Title

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INORMUS: Coordinating a Large-Scale Multicenter Global Prospective Cohort Study

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Abstract

Traditionally, the orthopaedic trauma literature has been dominated by small studies that were largely single-centre initiatives. More recently, there has been a paradigm shift towards larger, multi-centre studies, as the orthopaedic community embraced the concepts of evidence-based medicine and the need for high quality research to guide clinical practice. The International Orthopaedic Multi-Center Study in Fracture Care (IMORMUS) is a large multi-center international cohort study in musculoskeletal trauma in Africa, Asia, and Latin America. This is the first study of this magnitude within the global orthopaedic trauma community. The INORMUS study has provided an opportunity to form new international collaborative relationships, and to develop new research capacity and global collaborative relationships that will provide the foundation for future studies in injury prevention and management.

Levels of Evidence: IV

*Please refer to Appendix B for a full list of the INORMUS Investigators

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Conflict of interest disclosure:

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Keywords

musculoskeletal trauma; INORMUS; global studies; international collaboration

Global Research in Orthopaedic Trauma

Traditionally, the orthopaedic trauma literature has been dominated by small studies that were largely single-centre initiatives. More recently, there has been a paradigm shift towards larger, multi-centre studies, as the orthopaedic community embraced the concepts of evidence-based medicine and the need for high quality research to guide clinical practice. This shift has fostered new international collaborative relationships within the orthopaedic trauma community and the establishment of research networks capable of conducting large international studies. However, to date, relatively few of these research initiatives have included investigators and clinical centres outside of North America, Europe, and Australia or have addressed the gap in our knowledge regarding prognosis and outcomes associated with musculoskeletal injuries on a global scale.

We describe our experiences with organizing a large cohort study in musculoskeletal trauma in Africa, Asia, and Latin America. The International Orthopaedic Multi-Center Study in Fracture Care (IMORMUS) has the potential to increase our understanding of the global burden of trauma. However, even more importantly, this study has provided an opportunity to develop new research capacity and global collaborative relationships that will provide the foundation for future studies in injury prevention and management.

The INORMUS Study

The International Orthopaedic Multi-Center Study in Fracture Care (INORMUS) is a large prospective cohort study of 40,000 men and women with musculoskeletal trauma in LMICs. INORMUS aims to determine the incidence of major complications (mortality, re-operation, and infection) of musculoskeletal trauma adult patients within 30 days post hospital admission, and to determine factors associated with these major complications.[1] The secondary objective of the study is to determine the rates of major complications within 30 days post-hospital admission by type of fracture treatment provided. All patients 18 years of age or older admitted to a recruiting hospital for treatment of an orthopaedic injury that occurred within 3 months will be eligible for participation. Patients who are diagnosed with an orthopaedic fracture, dislocation, or fracture dislocation of the appendicular skeleton or spine are eligible for inclusion. The primary outcome is mortality within 30 days from hospital admission for all of our research objectives. The secondary outcomes are re-operation and infection within 30 days from hospital admission.

As of April 2018, 29,500 patients have been enrolled in the INORMUS study at 50 hospitals in 17 countries including China, Uganda, Kenya, Tanzania, South Africa, Nigeria, Botswana, Ghana, India, Pakistan, Nepal, Vietnam, Thailand, Philippines, Iran, Mexico, and Venezuela (Figure 1). We have recently recruited 6 additional hospitals in Brazil, Ecuador, Bolivia, Paraguay and Uruguay and expect to recruit a total of 5,000 patients in Latin America.

Laying the Groundwork

1. The INORMUS Pilot Study

To assess the feasibility of the proposed INORMUS study, we conducted a pilot study at 14 hospitals with a wide geographic distribution in India.[2] Approximately 5,000 patients were enrolled in the pilot phase of the study between October 2011 and June 2012. This pilot study allowed us to develop our core study infrastructure and assess the feasibility of recruiting within our proposed study timelines. It also enabled us to refine our protocol and case report forms to ensure that our simplified study design and minimal dataset would facilitate data collection on a global scale. This pilot study also provided an opportunity for bidirectional learning in which all parties were able to share their respective expertise.

Our successful completion of the pilot phase of INORMUS was made possible through our ability to leverage existing collaborative relationships with key researchers in India. Through these pre-existing relationships, we were able to identify and engage a network of investigators and clinical sites, and to work collaboratively to resolve logistical challenges associated with the start-up and daily management of the study from Center for Evidence-Based Orthopaedics (CEO) methods centre at McMaster University in Hamilton, ON, Canada.

2. Building International Partnerships and Collaborations

The success of the INORMUS pilot study in India demonstrated feasibility of the INORMUS protocol and enabled our team to secure funding from the Canadian Institutes for Health Research (CIHR) in 2014 for the global phase of the study. However, we encountered a number of challenges during the initiation of the definitive study. These challenges included identifying and engaging local investigators in countries where our team had few or no existing relationships, evaluating potential sites' ability to participate in the study with respect to infrastructure and resources, and understanding local and/or national guidelines, policies, and practices for conducting research. These challenges highlighted the need to engage partners with local expertise in each global region. Consequently, we identified regional leads or "champions" for each geographic region. These individuals, who are all highly invested in improving the care of trauma patients, generated interest in the study through their personal contacts and through networking at local meetings and conferences. They also serve as liaisons between the local site investigators, the Principal Investigators, and the CEO methods centre team. Their knowledge and expertise have been instrumental during all phases of the study including selection and evaluation of potential sites, site start-up and training, and ongoing conduct of the trial at sites within their regions.

Another need we identified early in the process of global expansion was the need establish a larger central investigative team with established researchers to both develop study methodology and to facilitate conduct of the study globally. This was particularly important for recruitment of patients from centres in geographically distant regions from Canada including Asia, Africa and Latin America. In 2014, The George Institute of Global Health (TGI) in Sydney, Australia joined the INORMUS team. The TGI group has extensive experience in leading large-scale studies on injury prevention and management in

India, China, and Southeast Asia. Their research offices in India and China are staffed with research personnel who are fluent in local languages and have a comprehensive understanding of both the local policies and the cultural sensitivities involved in conducting research in this geographic region. Additionally, TGI has a large and well-established network of surgeons and researchers who are highly invested in the care of trauma patients. The GI research teams serve as liaisons between the McMaster global methods centre and our participating sites in China and India. They have played an integral role in all aspects of study management including site identification, initiation and training, monitoring data quality, and conducting on-site monitoring visits for all sites across India, China, Southeast Asia and multiple sites in Africa. We were also successful in leveraging our initial CIHR funding to obtain significant funding from Australia's National Health and Medical Research Council (NHMRC) to support the INORMUS initiative in Asia and Africa.

Using the same collaborative model, we have partnered with the Institute of Global Orthopaedics and Traumatology (IGOT) at the University of California, San Francisco to launch the INORMUS study in Latin America. The IGOT team is dedicated to the treatment of musculoskeletal injuries in LMICs through sustainable research and educational programs. A main focus of IGOT is to build research capacity of orthopaedic and trauma surgeons in resource-constrained environments through sustainable programs that address locally-relevant research questions, quality and efficiency of care, and health care advocacy. Since its foundation in 2006, IGOT has established a network of over 28 partners and affiliates across 14 countries in Latin America, and has extensive experience in conducting research in this region. Our INORMUS study team is currently leveraging IGOT's expertise to expand the INORMUS study in Latin America and to pursue additional funding to support participating sites in this region.

INORMUS Study Organizational Structure and Study Management

1. Study Organization and Committees

This global study is being collaboratively led by a multi-national team of Principal Investigators from CEO, TGI, and IGOT. The Principal Investigators are supported by established methods centre infrastructure at all three institutions and a number of study committees consisting of key collaborators from around the world (Figure 2).

The Operations Committee is comprised of a small number of key investigators from the three lead institutions. They provide guidance and direction to the overall study and will also be responsible for leading knowledge dissemination activities. The Global Steering Committee includes orthopaedic surgeons, research methodologists, and a statistician. This committee provides guidance and direction to the overall study, and is responsible for resolving and challenges that arise during the study. The Steering Committee's membership includes the members of the Operations Committee as well as region lead experts (Figure 2). Each region's Lead and Co-Lead are also responsible for managing the clinical sites within each of their jurisdictions and reporting any issues to the Principal Investigators and Steering Committee members. At the completion of the study, the Steering Committee will oversee manuscript preparation on behalf of all study investigators and participating clinical sites.

2. Methods Centers and Day-to Day Management of the Study

The CEO global methods centre at McMaster University is responsible for central coordination of the study. The CEO has established the necessary personnel and physical infrastructure to successfully lead global surgical trials and large observational studies. Research personnel include research methodologists, research project managers, research assistants, data managers, statisticians, and data analysts. Project Managers at the CEO methods centre work closely with their counterparts at the GI and IGOT methods centres to manage the day-to-day activities of the study. Within their geographic regions, the GI and IGOT investigators and research personnel liaise between the clinical site investigators and the CEO methods centre. They are actively engaged in identifying and selecting new site investigators, and assisting newly selected clinical sites with start-up activities including obtaining ethics approval, negotiating contracts, and developing local study processes.

The CEO methods centre is responsible for overall data management for the trial. Project Managers at the CEO review and validate the clinical data, conduct remote data monitoring, address queries, prepare screening and enrolment reports, prepare study updates, and generate quality control reports. The INORMUS study teams at GI and IGOT communicate regularly with the clinical sites in their geographic regions, including following up on data quality issues, answering study-related questions, and conducting on-site monitoring visits as appropriate. In addition to this regular communication, all site investigators and research personnel receive regular updates on enrollment and study progress through electronic newsletters. Annual orthopaedic conferences and meetings of international research networks, including the Asociasion de Cirujanos Traumatologos en las Americas (ACTUAR), provide an opportunity for INORMUS collaborators to meet face-to-face. Ongoing concerns regarding participating clinical sites including contracting issues, data quality issues, and rates of recruitment or follow-up are escalated by the CEO, GI, and IGOT project management teams to the regional leads and Operations Committee. Any issues that cannot be unresolved by the regional leads are then escalated to Operations Committee and Steering Committee as appropriate.

Conclusion

INORMUS is among one of the largest cohort studies conducted to date in the field of orthopaedic surgery. We have succeeded in initiating 50 clinical sites and enrolling over 25,000 patients by engaging a collaborative global team of investigators and methods centres. Their expertise and dedication have been instrumental in understanding and working through the infrastructure limitations as well as the ethical, cultural and operational challenges associated with conducting high quality global research.

While the INORMUS study is poised to directly address a critical gap in our knowledge regarding the burden of trauma, the most important contribution of INORMUS is the establishment of global research infrastructure. Furthermore, it will lay the groundwork for the development of future trials to test simple, life and limb saving interventions that have the potential to dramatically improve global care of musculoskeletal injuries. The lessons learned from INORMUS in regards to building research capacity and the collaborative

relationships that we have fostered will enable the global orthopaedic community to answer many important questions in injury care for years to come.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Appendix A: Funding Sources

The INORMUS study is funded by grants from the National Health and Medical Research Council of Australia (APP1084967), the Canadian Institutes of Health Research (MOP133609), McMaster Surgical Associates, and Hamilton Health Sciences.

Appendix B: INORMUS Investigators

Steering Committee: Mohit Bhandari (Chair, McMaster University); PJ Devereaux (Co-Chair, McMaster University); Gordon Guyatt, Brad Petrisor, Lehana Thabane (McMaster University); Respicious Boniface (Muhimbili Orthopaedic Institute); Bruce Browner (University of Connecticut Health Center); Fernando de la Huerta (Mexican Institute for Social Security); Rebecca Q Ivers (The George Institute for Global Health); Theodore Miclau III (University of California); Paul Moroz (Ottawa University); Andrew Pollak, Gerard Slobogean (University of Maryland); Parag Sancheti (Sancheti Institute for Orthopaedics and Rehabilitation); Emil Schemitsch (University of Toronto); and Junlin Zhou (Beijing Chaoyang Hospital, Capital Medical University).

McMaster University Global Method Center: Mohit Bhandari (Principal Investigator); Sheila Sprague (Research Methodologist); Paula McKay, Chuan Silvia Li, Raman Mundi, Nathan O'Hara (Project Management); Diane Heels-Ansdell (Data Analysis); Lisa Buckingham (Data Management); and Nicole Simunovic (Grants Management).

The George Institute for Global Health Method Center: Rebecca Q Ivers (Lead Investigator); Jagnoor Jagnoor, Robyn Norton, Jing Zhang, Maoyi Tian, Soumyadeep Bhaumik (Project Management).

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Figure 1:

Hospital admission delay disaggregated by sex and region in all patients (A), where delay is defined as >24 hours, and open fracture patients (B), where delay is defined as >2 hours. Time is reported as the log10 transformation of days to hospital admission.

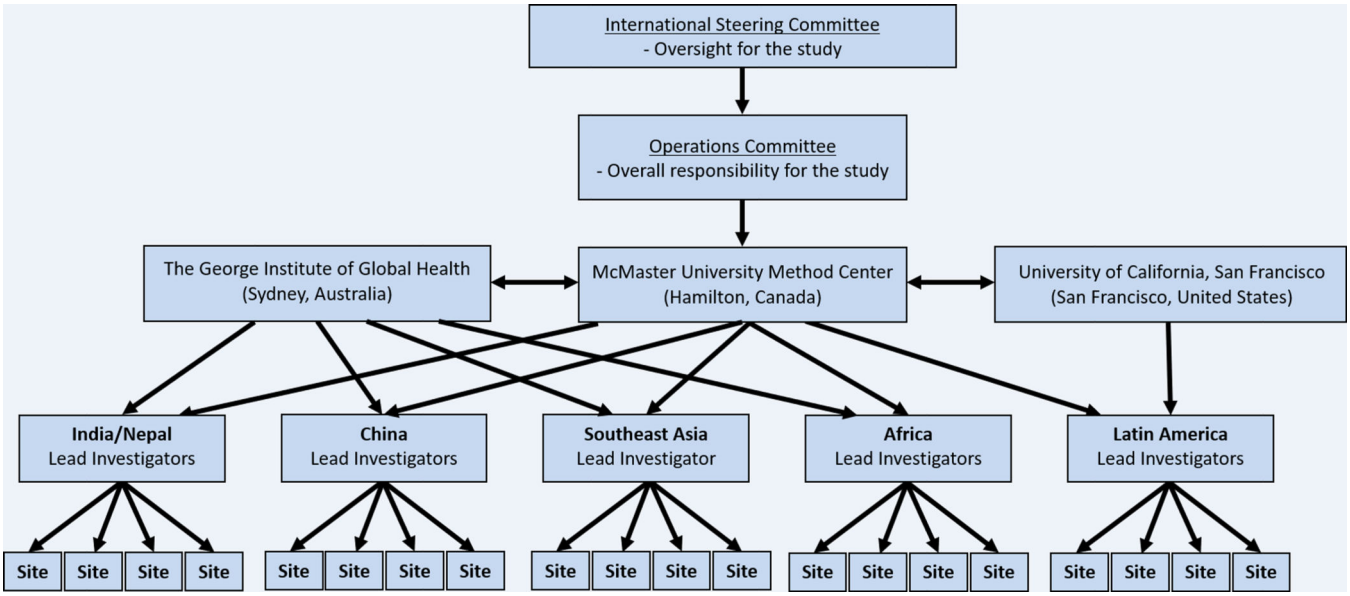

Figure 2:

The reasons for hospital admission delay of > 24 hours disaggregated by sex (A) and the distribution of hospital admission times for each reason for delay disaggregated by sex (B). Time is reported as the log10 transformation of days to hospital admission.