Trauma

Leadership

Sheila Sprague, PhD

Brad Petrisor, MSc, MD, FRCSC

Mohit Bhandari, MD, PhD, FRCSC

Herman Johal, MD, MPH, FRCSC, PhD (cand)

Bill Ristevski, MD, MSc, FRCSC

Trauma is the leading cause of death in the first four decades of life surpassed only by cancer and atherosclerosis as the major cause of death in all age groups. For every person killed as a result of an injury, threefold more survive and are left permanently disabled. CEO is committed to addressing important gaps in fracture care through research studies aimed at identifying modifiable surgical risk factors and evaluating simple and cost-effective therapies to improve global fracture care. The Trauma research team at CEO is actively engaged in multiple research studies on optimizing the care of fracture patients, global trauma, interpersonal violence, and distracted driving. These areas of research are detailed below.

Optimizing Care of Fracture Patients

Clinical outcomes following operatively managed fractures of the extremities are variable and complications including infection and persistent pain and many patients continue to experience persistent pain and disability one-year after surgery and beyond. Building on the success of the SPRINT and FLOW trials, the trauma team is conducting a number of large, pragmatic randomized trials aimed at improving outcomes for extremity fracture patients. The PREP-IT program consists of two trials evaluating the effectiveness of alternative skin preparation solutions in both open and closed fractures, and the COPE trial is evaluating the potential for cognitive behavioral therapy to reduce persistent pain following traumatic injuries.

Global Trauma

Worldwide, trauma is the leading cause of death in the first four decades of life. For every death attributable to trauma, three patients survive but are permanently disabled. Globally, the majority of trauma results from road traffic accidents and ranks in the top 10 causes of all-cause disability. Over 90% of road traffic deaths occur in low-middle income countries (LMICs), which account for 84% of the world's population. In alignment with the World Health Organization's objectives for the 'Decade of Action for Road Safety', there is a dire need to identify potentially modifiable risk factors associated with major adverse outcomes in patients

with musculoskeletal injuries. The INORMUS study was designed to investigate global trauma and is currently enrolling across 29 countries worldwide.

Intimate Partner Violence (IPV)

33% of all female fracture clinic patients have experienced IPV at some point in their lives and 17% have experienced it in the past year. As a consequence of abuse, IPV victims suffer from more physical and mental health problems and use health care resources more frequently than non-victims leading to an estimated annual IPV cost of $7.4 billion in Canada. With the desire to help victims of IPV, the CEO is dedicated to developing and evaluating programs that optimize the fracture clinics to provide the best possible care to victims of IPV. In partnership with the Canadian Orthopaedic Association, CEO has completed a number of scoping reviews on IPV in the fracture clinic setting, conducted an international study on the prevalence of IPV in fracture patients (PRAISE), and developed, evaluated and implemented the EDUCATE program.

EDUCATE

The EDUCATE program is an IPV educational program that provides orthopaedic surgeons and health care providers working in fracture clinics with the knowledge and skills that will allow them to comfortably assist women who are victims of intimate partner violence. The EDUCATE program is designed to be both pragmatic and simple in its execution to ensure that it is feasible for busy health care providers to complete. From start to finish the entire program takes only 1 hour. It is delivered using a train-the-trainer model and uses a multi-faceted approach, including: an in-person presentation, videos, case sharing, and interactive discussions. The EDUCATE program is available through our website: www.IPVeducate.com

Distracted Driving

Worldwide, road traffic collisions are a leading cause of traumatic injuries. By 2030, road traffic collisions are anticipated to rank in the top 3 reasons of all-cause disability. In Ontario specifically, the provincial police report that distracted driving is a causal factor in 30% to 50% of road traffic collisions. There is a lack of research describing the devastating impact and economic burden of musculoskeletal injuries sustained as a result of distracted driving. The DRIVSAFE study was developed to fill this gap in knowledge.

Hamilton General – Clinical Program in Trauma

The Trauma Clinical Research Team, sited at the Hamilton General site of Hamilton Health Sciences, is participating as a recruiting centre for several clinical studies being led by CEO researchers. They are also a recruiting centre for a number of prospective multi-centre trauma studies being led by other research teams, including Johns Hopkins, University of Maryland Baltimore, and the Canadian Orthopadic Trauma Society (COTS).

COTS

Current Studies – CEO Methods Centre

PREPARE
(PREP-IT Program)

PREPARE is a cluster randomized crossover trial of at least 7,820 patients with open and closed fractures comparing the effectiveness of two antiseptic skin preparation solutions, iodine-povacrylex (0.7% free iodine) in alcohol versus 2% chlorhexidine gluconate. The primary outcome is surgical site infection and secondary outcomes are unplanned fracture-related reoperation and health-related quality of life.

Principal Investigators: Dr. Gerard Slobogean, Dr. Sheila Sprague, and Dr. Mohit Bhandari

A-PREP
(PREP-IT Program)

Aqueous-PREP is a cluster randomized crossover trial of at least 1,540 patients with open fractures comparing the effectiveness of two aqueous antiseptic skin preparation solutions, 10% povidone-iodine (1% free iodine) and 4% chlorhexidine gluconate. The primary outcome is surgical site infection and secondary outcome is unplanned fracture-related reoperation.

Principal Investigators: Dr. Gerard Slobogean**,** Dr. Sheila Sprague, and Dr. Mohit Bhandari

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COPE

COPE is a randomized controlled trial evaluating cognitive behavioral therapy (CBT) and its effect on persistent post-surgical pain in patients an open or closed fracture of the appendicular skeleton. 1000 patients will be randomly assigned to either usual care or 6-12 weeks of CBT. The pilot study is currently underway.

Principal Investigators: Dr. Jason Busse and Dr. Sheila Sprague

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INORMUS

http://www.inormus.ca/

The **INORMUS** study is a large multi-centre, international, prospective cohort study that will include 40,000 patients with musculoskeletal trauma (fractures and/or dislocations) from Africa, Asia, and Latin America. The objective of the INORMUS study is to determine the incidence of major complications (mortality, re-operation and infection) and the factors associated with these major complications.

Principal Investigators: Dr. Mohit Bhandari, Dr. PJ Devereaux, Dr. Rebecca Ivers, and Dr. Ted Miclau

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Vita-Shock
Optimal Vitamin D_3 Supplementation Strategies for Acute Fracture Healing

Vita-Shock is a single-center phase II exploratory clinical trial seeking to improve patient outcomes in tibia and femur fractures by addressing the nutritional optimization of bone health. Using a randomized placebo-controlled design, the trial compares three different doses of vitamin D_3 and a control (placebo) to assess their effect on fracture healing at three months in 96 patients ages 18-50. Each participant is randomized to one of four treatment groups: 1) 150,000 IU loading dose vitamin D_3 plus daily dose placebo; 2) loading dose placebo plus 4,000 IU vitamin D_3 per day; 3) loading dose placebo plus 600 IU vitamin D_3 per day; or 4) loading dose placebo plus daily dose placebo. The daily treatment commences within one week of injury and is taken for three months. The loading doses are given within one week of injury and at six-weeks post-injury. Participants are followed for 12 months.

Principal Investigators: Dr. Sheila Sprague and Dr. Gerard Slobogean

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Nutrition Study

The Nutrition Study is a cross-sectional survey evaluating the nutritional profile and prevalence of comorbidities among fragility and non-fragility fracture patients aged 18 years or older who present to a fracture clinic. This study also aims to determine the knowledge of different diet strategies among this patient population. This study is currently recruiting participants at the Hamilton General Hospital, with a target enrolment of 363 participants.

Principal Investigators: Dr. Brad Petrisor and Dr. Sheila Sprague

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PRA!SE-2

PRospective Abuse and Intimate Partner violence surgical Evaluation

PRAISE-2 is a pilot prospective cohort study of 300 women with fractures that aimed to determine the feasibility of a large multinational cohort study that examined surgical outcomes (time to fracture healing, fracture-related adverse events, and return to pre-injury function) among those injured women who report, or do not report, a history of abuse. This was the first study to evaluate differences in orthopaedic outcomes between abused and non-abused women and preliminarily assessed whether an injury can lead to worsening abuse by an intimate partner.

Principal Investigators: Dr. Brad Petrisor, Dr. Sheila Sprague

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DRIVSAFE

DRIVSAFE is a multi-site, cross-sectional study, designed to assess the burden of distracted driving on 1315 patients who presented to orthopaedic fracture clinics. The primary aims of the study were to determine: (1) what proportion of patients present with a musculoskeletal injury that was the direct or indirect result of distracted driving; and (2) what types and severity of injuries distracted driving can lead to.

Principal Investigator: Dr. Bill Ristevski

Current Studies – Hamilton General Clinical Program

A-PREP

Aqueous-PREP is a cluster randomized crossover trial of at least 1,540 patients with open fractures comparing the effectiveness of two aqueous antiseptic skin preparation solutions, 10% povidone-iodine (1% free iodine) and 4% chlorhexidine gluconate. The primary outcome is surgical site infection and secondary outcome is unplanned fracture-related reoperation.

Local Principal Investigator: Dr. Brad Petrisor

PREPARE	**PREPARE** is a cluster randomized crossover trial of at least 7,820 patients with open and closed fractures comparing the effectiveness of two antiseptic skin preparation solutions, iodine-povacrylex (0.7% free iodine) in alcohol versus 2% chlorhexidine gluconate. The primary outcome is surgical site infection and secondary outcomes are unplanned fracture-related reoperation and health-related quality of life. **Local Principal Investigator:** Dr. Herman Johal
COPE	**COPE** is a randomized controlled trial evaluating cognitive behavioral therapy (CBT) and its effect on persistent post-surgical pain in patients an open or closed fracture of the appendicular skeleton. 1000 patients will be randomly assigned to either usual care or 6-12 weeks of CBT. The pilot study is currently underway. **Local Principal Investigator:** Dr. Herman Johal
PREVENT-CLOT	PREVENT-CLOT is a multi-centre randomized trial comparing Aspirin versus low molecular weight heparin for the prevention of clinically important blood clots in trauma patients. The trial will enroll over 12,000 participants at up to 30 clinical sites in the United States and Canada. **Local Principal Investigator:** Dr. Herman Johal
INSURT	INSURT is a multi-site randomized trial of 202 patients that compares two different approaches to see if one results in a lower rate and/or intensity of knee pain. One approach is to use a skin incision just below the kneecap (IP); the other involves an incision above (SP). **Local Principal Investigator:** Dr. Brad Petrisor
IMPROVE	IMPROVE is a multi-centre, randomized trial comparing Autologous Platelet Rich Plasma (PRP) versus Autologous Whole Blood versus Dry Needle Tendon Fenestration versus physical therapy exercises alone on pain and quality of life in patients with lateral epicondylitis as measured by the VAS at 12 months. **Local Principal Investigator:** Dr. Mary Chiavaras
Reamer Irrigator Aspirator versus Autogenous Iliac Crest bone graft for the Treatment of Non-Unions: A Multi-Centre Randomized Controlled Trial (RIA vs AICBG)	This multi-site randomized controlled trial compares two bone graft procedures for the treatment of iliac crest non-unions in 104 patients. The primary objective is to determine if one procedure provides the same quantity and quality of bone graft for the treatment of non-unions, as well as a reduction in post-operative pain and a lower rate of complications as the other procedure. **Local Principal Investigator:** Dr. Brad Petrisor

DECIPHER	DECIPHER is a prospective, multi-centre, longitudinal cohort study of proximal humerus fractures aged 50 years or older, with the overarching objective of characterizing patient factors and outcomes in light of the interventions they receive. DECIPHER will address important questions related to the management of patients with proximal humerus fractures and facilitate evidence-based clinical decision making in a field overwhelmed by conflicting opinions. **Local Principal Investigator:** Dr. Bill Ristevski
Nutrition Study	This cross-sectional study aims to determine the nutritional profile and prevalence of comorbidities among fragility and non-fragility fracture patients aged 18 years or older attending a fracture clinic in an academic trauma setting. **Local Principal Investigator:** Dr. Brad Petrisor

Completed Studies – CEO Methods Centre

Primary Paper
SPRINT Investigators. Randomized trial of reamed and unreamed intramedullary nailing of tibial shaft fractures. Journal of Bone and Joint Surgery American. 2008;90(12):2567-78.

Protocol Paper
SPRINT Investigators. Study to prospectively evaluate reamed intramedullary nails in patients with tibial fractures (S.P.R.I.N.T.): study rationale and design. BMC Musculoskeletal Disorders. 2008;9:91.

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Busse JW, Bhandari M, Guyatt GH, Heels-Ansdell D, Kulkarni AV, Mandel S, Sanders D, Schemitsch E, Swiontkowski M, Tornetta P 3rd, Wai E, Walter SD; SPRINT Investigators & the Medically Unexplained Syndromes Study Group. Development and validation of an instrument to predict functional recovery in tibial fracture patients: the Somatic Pre-Occupation and Coping (SPOC) questionnaire. Journal of Orthopaedic Trauma. 2012 Jun;26(6):370-8

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TRUST

Primary Paper

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Secondary Papers

Chang Y, Busse J, Bhandari M, Wei Q, Wang L, Heels-Ansdell D, Zhou Q, Thabane L, Wang M, Lun Zhu K, Petrisor B, Jin L, Kennedy SA, Sprague S, McKay P, Simunovic N, Hu S, Zhang Y, Zhang Y, Guyatt GH, on behalf of the TRUST Investigators. Risk factors for persistent post-surgical pain after tibia fracture: a longitudinal study. Hong Kong Journal of Orthopaedic Research. 2018; 1(1):09-17.

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FLOW Investigators, Bhandari M, Jeray KJ, Petrisor BA, Devereaux PJ, Heels-Ansdell D, Schemitsch EH, Anglen J, Della Rocca GJ, Jones C, Kreder H, Liew S, McKay P, Papp S, Sancheti P, Sprague S, Stone TB, Sun X, Tanner SL, Tornetta P 3rd, Tufescu T, Walter S, Guyatt GH. A Trial of Wound Irrigation in the Initial Management of Open Fracture Wounds. New England Journal of Medicine. 2015;373(27):2629-41.

Protocol Paper

FLOW Investigators. Fluid Lavage of Open Wounds (FLOW): a multicenter, blinded factorial pilot trial comparing alternative irrigating solutions and pressures in patients with open fractures. J Trauma. 2011;71(3):596-606.

Secondary Papers

Petrisor B, Jeray K, Schemitsch E, Hanson B, Sprague S, Sanders D, Bhandari M, On Behalf Of The Flow Investigators. Fluid lavage in patients with open fracture wounds (FLOW): an international survey of 984 surgeons. BMC Musculoskeletal Disorders. 2008;9:7.

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Bhandari M, Devereaux PJ, Guyatt G, Thabane L, Walter S, Heetveld MJ, Jeray KJ, Liew S, Schemitsch EH, Tornetta III P, Della Rocca GJ, Buckley RE, McCormack R, Oliver TM, Segers MJM, Rangan A, Richardson M, Sprague S, Scott T, Agel J, Garibaldi A, Zhou Q, Heels-Ansdell D, Viveiros H, Zielinski SM, Van Lieshout EMM, Johal H, Hanusch BC, Swiontkowski M; FAITH Investigators. A Trial of Fracture Fixation in the Operative Management of Hip Fractures. Lancet. 2017;389(10078):1519-1527.

Protocol Paper

The FAITH Investigators. Fixation using alternative implants for the treatment of hip fractures (FAITH): design and rationale for a multi-centre randomized trial comparing sliding hip screws and cancellous screws on revision surgery rates and quality of life in the treatment of femoral neck fractures. BMC Musculoskelet Disord. 2014;15(1):219.

Secondary Papers

Zielinski SM, Viveiros H, Heetveld MJ, Swiontkowski MF, Bhandari M, Patka P, Van Lieshout EM; FAITH trial investigators. Central coordination as an alternative to per patient payment in a multicenter randomized controlled trial: the FAITH trial experience. Trials. 2012;13:5. doi: 10.1186/1745-6215-13-5.

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Slobogean GP, Felton J, Jackson SS, Dell Rocca GJ, Liew S, Haverlag R, Jeray KJ, Sprague S, O'Hara NN, Swiontkowski M, Bhandari M. Femoral Neck Shortening After Hip Fracture Fixation is Associated with Inferior Hip

Function: Results from the FAITH Trial. Journal of Orthopaedic Trauma. 2019 Aug 26. [Epub ahead of print]

Okike K, Udogwu UN, Isaac M, Sprague S, Swiontkowski M, Bhandari M, Slobogean G, on behalf of the FAITH Investigators. Not All Garden-I and II Femoral Neck Fractures in the Elderly Should Be Fixed: Effect of Posterior Tilt on Rates of Subsequent Arthroplasty. JBJS. 2019 Oct; 101(20): 1852-1859.

PRAISE

PRevalence of Abuse and Intimate Partner Violence Surgical Evaluation

Primary Paper

PRAISE Investigators, Sprague S, Bhandari M, Della Rocca GJ, Goslings JC, Poolman RW, Madden K, Simunovic N, Dosanjh S, Schemisch EH. Prevalence of Abuse and Intimate partner violence Surgical Evaluation (PRAISE) in orthopaedic fracture clinics: A multi-national prevalence study. The Lancet. 2013;382(9895):866-876.

Protocol Paper

PRAISE Investigators. PRevalence of Abuse and_Intimate Partner Violence Surgical Evaluation (P.R.A.I.S.E.): Rationale and design of a multi-center cross-sectional study. BMC Musculoskeletal Disorders. 2010;11:77.

IPV Scoping Review

Primary Paper

Sprague S, Scott T, Garibaldi A, Bzovsky S, Slobogean GP, McKay P, Spurr H, Arseneau E, Memon M, Bhandari M, Swaminathan A. A scoping review of intimate partner violence assistance programmes within health care settings. Eur J Psychotraumatol. 2017 May 5;8(1):1314159. doi: 10.1080/20008198.2017.1314159. eCollection 2017.

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EDUCATE

www.IPVeducate.com

Primary Paper

EDUCATE Investigators. Novel educational program improves readiness to manage intimate partner violence

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Secondary Paper
Sprague S, EDUCATE Investigators. A Qualitative Evaluation of the Implementation of an Intimate Partner Violence Education Program in Fracture Clinics. Journal of Family Violence. 2018 May 11; 0885-7482.

Primary Paper
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FAITH-2 Investigators, Slobogean GP, Sprague S, Bzovsky S, Heels-Ansdell D, Thabane L, Scott T, Bhandari M. Fixation using alternative implants for the treatment of hip fractures (FAITH-2): design and rationale for a pilot multi-centre 2 × 2 factorial randomized controlled trial in young femoral neck fracture patients. Pilot Feasibility Studies. 2019 May 28;5:70.

Health
Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty Versus Hemi-Arthroplasty

Primary Paper
HEALTH Investigators, Bhandari M, Einhorn TA, Guyatt G, Schemitsch EH, Zura RD, Sprague S, Frihagen F, Guerra-Farfán E, Kleinlugtenbelt YV, Poolman RW, Rangan A, Bzovsky S, Heels-Ansdell D, Thabane L, Walter SD, Devereaux PJ. Total Hip Arthroplasty or Hemiarthroplasty for Hip Fracture. New England Journal of Medicine. 2019 Sep 26. [Epub ahead of print]

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Bhandari M, Devereaux PJ, Einhorn TA, Thabane L, Schemitsch EH, Koval KJ, Frihagen F, Poolman RW, Tetsworth K, Guerra-Farfán E, Madden K, Sprague S, Guyatt G; HEALTH Investigators. Hip fracture evaluation with alternatives of total hip arthroplasty versus hemiarthroplasty (HEALTH): protocol for a multicentre randomised trial. BMJ Open. 2015:13;5.

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