management of ambulatory patients with urgent health concerns reflects the assumption that primary care facilities can offer high-quality and more affordable ambulatory emergency care. However, no performance assessment framework has been developed for ambulatory emergency care and consequently, quality of care provided in these alternate settings has never been formally compared. Primary objective: To identify structure, process and outcome indicators for ambulatory emergency care. Methods: We will identify and develop quality indicators (QIs) for ambulatory emergency care using a RAND/UCLA Appropriateness Method (RAM) composed of three different steps. First, we will perform a scoping literature review to inventory 1) all previously recommended QIs assessing care provided to ambulatory emergency patients in the ED or the primary care settings; 2) all conditions evaluated with the retrieved QIs; and 3) all outcomes measured by the same QIs. Second, a steering committee composed of the research team and of international experts in performance assessment in emergency and primary care will be presented with the lists of QIrelated conditions and outcomes. They will be asked to identify potential outcome indicators for ambulatory emergency care by generating any relevant combinations of one condition and one outcome (e.g. acute asthma exacerbation/re-consultation). Committee members will be given the latitude to use and pair any conditions or outcomes not included in the lists as long as they think the resulting indicators are compatible with the study objectives. Using a structured nominal group approach, they will combine their suggestions and refine the list of potential QIs. This list of potential outcome indicators composed of pairs "condition/outcome" will be merged with the list of already published QIs identified during the literature review. Third, as per the RAM standards, we will assemble an international multidisciplinary panel (n = 20) of patients, emergency and primary care providers, researchers and decision makers, after recommendations from international emergency and primary care associations, and from the Canadian Strategy for Patient-Oriented Research (SPOR) Support Units. Through iterative rounds of ratings using both web-based survey tools and videoconferencing, panelists will independently assess all candidate QIs. They will be asked to rate on a nine-level scale to what extent each QI is a relevant and useful measure of ambulatory emergency care quality. From one round to the next, QIs with a median panelist rating score of one to three will be excluded. Those with a median score of seven or more will be automatically included in the final list. OIs with median score of four to six will be retained for future deliberations among the panelists. Rounds of ratings will be conducted until all QIs are classified. Impact: The QIs identified will be used to develop a performance assessment framework for ambulatory emergency care. This will represent an essential step toward testing the assumption that EDs and primary care walk-in clinics provide equivalent care quality to low acuity patients.

GD03

Hyoscine butylbromide (Buscopan) versus acetaminophen for nonsurgical abdominal pain in children: a randomized controlled superiority trial

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Background: Children with abdominal pain in the emergency department (ED) are at particular risk of suboptimal analgesia due to fears of missing appendicitis and absent guidelines. Many still experience pain at discharge. Acetaminophen is the most commonly used analgesic and efficacy of hyoscine butylbromide (HBB) is supported by adult evidence. However, no evidence exists for either agent in children with

abdominal pain. Objective: To determine if HBB is superior to acetaminophen for abdominal pain in children. Methods: We will consecutively recruit children 8-17 years presenting to the ED with presumed non-surgical abdominal pain rated >4/10 on the Faces Pain Scale - Revised (FPS-R) and described as colicky, excluding:-Suspected appendicitis or bowel obstruction-Anticholinergic, analgesic, or antispasmodic <12 hours-Peritoneal inflammation-Unable to swallow pills-Hypersensitivity to either intervention-Medically unstable-Previous bowel obstruction, abdominal surgery, myasthenia gravis, liver disease, glaucoma, or recent abdominal trauma (<48 hours)-Toxin ingestion (<24 hours)-Vomiting-Pregnancy Randomization and allocation concealment will be pharmacy-controlled and performed using a computerized random number generator and sequentially numbered, opaque, sealed envelopes, respectively. The physician, research assistant, nurse, and participant will be blinded. Due to perceptible differences, participants will be randomized in a double-dummy approach to:-HBB 10 mg tablet + acetaminophen placebo OR-Acetaminophen 15 mg/kg liquid (maximum 975 mg) + HBB placebo. The primary outcome will be the difference from baseline on the FPS-R at 120 minutes, reflecting HBB's time to peak plasma concentration. The FPS-R has been validated in children > five years. Secondary outcomes include:-Pain scores at 15, 30, 45, 60, 80, 100, and 120 minutes postintervention (FPS-R and 100 mm visual analog scale)-Discharge pain score-Rescue analgesia-Time to achieve a 20% reduction in pain-Adverse effects-Recidivism <48 hours-Missed surgical diagnoses (National Ambulatory Care Reporting System (NACRS) database)-Caregiver satisfaction (five-item Likert scale). Using the intention to treat principle, ordinal, ratio, and categorical data will be analyzed using the Mann-Whitney, paired t-test, and Pearson's chi-square, respectively and summarized using 95% confidence intervals. Assuming a standard deviation of 2 faces, 83 children per group will be required to detect a 1-face difference at 5% significance with 90% power. Increasing by 20% equals 100 participants per group. P values <0.05 will be considered significant. An institutional audit revealed 380 eligible patients per year during research assistant availability. Given a 30% refusal rate, we expect five participants enrolled per week for 40 weeks. Importance: Our findings will guide evidence-based analgesic choices for children with non-surgical abdominal pain in the ED.

GD04

A blinded, randomized controlled trial of opioid analgesics for the management of acute fracture pain in older adults discharged from the emergency department

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Background: Emergency department (ED) providers are frequently challenged with how best to treat acute pain in older patients, specifically when non-opioid analgesics are ineffective or contraindicated. Studies have documented older patients presenting to the ED with painful conditions are less likely to receive pain medications than younger patients, and this oligoanalgesia has been associated with increased risk of delirium and longer hospital stays. Given the concerns for drug interactions, side effects, over-sedation and addiction, emergency physicians often report uncertainty regarding the ideal choice of opioid analgesic in older adults. There are no guidelines informing best practice for the management of acute pain in this population. **Objective:** The primary objective is to compare the efficacy of codeine, oxycodone and hydromorphone for acute fracture pain in older patients discharged from the ED. **Methods:** This will be a blinded, randomized controlled

trial of older adults (age > 70) discharged home from the ED with acute pain secondary to an upper extremity, lower extremity, rib, pelvic or vertebral compression fracture. Patients will be randomized to receive a 3-day supply of codeine, oxycodone or hydromorphone. Patients will also be given acetaminophen. Patients will be contacted by phone or email 3 days following their ED visit. The primary outcome will be differences in pain scores at 3 days assessed using the validated Brief Pain Inventory (Short Form). Secondary outcomes will include side effects (ie: confusion, constipation), adverse events (ie: falls, healthcare visits) and pain interference with daily activity. Patients, physicians and all research staff will be blinded to group allocation. Data Analysis Plan: The study design assumed three arms (codeine, oxycodone and hydromorphone), therefore the 2-tailed alpha will be set to 0.025 to adjust for the increased risk of type-I error with 3 pairwise comparisons. To test for pairwise equality between groups, a 1-way ANOVA will be employed. Proportional differences will be assessed using Pearson chi-square statistic. Sample size calculation: Assuming a mean (SD) change in pain scores between groups of 2.2 (3.0), a minimum clinically important difference on the Brief Pain Inventory of 2.0, a 2-tailed alpha of 0.025 to adjust for 3 pairwise comparisons and a beta of 0.20, we estimate that 47 patients per group (N = 141) will be required. To account for potential loss to follow-up, we will increase our sample size by 25% per group, resulting in a final sample size of 177 patients (59 per group). Importance: All analgesics (including opioids) prescribed to older adults are associated with risk of adverse events. This study seeks to inform ED providers of opioid efficacy, side effects and patientimportant, functional outcomes in this growing patient population.

GD05

Careful Anticoagulation Review in Emergency Medicine (CARe-EM) <u>K. de Wit, MBChB, MD, MSc</u>, M. Mercuri, PhD, A. Worster, MD, McMaster University, Hamilton, ON

Background: The number of patients prescribed anticoagulation for stroke prevention is increasing, along with the proportion of emergency department (ED) patients who are anticoagulant users. Bleeding is the most common side effect. Inappropriate dosing, co-prescription of anti-inflammatories or aspirin, and renal impairment all increase the bleeding risk. An ED visit is an opportunity to review anticoagulant bleeding risks and intervene to prevent bleeding in patients at high risk. Objectives: To establish the 12-month incidence of bleeding in anticoagulated patients visiting the ED, to develop an ED specific anticoagulant-associated bleeding prediction score, to evaluate the ED utility of existing prediction scores. Methods: Research ethics board approval has been granted. Patients will be identified in Hamilton General and Juravinski EDs. Each patient will be followed forward in time for 12 months to document bleeding events. Population: Inclusion criteria: ED patients prescribed warfarin, rivaroxaban, dabigatran, apixaban, edoxaban or low molecular weight heparin (prevalent users). Exclusion criteria: Patients under 16 years of age. Primary outcome: The incidence of major bleeding (defined by ISTH criteria) within 12 months from the index ED visit. Secondary outcomes: Derivation of an ED prediction score to identify patients at high risk of anticoagulant-associated bleeding within 12 months. Tertiary outcomes: Evaluation of ATRIA, modified HAS-BLED and HEMORR2HAGES scores utility in predicting bleeding within 12 months. Data management: The data will be stored anonymously and securely on RedCAP. A literature search/expert discussion has identified multiple potential risk factors for bleeding. This data is collected at the time of the index ED presentation. A committee of emergency, thrombosis, gastroenterology and cardiology physicians will review each major bleeding case. Analysis: Primary analysis: a multiple logistic regression analysis to identify variables associated with major bleeding diagnosed within 12 months of the index presentation. Using the model β coefficients we will derive a simple clinical decision rule. Secondary analysis: assessing the area under the curve and optimal cut points for pre-existing bleeding prediction scores for predicting major bleeding within 12 months. **Sample size calculation:** With 3000 patients we expect 2700 to be anticoagulated long term, and at least 135/2700 patients will have a major bleed. This is a sufficient number for multivariate analysis to establish a simple model. We estimate 20,000 anticoagulated ED patient attendances/year. **Importance:** This is the first study to consider the ED visit an opportunity to prevent bleeding. We will establish a method to identify ED patients at high risk of anticoagulant-associated bleeding.

GD06

Derivation and internal validation of a clinical prognostic tool for recurrent emergency visits for hyperglycemia in patients with diabetes mellitus: a multicentre prospective cohort study

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Background: Patients with poorly controlled diabetes mellitus (DM) often visit the emergency department (ED) for management of hyperglycemic episodes, including diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS). It has been previously reported that risk factors for readmission to the intensive care unit (ICU) in DKA include older age, female sex and the presence of significant comorbidity including sepsis. However, there are no ED-based studies on this topic, particularly in a Canadian setting, and data on outcomes such as recurrent ED visits, hospital or ICU admission after discharge in these patients is lacking. **Objectives**: The primary objective of this study is to derive and internally validate a clinical risk tool for prognosis of patients presenting with hyperglycemic emergencies to identify those at higher risk of adverse outcomes within 30 days of initial ED presentation. Methods: This will be a multicentre prospective cohort study of eligible consecutive adult patients with an ED diagnosis of hyperglycemia, DKA or HHS. We will include all visits of adult (≥18 years) ED patients with either a known or unknown history of DM and a diagnosis of hyperglycemia (blood glucose >11.0 mmol/L), DKA or HHS. We will include patients with co-morbid diagnoses in addition to hyperglycemia. We will exclude patients: a) with advanced care directives for resuscitation involving refusal of treatment, and b) who are initially assessed at a peripheral hospital and transferred to our sites for ongoing management. Research assistants will then contact the enrolled participants via telephone for follow-up regarding clinical outcomes, including repeat visits to see a health care provider, changes in diabetic medications, and time taken off of work or school. Participants will be followed to determine if they have further ED visits, admissions or ICU admissions after their ED visit for hyperglycemia. Data on missed patients or those who refused consent will be collected to assess for selection/enrolment bias. Statistical considerations: The primary outcome will be an unplanned return ED visit for hyperglycemia within 30 days of initial presentation. Secondary outcomes will include unplanned admission to hospital or ICU for hyperglycemia, or death within 30 days of the index ED visit. Additionally, we hope to characterize patient-important and health-care system outcomes such as time taken off work or school and follow-up visits to see a healthcare provider. We will conduct descriptive statistics on investigations, treatments, disposition and patient-important outcomes. We will