes
No
REQUIREMENT: Request Response

31. Please RATE how helpful the Venting Wisely **practice guideline** was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 31 is checked: yes.
REQUIREMENT: Request Response

32. I RECALL receiving Venting Wisely **audit and feedback** pathway adherence rates.
(see below)

Pathway element	Baseline	Jan 2022	Feb 2022	Mar 2022	Target	Comments
Height documented on ventilated patients within **1H** of admission	9%	**68%**	**73%**	**80%**	100%	Let's get to our target! Remember the "RT Golden Hour". **FYI: the average for height documented ever is 97% in Jan, and 100% in Feb ☺**
Tidal volume ≤8mL/Kg on controlled mode, PF ≤ 300 (daily)	83%	**97%**	**97%**	**100%**	AWESOME!	
Plateau Pressure on controlled mode, PF ≤300 (daily)	14%	**71%**	**75%**	**83%**	We can really see the effort that's gone into ensuring Pplats are measured on patients.	

Yes
No
REQUIREMENT: Request Response
32a. The Venting Wisely **audit and feedback** that I RECALL was:
(choose all that apply)

In a poster on my unit
In an email
In a meeting (e.g. at a unit meeting or an audit and feedback meeting)
Other (please specify) _____
Not sure where I saw it
BRANCHING LOGIC if 32 is checked: yes.
REQUIREMENT: Request Response

32b. Please RATE how helpful the Venting Wisely **audit and feedback** was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 32 is checked: yes.

REQUIREMENT: Request Response

33. I RECALL receiving support to use the Venting Wisely pathway, for example verbal or email reminders, support from educators or Practice Leads.
Yes
No
REQUIREMENT: Request Response

33a. The support I received to help use the Venting Wisely pathway was:
(check all that apply)

Verbal reminders or coaching from educators
Email or website reminders
Knowledge Translation Practice Lead support
A local clinical leader championing the pathway
A Quality Improvement team member
Other (please specify)
BRANCHING LOGIC if 33 is checked: yes.
REQUIREMENT: Request Response

33b. Please RATE how helpful the Venting Wisely **above help** was in encouraging uptake of the Venting Wisely pathway.
Wisely pathway.
Not at all helpful
Slightly helpful
Somewhat helpful
Very helpful
Extremely helpful
BRANCHING LOGIC if 33 is checked: yes.
REQUIREMENT: Request Response

36. Do you have any comments or suggestions about the Venting Wisely Pathway?

Thank you for participating! If you have any questions please contact Dr. Ken Parhar
ken.parhar@albertahealthservices.ca

Attachment 10. Interview Guide for Clinician Focus Groups

Briefing (5 minutes)

1. Welcome and thank you for agreeing to take part in this focus group discussion about the Venting Wisely pathway.
2. [Introduce self]
3. As described in our email, we are interested in hearing about your perceptions of the Venting Wisely pathway as well as feedback on what can be done to improve and sustain its implementation.
4. We emailed you a copy of the informed consent form. The consent form is part of the process of informed consent. It should give you a basic idea of what the research is about and what your participation will involve. Did everyone receive the consent form and have a chance to read through it Good. Because it is important that you understand your rights as a participant, I just want to review the main elements in the consent form:

[Interviewer will read the REB approved Oral Consent Script]

5. All information I collect is confidential. I hope this encourages you to speak freely. We would like the discussion to be informal, so there's no need to wait for us to call on you to respond. In fact, we encourage you to respond directly to the comments other people make. If you don't understand a question, please let us know. We are here to ask questions, listen, and make sure everyone has a chance to share.
6. Does anyone object to me recording our conversation? The recording will be typed out, but everything you say will be anonymous.

[Press record]

Ground rules

- The most important rule is that only one person speaks at a time.
- There are no right or wrong answers
- You do not have to speak in any particular order
- You do not have to agree with the views of other people in the group
- Does anyone have any questions? (answers).
- Ok let's begin:

You have been asked to participate in this study because you work in an ICU where the Venting Wisely pathway was implemented. Briefly, this was an evidence-based, stakeholder-informed pathway for the diagnosis and management of hypoxemic respiratory failure. This pathway included six steps: 1) Measure: where all mechanically ventilated patients had their height and predicted body weight measured and recorded; 2) Screen: Where patients were screened for the presence of HRF using PF ratios. 3) Manage: Lung Protective Ventilation was initiated for patients with HRF; 4) Monitor: plateau pressure & driving pressure, optimal PEEP study; 5) Paralysis: if the patient develops worsening HRF and does not meet LPV goals, therapy was escalated using a neuromuscular blockade. Patients with worsening PF ratio despite steps 1-4 will be considered for prone positioning followed by proning, followed by ECLS.

Warm up

I'd like everyone to introduce themselves. Please tell us your name and a sentence or two about the background that brings you here		
Question	**Probe**	**Notes**
1. I'm going to give you a minute to think about your experience as a clinician using the Venting Wisely (VW) pathway: How do you feel about the Venting Wisely pathway? *Affective Attitude: How an individual feels about an intervention*	What did you like about it? (Ask about implementation or the pathway itself) What did you dislike about it? (Ask about implementation or the pathway itself)	
2. How do you think using the Venting Wisely pathway will impact the use of evidence-based care and improve patient outcomes? *Perceived effectiveness: The extent to which the intervention is perceived as likely to achieve its purpose*	If yes, what do you think some of the benefits of the VW are? If not, is this due to a problem with implementation of the pathway on your unit? Or with the pathway itself? (maybe ask more neutral as this is leading: could just ask why and ask probing questions to understand)	
3. How did the Venting Wisely pathway change your confidence in caring for HRF / ARDS patients? *Self-efficacy: The participant's confidence that they can perform the behaviour(s) required to participant in the intervention*	What's your confidence level that you can perform all of the Venting Wisely pathway therapies associated with your discipline? What kind of support was helpful in gaining confidence? • Implementation support (e.g. education at Grand Rounds)? • Experience with the pathway post implementation? Is there something that **could have** supported you in gaining confidence? • During implementation?	

	Within the pathway itself?	
4. How much time or effort was it to use the Venting Wisely pathway? *Burden: The perceived amount of effort that is required to participate in the intervention*	If a lot, ask about implementation or the use of the pathway itself. If not much, did it make your day more efficient?	
5. What is your understanding of the goal of the Venting Wisely pathway and how it works? *Intervention coherence: The extent to which the participant understands the intervention and how it works*	What was (or would be) most helpful (for you to understand the goals of VW and how to perform the pathway?	
6. What was it like to balance the Venting Wisely pathway with all the other daily tasks for your patients? *Opportunity costs: The extent to which benefits, profits, or values must be given up to engage in the intervention*	Were there patient care tasks you felt you had to give up, or do more quickly, to incorporate VW pathway therapies? If yes, what part of the pathway took too much time and what did you end up giving up (pathway or other)?	
7. Do you think the Venting Wisely pathway is in the best interest of patient? What about the best interests of the provider? *Ethicality: The extent to which the intervention has good fit with an individual's value system*	Which parts are in the best interests of patient or provider? Which parts are NOT in the best interests of patient or provider?	
8. Our aim is that VW becomes part of daily clinical practice. What could help this sustained once the project team is no longer available?	Which elements of the path will be most difficult to sustain?	

Optional, time permitting: What did your unit do really well in adopting Venting Wisely?	Why do you think you were so successful?	
Is there anything else you would like to share with us?	If no one answers, go around and ask what is one thing you would like to tell the study team about the Venting Wisely pathway?	
Do you have any questions for us?		

Summary (depending on time)

Do you have any questions for us?

Thank you for sharing your time and personal experience!

Attachment 11. Ethics Modifications

Modification 1 (protocol version 1.0 to 2.0 December 9, 2020)

(1) Update Principal Investigator's email address on the protocol

(2) Add EPIC Connect Care
Alberta Health Services is launching a new electronic clinical information system: EPIC Connect Care. Connect care Implementation began in 2019 and roll out will continue in a sequence of nine waves, completing in 2023. To collect data for the above study we will need to access EPIC Connect Care**. No additional data metrics will be collected.**

(3) Add new funding source
In October 2020, Dr. Parhar was successful in securing Health Innovation and Implementation Spread (HIIS) Funding (Alberta Health Services). This funding will ensure Knowledge Translation of the TheraPPP Study (REB20-0646). The funds will become available in January 2020.

Modification 2 (protocol version 2.0 to 2.1 February 23, 2022)

We are submitting this ethics modification to request direct access to manually collect data from paper charts to acquire missing data for patients cared for in non-traditional ICU settings (Coronary Care Unit, Post-operative care unit) due to Covid surges.
We are also providing updates on:

(1) Minor updates as a result of the completion of the Statistical Analysis Plan by the Scientific Steering Group:
   i. Details added to outcomes
   ii. Duration of follow up period increased from two to four months to ensure a sufficient number of patients with sustained ARDS

(2) Updates to the implementation strategy based on our finalized analysis of barriers to *Venting Wisely* implementation.

(3) Minor changes to focus groups (finalized as we will conduct soon)
   i. Interview guide
   ii. Invitation
   iii. Group make up (4 to 8 single discipline, eg. RN, RT, MD, per focus group = 50 to 100 total participants)
   iv. Informed consents (full consent to be emailed before the focus group, oral consent will be obtained at the focus group)
   v. Add Rev.com listed as the transcription service we will use
   vi. Add Zoom as the way focus groups will be conducted and add Zoom recording to audiotaping of the focus groups
   vii. Demographic sheet added
   viii. Branding added

(4) Updates to acceptability survey (finalized as we will conduct soon)
   i. Timing of acceptability survey
   ii. Survey questions
   iii. Branding added to invitation letter
   iv. Informed consent updated with the name of the pathway *(Venting Wisely)*
   v. One survey to be administered to RN, MD and RT (not a different survey for RNs)
   vi. Change in estimate for surveys (625 responses are a conservative estimate, we may receive up to 1000)

(5) Updates to site resources and protocol with Venting Wisely pathway branding

(6) Update Principal Investigator's title

Modification 3 – No protocol amendment

To ensure completion of the demographics survey for the focus groups and to preserve the confidentiality of the participants, we will be using Qualtrics to collect focus group participant demographic information. A discussion of the use of Qualtrics to collect demographic data was added to the Focus Group consents (consent and oral consent).

Modification 4 (protocol version 2.1 to 2.2 June 13, 2022)We are submitting this ethics modification to request permission to provide a $50 gift card to clinicians who participate in a focus group to thank them for their time. For the past six weeks have been recruiting clinicians for our first six focus groups. The response rate has been less than 30%. We hope that the cash incentive will boost recruitment and allow us to conduct focus groups.

Modification 5 (protocol version 2.2 to 2.3 September 2, 2022)

To the TheraPPP protocol:
(1) Clarified that sampling in the focus group would be homologous by discipline
(2) Increased the total number of focus groups from 8-12 to "up to 17" in the protocol
(3) Changed the wording from "a total of 32-96" to "approximately 100" participants

To the consent form:
(1) Added details about how the gift card would be provided

To both the consent form and the protocol:
(1) Added the clinician discipline: "Nurse Practitioner"

Modification 6 (protocol version 2.3 to 2.4 October 28, 2022)

We are submitting this ethics modification to:

(1) Request permission to provide one $200 gift card to the unit manager of any of our ICU sites who complete at least 30 acceptability surveys to thank units for their time. In other studies, we have experienced challenges recruiting ICU staff for surveys since Covid-19. We experienced similar challenges recruiting clinicians to this studies' focus groups until we offered a small incentive.
(2) Detail how we will store emails that we use to send the survey.
(3) Update our survey before we send it.

Modification 7 (protocol version 2.4 to 2.5 February 14, 2023)

Editorial updates, added a summary of protocol amendments table. Clarified that the ventilator duration, which is a component of VFDs, will be reported as a secondary outcome.

TITLE: Identification and Treatment of Hypoxemic Respiratory Failure (HRF) and ARDS with Protection, Paralysis, and Proning: TheraPPP (Acceptability Survey – Venting Wisely pathway)

INVESTIGATORS: Dr. Ken Parhar (PI)

SPONSOR: Dr. Tom Stelfox (Department of Critical Care Medicine)
Canadian Institutes of Health Research (CIHR)

This information sheet is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information.

BACKGROUND

Acute hypoxemic respiratory failure (HRF) is common within the Intensive Care Unit (ICU). A significant proportion of these patients develop Acute Respiratory Distress Syndrome (ARDS), which is associated with a mortality of 40-60% in severe cases. Three interventions have been shown to improve the survival of patients with ARDS: Lung Protective Ventilation (LPV), neuromuscular blockade (paralysis), and prone positioning. The lack of a standardized approach outlining the management of ARDS patients has resulted in significant variability in the application of these interventions. Moreover, evidence suggests that the rational and algorithmic/pathway approach to the application of these interventions is associated with improved outcomes.

To bridge the gap between research and patient care, and deliver lifesaving therapies for HRF patients in a fair and rational way, the Department of Critical Care Medicine (DCCM) is implementing an evidence-based, stakeholder-informed care pathway (*Venting Wisely*). The pathway was developed using a consensus process and relevant literature findings, and was validated by a broad group of stakeholders across Alberta. The *Venting Wisely* pathway standardizes the diagnosis and management of patients with HRF with the goal of reducing practice variation and improving adherence to evidence-informed therapy.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate the *Venting Wisely* pathway. The specific purpose of this survey is to evaluate clinician knowledge and perceptions about the acceptability of the *Venting Wisely* pathway following implementation.

WHAT WOULD I HAVE TO DO?

You are being asked to take part in a survey to evaluate knowledge about and acceptability of the implementation of the *Venting Wisely* pathway. Because you are an ICU clinician who used the pathway, your knowledge and feedback about pathway implementation is very important. Should you agree to participate, you will complete a short survey (15 minutes) to assess knowledge and acceptability of the pathway.

WHAT ARE THE RISKS?

There are no foreseen risks to participating in this study. You will not be asked to provide any identifying data. All responses will be kept anonymous. Data will be presented in aggregate.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study, there may or may not be a direct benefit to you. The information we gain from this process will be used to inform the full implementation of the pathway. The information you provide will also help with the design of other quality improvement initiatives. It is anticipated the results of this study will be shared with others in the following ways: medical journal articles, medical conferences, and summary report sheets for participants.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary. If you decide to take part, your consent to participate will be implied. You may decline to take part in this study, or at any time during the study you may decide to stop your participation without penalty. Once the survey is submitted, it will be impossible to isolate individual participants which limits data withdrawal from the study at that point.

You will be advised in a timely manner of any new information that becomes available that may affect your willingness to remain in the study.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

To thank you for completing the survey and to encourage participation, if your intensive care unit completes at least 30 surveys, we will provide a $200 gift card to your manager for your unit.

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WILL MY RECORDS BE KEPT PRIVATE?

Your privacy is important to us. The information collected will be stored and maintained confidentially and destroyed as required by law. Your name and personal information will not be made available to anyone who is not involved in this study unless disclosure is required by law.

The results of this study will be published in a medical literature, but your personal information will not be revealed.

AGREEMENT TO PARTICIPATE

Your decision to complete this survey will be interpreted as an indication of your agreement to participate. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time.

If you have further questions concerning matters related to this research, please contact:

Gwen Knight, Research Associate (403) 944-0735
Or
Dr. Ken Parhar (403) 944-0735

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, Research Services, University of Calgary, 403-220-7990.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

TITLE: Identification and Treatment of Hypoxemic Respiratory Failure (HRF) and ARDS with Protection, Paralysis, and Proning: TheraPPP (Focus Group – Venting Wisely pathway)

INVESTIGATORS: Dr. Ken Parhar (PI)

SPONSOR: Dr. Tom Stelfox (Department of Critical Care Medicine)
Canadian Institutes of Health Research (CIHR)

This information sheet is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information.

BACKGROUND

Acute hypoxemic respiratory failure (HRF) is common within the Intensive Care Unit (ICU). A significant proportion of these patients develop Acute Respiratory Distress Syndrome (ARDS), which is associated with a mortality of 40-60% in severe cases. Three interventions have been shown to improve the survival of patients with ARDS: Lung Protective Ventilation (LPV), neuromuscular blockade (paralysis), and prone positioning. The lack of a standardized approach outlining the management of ARDS patients has resulted in significant variability in the application of these interventions. Moreover, evidence suggests that the rational and algorithmic/pathway approach to the application of these interventions is associated with improved outcomes.

To bridge the gap between research and patient care, and deliver lifesaving therapies for HRF patients in a fair and rational way, the Department of Critical Care Medicine (DCCM) is implementing an evidence-based, stakeholder-informed care pathway (*Venting Wisely* pathway). The pathway was developed using a consensus process and relevant literature findings, and was validated by a broad group of stakeholders across Alberta. *Venting Wisely* standardizes the diagnosis and management of patients with HRF with the goal of reducing practice variation and improving adherence to evidence-informed therapy.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate effectiveness and acceptability of the *Venting Wisely* pathway. The specific purpose of this focus group is to evaluate clinician perceptions about the acceptability of the *Venting Wisely* pathway following implementation.

WHAT WOULD I HAVE TO DO?

You are being asked to take part in a focus group to evaluate the acceptability of the *Venting Wisely* implementation. Because you are an ICU clinician who used the pathway, your feedback and input to pathway implementation is very important.

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Complete a short demographic questionnaire in Qualtrics, an online survey platform, about you, your professional role, and hospital you work in.
- Join the focus group through your computer using the Zoom Videoconferencing platform (https://zoom.us) links provided to you by our research team. The focus group facilitator will provide you all the details you need to join the call prior to your focus group date.
- Participate in a discussion on the acceptability of the Venting Wisely pathway.
- Agree to have the study team record the audio of the focus group discussion. It is important to record the discussion so we can accurately document what it said.
- Once the interview is over, a member of the study team will send you a summary of the interview for you to review and provide feedback, should you want. The summary will be deidentified of participant personal information.

HOW LONG WILL I BE IN THE STUDY?

Your participation in this study will take about 1.5 -2 hours.

WHO ELSE WILL BE IN THE STUDY?

In each focus group, there will be up to to eight intensive care unit clinicians (Nurse Practitioners, Registered Respiratory Therapists, Registered Nurses, or physicians). Focus groups will include only one professional designation which means they will consist of only Nurse Practitioners, Registered Respiratory Therapists, or only Registered Nurses, or only physicians.

WHAT ARE THE RISKS?

There are no foreseen risks to participating in this study. You will not be asked to provide any identifying data. All responses will be kept anonymous. Your confidentiality cannot be guaranteed as participants may not hold material confidential. Data will be presented in aggregate.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study, there may or may not be a direct benefit to you. The information we gain from this process will be used to inform the full implementation of the pathway. The information you provide will also help with the design of other quality improvement initiatives. It is anticipated the results of this study will be shared with others in the following ways: medical journal articles, medical conferences, and summary report sheets for participants.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary. If you decide to take part, your consent to participate will be implied. You may decline to take part in this study, or at any time during the study you may decide to stop your participation without penalty. Once the audio recordings are transcribed it will be impossible to isolate individual participants which limits data withdrawal from the study at that point.

You will be advised in a timely manner of any new information that becomes available that may affect your willingness to remain in the study.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

To compensate your time, you will receive a $50 gift card for participating in this research study. After the focus group the facilitator will email participants a $50 "University of Calgary EverythingCard" redemption code. EverythingCard is Canada's most widely used gift card platform to simplify delivery of gift cards. The University of Calgary is using EverythingCard to allow researchers to purchase online codes for subject fees to be distributed to their research subjects as a token of appreciation for their time and effort in participating in a study. The EverythingCard platform allows participants to redeem their codes online and select their own gift card(s) from a variety of retailers.

WILL MY RECORDS BE KEPT PRIVATE?

Your privacy is important to us. The information collected will be stored and maintained confidentially and destroyed as required by law. Your name and personal information will not be made available to anyone who is not involved in this study unless disclosure is required by law. The results of this study will be published in a medical literature, but your personal information will not be revealed.

Your demographic data will be collected in Qualtrics an online survey platform with servers located in Toronto, Ontario, Canada. All data are encrypted and stored directly on its servers. Researcher access to the survey data is password-protected and the transmission is encrypted. IP tracking will be off. Survey responses cannot be linked to your computer. All information will be stored in a secured area (i.e. locked filing cabinet and/or password protected computer).

A third-party transcription service, Rev.com, will be used to transcribe the focus group interviews. Rev.com is an online transcription service that follows best practices handling personally identifiable information with guidance from the published General Data Protection Regulation. Information regarding their privacy policy can be found at https://www.rev.com/about/privacy.

AGREEMENT TO PARTICIPATE

Your participation in the focus group will be interpreted as explicit oral consent of your agreement to participate. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time.

If you have further questions concerning matters related to this research, please contact:

Gwen Knight, Research Associate (403) 944-0735
Or
Dr. Ken Parhar (403) 944-0735

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, Research Services, University of Calgary, 403-220-7990.

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