# MY JOURNEY

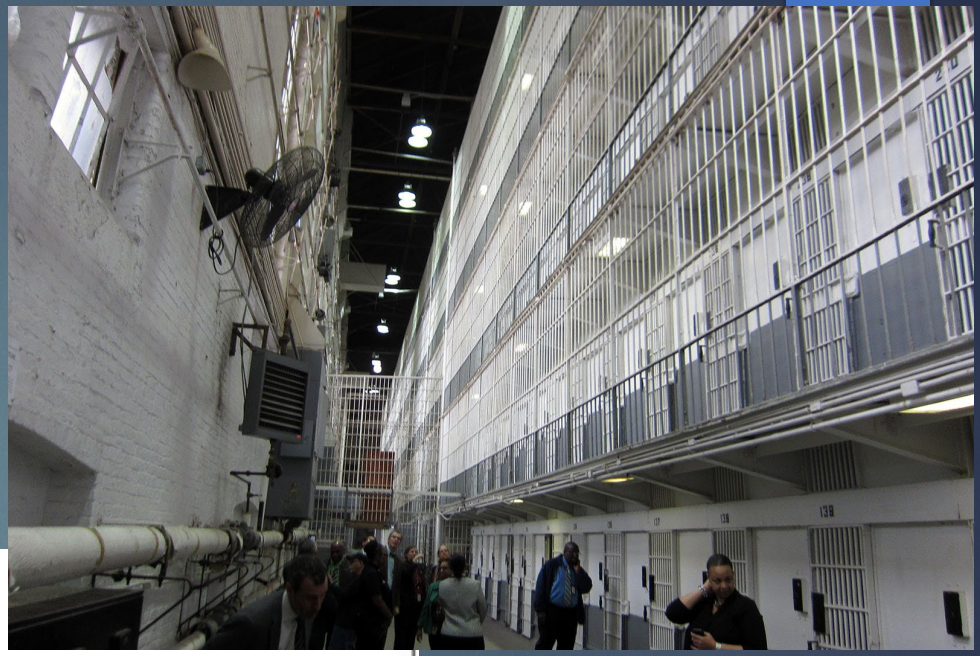
**Jeffrey L. Wells**

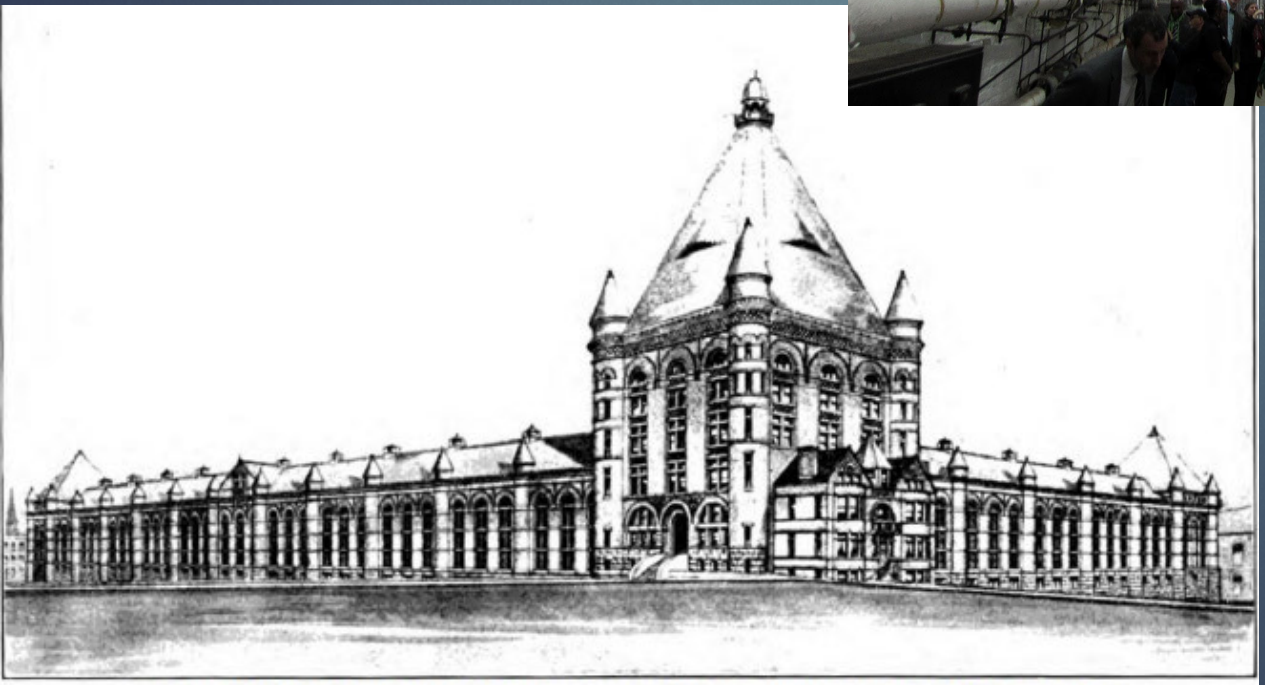
# CAREER JOURNEY


**MARYLAND DIVISION OF CORRECTION**

**1981 - 2003**

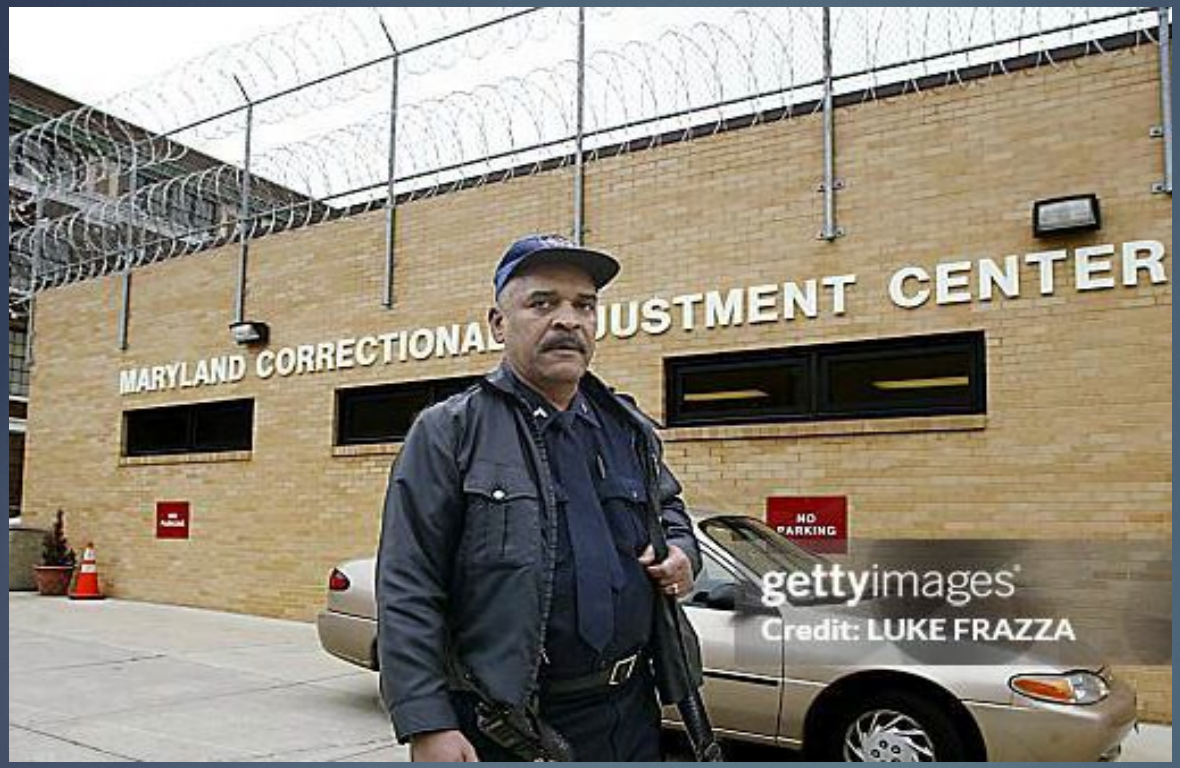
# MD PENITENTIARY





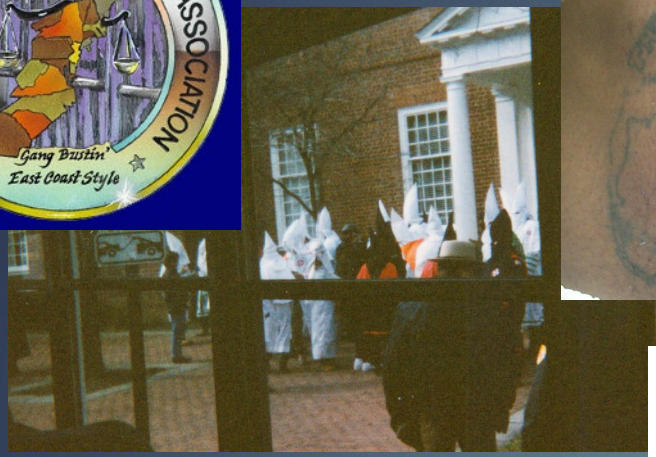
Architect's drawing of the Maryland Penitentiary, Warden's Annual Report, 1900 (Hathi Trust)

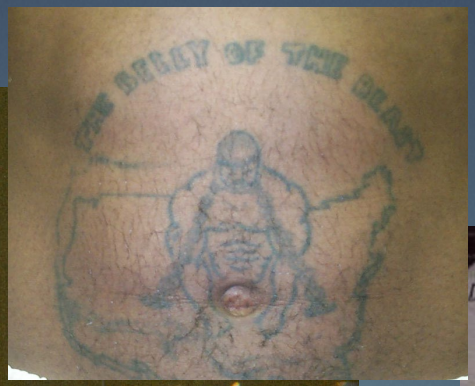
# “Super Max" Baltimore, MD - 25 October 2002

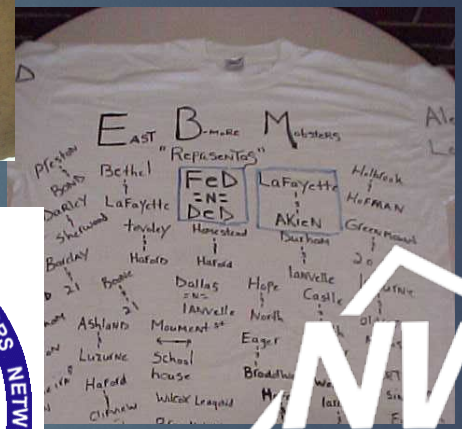



**Day the Beltway Snipers**
**John Muhammed and Lee Boyd Malvo**
**Arrived**

# INTEL






East B-more Mobsters
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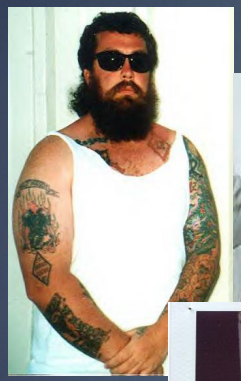
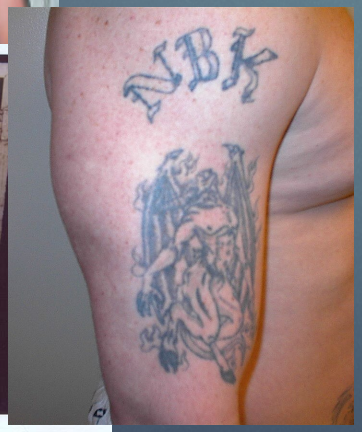
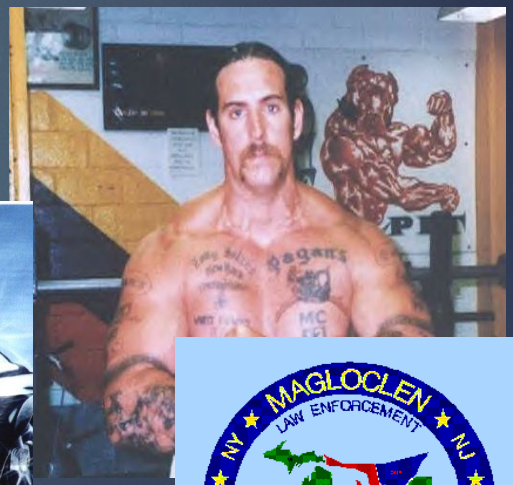



Pagans


WALL LOCKER IN CHRISTOPHER CARTER'S CUBE AREA ON 7/11/98


NBK


Pagans


MAGLOCLEN
LAW ENFORCEMENT
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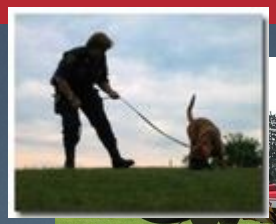
NETWORK

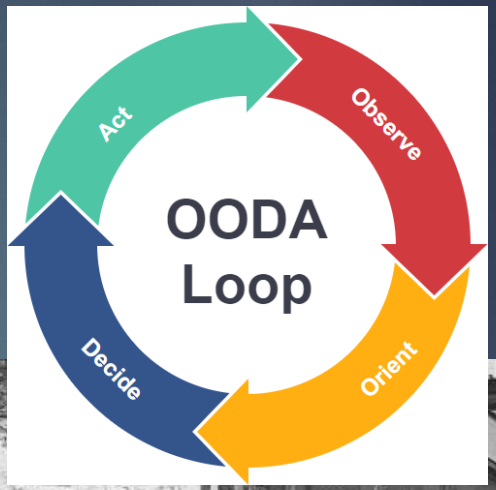

NAGIA

# K9

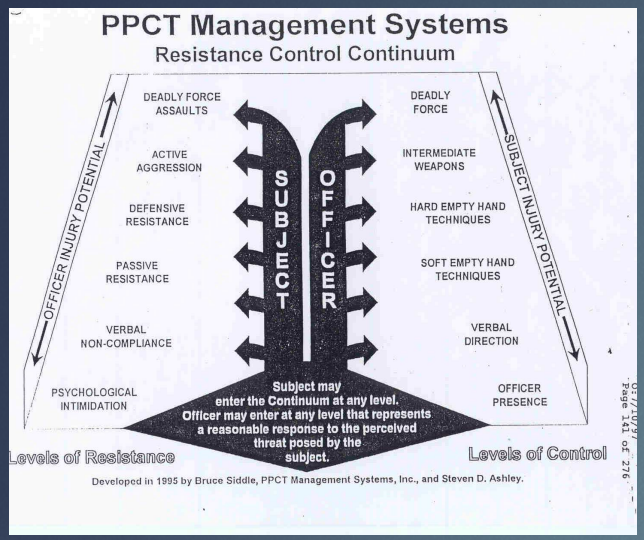





# TACTICAL TEAMS




# TRAINING

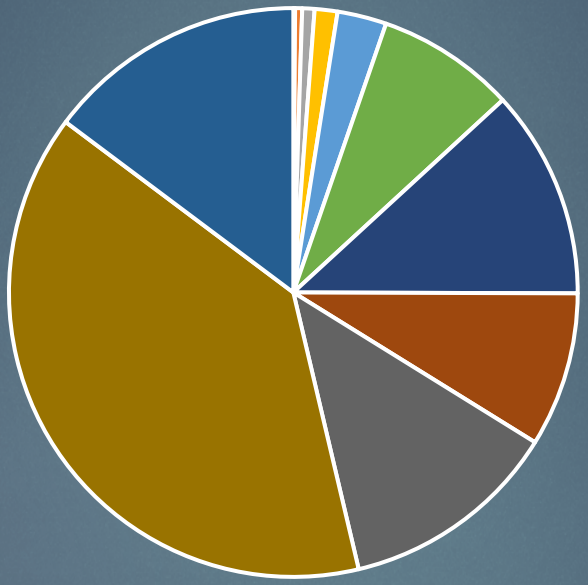

# TOULSON BOOT CAMP

# USE OF FORCE EXPERT WITNESS

## FEDERAL

## STATE

# MD DOC SENTENCE CHARACTERISTICS - 2022



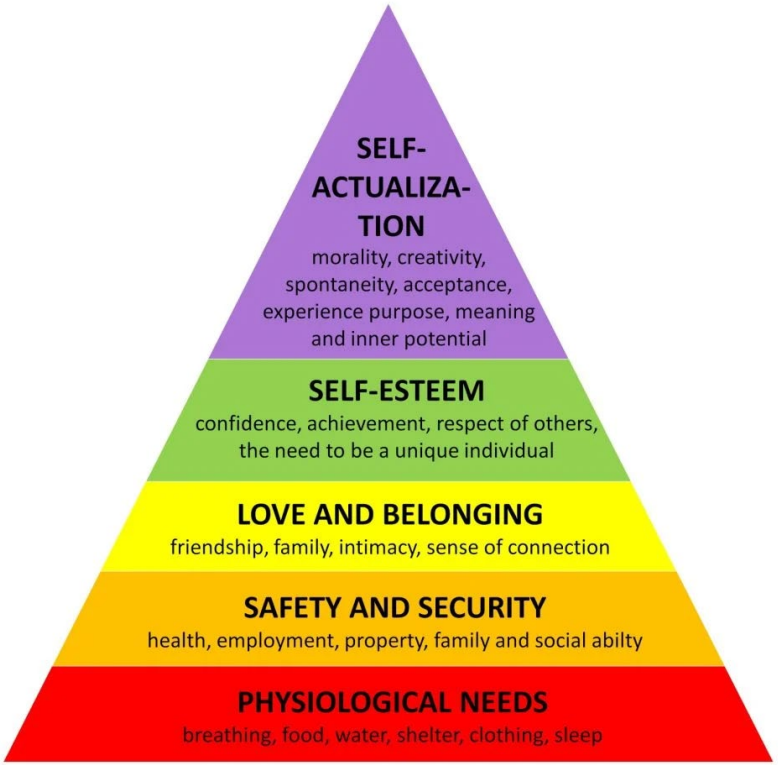
1-6 Months
7-12 Months
13-18 Months
19-24 Months
25-36 Months
37-60 Months
61-96 Months
97-120 Months
121-180 Months
Over 180 Months
Life

# Maryland Division of Correction

## 2023 Average Daily Population 15,425

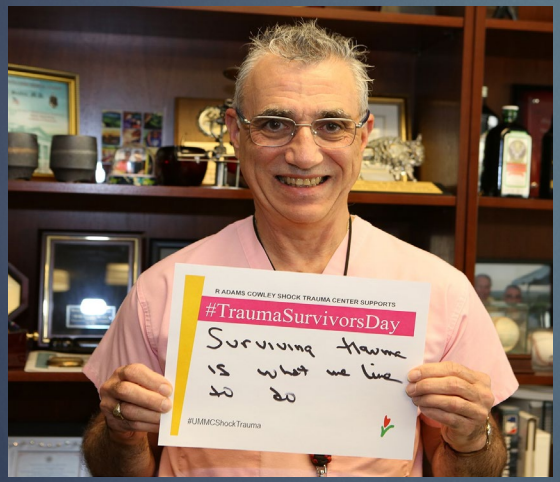
| Life with Parole | Life without Parole | Virtual | Total | Percent of Prison Population |
|---|---|---|---|---|
| 2240 | 444 | 1125 | 3809 | 21% |

# MEDICAL JOURNEY




## Maslow's Hierarchy of Needs

# 1. Physiological Needs




# 2. Safety and Security

# 3. Love and Belonging


# RESEARCH JOURNEY

# 4. Self Esteem

R Adams Cowley Shock Trauma Center
University of Maryland

CORI

McMaster University

# PREP-IT

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

Debra Marvel

Jana Palmer

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.)

JAMA Network Open

Original Investigation | Orthopedics

**Effectiveness of Iodophor vs Chlorhexidine Solutions for Surgical Site Infections and Unplanned Reoperations for Patients Who Underwent Fracture Repair**

The PREP-IT Master Protocol

The Program of Randomized Trials to Evaluate Pre-operative Antiseptic Skin Solutions in Orthopaedic Trauma (PREP-IT) Investigators

**Abstract**

**IMPORTANCE** The risk of developing a surgical site infection after extremity fracture repair is nearly 5 times greater than in most elective orthopedic surgical procedures. For all surgical procedures, it is standard practice to prepare the operative site with an antiseptic solution; however, there is limited evidence to guide the choice of solution used for orthopedic fracture repair.

**OBJECTIVE** To compare the effectiveness of iodophor vs chlorhexidine solutions to reduce surgical site infections and unplanned fracture-related reoperations for patients who underwent fracture repair.

**DESIGN, SETTING, AND PARTICIPANTS** The PREP-IT (Program of Randomized Trials to Evaluate Pre-operative Antiseptic Skin Solutions in Orthopaedic Trauma) master protocol will be followed to conduct 2 multicenter pragmatic cluster randomized crossover trials, Aqueous-PREP (Pragmatic Randomized Trial Evaluating Pre-Operative Aqueous Antiseptic Skin Solution in Open Fractures) and PREPARE (Pragmatic Randomized Trial Evaluating Pre-Operative Alcohol Skin Solutions in Fractured Extremities). The Aqueous-PREP trial will compare 4% aqueous chlorhexidine vs 10% povidone-iodine for patients with open extremity fractures. The PREPARE trial will compare 2% chlorhexidine in 70% isopropyl alcohol vs 0.7% iodine povacrylex in 74% isopropyl alcohol for patients with open extremity fractures and patients with closed lower extremity or pelvic fractures. Both trials will share key aspects of study design and trial infrastructure. The studies will follow a pragmatic cluster randomized crossover design with alternating treatment periods of approximately 2 months. The primary outcome will be surgical site infection and the secondary outcome will be unplanned 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 intention-to-treat principle and account for potential between-cluster and between-period variability. The patient-centered design, implementation, and dissemination of results are guided by a multidisciplinary team that includes 3 patients and other relevant stakeholders.

**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 clinical practice.

**TRIAL REGISTRATION** ClinicalTrials.gov Identifiers: NCT03385304 and NCT03523962

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

**Key Points**

**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?

**Findings** This trial master protocol describes 2 multicenter pragmatic cluster randomized crossover trials, Aqueous-PREP (Pragmatic Randomized Trial Evaluating Pre-Operative Aqueous and Antiseptic Skin Solution in Open Fractures) and PREPARE (Pragmatic Randomized Trial Evaluating Pre-Operative Alcohol Skin Solutions in Fractured Extremities), which seek to compare the effectiveness of iodophor and chlorhexidine surgical skin preparation solutions at reducing surgical site infections and unplanned fracture-related reoperations.

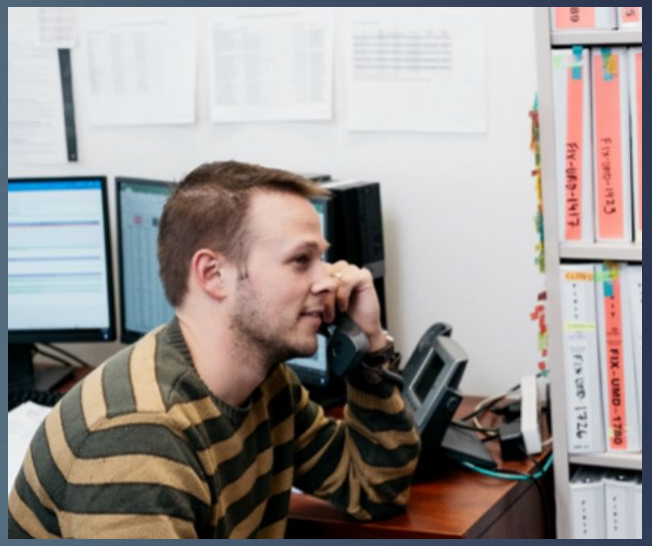
**Meaning** Because prophylactic skin antisepsis is used prior to all surgical procedures and the application, cost, and availability of all study solutions are similar, the results are poised to inform clinical guidelines and bring about change in clinical practice.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

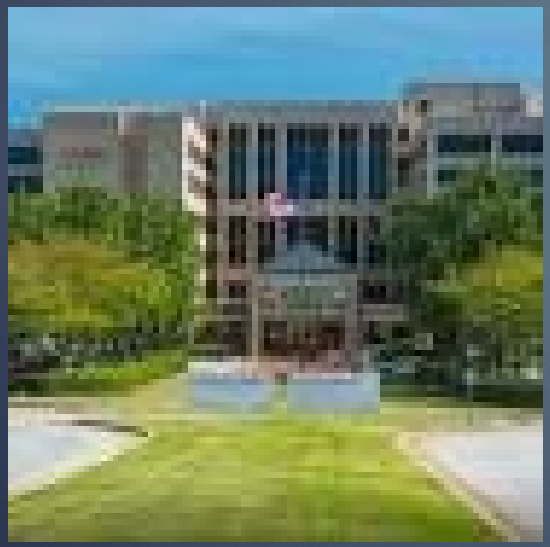
# Informed Consent Form Development

- 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

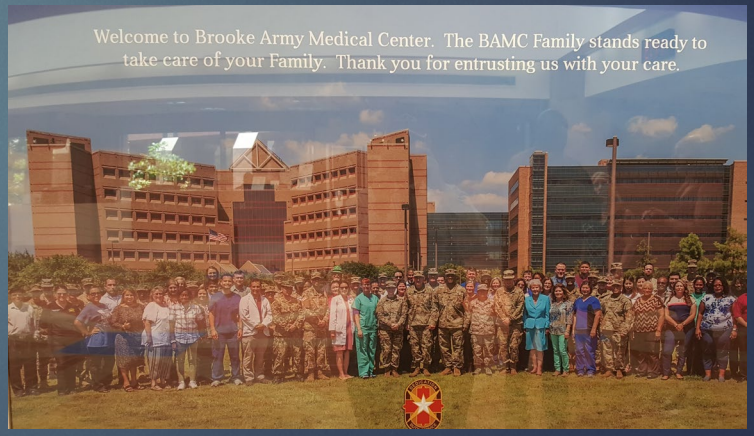


# Site Initiation Visits

JACKSONVILLE, FL

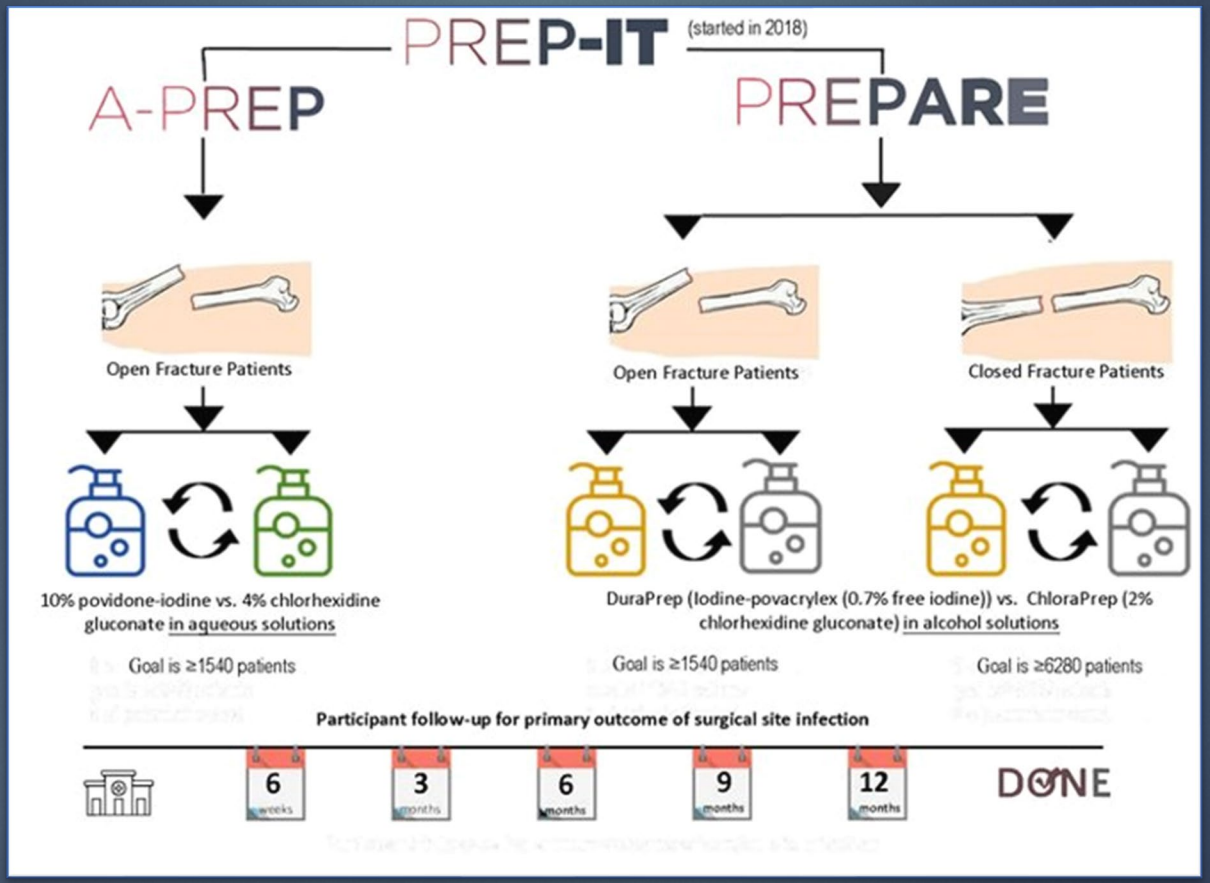


GREENVILLE , SC

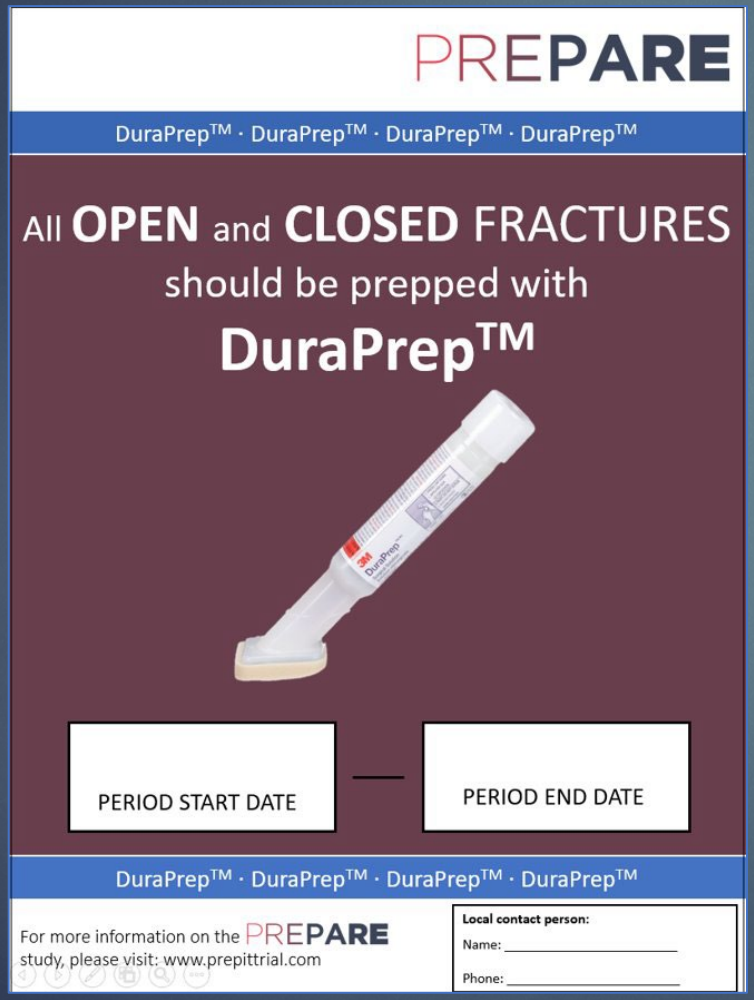


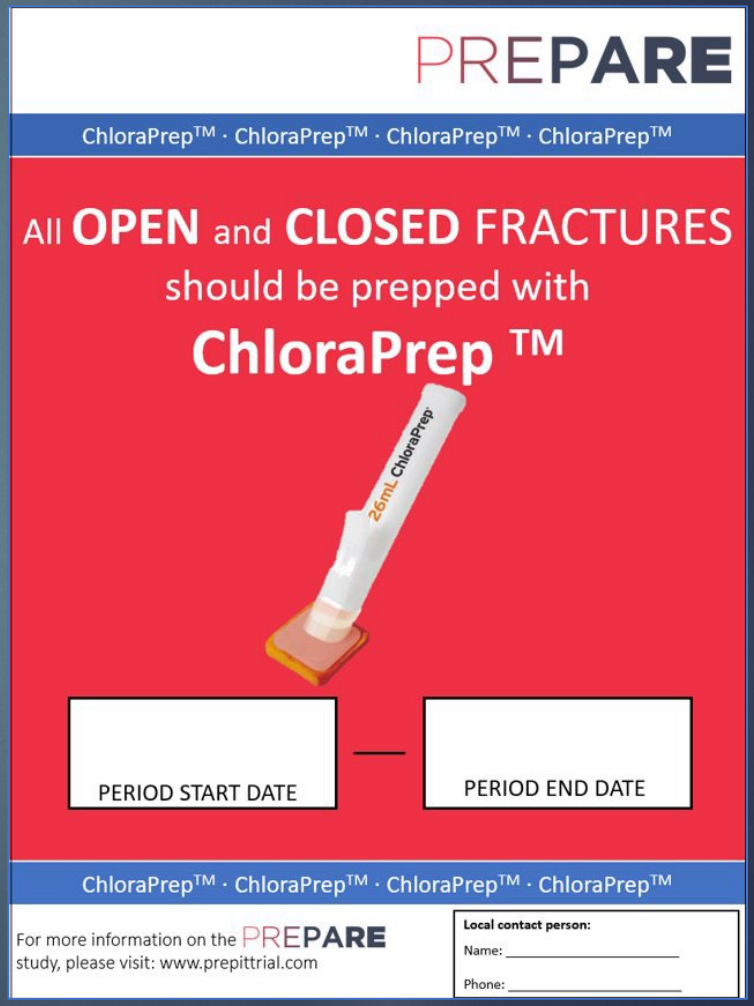

SAN ANTONIO, TX

# Development of a Trial Visual



# Development of Clinical Site Posters



# Newsletters

# PREP-IT

NEWSLETTER | February 2021

## 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 iodine povacrylex (0.7% free iodine) in 74% isopropyl 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 fracture-related 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

Aqueous-PREP has enrolled 1,562 participants across 14 sites (Table 3). Currently 7 sites are enrolling and have enrolled 26 participants in the month of February.

### PREPARE Enrolment Update

PREPARE-Open has enrolled 1,226 participants across 18 sites, with 26 participants enrolled in January (Table 6). PREPARE-Closed has enrolled 5,582 participants across 21 sites, with 164 participants enrolled in February (Table 7).

We are pleased to announce that there are two new sites that will be initiating 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!

### Q2 Invoices

The Methods Centre will be preparing invoices over the next few weeks. Please take some time to reply to queries 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 payment.

### Antibiotics Log

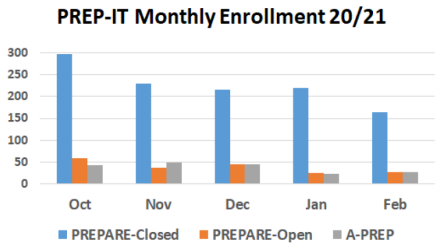
The first entry on the antibiotics log should correlate with the response to Q3 on the Peri-Operative Care Form. When completing these forms, make sure to check that these dates align.

### Heterotopic Acetabular (HO) Sub-study

We are very excited to have the HO sub-study underway at sites in the PREPARE trial. If your site requires local ethics approval, please let David know once approval is obtained to discuss the next steps.

Data entry tips for the HO sub-study:

1) The HO form can be added from the same drop down menu containing the Antibiotics Log and Planned Fracture Surgery Form.
2) Please use the date the form is completed as the 'Start Date' when adding an HO form.
3) 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.
4) Acetabular fractures treated via lateral and anterior-only approaches are not eligible. Please select 'No' to question 1 for these participants.






# 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 Baptist 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 success?**

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 same goals .

**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 queries.

**How has COVID-19 impacted the way you conduct the trial on a day-to-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 walking trails.

### Fun Fact.....

Krispy Kreme doughnuts originated in Winston-Salem. Swing by their factory when the 'HOT' sign is on and grab a fresh dozen to enjoy with your coffee!

## Meet the Wake Forest team!

# PREP-IT Educational Rounds

PREP-IT

PREP-IT ROUNDS
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.

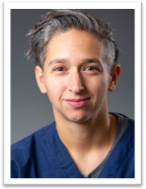
WORKSHOP OUTLINE

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.

PREP-IT

SAVE THE DATE: PREP-IT ROUNDS
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 GITAJN

Leah Gitajn 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.

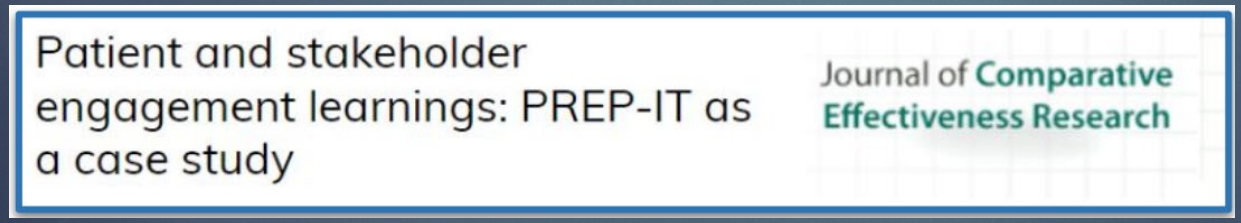
HOLLY PILSON

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**





# Poster Presentations

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

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 Gitajn, 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

### 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.[3]
- 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 sub-study. 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.
- 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.

**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) |

*Multiple responses could be selected

- 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, low-participant 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.

REFERENCES
1. Chalmers I. What do I want from health research and researchers when I am a patient? BMJ. 1995;310:1315–8.
2. Domecq JP, Prutsky G, Elraiyah T, et al. Patient engagement in research: A systematic review. BMC Health Services Research. 2014;14:89.
3. Patient-Centered Outcomes Research Institute. Patient-Centered Outcomes Research [Internet]. 2013 [cited 2022 Aug 12]. Available

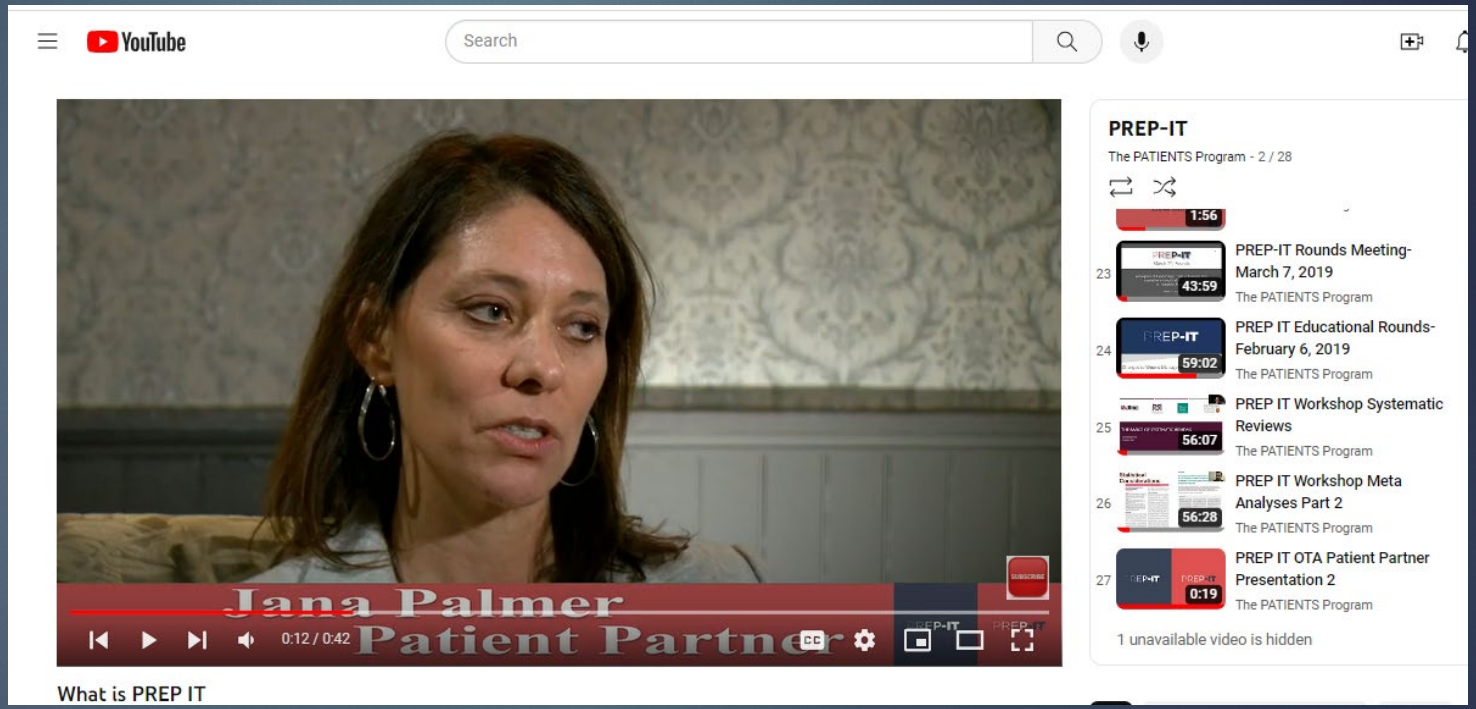
# PCORI Conferences


# PREP-IT

**Lessons Learned**

**Recordings are on Patients Program YouTube Channel**

**Used by sites to answer questions in patient's voice**

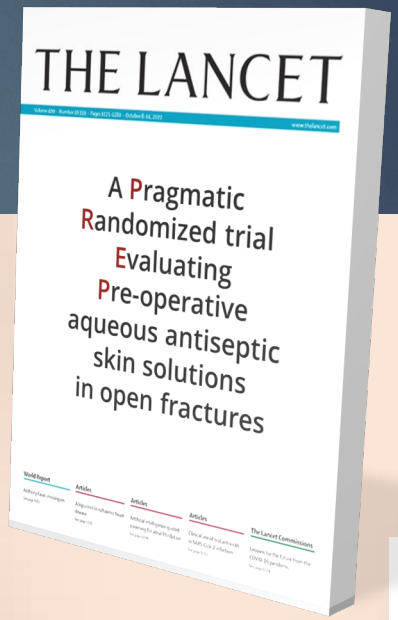


# Annual Investigator Meetings

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

## 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



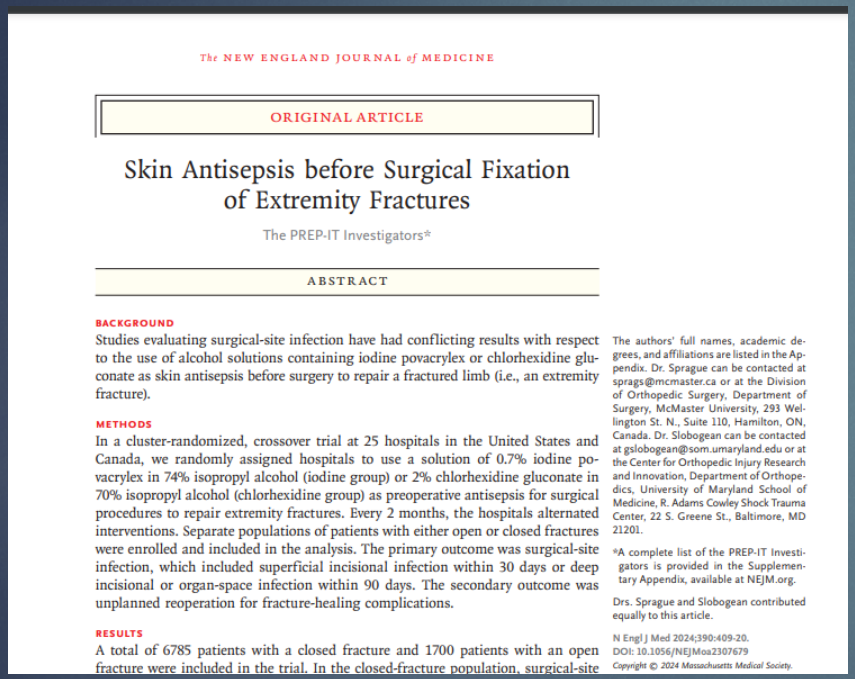

## PREP-IT Investigators

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

# PREP-IT Presentation


**Society of Clinical Trials**

# 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*

ABSTRACT

**BACKGROUND**

Studies evaluating surgical-site infection have had conflicting results with respect 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).

**METHODS**

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 70% isopropyl alcohol (chlorhexidine group) as preoperative antisepsis for surgical procedures to repair extremity fractures. Every 2 months, the hospitals alternated interventions. Separate populations of patients with either open or closed fractures were enrolled and included in the analysis. The primary outcome was surgical-site infection, which included superficial incisional infection within 30 days or deep incisional or organ-space infection within 90 days. The secondary outcome was unplanned reoperation for fracture-healing complications.

**RESULTS**

A total of 6785 patients with a closed fracture and 1700 patients with an open fracture were included in the trial. In the closed-fracture population, surgical-site

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Sprague can be contacted at sprags@mcmaster.ca or at the Division of Orthopedic Surgery, Department of Surgery, McMaster University, 293 Wellington St. N., Suite 110, Hamilton, ON, Canada. Dr. Slobogean can be contacted at gslobogean@som.umaryland.edu or at the Center for Orthopedic Injury Research and Innovation, Department of Orthopedics, University of Maryland School of Medicine, R. Adams Cowley Shock Trauma Center, 22 S. Greene St., Baltimore, MD 21201.

*A complete list of the PREP-IT Investigators is provided in the Supplementary Appendix, available at NEJM.org.

Drs. Sprague and Slobogean contributed equally to this article.

N Engl J Med 2024;390:409-20.
DOI: 10.1056/NEJMoa2307679

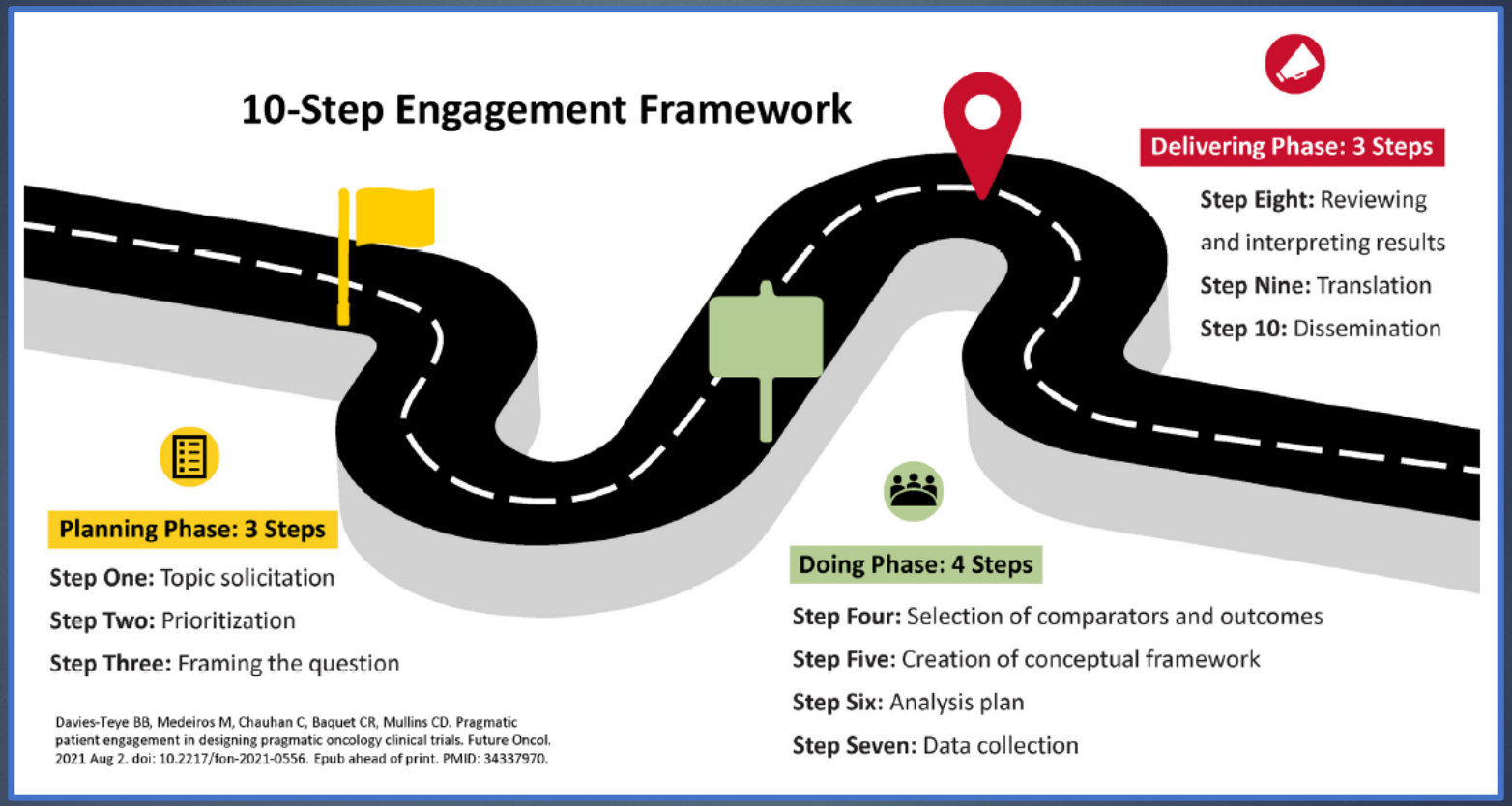


**Among patients with closed extremity fractures, skin antisepsis with iodine povacrylex in alcohol resulted in fewer surgical-site infections than antisepsis with chlorhexidine gluconate in alcohol.**

# PREP-IT Podcast

# New England Journal of Medicine

# Patient Engagement in PREP-IT




The **PATIENTS** Program
at the University of Maryland
School of Pharmacy

# PATIENTS Program

YouTube video on my recovery

Jeff Wells, From Patient to Research Advisor-
https://www.youtube.com/watch?v=sCBzbEzdSFE&list=WL&index=4

PATIENTS PROFESSORS Academy

Claude D. Pepper Older Americans Independence Center, Community Advisory Board

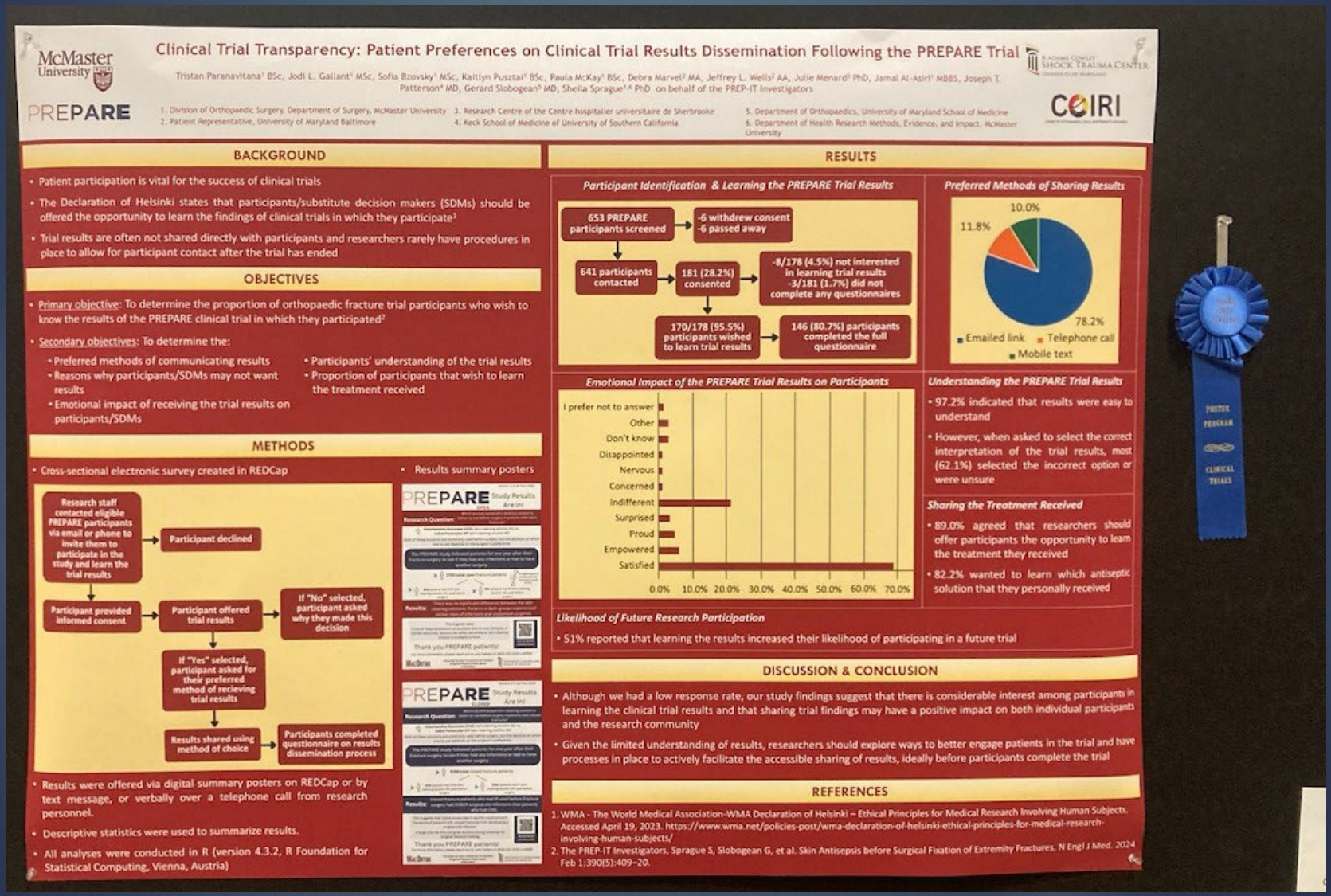
## 5. Self-Actualization

# FINAL INVESTIGATOR MEETING

## 6 Sites Brought Patients to see Engagement


# Dr. Lehana Thebane – Ortho POD

# PREP-IT Patient Experiences



## Clinical Trial Transparency: Patient Preferences on Clinical Trial Results Dissemination Following the PREPARE Trial

Tristan Paranavitana[1] BSc, Jodi L. Gallant[1] MSc, Sofia Bzovsky[1] MSc, Kaitlyn Pusztai[1] BSc, Paula McKay[1] BSc, Debra Marvel[2] MA, Jeffrey L. Wells[2] AA, Julie Menard[3] PhD, Jamal Al-Asiri[1] MBBS, Joseph T. Patterson[4] MD, Gerard Slobogean[5] MD, Sheila Sprague[1,6] PhD on behalf of the PREP-IT Investigators

1. Division of Orthopaedic Surgery, Department of Surgery, McMaster University
2. Patient Representative, University of Maryland Baltimore
3. Research Centre of the Centre hospitalier universitaire de Sherbrooke
4. Keck School of Medicine of University of Southern California
5. Department of Orthopaedics, University of Maryland School of Medicine
6. Department of Health Research Methods, Evidence, and Impact, McMaster University

### BACKGROUND

- Patient participation is vital for the success of clinical trials
- The Declaration of Helsinki states that participants/substitute decision makers (SDMs) should be offered the opportunity to learn the findings of clinical trials in which they participate[1]
- Trial results are often not shared directly with participants and researchers rarely have procedures in place to allow for participant contact after the trial has ended

### OBJECTIVES

- Primary objective: To determine the proportion of orthopaedic fracture trial participants who wish to know the results of the PREPARE clinical trial in which they participated[2]
- Secondary objectives: To determine the:
  - Preferred methods of communicating results
  - Reasons why participants/SDMs may not want results
  - Emotional impact of receiving the trial results on participants/SDMs
  - Participants' understanding of the trial results
  - Proportion of participants that wish to learn the treatment received

### METHODS

- Cross-sectional electronic survey created in REDCap




- Results summary posters




- Results were offered via digital summary posters on REDCap or by text message, or verbally over a telephone call from research personnel.
- Descriptive statistics were used to summarize results.
- All analyses were conducted in R (version 4.3.2, R Foundation for Statistical Computing, Vienna, Austria)

### RESULTS

#### Participant Identification & Learning the PREPARE Trial Results




#### Preferred Methods of Sharing Results




#### Emotional Impact of the PREPARE Trial Results on Participants




#### Understanding the PREPARE Trial Results

- 97.2% indicated that results were easy to understand
- However, when asked to select the correct interpretation of the trial results, most (62.1%) selected the incorrect option or were unsure

#### Sharing the Treatment Received

- 89.0% agreed that researchers should offer participants the opportunity to learn the treatment they received
- 82.2% wanted to learn which antiseptic solution that they personally received

#### Likelihood of Future Research Participation

- 51% reported that learning the results increased their likelihood of participating in a future trial

### DISCUSSION & CONCLUSION

- Although we had a low response rate, our study findings suggest that there is considerable interest among participants in learning the clinical trial results and that sharing trial findings may have a positive impact on both individual participants and the research community
- Given the limited understanding of results, researchers should explore ways to better engage patients in the trial and have processes in place to actively facilitate the accessible sharing of results, ideally before participants complete the trial

### REFERENCES

1. WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Accessed April 19, 2023. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
2. The PREP-IT Investigators, Sprague S, Slobogean G, et al. Skin Antisepsis before Surgical Fixation of Extremity Fractures. *N Engl J Med*. 2024 Feb 1;390(5):409–20.

# Research Patient Partners

Jana Palmer, Ed.D

Debra Marvel, MA

Jeff Wells, AA


oh cool

# RESEARCH PROTECTION JOURNEY

# Voice of the Patient

Society of Clinical Trials – SCT

Agency for Healthcare Research and Quality – AHRQ

American College of Surgeons – ACS

# Non-Scientist and Prisoner Representative

## Data Safety Monitoring Board - 2018

Johns Hopkins, Bloomberg School of Public Health

## Institutional Review Board - 2019

University of Maryland, Baltimore

## Institutional Review Board - 2024

National Institutes of Health

# Life is different, it is not over.