Conduct of critical care clinical trials in Regina intensive care units during the COVID-19 pandemic

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INTRODUCTION

• Critical care research is complex due to severity and diversity of clinical status among patients admitted to intensive care units (ICUs)
• Ethical complications due to inability of many ICU patients to provide informed consent to participate in clinical trials
• COVID-19 pandemic has significantly affected critical care research in Saskatchewan and internationally
• REMAP-CAP, REVISE, HEMOTION, and EARL are clinical trials in the Regina ICUs (Table 1)

Table 1: Clinical trials in the Regina General Hospital and Pasqua Hospital ICUs

Study Title	Study Design	ICU Population	Interventions
REMAP-CAP Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia	Randomized, embedded, multifactorial adaptive platform trial	Moderate-to-severe community-acquired pneumonia (CAP) and/or COVID-19	Existing and novel treatment options for CAP and/or COVID-19
REVISE Re-EValuating Inhibition of Stress Erosions	Randomized, controlled, double-blinded trial	Invasive mechanical ventilation in ICU	Placebo vs. Pantoprazole
HEMOTION HEMOglobin transfusion threshold in Traumatic brain Injury OptimizatioN	Randomized, controlled, open-label trial	Acute, blunt traumatic brain injury	Restrictive red blood cell (RBC) transfusion strategy vs. Liberal RBC transfusion strategy
EARL Early use of Airway pressure ReLease ventilation in acute respiratory distress syndrome	Randomized, controlled, open-label trial	Invasive mechanical ventilation with acute respiratory distress syndrome	Low tidal volume ventilation vs. Airway pressure release ventilation

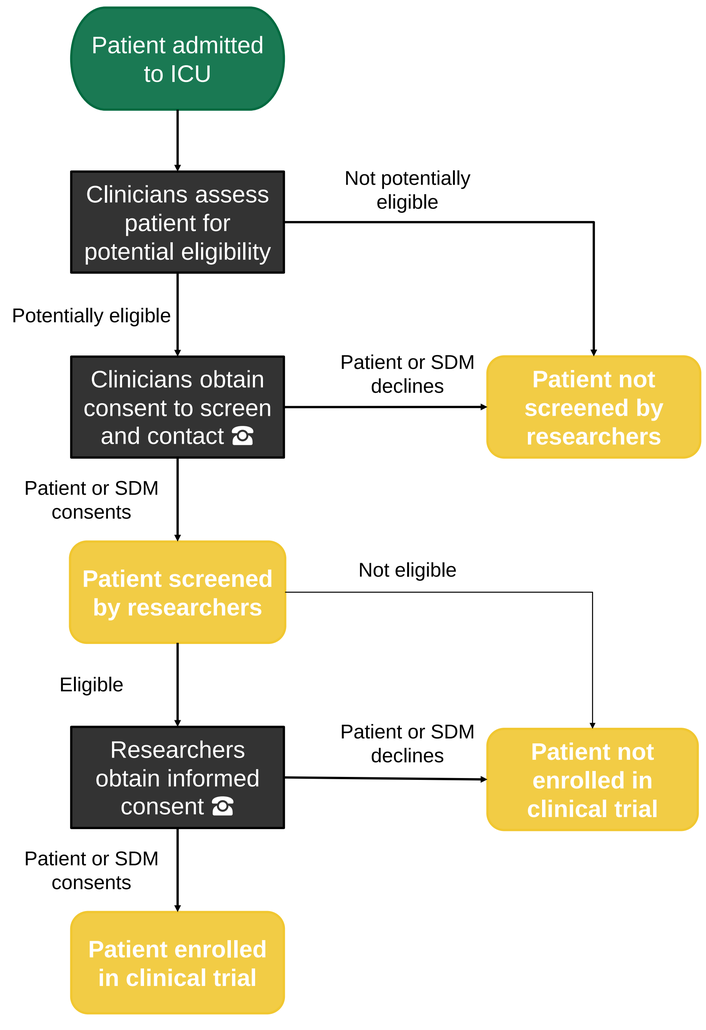
OBJECTIVES

• Describe strategies for and feasibility of conducting clinical research in Regina ICUs during the COVID-19 pandemic

METHODS

• Patient recruitment (Figure 1) adapted for remote enrolment during pandemic
• Over 36 weeks, number of patients screened for eligibility and enrolled, and mode of consent were calculated

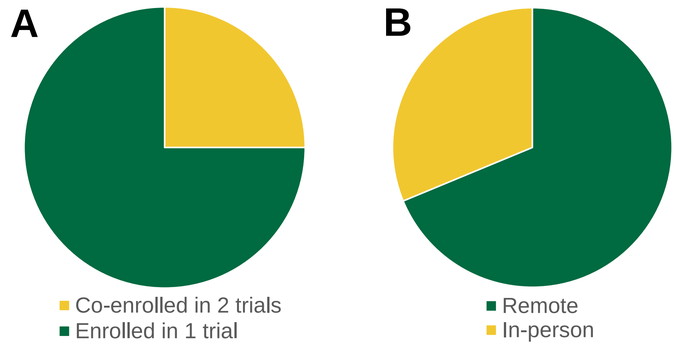
Figure 1: Patient recruitment process. Steps marked with a telephone symbol (☎) were conducted remotely.



RESULTS

• 78 patients admitted to ICU screened for eligibility for average screening rate of 2/week
• 32/78 (41%) screened patients eligible and consented for average enrolment rate of 1/week
• 8/32 (25%) enrolled participants were co-enrolled in two clinical trials (Figure 2A)
• 22/32 (69%) consent conversations occurred remotely (Figure 2B)

Figure 2: Patient recruitment. Figure 2A: Proportion of co-enrollment among enrolled patients. Figure 2B: Mode of consent obtained for clinical trial participants.



DISCUSSION

• Evaluating and adapting trial recruitment during COVID-19 pandemic allowed patient enrollment in ICU clinical trials
• Regina ICU clinical trial involvement provides Saskatchewan residents a previously unprecedented opportunity to participate in Canadian health research and access novel care

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