

# PREP-IT

## NEWSLETTER | August 2020

### Aqueous-PREP Overview

The overall objective is to compare the effectiveness of aqueous pre-operative 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 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.prepitttrial.com](http://www.prepitttrial.com).

The password to access study documents are "aprep" and "prepare."

### Aqueous-PREP Enrollment Update

Aqueous-PREP has enrolled 1,333 patients across 12 sites (Table 1), with 33 patients enrolled in August.

### PREPARE Enrollment Update

PREPARE-Open has enrolled 962 patients across 16 sites, with 44 patients enrolled in August (Table 4). PREPARE-Closed has enrolled 4,170 patients across 20 sites, with 257 patients enrolled in August (Table 5).

### Quarter 3 Invoices

The Methods Centre has started to prepare the Quarter 3 invoices and will send them to you for review in the coming weeks. Please reply to as many queries as you can over the next couple of weeks in order to maximize payment for this quarter. Please remember outstanding adjudication materials will impact payment. If you have any questions about your query list, please email or call Shannon, David, or Jordan.

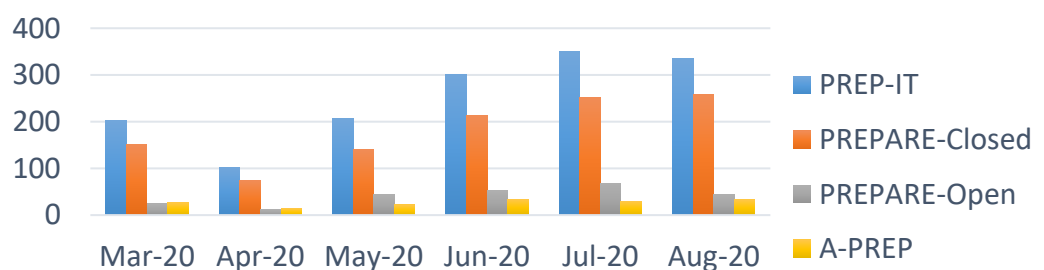
### 12 Month Follow Up Visit

If a participant is unable to be located or is incarcerated at the 12-month visit, please do not submit a Missed Visit form or an Early Withdrawal form. Please continue to contact the participant throughout the duration of the 12-month follow-up window and only submit an Early Withdrawal form after the 12-month follow-up window has closed.

### Publications

We are pleased to announce that the article: *What's Important: Patient Engagement in Research* has been published in the Journal of Bone & Joint Surgery. We are also pleased to announce that the article: *Cluster identification, selection, and description in cluster randomized crossover trials: the PREP-IT trials* has been published in the journal Trials. Thank you all for your continued hard work and dedication!

### PREP-IT Monthly Enrollment





# PREP-IT Spotlight: University of Mississippi Medical Centre

## Please describe your hospital and the demographic that your hospital serves.

The University of MS Medical Center (UMMC) is the state's only academic health science center, as well as it's only Level 1 trauma centre. We work diligently to provide exceptional patient care. UMMC has seven health science schools: medicine, nursing, dentistry, health related professions, graduate studies, population health, and pharmacy. There are over 3,000 student enrolled.

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

We are eager to participate in the PREPARE trial to continue to improve the quality of care for the patients that are enrolled in this study. The mission here at UUMC is to improve the health and well-being of patients and community through excellent training for health care professionals, engagement in innovative research, and the delivery of outstanding healthcare. Our research-driven mission towards the betterment of community health makes us better at what we do!

## Your site has one of the highest follow-up rates in the PREPARE trial. What are 1-2 tips that you would share with other sites to improve follow-up?

We have been following the protocol in terms of entering the data. If anything is not clear we reach out to the study coordinators and make sure that we are filling the data correctly. Once data is uploaded to REDCap daily, we make sure to check for any queries that may have been entered the day before. We begin to check the subject' files to make sure the data matches and if there are any errors that need to be corrected we make sure those are corrected at that time. Queries are checked at least twice a day. After the resolution of queries we make sure we do not make that particular mistake again with another participant. Check, and then double check and then triple check. That's the secret to a clean database.



## Visiting Jackson?

### If someone is visiting Jackson, what should they see or do while there?

Mississippi Museum of Natural Science is the largest museum in the state of Mississippi. Founded in 1933 by Francis A. Cook as part of the Mississippi Game and Fish Commission, the museum features aquariums, habitat exhibits, and nature trails.

The Mississippi Children Museum hosts an interactive exhibit, activities, and programs for kids. The museum focuses on arts, history, health, and science.

The Mississippi Civil Rights Museum's mission is to document, exhibit the history of, and educate the public about the American Civil Rights Movement in the U.S. state of Mississippi between 1945 and 1970.

### What is a fun fact about Jackson, Mississippi?

Every October, the 12-day Mississippi State Fair brings thousands of visitors to Jackson. There are many attractions including Ferris wheels and famous biscuit making booths. Also, the NFL superstar running back Walter Payton played at Jackson State University from 1971 to 1974. At the end of his graduation, he had an NCAA record for most points scored: 464 in a four-year period!

## Meet the UMMC Team!



Sheketha McGee, AA, RC, is the primary Research Coordinator for the A-PREP-IT trial. She leads the initial enrollment, data input, and follow-up calls. Additionally, she supports her team at the site with other studies.



Heather Champion, LPN, was the original Research Coordinator when the A-PREP-IT trial began. She was the backbone for the trial at the time of initiating enrollment, and continues to help out at all times.



Dr. Patrick Bergin, MD, is an orthopedic trauma surgeon and the local Principal Investigator for the A-PREP-IT trial. He is experienced, well-informed, and very educated, making him a valued investigator. His involvement in numerous studies within our department makes him an active researcher than any department would be happy to have.



Dr. Eldrin Bhanat, MD, MPH, is the Clinical Research Manager. He is a remarkable manager, and very knowledgeable when it comes to research. He plays a very important role in our team with several other studies along with the A-PREP-IT trial.

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### A-PREP Enrollment & Final Prep Contamination Update (Table 1) as of Sept 02

Clinical Site	Start Date	Enrolled Participants		Excluded Participants		Missed		Contamination Rate by Participant
		Past month	Total	Past month	Total	Past month	Total	
01 – Shock Trauma Center (STC) Baltimore, MD	03-Apr-18	N/A	83	N/A	82	N/A	3	12%
02 – Hamilton Health Sciences (HHS) Hamilton, ON	12-Mar-18	N/A	169	N/A	91	N/A	10	4%
03 – CORE Institute Phoenix, AZ	10-Jun-18	N/A	57	N/A	226	N/A	18	16%
04 – Indiana University Health (IU Health) Indianapolis, IN	01-Jul-18	8	207	16	179	0	7	6%
05 – University of Texas Health Science Center (UTHealth) Houston, TX	29-Jun-18	N/A	195	N/A	222	N/A	0	15%
07 – Greenville Health System (GHS) Greenville, SC	22-Oct-18	1	107	6	247	0	16	12%
08 – Vanderbilt Medical Center Nashville, TN	16-May-19	12	137	8	131	0	20	6%
09 – University of Florida Gainesville, FL	05-Oct-18	4	153	6	65	1	14	11%
10 – San Antonio Military Medical Center (SAMMC) Fort Sam Houston, TX	01-Nov-18	4	105	6	100	2	2	12%
11 – Wright State Dayton, OH	01-Jan-19	2	35	0	46	0	3	6%
12 – University of California, San Francisco (UCSF) San Francisco, CA	17-Dec-18	2	40	9	170	1	8	21%
13 – Banner University Medical Center Tucson, AZ	22-Apr-19	0	45	0	52	0	1	4%
<b>Total</b>		<b>33</b>	<b>1333</b>	<b>51</b>	<b>1611</b>	<b>4</b>	<b>102</b>	<b>9.84%</b>

### A-PREP Follow-up Update (Table 2) as of Sept 02

Clinical Sites	Enrolled	6 Months				12 Months		
		Complete	Missed	Due	Overdue	Complete	Due	Overdue*
01 – STC	83	67	14	0	0	74	0	7
02 – HHS	169	157	4	1	0	105	15	11
03 – CORE Institute	57	45	8	0	0	26	1	20
04 – IU Health	207	140	15	0	3	92	2	22
05 – UTHealth	195	161	34	0	0	183	0	8
07 – GHS	107	90	12	0	1	43	6	10
08 – Vanderbilt	137	43	22	0	0	11	10	20
09 – University of Florida	153	124	18	0	0	71	10	18
10 – SAMMC	105	67	14	0	0	41	7	15
11 – Wright State	35	18	1	0	1	2	2	1
12 – UCSF	40	25	11	0	0	17	1	9
13 – Banner	45	35	5	0	0	13	5	7

\*Overdue defined as ≥ 4 weeks past due date

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### A-PREP Clinical Site Start-Up Update (Table 3)

Clinical Site	IRB Status	DoD Approval	Contract Status	SIV Status
14 – Hospital Parc Tauli de Sabadell (Barcelona, Spain)	Approved	Step 1 ✓ Step 2 ✓	Ready for Signature	September 2020
15 – Vall d’Hebron University Hospital (Barcelona, Spain)	Approved	Step 1 ✓ Step 2 ✓	Under review	TBD

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### PREPARE - Open Enrollment & Final Prep Contamination Update (Table 4) as of August 28

Clinical Site	Start Date	Enrolled Participants		Excluded Participants		Missed		Contamination Rate by Participant
		Past month	Total	Past month	Total	Past month	Total	
01 – Shock Trauma Center (STC) Baltimore, MD	24-Sep-18	9	35	30	493	0	3	3%
32 – Inova Fairfax Falls Church, VA	18-Oct-18	2	39	3	156	2	50	4%
31 – MetroHealth Cleveland, OH	09-Nov-18	6	22	4	89	0	23	20%
35 – Wake Forest Winston-Salem, NC	12-Feb-19	5	37	5	132	4	35	1%
40 – Carolina’s HealthCare System Charlotte, NC	01-Mar-19		27		140	1	77	6%
41 – Royal Columbian Hospital (RCH) New Westminster, BC	28-Mar-19	2	16	4	40	0	5	0%
42 – University of Utah Hospital Salt Lake City, UT	01-Apr-19	0	19	0	54	0	7	8%
39 – University of Pennsylvania Philadelphia, PA	28-Apr-19	5	31	0	53	4	22	5%
34 – Dartmouth – Hitchcock Lebanon, NH	01-May-19	5	29	0	46	0	6	0%
44 – Sanford Health Sioux Falls, SD	16-May-19	1	9	2	41	0	1	7%
37 – Brigham and Women’s Hospital (BWH) Boston, MA	10-Jun-19	0	35	0	17	0	7	13%
38 – Massachusetts General Hospital (MGH) Boston, MA	10-Jun-19	0	39	1	28	0	7	5%
43 – University of Maryland (U of M) Capital Region Health Cheverly, MD	08-Jul-19	0	22	3	53	1	11	6%
36 – Duke University Durham, NC	17-Jul-19	4	37	2	41	3	16	7%
45 – Regional Medical Center of San Jose San Jose, CA	09-Dec-19	0	27	1	32	0	0	11%
02 – Hamilton Health Sciences (HHS) Hamilton, ON	09-Apr-20	5	21	0	28	7	7	0%
<b>Total</b>		<b>44</b>	<b>962</b>	<b>55</b>	<b>1443</b>	<b>22</b>	<b>277</b>	<b>5%</b>

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### PREPARE - Closed Enrollment & Final Prep Contamination Update (Table 5) as of August 31

Clinical Site	Start Date	Enrolled Participants		Excluded Participants		Missed		Contamination Rate by Participant
		Past month	Total	Past month	Total	Past month	Total	
01 – Shock Trauma Center (STC) Baltimore, MD	24-Sep-18	14	470	59	1088	1	37	1%
32 – Inova Fairfax Falls Church, VA	18-Oct-18	22	351	58	1176	5	220	1%
31 – MetroHealth Cleveland, OH	09-Nov-18	14	367	20	593	0	80	6%
35 – Wake Forest Winston-Salem, NC	12-Feb-19	12	164	53	788	2	17	1%
40 – Carolina’s HealthCare System Charlotte, NC	01-Mar-19		209		570	0	95	3%
33 – University of Mississippi Medical Center (UMMC) Jackson, MS	25-Mar-19	24	232	55	937	0	1	0%
41 – Royal Columbian Hospital (RCH) New Westminster, BC	28-Mar-19	34	478	12	364	4	101	1%
42 – University of Utah Hospital Salt Lake City, UT	01-Apr-19	15	308	9	351	12	87	3%
39 – University of Pennsylvania Philadelphia, PA	28-Apr-19	8	126	22	346	29	156	1%
34 – Dartmouth – Hitchcock Lebanon, NH	01-May-19	7	171	0	195	0	0	1%
44 – Sanford Health Sioux Falls, SD	16-May-19	20	230	4	225	2	18	0%
37 – Brigham and Women’s Hospital (BWH) Boston, MA	10-Jun-19	7	122	2	209	0	54	2%
38 – Massachusetts General Hospital (MGH) Boston, MA	10-Jun-19	4	128	3	288	0	79	2%
43 – University of Maryland (U of M) Capital Region Health Cheverly, MD	08-Jul-19	2	93	2	119	0	15	2%
36 – Duke University Durham, NC	17-Jul-19	16	176	15	283	2	56	2%
02 – Hamilton Health Sciences (HHS) Hamilton, ON	31-Jul-19	27	266	14	131	11	11	0%
04 – IU Health Indianapolis, IN	09-Oct-19	8	132	3	233	3	12	3%
45 – Regional Medical Center of San Jose San Jose, CA	09-Dec-19	1	39	28	210	0	0	15%
07 – Greenville Health System (GHS) Greenville, SC	11-Dec-19	14	75	0	190	0	8	4%
10 – San Antonio Military Medical Center (SAMMC) Fort Sam Houston, TX	09-Mar-20	8	33	10	60	0	0	18%
<b>Total</b>		<b>257</b>	<b>4170</b>	<b>369</b>	<b>8356</b>	<b>71</b>	<b>1047</b>	<b>2%</b>

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### PREPARE - Open Follow-Up Update (Table 6) as of August 28

Clinical Sites	Enrolled	6 Months				12 Months		
		Complete	Missed	Due	Overdue	Complete	Due	Overdue*
01 – Shock Trauma Center (STC)	320	201	24	0	14	137	10	47
32 – Inova Fairfax	69	45	2	3	2	28	2	9
31 – MetroHealth	71	34	12	3	0	9	5	17
35 – Wake Forest	114	78	10	3	1	37	10	6
40 – Carolina’s HealthCare System	103	88	14	1	0	23	6	33
41 – Royal Columbian Hospital	35	26	2	0	0	13	1	1
42 – University of Utah Hospital	39	19	7	1	0	3	6	7
39 – University of Pennsylvania	22	5	3	0	0	3	2	1
34 – Dartmouth-Hitchcock	37	19	2	1	0	10	3	1
44 – Sanford Health	27	15	1	0	0	2	1	
37 – Brigham and Women’s Hospital (BWH)	16	10	2	3	0	1	2	5
38 – Massachusetts General Hospital (MGH)	19	10	4	4	1	0	1	6
43 – U of M Capital Region Health	31	11	1	6	7	0	5	2
36 – Duke University	29	21	0	0	0	4	1	0
45 – San Jose Regional Medical Center	9							
02 – Hamilton Health Sciences (HHS)	21							

\*Overdue defined as ≥ 4 weeks past due date

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### PREPARE - Closed Follow-Up Update (Table 7) as of August 31

Clinical Sites	Enrolled	6 Months				12 Months		
		Complete	Missed	Due	Overdue	Complete	Due	Overdue*
01 – Shock Trauma Center (STC)	470	305	33	2	6	189	19	54
32 – Inova Fairfax	351	177	19	16	32	113	16	28
31 - MetroHealth	367	210	75	11	0	96	5	108
35 – Wake Forest	164	101	12	8	1	45	3	3
40 – Carolina’s HealthCare System	209	153	46	4	1	27	18	94
33 – University of Mississippi Medical Center (UMMC)	232	83	23	27	0	44	2	4
41 – Royal Columbian Hospital	478	334	23	4	6	151	15	16
42 – University of Utah Hospital	308	152	66	19	2	60	22	37
39 – University of Pennsylvania	126	38	36	12	2	3	13	31
34 – Dartmouth-Hitchcock	171	121	9	8	0	40	8	7
44 – Sanford Health	230	155	1	2	1	35	3	0
37 – Brigham and Women’s Hospital (BWH)	122	67	20	14	1	4	12	30
38 – Massachusetts General Hospital (MGH)	128	69	19	18	9	0	7	43
43 – U of M Capital Region Health	93	41	5	13	16	0	10	11
36 – Duke University	176	120	5	3	1	7	15	1
02 – Hamilton Health Sciences (HHS)	266	140	8	23	3	0	36	8
04 – IU Health Methodist Hospital	132	59	3	9	4			
45 – San Jose Regional Medical Center	39	3	0	6	2			
07 – Greenville Health System	75	45	0	3	1			
10 – San Antonio Military Medical Center	33							

\*Overdue defined as  $\geq 4$  weeks past due date