Welcome to the May 16, 2024 Society of Clinical Research Associates (SOCRA) Baltimore Chapter Meeting



https://www.socra.org/chapters/list-of-chapters/view/Baltimore

https://www.linkedin.com/showcase/baltimore-socra-chapter/

SOCRABaltimore@gmail.com

Etiquette and Reminders

- Audio off, Video on (if you can)
- Hold questions to the Q&A (chat or unmute if prompted)
- Continuing Education (CE) credit and slides:
 - Available only to SOCRA members upon survey completion (download from "end of survey" page)
 - Survey link posted in chat at end of meeting
 - Slides/CE will not be emailed or automatically given!



SOCRA Baltimore Chapter Committee

Media Coordinator

Sarah L. Wicks, MPH, J.D.



Development Coordinator

Michelle Medeiros, MS, MA, CCRP



Chair

Casey Jackson, MS, CCRP



Administrator

Ezzat Mostafa, CCRP



Co-Chair

Scott Wehage, MS, CCRP



About



In order to promote quality clinical research, to protect the welfare of research participants, and improve global health, SOCRA's mission is:

- To establish educational programming and provide continuing education for clinical research professionals
- To establish an internationally recognized certification program for clinical research professionals (CCRP®)
- To foster the professional development and peer recognition of clinical research professionals



Offerings

Professional certification (CCRP)

https://www.socra.org/certification/program-overview

- No-cost CITI program access
- SOCRA Source journal
- 17 different types of live, in-person conferences
- Multiple ongoing live, virtual webinars
- Numerous online courses on a variety of topics

https://www.socra.org/conferences-and-education/

Networking and community!

- Stay tuned for in-person local chapter meet & greet!
- Many local chapters have open meetings!

https://www.socra.org/chapters/list-of-chapters/

SOCRA Events, News, and Info

- Board of Directors Elections complete, congrats to incoming board!
- Annual Conference 2024- Vegas!
 - Registration: https://www.socra.org/annual-conference/2024/register-to-attend/
 - Poster Program- deadline 7/21: https://www.socra.org/annual-conference/poster-program/poster-program/
 - Ask your employer for support! https://www.socra.org/resources-and-faq/support-justification-letters/
- ► SOCRA is on YouTube! https://www.youtube.com/@socra/videos
- Upcoming Events

https://www.socra.org/conferences-and-education/events-calendar/

Clinical Trials Day! May 20th, 2024: https://www.socra.org/membership/volunteer/clinicaltrialsday/

Member Highlight: Sydnee Moses

- Role: Pediatric Oncology Clinical Research Coordinator/Carilion Clinic
- Research Experience: Research Assistant for 2
 yrs, CRC for 9 months. Part of a team that
 compared mouse and human optic nerve to
 develop new drug treating optic nerve
 astrogliosis. Enjoy working in pediatric
 oncology to see how research cures cancer.



- SOCRA membership: 9 months
- Unique Fact: I just bought my first house! I also own a basset hound and German Shorthaired Pointer.



2024 Baltimore SOCRA Chapter Goals: Progress

- ► In-person networking event planning
- ► Increase media presence- ongoing
- ► Chapter committee expansion Done (Welcome Ezzat!)
- ► Chapter Member Highlights- Started
 - -Crystal Vaughn, Sydnee Moses
- ► Chapter member presentation- ongoing
 - -Scott Wehage, Functional Medicine
 - -Who else????!!!!
- Chapter member poster submission for annual conference
 - -Come on! You can do it!

Today's Speaker



Jeffrey Wells
Patient Professor
NIH and UMB IRB Member
Rockstar Human Being

PREPHI

THE VOICE OF THE PATIENT

Jeffrey L. Wells

SELF-ACTUALIZA-TION

morality, creativity, spontaneity, acceptance, experience purpose, meaning and inner potential

SELF-ESTEEM

confidence, achievement, respect of others, the need to be a unique individual

LOVE AND BELONGING

friendship, family, intimacy, sense of connection

SAFETY AND SECURITY

health, employment, property, family and social abilty

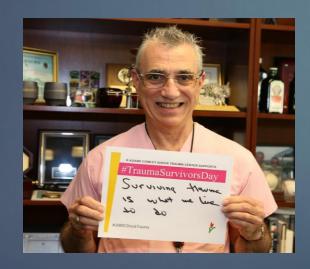
PHYSIOLOGICAL NEEDS

breathing, food, water, shelter, clothing, sleep

Maslow's Hierarchy of Needs

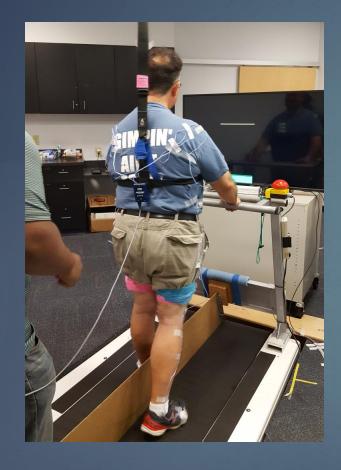
1. Physiological Needs







2. Safety and Security





3. Love and Belonging









13

4. Self Esteem







PREP-III

A Program of Randomized trials to Evaluate Pre-operative antiseptic skin solutions In orthopaedic Trauma

The PREP-IT Investigators

A-PREP PREPARE

Question

What is the effectiveness of surgical skin preparation with iodophor solutions vs chlorhexidine solutions at reducing 90-day surgical site infections and unplanned fracture-related reoperations within 1 year of injury?

Huh?

Patient Partners



Jana Palmer



Debra Marvel



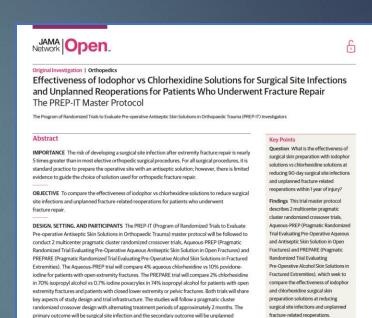
Jeff Wells

The PREP-IT Patients-Centered Outcome Core

Will be responsible for representing patient and caregiver values and for providing direction on all patient and stakeholder engagement activities

Informed Key Aspects of the Protocol

- Deferred consent model
- Eligibility criteria
- Outcomes
- Follow-up schedule
- Language (e.g., avoid abbreviations, define complex terms, etc.)



Meaning Because prophylactic skin

antisepsis is used prior to all surgica

procedures and the application, cost,

and availability of all study solutions are

similar, the results are poised to inform

clinical guidelines and bring about

Author affiliations and article information are

change in clinical practice.

listed at the end of this article.

fracture-related reoperations within 12 months. The Aqueous-PREP trial will enroll a minimum of

1540 patients with open extremity fractures from at least 12 hospitals; PREPARE will enroll a

minimum of 1540 patients with open extremity fractures and 6280 patients with closed lower

extremity and pelvic fractures from at least 18 hospitals. The primary analyses will adhere to the

variability. The patient-centered design, implementation, and dissemination of results are guided by

DISCUSSION The PREP-IT master protocol increases efficiency through shared trial infrastructure and study design components. Because prophylactic skin antisepsis is used prior to all surgical procedures and the application, cost, and availability of all study solutions are similar, the results of

the PREP-IT trials are poised to inform clinical guidelines and bring about an immediate change in

TRIAL REGISTRATION Clinical Trials.gov Identifiers: NCTO33853O4 and NCTO3523962

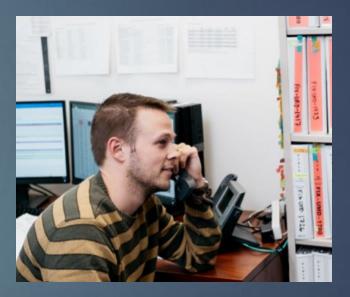
JAMA Network Open, 2020;3(4):e202215.

intention-to-treat principle and account for potential between-cluster and between-period

a multidisciplinary team that includes 3 patients and other relevant stakeholders.

Informed Consent Form Development

- Discussed the purpose of informed consent
- Patient partner shared their experience as a study participant during the consent process
- Reviewed timing of the consent
- Simplified the language in the informed consent form
- Informed the use of telephone consent



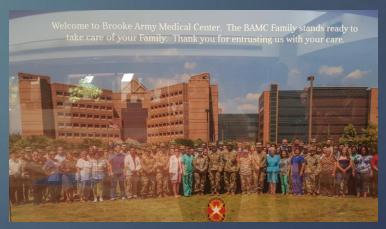
Site Initiation Visits



JACKSONVILLE, FL

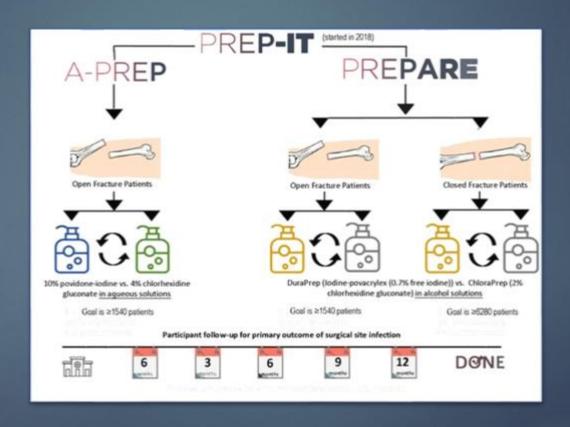


GREENVILLE, SC

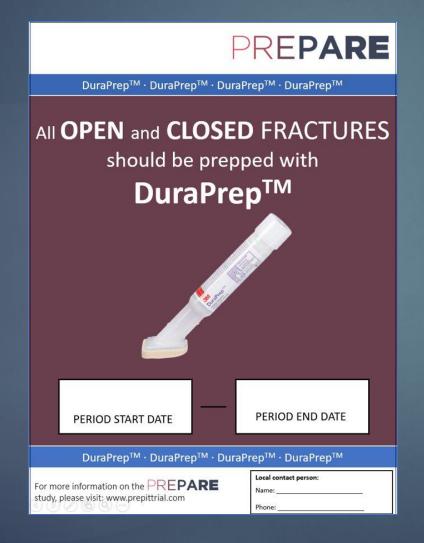


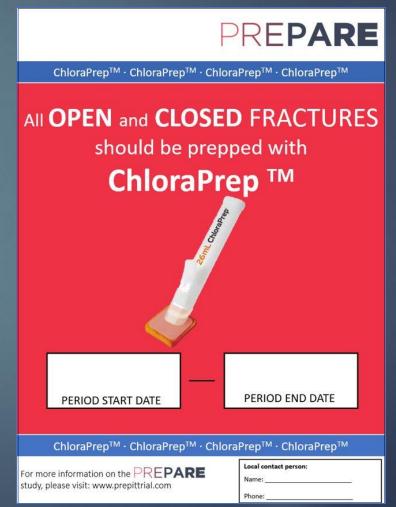
SAN ANTONIO, TX

Development of a Trial Visual



Development of Clinical Site Posters





Newsletters

Aqueous-PREP Overview

The overall objective is to compare the effectiveness of aqueous preoperative antiseptic skin preparation with 10% povidone-iodine vs. 4% chlorhexidine gluconate (CHG) for the management of open fractures. The primary outcome for comparison is surgical site infection (SSI) and the secondary outcome is unplanned fracture-related reoperation.

PREPARE Overview

The overall objective of this trial is to compare the effectiveness of jodine povacrylex (0.7% free iodine) in 74% sopropyl alcohol (DuraPrep™) vs. 2% CHG in 70% isopropyl alcohol (ChloraPrep™) for the management of open fractures and closed lower extremity and pelvic fractures. The primary outcome for comparison is surgical site infection (SSI) and the secondary outcome is unplanned fracturerelated reoperation.

PREP-IT Rounds

REMINDER! Our March PREP-IT Rounds Session is this Friday March 5th, 2021 from 1pm to 3pm EST. Leah, Lucas, and Roman will be presenting on time to ORs during the COVID-19 pandemic, fracture classifications, and injury severity scores, This information packed session is one not to miss!

PREP-IT Website

Did you know that we have a PREP-IT website? If you are looking for trial updates, current resource binder documents, recordings of past rounds, you can find it all here: www.prepittrial.com. The password to access study documents are "aprep" and "prepare."

Aqueous-PREP Enrolment Update

NEWSLETTER | February 2021

Aqueous-PREP has enrolled 1,562 The first entry on the antibiotics log should participants across 14 sites (Table 3), correlate with the response to Q3 on the Currently 7 sites are enrolling and have Peri-Operative Care Form. When completing enrolled 26 participants in the month of these forms, make sure to check that these February.

PREPARE Enrolment Update

PREPARE-Open has enrolled 1,226 study participants across 18 sites, with 26 We are very excited to have the HO subparticipants enrolled in January (Table 6), study underway at sites in the PREPARE trial. PREPARE-Closed has enrolled 5,582 If your site requires local ethics approval, participants across 21 sites, with 164 please let David know once approval is participants enrolled in February (Table 7). obtained to discuss the next steps.

We are pleased to announce that there are Data entry tips for the HO sub-study: two new sites that will be initiating 1) enrolment in the PREPARE trial. Cedars Sinai Medical Center has recently received ethics approval finalized their contract, and will be starting their run-in period in the coming weeks. Bryan Health Trauma Center has started their run-in period on March 3.

Congratulations to both sites!

The Methods Centre will be preparing invoices over the next few weeks. Please take some time to reply to gueries and complete data entry in an effort to maximize payment for this quarter. We would like to remind you that incomplete event forms and missing adjudication source will impact

Heterotopic Acetabular (HO) Sub-

- The HO form can be added from the same drop down menu containing the Antibiotics Log and Planned Fracture Surgery Form.
- Please use the date the form is completed as the 'Start Date' when adding an HO form.
- There is no minimum amount of time from the date of injury before the HO CRF can be completed. If the participant has multiple follow-up visits completed please use the most recent visit.
- Acetabular fractures treated via lateral and anterior-only approaches are not eligible. Please select 'No' to question 1 for these participants.

PREP-IT Monthly Enrollment 20/21



PREP-IT Spotlight Wake Forest Baptist Health

Wake Forest Baptist Medical Center is an academic medical center located in Winston-Salem, North Carolina, which is part of Charlotte-based Atrium Health. Wake Forest Bantist Medical Center has 885 beds and 1 334 School of Medicine Faculty. The hospital provides \$373.9 million in annual community benefit through community health, education and uncompensated charity care. Wake Forest Baptist Medical Center is also a Level 1 trauma center serving the entire Piedmont region of North Carolina. It houses one of three Level 1 Pediatric Trauma Centers in North Carolina.

What motivates your site to work hard to make the PREPARE trial a

Working at Wake Forest Baptist Health with such a great study staff alone is motivating. It's easier to work hard when everyone on the team share the

How does your site keep your data consistently clean and query free? ORGANIZATION! We thoroughly review each participant's medical record taking note of every detail, ensuring data is captured correctly. We always ask questions if we are not 100% sure about something. It is always beneficial to get a second opinion from the study surgeon or from another member of your study team! If you work as a team and set up a system, the study workflow is better. We quickly double check each other's work which helps minimize

How has COVID-19 impacted the way you conduct the trial on a dayto-day basis?

Communication between the team has been key during the pandemic. especially since we have had to work remotely at times. We connect regarding study issues via email, telephone, and virtual meetings. We prioritize study tasks and split up the responsibilities between the team. We provide daily updates on what we have accomplished to reduce duplicate work.

PA Janet Syme has played an integral part in maintaining study enrollment during COVID. We provide her with a daily list of in house candidates and she approaches them as she does her daily rounds. If the patient is interested, she lets us know and we consent them via telephone.



Visiting Winston-Salem?

Old Salem Museums and Gardens is a must see if you are visiting Winston-Salem. It is the historic settlement of the Moravians founded in 1766 and consists of preserved houses and buildings in the town. Make a stop at Reynolda House, the centerpiece of the Reynolda District, adjacent to the Wake Forest campus. This 1917 restored mansion houses a premier collection of American art. Visitors can stroll the formal gardens, greenhouses and woodland

Fun Fact.....

Krispy Kreme doughnuts originated in Winston-Salem. Swing by their factory when the 'HOT' sign is on and grab a

Meet the Wake Forest team















PREP-IT Educational Rounds



PREP-ITROUNDS FRIDAY MARCH 5, 2021 12:00PM – 1:00PM EST

Please join us for the PREP-IT Rounds hosted by Sheila Sprague and Gerard Slobogean, featuring presentations by Roman Natoli, and Lucas Marchand.



ROMAN NATOLI

Roman Natoli is an orthopaedic surgeon at Indiana University Health. His centre is participating in both the Aqueous-PREP trial and the PREPARE trial. Roman will review the AO/OTA Classification and Gustillo Classification system. He will also provide case examples.

LUCAS MARCHAND

Lucas Marchand is an orthopaedic surgeon at the University of Utah Hospital in Salt Lake City. His centre is participating in the PREPARE trial. Lucas will review the Injury Severity Score (ISS) and will provide case examples on how to score the ISS.



PREP-IT

PREP-IT ROUNDS FRIDAY FEBRUARY 5, 2021 1:00PM – 3:00PM EST

Please join us for the PREP-IT Rounds hosted by Sheila Sprague and Gerard Slobogean, featuring a workshop on research workflow with Bianca Manago.



ABOUT THE SPEAKER

Bianca Manago is an Assistant Professor in the Department of Sociology at Vanderbilt University. Her research has been funded by the National Science Foundation and has appeared in outlets such as the: American Sociological Review, Social Forces, Proceedings of the National Academy of Sciences, and the Annual Review of Sociology. Her methodological work focuses on experimental design, statistical analyses, and workflow of data analysis. She has taught workflow at Indiana University, Vanderbilt University, Texas A&M University, ICPSR, and for Statistical/Code Horizons.

WORKSHOP OUTLINE

Researchers often spend time learning how to improve their methods, data analysis, and writing skills. Generally, less time is spent learning how to optimize our time and energy. A careful consideration of workflow can make clinical research more efficient, accurate, reproducible, and less frustrating. This workflow workshop will cover the following topics: principles of good workflow, time management, directory structures, file naming, data management, and tools for effective workflow. By practicing these workflow strategies, researchers will be more efficient, and their research will be more accurate and reliable.



SAVE THE DATE: PREP-IT ROUND FRIDAY APRIL 9, 2021 12:00PM – 1:00PM EST

Please join us for the PREP-IT Rounds hosted by Sheila Sprague and Gerard Slobogean, featuring presentations by Leah Gitajn and Holly Pilson.



LEAH GITAIN

Leah Gitain is as an orthopaedic surgeon at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. Her centre is participating in the PREPARE trial. Leah will be presenting the results of the PREP-IT sub-study titled: The Effect of COVID-19 on Achieving Time-to-Surgery Benchmarks in Musculoskeletal Trauma.

HOLLY PILSON

Holly Pilson is an orthopaedic surgeon at Wake Forest Baptist Health in Winston-Salem, North Carolina. Her centre is participating in the PREPARE trial. Holly will review the anatomy and different treatments of acetabular and pelvic fractures and will provide case examples.



Engagement Manuscripts and Sub-Studies

- Contributed to multiple manuscripts and sub-studies
- Included as co-authors or contributors on all publications





Patient and stakeholder engagement learnings: PREP-IT as a case study

Journal of Comparative Effectiveness Research

Poster Presentations







Pragmatic Design and Inclusion of Patient-Partner Representatives Improves Participant Experience in Clinical Research





MAC ORTHO

David Pogorzelski, Jeffrey L. Wells, Debra Marvel, Jana E. Palmer, C. Daniel Mullins, Michelle Medeiros, Jodi L. Gallant, Ella Spicer, Patrick F. Bergin, I. Leah Gitain, Devin S. Mullin, Greg E. Gaski, Robert Hymes, Sofia Bzovsky, Gerard P. Slobogean, Sheila Sprague, the PREP-IT Investigators

*A full list of PREP-IT Investigators is available in the OTA International Appendix **The authors have no relevant disclosures



PREPARE

A-PREP

BACKGROUND

- Meaningful patient engagement in the design of randomized controlled trials is an essential component of a trial's success.1,2
- The PREP-IT trials followed the patient-centered outcomes research (PCOR) approach, which includes allowing patient voices to be heard and focusing on outcomes that are relevant to patients and their caregivers.
- The PREP-IT trials evaluate different skin preparation solutions in patients with fractures.
- These trials aim to improve orthopaedic fracture research through meaningful engagement with patient-partners and to identify ways to better engage with study participants.

OBJECTIVE

· To explore participants' experiences with clinical research and participation in the PREP-IT trials.

METHODS

- At the final follow-up visit (12 months after their fracture), patients participating in the PREP-IT trials were invited to participate in the sub-study.
- After providing informed consent, participants completed a questionnaire that asked about their experience and satisfaction with participating in the PREP IT trials.
- · Descriptive statistics were used to summarize the findings.

RESULTS

- Demographics: 402 participants were included in the substudy. The mean age of the participants was 53.1 years (SD 18.3 years) and 57% were female.
- Previous Experience with Clinical Trials: 78% of participants indicated that PREP-IT was the first research study that they had taken part in and 9% indicated that they were participating in another study at the same time as PREP-IT.

Table 1. Reasons for participating in PREP-IT

| | Total N (%) N=402 |
|--|----------------------|
| Reason for taking part in this study* | |
| To help future patients with broken bones | 279 (69.4) |
| To make a contribution to science | 223 (55.5) |
| To feel part of something | 73 (18.2) |
| Other (details not specified) | 63 (15.7) |
| Items that influenced decision to take part in this study* | |
| None of these influenced my decision | 217 (54.0) |
| No extra clinic visits | 141 (35.1) |
| Limited time commitment | 125 (31.1) |
| No additional medications | 118 (29.4) |
| Few questionnaires or surveys | 111 (27.6) |
| No additional x-rays or tests | 106 (26.4) |

- Satisfaction with Participation in PREP-IT: 87% of participants indicated that their experience in the trial was excellent or good. No participants indicated a poor or very poor experience. 83% of participants felt that their participation was appreciated a lot. 87% of participants indicated that they would definitely or probably participate in another clinical study.
- Reasons for Participating in PREP-IT: 69% of participants indicated that they wanted "to help future patients with broken bones", and 56% indicated that they wanted "to contribute to science". When participants were asked to select all items associated with the trial design that influenced their decision to participate, 46% selected at least one item. This includes: no extra clinic visits (35%), limited time commitment (31%), no additional medications (29%), few questionnaires (28%), and no additional test (26%).

DISCUSSION

 Most participants reported a positive experience with participating in the PREP-IT trials. Altruism was the largest motivator for participating in this research. Approximately half of the participants indicated that the pragmatic, lowparticipant burden design of the trial influenced their decision to participate. Meaningful patient engagement, a pragmatic and low burden protocol led to high levels of participant satisfaction.

Arbitaires I. What do I want from health research and researchers when I am a patient? BMJ. 1995;310:1315-8.

Domecq JP. Prutzky G, Etralyah T, et al. Patient engagement in research: A systematic review. BMC Health Services Research. 2014;14:89.

Talaient-Centred Outcomes Research institute. Patient-Centered Outcomes Research, Internet, 2013 (sicied 2022 Aug 12), Available

PCORI Conferences



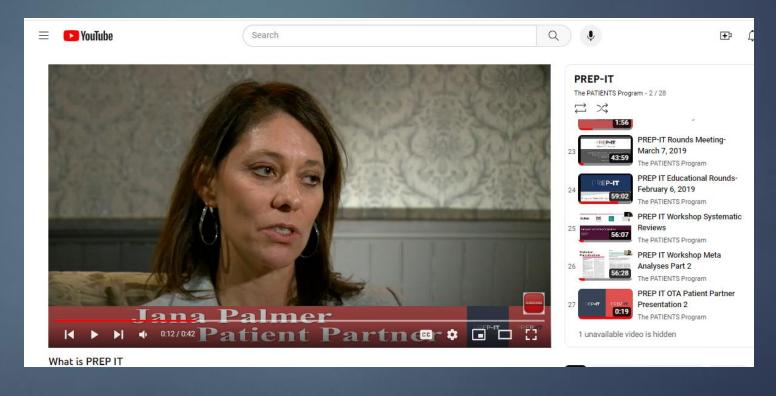


PREPHI

Lessons Learned

Recordings are on Patients Program YouTube Channel

Used by sites to answer questions in patient's voice



Annual Investigator Meetings

- Meetings began with a patient focus
- Topics relevant to patient partners
- Guest speakers
- Discussions of challenges faced during the trial
- Celebrations of successes

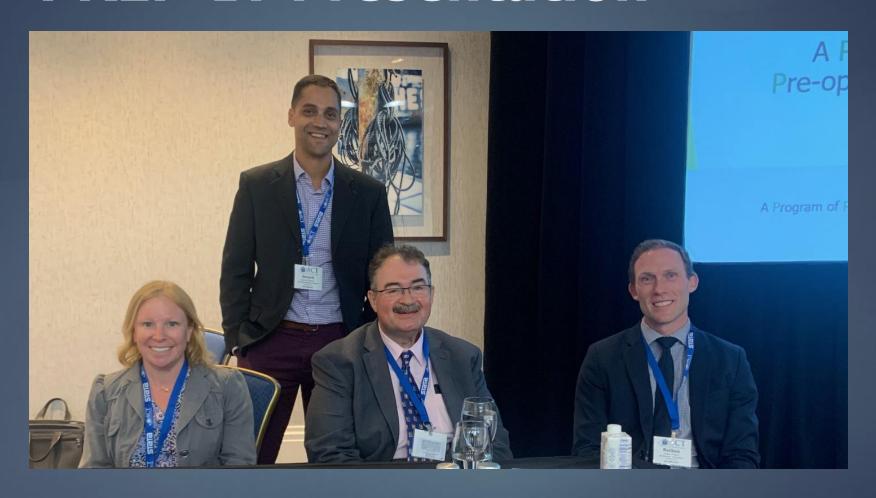




PREP-IT Podcast



PREP-IT Presentation



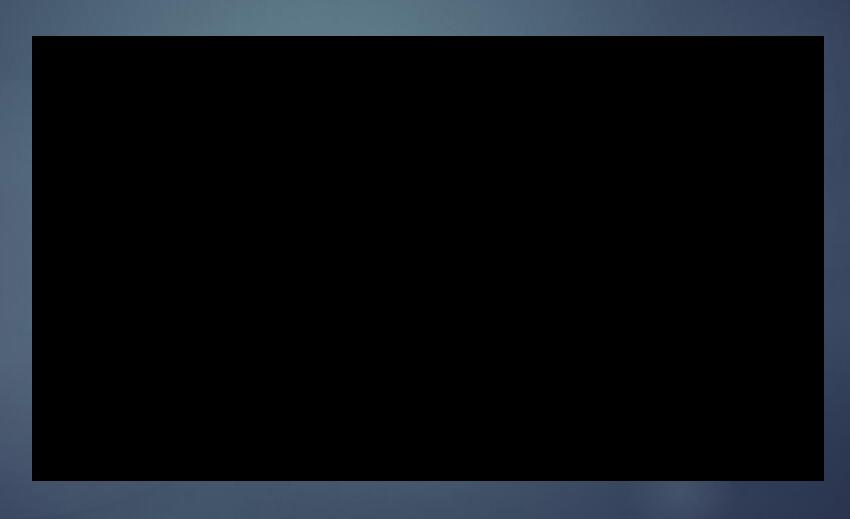
Society of Clinical Trials

PREP-IT Patient Advisors

- Jeff, Debra, and Jana participated because they would like to give back to their healthcare professionals and help future patients
- Were involved from start to finish
- Initial grant development meeting in 2017
- Trial results meeting in May 2023
- Multiple meetings in-between



Knowledge Dissemination of Primary Results



A-PREP trial is very unique



- > Full commitment to patient engagement
- → Multiple period, cluster randomized, crossover trial
- Results published in The Lancet 2022; 400:1334-44

PREP-IT Investigators



- → 30 sites, 300+ collaborators
- 10 papers related to patient engagement, clinical practice patterns, or research methods

THE LANCET

A Pragmatic
Randomized trial
Evaluating
Pre-operative
aqueous antiseptic
skin solutions
in open fractures



NEW ENGLAND JOURNAL OF MEDICINE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Skin Antisepsis before Surgical Fixation of Extremity Fractures

The PREP-IT Investigators*

ARSTRACT

Studies evaluating surgical-site infection have had conflicting results with respect The authors' full names, academic de to the use of alcohol solutions containing iodine povacrylex or chlorhexidine gluconate as skin antisepsis before surgery to repair a fractured limb (i.e., an extremity fracture).

In a cluster-randomized, crossover trial at 25 hospitals in the United States and Canada, we randomly assigned hospitals to use a solution of 0.7% iodine povacrylex in 74% isopropyl alcohol (iodine group) or 2% chlorhexidine gluconate in and Innovation, Department of Orthope 70% isopropyl alcohol (chlorhexidine group) as preoperative antisepsis for surgical Medicine, R. Adams Cowley Shock Trauma procedures to repair extremity fractures. Every 2 months, the hospitals alternated Center, 22 S. Greene St., Baltimore, MD interventions. Separate populations of patients with either open or closed fractures 21201 were enrolled and included in the analysis. The primary outcome was surgical-site *A complete list of the PREP-IT Investi infection, which included superficial incisional infection within 30 days or deep gators is provided in the Supplement incisional or organ-space infection within 90 days. The secondary outcome was unplanned reoperation for fracture-healing complications.

A total of 6785 patients with a closed fracture and 1700 patients with an open DOI: 10.1056/NEJMoa2307679 fracture were included in the trial. In the closed-fracture population, surgical-site Copyright © 2024 Massachusetts Medical Society

pendix. Dr. Sprague can be contacted at sprags@mcmaster.ca or at the Division f Orthopedic Surgery, Department of on St. N., Suite 110, Hamilton, ON Canada, Dr. Slobogean can be contacted at aslobogean@som umaryland edu or at

tary Appendix, available at NEIM.org.

Drs. Sprague and Slobogean contributed

N Engl J Med 2024;390:409-20.

Among patients with closed extremity fractures, skin antisepsis with iodine povacrylex in alcohol resulted in fewer surgicalsite infections than antisepsis with chlorhexidine gluconate in alcohol.



PREPARE

- → A-PREP & PREPARE-Open (n=3,338)
- No differences in SSI or reoperation detected between iodine or CHG antisepsis
 - Alcohol or aqueous solutions
- Why are the results different for open versus closed fractures?
 - Open wound exposed to environmental bacteria for hours prior to antisepsis
 - Immediate irrigation of open fracture wound
 - Antisepsis most effective for intact skin immediately prior to incision



0.7% iodine povacrylex in alcohol reduced the odds of infection by 26% amongst closed fractures

- → Absolute effect 0.8%
- → NNT 125 closed fractures

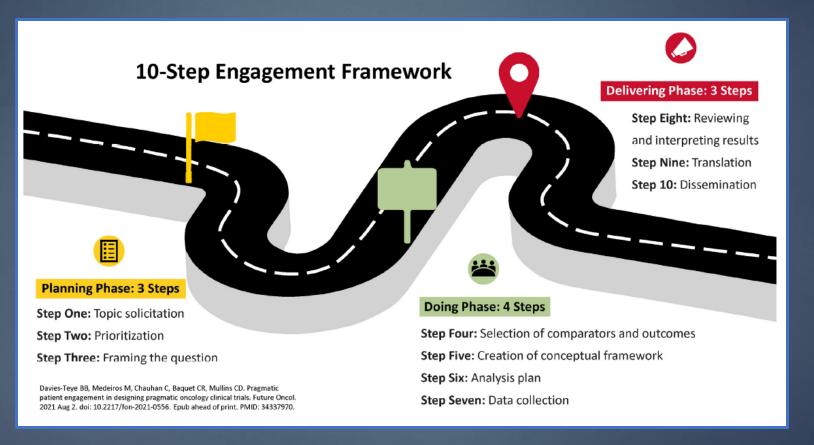
lodophor used in PREPARE differs from povidone-iodine

- → Povacrylex is a water insoluble deliverer of free iodine
- → Resistant to fluid and blood
- Provides longer protection / action of the iodine

Water insoluble delivery may provide the mechanism for the treatment effect



Patient Engagement in PREP-IT



The **PATIENTS** Program

at the University of Maryland School of Pharmacy

5. Self-Actualization FINAL INVESTIGATOR MEETING



6 Sites Brought Patients to see Engagement

www.patients.umaryland.edu patients@rx.umaryland.edu 410.706.3839



Dr. Lehana Thebane – Ortho POD

Patient Partners



Jana Palmer, Ed.D



Debra Marvel, MS



Jeff Wells, AA